A Combined Telemedicine and Ambulatory Wound Care Team Intervention for Improving Cross-Sector Outpatient Chronic Wound Management: The TELE-AMBUS Research Project Protocol

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Abstract

Background: There is a growing prevalence of non-healing wounds and chronic diseases in societies, and an associated need for wound management solutions that include the use of telemedicine. There is also a broad spectrum of factors influencing the planning and execution of interventions within telemedicine in chronic wound management, spanning organization, technology, and individuals including the professional and the patient. The TELE-AMBUS project applies a whole system research approach to account for this spectrum of factors.

Objective: The primary objective is to explore and analyse implementation and consequences of an outpatient wound management model comprised of two interconnected quality improvement interventions – telemedicine and ambulatory wound care team – aimed at elderly and vulnerable chronic wound patients across the specialist and primary healthcare sectors. Embedded in this objective is the aim to improve competence levels of healthcare providers and consequently service quality of outpatient wound management across specialist and primary healthcare services.

Methods: By means of a combined process and economic evaluation research strategy, this project examines implementation and consequences of an outpatient wound management model. A sociotechnical system theory approach and multiple work package design support the examination. The project employs observations, conversations, interviews, and economic assessments to gather rich in-depth insight and the basis for understanding why and how the new wound management model contributes to a change or not, compared to the traditional treatment model.

Results: The project was funded from 2021 to 2025. A systematic review and synthesis of knowledge on telemedicine interventions in chronic wound management was published in the International Wound Journal in July 2022. Baseline interviews have been conducted since April 2022 and are expected to conclude in early 2024. Field work including non-participant observations, semi-structured interviews, and informal conversations have been conducted since November 2022 and are expected to conclude in March 2025. Initial empirical results from the baseline interviews were presented at the Organizational Design and Management Conference 2023 conference.

Conclusions: We apply a socio-technical system framework in multiple and creative ways, i.e., to design/inform our field work and to explore and redesign an outpatient model and work systems across sectors, with SEIPS becoming a pedagogic tool to translate and implement project findings into practice across services. This approach has to our knowledge not been undertaken in human factors and ergonomics literature more broadly as well as telemedicine in chronic wound management literature. Thus, our approach can produce both original and novel research and theoretical results internationally. Clinical Trial: The TELE-

AMBUS research project was accepted by the ethical committee REC West in Norway (application id. 375986) and approved by NSD Norwegian Centre for Research Data (reference no. 236558). The project has also been agreed by the internal data protection representative at Stavanger University Hospital (SUH) (protocol no. 2847-2847).

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Abstract

Background: Society is experiencing a growing prevalence of non-healing wounds and chronic diseases, and there is an associated need for wound management solutions that include the use of telemedicine. A broad spectrum of factors influences the planning and execution of interventions within telemedicine in chronic wound management, spanning organization, technology, and individuals, including the professional and the patient. The TELE-AMBUS project applies a whole system research approach to account for this spectrum of factors.

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Methods: This project examines the implementation and consequences of an outpatient wound management model through a combined process and economic evaluation research strategy. A sociotechnical system theory approach and multiple work package design support the examination. The project employs observations, conversations, interviews, and economic assessments to gather rich, in-depth insight and the basis for understanding why and how the new wound management model contributes to a change or not compared to the traditional treatment model.

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Conclusions: We apply a whole-system approach in multiple ways, i.e., to design/inform our fieldwork and to explore, evaluate, and translate project findings into practice across services. To our knowledge, this approach has not been undertaken in telemedicine in chronic wound management literature and associated human factors and ergonomics research. Thus, our approach can produce both original and novel research and theoretical results internationally.

Trial Registration: The TELE-AMBUS research project was accepted by the Regional Committee for Medical Research Ethics Western Norway (application id. 375986) and approved by the Norwegian Centre for Research Data (reference no. 236558). The project has also been cleared by the internal data protection representative at Stavanger University Hospital (protocol no. 2847-2847).

KEYWORDS

Chronic wound management; specialist healthcare sector; primary healthcare sector; ambulatory wound care team; telemedicine; process evaluation; economic evaluation; observations; interviews; whole system framework.

Introduction

The prevalence of non-healing wounds (i.e., not healing within six weeks) and chronic diseases in society is growing, which impacts both patients' quality of life and the costs of healthcare delivery [1-3]. Moreover, society is facing an increasingly overburdened and financially strained healthcare system due to global pandemics, multi-front conflicts and wars, economic decline, and so forth. To alleviate the overall burden on the healthcare system, the Norwegian National Health and Hospital Plan 2020-2023 focuses on integrated healthcare services that are closer to patients' homes. The plan emphasizes the creation of outreach hospitals that will provide more healthcare in patients' homes, collaborate better with municipal health and care services, in person and virtually, and work more closely with other hospitals [4]. Aligning with this plan, the Norwegian Digital Strategy for the Public Sector 2019–2025 highlights that public services shall be perceived as seamless and integrated by the users [5]. Reflecting the concern for chronic states in society and associated political measures, as manifested in national health planning, this article presents the protocol for the research project "TELE-AMBUS – Exploring and redesigning a cross-sector outpatient chronic wound management model comprising telemedicine and ambulatory wound care interventions." The TELE-AMBUS project was initiated based on a) a strong desire of our project partner, the Wound Diagnostic Centre (WDC) in Stavanger, to test an outpatient chronic wound management model, combined with b) identified knowledge needs within the domain of telemedicine (TM) in chronic wound management interventions.

Regarding current domain knowledge, our systematic literature review revealed a need for broader or more comprehensive empirical exploration into quality improvement and integration of TM and chronic wound management [6]. These explorations should expand on and extend beyond the currently identified intervention barriers and opportunities. Specifically, TM in chronic wound management barriers include delays in installing the TM software and workforce shortages, over time leading to a steep decline in individuals using TM [7]; limitations set by the organization and technology in terms of management focus, resources, economy, consultation time, wound training, and the need for updated equipment [8,9]; and qualities of the individual/professional such as the patient's confidence in the competence and professional skills of health professional [10]. On the flip side, opportunities generated by TM in chronic wound management include the (TM) technology's potential for improving wound evaluation accuracy by means of tools and software developments [11-14]; the potential that gathering individual healthcare professionals with a shared focus on the patient can enhance clinical outcomes across the wound spectrum, clinical care settings, and geographical locations [15]; and the health-related quality of life dimension that professional, patient, and next-of-kin express satisfaction with TM as a treatment method [14,16]. Shedding light on both quality of life and monetary cost reduction opportunities, Dardari et al [17] found that a "telemedical intervention with an expert nurse could lead to a length of hospitalization and direct costs that are two times lower compared to conventional follow-up" (p. 10).

Concerning the specific outpatient model explored in the TELE-AMBUS project, wound specialist nurses at the WDC expressed a years-long desire to explore an outpatient model where a team of specialist nurses, in consultation with the relevant hospital physician, provides ambulatory wound care diagnosis and treatment to vulnerable chronic wound patients with non-healing wounds that have various mobility challenges and reside in the municipalities. The mobility challenges include the patient being elderly/frail, having advanced or complex wounds, and/or experiencing travel stress and appointment difficulties. The underlying rationale for testing the model is as follows: (i) Patients may be evaluated by nursing and physician specialists before their conditions deteriorate; (ii) vulnerable patients' quality of life may improve as the suffering caused by wounds is reduced; (iii) primary care (municipal) healthcare professionals may learn from the specialist ambulatory wound care team (AWCT) and be provided with a more direct line of communication with the hospital specialists via TM, thus improving general wound care for patients; and (iv) the AWCT provides early interventions aided by the TM solution that may reduce costs levels at the hospital and primary

care facilities.

Illustrated by the contextual backdrop of national plans and strategies, the current knowledge status, and the outpatient wound management model, intervention barriers and opportunities have as much to do with the organizations and the individuals involved as with the technology. Thus, research conducted on interventions within TM in chronic wound management needs to consider a broad spectrum of factors that can influence the planning and execution of interventions with factors spanning organization, technology, and individuals, including professionals and patients. This spectrum of factors or conditions has been accounted for in the TELE-AMBUS project's whole system research approach (see the methods section). Our approach resonates with Kahn's [18] suggestion that "researchers should explore the crucial issue of context, studying not only whether telemedicine [and by extension, the overall outpatient model in this project] works but also how, when, and where it works best, to provide a roadmap for more effective implementation" (p. 1684).

Key Definitions

Telemedicine (TM), as a central concept in the outpatient model of the TELE-AMBUS project, can be clarified as the use of electronic information and communication technology (ICT) to exchange healthcare information between healthcare practitioners across sites/distances, which can improve healthcare delivery and outcomes including patients' health status [19]. The TM solution selected for the TELE-AMBUS project involves the primary care nurses using a secure cell phone to send wound pictures to the specialist AWCT, who reviews and logs the pictures (via the patient's journal) and responds to the primary care nurses with suggestions and/or recommendations. This is not a dedicated TM solution, currently unavailable in Norway. TM is part of e-health, which is understood as healthcare services provided electronically via the Internet.

The specialist ambulatory wound care team (AWCT) is a team of specialized wound nurses who travel to the patient's home, examine and treat the patient, and educate the present municipal health personnel on the wound treatment procedure applied to the patient.

Primary and Secondary Project Objectives

Targeting the knowledge needs identified above, as well as the WDC's desire to test an outpatient chronic wound management model, the TELE-AMBUS research project has the following primary objective: To explore and analyze the implementation and consequences of an outpatient model comprised of two interconnected quality improvement interventions – TM and AWCT – aimed at elderly and vulnerable chronic wound patients across the specialist and primary healthcare sectors. Embedded in this objective is the aim to improve the competence levels of healthcare providers and, consequently, service quality of outpatient wound management (diagnosis and treatment) across specialist and primary healthcare services.

Four secondary objectives are supporting and extending the primary objective, grounded in qualitative and quantitative approaches: (i) To systematically review and synthesize existing knowledge on interventions within TM in chronic wound management, including barriers and opportunities and associated measures/elevation efforts across the specialist and primary healthcare sectors (see the introduction section, and Høyland et al [6]); (ii) from a socio-technical system theory approach focused on the SEIPS model, to explore and analyze the outpatient model/interventions and cross-sector work system (see methods section); (iii) from a health economic perspective, to assess the cost-effectiveness of implementing an outpatient model across the specialist and primary healthcare sectors; (iv) to transform project findings into managerial and employee strategies and practices across specialist and primary healthcare. Each secondary objective constitutes an individual work package in the TELE-AMBUS project.

Methods

Setting and Participant Recruitment

The WDC, responsible for organizing and running the new outpatient wound intervention, is located at the Department of Dermatology, Stavanger University Hospital (SUS), Norway. SUS employs more than 7600 individuals and provides healthcare services to 18 municipalities with a population

of about 350,000. The WDC is unique in a Norwegian context, as specialists from different professions and disciplines (wound specialist nurses, a vascular surgeon, a dermatologist) gather to examine patients in one location comprehensively and assemble coherent treatment plans. The WDC operates each Tuesday with cross-disciplinary wound assessment and treatment. Each week, the WDC has an average of 2 diabetic wounds, 1-2 arterial wounds, 3 venous wounds, 2 immunological wounds, and 1 pressure wound, totaling 10 patients. The size of the ulcerations varies from a pin size to most of the leg. Healing varies according to wound size, the patient's condition (physical and mental), activity levels and self-insight, the competency levels of municipal health personnel, including wound follow-up, and more.

Other interdisciplinary wound centers compare to the WDC in Norway in terms of being interdisciplinary and/or outpatient-focused and sharing publicly financed healthcare systems and institutions. Within the Nordics, we find the Copenhagen Wound Healing Centre at Bispebjerg University Hospital (Denmark), the University Center of Wound Healing in Odense (Denmark), and the Wound Center (Haavakeskus) at Helsinki University Hospital (Finland). Extending further, we find the former Welsh Wound Innovation Centre (WWIC) in the UK focused on outpatient chronic wound healing and innovation.

The project manager from the Norwegian Research Centre (NORCE), in dialogue with WDC, conducted the initial municipal partner recruitment process as well as subsequent calls for additions or adjustments of included subunits (home care services and nursing homes), with the latter process being facilitated by the project manager's contact with appointed coordinators in each municipality. The WDC's main criterion for selecting municipalities was practical proximity to the hospital running the outpatient intervention, specifically, about one hour driving distance. In addition to a regional university hospital in Norway, a total of six municipalities, varying in size, chose to participate in the research project. Five of the municipalities included home care services and nursing homes, while one municipality limited inclusion to nursing homes and only 1 of 5 home care services zones. Regarding recruitment of patient cases for the intervention, the AWCT at the WDC receives and processes ongoing patient referrals from units in the municipalities. Specifically, the wound specialist nurses/AWCT receive patient referrals from general practitioners (GPs) in the municipalities. The AWCT assesses whether the referred patient is a suitable candidate for the intervention, with the selection criteria being hard-to-heal wounds and the patient having a multimorbid condition. The exclusion criteria are immunological and diabetic wounds. Both the WDC and municipalities self-organize the internal recruitment of study participants for research activities in the TELE-AMBUS project.

To gain empirical insights into the process of implementing and operating the outpatient intervention – combining AWCT and TM implementation and operation – individuals involved with the intervention will be asked to participate in research activities, including observations (i.e., being observed by the researchers), semi-structured interviews, and informal conversations. Combining observations with asking questions, including clarification questions, constitutes a contextual design approach [20]. To account for both service ends of the intervention, invited participants will include the AWCT, which was comprised of two wound specialist nurses and the nursing staff in the municipalities (from home care services and nursing homes). In addition, key informants associated with the outpatient intervention will be invited to participate in semi-structured interviews, including healthcare managers, IT personnel, and other stakeholders at different levels of the hospital system. Table 1 provides an overview of the participants involved in the project's intervention and/or research activities.

To summarize, the TELE-AMBUS project applied the following inclusion criteria: (i) municipalities with practical proximity to the hospital running the outpatient intervention; (ii) vulnerable chronic wound patients with non-healing wounds who have various mobility challenges and reside in the municipalities (see the Introduction section); (iii) all healthcare professionals and levels involved in the AWT intervention (see Table 1). In addition, the study applied the following exclusion criterion:

Patients with diabetic foot ulcers who belong to another hospital department and are not involved in the outpatient intervention.

Project participant category	Project participant type	Specific roles
Regional partner: University hospital	Wound specialist nurses, a dermatologist, a vascular surgeon, a general surgeon, IT-personnel, higher- and mid-level managers, including the local project coordinator and economy department	Operated the new wound management model; participated in observations, conversations, and/or interviews; participated in regular scientific advisory meetings
Regional partners: 6 Municipalities	Medical and non-medical trained nursing staff at home care services and nursing homes; higher- and mid-level managers at the municipal level, including local project coordinator and economy department	Participated in observations, conversations, and/or interviews; one municipal partner participated in regular internal meetings at the university hospital
National partner: Norwegian Centre for E-health Research	Senior Advisor	Participated in regular scientific advisory meetings, partner-specific meetings, and dissemination activities
International partners: Welsh Wound Innovation Centre (WWIC) and the University of Wisconsin-Madison	WWIC: chief operating officer, clinical research director, professor in chronic wounds; University of Wisconsin-Madison: professor in system theories	Participated in regular scientific advisory meetings, partner-specific meetings, and dissemination activities

Table 1. Categories and types of participants involved in the intervention and/or research activities in the TELE-AMBUS project, including regional, national, and international partners.

Given that we study a hospital-initiated intervention where patient visits (cases) are generated by referrals from the involved municipalities, no sample size limitation was defined. However, we have recently crossed a 30 patient visits/cases threshold, which includes 30 observations (by 1-2 participating researchers) and associated on-site and later follow-up interviews with municipal health personnel and the AWT. Our impressions of the newer patient visits are beginning to converge with impressions from previous visits, suggesting the effect of data saturation. However, due to the ongoing nature of this intervention and our desire to pursue “challenging” cases (where things go less according to plan), of which we have fewer, we expect that further patient visits will be conducted till the first quarter of 2025 and perhaps beyond (depending on perceived data saturation), likely ending with around a total of plus/minus 40 patient visits/cases.

Research Approach

Improvement interventions, defined broadly as purposeful efforts to secure positive change, have become an increasingly important focus of activity within healthcare, including wound management [21-23]. The larger intervention studied in the TELE-AMBUS project is the outpatient wound management model itself, which can be considered an improvement intervention in its initial form improvement rather than research-directed [21] due to the wound specialist nurses’ ownership and desire to explore the model in the context of elderly and vulnerable patients. It is also a complex coordinated care intervention, comprising multiple interacting and intertwined components (TM and AWCT) across different levels and organizations, in this case, involving primary and specialist healthcare services, and in the case of primary healthcare, numerous municipalities with specific characteristics [15]. Therefore, the most appropriate design is process evaluation because it can “assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes” [24]. Supportive of this design, we identified a need for broader or more comprehensive empirical explorations into quality improvement and integration

of TM in chronic wound management to capture the complexity of organization, technology, and individual interplay across sectors (see the introduction section).

The Process Evaluation

For the TELE-AMBUS project, we employ a qualitative longitudinal study design, following and analyzing the intervention as it unfolds in practice. We apply the process evaluation framework by Moore et al [25], with descriptions of the intervention, the implementation, the mechanisms, and the outcomes in relation to the context, and where we utilize several data collection and analysis methods. The qualitative research approach comprises situated methods and data collection that is carried out for a sustained period of time (for this project, systematic literature review, non-participant observations, semi-structured interviews, and informal conversations are situated and carried out in an outpatient wound management setting for a sustained period of time); a view that the social world is multi-faceted and thus requires a certain degree of interpretation (outpatient chronic wound care occurs in a complex setting of multiple disciplines and technologies, types of patients, and so forth across sectors); and an inherent exploratory nature suited to the study and conceptualization of new or emerging phenomena, such as this project's tandem exploration of TM and AWCT [26-31].

Findings of our systematic literature review on the topics of TM and ambulatory wound care management interventions [6] shape a basic mental orientation for the fieldwork, including the observational protocol and associated observations of the AWCT and nursing staff during patient consultations. This mental orientation also assists in identifying the broader and more specific questions to raise during informal conversations and in-depth semi-structured interviews with managers and employees across specialist and primary healthcare case organizations. Seminars and digital meetings with project partners conducted throughout the project period, where partner insights and experiences – including from specialists in wound management, innovation, e-health, health economy, and system perspectives – and empirical findings are presented, serve to adjust and "sharpen our field lens" in terms of observational and interview focus (such as, what barriers or outcomes to explore further) for the continuing fieldwork. Moreover, the lens sharpening effect is also reversed, whereby we as researchers apply our whole system perspective in partner meetings/dialogue as well as during the intervention (through observations, interviews, and conversations), thus challenging the partners to adopt a broader understanding of systems, organizations, and change.

The Economic Evaluation

Regarding the quantitative approach applied in the project, we aim to conduct a health economic evaluation of the outpatient model (intervention) compared to the regular clinical wound management model. An economic evaluation will measure two parameters, costs and outcome(s)/effect(s), and compare the two approaches. Intended to inform decision-making, the idea behind an economic evaluation is not necessarily to identify which of the two improvement interventions is the "better" one; rather, if the cheapest option is the most effective, it will be the most cost-effective/dominant option, or if the cheapest option is not the most effective, incremental cost-effectiveness ratio will be measured [32]. There are several methods for the economic evaluation of healthcare programs. In the context of this project, it is relevant to focus on the intervention. Since the new model/intervention will also have consequences for resource allocation, considerations of both cost and benefits (here, health improvement) are necessary and fundamental to quality improvement evaluation (e.g., the Institute for Healthcare Improvement, USA). There are alternative perspectives on the economic evaluation of healthcare programs as well. In this project, we are concerned with a healthcare sector perspective, i.e., focusing on consequences for primary and specialist healthcare and the patient. Potentially, the intervention may lead to both short-term and long(er) term health improvements. Short-term improvements may follow from earlier referrals to specialist healthcare, thereby resulting in less severe admissions to the hospital, shorter length of stay, less pain and discomfort for the patients, and potentially quicker recovery. In the longer term,

increasing competence and awareness in primary healthcare services can potentially reduce the number of severe cases admitted to the hospital. Specific measures/outcomes of health improvements are in the short-term analyses change in the number of hospital admissions due to a reduction in serious and complicated cases compared to the regular wound model. In the longer term, a change in the number of admitted wound patients, regardless of whether they are complicated or not, compared to the regular wound model. Costs may change, too, for both primary and specialist healthcare services, and the relative distribution of costs between services may change. The regular wound model too often seems to result in severe and complicated admissions to the hospital, a situation that increases costs both at primary care and specialist care levels. However, one consequence of a sub-optimal level of competence and capacity at the primary healthcare level is that some of the treatment costs are passed on to specialist healthcare. Hospitals are compensated for at least part of these costs through the remuneration system (DRG-based), but that is not a relevant issue from a societal/healthcare sector perspective.

The economic evaluation will be based on case data collected during the intervention period. The data include reported time usage by nurses and physicians, allowing cost calculations to be made in NOK. The intervention's costs, including equipment costs, are compared to treatment as usual costs collected from participating municipalities. Based on relevant ICD-10 codes, register data from the Norwegian Patient Register (NPR) is used to estimate nationwide costs associated with wound treatment. To the extent the intervention contributes to reducing the use of hospital care/hospital resources for the treatment, we can estimate net benefits and model the potential aggregate net benefits nationwide of the intervention.

Summarized, the TELE-AMBUS project applies a combined process and economic evaluation research strategy with associated qualitative and quantitative endpoints that can affect the primary and specialist healthcare systems within and across. The endpoints include improvements in cost-effectiveness (economic evaluation) and competence and service quality (process evaluation) of the new outpatient model versus the regular clinical wound management model.

Sociotechnical system approach

Reflecting the knowledge limitations identified in the introduction, our conceptual and analytical whole system approach selected for this project is based on system theories. Sociotechnical system (STS) theory concerns interactions between and joint design of the technological subsystem, the personnel subsystem, and relevant external surroundings, being mutually interdependent and where any alterations or changes in one part of a system (e.g., technology such as telemedicine) will impact other parts of the system [33]. Embedded in the STS tradition is the Human Factors / Ergonomics (HF/E) discipline focusing on systems where humans interact with the environment “to jointly improve performance and well-being by designing the integrative whole better, and by integrating the human into the system better” [34]. The core characteristics of the HF/E discipline are, therefore, (i) the system approach and (ii) the design-driven approach, as well as (iii) the focus on outcomes related to both system performance and well-being [34]. Perspectives and models from the HF/E discipline are recommended in the World Health Organization's Global Patient Safety Action Plan [35], specifically the second strategic objective to «build high-reliability systems and health organizations that protect patients daily from harm,» i.e., the emphasis is on designing safe and sustainable healthcare systems for the future.

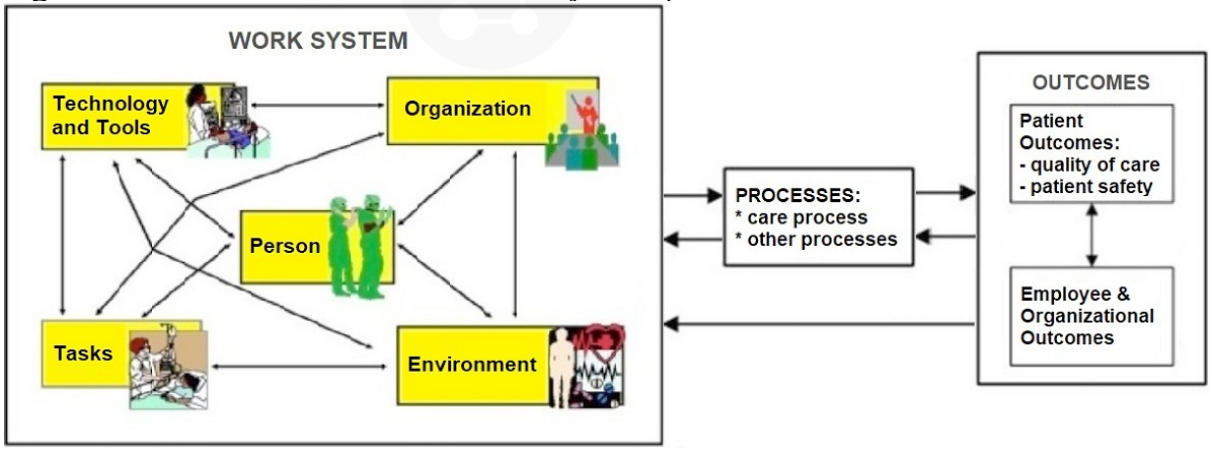
Anchored within the STS tradition is the SEIPS (Systems Engineering Initiative for Patient Safety) framework, shown in Figure 1, which applies a whole system perspective on healthcare [36]. The framework details elements within a work system (person, technology and tools, task, environment, and organization) that interact and are mutually interdependent. The design of the work system affects different processes (e.g., clinical treatment and patient follow-up) that influence different outcomes related to patient, employee, and organizational outcomes [36]. A core aspect of the SEIPS framework, in relation to the TELE-AMBUS project, lies in its ability to inform implementation, change management, and overall design of complex systems, thereby contributing towards

prevention/avoidance of undesired outcomes across system performance and well-being in a health care context, specifically in terms of patient outcomes (mortality, complications, quality of life, medical errors), organizational outcomes (efficiency, treatment time), and employee outcomes (well-being aspects such as job satisfaction and motivation) [37]. The feedback loops in the framework suggest that knowledge/insights into the dynamics of the model, including outcomes, can be applied to adjust and redesign the work system [37].

The outpatient model relates to the SEIPS framework/Figure 1 as follows: The specialist ambulatory wound care team and primary care nurses constitute the center of the work system (person aspects), enabled or constrained by other aspects of the work system spanning both specialist and primary health care. For example, technology aspects of the work system include the TM application (used by both specialist and primary health care) and the patient journal system DIPS (used by specialist health care), while organizational aspects include staffing and competency levels and priority given/time allocated to outpatient wound management in everyday practices. Thus, the outpatient model and work system understanding take on an inter-organizational and interprofessional form, encompassing persons involved, the technology used, the specifics of the organization, and so forth across services. This cross-sector work system influences the outpatient wound care process (middle part of SEIPS) in terms of enabling or constraining the work tasks of the wound specialist nurses (e.g., evaluation of the patient's wound, bedside teaching of primary care nurses in wound care procedure and how to use the TM application) and the primary care nurses (e.g., follow-up of wound development including transference of pictures via the TM application). Finally, the quality of the outpatient wound care process produces organizational and individual outcomes (the right part of SEIPS) that are desirable to a larger or lesser degree. For the TELE-AMBUS project, these outcomes concern (a) the costs and benefits of the regular clinical versus outpatient treatment models and (b) changes in healthcare provider competence and quality across specialist and primary healthcare services. The latter outcome is tied to the project's degree of success or not in transforming empirical findings into managerial and employee strategies and practices across services.

While studies using the SEIPS framework have become substantial in recent years, there is a lack of intervention SEIPS-based studies, in particular (i) studies that jointly consider physical, cognitive, and organizational HF/E issues and (ii) studies that apply a broad approach to outcomes linking design with patient outcomes [37]. Moreover, the involvement of end-users (patients and providers) is emphasized from a participatory perspective [37]. Finally, reviews show that with a few exceptions, there is a lack of studies analyzing healthcare with an HF/E perspective within the Scandinavian context [37-39]. The operationalized SEIPS framework enables us to explore and analyze implementation and design aspects of the outpatient model, comprised of interconnected TM and AWCT interventions embedded within existing organizations and practices across the specialist healthcare services, the primary healthcare services, and, not least, the specific context of the chronic wound patient.

Figure 1. The SEIPS framework of work system, processes, and outcomes.



The model can analytically appear daunting due to its dynamic nature, i.e., in the presentation of mutually interacting work system relationships, but when purposefully operationalized, it enables the researcher(s) to capture the intricacy of the human-technological-organizational complexity under study. In our operationalization, we applied the five work system dimensions of the SEIPS model – internal environment, external environment, individual and team, organization, and technology and tools – not only to create a mental orientation for our fieldwork (in terms of what to look for during the patient visits) but also as coding guidance when processing data in the computer-assisted qualitative data analysis software (CAQDAS) QSR NVivo and Dedoose.

Ethics Approval

The TELE-AMBUS research project was accepted by the Regional Committee for Medical Research Ethics Western Norway (application id. 375 986) and approved by the Norwegian Centre for Research Data (reference no. 236558). The project has also been agreed upon by the internal data protection representative at Stavanger University Hospital (protocol nr. 2847–2847).

Data Collection and Analysis

As part of this project's qualitative longitudinal study design (see earlier section on research methods), empirical field data are gathered through observations, semi-structured interviews, and informal conversations across the specialist and primary healthcare services. The resulting data are analyzed via QSR NVivo and Dedoose, which enables systematization and transparency in both the analysis and dissemination of results, improving the reliability and trustworthiness of the study [27,40]. As we apply these approaches to the TELE-AMBUS project, we seek to map emergent patterns and connections in the data material related to (a) implementation and consequences of the outpatient wound management model and (b) associated improvements in healthcare provider competence and overall service quality across specialist and primary healthcare services (see section on primary and secondary project objectives).

As part of economic evaluation (see earlier section on research methods) and based on data gathered through the qualitative empirical fieldwork (as described above), costs associated with a generic pathway in the regular clinical wound model are calculated: costs at the primary healthcare level (e.g., staff hours, wages, medical equipment, and so forth) and costs at the specialist healthcare level (e.g., staff hours, wages, length of inpatient stay, and so forth). We do the same costing exercise for the new outpatient model comprising TM and the AWCT. We conduct one-way and deterministic sensitivity analyses as well as probabilistic sensitivity analyses (if feasible) for the quantitative cost-benefit analyses. The analyses feed into the overall objective of mapping emergent patterns and connections in the data material related to the implementation and consequences of the outpatient wound management model and associated improvements in provider competence and service quality.

Results

A series of baseline qualitative focus group interviews and semi-structured interviews with project participants/stakeholders at the hospital and in the 6 municipalities have been conducted since April 2022 and are expected to conclude in early 2024. Starting November 2022, the AWT has conducted outpatient visits and follow-up TM consultations, with the latter part lasting until the wound has healed or the patient's death (typically, patients are elderly with multimorbid conditions). The patient's wound condition is evaluated during the initial visit and subsequent follow-up TM consultations. The outpatient visits are expected to end in mid-2025. Field work, including observations, semi-structured interviews, and informal conversations, has been undertaken with project participants/stakeholders at the hospital and in the 6 municipalities since November 2022 and is expected to conclude in March 2025. The baseline interviews and subsequent fieldwork cover WP2 and WP3 in the TELE-AMBUS project, focused on exploring the intervention from a socio-technical system perspective as well as documenting health economic costs and effects of implementing the intervention, respectively (see Table 2). The results of WP2 and WP3 feed into WP4 on transforming project findings into cross-sectoral managerial and employee strategies and practices. Initial empirical results from the baseline interviews were presented at the 14th

Organizational Design and Management Conference [41]. One peer-reviewed publication has been published in the International Wound Journal [6], as part of WP1 targeting a cross-sector synthesis of existing knowledge on TM and chronic wound management interventions (see Table 2).

Table 2. TELE-AMBUS Gantt Chart 2021-2025, detailing project activities and participants across work packages and years. Table abbreviations are listed in the Abbreviations section.

	ACTIVITY/MAIN TASK DETAILS (T1-X)	PARTICIPANTS AND ROLES	SUPPORTING ACTIVITIES	2021		2022				2023				2024				2025		
				Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
WP0	T1: Project management and communication across partners, countries, sectors, and so forth	The NORCE project manager conducts the task	NORCE project support/FAST team, etc																	
WP1	T1: Initial systematic mapping review T2: Cross-sector systematic literature review/STARLITE T3: Synthesis/literature-informed SEIPS framework	CRG conducts the tasks; EIRG and ISAB provide critical input on tasks	Initial and end-of-WP digital meetings with EIRG and ISAB																	
WP2	T1: Based on WP1/SEIPS, exploring the outpatient model, identifying barriers, facilitators, and outcomes T2: Via findings and partner inputs, redesigning the outpatient model using the SEIPS framework	CRG conducts the tasks; all other partners provide critical input on SEIPS framework, field design, and/or findings	Initial, middle, and end-of-WP digital meetings and seminars involving EIRG, ISAB, CPAB, RMU, and PRO																	
WP3	T1: Cost-effectiveness assessments of the outpatient model compared to the traditional service delivery model	CRG conducts the tasks; EIRG and ISAB provide critical input on task	Initial, middle, and end-of-WP digital meetings with EIRG and ISAB																	
WP4	T1: Based on WP1-3/SEIPS, transforming knowledge into cross-sector management and practices, including a redesign of the current outpatient model T2: Main dissemination of project deliverables/outputs	CRG and EIRG conduct the tasks, merging national and international insights and experiences	Initial, middle, and end-of-WP digital meetings and seminars involving EIRG, ISAB, CPAB, RMU, and PRO																	

Note that the Gantt chart provided in Table 2 also elaborates on the roles and tasks of the project participants, such as designated researcher groups and advisory boards spanning the years and quarters of the project's time span.

Discussion

In terms of the TELE-AMBUS project status, findings of systematic reviews conducted in WP1 indicate that there is a pressing need for more comprehensive empirical explorations into quality improvement and integration of TM in chronic wound management, including using system frameworks that can capture cross-sector system perspectives and associated implications. We specifically suggest that the design and execution of TM improvement interventions and associated research projects should be conducted in close cooperation with managers and practitioners knowledgeable about barriers and opportunities that can influence the implementation of important interventions within chronic wound management [6]. The baseline results from WP2 and WP3, to be finalized this year, and the larger fieldwork data collection and analysis processes, to conclude in March 2025, are expected to reveal insights into organizational, environmental, technological, individual (personnel), and cost-effect considerations that are critical to account for in the (re)design of TM and outpatient model interventions across the primary and specialist healthcare sectors.

We apply the socio-technical SEIPS framework in multiple and creative ways, i.e., to design/inform our fieldwork and explore, evaluate, and redesign the outpatient wound management model and work systems across the primary and specialist healthcare sectors. Thus, SEIPS becomes a pedagogic tool to translate and implement project findings into practice across services. To our knowledge, such an approach has not been undertaken in TM in chronic wound management literature or associated human factors and ergonomics research. Specifically, existing cross-sector quality improvement studies focus on identifying TM-related barriers, benefits, acceptance levels, and outcome variables rather than on transforming findings into cross-sectoral managerial and employee strategies and practices and redesigning (work) systems across the primary and specialist healthcare sectors and

services [6, 42]. Thus, our approach can produce both original and novel research and theoretical results internationally. The project's tandem exploration of two quality improvement interventions within TM in chronic wound management – combining TM and AWCT to bring specialist and primary healthcare sectors closer – has, to our knowledge, not been undertaken in a Norwegian context and thus can produce novel national results within the field of TM and chronic wound management.

Strengths and limitations

As is the case for any research project employing a qualitative design approach, extrapolation and generalizability of the resulting findings can be problematic and, thus a limitation [43,44]. However, a qualitative approach offers unique, in-depth insight into the richness and complexity of the phenomenon under study. Applied to the TELE-AMBUS project, we utilize process and economic evaluations to capture why and how the studied intervention (outpatient model) contributed to change or not, including the associated mechanisms and outcomes at individual and organizational levels. Our primary research interest lies in knowing how the intervention works in practice across the involved organizations and influencing work system factors, hence allowing for redesigning/adjusting per the identified barriers. Thus, we address calls for whole system approaches within TM in chronic wound management research and STS research (see the introduction and research approach sections, respectively).

Conclusions

As noted in our systematic review [6], TM interventions in chronic wound management must adopt a longitudinal and broader system perspective across primary and specialist healthcare services that accounts for clinical applications, team approaches, and wound management and implementation strategies. The system perspective must also consider the quality of life, the existing care system, and cost aspects. These research needs are reflected in the new wound management model explored in the TELE-AMBUS project. This includes not only insights the project produces by means of identifying socio-technical barriers and facilitators and cost-effectiveness aspects associated with the outpatient model – in the latter case/analyses compared to a regular treatment model – but also by *thinking system redesign* including everyday healthcare management and professional strategies and practices across the primary and specialist healthcare sectors. This way of connecting system theory and empirical findings to actual practice (transformation) represents a key element and novelty of the TELE-AMBUS project with a potential impact spanning research and practice fields from HF/E to e-health and chronic wound management.

Authors' Contributions

SAH (NORCE) conceptualized, administrated, and drafted the research project and conducted the empirical investigation and formal data analysis. KAH, OØ, KI, EK, and RG-S contributed to conceptualizing the project, empirical investigation, and formal data analysis. SAH (SUS) and HRW contributed to conceptualizing the project and the empirical investigation. As Scientific advisory board members and project partners, PC, MF, SB, MG, SEH, and ER provided input on the project conceptualization, empirical investigation, and formal analysis. SAH (NORCE) drafted the manuscript, while all other authors reviewed, edited, read, and approved the final manuscript.

Conflicts of Interest

The authors declare no conflicts of interest.

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Data Availability

The economic data sets generated and analyzed during this study will be limitedly accessible in the Norwegian Centre for Research Data repository [https://sikt.no/en/find-data] once the embargo is lifted on 01.01.2027.

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Abbreviations

WDC: Wound Diagnostic Centre
TM: telemedicine
AWCT: ambulatory wound care team
ICT: information and communication technology
NORCE: Norwegian Research Centre
WWIC: Welsh Wound Innovation Centre
DRG: diagnosis-related groups
ICD-10: International Classification of Diseases, Tenth Revision
NPR: Norwegian Patient Register
STS: Sociotechnical system
HF/E: Human Factors / Ergonomics
SEIPS: Systems Engineering Initiative for Patient Safety
CAQDAS: computer-assisted qualitative data analysis software
WP = work package
CRG = core research group
EIRG = extended international researcher group
ISAB = International Scientific Advisory Board
CPAB = Clinical Practice Advisory Board
RMU = regional municipalities
PRO = Patient Representative Organization.

Supplementary Files

Figures

The SEIPS framework of work system, processes, and outcomes.