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Bridging organizational boundaries in complex care pathways: lessons from a Lean & Safety Management approach

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Abstract

Background: Complex care processes that span hospital and community settings represent a growing organizational challenge for healthcare systems, particularly in the management of chronic conditions. These pathways involve interdependent activities distributed across multiple facilities, professional groups, and levels of care, increasing the risk of fragmentation, inefficiency, and patient harm. While Lean Healthcare (LH) has been widely adopted to improve healthcare performance, its application has largely remained confined to single hospital units, with limited attention to care integration and patient safety. Evidence on how to design and implement improvement initiatives across hospital–community interfaces remains scarce.

Methods: This study developed, tested, and refined an integrated Lean and Safety Management (L&SM) methodology by combining LH with Clinical Risk Management to proactively address both waste and risk throughout the care process. The methodology was designed and empirically validated through three iterative Action Research cycles conducted in a real-world healthcare setting involving complex chronic care pathways bridging hospital and community services. Data were

collected through direct observation, document analysis, and stakeholder engagement, and analyzed iteratively across cycles to identify key activities, tools, barriers, and enablers of implementation.

Results: The proposed L&SM methodology demonstrated its applicability and effectiveness in improving the performance of complex care processes across organizational boundaries. The findings reveal key activities, tools, barriers, and enablers for implementing L&SM across hospital–community interfaces, while also uncovering cultural and organizational dynamics that shape improvement efforts. Beyond health care, these results shed light on how organizations operating in complex, high-stakes environments can jointly pursue efficiency and patient safety while fostering a culture of continuous improvement.

Conclusions: This study addresses a significant gap in the health services research literature by extending L&SM knowledge beyond hospital boundaries, addressing gaps in current literature. The research provides a structured, step-by-step methodology for implementing L&SM in complex care processes, tackling the managerial and organizational complexities of hospital–community integration, pursuing multi-dimensional performance improvement and aligning with global health priorities, thus offering an actionable guidance for healthcare managers and practitioners.

Keywords: Lean Healthcare, Lean implementation, continuous improvement, quality improvement, sustainability, action research

1. Introduction

Over the last decades, healthcare systems worldwide have faced escalating economic and social challenges that threaten their long-term sustainability. Population ageing and the growing burden of chronic diseases, responsible for 71% of all deaths globally (1), exert increasing pressure on healthcare delivery. Chronic conditions require continuous, resource-intensive care, with annual management costs estimated at €530 billion in the EU alone, equivalent to 3.13% of its combined annual GDP in 2023 (2). Beyond their economic impact, chronic diseases entail also social issues, reducing quality of life, exacerbating health inequalities, and increasing barriers to care. As a result, strengthening the integration between hospital and community services has become a strategic priority for the sustainability of healthcare systems (3,4).

Despite widespread recognition of the need for continuity of care, most healthcare systems remain highly fragmented. Hospitals, outpatient clinics, and primary care providers often operate in functional silos, with disconnected and redundant workflows, poor information sharing, cultural barriers, conflicting priorities, and weak cross-boundary coordination. Such fragmentation leads to duplication of activities, discontinued services, inefficiencies, delays, and risks (5,6), ultimately impacting on mortality and hospitalization rates. In this regard, (7) demonstrated how delays due to inefficient care delivery can be eliminated by improving coordination, planning and scheduling. Enhancing the integration between hospital and community care is therefore critical to improve patient

outcomes and support the economic and social sustainability of healthcare systems. Hence, it emerges the necessity to intervene, focusing on those pathways that bridge hospital and community (i.e.: chronic care), understanding how to improve their performance while addressing the challenges arisen by the complex, high-stakes socio-technical systems characterized by multiple missions, diverse professional identities, and distributed authority.

To meet these challenges, the adoption of managerial methodologies has become increasingly relevant. Among these, Lean Healthcare (LH) has emerged as one of the most widely adopted and effective approaches (8). LH aims to maximize patient value by reducing non–value-adding activities (9), through a set of operational tools, organizational and cultural practices (10). Empirical evidence highlights its potential to enhance efficiency, decision-making, patient satisfaction, and cost containment (11). However, most LH projects remain limited to single hospital departments (e.g., emergency, surgery, radiology), focusing primarily on operational dimensions such as efficiency and timeliness (12,13), limiting the ability to address broader quality dimensions. To address these gaps, this study proposes an integrated Lean and Safety Management (L&SM) approach, which combines LH with Clinical Risk Management (CRM) to proactively manage both wastes and risks throughout the care process (14,15). In particular, the present research develops and validates a structured step-by-step methodology, referred to as Lean & Safety Chronic Care (L&SCC), to implement L&SM in complex chronic care pathways that span hospital and community settings. These pathways are characterized by: i) long and

articulated processes involving multiple care levels, facilities and a network of actors; ii) interdisciplinary teams with diverse roles, responsibilities, and organizational affiliations; iii) patients with high clinical complexity and resource needs.

The study responds to a dual motivation. From a practical and managerial perspective, it explores how to improve complex care pathways bridging multiple organizational boundaries in an integrated way, offering practical guidance for healthcare providers and policy makers seeking to reduce wastes, manage risks, and improve the quality of chronic care. The urgency of this research is reinforced by the COVID-19 pandemic, which exposed the fragility of healthcare systems and the need to strengthen outpatient and primary care services to alleviate hospital overcrowding, reduce waiting lists, prevent clinician burnout, and enhance patient safety (16). From an academic perspective, it addresses the critical gap in the LH literature regarding implementations that integrate hospital and community care, while providing a replicable methodology that combines lean tools with cultural and organizational change principles.

2. Theoretical Background

Lean Healthcare (LH) can be defined as the adaptation of the lean thinking approach to the healthcare sector (17). Lean thinking is a managerial philosophy rooted in the principles of the Toyota Production System and comprises a set of technical tools, organizational practices and cultural aspects aimed at improving flow efficiency while minimizing non-value-adding activities (18). In healthcare, this is achieved by applying lean

principles to care pathways, which are conceptualized as sequences of interrelated activities analyzed from a process perspective (19). Accordingly, lean tools and cultural pillars need to be tailored to the specific organizational, professional and regulatory characteristics of healthcare settings (20). Within this framework, LH applies hard and soft practices to healthcare processes, often supported by the implementation of structured operational framework for problem solving, such as PDCA and DMAIC cycles, with the purpose of enhancing patient-perceived value by improving both the quality of care delivered and operational performance (11,21). Traditionally, LH focuses mainly on efficiency and timeliness (i.e.: waiting times and process redundancies reduction) (22). This narrow perspective overlooks critical dimensions of care quality, such as patient safety, access, integration, and equity (23). Recent research emphasizes the importance of multi-dimensional quality improvement, including patient safety, equity, integration, and access to care (23–26). According to the World Health Organization (27), patient safety is: “A framework of organized activities that creates cultures, processes, procedures, behaviors, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make errors less likely and reduce the impact of harm when it does occur.” Patient safety issues affect multiple dimensions of healthcare organizations, including clinical outcomes, organizational culture, operational efficiency, and financial sustainability. Hence, beyond their clinical implications, patient safety failures entail substantial economic and societal consequences (26). In high-income healthcare

systems, the direct costs associated with treating patients harmed during care delivery account for 13% of total health expenditure. Moreover, the economic impact of unsafe care goes beyond direct healthcare costs, as indirect effects (i.e.: productivity losses, long-term disability, and wider social consequences) further increase the overall burden (28). Although errors and adverse events cannot be entirely eliminated in healthcare organizations, Clinical Risk Management (CRM) aims to control and prevent their probability of occurrence, by adopting tools and techniques typical of risk assessment (i.e.: PDSA, checklists, risk register, FMEA, 5 whys analysis). CRM can be considered a specialized subset of the wider safety management system (29,30), focusing on the identification, assessment, and mitigation of clinical and organizational risks (i.e.: delays, communication failures, and lack of coordination) that undermine patient safety and care quality throughout the care delivery process (31). Clinical risks arise not only from medical activities directly involving patients but also from organizational dynamics, environmental factors, and interprofessional coordination (31). Within this perspective, LH was combined with CRM into a unified L&SM approach (32). The synergy between LH and CRM extends the traditional lean focus beyond efficiency to include patient safety, care integration, and multi-dimensional performance optimization (32). LH supports the proactive implementation of CRM by promoting a systemic perspective, fostering a culture of transparency, commitment, continuous learning and staff empowerment (15). Empirical evidence supports the feasibility of this integrated approach, reporting positive outcomes on performance and on patient and

employee safety. Reported outcomes include reductions in infection and complication risks, falls, mortality and morbidity rates, and improvements in safe medication administration, achieved without compromising efficiency or costs (15,24,32).

However, the implementation of LH and L&SM in care pathways bridging hospital and community services remains largely unexplored. Existing initiatives are predominantly confined to single hospital units (e.g., emergency, ICU, surgery, radiology), rarely adopting an end-to-end perspective that spans primary, secondary, and hospital care (12,33,34). While structured methodologies exist for LH projects within hospitals (35–37), there is a gap in the literature regarding how to implement L&SM in complex care processes that integrate hospital and community care (25). This setting introduces additional managerial, organizational and cultural challenges, including heterogeneous organizational structures, diverse professional backgrounds, conflicting stakeholder interests, physical distance between facilities, and persistent functional silos that hinder communication, collaboration and teamwork (6,38). Overcoming these barriers requires more than the mere application of technical lean tools, which account for only a limited share of the effort required in improvement initiatives. Rather, successful and sustainable implementation depends also on strong leadership, staff empowerment, and a shared organizational culture that fosters multidisciplinary teamwork and cross-boundary integration (37,39–42), especially in complex and articulated settings, where organizational and cultural factors play a crucial role. Nevertheless, existing studies often adopt a tool-centric

or piecemeal approach, focusing on individual lean techniques rather than a holistic cultural and organizational transformation (38,43). Consequently, the need for a structured implementation framework that integrates technical tools with organizational culture, leadership, and staff engagement is increasingly evident (44–47).

Hence, the challenge of defining a standardized approach to implement L&SM projects in ordinary healthcare settings (i.e.: hospital departments), is further emphasized in cross-departmental and cross-institutional complex care processes across hospital and community care. Such complexity requires a structured and scalable implementation framework addressing (44): i) technical aspects (managerial tools and techniques); ii) organizational aspects; iii) cultural aspects; iv) Project Management Principles to effectively plan, execute and monitor the improvement initiative.

This research offers three main contributions:

1. a novel, structured methodology with technical, organizational and cultural pillars for implementing L&SM in complex care pathways across hospital and community settings;
2. empirical insights on how this approach improves quality, safety, and integration of care while maintaining efficiency;
3. actionable guidance for healthcare managers to enhance quality and sustainability of healthcare systems through the application of socio-technical elements.

3. Methods

To define how to structure a L&SM project in complex care processes bridging hospitals and community care, this study develops and tests a Lean & Safety Chronic Care (L&SCC) methodology. This methodology represents the first attempt at developing a structured, step-by-step roadmap to overcome fragmentation and silos in healthcare processes. While designed for chronic care pathways, its design is applicable to a broader range of complex care processes, that require integration across organizational boundaries.

Based on this objective, three research questions (RQs) were formulated:

1. Methodology pillars: technical elements constituting the foundations of the proposed methodology.

RQ1: *What are the activities, tools, and organizational practices to improve complex care processes through L&SM?*

2. The methodology hallmarks: organizational and cultural factors that foster or hinder the improvement initiative.

RQ2: *What are the critical success factors for implementing L&SM in care processes bridging multiple organizational boundaries?*

3. The methodology effectiveness: ability of the L&SCC methodology to improve performance and quality of care.

RQ3: *What are the outcomes achieved by adopting the L&SCC methodology?*

Given the dual aim of generating theoretical knowledge and producing practical improvements, Action Research (AR) was adopted as the research methodology. AR is a research methodology aiming at both taking action and creating knowledge about that action (48). In particular, AR employs a scientific approach to analyse and solve social or organizational issues while developing scientific knowledge about the action taken, following iterative cycles, constituted of a four-step process: diagnosis, planning action, taking action, evaluating and learning (48). This iterative process results in being suited for developing, testing and refining the L&SCC methodology, but also to achieve positive effects on the field, particularly on organizational and managerial issues. In this way, the current research created new scientific contributions and at the same time accomplished practical changes needed in the real world.

The participatory nature of AR ensured continuous collaboration between academics and practitioners, a critical factor for implementing L&SM projects successfully. The L&SCC methodology was tested in a two-year project born from a collaboration between the University of Padova (UNIPD) and the Italian local health organization (LHO) Azienda ULSS 2 Marca Trevigiana and financially supported by the top management of both organizations. Academics and practitioners were actively engaged and collaborated throughout all research steps.

AR was deployed into 3 consecutive cycles (Figure 1):

1. *1st AR CYCLE: Designing the L&SCC methodology*.

Based on the existing academic and managerial literature, the L&SCC methodology was developed by academics, practitioners and experts. The

formulation of the methodology followed the cyclical and iterative AR four-step process:

- Diagnosis: identification of key gaps about L&SM implementations in complex care processes outside hospital boundaries according to academic and managerial literature.
- Planning action: selecting the key methodology variables emerging from theoretical frameworks grasped in academic literature.
- Taking action: populating the methodology framework with insights from academic and managerial literature and expert brainstorming.
- Evaluating and learning: iterative review and refinement of the methodology via feedback from experts, academics, and practitioners, during meetings, conferences, and seminars.

This cycle addressed RQ1, by defining the activities, tools, and organizational practices of the L&SCC methodology.

The result is a methodology which can be implemented in complex processes that require a hospital-community care integrated system, such as chronic care pathways: the sequence of phases, activities, milestones and organisational practices can be considered universally valid. The proposed methodology is adaptable to diverse project contexts by selecting appropriate tools, practices, and stakeholders from the available set, according to the specific characteristics of each case. This flexibility is fundamental to tailoring the L&SCC methodology and ensuring its practical applicability.

2. 2nd AR CYCLE: Testing the L&SCC methodology.

To validate the L&SCC methodology and assess its effectiveness in a real-world setting, a L&SM project was implemented within the selected LHO. The current analysis focused on one general hospital (providing tertiary and secondary care) and the community services delivering primary care and social services within the territorial network.

This case study yielded valuable insights for both practice and research. Indeed, the AR *evaluating and learning* step enabled the transfer of practical knowledge back into the academic domain. This second AR cycle addressed RQ1 and RQ2, validating the L&SCC applicability and identifying CSFs emergent from practice. In fact, they were derived from the empirical experience of academics and practitioners.

3. 3rd AR CYCLE: Reviewing and refining the L&SCC methodology.

Managerial and organizational insights from the testing cycle were used to refine L&SCC. This review followed the AR steps: *diagnosing* the critical issues of the L&SCC methodology, *planning* the appropriate solutions, optimizing its design, collecting feedback about the changes and assessing its validity and effectiveness.

This AR cycle contributed to addressing RQ1 and RQ2 by finalizing the definition of activities, tools, practices, and CSFs that emerged from the review process; RQ3 by evaluating the project outcomes in terms of performance indicators and “innovation and learning results”, related to people, processes, and organizational culture

Figure 1 illustrates how the RQs have been addressed through the AR cycles.

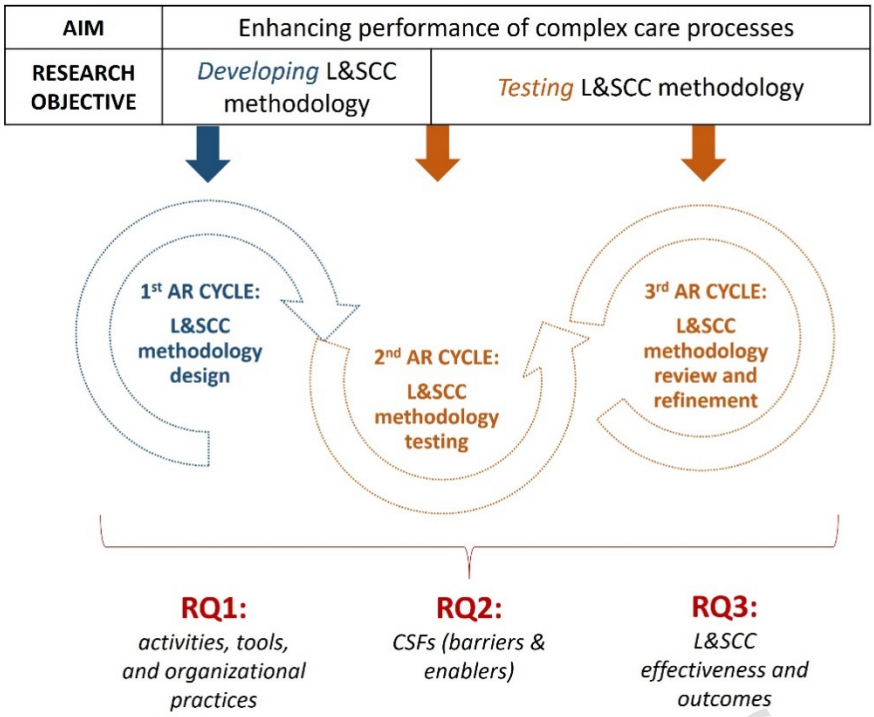


Figure 1 - Research objective, RQs and AR cycles (Source: Authors own work)

3.1. Research context

The selection of the empirical context was guided by two main criteria:

1. The study required a health organization providing both hospital-based and community-based services. Accordingly, the selected LHO operates within the Italian National Health Service, a tax-funded and regionally organized healthcare system characterized by universal coverage and strong public governance. The LHO serves nearly one million residents across approximately 100 municipalities. Its healthcare network comprises six interconnected acute-care hospitals organized according to a hub-and-spoke model, one specialized rehabilitation center, and one nursing home.

2. The LHO needed to demonstrate a strong willingness to engage in a research project extending beyond the implementation of lean initiatives. In this respect, the selected LHO hosts an Innovation Unit with extensive experience in managing research projects and academic collaborations. Moreover, this unit has actively supported the implementation of multiple lean initiatives over recent years.

The present analysis focuses on the general hospital, which serves as the reference hub for the entire network. The hospital provides both tertiary and secondary care through a combination of specialized and general medical wards, offering advanced outpatient services as well as inpatient care. Primary care services are delivered through the local health districts (LHDs), which are territorial organizational units responsible for integrating healthcare facilities with social services to ensure continuity of care within the community. The LHDs coordinate a wide range of services, including primary medical care (i.e.: family physician, pediatrician), nursing care, social services, rehabilitation, screening and prevention programs, specialistic outpatient care, palliative and home care. Given the complexity of these activities, an additional organizational unit, named Territorial Operations Center (COT), supports the LHDs in managing territorial services and care transitions across settings. The selected LHO comprises four LHDs, each defined by geographical boundaries. The current research focused on one specific LHD, referred to as *LHD_A* for confidentiality reasons. Consequently, the empirical research setting includes inpatient services at the general hospital and community-based

services managed by *LHD_A*, while the remaining districts of the LHO are excluded from the analysis.

A major challenge faced by Italian LHOs is the limited integration between hospital-based services and community care, even within the same healthcare network. This issue is particularly salient in a context characterized by an aging population and the high prevalence of chronic conditions and frailty, which increase the need for coordinated care pathways. In the case under study, care coordination and continuity between the general hospital and the LHDs are hindered by organizational, communicational, and cultural barriers, particularly during care transitions. Hospital discharge processes are especially critical for frail patients, who require carefully coordinated transitions from inpatient care to community and home-based services. However, within the analyzed LHO, patients discharged home are supported exclusively through nursing services, with limited involvement of medical professionals in post-discharge management. This approach generates significant gaps in continuity of care and increases the risk of potentially avoidable hospital readmissions. The setting thus represents a critical and illustrative case of hospital–community fragmentation within a publicly funded healthcare system.

To address these issues, especially among chronic patients, the project was designed and launched by a research team composed of academics (2 professors, 1 research fellow, 2 PhD students, and 2 Management Engineering students) and one management engineer employed in the Innovation Unit of the selected LHO. Over the course of the project, more

than thirty participants were involved in the project team, including academics and practitioners (1 management engineer, 2 chief physicians, 6 doctors, 16 nurses).

3.2. Data collection and analysis

All data used in this study were anonymous and aggregated, ensuring that neither patients nor healthcare staff could be identified. Information was collected through multiple sources to allow a comprehensive analysis of the care pathway and the organizational context:

- field observation: academics observed through *gemba* walks the activities performed in the process to understand their nature and characteristics, their sequence, the actors involved and eventual criticalities. Moreover, the healthcare staff involved in the project team self-measured some critical activities, filling in detection sheets to record data not available in hospital databases (i.e.: internal meetings duration and utility, adequacy of clinical reports, delayed patient discharges and their reasons, phone calls duration, frequency and purpose). These tasks were carried out for 3 weeks, covering multiple sessions per department until the sample was considered sufficient (see Additional File 3 for details on processes, sessions, and hours observed);
- semi-structured interviews: conducted by academics and the management engineer to experts and practitioners of the project team to gather information about process activities and criticalities. A total of 20 interviews were carried out, each lasting on average 1,5 hours

(further details in Additional File 2). The interview guide is reported in Additional File 1;

- meetings and focus groups: team sessions were held to share ideas, validate and discuss intermediate project outcomes. Details on duration, frequency, participants, and content of all meetings and focus groups are provided in Additional File 3.
- workshops: collaborative sessions were organized to train the healthcare staff on L&SM tools, and to apply them to the project;
- Documents and guidelines: Analysis included internal and external documents about care process regulations, timings, and criteria (e.g., WHO and OECD reports on chronic diseases, Regional Diagnostic and Therapeutic Care Pathways, and Early Supported Discharge guidelines);
- Hospital database data mining: aggregated and anonymized data were extracted from multiple sources:
    - Advenias: data on Early Supported Discharge
    - Auxilium: data on medical device prescriptions;
    - ADT: data on specialistic and diagnostic exams prescriptions;
    - SIT: data on care provided by the primary care unit;
    - HDC: information about patient hospitalization

Data collection and analysis were conducted by the core project team. In particular, the management engineer supported field observations, interviews, focus groups and workshops, and performed the hospital database data mining and analysis. The academics conducted interviews,

focus groups and workshops, and transcribed, analyzed and discussed the information collected.

Data analysis was process-focused rather than thematic: observations, interviews, workshops, documents, and hospital database outputs were organized into structured templates and process maps to reconstruct workflows, identify bottlenecks, and propose improvement solutions collaboratively.

4. Results

4.1 The resulting L&SCC Methodology

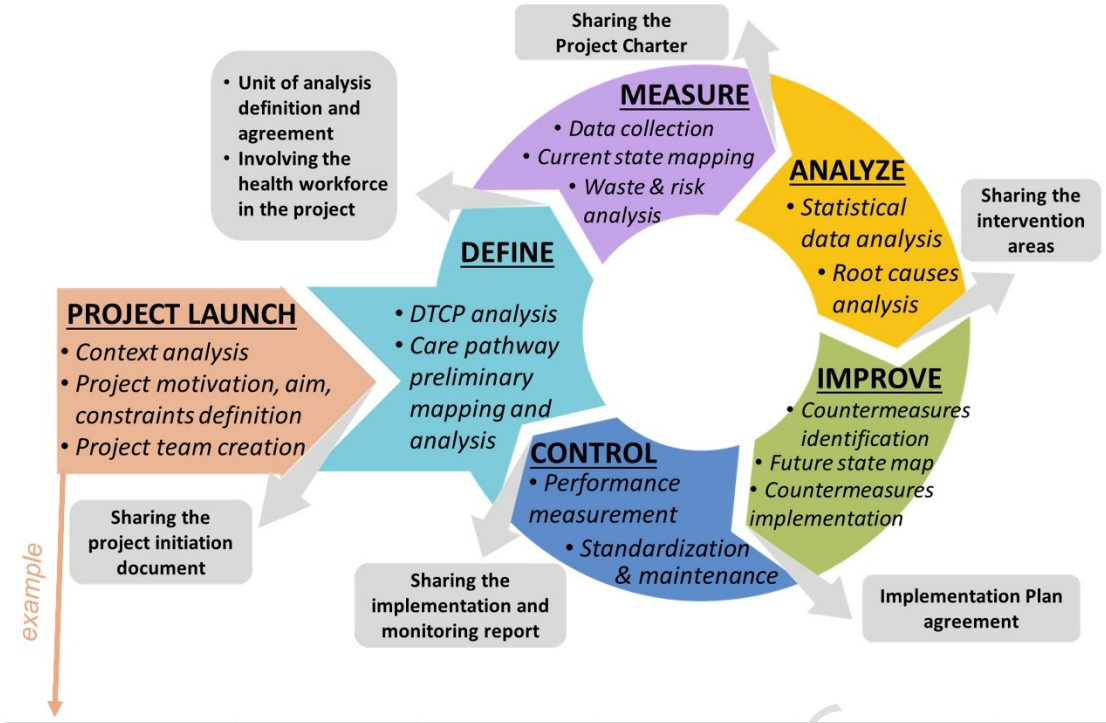
The design of the L&SCC methodology relied on a theoretical framework (49) collecting the fundamental variables of L&SM projects, further supported by relevant managerial literature. In particular, the L&SCC methodology adopts a modified DMAIC cycle (50), used in this study as a structured problem-solving framework to support lean implementation, rather than as a statistically driven Six Sigma methodology. The DMAIC cycle is complemented by an additional "Project Launch" phase, derived from Project Management principles, to ensure proper project initiation and alignment. The L&SCC methodology integrates foundational principles, concepts, and practices from LH, CRM, and Project Management to create a robust and multidisciplinary foundation. Innovative elements include the development of new tools, created through the integration of existing LH and CRM instruments. As shown in Figure 2, the L&SCC methodology encompasses not only operational aspects (i.e.:

sequence of phases and activities, inputs of each activity, tools, milestones), but also organisational aspects (i.e.: meetings, training) essential for the project progress.

The L&SCC methodology is structured into six sequential phases:

1. **Project Launch***:* define the project's scope, aim, and constraints. It also involves identifying a project sponsor, crucial for promoting the initiative and ensuring staff engagement for the entire project duration. Also, the project team is created.
2. **Define:** this phase coincides with the initial problem definition. To this end, an analysis of the process should be accomplished. For chronic care pathways, this involves examining the Diagnostic and Therapeutical Care Pathway (DTCP), which outlines the ideal process according to national or international guidelines. Comparing DTCP with actual practice helps define the gaps to be addressed, thus the project focus.
3. **Measure:** quantify the problem through the collection and analysis of qualitative and quantitative data, and process maps. The development of a project charter formalizes project motivations and objectives, responsibilities, and the timeline.
4. **Analyse:** the process issues are deeply investigated, mainly through statistical data analysis and brainstorming. Through a root causes analysis of the encountered risks and wastes, the main criticalities affecting the process performance are detected.
5. **Improve:** once selected the intervention areas, the project team generates countermeasures to be implemented.

6. **Control:** assesses the effectiveness of the changes introduced by measuring results on performance. Successful interventions are standardized and maintained through long-term monitoring to ensure sustainability over time.



Phases	Activities	Information sources	Actors involved	Tools and practices	Milestones
PROJECT LAUNCH 1. *Project name* 2. *Purpose* 3. *Roles and responsibilities* 4. *Focus and constraints* 5. *Project planning*	Context analysis	• National and local health documents • Ministry of Health website • WHO website and publications • Laws and regulations	• Quality improvement facilitators • LHO management	• Academic and 'managerial literature • Interviews • Meeting • Brainstorming • EHR • Gantt diagram • Statistical analysis • Workshops • Document analysis	Project Initiation Document
	Core project team definition	….	….		
	Definition of: - Project motivations - Project aim - Constraints	….	….		
	Project team definition	….	….		
Organizational practices: Sharing the project initiation document: meeting with the involved stakeholders					

Figure 2 - L&SCC methodology (Source: Authors own work)

The development of the L&SCC methodology followed an iterative process characterized by continuous cycles of review and refinement, alternating

phases of *planning* and *taking action* with *evaluation and learning* activities during four months. To ensure broader validation and gain additional expert feedback, the methodology was presented at international conferences and doctoral seminars specializing in healthcare operations management. Also practitioners from the selected LHO actively participated in reviewing the L&SCC methodology based on their managerial expertise. To this end, a core team comprising academics and practitioners (a management engineer, the head of Geriatrics and the head of the primary care unit) was created. At the conclusion of the first AR cycle, the finalized version of the L&SCC methodology was produced (Figure 2).

4.2 The L&SCC Methodology Testing

The overarching aim of the project was to enhance the quality of care delivered within chronic care pathways spanning both hospital and community settings. With the twofold objective of testing and validating the L&SCC methodology and improving the performance of complex care processes, the methodology was step-by-step implemented in a real-world COPD (chronic obstructive pulmonary disease) pathway. COPD was selected due to its clinical, managerial and organizational complexity and significant burden on the healthcare system. Within the selected LHO, COPD is associated with high mortality rates, prolonged lengths of hospital stay, frequent hospital readmissions, and persistently low diagnosis rates. In addition, the discharge process for COPD patients emerged as a critical organizational vulnerability, as these patients require structured and multidisciplinary transitions from inpatient care to community-based

management to prevent exacerbations. However, the current Early Supported Discharge (ESD) pathway implemented within the LHO is narrowly focused on home-based nursing services and lacks systematic medical involvement in post-discharge care. This organizational design results in fragmented care transitions, undermines continuity of care, and contributes to an increased risk of potentially avoidable hospital readmissions.

4.2.1 Project Launch

This preliminary phase was crucial for establishing the foundations for the effective implementation of the L&SM project, adapting the L&SCC methodology to the specific context, and defining the project governance, team and objective.

The core project team created in the first AR cycle held a strategic and managerial role, by planning the entire project implementation and tailoring the L&SCC methodology to local healthcare context. Including two physicians in the core project team was essential not only to guide project development but also to engage the broader health workforce, fostering the internal promotion of the initiative among clinical staff and sharing organizational insights with the academic researchers. To reinforce collaboration between academics and practitioners throughout all stages of the project, several joint meetings and organizational events were held. To ensure a multidisciplinary and cross-functional approach, the core team was expanded to include an “operational team” of 25 clinicians (nurses, physicians, and nurse coordinators) directly involved in managing

COPD pathways, as outlined in the Italian DTCP. The hospital side comprised units of pneumology, emergency room (ER), emergency medicine, internal medicine (IM) and geriatrics, while the territorial side included the primary care (PC) unit and COT (Territorial Operations Centre) which supports the LHD (local health district) by coordinating territorial services, ensuring continuity and patient safety in care transitions.

In total, the project team, encompassing core, operational, and support members, consisted of 31 individuals (as detailed in Figure 3):

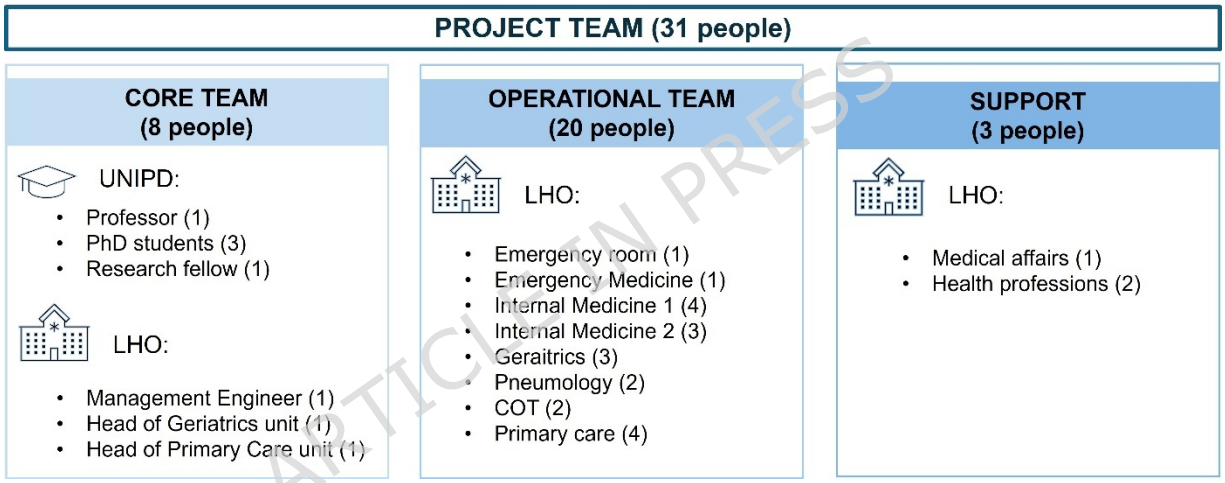


Figure 3 - Project team composition (Source: Authors own work)

To ensure the effective engagement of all clinicians within the project team, the hospital's top management organized a plenary meeting to share the project plan, the L&SCC methodology, and a comprehensive project initiation document. Additionally, dedicated Lean training sessions were conducted, incorporating real case studies, theoretical concepts, and interactive team-based exercises, thereby fostering a shared understanding and commitment to the initiative.

4.2.2 Define

The COPD clinical pathways implemented within the project context were analysed and mapped to compare the actual care processes to the ideal one (based on Italian DTCP), in terms of involved actors, activities, clinical parameters, and therapeutic interventions.

Two rounds of semi-structured interviews were conducted with the project team members. The interview guide is available in Additional File 1. The results were synthesized into six qualitative Value Stream Maps (VSMs), each representing a different departmental perspective and collectively highlighting key process criticalities. The primary issue that emerged was the lack of coordination at hospital-community interfaces.

To target the units most engaged in COPD care, patient demand and flow data were extracted from Hospital Discharge Records (HDR), as illustrated in Figure 4.

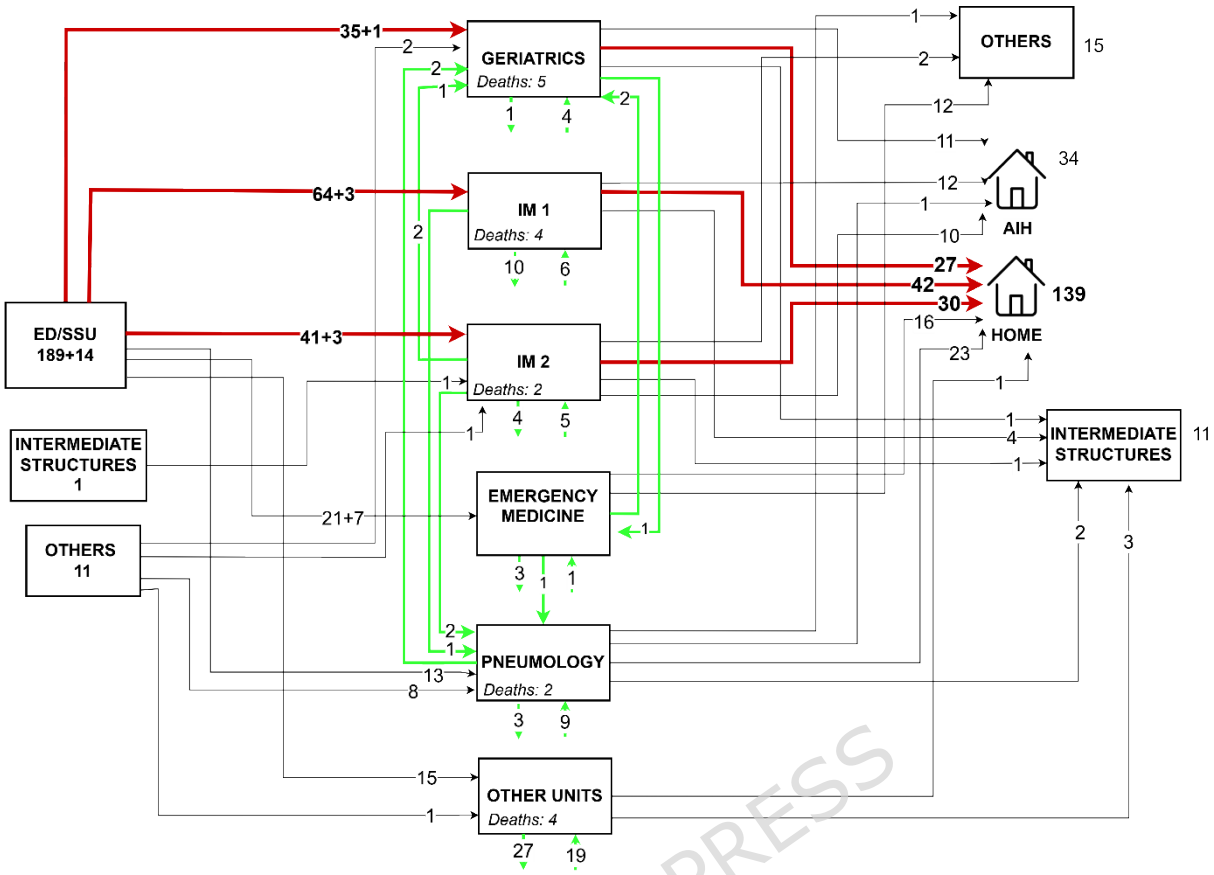
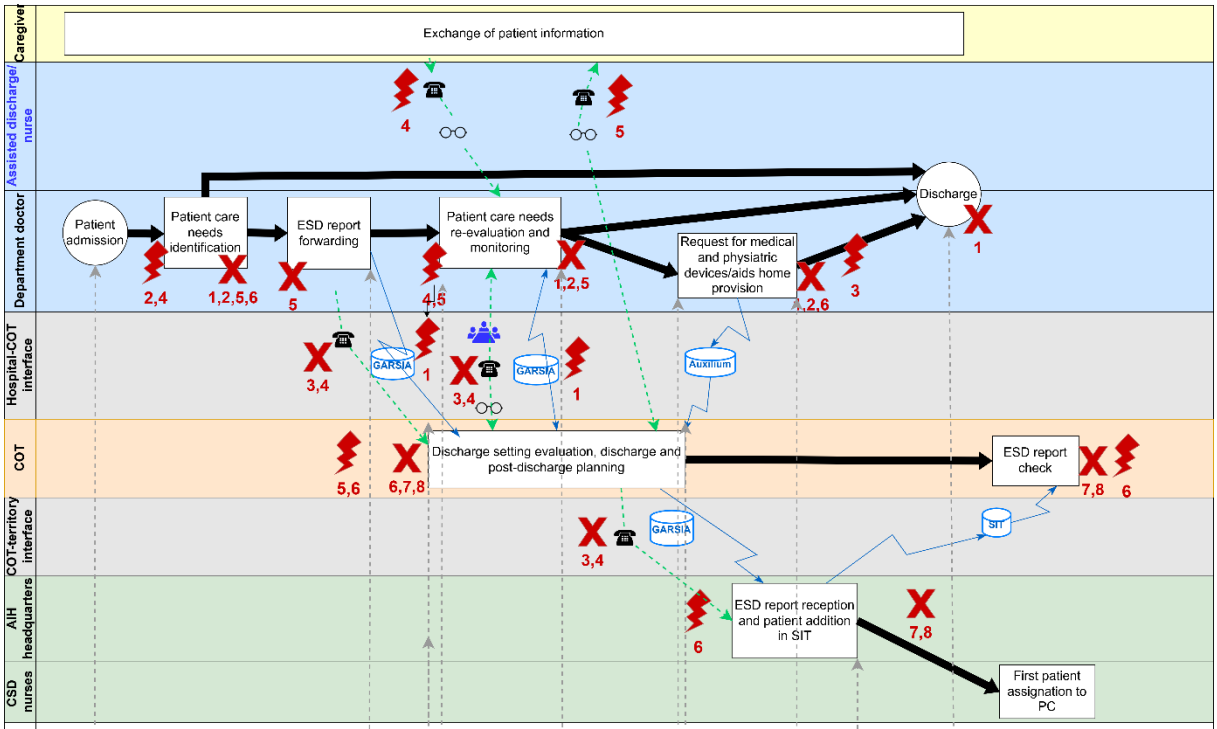


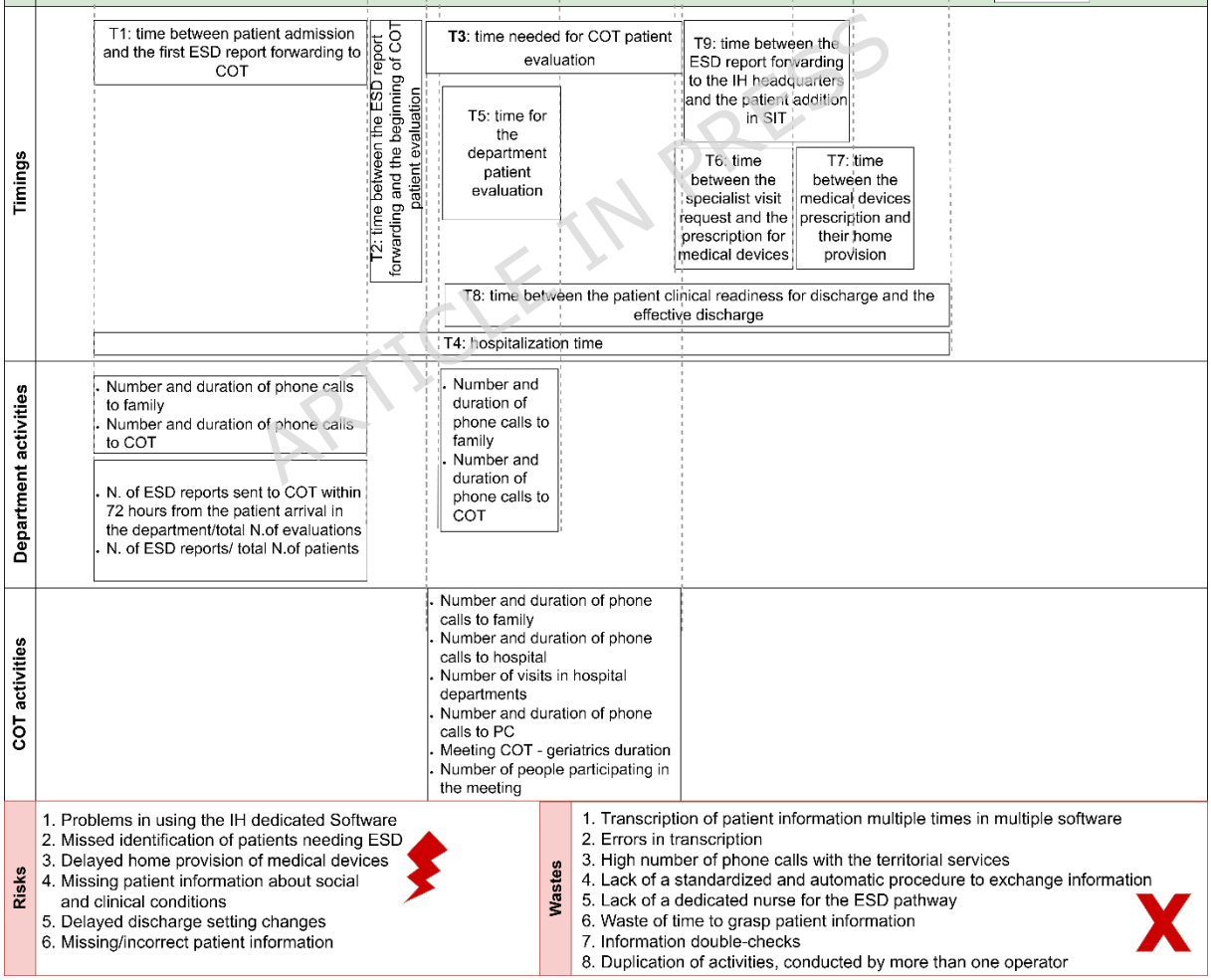
Figure 4 - Demand Map: COPD hospitalization pathway (Source: Authors own work)

Based on patient volume, the analysis focused on IM 1, IM 2 and Geriatrics, with particular attention to two discharge pathways: home discharge and Integrated Homecare discharge (IH). IH provides post-discharge nursing care at home, delivered by the Primary Care (PC) unit with support from the Territorial Operations Centre (COT), which assesses clinical and social patient needs for safe transitions. This analysis defined the project's focus as the interface between the hospital units (Geriatrics and Internal Medicine) and community care (PC unit and COT), focusing on the decision-making processes related to IH assignment. Notably, only 20% of COPD patients received IH support, despite high readmission rates,

revealing a critical gap in continuity of care. These findings underscored the need to guarantee more integrated care to COPD patients, improving patient needs assessment and expanding territorial services to ensure that all eligible patients receive appropriate home-based care.

To support this analysis, a final map of this process was designed, using a customized version of the lean *Makigami* mapping tool (51) (Figure 5). Unlike traditional *Makigami* diagrams, which display transactional processes, associating each activity with personalized metrics, this adapted version incorporated also information flows using the visual language of VSM, allowing for clearer representation of interactions between hospital and community-based services. A further innovation is that process risks and wastes are reported in a numbered list at the bottom of the map and referenced within the map at the corresponding activities using a red lightning bolt or an "X". Hence, *Makigami* provided a high-level overview of macro-activities performed by each unit and supported a shared understanding of the target process and its criticalities. Moreover, it helped define key indicators for process analysis, including 8 timing indicators, 8 for process assessment, and 9 related to COT activities.





Risks

1. Problems in using the IH dedicated Software
2. Missed identification of patients needing ESD
3. Delayed home provision of medical devices
4. Missing patient information about social and clinical conditions
5. Delayed discharge setting changes
6. Missing/incorrect patient information

Wastes

1. Transcription of patient information multiple times in multiple software
2. Errors in transcription
3. High number of phone calls with the territorial services
4. Lack of a standardized and automatic procedure to exchange information
5. Lack of a dedicated nurse for the ESD pathway
6. Waste of time to grasp patient information
7. Information double-checks
8. Duplication of activities, conducted by more than one operator

Figure 5 – Makigami of the IH process: process activities, information flows, actors involved, process indicators, risks and wastes (Source: Authors own work)

4.2.3 Measure

To enable a quantitative assessment of the COPD care pathway, the project team collaboratively defined a set of process indicators (PIs) during dedicated meetings.

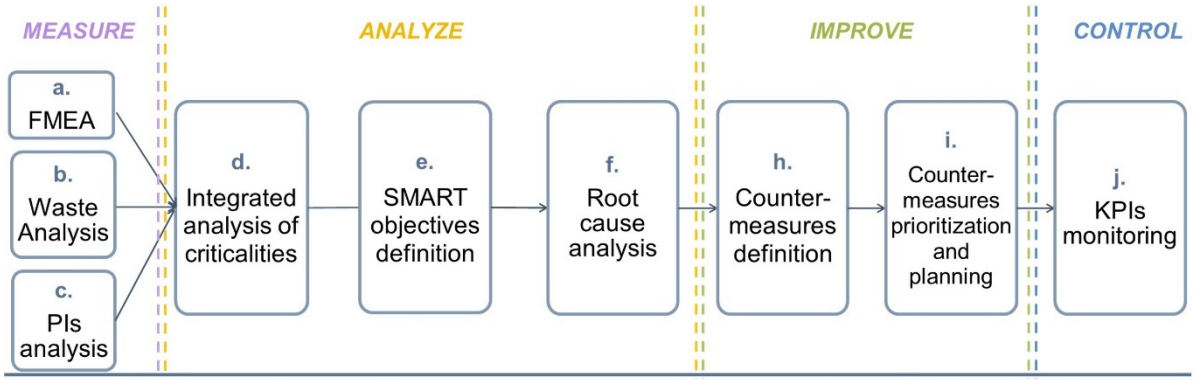
Data were collected from three complementary sources: a) hospital database mining, b) structured observation forms completed by physicians and nurses to record timings and redundancies, and c) direct field observation by the research team. These inputs supported the development of four cross-functional flowcharts of the IH processes in each hospital unit, mapping roles, responsibilities, activities and key interaction points between hospital and community actors. They revealed significant criticalities regarding coordination and integration among different units, particularly at the hospital–territory interface, along with process inadequacies, duplicated tasks, process errors and time wastes (highlighted in Figure 5 with a red “X”).

In addition to identifying wastes, the team also assessed process-related risks using the Failure Mode and Effect Analysis (FMEA) technique. For each activity, potential risks were examined by evaluating their effects on patient safety, underlying causes, and the current control mechanisms in place, with a scale from 1 to 5, thus producing a cumulative risk index. The most severe risks (marked in Figure 5 with red lightning bolts) were

identified either by a high-risk index (greater than 30), high severity scores (greater than 3), or significant influence on patient length of stay or discharge planning.

4.2.4 Analyze and Improve

A comprehensive assessment was conducted by integrating findings from three key sources: process wastes, risks uncovered through FMEA, and results from the statistical analysis on PIs, which fostered the identification of the key performance indicators (KPIs). This multi-layered approach enabled the project team to develop a more holistic understanding of the process to connect performance with process criticalities and trace gaps back to their root causes. The root cause analysis laid the foundation for co-developing targeted countermeasures with the active involvement of the project team, thus ensuring their feasibility and appropriateness. Countermeasures were prioritized based on their effort and impact implementation plan was formulated, detailing the actions to be taken, responsibilities assigned, and timelines for execution. The overall process is reported in Figure 6.



c. PIs statistical analysis based on data extracted from the HDR and observation forms (i.e.: *One-way ANOVA, Chi-Square Test, Correlation Analysis)*

d. Integrated analysis of criticalities: integration of wastes, risks and PIs analysis into a single chart to highlight the relationship between them (i.e.: cause-effect relation between wastes and risks) and define a list of KPIs critical on quality.

ACTIVITY	WASTE	RISK	KPIs
Patient information collection	Duplicated transcription: paper and software	• Transcription errors • Lack of information	• T1>72 h • T4
…	…	….	

e. SMART objectives definition

KPI	KPI description	SMART objectives
C1	N. of COT's phone calls	• 100% reduction of COT's phone calls to families in case of IH discharge
T4	hospitalization time	• 5% reduction of the hospitalization
…	…	….

f. Root cause analysis: 5 whys technique to identify the sources of wastes and criticalities

g. Countermeasures definition: for each root cause, a countermeasure was identified through brainstorming sessions with the project team (65 proposals), validated and approved by the head of each department and hospital top management.

h. Countermeasures prioritization and planning:
33 countermeasure clusters (Annex) were prioritized in a feasibility-impact matrix. An intervention plan was arranged, shared with the team and implemented.

IMPACT				
	High	Evaluate	Implement	Implement
	Medium	Evaluate	Evaluate	Implement
	Low	Eliminate	Postpone	Postpone
		High	*Medium*	*Low*
		EFFORT		

			INTERVENTION PLAN		
ID	INTERVENTION	Variables measured	Team	Goal	Starting date
2	Online confirmation by the hospital unit of the occurred discharge	• C2 • Wastes	PP, PP	COT phone calls reduction	16/06/2023
7	Preventive caregiver identification and personal data collection	• T1 • Wastes & Risks	AF, MM	Collecting caregivers data at ED triage	15/09/2023
8	Definition of a tool for the early evaluation of patients' social conditions	• T1 • Risks	VB, AF, TT, SG	Collecting patient social condition	15/09/2023
14	Elimination of contacts between COT and families/caregivers in case of IH discharge	• C1 • Wastes	VB, PP, NC	Avoiding the replication of information	24/07/2023
15	Diffusion and adoption of the procedure regarding the medical aids prescription	• T6, T4	SB, EP,CG	Anticipating the medical devices prescription	24/07/2023
17	Software improvement	• Wastes & Risks	VB, PP, LM, NC	Adding notifications for new notes	15/09/2023

* PIs: process indicators; KPIs: key performance indicators; FMEA: Failure Mode and Effect Analysis; COT: Territorial Operations Centre; IH: Integrated Homecare discharge

Figure 6 - Analyze and Improve phase summary (Source: Authors own work)

4.2.5 Control

Frequent communication and iterative feedback loops allowed the project team to track progress. Regular information exchanges enabled to share both successful results and challenges, fostering a collaborative environment where problems could be openly discussed and addressed jointly. After three weeks of implementation, the team collected quantitative data from the hospital data warehouse and observation forms to assess the short-term outcomes on KPIs. In addition, wastes and risks associated with each intervention were re-examined through brainstorming sessions, field observation, and updated FMEAs to recalculate the risk indexes. This assessment was repeated three months later to monitor medium-term outcomes, achieving:

- Risks and wastes reduction: several sources of inefficiencies were notably reduced or eliminated, and all risk indexes declined, reflecting a tangible reduction in potential harms during care transitions.
- Performance gains: post-implementation comparisons demonstrated positive trend on KPIs, with a 15% reduction in T1, 20% increase in R3 and 60% improvement in C1 e C2.

To formally conclude the project and consolidate learning, results were shared with the project team, hospital top management and key stakeholders. The team also engaged in structured brainstorming sessions

to identify and discuss the Critical Success Factors (CSFs) that supported the project's success, as well as the practices required to manage them effectively.

Finally, six months after the project completion (and nine months post-countermeasure implementation), a follow-up event confirmed the sustainment of integrated, boundary-spanning care improvements and validated the CSFs, as illustrated in Figure 7:

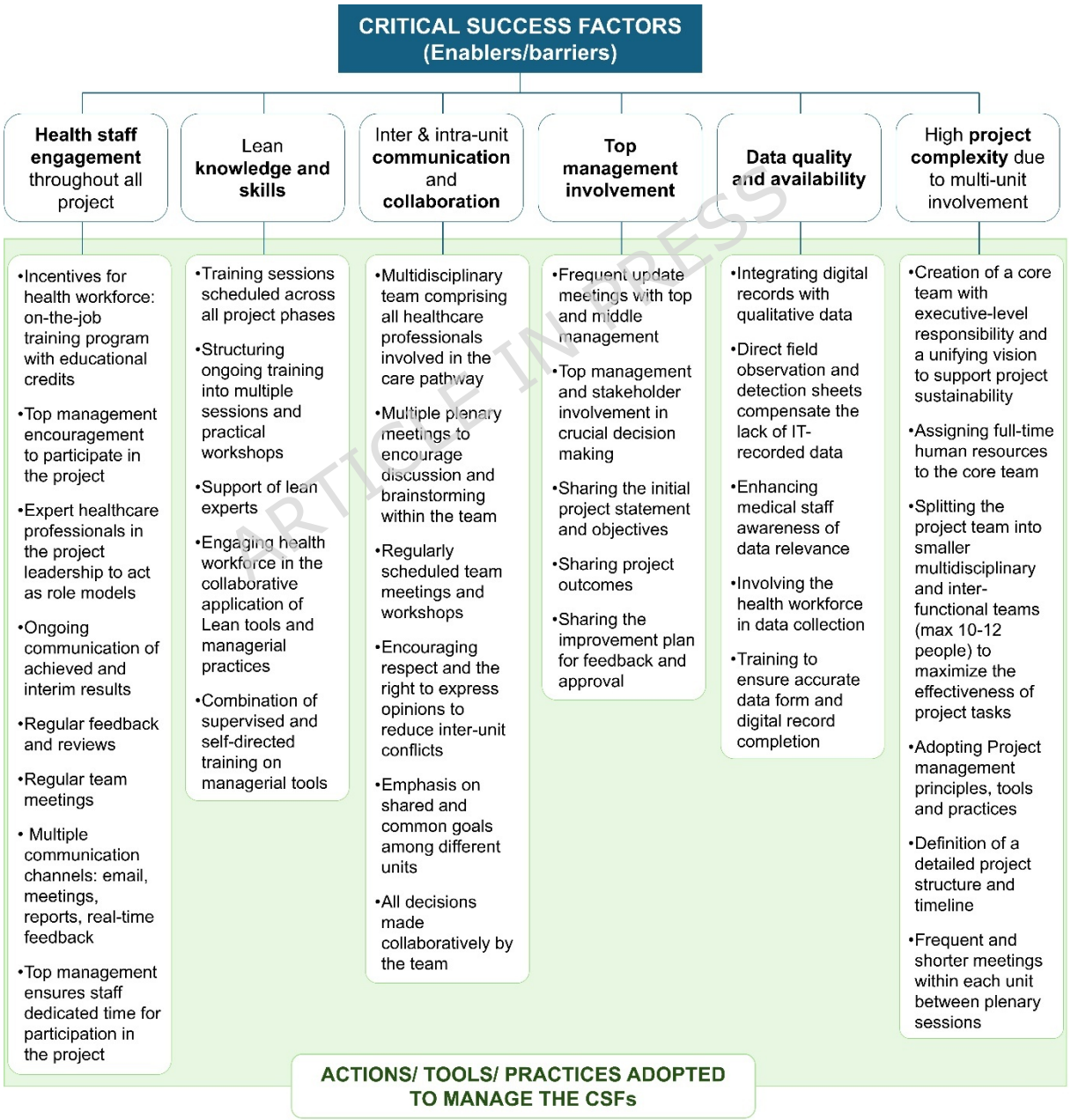
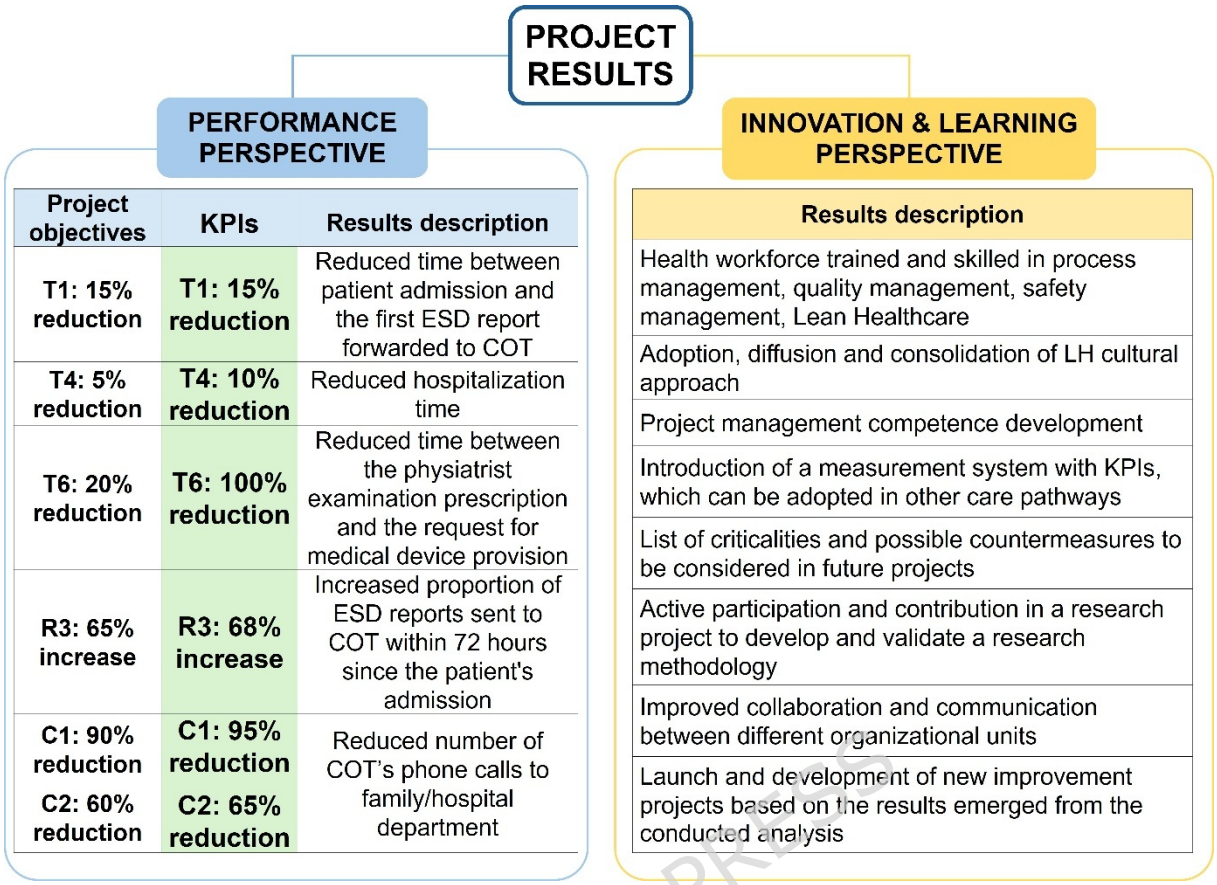


Figure 7 – Management of the Critical Success Factors (Source: Authors own work)

A key outcome of the L&SCC implementation was a marked strengthening of collaboration across hospital and territorial units and people, which helped break down long-standing boundaries and overcome the prevailing silos mindset. This cross-unit cooperation extended beyond the immediate project, seeding a lean, continuous-improvement culture that now serves as a foundation for new initiatives and broader organizational learning.

4.3 The L&SCC Methodology Review and Refinement

The L&SCC effectiveness and applicability in real healthcare settings were confirmed by the positive KPIs outcomes achieved in the control phase of the project (as shown in Figure 8 with green cells). Beyond improving efficiency and safety, the project sparked innovation and learning benefits across people, processes, and organizational culture, revealing how structured lean improvement efforts can simultaneously deliver operational results and cultivate a more adaptive, improvement-oriented system:



Project objectives	KPIs	Results description
T1: 15% reduction	T1: 15% reduction	Reduced time between patient admission and the first ESD report forwarded to COT
T4: 5% reduction	T4: 10% reduction	Reduced hospitalization time
T6: 20% reduction	T6: 100% reduction	Reduced time between the physiatrist examination prescription and the request for medical device provision
R3: 65% increase	R3: 68% increase	Increased proportion of ESD reports sent to COT within 72 hours since the patient's admission
C1: 90% reduction C2: 60% reduction	C1: 95% reduction C2: 65% reduction	Reduced number of COT's phone calls to family/hospital department

Results description
Health workforce trained and skilled in process management, quality management, safety management, Lean Healthcare
Adoption, diffusion and consolidation of LH cultural approach
Project management competence development
Introduction of a measurement system with KPIs, which can be adopted in other care pathways
List of criticalities and possible countermeasures to be considered in future projects
Active participation and contribution in a research project to develop and validate a research methodology
Improved collaboration and communication between different organizational units
Launch and development of new improvement projects based on the results emerged from the conducted analysis

* ESD: early discharge report; COT: Territorial Operations Centre

Figure 8 - Project outcomes (Source: Authors own work)

Based on AR feedback and outcome evaluation, the L&SCC methodology was thoroughly revised and refined, leading to its finalized version, presented in Additional File 4. Key refinements include:

- Reordering the sequence of activities (i.e.: anticipating the engagement of hospital top management to the first project phase among the first activities; postponing the project goal definition)
- Adding new activities (i.e.: qualitative mapping of the current state prior to quantitative measurements, and KPIs definition)

- Changes in role assignments and actors' involvement (i.e.: health workforce inclusion in the core project team with leadership responsibilities)
- Adding socio-cultural practices and enabling factors (i.e.: definition of incentive mechanisms to boost project team engagement; extending training activities throughout the project's life cycle)
- Adjustments to tools and practices (i.e.: creation of a new integrated tool to assess risks, wastes, and KPIs simultaneously)
- Increased frequency of organizational practices (i.e.: regular team meetings)

Overall, these refinements increased the methodology's applicability, sustainability, and effectiveness, enhancing its capacity to support improvement initiatives in complex care processes bridging hospital and community care. The methodology also produced secondary learning outcomes, enhancing collaboration, organizational culture, and staff empowerment.

5. Discussion

The research developed the "Lean and Safety Chronic Care" methodology, a structured approach to improving performance and quality of care along complex care pathways that span hospital and community-based services. The methodology was empirically tested within COPD pathways, selected due to the substantial burden that chronic conditions impose on healthcare systems worldwide. COPD, in particular, represents one of the leading

causes of mortality globally, yet it remains underdiagnosed and insufficiently recognized. Evidence consistently shows that high mortality, hospitalization, and exacerbation rates are closely linked to low levels of disease detection and prevention, resulting in delayed diagnosis and suboptimal care trajectories. COPD patients typically present high clinical complexity, frequently affected by multimorbidity and requiring continuous, coordinated, and multidisciplinary care. These features are not unique to COPD but are common across chronic diseases more broadly. Chronic conditions are characterized by long-term care pathways involving multiple professionals operating across different levels of care, including specialized hospital services, primary care, and home-based care. Importantly, the L&SCC methodology is not tailored to a specific clinical condition. Rather, it is designed to address the organizational characteristics of complex care pathways, namely: i) long and articulated processes spanning multiple care levels, facilities and a network of actors; ii) interdisciplinary teams with heterogeneous roles, responsibilities, and organizational affiliations; iii) patient populations characterized by high clinical complexity and intensive resource needs.

As such, the L&SCC methodology is applicable to a wide range of healthcare contexts exhibiting these characteristics, extending its relevance well beyond the specific pathology investigated in this study.

Key findings of the study include:

1. The reconfiguration of inter-organizational collaboration: the implementation of L&SCC facilitated more effective coordination across hospital and territorial units, contributing to the reduction of

fragmentation and to the mitigation of the “silo mentality” that frequently hampers integrated care. By aligning actors with diverse professional identities and institutional affiliations around common objectives, the project enabled the emergence of new, cross-boundary work practices. This highlights how structured improvement initiatives can operate as vehicles for organizational integration and cultural change, fostering shared accountability across care settings (52);

2. The role of a structured methodology in complex organizational systems: the project also demonstrated the importance of adopting a structured methodological framework in complex, multi-stakeholder systems. While Lean initiatives in health care often rely primarily on the mere application of tools, the L&SCC methodology integrates these tools within a clearly articulated project structure that builds upon, yet extends, the DMAIC cycle (24,45,49,53,54). This structure proved essential for balancing divergent priorities across multiple units and coordinating distributed teams. The evidence suggests that methodological discipline can enhance organizational adaptability, enabling more effective responses to the inherent uncertainty and variability of health care processes.
3. Synergies between efficiency, patient safety, and continuity of care: a further insight concerns the complementarity between efficiency, safety, and continuity objectives. These dimensions are often treated as conflicting in both theory and practice, while this study addressed multi-dimensional performance objectives. The integrated Lean and Safety perspective revealed that improvements in process efficiency frequently

coincided with enhanced patient safety and smoother care transitions. Often, waste elimination and risk mitigation were not independent pursuits but mutually reinforcing mechanisms. This suggests that adopting a holistic, system-wide view of performance may allow organizations to achieve sustainable improvements contributing to core values of care quality and patient safety.

4. Socio-technical integration and sustainability of change: the study emphasizes the pivotal role of socio-technical integration in sustaining long-term improvement. The L&SCC methodology provides a holistic framework that integrates LH and CRM, across three dimensions: (i) project management (phases, activities, and milestones that structure implementation) (55); (ii) operational (the use of Lean and Safety tools and practices); and (iii) socio-cultural (organizational practices and critical success factors that enable change). Technical instruments, such as VSM, *Makigami*, KPI monitoring, generate sustainable results only when embedded within an enabling environment characterized by leadership commitment, multidisciplinary teamwork, open communication, participative decision-making and a non-punitive culture (24,32,39,43,45,56–58). Findings confirm that Lean and Safety initiatives are effective when conceived as socio-technical systems, where technical and social elements co-evolve to foster learning and performance improvement. Within this view, several practices emerged as essential to sustain change in complex organizational settings, coherently with current literature (42,46):

a) the establishment of strong lean leadership and a core multidisciplinary team including clinical champions (45,56,59), responsible for project governance and engagement;

b) the inclusion of frontline healthcare workers within an operational team, fostering employee-driven innovation (60) and interprofessional collaboration among clinicians, managerial engineers, researchers, and Quality Improvement experts (52);

c) a structured project framework and SMART objectives, jointly developed by the University and LHO representatives, which enhanced project coherence and accountability (46);

d) organizational practices (i.e.: regular team meetings, continuous reviews and real-time feedback, workshops and targeted training sessions) to counteract the prevailing silo mentality and resistance to change (24,43,59,61,62). These mechanisms not only facilitated knowledge sharing and employee engagement but also supported cross-boundary collaboration and reinforced the long-term sustainability of improvement efforts.

5. Action Research as a mechanism for organizational learning: the adoption of AR proved instrumental not only as a methodological choice but also as a mechanism for organizational learning. Through iterative reflection and continuous feedback, AR cycles enabled the joint production of actionable knowledge between researchers and practitioners. This participatory approach promoted a shift from episodic to continuous learning, embedding reflective practices into daily operations. The findings reinforce the role of AR as an

organizational design feature that can strengthen collective sensemaking, learning, and knowledge integration across professional and hierarchical boundaries.

In sum, the L&SCC project illustrates how structured improvement approaches can act as catalysts for organizational learning and boundary-spanning collaboration in healthcare. By integrating efficiency and safety logics, the methodology fostered new ways of coordinating across professional and institutional divides. These insights extend beyond the specific setting, offering a basis for theorizing how healthcare organizations can build adaptive capabilities to navigate complexity and pursue sustainable improvement.

6. Conclusions

The current research advances the application of L&SM in complex healthcare settings, addressing the absence of a standardized framework to guide such interventions.

Through the development and real-world implementation of the L&SCC methodology, the study pursued a dual goal: to improve the performance of integrated chronic care pathways and to contribute to the theoretical advancement of L&SM. Using AR as the research methodology, three iterative cycles were conducted to address the RQs, enabling both the methodological development and empirical validation of the L&SCC framework. Findings delineate the key activities, tools, and practices required for L&SM implementation in hospital–community integrated care (RQ1), identify contextual barriers and enablers (RQ2), and demonstrate

tangible performance and learning-related outcomes (RQ3). From an academic standpoint, this study fills the literature gaps by providing a structured and replicable L&SCC methodology, tailored for complex, inter-organizational care processes. It provides empirical validation through its application in COPD pathways, suggesting novel insights, including: the clinical pathways analysis, the multi-dimensional performance objectives, the development of integrated tools and practices drawing from CRM and LH, the constitution of the dual-level project teams (core and operational), and interventions supporting care integration. Additionally, it deepens understanding of the synergic adoption of LH and CRM, offering insights that may extend beyond healthcare to other complex service systems.

From a managerial perspective, the research delivers actionable implications for healthcare leaders and practitioners: i) a replicable methodology guiding L&SM implementations; ii) identification of Critical Success Factors; iii) a demonstrative case of successful application; iv) tools that integrates LH, Clinical Risk Management and Project Management; v) a structured and replicable framework to support a culture of continuous process improvement within healthcare organizations.

The research also holds societal implications, especially in addressing the rising burden of chronic diseases and ageing populations. By improving the management of chronic care, the methodology may contribute to enhanced patient outcomes, such as quality of life, life expectancy, and access to care, while simultaneously reducing healthcare costs and promoting system sustainability. Nonetheless, the study acknowledges limitations.

Only one full DMAIC cycle was implemented due to feasibility constraints, and findings remain context-dependent. Future research should extend validation across diverse healthcare settings, explore varying organizational cultures, and integrate patient perspectives within L&SM initiatives, thereby aligning with value-based and service-dominant healthcare paradigms.

Beyond its organizational and managerial contributions, this study illuminates how structured improvement efforts can serve as levers for societal value creation, by enhancing the quality, safety, and equity of care while strengthening the sustainability of health systems.

List of abbreviations

LH: Lean Healthcare

L&SM: Lean and safety Management

CRM: Clinical Risk Management

L&CC: Lean & Safety Chronic Care

RQ: research question

AR: Action Research

LHO: local health organization

LHD: local health district

CSF: critical success factors

DTCP: Diagnostic and Therapeutical Care Pathway

HDR: Hospital Discharge Report

VSM: Value Stream Map

COPD: Chronic Obstructive Pulmonary Disease

IM: internal medicine

PC: primary care

IH: Integrated Homecare

ESD: early discharge report

COT: Territorial Operations Centre

FMEA: Failure Mode and Effect Analysis

PI: process indicator

KPI: key performance indicator

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Authors' contributions

The study was conceived by CV and MC. The research proposal was written by CV, MC, AT and CP. CV was responsible for coordinating the research planning and execution, and together with MC for securing financial support. The empirical analysis was performed by AT, CP, MC with the supervision and support of CV. The conceptualization, design and drafting

of the paper was conducted by AT and CV. AT, CP, CV and MC reviewed and revised it. All authors contributed to the manuscript's writing and development and approved the final manuscript.

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Availability of data and materials

The interview guide is available in Additional File 1, the COREQ framework (63) for interviews and focus groups in Additional File 2, the details about data collection methods in Additional File 3, and the L&SCC methodology is available in Additional File 4. Additional data and materials are not publicly available due to confidentiality issues but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was based on aggregated and fully anonymized administrative data derived from Hospital Discharge Records. No individual-level or identifiable patient data were collected or analyzed. In addition, direct observations and qualitative data collection were conducted exclusively on hospital care processes and healthcare professionals' routine activities, without involving patients and without collecting personal or identifiable data on healthcare staff. All data collection, information sharing, analyses,

and dissemination of results were carried out within the framework of a training course provided by the hospital and accredited with continuing medical education credits for healthcare professionals. Informed consent was obtained from all participants. Healthcare staff were informed about the aims of the study, the voluntary nature of participation, data handling and confidentiality, and their right to withdraw at any time without consequences. Participation in the course implied consent to take part in the study activities, and explicit consent was obtained from participants prior to each interview. All members of the academic and research team formally agreed to maintain the confidentiality of the data and to use them exclusively for research purposes.

According to Italian national regulations and the General Data Protection Regulation (EU Regulation 2016/679), this type of study did not require submission to or approval by a local ethics committee or Institutional Review Board. In the present study, no patients, identifiable patient data, or biological materials were involved. Healthcare professionals participated as adult volunteers in a non-interventional, organizational and educational context, through interviews, direct observation of routine work processes, and collaborative development of organizational solutions within an accredited hospital training program. The study did not involve any intervention on participants' health, nor the collection of health-related data concerning the participants themselves. For these reasons, while the study does not fall within the core scope of medical research targeted by the Declaration of Helsinki, we have ensured that all procedures were conducted in accordance with its ethical principles, as applicable,

including voluntariness of participation, informed consent, confidentiality, and the right to withdraw at any time.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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