Designing an intervention to improve medication safety in nursing home residents based on experiential knowledge related to patient safety culture at the nursing home frontline: A co-creative process.

Marie Haase Juhl, Ann Lykkegaard Soerensen, Henrik Vardinghus-Nielsen, Jette Kolding Kristensen, Anne Estrup Olesen, Lea Sinding Mortensen

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Table of Contents

Original Manuscript **5**
Supplementary Files **39**
Figures **40**
Figure 1 ..... **41**
Figure 2 ..... **42**
Figure 3 ..... **43**
Multimedia Appendixes **44**
Multimedia Appendix 1 ..... **45**
CONSORT (or other) checklists **46**
CONSORT (or other) checklist 0 ..... **46**

Designing an intervention to improve medication safety in nursing home residents based on experiential knowledge related to patient safety culture at the nursing home frontline: A co-creative process.

Marie Haase Juhl[1, 2] MD; Ann Lykkegaard Soerensen[2, 3] SciSA, PhD; Henrik Vardinghus-Nielsen[4] PhD, Prof Dr; Jette Kolding Kristensen[1] MD, PhD, Prof Dr; Anne Estrup Olesen[1, 2] MScPH, PhD, Prof Dr; Lea Sinding Mortensen[5]

[1]Department of Clinical Medicine University of Aalborg Aalborg DK
[2]Department of Clinical Pharmacology Aalborg University Hospital Aalborg DK
[3]University College of Northern Denmark Aalborg DK
[4]Department of Health Science and Technology Aalborg University Aalborg DK
[5]Senior and Care Municipality of Aalborg Aalborg DK

Corresponding Author:
Anne Estrup Olesen MScPH, PhD, Prof Dr
Department of Clinical Pharmacology
Aalborg University Hospital
Mølleparkvej 8a, Gartnerboligen, ground floor
Aalborg
DK

Abstract

Background: Nursing homes constitute the home of frail people of older age, living with multiple chronic diseases and polypharmacy possibly related to medication errors and unsafe medication practices. Evidence on interventions to improve medication safety in nursing homes is scarce and inconclusive but earlier research indicate patient safety culture might hold a key. This study introduces an integrative approach to intervention development, navigating the complex terrain of patient safety through a co-creative process inspired by the Safety II Theory and Integrated Knowledge Translation (IKT).

Objective: The overarching aim of this study was to develop an intervention to improve medication safety in nursing home residents in a co-creative process focused on frontline experiential knowledge on patient safety culture.

Methods: The study employed a multistage co-creative process, incorporating exploratory focus groups and a multidisciplinary workshop. Research validation and contextualization were keys to result generation, to generate experiential knowledge and intervention components. An abductive approach to data analysis was undertaken Safety II Theory informed and IKT principles guided this study.

Results: Exploration of patient safety culture was done in semi structured focus group interviews including social -and healthcare assistants and helpers besides from representatives of nursing home residents. Focus groups led to experiential knowledge represented by three main themes: 1) Closed subsystems and gaps between functions, 2) Resource interpretation and untapped potential, and 3) Community of medication safety and surveillance. Experiential knowledge informed the development of potential intervention components in a multidisciplinary workshop. Research validation and contextualization resulted in two potential intervention components developed 1) Campaign material visualizing key roles and responsibilities in medication in nursing home residents and 2) Creation of “Medication safety reflexive spaces”, covering the multifaceted design of the final intervention.

Conclusions: The purposively designed, co-creative process generated new experiential knowledge on patient safety culture based on nursing home frontline perceptions that informed the development of a new intervention. Through exploration of deep and vulnerable issues related to medication safety, represented by some of the most important but often underrepresented in research, the study generated results adding important new insights into the wicked challenge of medication safety in primary care.
Our study brought attention to closed subsystems within medication management functions, revealing gaps between these functions. It underscored the untapped potential of experiential knowledge and emphasized the value of a sense of community as a resource. Additionally, we observed the emergence of surveillant communities in medication safety. These insights provide a

valuable understanding of healthcare system dynamics and highlight opportunities for improvement. Clinical Trial: The trial is registered on ClinicalTrials.gov (NCT04990986)

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Title: Designing an intervention to improve medication safety in nursing home residents based on experiential knowledge related to patient safety culture at the nursing home frontline: A co-creative process.

Authors

Juhl MH[1,2], Sørensen AL[2,3], Vardinghus-Nielsen H[4], Mortensen LS[5], Kristensen JK[1,6], Olesen AE[1,2]
1. Department of Clinical Medicine, Aalborg University, Aalborg, Denmark
2. Department of Clinical Pharmacology, Aalborg University Hospital, Aalborg, Denmark
3. University College of Northern Denmark, Aalborg, Denmark
4. Department of Health Science and Technology, Aalborg University, Denmark.
5. Senior and Care, Municipality of Aalborg, Denmark
6. Research Unit for General Practice in Aalborg, Aalborg University, Aalborg, Denmark

Abstract

Background

Despite years of attention, avoiding medication-related harm remains a global challenge. Nursing homes provide essential healthcare for frail elderly individuals, who often suffer from multiple chronic diseases and polypharmacy, increasing their risk of medication errors. Evidence on effective interventions to improve medication safety in these settings is inconclusive. Focusing on patient safety culture is a potential key to intervention development, as it forms the foundation for overall patient safety and is associated with medication errors. This study aims to develop an intervention to enhance medication safety for nursing home residents through a co-creative process guided by Integrated Knowledge Translation (IKT) and experience-based co-design (EBCD).

Methods

This study employed a co-creative process, guided by Integrated Knowledge Translation (IKT) and Experience Based Co-Designing (EBCD) principles. Evidence on patient safety culture was used as an inspirational source for exploration of medication safety. Data collection covered semi-structured focus groups to generate experiential knowledge (Stage 1) to inform intervention design in a multidisciplinary workshop (Stage 2). Research validation, engaging different research expertise and municipal managerial representants in finalizing the intervention design was essential. Acceptance of the final intervention for evaluation was aimed for though contextualization focused on partnership in a municipal advisory board. An abductive, rapid qualitative analytical approach to data analysis was chosen, utilizing elements from “analyzing in the presents”, addressing the time-dependent, context-bound aspects of the co-creative process.

Results

Experiential knowledge was represented by three main themes: 1) Closed systems and gaps between functions, 2) Resource interpretation and untapped potential, and 3) Community of medication safety and surveillance. The main themes informed the design of preliminary intervention components in a multidisciplinary workshop. An intervention designing process focused on research validation besides from contextualization resulted in the SAME intervention covering 1) Campaign material visualizing key roles and responsibilities in medication in nursing home residents and 2) “Medication safety reflexive spaces” focused on social- and healthcare assistants.

Conclusions

The co-creative process successfully resulted in the multifaceted SAME intervention grounded in lived experiences shared by some of the most important but often underrepresented in research, frontline healthcare professionals and representants of nursing home residents. This study brought attention towards closed systems related to functions in medication management and surveillance not only informing the SAME intervention design, but as opportunities for further exploration in future research. Evaluation of the intervention is an important next step. Overall, this study represents an important contribution into the complex field of medication safety.

Ethical Considerations

According to study protocol, The North Denmark Region Committee on Health Research Ethics reviewed and deemed the SAME study exempt according to the study design (2020-000992). The study was registered at and approved by the institutional data protection department, Department of Research Data and Statistics, Aalborg University Hospital (2021-015). The trial is registered on

ClinicalTrials.gov (NCT04990986), adhering to highest standards of transparency and accountability.

Keywords

Intervention development, Nursing home, Frontline professionals, Medication safety, Quality improvement, Patient safety culture, Experiential knowledge, Co-creation, Resilient healthcare systems, Safety II perspective, Human resources, Integrated Knowledge Translation

Background

Despite years of focus [1], interventions to improve medication safety remain a key challenge of healthcare systems, taking on a critical role in ensuring overall patient safety [1–3]. In the context of primary care, social disparities have been found in nursing home residents, considered a marginalized population in higher risk of avoidable harm in healthcare [4–6]. , characterized by advanced age and multiple co-morbidities, nursing home residents are often subjected to complex medication regimens and polypharmacy [7–9]. These circumstances, while aimed at improving their overall health, paradoxically expose them to heightened risks of medication errors and unsafe mediation practices [1,5,10]. Medication dispensing and administration realized within nursing homes and communication incidents have been reported main sources of unsafe care in older adults in primary care [11]. Additionally, cognitive, and physical impairments prevalent in nursing home residents can lead to high dependency on others for their medication management. Thereby, potential benefits of their active engagement in their safety may diminish [12]. In Denmark, nursing homes form part of primary care, of municipal responsibility[13]. In Denmark, a non-licensed delegation of social- and healthcare assistants and helpers represent more than 80% of the frontline in nursing homes, oppositely to hospital settings where doctors and nurses are more frequently present at the frontline. A growing interest in medication safety in primary care has developed the past years, with initiatives aimed at improvement reported [14]. Nevertheless, studies focused on residential aged-care facilities, including nursing homes remains scarce [15]. A more recent example includes a multifaceted intervention design focused on pharmacists' medication review and interprofessional collaboration [16]. Aligning with earlier research investigating potential effects of interventions to improve medication safety in primary care, the randomised controlled trial reported to assess effects of the multifaceted intervention remained inconclusive [14,17].

A recognized need for interventions addressing aspects of medication safety beyond prescribing has been shared [18]. Aligning with other Scandinavian countries, general practitioners are overall responsible for medication management in nursing home residents in Denmark [19]. General practitioners realize medication prescription, while final dosage and administration of medication is performed by a non-licensed delegation of, frontline healthcare professionals, including social- and healthcare assistants. Also, social -and healthcare helpers are crucial partners in medication management, as they count the dispensed number of pills and assess alignment with prescribed medication from the locally shared, electronical medication registration system. Nurses are referred to in complex cases, while not often being physically present in Danish nursing homes. Nursing home residents themselves also play an important role in medication safety but are often impaired both physically and cognitively. Thus, frontline healthcare professionals can be critical observants and communicators on behalf of the nursing home residents and served a critical focus to mediation safety improvement. Moreover, relatives of nursing home residents may serve as primary advocates of nursing home residents in regards to mediation safety [5].

Integrated Knowledge Translation (IKT) provides a co-creative approach to research focused on equally powered partnerships between researcher, knowledge-users, and decision-makers. Integration of different knowledge sources and implementation is considered essential to IKT [20,21]. This aligns with experienced based co-designing principles (EBCD), emphasizing experiential knowledge from end-users as critical in developing interventions to address actual needs and experiences of those targeted the intervention [22]e. While a multicomponent intervention design is supported to enhance medication safety in residential aged-care settings including nursing homes [15], evidence of effects of the reported medication safety programs remains limited [14].

Patient safety culture can be defined as "a reflection of professionals' shared assumptions, values, beliefs, and practices" [23] and is seen foundational not only overall patient safety [3,24] but also in prevention of medication errors [25]. Earlier research suggesting interventions aimed at continuous

improvement of organizational culture in long-term care facilities to enhance patient safety [26]. Thus, patient safety culture holds a promising avenue for interventions aimed to improve medication safety. According to an umbrella review investigating existing tools to measure organizational culture in healthcare organizations, tangible themes relating to patient safety culture may be assessed using existing quantitative questionnaires [27]. Importantly, the umbrella review further identified nine intangible themes, needing their disentanglement in future studies through use of qualitative methods. In doing so, potential new insight could be revealed, setting new direction in intervention development aimed to improve medication safety. Thus, in this study, emphasis on developing an intervention to improve medication safety in nursing home residents focused on co-creation guided by IKT and EBCD principles and intangible themes related to patient safety culture [27].

Objectives

This study aimed to develop an intervention to improve medication safety in nursing home residents in a co-creative process grounded in lived experiences on medication safety. This paper covers a co-creative process with the specific objectives: 1) To generate experiential knowledge on medication safety grounded in evidence on patient safety culture to inform 2) the designing of the intervention.

Methods

Overall study design

This study introduces an innovative approach to intervention development, applying a co-creative process guided by IKT and EBCD principles . The co-creative process covered a multistage, combined developmental study design [28]. Taking an integrative stance, results of an initial explorative stage (stage 1) informed subsequent intervention designing (stage 2). No pre-defined intervention target area was established. An abductive strategy was chosen, emphasizing inductive exploratory approach to intervention development, deductively informed by evidence on patient safety culture. IKT principles concerned integration of evidence on patient safety culture and lived experience in the generation of experiential knowledge on medication safety. Furthermore, focus on implementation based on partnership formation in a municipal advisory board aligned with the IKT principles. EBCD activities included semi-structured focus groups with frontline healthcare professionals and representatives of nursing home residents and a multidisciplinary workshop. These activities supported a bottom-up leveled intervention development emphasizing marginalized voices. Combining IKT and EBCS principles in guiding the co-creative process was chosen with the aim of developing an intervention addressing actual needs and experiences of representatives of nursing home residents, encompassing their relatives, besides from frontline healthcare professionals. At the same time, this combination acknowledged contextualization of the intervention as equally important to intervention design, supporting translation of research into practice.
Referring to Work Package 1, this study covers a co-creative process embedded within a larger mixed-method research project, the “SAfe MEdication in nursing home residents” (SAME study) [29]. (ClinicalTrials.gov NCT04990986) [29]. The co-creative process is illustrated in Figure 1, with further details provided in this section.

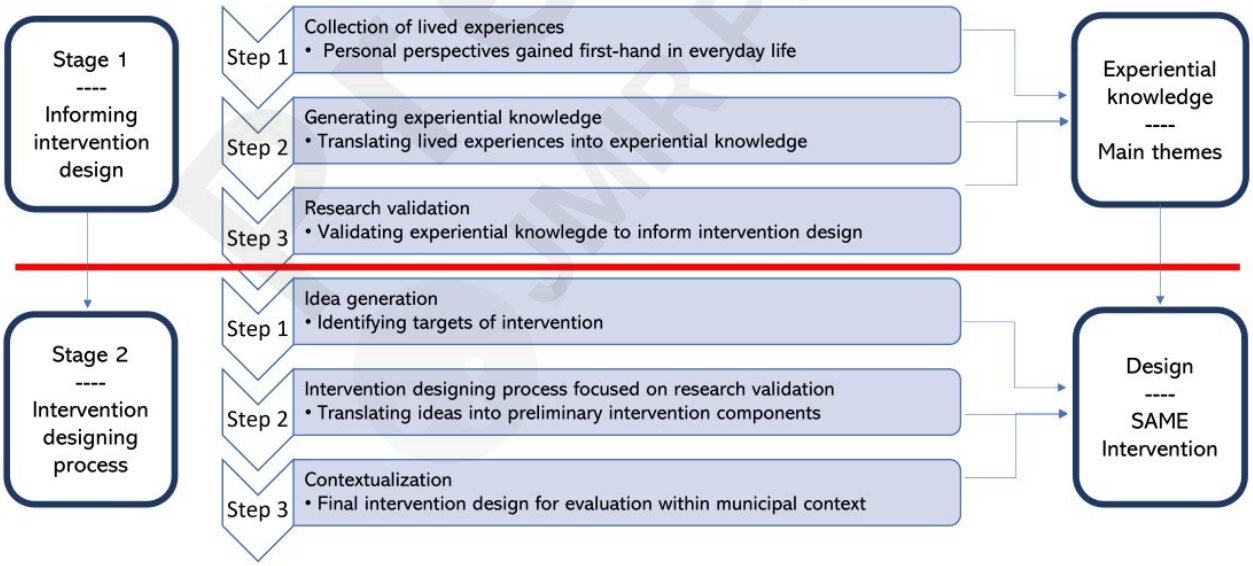


Figure 1. The co-creative process. Illustration of the iterative, integrative, co-creative process of intervention development including main stages and respective steps

Stage 1: Generating experiential knowledge on medication safety to inform intervention design

- Step 1: Conducting exploratory focus groups to collect individual lived experiences from representatives of nursing home residents and nursing home frontline healthcare

professionals.
- Step 2: Translating these individual experiences into a shared understanding of medication safety in nursing home residents in a triangulated process, forming experiential knowledge represented as main themes.
- Step 3: Validating the experiential knowledge by researchers holding different fields of expertise, including qualitative, quantitative, and participatory research methods to ensure reliability and validity of the experiential knowledge.

Stage 2: Designing the intervention
- Step 1: Facilitating idea-generation for preliminary intervention components in a multidisciplinary workshop, informed by validated experiential knowledge from Stage 1.
- Step 2: transforming ideas into preliminary intervention components
- through exploratory focus groups, including translation of individual, lived experience (step 1) into a shared understanding of medication safety in nursing home residents (experiential knowledge; step 2) and research validation (step 3). Stage 2: Designing the final intervention in a multidisciplinary workshop though idea generation informed by experiential knowledge resulting from stage 1 (step 1), research validation (step 2) and contextualization (step 3)

Co-creative approach

Despite the absence of a definitive standard for co-creation in healthcare [30], IKT principles were chosen for their historical roots in medicine [21]. IKT can facilitate innovation by bridging research and practice though equally powered partnerships, thereby guiding the development of impactful interventions [31]. Integration of different knowledge is also considered essential in IKT. In this study, concerning evidence on patient safety culture and experiential knowledge on medication safety. Furthermore, focus on engaging frontline healthcare professionals, nursing home residents, and families in intervention development was set key to intervention development [31,32]. This resonates with the use of Experience Based Co-Designing principles (EBCD), promoting bottom-up intervention design through participatory research methods like focus groups and workshops [22]. Combining IKT and EBCD principles was therefore found to support development of an evidence-informed intervention that addresses genuine needs while remaining contextually grounded for seamless implementation.

Co-Creative activities: Focus groups and a multidisciplinary workshop

Inspired by EBCD, key co-creative activities were covered within the co-creative process including exploratory, semi-structured focus groups to engage nursing home residents, their relatives, and non-licensed frontline healthcare professionals. Through semi-structured discussions, participants were supposed to share their subjective experiences concerning medication safety, enabling the identification of novel insights and focus areas for intervention.

Also, a multidisciplinary workshop was utilized, to create idea-generation, drawing on insights from the focus groups. Inspired by the principles of "future workshop" [33]. this session aimed to foster critical discussion and creative thinking, building an innovative platform for intervention development. Overall, focus groups took an organizational perspective to medication safety, emphasizing the importance of local nursing home environment in realizing interventions, while the workshop aimed to achieve a system-leveled frame of intervention design to support a sustainable intervention with increased generalizability despite local tailoring.

Settings

The focus groups and workshops were conducted at the municipal headquarters of Aalborg, Denmark from April to October 2021. Focus group sessions lasted 3 hours, while a 1-day workshop extended over 6 hours, incorporating a lunch break (45 minutes), smaller breaks (10-15 minutes). All co-

creative activities were ended with a 15-minute plenum evaluation.

Facilitation

The facilitation of focus groups and workshop was led by an external consultant in co-creativity and communication, complemented by researchers from the SAME study [29]. In focus groups, a researcher participated primarily in generating field notes and audiotapes, while three researchers served as co-facilitators and field note generators during the workshop. Immediately after the workshop, a shared document capturing researchers' reflections was produced. The external consultant provided individual, written reflections and verbal feedback to researchers' reflections. The researchers and external consultant played pivotal roles in knowledge translation, integrating research expertise with experiential knowledge related to practical co-creation within municipalities. The external consultant in co-creation and communication held experience as inspirator, coach and process-manager, aiding individuals, and organisation in promoting new thought, vision, language-use, and behavior. The essence of the facilitators' competencies lied in perspectivations of challenges and focus on positive areas of development. The consultant had several years of experience in politics besides from process-management in partnership with Danish municipalities. Additionally, a municipal risk manager, also a member of the municipal advisory board, collaborated with researchers, contributing actively to the focus group evaluation (10 minutes) following the initial assessment.

Theoretical perspectives on medication safety

To a safe environment for sharing lived experiences, prevailing safety I theoretical perspective and recommended safety II perspective were presented as part of the initiation of both focus groups and workshop. Whereas a safety I perspective focus on safety reactively, the safety II perspective provides a more proactive perspective. A safety II perspective to intervention development highlights humans not only as root-cause to errors, but as resources to address continuous change within healthcare environments. By presenting different perspectives to medication safety, a "safe sharing space" was aimed for, to minimize risk of "shame and blame", thereby supporting more honest and vulnerable sharing of lived experience and discussion spanning the co-creative process [34].

Participating co-creators

To address the challenge of dependency in nursing home residents, inclusion of relatives and non-licensed frontline healthcare professionals were chosen for inclusion, also taking a pragmatic stance to time- and resource limitations inherited in this study [29]. In total, four semi-structured focus groups were conducted, based on three differing roles, including 1) social- and healthcare assistants (n=2), 2) social and healthcare helpers (n=1) and 3) representatives of nursing home residents, including relatives and non-for-profit organisations concerned of people of older age (n=1). Social- and healthcare assistants are educated to focus on nursing care but also medication administration with a duration of approximately 4 years. Social- and healthcare helpers' education relates to competences in care and practical service with emphasis on being able to react properly with changes in patients' habitual status and communicate with residents and their relatives. Representatives of nursing home residents, included members of the Senior Council, Aalborg, Denmark, the DaneAge Society, and relatives engaged in nursing home councils of users and relatives, a particular initiative of the Municipality of Aalborg [35]. Nurses of municipal employment, being either home care nurses or nursing home nurses, were aimed for inclusion as both groups are implicated in medication in nursing home residents. Unfortunately, the COVID-19 pandemic situation and a general strike held by nurses during the study period did not allow for their recruitment during the study period.

Overall recruitment

The recruitment process was grounded in partnership between SAME researchers- and the municipal

risk manager, through the municipal advisory board. Information material was initially developed by SAME researchers with the municipal advisory board providing subsequent feedback The municipal risk manager helped in ensuring that the design of the material aligned with municipal design-principles before final acceptance was obtained by the municipal advisory board representants. After acceptance, co-creators were invited through e-mail. Invitations were specifically directed to eligible co-creators but also their registered nursing home managers, to ensure managerial acceptance of the co-creators' engagement. This included the time expected to be used on the study to fit with local workloads. Also, the overarching partnering role of the municipality with the study being part of the overarching SAME study was specified. Recruitment of representatives of nursing home residents was done through contact with existing groups of relatives present in nursing homes within the municipality of Aalborg, Denmark. For further details concerning study methods, the study protocol is referred to [29]. Table 1 provides an overview of co-creators and outputs from each stage and step.

Table 1. Overview of the SAME intervention development: Study stages, steps and related methods, participating and facilitating co-creators, and outputs.

The SAME intervention development		
Study stages, steps, and related methods	**Co-creators**	**Outputs**
Stage 1. Generating experiential knowledge on medication safety		
Step 1 **Semi-structured focus groups** Collecting lived experiences in exploratory focus groups	Nursing home focus group attendees Social- and healthcare assistants (n=5) Social- and healthcare helpers (n=4) Representants of nursing home residents and their relatives (n=4) Facilitators External consultant in co-creativity and communication SAME researcher	**Empirical material** Lived experiences on medication safety grounded in patient safety culture
Step 2 **Triangulated analytical process** Transforming lived experiences into experiential knowledge in a triangulated process	Internal, multidisciplinary research partners SAME researchers and external consultant in co-creativity and communication Facilitator: Researcher	**Experiential knowledge** Main themes to inform intervention design
Step 3 **Individual feedback sessions** Research validation of experiential knowledge to ensure reliability and validity of experiential knowledge to inform intervention design integrating external research and clinical field-expertise	Individual researchers with expertise in: Qualitative, quantitative, and participatory research methods and representing multidisciplinary clinical fields including nursing, medicine, and pharmacology. Facilitators External consultant in co-creativity and communication SAME researcher	**Research validated experiential knowledge** Validated main themes to inform intervention design

Stage 2. Designing the intervention in a multidisciplinary workshop		
Step 1 **Multidisciplinary workshop** Idea-generation based on critical reflection including different perspectives Translating ideas into preliminary intervention design	Multidisciplinary workshop attendees • Representants of nursing home residents (n=2) • Social- and healthcare assistants (n=3) • Social- and healthcare helpers (n=1) • General practitioner dedicated to nursing homes (n=2) • Municipal risk manager (n=1) • Hospital risk manager (n=1) • Assisting leader of the Nursing home area (n=1) • Representative of nurses (related to nursing homes) (n=1) • Representative of nursing home manager (n=1) • Consultant in general practice (focus on those older of age) (n=0)	**Idea generation and preliminary intervention components** Ideas of interventions to improve medication safety in nursing home residents and translation of ideas into preliminary intervention components, based on whether consensus to support the ideas is obtained by all co-creators participating in the workshop and SAME researchers
Step 2 **Individual intervention designing feedback sessions** Intervention designing process integrating different fields of research expertise to ensure reliability and validation of preliminary intervention components integrating external research and clinical field-expertise	Internal, multidisciplinary research partners Three researchers and external consultant in co-creativity and communication External multidisciplinary research partners with expertise in qualitative, quantitative, and participatory research methods and representing multidisciplinary clinical fields including nursing, medicine, and pharmacology. Facilitators: External consultant in co-creativity and communication Researcher	**Validated preliminary intervention components** Validated preliminary intervention components for contextualization
Step 3 **A contextualizing process concerning the municipal advisory board** Focus on equally powered partnership: Municipal advisory board Integrating research evidence and management/leadership-based knowledge;	**Municipal advisory board partners:** Internal research partners Three researchers and external consultant in co-creativity and communication Municipal leader/management representants • Municipal risk manager • Assisting nursing home area leaders • Nursing home manager • Leader of the municipal department of quality- and innovation	**The SAME intervention** Final intervention design accepted for evaluation within local context (the SAME intervention)

Fit intervention to local resource-frame(s)		

The co-creative process

Stage 1. Generating experiential knowledge on medication safety to inform intervention design

In stage 1, exploratory, semi-structured focus groups were utilized to generate experiential knowledge represented as main themes to inform subsequent intervention design in Stage 2. Main themes structured lived experiences to present a shared understanding of medication safety, based on lived experience shared in focus groups, thereby drawing specific attention towards local context. Addressing this context bound aspect and real-world focus of this study, “Rapid Qualitative Analysis” (RQA) was found appropriate for data-analysis [36]. The RQA included principles of listening and re-listening of audiotapes as a principal analytical strategy, inspired by “Analyzing in the Present” [37].

Defining experiential knowledge

Experiential knowledge, introducing lived experience as a core type of knowledge in research, played a pivotal role in intervention development, recognizing experiential knowledge's subjective nature within specific contexts [38]. This type of knowledge, rooted in patient but also professional experiences, contrasts with scientific, factual knowledge commonly referred to as evidence [38]. The emphasis on equally important voices related to experiential knowledge distinguishes it from evidence, which often places end-users perspectives at a taxonomic bottom [38]. Use of experiential knowledge supported the integration of voices from different subgroups, not often represented in evidence centered on scientific knowledge when it comes to targeting interventions to improve medication safety. In this study, perspectives on medication safety shared as lived experiences at first-hand by those actively realizing medication safety within the nursing home setting, including representants of frontline healthcare professionals and nursing home residents, including their relatives, was central in informing intervention development.

Step 1: Collection of lived experience

Initially, lived experiences regarding medication safety were collected in exploratory, semi-structured focus groups (step 1). Data included audiotapes and fieldnotes. A semi structured interview guide was developed for data collection in stage 1. As the guide is in Danish, it is not reported here, but essential aspects of its development are presented in the following.

The semi-structured interview guide

A qualitative semi-structured interview guide was crafted in Danish, structured around three levels of exploration encompassing a total of 11 themes. The framework for a qualitative semi-structured interview guide was used to design a semi-structured interview guide [47]. The semi structured interview guide aimed to formulate exploratory, inductive questions, with a deliberate emphasis on existing evidence on patient safety culture, emerging as a potential key to medication safety and foundational to intervention development in literature [27]. Literature highlights both tangible (including leadership, teamwork, training and development, patient orientation, employee and job attributes, organizational structures and processes, communication system) and intangible themes (commitment, trust, psychological safety, power dynamics, support, communication openness, blame and shame, moral values, ethical considerations, cohesion) relating to tools to measure patient safety culture [27]. With tangible themes related to patient safety culture being readily assessable through existing quantitative measures, intangible themes remained largely unexplored. Recognizing the

significance of these uncharted intangible themes, they were prioritized as the primary inspiration for shaping the interview guide, serving as guiding principles rather than definitive frames. This abductive approach allowed for the exploration of novel areas.

The involvement of an external consultant in co-creation and communication (see Table 1) was engaged in the interview guide development. This consultant played a crucial role in refining the wording of the guide and translating evidence into practical language, ensuring clarity and relevance for the intended audience. This collaborative effort aimed to bridge the gap between research evidence and real-world application, enhancing the usability and effectiveness of the interview guide. The final guide underwent pilot testing within a focus group of social and healthcare assistants. With no major adjustments required, it focused on three main themes: “the challenge,” “the individual,” and “the community,” aligning with the exploratory aim of this study.

Step 2: Generation of experiential knowledge

In step 2, lived experience was translated into experiential knowledge, represented as main themes (step 2). Experiential knowledge of those actively realizing medication safety in nursing homes refers to a socially produced, shared understanding of medication safety based on subjective, lived experiences.

The triangulated analytical process

Translation of lived experiences into experiential knowledge emphasized a triangulated, analytical process in which lived experiences were structured into main themes and related subthemes by researchers and external consultant in co-creativity and communication, grasping the essence of rapid qualitative analysis methodology and co-creative principles of partnership and multi-source knowledge. The triangulated, analytical process constituted of two consecutive steps illustrated in Figure 3.

Merging lived experience and scientific knowledge in a triangulated analytical process was therefore essential to data-analysis. Key elements of the triangulated analytical process are visualized in figure 2. Thematic analysis was initiated with data-collection by the researcher, observing the focus group sessions, following the RQA approach. Post-sessions, the observant researcher (Researcher A) and a senior researcher (Researcher B), with expertise in qualitative methods besides from an external consultant in co-creativity and communication (Consultant), independently listened to audio-recordings from focus groups. Individual feedback sessions between the researchers and the consultant resulted in the generation of preliminary themes. Subsequent triangulation and shared analysis process occurred. A whole-day workshop was set for SAME researchers and the external consultant, using mind-mapping forms, fieldnotes and triangulated preliminary themes to identify the final main themes, representing experiential knowledge accepted for research validation with the purpose of informing intervention design.

Figure 2. The triangulated analytical process to translate lived experience into experiential knowledge. Initially, researcher A was responsible for gathering individual analyses of all co-creators

involved (left figure). Secondly, all co-creators met and discussed what was found and collaboratively decided on the outcome (right figure). [a]External consultant refers to the external consultant in co-creation and communication representing a co-creator in SAME

Step 3: Research validation

Finally, external researchers holding different field of expertise including qualitative methods validated the experiential knowledge in individual feedback-sessions, referring to research validation (step 3). A whole-day session was performed, with SAME researcher as facilitator, and the external consultant in communication and co-creation as co-facilitator. The research validation process included individual feedback sessions with three senior researchers holding expertise from different, clinically relevant fields (Table 1). Both internal and external, multidisciplinary research partners clinical were invited to engage in research validation. Thus, both researchers partnering in the SAME study (co-creators) and researchers not engaged in the co-creative process were invited for inclusion.

Stage 2. Designing the intervention

For intervention design, a multidisciplinary workshop was designed in the second stage, divided into three iterative steps (Figure 1), described in the following. Aspects of “future workshop” design [39] inspired the workshop design, embracing a democratic problem-solving strategy with the purpose of combining different interests, experiences, and positions in generating ideas on futures solutions to an existing problem. The workshop was planned to include focus concerning preparation, introducing the safety II perspective to safety, critique though presentation of experiential knowledge, creative thinking and implementation though practical implications emphasizing different viewpoints and ideas.

Step 1. Idea generation and preliminary intervention components

The presentation of experiential knowledge was conducted through textual formats. Table 1 provides an overview of co-creators in the workshop. Initially, attendees were introduced to the concepts of Safety II perspectives and the main themes and insights identified in Stage 1. Attendees were organized into smaller, multidisciplinary groups with rotating co-facilitators. Within these groups, participants proposed and discussed ideas related to intervention components. These group discussions were instrumental in generating diverse perspectives and innovative concepts. Subsequently, the proposed intervention component ideas were shared and discussed within the larger workshop setting. A consensus-building evaluation occurred in the plenum, where preliminary intervention components were discussed. Components deemed non-essential, based on participant arguments, were excluded from further research validation.

Step 2. Research validation

Research validation encompassed internal, external, and local perspectives, knowledge bases, and clinical skills. Internal research validation included two researchers and an external consultant independently analysed recorded material through a listening and re-listening process of focus group interviews and workshops. Analytical triangulation, as illustrated in Figure 2, involved individual analyses by researcher A and subsequent collaborative decision-making by all co-creators. New, mutually agreed-upon categories emerged during collaborative analysis, further developed in a 1-day session attended by researchers and external consultants, leading to the identification of main themes. During this collaborative analysis, new, mutually agreed-upon categories were generated. These categories were then further developed during a one-day session attended by the researchers and external consultants, resulting in the identification of main themes.

External research validation focused on Researchers with expertise in different methodologies, who did not participate in the workshop, were individually presented with Step 1 outputs for feedback. In addition, a feedback session was held with participation from of an external researcher, serving as the head of municipality-related research, besides from a representant (Assisting leader of nursing homes) from the municipal advisory board. This feedback session took place to bridge the validation process from internal validation, towards contextualization.

Step 3. Contextualization

The final design of the SAME intervention for further evaluation was done in collaboration with the municipal advisory board. As part of the iterative study design, the municipal research director (Aalborg) attended in a 2-hour face-to-face session with SAME researchers with the aim of giving feedback on the preliminary intervention design particularly identifying issues related to future implementation and overall municipal values and actual safety improvement strategies. Subsequently, the contextualization involved SAME researchers and the municipal advisory board. The municipal risk manager played a crucial role in information exchange throughout the contextualization process, with meetings involving all partners at multiple points. Emphasis on resource allocation within narrow limitations throughout the contextualizing process aimed to strengthen future implementation potential.

Ethical considerations

The North Denmark Region Committee on Health Research Ethics has reviewed and deemed the SAME study exempt according to the study design and the emphasis on the sole use of survey, interview, and national register methodology (2020-000992). Participation was voluntary, and informed consent was obtained by all participant and could be withdrawn at any point in time. Privacy and confidentiality protection was successfully ensured. No quotations are presented in the paper, to ensure anonymity, with the revised paper including summarized results. Only general practitioners were compensated for participation (950 DKK/hour) according to the Danish “Agreement on General Practice”. All other participants received no compensation. The study was registered at and approved by the institutional data protection department, Department of Research Data and Statistics, Aalborg University Hospital (2021-015) and in ClinicalTrials.gov (NCT04990986). Participation was voluntary, and informed consent was obtained and could be withdrawn at any point in time. The study was conducted according to the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013

Results

These themes represent a shared understanding of medication safety in nursing home residents, grounded in lived experiences of social- and healthcare assistants, social- and healthcare helpers (frontline healthcare professionals) and representatives of nursing home residents. Thus, main themes centered on the local nursing home environment. Furthermore, key results from stage 2 including ideas and preliminary intervention components are presented in this section. An overview of main themes (stage 1), ideas and preliminary intervention components (stage 2 (step 1 and 2)) are presented in Table 2. Due to limited space and to ensure anonymity, main themes are presented here in summarized form, while examples of data-analysis are available upon request. As an unexpected finding, representatives of nursing home residents were found to reflect “relatives representing nursing home residents”, underscoring peer-support rather than the “voice of nursing home residents”. All participant representing nursing home residents were found to hold the experience of being a relative. Thus, “relatives representing nursing home residents” was set the focus in generation of following results.

Results from exploratory focus groups: Experiential knowledge on medication safety

As a result of the exploratory focus groups, experiential knowledge on medication safety to inform intervention design was generated, represented by three main themes including: 1) Closed Systems and Gaps Between Functions, 2) Resource interpretation and untapped potential, and 3) Community in medication safety and surveillance. In summary, the focus groups revealed key themes regarding medication safety in nursing homes: a closed system of frontline healthcare professionals versus an open system of relatives, the implicit community in medication safety extending from the nursing home setting, lacking guidance/structured communication, and the potential for untapped resources through enhanced transparency and engagement emphasizing focus on frontline healthcare professionals and relatives. Here, the three main themes are presented.

Closed systems and gaps between functions

This theme highlighted interdependency between specified functions in medication management supporting the creation of a closed system including frontline healthcare professionals (Social- and healthcare assistants and social- and healthcare helpers). Unexpectedly, representatives of nursing home residents were all expressing their representation as “relatives” of nursing home residents. The role as “peer-support” was reflected in shared experiences, rather than representative “voices of nursing home residents”. Thus, “representatives of nursing home residents shifted into “relatives representing nursing home residents”.

Medication management was identified as a shared challenge among frontline healthcare professionals, reflecting common values centered on patient safety and the goal of avoiding harm. Social- and healthcare assistants and helpers consistently associated "patient safety" and "medication safety" with avoiding harm, exemplified by one assistant who emphasized the importance of not causing harm to patients. In contrast, relatives had varied perspectives, with some prioritizing happiness over strict involvement in medication processes and others expressing a need for clear guidelines on how to effectively participate in medication management. Frontline healthcare professionals viewed their roles as interdependent and clearly defined, creating a stark contrast with the relatives’ less defined roles. This discrepancy resulted in a gap between the two groups, indicating a closed system among nursing home professionals and a separate, open system among relatives in terms of safety culture. A critical aspect of this closed system was the use of silence in communication to avoid conflicts, particularly when relatives posed questions or demands about medication that professionals felt unprepared to address. This strategy of purposeful silence, driven

by a perceived risk of conflict, was explicitly mentioned by healthcare professionals. Relatives felt excluded from communication, aligning with the professionals' use of silence. For instance, professionals shared experiences of feeling threatened by relatives' questions, leading to avoidance of engagement to prevent conflict. Better guidelines and support to foster effective communication was experienced a clear need in improving medication safety across all focus groups.

Resource Interpretation and Untapped Potential

This theme focused on the untapped potential within the nursing home environment, emphasizing the need to translate available resources into practical assets to improve medication safety. Participants recognized the importance of maximizing the use of existing resources to address the limited resources within healthcare. Untapped potential was identified as a key area for improvement, with innovative interpretation and utilization of existing assets seen as promising avenues for enhancing medication safety. Participants defined resources broadly, encompassing anything useful for addressing gaps in medication safety. They unanimously called for a key person to bridge knowledge and practice in medication management, highlighting the need for systematization and transparency. Untapped potential was identified in the lack of clear roles and responsibilities for social- and healthcare helpers and relatives, which increased communication risks. Enhancing transparency and addressing unspoken concerns were seen as crucial steps to bridge gaps between functions, fostering a cohesive medication safety system and minimizing conflicts and safety hazards. The role of the nursing home general practitioner was seen as important in bridging information and knowledge gaps, though their physical absence in daily activities was noted. Oppositely, relatives' active engagement was experienced to be of focus, as relatives were experienced to be physically present within the nursing home settings in general. Frontline professionals valued physical space and time for peer discussions to reduce perceived risks of condemnation and mistrust, indicating that the physical presence of relatives was perceived a threat in communication for healthcare professionals, aligning with the finding of silence in communication by frontline healthcare professionals when relatives sought active engagement. Thus, engagement of relatives was warranted when other collaborators were not available, with emphasis on communication between ursing homes and other healthcare settings. Yet, active engagement of relatives in general was not warranted by frontline healthcare professionals due to a perceived risk of conflict. For example, one assistant mentioned the lack of a private meeting space, making it difficult to discuss sensitive issues without involving residents.

Community in Medication Safety and Surveillance

This theme emphasized the importance of a community in medication safety experienced as essential in medication safety. Focus on general practitioners, nurses, social- and healthcare assistants and social- and healthcare helpers besides from relatives was identified. Focus group participants generally perceived robust collaboration within the nursing home setting among general practitioners, social- and healthcare helpers, and social- and healthcare assistants. This collaboration fostered a sense of community and psychological safety, contributing positively to medication safety. However, nurses and relatives were not experienced as key partners in medication management by frontline healthcare professionals. Frontline healthcare professionals noted that the perceived lack of key partnership with nurses and relatives might be related to the physical absence of nurses during routine care, as they were often only present during emergent situations. Consequently, communication with nurses was not readily addressed, aligning with their general non-presence within the nursing homes. In contrast, general practitioners dedicated to nursing homes, who were employed a couple of years ago, significantly improved the collaborative experience. Relatives, on the other hand, were included in the shared experience of the community, aligning with their physical presence in the nursing home. They considered nurses crucial partners in information-sharing, which supported trust between relatives and the nursing home organization. Relatives valued the essential

information nurses provided but noted that it was often limited to emergent cases, identifying this as a safety issue. The psychological safety experienced by frontline healthcare professionals contrasted with some relatives' experiences of distrust towards these professionals, indicating a mismatch in experiences. Additionally, the focus group representing relatives revealed heterogeneous experiences and did not reach a consensus, aligning with the first main theme of varied perspectives and engagement in medication safety.

The collaboration among general practitioners, social- and healthcare helpers, and assistants formed a "community of medication safety." However, communication issues were notable, particularly with nurses, and there was a lack of guidelines for interprofessional communication. The differing "languages" used by various professionals in decision-making highlighted the power dynamics in verbal communication, as those who could articulate their arguments most effectively often influenced the course of action. This further underscored the need for better-defined collaboration structures and support to foster effective communication between healthcare professionals and relatives.

Results from the multidisciplinary workshop: Idea generation and preliminary intervention components

We enlisted a total of 14 co-creators to actively engage in the workshop. An overview of co-creators is presented in Table 1. Several ideas were shared in the workshop, including a key frontline healthcare professional engaged specifically in medication in nursing home residents, active engagement in medication management by relatives, technological employees to assist in using local technological solutions (without resource frame), a council of relatives (already in place), integration of pharmacists in daily work with medication (not found useful by general practitioners, holding overall responsibility in medication management), representing a few, that were not leveraged for research validation of the reasons listed. Clearly, focus on three key ideas was supported, including: “Visualizing key roles and responsibilities in medication management”, “Visualize the self-reported expectation/need of relatives of nursing home residents to be involved/engaged in the medication management process”, and “Medication safety reflexive spaces to support frontline healthcare professionals to share experiences related to medication safety with peers across nursing homes”. Thus, the agreed upon ideas focused on increased transparency to support communication openness regarding medication safety, relatives as an untapped potential, yet acknowledged heterogeneity in perceived function as relatives, and reflexivity in frontline healthcare professionals to support collaborative, continuous learning across nursing homes as keys to medication safety.

Step 2: Intervention designing process focused on research validation

Resulting from the workshop, specific ideas with obtained consensus included three preliminary intervention components: 1) “Visualization of key roles and responsibilities in medication management” 2) “Self-plot regarding relatives’ own expected engagement in nursing home residents’ medication””, and 3) “Medication safety reflexive spaces” with elementary descriptions provided here. These preliminary intervention components represented untapped potential to be translated into resources though intervention implementation, focused on transparency in medication management, guided communication emphasizing relatives, supported collaborative learning, sharing of experiences related to medication safety across nursing homes, besides from frontline healthcare professionals and relatives identified as key untapped resources.

“Visualization of key roles and responsibilities in medication management”

To visualize key roles and responsibilities in medication management, campaign material including posters, flyers and batches outlining key functions was identified as a preliminary intervention

component. Focused on opening communication regarding questions to be asked and potential answers to be expected aimed to minimize interruptions in daily work related to medication management besides from minimizing misunderstandings based on lack of transparency and knowledge regarding medication in nursing home residents. Fostering trust and psychological safety through guided communication regarding medication management, medication safety improvement was thereby hypothesized. The campaign material was focused on a relatively generic design, to enable use across a range of healthcare organizations, including nursing homes, geriatric departments, general practices and other settings implicated in medication in nursing home residents. This preliminary intervention component covered an idea of the campaign material, realized though contextualization in step 3.

“Self-plot regarding relatives’ own expected engagement in nursing home residents’ medication”

A tool for relatives to reflect on and visualize their expectations of engagement in medication management to guide healthcare professionals in communication was identified a preliminary intervention component. Acknowledging the heterogeneity in experiential knowledge regarding medication safety found in stage 1, let to visualization of “expectations of engagement” an initially, important step to integrate relatives as active partners in medication safety in future improvement efforts. The concept of the self-plot for relatives aimed to facilitate clarity in expected engagement in medication among relatives, supporting communication between them and healthcare professionals. A simple plot on paper, provided as part of existing introductory interviews taking place in relation to obtained nursing home residency was chosen to address any language difficulties present in frontline healthcare professionals. This aimed to minimize wording, as “monitoring” and “registration” was found to represent a timely aspect of medication safety by participants in the workshop. This component addressed the heterogeneous values and perceptions among relatives regarding their involvement in medication management and education across disciplines, leading to direct engagement of relatives not found to possible in educational terms. Furthermore, three different areas of the plot were defined to include 1) emergency, 2) ambulatory, and 3) daily medication.

“Medication safety reflexive spaces”

The preliminary intervention component of “medication safety reflexive spaces was validated through research and accepted for further contextualization. Detailed design elements were refined and incorporated into the final SAME intervention design. These spaces were intended to transform surveillance from a negative element to a positive learning capacity, enhancing the inter-dependency and communication among social and healthcare assistants and helpers. The concept of "Medication safety reflexive spaces" emerged as a preliminary intervention component, addressing all three main systems identified in the study. These reflexive spaces are presented in Table X and relate to main theme 3: "Community in Medication Safety and Surveillance." The idea of “Learning Reflexive Spaces,” focused on collaborative learning across nursing homes, was suggested in relation to this theme. However, this preliminary intervention component also addressed the other main themes, integrating a comprehensive approach to medication safety.

Addressing closed systems and gaps between functions: Medication Safety Reflexive Spaces aimed to bridge the closed systems and gaps between functions though awareness of their existence, within the nursing home setting. The focus was on frontline healthcare professionals, particularly social and healthcare assistants, and social- and healthcare helpers, who were identified as an untapped resource and represented a closed system. This intervention component emphasized the need for these professionals to be recognized and utilized effectively within the organizational framework of nursing homes. Another critical aspect of the medication safety reflexive spaces was the emphasis on

positive values in surveillance. The intervention component was designed to promote collaborative learning across different nursing homes by focusing on positive feedback mechanisms among frontline healthcare professionals. This approach was rooted in the idea that positive reinforcement can significantly enhance medication safety practices. The design of the medication safety reflexive spaces aimed to included activities to support open communication and learning among frontline healthcare professionals. Workshop results highlighted the importance of focusing on these professionals and fostering a culture of "positive surveillance." This approach encouraged individual, lived experiences to inform collaborative learning efforts. Furthermore, an action-supportive question aimed at promoting reflexivity through positive feedback: "How can I make it easy for my colleague to take over regarding medication in nursing home residents?" This question, inspired by a safety II theoretical perspective, aimed to shift the focus from identifying failures to recognizing and building on daily successes, following workshop discussion related to main theme 3. This shift in perspective was intended to generate new experiences that could further inform reflexivity among participants in the medication safety reflexive spaces.

Table 2. Presentation of key results of the co-creative process, preceding the final SAME intervention design including main themes representing validated experiential knowledge (Stage 1; Step 3), ideas (with obtained consensus) (Stage 2; Step 1) and validated preliminary intervention components (Stage 2; Step 2).

Main theme	Ideas	Validated preliminary intervention components
Closed systems and gaps between function	- Social- and healthcare helpers participating in annual health controls with the general practitioner, including medication review - Contact person regarding medication specifically - Creation of specific, shared "language" extending from the nursing home setting, for specific situations related to mediation (emergency, daily or ambulatory) - Active engagement of relatives in medication management - Feedback to frontline healthcare professionals ensured, regarding adverse event reporting related to medication - Guided communication and awareness of difference between communication and information: visualization of key functions in medication management - Professional relatives ("school for relatives")	Campaign material to visualize key functions in medication management, including general practitioners, nurses, social- and healthcare assistants and social- and healthcare helpers.
Resource interpretation and untapped potential	- Awareness of relatives' expectations regarding engagement in medication management - Technological assistants addressing	Self-plot regarding relatives' expected engagement in nursing home residents' medication

	challenges regarding IT solutions - iPad in each resident-home with ID-login - Inclusion of pharmacist in daily work in nursing homes - Medical doctors in geriatrics as collaborators in medication - Transparency regarding intervention already offered by the municipality	
Community in medication safety and surveillance	- Support a positive culture regarding surveillance as collaboration, supporting shared learning across nursing homes - Cross-sectoral analysis of errors - Less monitoring, more supervision and collaboration- positive aspects of surveillance including reflexivity in frontline healthcare professionals	Medication safety reflexive spaces with focus on reflexivity in frontline healthcare professionals in a reflexive process, based on experiences shared by representants across nursing homes.

Step 3: Contextualization of validated preliminary intervention components (the SAME intervention)

Following research validation, contextualization resulted in the final SAME intervention design, detailed in the following section. Overall, the co-creative process led to the development of a multifaceted, non-technological intervention. This intervention comprises both a structural component (campaign material visualizing key roles and responsibilities in medication management) and a reflexive component (medication safety reflexive spaces). Combined, these components were hypothesized to increase transparency regarding actual functions in medication management and to promote reflexivity among frontline healthcare professionals. This approach aimed to enhance communication openness and collaborative learning, supporting trust and psychological safety across nursing homes. Thereby improving medication safety in nursing home residents thorough patient safety culture.

The intervention components were designed to work in tandem but reflects individual aspects to promote medication safety. Supporting a shift from a sole focus on failures to recognizing and learning from successful processes in medication management was emphasized. This approach included the incorporation of positive feedback as a crucial element. The interplay between these components was suggested to improve medication safety among nursing home residents by fostering a patient safety culture grounded in open communication and psychological safety. The partnership between knowledge users (frontline healthcare professionals and relatives) and stakeholders (municipal managerial representatives and researchers) in decision-making was a key aspect of the intervention's design. Notably, focus on social- and healthcare assistants and the municipal risk manager as an active participant in the multidisciplinary workshop also partnering in the contextualization process, aligned with the co-creative IKT and EBCD principles.

The structural component: Visualizing key roles and responsibilities in medication management

The core of the structural component “transparency” (1. a) is campaign material to support potential questions related to medication. Furthermore, it visualizes the key roles of healthcare professionals and their responsibilities related to medication management with a focus on setting the right direction of questions potentially generated by all persons implicated in nursing home residents’ medication.
The material was developed for use as both posters and folders. To further increase transparency, badges were also designed, representing the four key roles, including 1) General practitioner dedicated to nursing homes, 2) Nurses, 3) Social- and healthcare assistants- and 4) Social- and healthcare helpers, also presented in the other campaign material. The material was developed in a generic model (Figure 3), supporting its implementation within nursing home settings, but also for use in other healthcare settings implicated in the medication of nursing home residents, including geriatric hospital departments, general practices, and municipal home care.

Planned diffusion

The campaign material aimed to be physically presented as wall-posters across nursing homes, with a focus on common areas within individual nursing homes. Folders are to be shared and explained when initiating residency, at a scheduled introduction meeting in which new residents but also relatives are invited to take part. Badges are to be worn by the represented healthcare professionals daily.

The reflexive component: Medication safety reflexive spaces

The reflexive component of the SAME intervention covers a reflexive process, grounded in theory on experiential learning [40]. Integrating three medication safety reflexive spaces facilitated within neutral, external settings, supporting action within individual nursing homes in between sessions, the reflexive component aimed to support reflexivity in social- and healthcare assistants, hypothesizing that reflexivity can realize medication safety improvement as a mediator of patient safety cultural change. As social and healthcare assistants represented a managing partner to social and healthcare helpers, realizing medication dosage, focus on this group was emphasized by both researchers and the municipal advisory board, representing nursing home leaders. Thus, the reflexive component aims to increase reflexivity in non-licensed healthcare professionals, while also addressing a closed system within the nursing home frontline as indicated in stage 1.
The overall intervention covered three medication safety reflexive spaces, all integrating the experiences of those participating but holding different aspects. Figure 3 illustrates the overall design of the reflexive component as an overall iterative intervention process, integrating a Safety II perspective, focusing on sharing experiences, and shared decision on a focus area to generate new experiences. This process is hypothesized to support reflexivity, based on awareness of own and others’ assumptions, critical reflection within a group of professionals holding shared roles and responsibilities across different nursing home units. “Lived experience” was essential to initiate the reflexive process.
As reflexivity includes critical reflection, a key element of the reflexive component is to visualize different perspectives. This includes safety theory, introducing both actual safety I and recommended safety II perspectives (REF). Moreover, experiential knowledge shared by those actively realizing medication safety at the nursing home frontline, is hypothesized key to medication safety improvement. To initiate the reflexive intervention process, findings from focus groups were therefore presented. This was done to induce sharing of diverse, vulnerable lived experience, aligning with facilitation of the workshop covered in this paper.
Transforming Facilitation: Facilitation of the "medication safety reflexive spaces" by an experienced researcher and municipal risk manager is core to the reflexive intervention component. As part of the

third reflexive space, the risk manager was set as a co-facilitator to increase future feasibility and implementation, besides from participation in shared evaluation at the end of each session. Each session calls for action by participants, encouraging their experiences to be critically reflected upon both within the "medication safety reflexive space" and as part of ongoing clinical practice. This to support transformation from awareness of own assumptions and behavior towards reflexivity though shared, critical reflection based on individual lived experience. Importantly, each session's output depends on the input delivered, whether it be existing or new experiences of participants (Figure 3).

Initiation of medication safety reflexive spaces supporting a safe space: Before sharing experiences, the shared challenge of medication safety improvement in nursing home residents was presented, including introducing Safety I theory as the usual perspective to address the problem. Then, Safety II perspectives were presented to offer an alternative perspective, supporting a focus on successes experienced to be shared.

Theory of change: The theory of change of the reflexive intervention component focuses on behavior change related to challenging current practices through a Safety II perspective and focus on an area experienced of importance to frontline healthcare professionals, actively realizing medication safety in nursing homes. With reflexivity being a contextually bound concept, the iterative process with continuous participation in both "safe spaces" outside the nursing home context and active practice supported in daily clinical practice is essential to the reflexive intervention component.

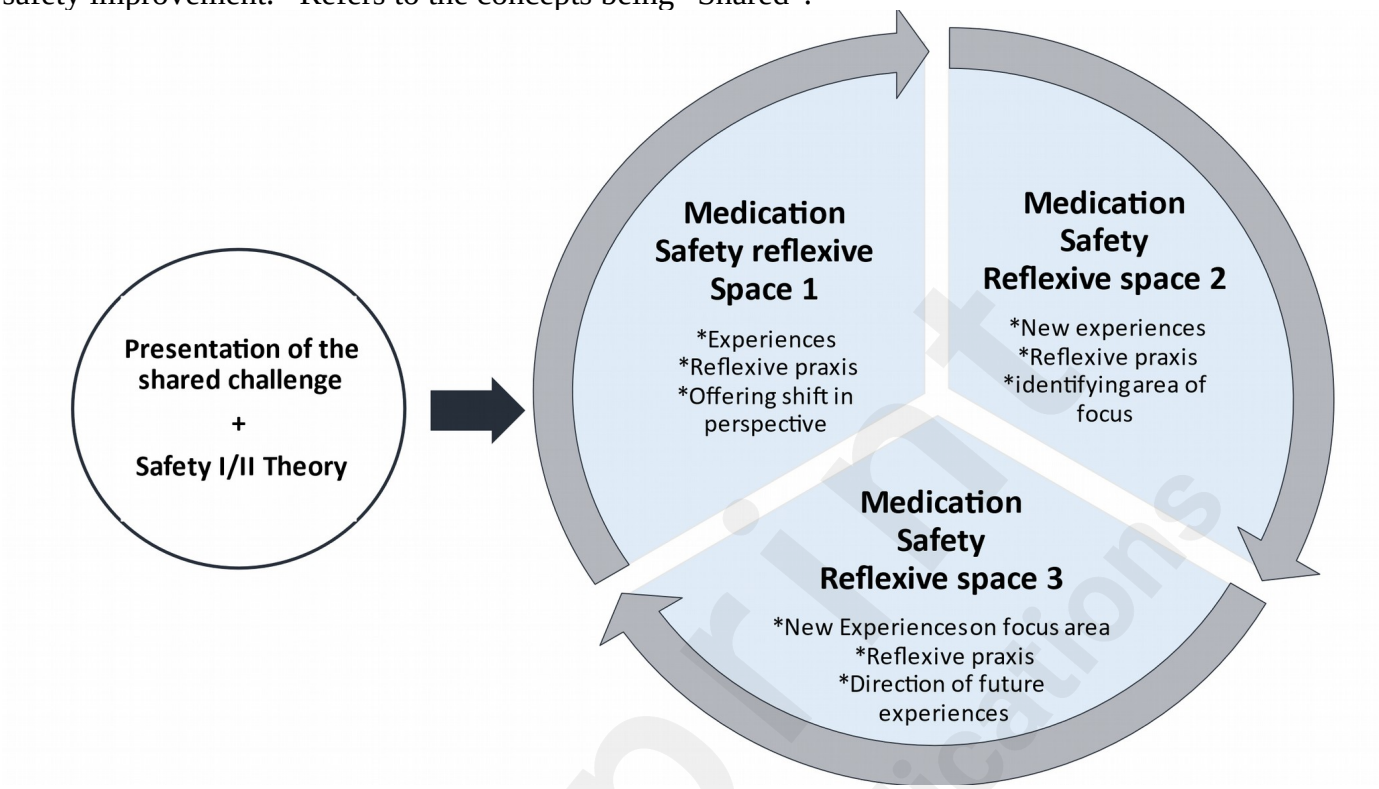
Thus, “medication safety reflexive spaces” involves integration of external facilitation and local contextualization, supporting reflexive praxis. Focus on frontline healthcare professionals includes social- and healthcare assistants in focus as participants. The term “reflexive space” is conceptualized as a physical platform for social- and healthcare assistants to engage in critical reflection based on their own lived experiences across different nursing homes. The iterative conduction of the individual intervention sessions, allowing for active experimentation within local nursing home environments is key to translate reflection into reflexivity (REF). To keep attention towards medication safety, presentation of experiential knowledge (main themes) from stage 1 covered in this paper, was chosen to initiate medication safety reflexive spaces. In Figure 3, an overview of the three iterative "medication safety reflexive spaces" is presented. Further descriptions of the individual sessions are provided in appendix.

Setting and time-schedule: **Relatively neutral location situated within municipal headquarters, was chosen for conduction of the medication safety reflexive spaces. These headquarters are situated within beautiful nature surroundings, with easy reach, including free parking. All reflexive spaces were held during workhours (daytime) according to agreement in study design based on partnering in the municipal advisory board. A three-month interval and a duration of three hours each, including a light meal and smaller breaks was decided the frame of the intervention component. 15 minutes at the end of each session was assigned to shared evaluation of the shared experiences and participation. All together, these actors were predefined to enable implementation of the intervention, addressing actual resource frame available.**

Eligible participants: Social- and healthcare assistants permanently employed in a public nursing home by the Municipality of Aalborg, and with experience in the professional field and medication management exceeding three months.

Figure 3. Overview of the generic model of the reflexive component (Component 2) of the SAME intervention consisting of three iterative “medication safety reflexive spaces”. Improving mediation safety was hypothesized though continuous, collaborative learning supporting reflexivity in social-

and healthcare assistants, based on diverse perspectives, including safety theoretical perspectives to medication safety (Safety I/II Theory). Focus on experiential knowledge set a key in medication safety improvement. *Refers to the concepts being “Shared”.



Discussion

Principal results

The co-creative process resulted in the development of a multifaceted, non-technological intervention with both structural and reflexive components. This supports the need to look beyond technological aspects of healthcare innovation and underscores the importance of human resources within nursing home settings to support safe medication practices. The multifaceted, contextualized intervention includes the visualization of key roles and responsibilities in medication management and the establishment of "medication safety reflexive spaces" aiming to improve medication safety in nursing home residents.

Comparison with prior work

The emphasis on transparency of roles and responsibilities in the medication management process emerged as a pivotal catalyst for change by co-creators. This finding supports a knowledge-to action gap in transparency from literature to exchange of information in practice [43]. Transparency is acknowledged foundational to safety improvement in healthcare, at the same time potentially leading to increased control and lack of confidential spaces, that are needed to address potential conflicts, mistakes, and new ideas between healthcare professionals [44]. Here, the multifaceted construct of the intervention developed in this study becomes a potential benefit, minding this paradox issue. The structural component contributes to increased transparency by clarifying roles and related responsibilities of key healthcare professionals implicated in medication in nursing home residents. This could lead to enhanced communication clarity, thereby minimizing interruptions in the medication management process, potentially reducing medication-related failures [14], whereas the reflexive intervention component, the “safe medication reflexive spaces”, dimmish the potential negative effects of increased transparency. Recent research also supports the beneficial notion of the creation of reflexive spaces within healthcare, but this research focused on hospital settings [45]. In the literature, a clear gap in knowledge on interventions to improve medication safety in nursing homes exists [16,46,47], although few studies have been reported. Turning towards interventions to enhance safety cultures for nursing home professionals in long-term care, studies are also limited, but researchers have found the inclusion of collegial exchange of experiences and learnings, integration of staff's perceptions, external facilitation, staff training, and a structured, multi-step procedure of the intervention process to be promising approaches. All aspects were integrated into the present study. In hospitals, a recently published study using a co-creative approach resulted in the creation of reflexive spaces with collective sharing of experiences between hospitals, next of kin, and healthcare professionals to support collaborative learning and co-creation of resilient healthcare [48], supporting the co-creation of the reflexive component of the developed intervention. Taken together, the results indicate that co-creation could lead to new but aligned directions across healthcare sectors, indicating a need for reflection to be integrated into safety improvement work, as stated by co-creators in both this study and in hospitals [48]. As we cannot conclude how such reflexive practice should be put in place to succeed and lead to positive effects on medication safety, evaluation of the intervention is therefore highly warranted.

Multifaceted intervention design

The emphasis on transparency of roles and responsibilities in the medication management process emerged as a pivotal catalyst for change by co-creators. This finding supports a knowledge-to action gap in transparency from literature to exchange of information in practice [41]. Transparency is acknowledged foundational to safety improvement in healthcare, at the same time potentially leading to increased control and lack of confidential spaces, that are needed to address potential conflicts,

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Medication management process and transparency

The structural component of the intervention is designed to enhance clarity regarding roles and responsibilities. With the purpose of improving communication, this intervention component could facilitate more effective and precise interactions, thereby possibly reducing failures in the medication management process[45]. Moreover, this component supports the articulation of questions and directs them to the appropriate professional subgroups, minimizing potential interruptions, a previously discussed risk hazard in medication safety [46]. Additionally, unclear knowledge concerning specific roles and responsibilities potentially drives the development of unrealistic expectations held by representatives of relatives as found in this study, is addressed by the structural intervention component of the SAME intervention. This element promotes transparency by visually depicting the roles and responsibilities of multidisciplinary healthcare professionals who, while collaborating, may lack daily direct interaction in nursing home settings. An essential outcome of increased transparency is the promotion of awareness that questions can and should be posed. Furthermore, offering patients more realistic expectations of care has been suggested as potentially beneficial for reducing threats to patient safety in primary care [47].

Addressing key challenges in intervention development

Developing interventions in healthcare poses various challenges, necessitating the integration of voices representing nursing home residents, including relatives, besides frontline healthcare professionals—an imperative acknowledged in existing literature [48]. Additionally, concerns were acknowledged regarding the potential disconnection between research and the practical needs of healthcare service users. To address possible hierarchical power imbalances within healthcare organizations [49] and to promote diversity, a bottom-up, iterative co-creative process was implemented. This aligns with recommendations from a 2021 narrative review on interventions to optimize medication use in nursing homes. The review suggested conducting large-scale evaluations of under-researched intervention components and interventions addressing medication use aspects beyond prescribing, among other recommendations [18].

Utilizing a combined co-creative approach: Focus on patient safety culture, marginalized voices, and implementation

In the pursuit of enhancing medication safety for nursing home residents, this study adopted a co-creative approach guided by IKT and EBCD principles [20,22]. This required collaborative efforts between knowledge users and researchers (stakeholders), emphasizing partnership-building spanning the entire co-creative process. The collaboration encompassed the identification of key priorities, the formulation of research inquiries to be responsive to real-world needs, the interpretation of findings, and the facilitation of the practical application of research outcomes [16]. It is noteworthy that IKT differs from conventional Knowledge Translation (KT) methods in its emphasis on co-creation, shared decision-making, and the integration of different knowledge and evidence [22, 23]. The IKT principles were chosen due to their origin in medicine and recognized significance in supporting

research aimed at addressing health disparities and improving healthcare service delivery. It is important to acknowledge that the existing empirical evidence substantiating the impact of these principles remains limited [20,50].

External facilitator integration

An external facilitator, experienced in communication and innovation within municipal settings in Denmark, played a vital role in the co-creative process. This individual was not merely a facilitator but an integral co-creative partner who actively contributed to the design, facilitation, and knowledge-generation processes. The partnership between the external consultant and the research team nevertheless also did provide potential of disruption. This related to unlearning [51–53] as an innovative key strategy used by the external consultant partnering in SAME. As there is no golden standard of collaborative learning within healthcare organizations engaging other types of stakeholders could have led to other innovative strategies but more knowledge within this field is needed. This study underscores the importance in future focus on external consultants being integral partners in co-creation, reflecting actual practice in improvement work within primary care settings. External consultants may or may not have research expertise, challenging the research aspect of this study. Nevertheless, the research validation and feedback sessions integrating researchers holding a wide range of expertise within quantitative, qualitative, and co-creative research fields addresses this issue. In fact, the integration of the external consultant in co-creation and communication in this study may be essential to the open and honest sharing, experienced as part of the co-creative process, holding a supportive, neutral role between research and clinical practice. The external facilitator could play a key role in actively using IKT principles to develop equally powered partnerships. This study, nevertheless, remains inconclusive regarding this matter of facilitation, why clearly so much more research is needed.

Future perspectives

Focus on collaborative learning: Safe mediation reflexive spaces

While technological interventions are often highlighted to address resource constraints in healthcare, this study resulted in a non-technological intervention, emphasizing the significance of knowledge and communication factors. The development of safe reflexive spaces, as component 2 of the intervention, warrants further evaluation to understand its implications in meeting the need for a safe space expressed by co-creators. The integrative approach, acknowledging diverse perspectives, was crucial. Recognizing variations among organizational subgroups, and tailoring interventions to their experiences enhances contextual relevance. The generic design of medication safety reflexive spaces could allow for use in various nursing homes, expanding the intervention's reach. A qualitative study on safe administration of medication in a sample of Norwegian nursing homes found interruptions and double-checking adaptive behavioral patterns related to physical distance between rooms dedicated to medication and the nursing home residents, creating possible barriers of safe medication administration [43]. In this study a general lack in physical room dedicated medication was experiences by frontline healthcare professionals. As resources of this study did not allow for extended physical rooms in nursing homes, generating a room dedicated medication safety could be a facilitator and not a barrier despite physical distance being even greater than presented in the Norwegian study. Also, diffusion across different professions or involving residents and their relatives could amplify impact, potentially influencing healthcare at a system level.

The importance of relatives

Co-creation supports the integration of perspectives across a wide range of people, including patients, in this study referring to nursing home residents. Earlier researchers have called for integrating voices of patients and their relatives in assessing organizational cultural aspects in

healthcare [27]. Supporting nursing home residents' communication of their needs through the integration of representative voices informing intervention development in this study is a strength, supporting research focused on the improvement of patient safety in primary care[47]. Nevertheless, the "voices of nursing home residents" resulted in identification of "relatives representing nursing home residents. Furthermore, results indicated that "relatives" represented an "open system", with no specific function in medication management challenging communication and active engagement, otherwise supported and valued at municipal and national levels concerning patient safety. Results of this study indicate that relatives do not form an integral part of the nursing home frontline, challenging identification of agreement across focus groups, potentially limiting consensus in the workshop. At the same time, this could have increased the innovative potential of the co-creative process, supporting the including of challenging perspectives, reflecting the societal environment external to the nursing home organization. Integrating relatives' experiences into the workshop could have led to more realistic expectations of areas susceptible to intervention through the identification and presentation of different perspectives, also representing a promising mechanism [47]. Focus on relatives as target of intervention was identified to hold untapped potential in the workshop and resulted in an initial development of a preliminary intervention component. Nevertheless, this intervention component was not prioritized for further contextualization. Although not included for further evaluation in the frame of the SAME study, focus on relatives' own expected level of engagement in medication management could be an important field of future exploration, with the preliminary intervention component excluded from contextualization representing a starting point.

Attention towards closed system in medication safety

The importance of tailoring interventions to specific subcultures has been proposed a potential key to improvement [55]. Furthermore, a key to medication safety improvement could lie within the concept of systems, as identified in this study, also referred to as subcultures. Subcultures are present within organizational cultures, including patient safety cultures [56]. If subcultures close upon themselves, it might represent a safety hazard, not readily measurable though quantitative instruments. Thus, subcultures, or closed systems, warrant further investigation, including qualitative in-depth inquiry, and focus on different cultural language including conceptions and silence could be important aspects of exploration possessing potential power in improvement terms. This could support earlier quantitative research supporting existence of subcultural aspects of patient safety culture in nursing homes [57]. Furthermore, a qualitative study from Swedish hospitals suggested intervention to be tailored to both registered nurses' and nurse assistants' patient safety-related assumptions, values and norms [58]. Altogether, these studies support the final design of the SAME intervention, with initial focus on social- and healthcare assistants, addressing the potential power of a profession-related subculture in need of target before a broader target of intervention, where decision-making could potentially be limited by power-hierarchies indicated to be present related to systems found in this study.

Supporting the development of resilient healthcare systems

The co-creative approach combined IKT and EBCD principles, representing an innovative approach to intervention development. This study not only adds to a growing body of interventions to enhance medication safety in nursing home residents, but also supports knowledge translation into action in the field of resilient healthcare. Importantly, implementation was integrated into the co-creative process, grounded in the municipal advisory board and contextualization as a final step in intervention designing. The SAME intervention is constructed of a structural- and a reflexive component targeting different aspects than prescribing, being one of the most researched aspects in the field of medication safety [15,18]. It cannot be ruled out as a potential consequence of using a co-creative approach. Results support recent research emphasizing the important role of collaborative learning in healthcare, focused on reflexive spaces in hospital settings as a resilient healthcare

capacity [44,59]. Furthermore, the reflexive intervention component supports principles for developing learning tools to help translate resilience into practice [60]. Thus, the SAME intervention holds resilient potential.

Strengths and limitations

Strengths of the study lie in its innovative co-creative approach, which fosters critical discussion and creative thinking, resulting in an intervention grounded in lived experiences and patient safety culture. Nevertheless, the innovative approach also serves an important limitation, with limited use of classical methods in this study. The inclusion of nursing home residents' voices, albeit through representatives, provides a realistic depiction of medication safety issues. Engaging relatives aligns holds an addition innovative potential, challenging a potential “closed system” of healthcare professionals representing the nursing home frontline. Integration of diverse healthcare professionals and partnership with the municipal advisory board enhance implementation potential. Addressing sensitivity through a Safety II perspective fosters open communication. However, limitations include the exclusion of nursing home residents themselves, potentially hindering the depth of insights. Subjectivity in perceived complexity and single-session focus groups may limit data richness. Generalizability beyond the specific context should be approached cautiously. Nevertheless, generic elements in both co-creative process and the resulting SAME intervention hold promise for adaptation and future use within other healthcare settings. Resource constraints and time limitations, along with the absence of nurses as co-creators, pose challenges. Additionally, while the study demonstrates co-creation, it falls short as lived experience individuals were not part of the research team.

Conclusion

The co-creative process successfully resulted in the multifaceted SAME intervention grounded in lived experiences shared by some of the most important but often underrepresented in research, frontline healthcare professionals and representants of nursing home residents. This study brought attention towards closed systems related to functions in medication management and surveillance not only informing the SAME intervention design, but as opportunities for further exploration in future research. Evaluation of the intervention is an important next step. Overall, this study represents an important contribution into the complex field of medication safety.

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Artificial intelligence (AI) technology was exclusively utilized for the purpose of rewording existing text and not for generating original content for this manuscript.

Conflicts of Interest

No conflicts of interest declared.

Data availability

The data produced in this study are not accessible to the public because of the sensitive nature of the information and personal data shared by participants. However, interested parties can obtain the data and other study materials from the corresponding author upon request.

Abbreviations

IKT: Integrated Knowledge Translation

References

1. Donaldson LJ, Kelley ET, Dhingra-Kumar N, Kieny M-P, Sheikh A. Medication Without Harm: WHO's Third Global Patient Safety Challenge. Lancet (London, England) England; 2017 Apr;389(10080):1680–1681. PMID:28463129
2. World Health Organisation. Ageing and health. 2022. p. https://www.who.int/news-room/fact-sheets/detail/a.
3. WHO. Global Patient Safety Action Plan 2021-2030. https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan 2021;(1):100. Available from: https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan
4. Cheraghi-Sohi S, Panagioti M, Daker-White G, Giles S, Riste L, Kirk S, Ong BN, Poppleton A, Campbell S, Sanders C. Patient safety in marginalised groups: a narrative scoping review. Int J Equity Health 2020 Feb;19(1):26. PMID:32050976
5. Bates DW, Zebrowski J. Medication safety in nursing home patients. BMJ Qual & Saf 2022 Dec 1;31(12):849 LP – 852. doi: 10.1136/bmjqs-2022-014791
6. Piccardi C, Detollenaere J, Vanden Bussche P, Willems S. Social disparities in patient safety in primary care: a systematic review. Int J Equity Health International Journal for Equity in Health; 2018;17(1):1–9. PMID:30086754
7. Lundby C, Jensen J, Larsen SP, Hoffmann H, Pottegård A, Reilev M. Use of medication among nursing home residents: a Danish drug utilisation study. Age Ageing England; 2020 Aug;49(5):814–820. PMID:32147721
8. Astorp J, Gjela M, Jensen P, Bak RD, Gazerani P. Patterns and characteristics of polypharmacy among elderly residents in Danish nursing homes. Futur Sci OA 2020 May;6(8):FSO590. PMID:32983560
9. Reilev M, Lundby C, Jensen J, Larsen SP, Hoffmann H, Pottegård A. Morbidity and mortality among older people admitted to nursing home. Age Ageing England; 2019 Dec;49(1):67–73. PMID:31763682
10. Assiri GA, Shebl NA, Mahmoud MA, Aloudah N, Grant E, Aljadhey H, Sheikh A. What is the epidemiology of medication errors, error-related adverse events and risk factors for errors in adults managed in community care contexts? A systematic review of the international literature. BMJ Open 2018 May;8(5):e019101. PMID:29730617
11. Cooper A, Edwards A, Williams H, Evans HP, Avery A, Hibbert P, Makeham M, Sheikh A, Donaldson LJ, Carson-Stevens A, J Donaldson L, Carson-Stevens A. Sources of unsafe primary care for older adults: a mixed-methods analysis of patient safety incident reports. Age Ageing Oxford University Press; 2017 Sep 1;46(5):833–839. PMID:28520904
12. Manias E, Bucknall T, Hutchinson A, Dow B, Borrott N. Resident and family engagement in medication management in aged care facilities: a systematic review. Expert Opin Drug Saf England; 2021 Nov;20(11):1391–1409. PMID:34058923
13. Stuart M, Weinrich M. Home is where the help is: community-based care in Denmark. J Aging Soc Policy England; 2001;12(4):81–101. PMID:11799916
14. Khalil H, Shahid M, Roughead L. Medication safety programs in primary care: a scoping review. JBI Evid Synth 2017;15(10). Available from: https://journals.lww.com/jbisrir/Fulltext/2017/10000/Medication_safety_programs_in_primary_care__a.16.aspx
15. Alruthea S, Bowman P, Tariq A, Hinchcliff R. Interventions to enhance medication safety in residential aged-care settings: an umbrella review. Br J Clin Pharmacol John Wiley & Sons,

Ltd; 2022 Apr 1;88(4):1630–1643. doi: https://doi.org/10.1111/bcp.15109
16. Krause O, Wiese B, Doyle I-M, Kirsch C, Thürmann P, Wilm S, Sparenberg L, Stolz R, Freytag A, Bleidorn J, Junius-Walker U, Bernard S, Kortekamp S, Fuchs A, Mortsiefer A, Wollny A, Altiner A, Haumann H, Joos S, Schneider N, Grobe TG, Günster C, Group for the H-3-iTBX study. Multidisciplinary intervention to improve medication safety in nursing home residents: protocol of a cluster randomised controlled trial (HIOPP-3-iTBX study). BMC Geriatr 2019;19(1):24. PMID:30683060
17. Junius-Walker U, Krause O, Thürmann P, Bernhard S, Fuchs A, Sparenberg L, Wollny A, Stolz R, Haumann H, Freytag A, Kirsch C, Usacheva S, Wilm S, Wiese B. Drug Safety for Nursing-Home Residents-Findings of a Pragmatic, Cluster-Randomized, Controlled Intervention Trialin 44 Nursing Homes. Dtsch Arztebl Int Germany; 2021 Oct;118(42):705–712. PMID:34366004
18. Spinewine A, Evrard P, Hughes C. Interventions to optimize medication use in nursing homes: a narrative review. Eur Geriatr Med Switzerland; 2021; PMID:33751478
19. Alftberg Å. Medication management in Swedish nursing homes: an ethnographic study of resistance, negotiation and control. Eur J Soc Work Routledge; 2022 Mar 4;25(2):186–197. doi: 10.1080/13691457.2020.1870214
20. Gagliardi AR, Berta W, Kothari A, Boyko J, Urquhart R. Integrated knowledge translation (IKT) in health care: a scoping review. Implement Sci 2016;11(1):38. doi: 10.1186/s13012-016-0399-1
21. Nguyen T, Graham ID, Mrklas KJ, Bowen S, Cargo M, Estabrooks CA, Kothari A, Lavis J, Macaulay AC, MacLeod M, Phipps D, Ramsden VR, Renfrew MJ, Salsberg J, Wallerstein N. How does integrated knowledge translation (IKT) compare to other collaborative research approaches to generating and translating knowledge? Learning from experts in the field. Heal Res Policy Syst 2020;18(1):35. doi: 10.1186/s12961-020-0539-6
22. Green T, Bonner A, Teleni L, Bradford N, Purtell L, Douglas C, Yates P, MacAndrew M, Dao HY, Chan RJ. Use and reporting of experience-based codesign studies in the healthcare setting: a systematic review. BMJ Qual & Saf 2020 Jan 1;29(1):64 LP – 76. doi: 10.1136/bmjqs-2019-009570
23. Kristensen S, Sabroe S, Bartels P, Mainz J, Christensen KB. Adaption and validation of the safety attitudes questionnaire for the danish hospital setting. Clin Epidemiol Dove Medical Press; 2015 Feb;7:149–160. doi: 10.2147/CLEP.S75560
24. De bienassis K, Kristensen S, Burtscher M, Brownwood I, Klazinga NS. Culture as a cure: Assessments of patient safety culture in OECD countries. OECD Heal Work Pap 2020; (119):0_1,3-6,10-100. doi: https://doi.org/10.1787/6ee1aeae-en.
25. Rodziewicz TL, Houseman B, Hipskind JE. Medical Error Prevention. Treasure Island (FL); 2020. PMID:29763131
26. Świtalski J, Wnuk K, Tatara T, Miazga W, Wiśniewska E, Banaś T, Partyka O, Karakiewicz-Krawczyk K, Jurczak J, Kaczmarski M, Dykowska G, Czerw A, Cipora E. Interventions to Increase Patient Safety in Long-Term Care Facilities—Umbrella Review. Int J Environ Res Public Health 2022;19(22):1–20. PMID:36430073
27. Malik RF, Buljac-Samardžić M, Akdemir N, Hilders C, Scheele F. What do we really assess with organisational culture tools in healthcare? An interpretive systematic umbrella review of tools in healthcare. BMJ open Qual 2020;9(1). PMID:32075804
28. O'Cathain A, Croot L, Sworn K, Duncan E, Rousseau N, Turner K, Yardley L, Hoddinott P. Taxonomy of approaches to developing interventions to improve health: a systematic methods overview. Pilot Feasibility Stud 2019;5(1):41. doi: 10.1186/s40814-019-0425-6
29. Juhl MH, Soerensen AL, Kristensen JK, Johnsen SP, Olesen AE. Safe Medication in Nursing Home Residents Through the Development and Evaluation of an Intervention (SAME): Protocol for a Fully Integrated Mixed Methods Study With a Cocreative Approach. JMIR Res

Protoc 2023;12:e43538. doi: 10.2196/43538
30. Grindell C, Coates E, Croot L, O'Cathain A. The use of co-production, co-design and co-creation to mobilise knowledge in the management of health conditions: a systematic review. BMC Health Serv Res 2022;22(1):877. doi: 10.1186/s12913-022-08079-y
31. Gainforth HL, Hoekstra F, McKay R, McBride CB, Sweet SN, Martin Ginis KA, Anderson K, Chernesky J, Clarke T, Forwell S, Maffin J, McPhail LT, Mortenson W Ben, Scarrow G, Schaefer L, Sibley KM, Athanasopoulos P, Willms R. Integrated knowledge translation guiding principles for conducting and disseminating spinal cord injury research in partnership. Arch Phys Med Rehabil 2021;102(4):656–663. doi: https://doi.org/10.1016/j.apmr.2020.09.393
32. Banner D, Bains M, Carroll S, Kandola DK, Rolfe DE, Wong C, Graham ID. Patient and public engagement in integrated knowledge translation research: are we there yet? Res Involv Engagem 2019;5(1):8. doi: 10.1186/s40900-019-0139-1
33. Carlsson J, Eriksson LO, Öhman K, Nordström E-M. Combining scientific and stakeholder knowledge in future scenario development — A forest landscape case study in northern Sweden. For Policy Econ 2015;61:122–134. doi: https://doi.org/10.1016/j.forpol.2015.08.008
34. Scott-Cawiezell J, Vogelsmeier A, McKenney C, Rantz M, Hicks L, Zellmer D. Moving from a culture of blame to a culture of safety in the nursing home setting. Nurs Forum United States; 2006;41(3):133–140. PMID:16879148
35. Aalborg Municipality. Vedtægter for bruger- og pårørenderåd på plejehjem. August 2021. 2021. Available from: https://www.aalborg.dk/politik-og-indflydelse/raad-naevn-og-andre-udvalg/raad/vedtaegter-for-bruger-og-paaroerenderaad-paa-plejehjem [accessed Nov 24, 2023]
36. Taylor B, Henshall C, Kenyon S, Litchfield I, Greenfield S. Can rapid approaches to qualitative analysis deliver timely, valid findings to clinical leaders? A mixed methods study comparing rapid and thematic analysis. BMJ Open 2018 Oct 1;8(10):e019993. doi: 10.1136/bmjopen-2017-019993
37. Revsbæk L, Tanggaard L. Analyzing in the Present. Qual Inq SAGE Publications Inc; 2015 Mar 18;21(4):376–387. doi: 10.1177/1077800414562896
38. Halloy A, Simon E, Hejoaka F. Defining patient's experiential knowledge: Who, what and how patients know. A narrative critical review. Sociol Health Illn England; 2023 Feb;45(2):405–422. PMID:36443986
39. Alminde S, Warming H. Future workshops as a means to democratic, inclusive and empowering research with children, young people and others. Qual Res SAGE Publications; 2019 Jul 27;20(4):432–448. doi: 10.1177/1468794119863165
40. Kolb DA. The Process of Experiential Learning. 2019;(July). doi: 10.1016/B978-0-7506-7223-8.50017-4
41. Lindhout P, Reniers G. The "Transparency for Safety" Triangle: Developing a Smart Transparency Framework to Achieve a Safety Learning Community. Int J Environ Res Public Health Switzerland; 2022 Sep;19(19). PMID:36231340
42. Wiig S, Aase K, Bourrier M, Røise O. Transparency in Health Care: Disclosing Adverse Events to the Public BT - Risk Communication for the Future: Towards Smart Risk Governance and Safety Management. In: Bourrier M, Bieder C, editors. Cham: Springer International Publishing; 2018. p. 111–125. doi: 10.1007/978-3-319-74098-0_8
43. Odberg KR, Aase K. Facilitators and Barriers to Safe Medication Administration in Nursing Homes. Medicat Saf Munic Heal Care Serv 2022;(2022):297–319. doi: 10.23865/noasp.172.ch14
44. Wiig S, Aase K, Bal R. Reflexive Spaces: Leveraging Resilience Into Healthcare Regulation and Management. J Patient Saf 2021;17(8). Available from: https://journals.lww.com/journalpatientsafety/Fulltext/2021/12000/

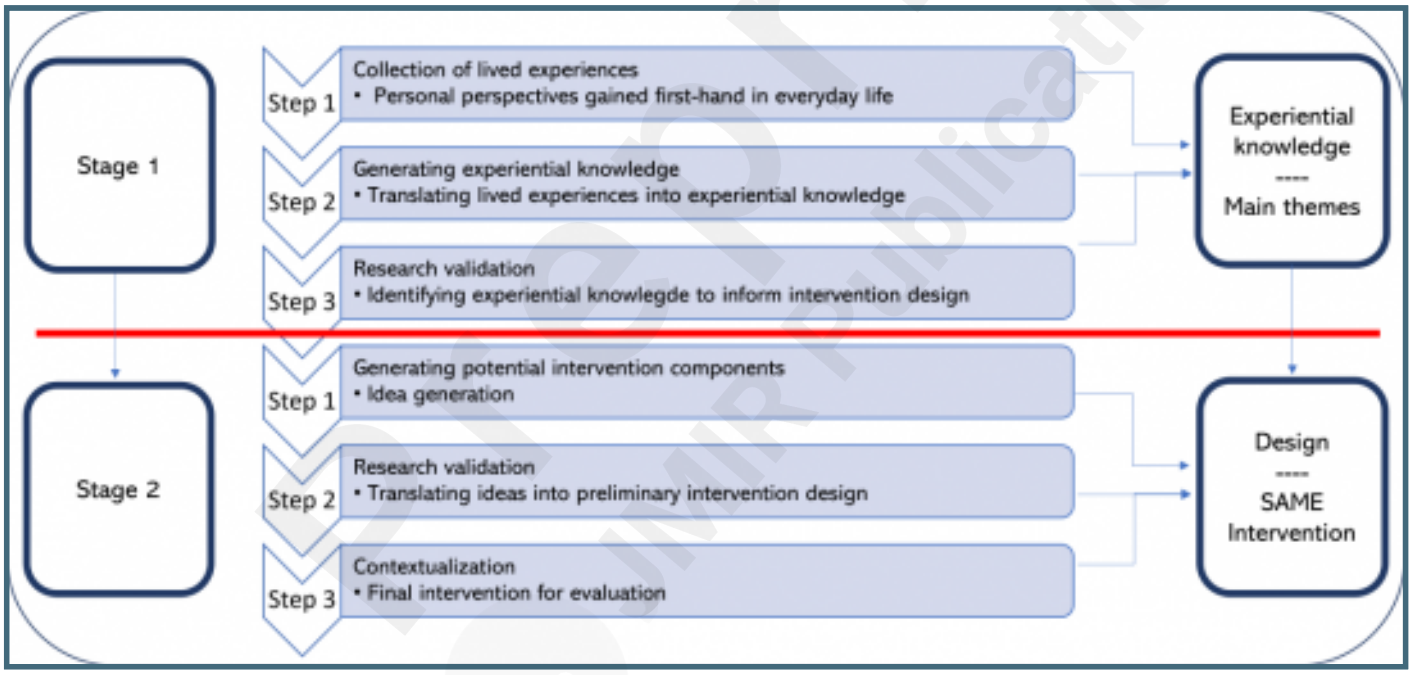
Reflexive_Spaces__Leveraging_Resilience_Into.137.aspx
45. Odberg KR, Hansen BS, Wangensteen S. Medication administration in nursing homes: A qualitative study of the nurse role. Nurs Open John Wiley & Sons, Ltd; 2019 Apr 1;6(2):384–392. doi: https://doi.org/10.1002/nop2.216
46. Odberg KR, Hansen BS, Aase K, Wangensteen S. Medication administration and interruptions in nursing homes: A qualitative observational study. J Clin Nurs England; 2018 Mar;27(5–6):1113–1124. PMID:29076582
47. Hays R, Daker-White G, Esmail A, Barlow W, Minor B, Brown B, Blakeman T, Sanders C, Bower P. Threats to patient safety in primary care reported by older people with multimorbidity: Baseline findings from a longitudinal qualitative study and implications for intervention. BMC Health Serv Res BioMed Central Ltd.; 2017 Nov 21;17(1). PMID:29162094
48. Cathain AO. Guidance on developing interventions to improve health and health care 2019. 2019;(August).
49. Noyes AL. Navigating the Hierarchy: Communicating Power Relationships in Collaborative Health Care Groups. Manag Commun Q SAGE Publications Inc; 2021 Jun 17;36(1):62–91. doi: 10.1177/08933189211025737
50. Graham ID, Kothari A, McCutcheon C, Angus D, Banner D, Bucknall T, Dunn S, Gagnon M, Gifford W, Godfrey C, Holmes B, Horsley T, Hutchinson AM, Jull J, Law S, MacLeod M, McLean RKD, Mrklas K, Nguyen T, Plamondon K, Rycroft-Malone J, Sibbald SL, Sibley KM, Stacey D, Wright DK, Yeung E, Leads O behalf of the IKTRNP. Moving knowledge into action for more effective practice, programmes and policy: protocol for a research programme on integrated knowledge translation. Implement Sci 2018;13(1):22. doi: 10.1186/s13012-017-0700-y
51. Peschl MF. Unlearning towards an uncertain future: on the back end of future-driven unlearning. Learn Organ Emerald Publishing Limited; 2019 Jan 1;26(5):454–469. doi: 10.1108/TLO-11-2018-0192
52. Rushmer R, Davies HTO. Unlearning in health care. Qual Saf Heal Care 2004 Dec 1;13(suppl 2):ii10 LP-ii15. doi: 10.1136/qshc.2003.009506
53. Esen A, Asik O, Ege T. Unlearning in organizations: Understanding and rethinking the way organizations learn and change. Pressacademia 2019 Jul 30;9:43–47. doi: 10.17261/Pressacademia.2019.1062
54. Braithwaite J, Wears RL, Hollnagel E. Resilient health care: turning patient safety on its head. Int J Qual Heal care J Int Soc Qual Heal Care England; 2015 Oct;27(5):418–420. PMID:26294709
55. Tocco Tussardi I, Cazzoletti L, Zanolin ME, Comini A, Visentin D, Torri E, Tardivo S, Moretti F. Patient Safety Subcultures among Nursing Home Staff in Italy: A Cross-Sectional Study. Healthc (Basel, Switzerland) Switzerland; 2023 Jul;11(13). PMID:37444796
56. Mannion R, Davies H. Understanding organisational culture for healthcare quality improvement. BMJ 2018 Nov 28;363:k4907. doi: 10.1136/bmj.k4907
57. Deilkås ECT, Hofoss D, Hansen EH, Bondevik GT. Variation in staff perceptions of patient safety climate across work sites in Norwegian general practitioner practices and out-of-hour clinics. PLoS One 2019;14(4):e0214914. PMID:30970041
58. Danielsson M, Nilsen P, Öhrn A, Rutberg H, Fock J, Carlfjord S. Patient safety subcultures among registered nurses and nurse assistants in Swedish hospital care: a qualitative study. BMC Nurs 2014;13(1):39. doi: 10.1186/s12912-014-0039-5
59. Lyng HB, Macrae C, Guise V, Haraldseid-Driftland C, Fagerdal B, Schibevaag L, Wiig S. Capacities for resilience in healthcare; a qualitative study across different healthcare contexts. BMC Health Serv Res 2022;22(1):474. doi: 10.1186/s12913-022-07887-6
60. Haraldseid-Driftland C, Lyng HB, Guise V, Waehle HV, Schibevaag L, Ree E, Fagerdal B,

Baxter R, Ellis LA, Braithwaite J, Wiig S. Learning does not just happen: establishing learning principles for tools to translate resilience into practice, based on a participatory approach. BMC Health Serv Res 2023;23(1):1–10. doi: 10.1186/s12913-023-09653-8

Supplementary Files

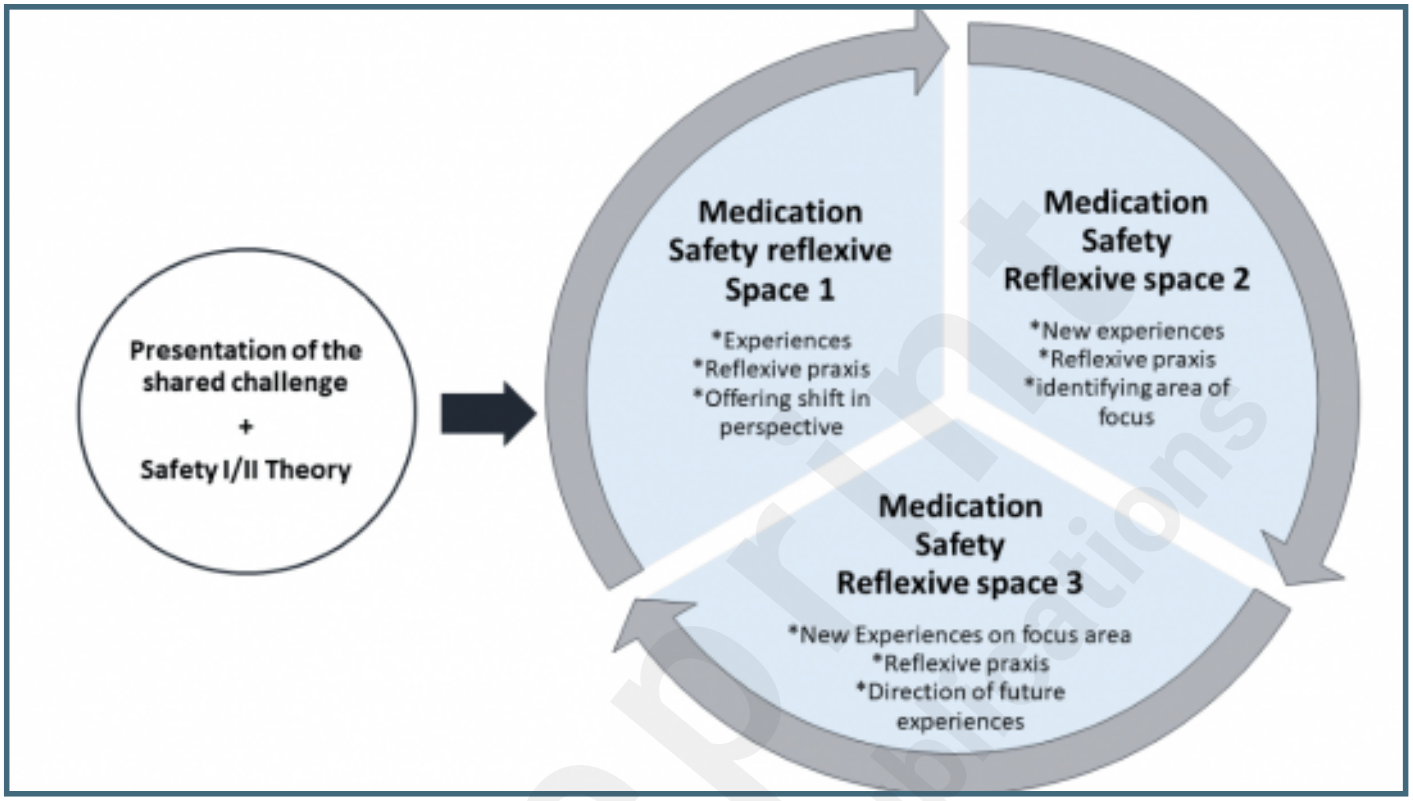
Figures

The co-creative process. Illustration of the iterative, integrative, co-creative process of intervention development including main stages and respective steps Stage 1: Generating experiential knowledge on medication safety to inform intervention design - Step 1: Conducting exploratory focus groups to collect individual lived experiences from representatives of nursing home residents including and nursing home frontline healthcare professionals. - Step 2: Translating these individual experiences into a shared understanding of medication safety in nursing home residents in a triangulated process, forming experiential knowledge represented as main themes. - Step 3: Validating the experiential knowledge by researchers holding different fields of expertise, including qualitative, quantitative, and participatory research methods to ensure reliability and validity of the experiential knowledge. Stage 2: Designing the intervention - Step 1: Facilitating idea-generation for preliminary intervention components in a multidisciplinary workshop, informed by validated experiential knowledge from Stage 1. - Step 2: transforming ideas into preliminary intervention components - through exploratory focus groups, including translation of individual, lived experience (step 1) into a shared understanding of medication safety in nursing home residents (experiential knowledge; step 2) and research validation (step 3). Stage 2: Designing the final intervention in a multidisciplinary workshop though idea generation informed by experiential knowledge resulting from stage 1 (step 1), research validation (step 2) and contextualization (step 3).



The analytical triangulated process. Firstly, researcher A was responsible for gathering individual analyses of all co-creators involved (left figure). Secondly, all co-creators met and discussed what was found and collaboratively decided on the outcome (right figure). a External consultant refers to the external consultant in communication- and innovation.

Overview of the general model of the reflexive component (Component 2) of the SAME intervention consisting of iterative "Medication safety reflexive spaces". Developing a culture of medication safety though continuous, collaborative learning, integrating Safety II Theory, and focusing on experiential knowledge.*Refers to the concepts being "Shared".



Multimedia Appendixes

Description of the individual "Medication safety reflexive spaces".
URL: http://asset.jmir.pub/assets/03aaece70a382c9a054a541066628fff.docx

CONSORT (or other) checklists

GUIDED checklist added comments.
URL: http://asset.jmir.pub/assets/891f31beadc010d72fa5c0043fd9ac35.pdf