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Results and fine-tuning of the initiatives

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S1.D5.3 Results and fine-tuning of the initiatives

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Author(s)	Vincenzo Atella (UNIROMA2)
Contributors	Gianluca Fiorentini, Matteo Lippi-Bruni, Rossella Verzulli, Eugenio Cannovale-Palermo (UNIBO), Roberto Grilli, Alberto Bandini, Marcello Galvani (AUSL Romagna), Paolo Parente, Andrea Barbara, Matteo Di Pumpo, Giorgio Filippi (ROMA1), Vito Angiulli, Grazia Fortunato, Mario Malcagni, Rosella Squicciarini (UNIBA), Tiziano Arduini, Federico Belotti, Andrea Piano Mortari, Daniela Vuri (UNIROMA2), Ginevra Gravili, Grazia Di Cuonzo (UNIBA)
Quality Assurance	Gianluca Fiorentini, Matteo Lippi-Bruni, Rossella Verzulli

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Publishable summary

This deliverable reports the results of Work Package 5 – Task 5.3 of the DARE project, focused on policy evaluation, impact analysis, and upscaling of digital health initiatives for the management of chronic conditions. The work contributes to the objectives of Spoke 1 by assessing how digital technologies, organizational models, and data-driven tools can support more effective, sustainable, and integrated healthcare systems.

The document presents three main research lines developed by different partners.

First, the UNIBA–ASL Bari unit outlines the completion of the theoretical and preparatory phase for evaluating integrated care models for Cardio-Renal-Metabolic (CRM) syndrome. This includes the development of a Data Protection Impact Assessment and an organizational framework structured around seven pillars—patient-centered care, holistic approach, digital integration, efficiency, workforce well-being, sustainable governance, and data-driven decision-making—aligned with DARE’s expected societal, economic, and policy impacts.

Second, the UNIBO–AUSL Romagna unit reports substantial progress in the implementation and use of a population risk stratification tool (ACG®) to support healthcare planning and policy assessment. The tool has been fully deployed, staff trained, and first applications completed, particularly for chronic heart failure patients. In parallel, several empirical evaluations of telemonitoring initiatives are described, including programs for chronic patients in remote areas, patients with implantable cardioverter-defibrillators, congestive heart failure patients supported by primary care nursing programs, and individuals with type 1 diabetes using automated insulin delivery systems. These studies provide evidence of improved adherence, reduced acute care utilization, and important insights for scaling up digital health interventions.

Third, in the UNIROMA2 and ASL Roma 1 units examine governance, regulatory, and organizational dimensions of digital health implementation, with particular attention to telemedicine pathways, eligibility criteria, privacy safeguards, and coordination among healthcare professionals. This research design emphasizes the importance of aligning technological innovation with regulatory compliance, organizational processes, and stakeholder engagement.

Overall, the deliverable demonstrates that effective digital prevention and chronic care require the joint adoption of advanced technologies, organizational innovation, and robust governance frameworks. The findings provide actionable evidence for policymakers on how to scale up digital health solutions in a sustainable, equitable, and evidence-based manner.

1. Introduction

The increasing prevalence of chronic diseases represents one of the most pressing challenges for contemporary healthcare systems. Population ageing, multimorbidity, and rising demand for long-term care are placing unprecedented pressure on health services, calling for a profound transformation in how care is organized, delivered, and evaluated. In this context, digital technologies, advanced data analytics, and integrated organizational models are increasingly recognized as key enablers of more effective, sustainable, and patient-centered healthcare systems. However, the successful adoption and scaling up of digital health solutions require robust evidence on their impacts, as well as appropriate governance frameworks, organizational readiness, and policy alignment.

Within this broader landscape, Work Package 5 (WP5) of the DARE project focuses on impact analysis, policy evaluation, and upscaling strategies for digital prevention and chronic care initiatives. In particular, Task 5.3 addresses the need to assess how digital tools, organizational innovations, and data-driven approaches can support policy-making and improve healthcare outcomes, while ensuring sustainability, equity, and regulatory compliance. Deliverable S1.D5.3 documents the results achieved in this task, bringing together complementary research designs developed by multiple partners and applied to real-world healthcare settings.

The overarching objective of this deliverable is twofold. First, it aims to provide a rigorous assessment of selected digital health initiatives, examining their effects on healthcare utilization, patient outcomes, and system performance. Second, it seeks to identify the organizational, technological, and governance conditions under which such initiatives can be effectively scaled up and integrated into routine healthcare practice. To this end, the deliverable adopts a multidisciplinary perspective, combining health economics, policy analysis, organizational studies, and empirical evaluation based on administrative and clinical data.

The document is structured around three main research designs, corresponding to Sections 2.1, 2.2, and 2.3, each addressing a distinct but interrelated dimension of digital prevention and chronic care.

Section 2.1, developed by UNIBA in collaboration with ASL Bari, focuses on the design of an integrated care model for patients affected by Cardio-Renal-Metabolic (CRM) syndrome, a complex clinical condition characterized by the coexistence of cardiovascular, renal, and metabolic disorders. The section documents the completion of the theoretical and preparatory phase of the evaluation process, including the development of a Data Protection Impact Assessment (DPIA) and a comprehensive review of organizational and economic models for integrated care. A key contribution of this work is the development of an original conceptual framework structured around seven interrelated pillars: patient-centered care, holistic care, digital integration, efficiency and cost-effectiveness, workforce well-being, sustainable governance, and data-driven decision-making. This framework provides a coherent methodological and organizational foundation for the subsequent

empirical implementation and economic evaluation of integrated CRM care pathways, explicitly addressing gaps identified in the existing literature, such as limited attention to people management, digital health integration, and long-term sustainability.

Section 2.2, developed by UNIBO and AUSL Romagna, represents the empirical core of the deliverable and addresses the use of digital technologies and advanced data analytics for policy assessment and impact evaluation. This section is articulated along two main lines of inquiry. The first concerns the implementation and use of a population risk stratification tool, namely the Johns Hopkins Adjusted Clinical Groups (ACG®) system, to support healthcare planning and policy analysis. The deliverable documents the substantial effort required to operationalize the tool, including data preparation, privacy-compliant patient identification, and extensive training of healthcare professionals. This work demonstrates how population risk stratification can enhance the ability of healthcare organizations to identify high-risk patients, allocate resources more efficiently, and support evidence-based policy decisions.

The second line of inquiry in Section 2.2 focuses on the evaluation of several telemonitoring initiatives implemented within AUSL Romagna. These include programs targeting chronic patients living in rural and remote areas, patients with implantable cardioverter-defibrillators, individuals with congestive heart failure supported by primary care nursing programs, and patients with type 1 diabetes using automated insulin delivery systems. Using longitudinal administrative data and advanced econometric methods—such as two-way fixed effects models and staggered Difference-in-Differences estimators—the analyses provide robust evidence of the impacts of telemonitoring and digitally supported care pathways. The results consistently point to improvements in treatment adherence, continuity of care, and reductions in emergency department visits and hospitalizations, highlighting a substitution effect whereby proactive and planned care replaces reactive, emergency-driven interventions. These findings offer concrete policy-relevant insights into the conditions under which digital health interventions can improve outcomes while alleviating pressure on acute care services.

Section 2.3, developed by UNIROMA2 in collaboration with ASL Roma 1, complements the empirical analyses by focusing on the governance, regulatory, and organizational dimensions of digital health implementation. This section examines telemedicine pathways from an institutional and operational perspective, detailing eligibility criteria, privacy and data protection measures, coordination mechanisms among healthcare professionals, and the role of territorial and hospital-based operational units. By explicitly addressing regulatory compliance, ethical considerations, and organizational workflows, this research design underscores that technological innovation alone is insufficient to generate impact unless it is embedded within coherent governance structures and supported by clear roles, responsibilities, and accountability mechanisms.

Taken together, the contributions presented in this deliverable provide a comprehensive and integrated assessment of digital prevention and chronic care initiatives within the DARE project. The document advances the state of knowledge in at least three key ways. First, it combines

conceptual model development with rigorous empirical evaluation, bridging the gap between theory and practice. Second, it demonstrates the value of advanced data analytics—such as population risk stratification and causal inference methods—for informing healthcare policy and organizational decision-making. Third, it highlights the central role of governance, workforce engagement, and regulatory alignment in enabling the sustainable adoption and scaling up of digital health solutions.

By providing evidence-based insights grounded in real-world healthcare settings, Deliverable S1.D5.3 contributes directly to the objectives of Spoke 1 of the DARE project and offers actionable guidance for policymakers, healthcare managers, and practitioners seeking to leverage digital technologies to improve prevention, chronic care management, and system sustainability.

2. Description of research designs

2.1. The UNIBA and ASL BA research design

This document describes the state of progress, at the thirty-sixth month, of the activities planned under Work Package 5 (WP5) of the project, which is aimed at evaluating the effectiveness of integrated management strategies for patients affected by Cardio-Renal-Metabolic (CRM) syndrome within the ASL Bari.

As of the reference date, WP5 has completed and consolidated the theoretical and preparatory phase of the project. In particular, the preparation of the Data Protection Impact Assessment (DPIA) to be submitted to the competent Ethics Committee has been finalized, and an in-depth theoretical analysis of the organizational and economic models relevant to the integrated management of CRM conditions has been completed. This activity constitutes the methodological, legal-organizational, and managerial foundation upon which the subsequent empirical phases of operational implementation and economic evaluation will be built.

The growing prevalence of chronic diseases, and in particular CRM syndrome, represents one of the main challenges for contemporary healthcare systems, requiring a shift in the care paradigm. The traditional approach—characterized by fragmented and hospital-centered care—shows clear limitations when faced with the need for integrated, multidisciplinary, and patient-oriented care pathways capable of combining clinical effectiveness, economic sustainability, and healthcare workforce well-being. Although international guidelines have long emphasized the importance of prevention, early diagnosis, and multidisciplinary collaboration, organizational structures remain marked by significant discontinuities, including limited interoperability among system actors, information fragmentation, insufficient integration of digital technologies, and inadequate attention to organizational sustainability and people management.

This gap highlights the lack of consolidated models capable of integrating technological innovation, process sustainability, human capital management, and the clinical specificities of CRM syndrome. To address these critical issues, a systematic review of the international literature (2015–2024) is currently underway to identify the main enabling factors—economic, technological, managerial, and educational—supporting the functioning of integrated care models.

The review focuses on a holistic model that considers the entire patient journey. Based on the analysis, an integrated organizational model for CRM has been developed, structured around seven pillars:

- Patient-centered care – placing the individual at the center and recognizing the patient as an active partner in the care process.
- Holistic approach – comprehensive management of clinical, psychological, social, and environmental aspects.
- Digital integration – use of telemedicine, clinical decision support systems, artificial intelligence, and remote monitoring.
- Efficiency & cost-effectiveness – optimization of resources and rationalization of costs.
- Workforce well-being – promotion of healthcare staff well-being, training, and motivation.
- Sustainable governance – adoption of ethical, sustainable organizational policies aligned with regulatory standards.
- Data-driven decision making – systematic use of clinical and operational data to support quality, safety, and sustainability.

Existing literature provides integration models—such as Integrated Care frameworks—but these are often general in nature, lack a specific focus on complex clinical conditions such as CRM syndrome, and do not consistently address people management, digital health, and sustainability dimensions.

The seven pillars also show a clear correspondence with the objectives and expected impacts of the **DARE project**:

1. **Patient-Centered & Holistic Care**

Target: improve health outcomes, promote preventive lifestyles, encourage self-monitoring and active participation.

Reference: health and societal impacts (personalized prevention, risk stratification, psychological well-being).

2. **Digital & AI-Enabled Solutions**

Target: strengthen telemedicine, teleconsultation, clinical decision tools, and monitoring platforms; promote data integration.

Reference: digital preparedness, digital capacity building, impact on primary research.

3. Evidence-Based Decision Making

Target: support policies and interventions with reliable data and cost-benefit analyses.

Reference: influence on policymaking, economic evaluations.

4. Sustainable People Management

Target: strengthen training, leadership, and staff motivation; promote inclusion and resilience.

Reference: capacity building, improvement of professional practices.

5. Organizational Efficiency & Resource Optimization

Target: optimize resource allocation and reduce inefficiencies.

Reference: short- and long-term economic impacts.

6. Governance & Integration

Target: promote integrated governance, coordination, and process standardization.

Reference: integrated care, data sharing, policy influence.

7. Societal & Cultural Transformation

Target: support cultural change, increase citizen awareness, and build trust in digital prevention.

Reference: cultural impact and transformation of organizational practices.

The relationship between the pillars and WP5 tasks can be summarized as follows:

- **Pillar 1 – Patient-centered & holistic care:** Task 5.3 (policy evaluation and training on patient-centered care); Deliverable D5.2.
- **Pillar 2 – Digital & AI-enabled solutions:** Tasks 5.1 and 5.2; Deliverable D5.1.
- **Pillar 3 – Evidence-based decision making:** Tasks 5.1 and 5.3; Deliverable D5.3.
- **Pillar 4 – Sustainable people management:** Task 5.2; Deliverable D5.2.
- **Pillar 5 – Organizational efficiency:** Task 5.1; transversal contribution from all deliverables.
- **Pillar 6 – Governance & integration:** Task 5.3 and coordination with WP1; transversal contribution from all deliverables.
- **Pillar 7 – Societal & cultural transformation:** Task 5.3; transversal contribution from all deliverables.

Organizational considerations and future activities

From an organizational perspective, the work undertaken confirms the objective of developing a CRM model that complies with the current regulatory framework, aligns with healthcare governance principles, and is capable of generating value for ASL Bari. The theoretical phase completed represents an essential step toward the subsequent operational implementation of the model.

- In the coming months, the model will be presented at several international conferences with the aim of translating the theoretical framework into implementable operational guidelines. In parallel, a project is underway to retrospectively estimate—over a ten-year horizon—the prevalence of CRM conditions within the ASL Bari population and the total and per-capita healthcare expenditure associated with routine patient management. This analysis, based on ASL BA administrative data, is subject to approval by the Ethics Committee.
- Preparatory activities for the clinical study, the DPIA, and the technical report have also been completed with the support of **Exprivia** and **INFN**. In particular, Exprivia contributed to the design of the technological architecture, the definition of ETL workflows for data extraction, normalization, and pseudonymization, the specification of analytical platform requirements, and the development of data quality procedures and consistency checks for information flows. In the coming months, project activities will be carried out in full compliance with the guidance provided by the Ethics Committee.

2.2. The UNIBO and AUSL Romagna research design

Consistently with the general objectives of SPOKE 1 WP5 and in line with the specific targets already outlined in Deliverables 5.1 and 5.2, the UNIBO and AUSL Romagna units have further advanced the set of activities initiated during the first two years of the DARE project. In addition to that, a few new projects have been launched and are at earlier stage of development. In this document, we cover here the advancements that took place since the completion of the previous report [Deliverable 5.2, December 2024]. In particular, we focus on the progress achieved across the main lines of action that have seen the UNIBO and AUSL Romagna units jointly involved and we provide a description of the aims of the new initiatives whose completion is scheduled for the end of 2026. The efforts have been directed in several directions. The first one involves progressing with the acquisition of a risk stratification tool and the definition of a set of cases and applications that allow for a sophisticated use of health data for policy evaluation purposes. The second one pertains to the design of the research and the collection of data to support the empirical evaluation of ongoing initiatives based on the adoption of technological devices for telemonitoring cohorts of home-based patients suffering from chronic conditions.

2.2.1. The stratification tool to support policy assessment

Deliverables 5.1 and 5.2 provided an extensive discussion of the potential advantages of applying population risk stratification (PRS) tools to inform healthcare policy design. For a more detailed analysis of this topic and its relevance to the DARE project, we refer to the previously submitted documents. In this new document, we outline the progress made over the past year within this line of research.

With reference to the activities described last year, the analytical work aimed at deepening the scientific groundwork that underpins the formulation of strategies for using the stratification tool has been finalised and completed in the first half of 2025. Consequently, most of the activity has been devoted to preparing the databases required to feed the stratification tool that was finally acquired during the year and to providing training to ASL and UNIBO staff in the use of the newly acquired tool.

2.2.2. In-depth analysis of stratification tool applications

The analysis of the literature background presented in Deliverable 5.1 was further developed in Deliverable 5.2 consistently with the task of WP5 s of evaluating the role of digital technologies for the management of chronic conditions. This objective was pursued mainly through the drafting of the scientific article *'Population Risk Stratification Tools and Interventions for Chronic Disease Management in Primary Care: A Systematic Literature Review'*. This segment of the project has been completed in 2025.

A detailed description of the contents of the article had already been provided in Deliverable 5.2, including a discussion of its specific contribution to the general purposes of the DARE project, and in particular to the activities of WP5. By the end of 2024, the draft of the paper was under review at BMC Health Services Research. It has been returned to the authors in February 2025 with invitation to revise and resubmit (*Major Revisions*).

In a few months the reviews were completed and the revised manuscript returned to the Journal for further consideration. The paper has been finally accepted for publication in April 2025. It has been published under the Open Access agreement, and the financial support of the DARE project is reported in the acknowledgment section. The full-text of the published version of the paper is included as [Annex BO-ROM1](#) to this document.

2.2.3. 1.2 The population risk stratification tool: updates and future steps

Training programs, implementation of the ACG software and first applications

In line with the procurement procedures and training activities described in the previous deliverable, the past year has seen the full implementation and a first application of the Johns Hopkins Adjusted Clinical Groups (ACG)[®] software within AUSL Romagna.

In December 2024, a training course on the use of the ACG stratification software was held in Ravenna. The course, in line with what was reported last year, consisted of three intensive in-person days and involved around twenty members of AUSL Romagna and UNIBO staff. The sessions were devoted to introducing the ACG software, with a detailed presentation of its main functionalities, input requirements and types of outputs. Particular attention was devoted to explaining the different risk and morbidity indicators produced by the software and the different reporting options, to enable participants not only to use the software, but also to correctly interpret its results for evaluation purposes.

In the first months of 2025 and up to September, the AUSL Romagna personnel worked to make the software fully operational, adapting it to the specific features of AUSL Romagna. This phase was characterized by a series of technical meetings between the personnel and the ACG experts, with the aim of preparing the five input files required for running the software. The process was long and complex. The first key decision concerned the criterion to be used for the geolocation of the assisted population, and in particular, whether to anchor each individual to their general practitioner (GP) or to their residence. At the same time, the tightening of AUSL Romagna's internal privacy policies made it necessary to create a new encrypted patient identifier, compliant with the updated internal data protection guidelines and able to ensure linkage between the various administrative data flows and the ACG software. Once these initial constraints had been addressed, it was possible to proceed with the construction of the five input files, an activity that required a substantial investment in information technology (IT) resources and coordination among different teams to ensure that the resulting files were complete, consistent and reliable.

Following the conclusion of this preparatory phase, the ACG software was loaded onto the assisted population for the year 2024 and, separately, also for the year 2023. In parallel, the ACG Business Intelligence (BI) environment was configured and adapted to the specific context of AUSL Romagna to make the information generated by the software easily accessible and usable also by professionals who do not have specific expertise in ACG. To become familiar with this user-friendly tool, in October 2025 a one-day introductory course was organized on the use of the BI for accessing and consulting ACG-based indicators. This course was attended by the same group of AUSL and UNIBO staff who participated in the December 2024 training.

At present, the ACG software and the associated BI tool are fully available and currently in use on several devices within AUSL Romagna. Their main functionalities and potential applications have been illustrated to the Health District Directors and to other AUSL personnel involved in the planning and management of primary care interventions. They have shown interest in the potentialities offered by the system in terms of population stratification, identification of target groups and analysis of territorial and organizational settings. A first use of the software involved the cohort of patients with chronic heart failure (CHF) in the assisted population of 2024. For this group, the different ACG outputs were extracted in tabular form and, within the BI environment, patients were geolocated and linked to a set of relevant organizational variables, including their GP

and the primary care unit (Nucleo di Cure Primarie) they belong to, the presence of multiple chronic conditions and the relative cost burden for the AUSL compared with the cost of assisted people without major chronic diseases. This analysis was conducted to assess whether individuals with a diagnosis of CHF, already identified by the Emilia-Romagna regional clinical guidelines, are also correctly flagged as such in the ACG system. By leveraging the different ACG outputs, their visualisation through charts and maps, the additional information on GPs and the information on whether they are enrolled in a chronic management program, this preliminary analysis aims to provide a comprehensive description of these patients and to relate them to how they are managed at the territorial level.

This descriptive analysis can be seen as a preliminary validation of the integrated ACG–BI system and as a tangible advancement towards the analytical objectives already outlined in the previous deliverable. In particular, it offers an initial opportunity for the Department of Economics (DSE) and AUSL Romagna dedicated teams, who are jointly responsible for the development and monitoring of primary care interventions, to start giving concrete form to the four main evaluation dimensions previously identified, namely:

- assessing to what extent the interventions reach the intended target groups, including, where appropriate, individuals at a very early stage of their disease;
- comparing different organizational models in order to understand whether some of them, after controlling for the characteristics of the treated individuals, are more effective in achieving the intended objectives;
- identifying which educational, economic or technological factors contribute more markedly to explaining the observed differences in intervention outcomes;
- deriving indications on how the design of the interventions may be adjusted or refined to better support the achievement of the policy goals.

The work carried out on the 2024 cohort of chronic heart failure patients represents the first concrete application of the integrated ACG–BI system to the four evaluation dimensions described above and is expected to serve as a reference for extending the use of the ACG System. In particular, it has paved the way for new, more in-depth analyses that will involve other chronic conditions and broader segments of the assisted population, in line with the overall aims of the DARE project.

2.2.4. Future steps for the use of the stratification tool

With reference to the activities described last year, the implementation of the ACG as part of AUSL Romagna's managerial routines now makes it possible to put into practice risk stratification for chronic diseases such as chronic heart failure, diabetes and chronic obstructive pulmonary disease (COPD). The ACG outputs provide a common language for describing clinical complexity and expected resource use across districts, primary care units, and provider networks, and can be used directly to identify individuals at high risk of specific chronic diseases.

In line with last year's objective of assessing how well chronic disease management programs, in particular the chronic care ambulatories, succeed in including high-risk individuals and excluding those who are not at high risk, the ACG software can now be used to construct, year by year, risk-stratified cohorts of patients with chronic diseases. For each condition, ACG-based indicators allow: (i) to compare the characteristics of patients actually enrolled in chronic care ambulatories with those of all ACG-identified eligible patients; (ii) to pay particular attention to multimorbid patients, who may be simultaneously eligible for different programs and thus require better coordination; and (iii) to analyse whether the capacity to intervene early on high-risk individuals is evenly distributed across districts and sub-areas or is concentrated where specific organizational solutions are in place (community homes, community nurses, specific GP organizational models, etc.).

Building on this infrastructure, a first research analysis will focus on patients with type 2 diabetes and CHF in the period 2017–2024, comparing GP-guided enrolment in chronic-care ambulatories with ACG-guided recruitment. The ACG will be used as a stratification tool to generate, each year, a recruitment list consistent with the diagnostic therapeutic care pathways (PDTA) eligibility criteria, and to describe both GP-enrolled and ACG-identified patients in terms of clinical complexity, multimorbidity, and expected workload and costs. The analysis will assess, by year and district, the overlap between the two groups, differences in ACG outputs, the implications for resource use and budget and key patient dimensions (age, sex, geography and deprivation index). Because the cohort will include both enrolled and non-enrolled patients followed over time, it will also be possible to examine whether ACG would have identified eligible patients earlier than their GP and the resulting implications for outcomes. This longitudinal comparison between GP-guided and ACG-guided enrolment is expected to provide policy-relevant evidence on the validity and efficiency of ACG-based risk stratification for targeting and prioritizing patients in chronic care pathways in Romagna, directly addressing the questions outlined in last year's deliverable. A detailed document describing the ACG system, its use in the literature, its outputs and its future prospects is included in [Annex BO-ROM2](#) to this document.

2.2.5. Evaluation of initiatives that use ITC devices to monitor chronic patients

The second area of investigation pursued by the UNIBO and AUSL Romagna units concerns the systematic mapping, appraisal, and evaluation of ongoing initiatives within the AUSL jurisdiction that deploy technological solutions for the remote monitoring of home-based patients with chronic conditions. As detailed in the previous progress reports (Deliverables 5.1 and 5.2), this line of activity encompasses two distinct interventions. The first one targets a cohort of patients residing in rural or otherwise remote areas and affected by conditions such as heart failure, diabetes, and/or chronic obstructive pulmonary disease (COPD). This intervention is coordinated by community-based healthcare professionals, including general practitioners, nurses, and multiprofessional teams, that operate within Community Health Centers. The second intervention involves the remote surveillance of patients equipped with implantable cardioverter-defibrillators, overseen by hospital-based units within the organizational structure.

2.2.6. Telemonitoring of chronic patients in rural and remote areas

In this section, we outline the progress made during the last 12 months in the policy evaluation analysis of the telemonitoring program for patients diagnosed with specific chronic conditions and living in remote areas. In the previous deliverables the general and specific objectives of the project had already been outlined. Among the Annexes of Deliverable 5.2 we included an extensive report discussing the role of telemedicine in the changing healthcare landscape, the institutional context of post-COVID initiatives in Italy, and including comprehensive review of the literature on telemonitoring, a description of the program design and a preliminary overview of the data currently available. We therefore refer to the previous reports for further details on these issues.

A first line of action involved the drafting of a scientific paper that illustrates and summarizes the main contents of the report submitted as part of previous deliverables. The paper is titled "*Telemonitoraggio dei pazienti cronici: l'esperienza della AUSL Romagna*" and is jointly coauthored by Unibo and Ausl Romagna staff. The list of authors also included the person responsible for the regional telemonitoring program within the Department of Health of the Emilia-Romagna Region.

The transition from a report format to a scientific article required an extensive revision of the text, including a substantial condensation of several sections, particularly those containing the detailed literature review and the more institutional aspects. The section relating to the impact assessment has retained an exploratory character, as the data collected pertains only to an initial time frame.

After an extensive reorganization of the material, the article was submitted to *Politiche Sanitarie* in April 2025. The response of the Journal arrived in June. Overall, the paper received a positive evaluation. The editorial decision allowed for publication conditionally on including revisions recommended by the referees.

Between late summer and autumn, the article underwent extensive revision. In particular, the discussion of the diffusion of innovations in healthcare was expanded, introducing a more structured theoretical framework. In addition, in line with the referees' suggestions, the institutional context and the design of the evaluation study were more clearly articulated. Finally, the discussion of methodological limitations and of the policy implications for scaling up telemonitoring initiatives to broader contexts was enriched. The revised version of the manuscript was then resubmitted to *Politiche Sanitarie*. The paper has now been accepted for publication and is forthcoming in the first issue of the year 2026: it will be published under Open Access agreement. The final version of the article is included as Annex BO-ROM3 (pre-print version).

Data collection

Consistent with one of the objectives outlined in the previous report, a parallel line of action has involved the collection of an additional block of data aimed at extending the observation window of the project from November 2023 to December 2024. Thanks to the collaboration between ASL

Romagna and the company managing the technological platform through which patient monitoring is carried out, detailed information on the measurements recorded has been acquired, extending the follow-up period by an additional 14 months.

Activities are currently underway to integrate the telemonitoring data with outcome indicators designed to capture changes in health conditions associated with program enrollment. Specifically, these indicators are extracted from administrative data sources of the ASL Romagna and include emergency department (ED) visits, hospitalizations, and outpatient services for both the pre- and post-enrollment periods. ED visits have been further disaggregated by severity/urgency codes and discharge type.

Future activities

The activities planned for the coming months involve in the first place the finalization of the dataset spanning from April 2021 to December 2024 on which we plan to perform a full impact evaluation analysis. In doing so we will have the chance of extensively monitoring patients after their enrolment, potentially doubling the median follow-up period compared to the preliminary assessment performed so far. In addition to that, we plan to cover access to health services for up to 24 months in the pre-enrollment period for all patients.

Secondly, we plan to employ more advanced empirical strategies to derive causal estimates of the impact of the program. A critical step will be the construction of a control group composed of individuals comparable to treated patients. For this group as well, information will be retrospectively reconstructed over a sufficiently long-time horizon, encompassing both the two years preceding enrollment and the follow-up period observed for treated individuals.

Once the dataset will be structured according to the design described above, regression-based analyses using a Difference-in-Differences (DiD) framework will be implemented, possibly complemented by propensity score matching techniques. Furthermore, given the staggered timing of patient enrollment, the evaluation design will benefit from recent methodological advancements in staggered DiD, thereby enhancing the robustness of causal identification. The objective is to draft a scientific paper to be submitted to an international journal. These activities will be carried out during the final year of the DARE project.

2.2.7. Telemonitoring of patients with Implantable cardioverter defibrillators

This section presents a summary of the empirical analysis of the telemonitoring program for Chronic Heart Failure (CHF) patients with implantable cardioverter-defibrillators, implemented within hospital-based structures of the AUSL of Romagna. The full version of the study is attached to this document as Annex BO-ROM4 (manuscript entitled "*Tertiary prevention and monitoring by specialists: The case of chronic heart failure patients with defibrillators*").

Background

Chronic Heart Failure (CHF) imposes an increasing burden on public health globally, particularly for patients with implantable cardioverter-defibrillators (ICDs), who face high risks of acute episodes and intensive follow-up needs. The AUSL Romagna has implemented a tertiary prevention program supported by structured telemonitoring and specialist outpatient care. The initiative aligns with broader efforts in chronic disease management to shift from reactive to proactive treatments, integrating digital tools into clinical workflows to strengthen continuity and appropriateness of patient pathways. The availability of administrative data spanning 2019–2024 enables a rigorous assessment of the effects of the program on adherence, healthcare utilization, and acute healthcare outcomes.

Objectives of the study

The study aims to assess the impact of the tertiary prevention program implemented for CHF patients with ICDs on both compliance with prescribed therapies and overall healthcare utilization patterns. Specifically, the analysis examines whether enrolment in the program enhances adherence to beta-blockers and increases the frequency of cardiology visits and diagnostic monitoring, while reducing emergency department access and hospital admissions. To address these objectives, the study assesses the causal effects of the program by leveraging the staggered timing of patient enrolment and applying econometric methods that allow to identify heterogeneous treatment effects over time.

Methods

The study draws on a cohort of 1,165 CHF patients observed over 11 semesters using administrative data from the AUSL Romagna. The empirical strategy implements both a two-way fixed effects (TWFE) model and a staggered Difference-in-Differences (DiD) estimator following Callaway & Sant'Anna (2021). The latter approach addresses known limitations of traditional TWFE models in staggered treatment settings and allows the analysis to exploit variation in enrolment timing across patients. The dataset incorporates socio-demographic characteristics, clinical information, adherence to therapeutic prescriptions as well as multiple indicators of service use, including cardiology visits, echocardiograms, ED attendances, and hospital admissions.

Main results and policy implications

Both TWFE and staggered DiD models reveal consistent findings. Enrolment in the tertiary prevention program is associated with increased adherence to beta blockers, specialist visits and echocardiograms, and with reductions in ED visits and hospitalizations, including those attributable to cardiovascular causes. Patients with ICDs exhibit higher baseline acute care utilization, but the

complementary effect of enrolment suggests that structured outpatient management mitigates clinical instability. Event-study results show an absence of pre-treatment differences and a clear post-enrolment decline in unplanned acute care, suggesting a substitution mechanism where proactive monitoring and planned follow-up replace emergency-driven care. For policymakers, the results highlight that integrated tertiary prevention models supported by digital monitoring tools can enhance outcomes while reducing pressure on emergency and inpatient services. The findings support investment in structured chronic care pathways, emphasizing the need for sustained funding for telemonitoring and specialist coordination as prevention strategies.

2.2.8. Telemonitoring patients with Congestive Heart Failure

This section presents a summary of the empirical analysis of the effects of the "Primary Care Nursing Program" (PCNPs) implemented in AUSL Romagna to support chronic patients with congestive heart failure (CHF). The main aims of the program were to increase patients' engagement through more frequent interactions (via telephone) with specialized nurses and to promote coordination (also via data integration) between the various professionals involved. The full version of the study is attached to this document as Annex BO-ROM5 (manuscript entitled "*Integrated Care, Engaging Patients and Financial Incentives: The Impact of Primary Care Nursing Programs*").

Background

Nurses are important drivers of this program and have significant responsibilities including identification, evaluation, and monitoring of patient needs, supporting the GP for the definition of clinical and assistance personal programs for each patient, implementation of educational interventions on medication adherence, healthy lifestyle and therapeutic education, implementation of periodic follow-ups on indicators of health (e.g. weight, Body Mass Index) and of health consumption (e.g., electrocardiogram, drug conciliation and specialist visits). A key responsibility of the nurse is patient recall, i.e., ensuring timely follow-ups. Based on follow-up, under the GP's supervision, the nurse implements the personalised care plan. The nurse also oversees the administrative management of the patient records. Nurses monitor the patients through various channels. The most common method, telephone contact, ranges from biannual to weekly. For patients with tele-monitoring kits, the nurse ensures weekly remote monitoring of key vitals such as blood pressure, heart rate, and body weight. If there are signs of worsening conditions or instability, the nurse notifies the GP.

Data

The dataset has a longitudinal structure. The unit of analysis consists of patients with heart failure who received an implantable cardioverter-defibrillator (ICD) during one of the observation quarters.

The paper uses quarterly administrative data from the LHA of Romagna, Italy, for individuals with CHF. This data is also linked to yearly supply-side data, i.e., data on individual GPs. The data are collected from 2017 to 2019, i.e., for 12 quarters. The analysis is restricted to the pre-COVID-19 period, because the pandemic prompted a substantial reallocation of healthcare resources, such as nursing staff, toward COVID-related care. The final dataset includes socio-demographic characteristics (e.g., age, gender, and district of residence), frailty indicators (e.g., deprivation index and Modified-Chronic Disease Score), healthcare utilization indicators (e.g., number of cardiology visits, number of echocardiograms, and number of integrated home care days), and patient outcome indicators (e.g., number of deaths, emergency room visits, and hospitalizations).

Methods

Exploiting enrolment timing, we apply a dynamic difference in difference to high-frequency individual-GP-linked administrative data to estimate the causal impact of enrollment in the chronic care hospital outpatient clinic on healthcare utilization and patient outcomes. The descriptive and impact analyses aim to offer critical insights to policymakers regarding the effectiveness of this organizational model, providing evidence to support potential expansion to broader patient populations.

Main results and policy implications

The main findings indicate that enrolment in PCNP leads to a modest increase in the use of healthcare and a decrease in the probability of hospitalisation for heart attacks. These results seem to be driven amongst patients of GPs who lacked support and financial incentives for chronic disease management. These results may be explained by the nurses' successful proactive outreach, increased engagement of the patient and the integration of PCNPs with community cardiologists, who contribute to patient care as needed.

2.2.9. Telemonitoring of diabetes type 1 patients (T1D) with automatic infusion devices

Starting in June 2025, the Diabetes Unit of Ravenna of the AUSL Romagna and the DSE launched a collaboration that led to the signing of an agreement ([Annex BO-ROM6](#)) to assess the overall impact of the policy adopted by the AUSL Romagna which, in a consolidated organizational context of monitoring and support, provides automatic insulin infusion systems to a cohort of patients with T1D when intensive insulin therapy and multiple injections fail to keep the patient within therapeutic targets. In particular, the program will evaluate the absorption of healthcare system resources (emergency room [ER] visits, specialist visits, and hospitalizations) and the development of disease-related complications before and after the application of the AUSL policy. The expected results will provide relevant evidence to guide choices regarding care and organizational models aimed at

promoting equitable access to these innovations and to identify the profiles of patients who can benefit most from them.

Background

Over the past two decades, T1D therapy has benefited from rapid pharmacological and technological innovations. Despite these advances, unmet clinical needs remain. According to the T1D Index, one-third of patients with T1D still die from complications related to the disease. In 2024, life expectancy for these individuals was reduced by approximately 13 years compared to the general population, with cardiovascular disease as the leading cause of mortality. While randomized clinical trials on AID systems combining new-generation insulin pumps, continuous glucose monitoring sensors, and, more recently, predictive algorithms have shown significant improvements in glycemic control and quality of life, there is still no significant evidence on the effects of the new organizational models associated with these innovations, with particular reference to the actual impact of AIDs in daily care practice, especially in public health services and in patients with poor adherence or metabolic instability.

Data

Data will be collected from the Auxilium database that includes all patients with diabetes mellitus who have been prescribed supplementary care strips for monitoring capillary blood glucose, pen injector needles, CGM systems, CSII, or AID. Auxilium is currently linked to the electronic medical record (EMR) for the provinces of Ravenna and Rimini, while integration with Forlì -Cesena is planned by the end of 2025. Additional data are collected through the Electronic Medical Records (EMR) Meteda, that is the EMR system used by the specialist diabetes centers of the AUSL Romagna that contains several clinical indicators, including the type of diabetes, anthropometric data, blood pressure values, and the main laboratory parameters. Finally, data are collected via the device AID that is a Hybrid Closed Loop (HCL) system, also known as a semi-automatic artificial pancreas, which integrates an insulin pump with a blood glucose monitoring system and an algorithm for automatic insulin infusion.

Methods

Patients in AID are not selected at random: they are the most critical for the reasons mentioned above giving rise to problems of structural asymmetry between the treated and control groups. Hence, depending on the actual availability of data, the analysis could be carried out in two phases: a first stage with pre-post analysis on patients who were administered AID in the provinces of Ravenna and Rimini without the creation of a control group, and a subsequent stage, with data relating to the entire AUSL Romagna, the creation of a control group, and the application of more

robust methodological approaches. The implementation of the analysis in a single phase (with a control group and application across all provinces) requires the rapid completion of the connection between Auxilium and EMR for the entire AUSL territory.

The first methodological approach consists of identifying a cohort of subjects with T1D in the “pre” phase and following them over time with T1D who are not eligible for AID because they already have target blood glucose levels and use a “simple” pen injector, i.e., they are on multiple daily injections (with or without continuous glucose monitoring), assuming that disease control in the experimental subjects will converge with that of the controls after AID installation. The (few) subjects who use non-automated microinfusion pumps, which are being phased out, should be excluded from the control group. This approach has already been applied to health data in an evaluation project developed as part of the DARE program. Ideally, subjects should be matched by (1) calendar period at the date of AID installation, (2) gender, (3) age group, (4) educational level, (5) health district, (6) duration of disease, and (7) certain prevalent and clinically relevant comorbidities from EMR. Where direct matching proves too restrictive (dimensionality issues), a propensity score-based method may be used, possibly supplemented by adjustment models. Since patients with T1D who meet glycemic targets tend to maintain this characteristic over time, there is minimal risk of misclassification. These patients remain on target for a variety of reasons: good self-management and compliance, but also favorable pathophysiological characteristics. Furthermore, with few exceptions, all subjects with T1D have at least two visits per year, regardless of AID use and glycemic control. It is physiological that, at the start of a new therapy or the installation of a device, checks are more frequent.

The second approach aims to estimate the causal effects of AID on health outcomes and healthcare service utilization using the Heckman's “selection model,” which corrects for distortions arising from the non-random distribution of AID. In the first stage, this approach uses a probit model to estimate the probability of being selected for AID administration using the clinical and sociodemographic variables that most influence the selection process. In the second stage, however, a regression model estimates the relationship between the variables of interest, including a correction term derived from the results of the first stage to take into account the distortion introduced by non-random selection.

A third approach will use an event study to estimate the dynamic effects of staggered treatments and, to this end, will exploit the staggering over time of AID administration to T1D patients. The adoption of a model by Sun and Abraham (2021) for estimating heterogeneous treatments—over time and by cohort—avoids the problems of traditional two-way difference-in-difference models with fixed effects, which produce biased estimates even when the assumption of parallel trends is satisfied and therefore do not allow for a causal interpretation of the effects of the treatment. Within this approach, not only individuals never treated with AID, but also those not yet treated are used in the control group to mitigate the distortions typically found when using traditional difference-in-difference models.

Future developments

Starting from an event-study approach, we intend to analyze the causal effects of AID by verifying the conditions for reconstructing a quasi-experimental situation due to the occurrence of the COVID-19 pandemic that also affected Romagna between 2020 and 2022, unexpectedly and exogenously reducing or delaying patients' access to all healthcare services and therefore also to the administration of AID and diabetes consultations. This random variation in the timing of administration for patients whose conditions would have led to administration under ordinary conditions could allow the causal effect of AID to be estimated, overcoming the problem of distortion due to the non-random selection of individuals treated. Similarly, it will be possible to use other exogenous factors that have changed treatment times in a way that could not be predicted in advance, with differences even between different areas, such as the floods of 2023 and 2024 that affected some areas of Romagna. Finally, the variation in administration times due to COVID-19 or the floods could allow for an unbiased estimation of the differential effects of different types of AID if they involved different intensities of data monitoring and different modes of intervention in critical situations by diabetes service personnel.

A generalization of this “quasi-experimental” approach involves a more in-depth analysis of the timing and practical methods of application of the model of care for patients with T1D with or without AID in the various diabetes clinics located in different areas of the AUSL Romagna. This analysis aims to assess whether, during the period considered, there was a differentiated adoption over time of the more structured model of patient support (with or without AID) based on planning choices due either to the desire to first evaluate one or more pilot experiences, or to the need to apply the model at different times/in different ways due to a shortage of specialized personnel (turnover blocks), problems in the availability of technologies (delivery delays or quotas), difficulties in integrating pre-existing ICT solutions with systems that support AIDs, or, finally, the impossibility of locating clinics in such a way as to guarantee relatively uniform distances (travel times) for the entire population potentially concerned. In all these conditions, there are exogenous factors that influence treatment times but do not depend on the clinical and sociodemographic characteristics of patients or the choices of the professionals directly involved and therefore, for the reasons mentioned above, could be useful for estimating the causal effect of AIDs by reducing or eliminating the problem of the non-random selection of the treated individuals.

After the signature of the agreement between AUSL Romagna and DSE, the research group started working on the available dataset to assess their reliability and utility with respect to the main target of evaluating the effectiveness of the AID program. The report ([Annex BO-ROM7](#)) provides the details of the first descriptive analysis of each of the main datasets and of the possibility to integrate them.

2.2.10. Barriers and facilitators for the adoption of digital health solutions: A survey of Emilia-Romagna residents

Background

The dynamics of institutional changes, combined with increasing demographic pressures, necessitate substantial adaptations in the organisation and delivery of health services. In publicly funded systems, such adjustments are generally driven by top-down planning decisions. However, evaluating the degree to which these processes align with patients' expectations is essential to ensure that innovations achieve satisfactory levels of uptake and produce welfare-enhancing effects. These concerns are especially relevant when the health system undergoes profound shifts in its underlying technological paradigm, since the adoption of new technologies may encounter substantial patient resistance. In recent years, the issue has become central for the implementation and diffusion of digital health initiatives, which are triggering a wide range of new challenges for policymakers and patients at the same time. However, the propensity of citizens to take up digital health tools is often overlooked, as greater attention is typically devoted to the impact evaluation of such initiatives.

From the institutional viewpoint, in Italy, a cornerstone of the Piano Nazionale di Ripresa e Resilienza (PNRR) is to enhance the efficiency and quality of the national healthcare system by promoting integrated, socially and economically sustainable strategies to improve care delivery, with particular emphasis on digital health solutions. This changing landscape has garnered significant attention as it requires the development of innovative frameworks for the organisation, implementation, and financing of digital health programs on a large scale.

Aim of the Survey

To tackle the issues outlined above, we designed and conducted a survey to elicit the views of Emilia-Romagna residents with a special focus on their attitude towards digital health solutions. Our aim is to provide new, evidence-based, actionable policy insights to support health decision-makers. An original feature of the survey is that it offers an in-depth assessment of how Emilia-Romagna residents perceive and utilise digital health solutions, providing an up-to-date overview of regional readiness for these technologies. In particular, the information collected through questionnaires enables us to identify the main barriers and facilitators affecting citizens' willingness to participate in digital health programs and to assess the socio-demographic factors associated to it.

Achievements to date and future developments

We successfully designed, developed and administered the survey on representative sample of residents in the Emilia-Romagna region of Italy, consisting of 3,000 adults (aged 18-74) residing in the Emilia-Romagna region of Italy. The survey itself comprises several modules in total, with one

specifically devoted to eliciting citizens' attitude towards digital health initiatives. Data were collected through an online survey conducted between October and November 2025. The fieldwork was conducted by Dynata, a global market research and data company. Upon completion of the fieldwork, the dataset has been stored in a designated folder. Data are now ready for analysis, and we are currently producing initial descriptive statistics to assess sample composition and representativeness.

The information maps respondents' experiences with the NHS and their attitudes towards digital health programs. More specifically, we investigate participants' ability to use and engage with the digital tools, to assess how comfortable respondents are with the use of these resources. Then, we inquire about which digital health services are utilised more frequently and elicit the main perceived obstacles that hinder the large-scale development of digital tools. Our plan for the final year of the DARE project is to use this data to draft a scientific paper examining demand-side barriers to telemedicine adoption. The literature review is currently underway, and we plan to start the econometric analysis in the coming months. We plan to have a first draft of the manuscript in summer 2026 and to submit it for publication in autumn.

2.3. The UNIROMA2 and ASL ROMA1 research design

2.3.1. Introduction

Digital health has now become an indispensable component for the evolution and sustainability of healthcare systems. The term refers to the structured integration of digital technologies into clinical and care processes, with the aim of improving the quality of care, facilitating access, and ensuring continuity of services. This approach involves not only healthcare professionals but also patients and caregivers, promoting a participatory, person-centered model of care. The expansion of ICT solutions has profoundly reshaped the delivery of healthcare services, introducing virtual tools as an integral part of patient care pathways.

The experience of the COVID-19 pandemic strongly highlighted the strategic value of digital technologies, which enabled healthcare systems to respond promptly to emerging needs while maintaining service continuity under critical conditions. In this context, telemedicine—defined as the remote delivery of healthcare services—proved to be a key resource for ensuring continuity of care, reducing in-person visits, and optimizing the use of available resources. However, with the return to ordinary conditions, pre-existing challenges have resurfaced, including system fragmentation, interoperability difficulties, data protection and privacy concerns, and a degree of resistance to change among healthcare professionals.

In Italy, the implementation of digital transformation has been strongly supported by the National Recovery and Resilience Plan (PNRR), which provides significant investments to modernize the digital infrastructure of the National Health Service. Among the priority actions, telemedicine plays

a central role, particularly in the management of patients with chronic conditions. The objective is to reach at least 300,000 patients by the end of 2025, through intermediate milestones and a multi-level governance framework (national, regional, and local) to ensure effective implementation. Within the framework of PNRR Mission 6 and Ministerial Decree 77/2022, the digitalization of care represents a key lever to strengthen the territorial reach and timeliness of healthcare services, facilitating seamless transitions across different levels of care and improving system equity. Telemedicine thus becomes an essential ally in bringing care closer to citizens, in line with the founding principles of the National Health Service established in 1978 by Law No. 833.

To support this transition, the Ministerial Decree of 29 April 2022 outlined the guidelines for the digitalization of home-based care, establishing the integration of telemedicine services within Individual Care Plans. The decree also emphasizes the need for local technical structures capable of effectively supporting both healthcare professionals and families, ensuring service accessibility and continuity.

The subsequent Ministerial Decree of 21 September 2022 specified the minimum functional requirements and service levels for telemedicine solutions funded by the PNRR. According to this framework, Regions are required to guarantee at least four types of services: teleconsultation, tele-visit, telemonitoring, and tele-assistance. Each regional infrastructure must include two components: Service Centers, responsible for technical and managerial support (maintenance, training, help desk), and Provider Centers, responsible for clinical service delivery by healthcare professionals. A significant innovation introduced by this decree is the definition of eligibility criteria for access to telemedicine services. In addition to clinical and care-related assessments, technological factors (such as device availability and internet connectivity), cultural aspects, functional autonomy, and the presence of a caregiver are also considered. This multidimensional evaluation is essential to ensure that remote services are both effective and accessible.

Finally, the Ministerial Decree of 30 September 2022 defined the procedures for selecting technological solutions and for their nationwide deployment. It also established criteria for evaluating regional proposals and adopted clinical-care guidelines developed by AGENAS. These guidelines identify priority clinical areas for the application of minimum telemedicine services and provide operational guidance on modes of service delivery, involved professional roles, and target populations. In particular, for telemonitoring, five priority categories of chronic patients are identified: individuals with diabetic, respiratory, cardiovascular, oncological, and neurological conditions.

In this context, pending the full implementation of the Regional Telemedicine Infrastructure (IRT)—to which various providers will gradually be required to adapt—and with the aim of piloting a new organizational model to support telemedicine service delivery, ASL Roma 1 has initiated a collaboration with Next Care, the details of which are set out in corporate resolution No. 542/2025, described below.

2.3.2. Objectives

The main purpose of this pilot project aimed at implementing a telemonitoring service is to test, with the support of a dedicated external Service Center and Provider Center, the use of digital solutions for the remote monitoring of patients' clinical conditions. The objective is to improve continuity and appropriateness of care, optimize the use of healthcare resources, and promote home-based care, particularly for patients affected by chronic conditions. Telemonitoring enables the continuous collection of relevant vital and clinical parameters (such as blood pressure, blood glucose levels, oxygen saturation, heart rate, body weight, and temperature), transmitting them in real time to healthcare professionals, who can promptly intervene in case of anomalies.

Among its specific objectives, the pilot project aims to:

- assess the clinical effectiveness of telemonitoring in preventing disease exacerbations and improving health outcomes;
- reduce inappropriate use of healthcare facilities, such as avoidable emergency department visits and hospital admissions;
- increase patient adherence to treatment through greater engagement and empowerment in managing their condition;
- test the integration of new digital tools within existing care pathways, verifying their compatibility with current organizational models;
- evaluate acceptability and satisfaction among patients, caregivers, and healthcare professionals;
- collect evidence to support the definition of replicable models in view of the systemic rollout of telemedicine services.

This pilot project, implemented following an agreement between ASL Roma 1 and Next Care, aims to manage the telemonitoring of a group of patients estimated to range between 200 and 250 individuals, who meet the established inclusion criteria. Telemonitoring will be carried out for a period ranging from six months to one year, depending on the personalized care plan that best addresses each patient's specific needs. These activities will be conducted by the Next Care Telemedicine Center, ensuring periodic monitoring (from several times per week to several times per day, according to the individual monitoring plan) and the management of patients' health conditions, in collaboration with the Territorial Operations Centers, which ensure coordination with treating physicians (e.g. General Practitioners). These physicians remain the overall clinical leads responsible for implementing the care plan and for any subsequent integration or modification.

2.3.3. Scope of application, inclusion and exclusion criteria

For this pilot project, the scope of application has been limited to community-based care and primary care, in coordination with outpatient specialist services and hospitals, with the aim of ensuring a comprehensive (360-degree) care pathway and continuity of care for patients. The objective is to prevent relapses or acute episodes and/or to enable early intervention in the event of a deterioration in the patient's clinical condition.

In particular, the inclusion criteria for enrolling patients in the project are as follows:

- Patients aged over 65 years and registered with the healthcare services of District 14 of ASL Roma 1;
- Patients assisted by General Practitioners of the San Zaccaria Papa Primary Care Unit of District 14, during the initial implementation phase;
- Patients affected by mild to moderate cardiological and/or pneumological conditions, or by mild to moderate frailty conditions;
- Patients who receive a positive assessment following completion of the clinical eligibility form by the treating physician (Annex 1);
- Patients who receive a positive assessment following completion of the socio-technological eligibility form by an operator of the Next Care Telemedicine Center, which entails the patient's autonomous and informed consent, the suitability and training of the patient and/or caregiver, the adequacy of the family and home environment and support network, and the structural and technological suitability of the home in relation to the clinical condition and the use of the required equipment (Annex 4);
- Home Integrated Care (ADI) not activated.

Exclusion criteria:

- All patients who do not meet the above inclusion criteria.

2.3.4. Main Actors

The main actors selected to participate in this pilot project are:

- Approximately 200–250 patients assisted by General Practitioners (GPs) affiliated with the San Zaccaria Papa Primary Care Unit (UCP) of District 14, and their caregivers;
- General Practitioners of the San Zaccaria Papa UCP of District 14;
- Where involved in the referral and care pathway, outpatient specialist physicians of the healthcare organization and/or hospital physicians responsible for patient discharge from the organization's hospital facilities;

- Staff of the Territorial Operations Center (COT) of District 14;
- Staff of the Next Care Telemedicine Operations Center and of any other services potentially involved (e.g. logistics services for the delivery and collection of devices).

DEFINITION AND ABBREVIATIONS

- ADI: Integrated Home Care
- AFT: Territorial Functional Aggregation
- COT / COT-D: Territorial Operations Center / District Territorial Operations Center
- ICT: Information and Communication Technology
- IRT: Regional Telemedicine Infrastructure
- MMG: General Practitioner
- PO: Hospital Facilities
- UCP: Primary Care Unit
- STIC: Information and Communication Technology Services
- UOC: Complex Operational Unit

2.3.5. Phases of the Care Pathway

ASL Roma 1, through the Corporate Telemedicine Services Coordinator or their designated project delegate, sends to the email address telemedicina@nextcaretelemedicina.it the nominal lists of General Practitioners and, more generally, of the operators from the various services involved in the project. These lists must include complete personal data, namely Tax Code, Surname, Name, and email address, to be authorized for access to the platform. The Telemedicine Activities Manager of Next Care receives these lists and forwards them to the Fleexi platform, which is responsible for authorizing users and generating platform access credentials. Fleexi then issues individual credentials, which are sent to the email addresses indicated in the received lists. At this stage, the communication procedures among the involved services are also defined. In general, inter-service communications will be facilitated by the Territorial Operations Center (COT) of District 14, whose email address is: centrale.distretto14@aslroma1.it.

Within the activation and delivery of the telemonitoring service, the various phases entail the coordinated involvement of different institutional and professional actors, each with specific responsibilities.

A) ENROLMENT

General Practitioners (GPs) identify eligible patients and are responsible for assessing and completing the documentation relating to the patient's clinical eligibility (Annex 1), collecting general and/or specific consent to care (Annex 2), and signing the privacy information notice

(Annex 3). At this stage, the most appropriate telemonitoring plan is also indicated (vital parameters to be measured, daily frequency, etc.). This documentation is then forwarded to the Territorial Operations Center (COT), which both performs an additional assessment with the GPs and enters the patient's demographic data into the platform, including any information regarding the caregiver. Once data entry is complete, ASL Roma 1 COT staff notify Next Care's telemedicine center of the preliminary enrolment via email to telemedicina@nextcaretelemedicina.it.

B) FIRST CONTACT

Once preliminary enrolment is completed, the first operational contact takes place between Next Care's operations center and the enrolled patient, possibly supported by their caregiver. First, Next Care verifies the patient's socio-technological eligibility (Annex 4) through a phone interview or video call. During this contact, staff provide dedicated support to the patient/caregiver for downloading the dedicated app and creating a personal profile. Clear and detailed information on the app's functionalities is also provided to ensure informed and autonomous use. The patient profile is then activated on the operational platform, and logistics are initiated for delivery of the device(s) required by the telemonitoring pathway prescribed by the enrolling physician. The patient (or caregiver) is required to actively cooperate by completing the socio-technological eligibility interview and installing/activating the app, thereby finalizing the start-up phase.

C) HOME DELIVERY OF DEVICE(S)

After the patient profile is activated and the package containing the required materials is prepared, device delivery takes place at the patient's home. Next Care's logistics service collects the package from Next Care's operations center. The package—customized for each patient—includes the assigned device(s), a welcome letter (Annex 5), an illustrated manual with instructions for proper device use, and delivery documentation to be signed by the patient or caregiver. Upon delivery, the logistics staff provide essential information to facilitate initiation of the pathway and collect the signature confirming receipt. Next Care logistics then notify Next Care's operations center via email (telemedicina@nextcaretelemedicina.it) that delivery has occurred. The signed documentation is returned to Next Care as official evidence. Finally, Next Care's operations center informs ASL Roma 1's COT that the patient has been taken in charge, via email to the address previously provided by the Health Authority.

D) TRAINING OF THE PATIENT AND/OR CAREGIVER

Once the device is delivered, a training phase follows to ensure correct use of the device(s) required by the care pathway. Next Care's operations center provides personalized training to the enrolled person and, where applicable, their caregiver. Conducted by a trained operator, the session aims to explain clearly and practically all device functionalities and

correct usage. The patient/caregiver may ask questions and acquire full awareness of the tasks to be performed independently. Particular attention is dedicated to interaction with the app, correct placement and use of the device(s), and data transmission to the central platform. The patient/caregiver is therefore required to learn the essential skills for using the device and ensure proper preservation, including keeping the delivery packaging, which may be needed for returns or technical support.

E) MEDICAL HISTORY AND INFORMATION COLLECTION

Following initial training—during the same video call—an anamnesis phase is conducted to systematically and thoroughly collect information on the enrolled person's health status and care needs. This is carried out by Next Care's operations center through a video interview conducted by an operator. During the interview, and possibly through questionnaires, various aspects of the patient's clinical, functional, and social condition are assessed in order to build a personalized map of health needs, supporting the GP in defining the telemonitoring plan. Additional information may be requested later, either through self-reporting via the app or with operator support, depending on the patient's capabilities and preferences or if specific needs emerge. The patient/caregiver is expected to cooperate fully, remaining available and allowing sufficient time for a complete and effective assessment.

F) ACTIVATION OF THE MONITORING PLAN INDICATED IN THE CLINICAL ELIGIBILITY ISSUED BY THE ENROLLING PHYSICIAN

Following the definition of clinical eligibility by the enrolling physician during preliminary enrolment (Annex 1), and after socio-technological eligibility is also confirmed (Annex 4), Next Care's operations center activates the patient's personalized monitoring plan. The plan includes measurements of the clinical parameters indicated in the eligibility form, scheduled at times generally agreed with the patient and/or caregiver, in line with the enrolling physician's general indications, to facilitate compliance and adherence. This collaboration is essential for ensuring effective and continuous telemedicine pathway management.

G) START OF THE PATIENT'S TELEMONITORING PLAN

Once the plan starts, Next Care's operations center monitors patient self-measurements in real time, according to the shared plan, from 8:00 a.m. to 8:00 p.m., seven days a week. The enrolled person, together with the caregiver, is responsible for taking measurements at the agreed times. Measurements may be performed within a flexible time window relative to the scheduled time: one hour before and thirty minutes after the planned time. Next Care operators receive transmitted data in real time and promptly assess trends. Data visible on the platform can also be consulted by ASL Roma 1's COT and the enrolling physician (both granted access).

H) MANAGEMENT OF ANY ALERTS

To manage patients and their care plans in a structured and standardized manner—including any alerts (out-of-range parameters)—the platform includes a set of digitalized operational procedures covering specific parameters and potential abnormalities, with particular attention to trends and deterioration risk. These include procedures for:

Blood pressure: hypertension / hypotension

Heart rate: tachycardia / bradycardia

Respiratory rate: tachypnea / bradypnea / ECG artefact respiratory rate

Body temperature: febrile states up to hyperthermia

Oxygen saturation: desaturation with oxygen therapy / without oxygen therapy / in COPD patients

Body weight

Spirometry

These procedures enable timely assessment and management of changes in vital parameters, helping prevent clinical deterioration. When an out-of-range value is detected, an alert is generated and Next Care intervenes promptly. The operator immediately contacts the patient via video call to guide an assisted re-measurement. If needed, the operator coordinates with the Next Care center physician, who may also join the video call for further clinical-diagnostic assessment. Responsibility for alert management lies with the Next Care center physician, who supervises and directs the diagnostic process. Depending on the outcome, the alert may be closed if well-being is restored; or, if severe clinical disorders are identified (e.g., hemodynamic instability), the Emergency-Urgency System (SEU) may be activated. Emergency calls may be made by the patient and/or caregiver; however, the telemonitoring healthcare professional will ensure they can contact the SEU in a timely manner or will activate the emergency service directly. Once activated, coordination transfers to the SEU, and telemonitoring provides support through the system in place until SEU takes charge. When the SEU confirms patient takeover, telemonitoring ends.

The patient and caregiver must keep the phone available for calls, respond promptly to communications, and activate emergency services when required. Each alert event and its management are promptly reported to the COT via email to the address communicated at the outset; moreover, each alert generates data sharing on the platform with both the COT and the prescribing physician. *Measurements received outside the time window defined in the care plan will still be managed during Next Care's operating hours (8:00–20:00) when an alert is generated.

I) MANAGEMENT OF MISSED MEASUREMENTS

If measurements are not transmitted within the established timeframes, a Next Care operator performs a phone check 31 minutes after the scheduled time (e.g., for a 10:00 a.m. measurement, the first check occurs at 10:31 a.m.), contacting the patient to understand the reasons. If there is no response, the missed measurement event is recorded in the patient's health file. The operator also contacts the caregiver and, if listed, another family member to inform them. At the same time, a missed-measurement report is sent to the district COT. A flexible time window applies: measurements may be taken up to one hour before and thirty minutes after the scheduled time. If not completed within this interval, the procedure described above is triggered and the event is recorded as a missed measurement. The enrolled person and caregiver remain responsible for performing measurements as scheduled and for keeping the phone available and responding promptly to calls from the operations center.

J) WEEKLY TELEASSISTANCE

At the end of the first week of telemonitoring—even in the absence of alerts—and thereafter on a weekly basis, Next Care's operations center schedules a video call with the patient, agreeing on the most suitable time. During the session, the operator completes weekly assistance through an in-depth assessment of key aspects to ensure continuity and effectiveness of care. Specifically, the regularity of measurements, any issues with device use, telemonitoring data, and questionnaire results are reviewed. Attention is also given to any emerging health issues, evolving care needs compared to the initial anamnesis, and requests or reports submitted by the patient. At the end of this review, the patient and operator may define personalized modalities and times for subsequent measurements and teleassistance sessions. If new care needs emerge, Next Care sends a report to the COT via the email address provided by ASL Roma 1; weekly notes are also shared on the platform and visible to both the COT and the prescribing physician. As repeatedly emphasized, the patient/caregiver must keep the phone available for calls and respond promptly to communications from the operations center.

K) MEDICAL TELECHECK WITH WEEKLY REASSESSMENT OF CARE COMPLEXITY BASED ON TELEMONITORING RESULTS

At the end of the first week of telemonitoring—and thereafter when necessary, periodically (weekly for Plan 3, every two weeks for Plan 2, monthly for Plan 1)—the Next Care center physician conducts a video call with the patient to perform a clinical assessment. The physician reviews telemonitoring data, questionnaire responses, and overall clinical conditions, with particular attention to alerts generated during the week, medication adherence, and the effectiveness of the assigned monitoring plan. In parallel, the operations center sends the COT reports on any new care needs identified during the evaluation to the email address indicated by ASL Roma 1.

L) REASSESSMENT AND ACTIVATION OF OTHER SERVICE LEVELS

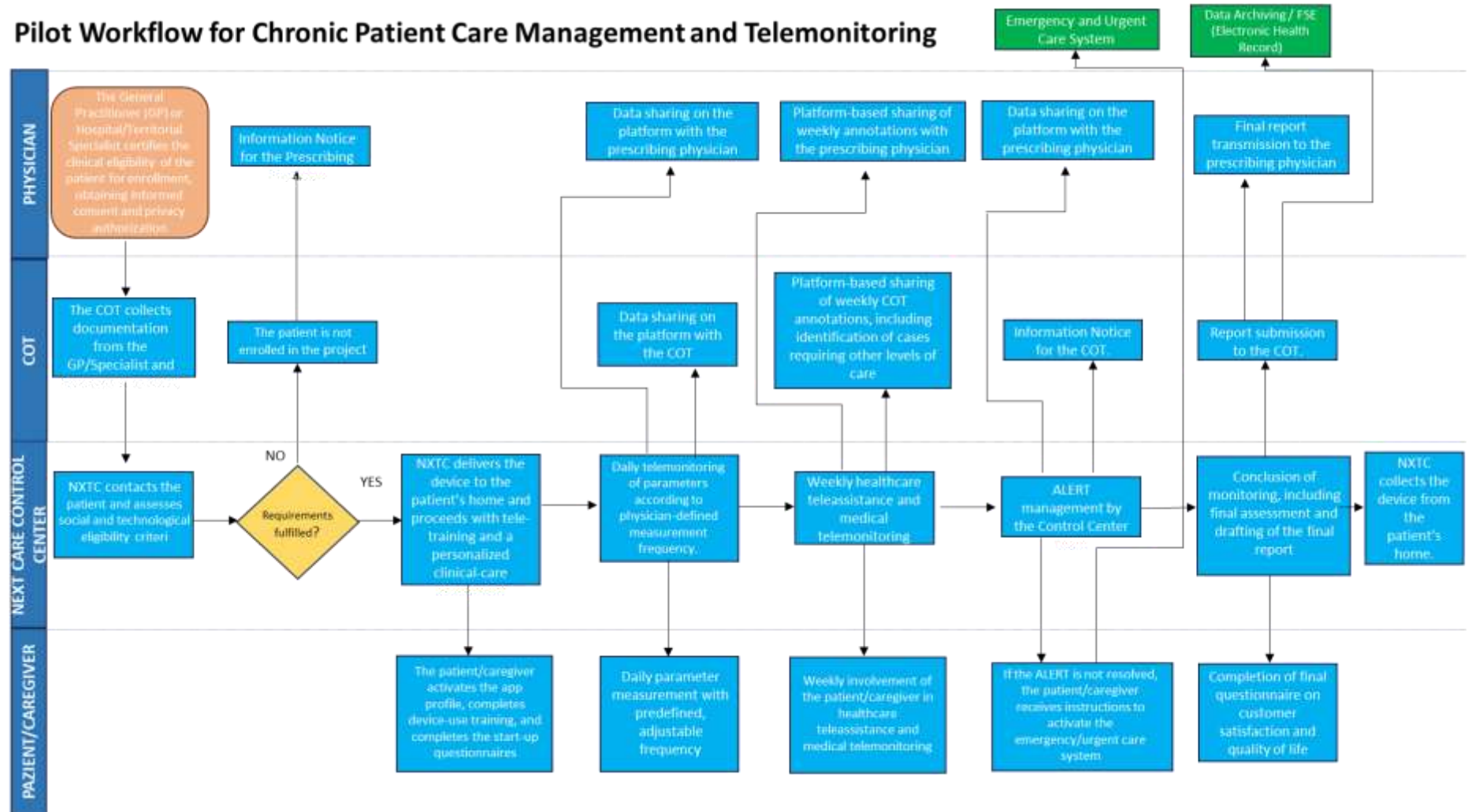
Based on the medical telecheck and teleassistance—which may highlight emerging health needs—as well as platform notes, the COT evaluates cases that may require home-based services and/or other levels of care, referring them to the district UVM for the definition of an Individualized Care Plan (PAI) integrating existing telemedicine services with home care interventions.

M) END OF THE TELEMONITORING PERIOD

At the end of the telemonitoring period provided for by the plan (maximum 6 months) prescribed by the enrolling treating physician, Next Care's operations center prepares an end-of-plan report for the COT and the treating physician. At this stage, the GP and COT staff—supported by the data and report produced by Next Care—assess whether to extend the same plan or adopt a different one, depending on the patient's clinical needs; reassessment and reconfiguration of the plan may occur whenever necessary. The final report is drafted by the treating physician (e.g., the GP), possibly in collaboration with the COT, as the overall clinical lead responsible for implementing the care plan and any modifications. The final report may also be uploaded to the Electronic Health Record (Fascicolo Sanitario Elettronico), if required by regional and national guidelines. Finally, at the end of the agreed telemonitoring period, Next Care administers the final customer satisfaction questionnaire to the patient or caregiver (either self-completed or assisted, depending on the patient's preference/needs; Annex 6) and activates logistics for home collection of the device(s), scheduling an appointment with the patient and/or caregiver.

1. Workflow

Pilot Workflow for Chronic Patient Care Management and Telemonitoring



2. Responsibility Matrix

ROLES \ PHASES	Enrolling Treating Physician (GP)	COT ASL Roma I	Next Care		
			Next Care Operations Center	Next Care Operations Center Physician	Next Care-Logistics
Enrollment and definition of the telemonitoring plan	R	C	-	-	-
Documentation review and entry of patient demographic data into the platform	I	R	C	-	-
Initial preparatory contact prior to program start	I	I	R	C	C
Home delivery of devices	I	I	C	I	R
Training of the patient and/or caregiver	I	I	R	I	I
Medical history collection and information gathering	I	I	R	I	-
Administration of questionnaires	I	I	R	I	-
Activation of the monitoring plan as defined by the clinical eligibility issued by the enrolling physician	C	I	R	I	-
Start of the telemonitoring plan	I	I	R	C	-
Alert management (8:00 a.m. – 8:00 p.m.)	C	C	R	R	-
Management of missing measurements (8:00 a.m. – 8:00 p.m.)	C	C	R	-	-
Weekly teleassistance	I	I	R	I	-
Medical telemonitoring (according to the monitoring plan)	C	C	C	R	-
Reassessment and activation of additional levels of care	C	R	C	I	-
End of the telemonitoring period	R	C	C	C	C

R= Responsible; C= Involved; I= Informed

2.3.6. Processing of Personal Data

The methods for processing the personal data of patients involved in the pilot project have been reviewed and approved by the company's Data Protection Officer (DPO), who prepared an information notice and a consent form for the processing of personal data related to the use of the dedicated IT services, namely the "Fleexi.Health" medical app (Annex 3). This documentation is to

be used during the enrolment phase by the enrolling treating physician (General Practitioner, outpatient specialist, or hospital specialist). The information notice is attached to this procedure.

2.3.1. Necessary resources

To initiate the pilot project, the following resources are required:

- Dedicated training for healthcare professionals (enrolling physicians and COT nurses);
- Updated educational and technological materials for healthcare professionals and for patients and/or caregivers;
- Training for patients and/or caregivers;
- Integrated IT tools to ensure coordination, continuity of care, and timely exchange of clinical information.

2.3.2. Indicators

In order to assess the effectiveness of the project, a control group will be identified with the same characteristics as the population enrolled in the program, but without, of course, being taken in charge through the telemonitoring service. The control population and the indicators will be calculated and monitored with the support of the Department of Epidemiology (DEP) and the UOC for the Management of Healthcare Information Flows and Analysis of Care Processes.

The identified indicators are as follows (illustrative and non-exhaustive list):

Clinical Indicators (Maintenance of Clinical Stability)	
Rate of exacerbations managed at home	% of alerts requiring intervention by the Next Care Operations Center physician that are resolved without activation of the Emergency and Urgent Care System, out of the total number of alerts
	No. of alerts resolved with repeat measurement / Total no. of alerts
Process Indicators	
Patient compliance	No. of measurements performed / No. of scheduled measurements
	No. of missing measurements / No. of scheduled measurements
Enrollment in Home Care Services (ADI)	Proportion of patients who discontinue telemonitoring due to enrollment in Home Care Services (ADI) over the total number of enrolled patients
	No. of patients taken into ADI / Total no. of enrolled patients
Patient-Reported Outcomes (PROs)	

Satisfaction / perceived quality	% of satisfaction questionnaires with results rated between fair and excellent out of the total number of administered questionnaires
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2.3.1. Annexes

- Annex 1: Patient clinical eligibility form
- Annex 2: Patient informed consent form
- Annex 3: Privacy notice and personal data processing information for the use of dedicated IT services, namely the “Fleexi.Health” medical app
- Annex 4: Socio-technological eligibility form
- Annex 5: Welcome letter accompanying the device inside the package delivered to the patient’s home by Next Care logistics
- Annex 6: Customer Satisfaction questionnaire

3. References

- ASL Roma 1. Nota prot. n. 86782 del 08/06/2023. Nomina Referente Sanitario Aziendale dei servizi di telemedicina. 2023.
- ASL Roma 1 - Deliberazione del Direttore Generale n. 542/2025
- Conferenza Stato-Regioni, Ministero della Salute. Indicazioni nazionali per l'erogazione di prestazioni di telemedicina. 2020. <https://www.statoregioni.it/media/3221/p-3-csr-rep-n-215-17dic2020.pdf> (consultato in data 07/07/2025)
- Golinelli D., Pecoraro V., Tedesco D., Negro A., Berti E., Camerlingo M:D., Alberghini L., Lippi Bruni M., Rolli M. & Grilli R. (2025) Population Risk Stratification Tools and Interventions for Chronic Disease Management in Primary Care: A Systematic Literature Review, BMC Health Services Research, (2025) 25:526. <https://doi.org/10.1186/s12913-025-12690-0> .
- Governo Italiano. Italia Domani - Portale PNRR [Internet]. <https://www.italiadomani.gov.it/content/sogei-ng/it/it/home.html> (consultato in data 07/07/2025)
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- Ministero della salute. Telemedicina. Linee di indirizzo nazionali. http://www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=2129 (consultato in data 07/07/2025)
- Ministero della Salute. Linee di indirizzo nazionali sulla telemedicina [Internet]. <https://www.salute.gov.it/portale/ehealth/dettaglioContenutiEHealth.jsp?lingua=italiano&id=5525&area=eHealth&menu=telemedicina> (consultato in data 07/07/2025)
- Ministero della Salute. Decreto 23 maggio 2022, n. 77. Regolamento recante la definizione di modelli e standard per lo sviluppo dell'assistenza territoriale nel Servizio sanitario nazionale (22G00085) (GU Serie Generale n.144 del 22-06-2022).
- Ministero della Salute. Decreto 29 aprile 2022. Approvazione delle linee guida organizzative contenenti il
- «Modello digitale per l'attuazione dell'assistenza domiciliare», ai fini del raggiungimento della Milestone EU M6C1-4, di cui all'Annex alla decisione di esecuzione del Consiglio ECOFIN del 13 luglio 2021, recante l'approvazione della valutazione del Piano per la ripresa e resilienza dell'Italia. (22A03098) (GU Serie Generale n.120 del 24-05-2022)
- Ministero della Salute. Decreto 21 settembre 2022. Approvazione delle linee guida per i servizi di telemedicina. (22A06184) (GU Serie Generale n.256 del 02-11-2022)
- Ministero della Salute. Decreto 30 settembre 2022. Procedure di selezione delle soluzioni di telemedicina e diffusione sul territorio nazionale, nonché i meccanismi di valutazione delle proposte di fabbisogno regionale per i servizi minimi di telemedicina e l'adozione delle Linee di indirizzo per i servizi di telemedicina. (22A07125) (GU Serie Generale n.298 del 22-12-2022)
- Telemedicina in Italia: dopo l'emergenza è il momento di fare sistema - Agenda Digitale [Internet]. <https://www.agendadigitale.eu/sanita/telemedicina-in-italia-dopo-lemergenza-e-il-momento-di-fare-sistema/> (consultato in data 07/07/2025)
- World Health Organization. Global strategy on digital health 2020-2025 [Internet]. Geneva; 2021. <http://apps.who.int/bookorders>

Annex 1: Patient clinical eligibility form

DATI PAZIENTE		
COGNOME		
NOME		
CF.		
RECAPITO TELEFONICO		
RECAPITO TELEFONICO CARE GIVER		
DIAGNOSI CLINICA		
INQUADRAMENTO CLINICO	CARDIOLOGICO	
	PNEUMOLOGICO	
	FRAGILE	

ELEGGIBILE ALLE ATTIVITA' CLINICO/ASSISTENZIALI RESE IN TELEMEDICINA DI:

TELEMONITORAGGIO, TELEASSISTENZA E TELECONTROLLO MEDICO

SI	NO

PIANO DI MONITORAGGIO

PIANO 1		3 RILEVAZIONI/SETTIMANA (P.A.-F.C.-F.R.-T.C.-SAT.O2-ECG)
PIANO 2		1 RILEVAZIONE/DIE (P.A.-F.C.-F.R.-T.C.-SAT.O2-ECG)
PIANO 3		2 RILEVAZIONI/DIE (P.A.-F.C.-F.R.-SAT.O2-ECG)
Piano 1	Piano 2	Piano 3
Attivazione App	Attivazione App	Attivazione App
3 rilevazioni/ settimana + 1 autorilevazione del peso/sett.	1 rilevazione/die + 1 autorilevazione del peso settimanale	2 rilevazioni/die + 1 autorilevazione del peso settimanale
Somministrazione questionari ogni 30 gg	Somministrazione questionari ogni 15 gg	Somministrazione questionari ogni 7 gg
1 teleassistenza/settimana	1 teleassistenza/settimana	1 teleassistenza/settimana
1 telecontrollo medico/mese	1 telecontrollo medico/quindicinale	1 telecontrollo medico/sett.

EVENTUALI INDICAZIONI RITENUTE UTILI AI FINI DEL TELEMONITORAGGIO (terapie in atto, indicazioni su specifici parametri da attenzionare, diverse soglie da impostare nel telemonitoraggio)	
--	--

LUOGO E DATA

FIRMA E TIMBRO DEL MEDICO:

Annex 2: Patient informed consent form

Allegato 2 - Consenso generale alle cure				
Io sottoscritto/a (Nome e Cognome)				
Nato/a a		il (GG/MM/AAAA)	___/___/___	
Documento identità	di	n.		Rilasciato da
Indirizzo di Domicilio				
Numero di Telefono				
In qualità di:	<input type="checkbox"/> Diretto interessato			
DICHIARO LIBERAMENTE E IN PIENA CONSAPEVOLEZZA:				
<input type="checkbox"/> Di VOLER ESSERE INFORMATO sulle mie condizioni di salute e sui trattamenti da intraprendere ai fini della corretta gestione del quadro sofferto, sulla base dei parametri emersi dal progetto pilota di telemonitoraggio.				
<input type="checkbox"/> DI AUTORIZZARE i curanti a trasmettere le informazioni alle persone di seguito riportate, in qualità di caregiver:				
Nome e Cognome (1)		Documento:		
Telefono (1)				
Nome e Cognome (2)		Documento		
Telefono (2)				
<input type="checkbox"/> DI NON AUTORIZZARE i curanti a trasmettere le informazioni ad altre persone.				
DICHIARO INOLTRE DI ESSERE A CONOSCENZA DEL FATTO CHE:				

- **Sono responsabile dell'esecuzione puntuale e corretta delle rilevazioni** dei parametri clinici secondo la frequenza e gli orari stabiliti nel mio Piano di monitoraggio e sono consapevole che saranno gestiti in maniera immediata solo gli alert rilevati all'interno della fascia oraria 08:00-20.00.
- **Dopo 31 minuti dall'orario previsto per la rilevazione, verrò contattato dalla Centrale Operativa per comprenderne le motivazioni.** In caso di mancata risposta sarà contattato il mio caregiver o un ulteriore familiare (se inserito nell'elenco contatti) per informarli della situazione. In assenza di riscontro, l'evento viene segnalato come mancata rilevazione;
- **È mia cura mantenere il cellulare in modalità di chiamata e rispondere tempestivamente** alle telefonate provenienti dalla Centrale Operativa;
- **Mi impegno ad informare tempestivamente la Centrale Operativa Next Care in caso di impossibilità a effettuare una o più misurazioni previste**, al fine di garantire la tracciabilità e la continuità del mio monitoraggio clinico;
- **Le misurazioni saranno monitorate** dalla Centrale operativa di Next Care e i dati visibili in piattaforma potranno essere consultati dal mio medico di medicina generale e dalla COT della ASL Roma 1 (Maggiori dettagli sono presenti nell'Informativa sulla Privacy, Allegato 3);
- **A seguito della rilevazione di valori anomali o fuori soglia, l'operatore della Centrale Operativa:**
 - Mi contatterà immediatamente tramite videochiamata per guidarmi nella ripetizione assistita della rilevazione;
 - Se necessario, avviserà il medico della Centrale Next Care, il quale, dopo aver valutato i dati, potrà entrare nella videochiamata per approfondire la valutazione;
 - Assisterà me o il mio caregiver nell'attivazione del sistema di emergenza qualora i parametri e i sintomi clinici lo richiedano.
- Al termine del processo, **ogni evento di alert e la relativa gestione verranno segnalati alla COT** del Distretto 14 della ASL Roma 1 e al mio medico di medicina generale.
- **La responsabilità della gestione della rilevazione alert è affidata al medico della centrale di Next Care**, che supervisiona e dirige il processo.
- **Dovrò essere disponibile ad effettuare delle videochiamate:**
 - **Di teleassistenza una volta a settimana** con un operatore della centrale operativa di Next Care per analizzare l'andamento delle rilevazioni, e per esaminare eventuali bisogni o criticità riscontrate nella settimana precedente;
 - **Di telecontrollo al termine della prima settimana di telemonitoraggio** (e, qualora necessario con cadenza periodica in base al proprio piano), con il medico di centrale di Next Care per effettuare una valutazione clinica sulla base anche delle rilevazioni avvenute nel periodo precedente.
- Se da tali valutazioni risulteranno dei bisogni sanitari emergenti, la COT, in collaborazione con il Medico di Medicina Generale, potrà valutare la necessità di eventuali ulteriori attività integrative.
- **Sono consapevole di poter revocare in qualsiasi momento il mio consenso** al servizio senza che ciò comporti la perdita del diritto all'assistenza sanitaria ordinaria.
- Tutte le informazioni che trasmetterò ai curanti ed al personale di assistenza e tutti i dati che i curanti ed il personale di assistenza ricaveranno dagli accertamenti e dai trattamenti che saranno eseguiti sulla mia persona sono riservati e coperti dal segreto professionale; potranno essere utilizzati per eventuali scopi di ricerca e studio, anche con finalità di pubblicazione su riviste scientifiche, ma solo nel rispetto della anonimizzazione.

Dichiaro di aver compreso le informazioni che mi sono state date e di essere stato/a informato/a della possibilità di rivolgere, in ogni momento, ulteriori domande di chiarimento al mio medico di medicina generale.

Firma della persona assistita:

DI CONSEGUENZA:

- ACCONSENTO a sottopormi alle cure ed alle indicazioni sopra dette;
- NON ACCONSENTO a sottopormi alle cure ed alle indicazioni sopra dette.

Data e firma della persona assistita

Data e firma del medico

Annex 3: Privacy notice and personal data processing information for the use of dedicated IT services

Servizi di Telemedicina Next Care

(Ai sensi del Regolamento Europeo 2016/679 e del Codice Privacy, come novellato dal D. Lgs. 101/2018)

L'Azienda Sanitaria Locale Roma 1 (di seguito "ASL Roma 1") con sede legale in Via Borgo Santo 3, 00193 Roma, in persona del commissario straordinario Dott. Giuseppe Quintavalle, in qualità di Titolare del trattamento, informa ai sensi dell'art. 13 Regolamento UE n. 2016/679 (in seguito "GDPR") e Codice Privacy, così come novellato dal D.lgs. 101/2018 che i dati personali saranno trattati con le modalità e per le finalità di seguito indicate.

1. Finalità e Base Giuridica del Trattamento

I dati personali raccolti dal Titolare sono trattati per fornire i servizi di Telemedicina e altre attività ad essa correlate, quali prevenzione, diagnosi, e cura nonché per le attività amministrative a esse collegate (quali, a titolo esemplificativo, attività amministrative correlate alla erogazione della Telemedicina, programmazione, gestione, controllo dell'assistenza sanitaria), anche attraverso l'utilizzo dei dispositivi medici assegnati e della piattaforma tecnologica utilizzata per la Telemedicina, Fleexi.Health, in particolare attraverso la creazione di una scheda sanitaria elettronica.

La base giuridica del trattamento si rinviene nell'art. 6, par. 1, lett. c) e) GDPR, nelle deroghe di cui all'art. 9, par. 2, lett. g) e h) GDPR e infine nell'art. 2-sexies, par. 2, lett. t) e v) del Codice Privacy ss.mm.ii. per quanto concerne le finalità di cura e correlate alla cura, mentre si rinviene nell'art. 6, par. 1, lett. a) GDPR e nell'art. 9, par. 2, lett. a) GDPR, per quanto concerne l'utilizzo dell'App "FLEEXI.HEALTH".

2. Categorie di dati trattati

Per le finalità di cui al punto n. 1 potranno essere raccolte e, successivamente trattate, le seguenti categorie di dati personali:

- dati anagrafici;
- dati di contatto;
- dati relativi alla salute e sanitari;
- dati socio tecnologici.

3. Modalità di trattamento

Il trattamento dei dati personali è realizzato per mezzo delle operazioni indicate all'art. 4, par. 1, n. 2 GDPR e più precisamente: raccolta, registrazione, organizzazione, conservazione, consultazione, elaborazione, selezione, estrazione, raffronto, utilizzo, comunicazione, cancellazione e distruzione dei dati.

I dati sono trattati dal Titolare del trattamento solo con modalità, strumenti e procedure cartacee e/o informatiche, strettamente necessarie per realizzare le finalità descritte al punto n. 1, in particolare attraverso la Piattaforma di Telemedicina, la relativa applicazione per dispositivi mobili, e i dispositivi medici assegnati. Il Titolare predispone misure di sicurezza fisiche, tecniche e organizzative ai sensi dell'art. 32 GDPR per prevenire la perdita dei dati, usi illeciti o non corretti ed accessi non autorizzati (*Data Breach*).

4. Periodo di Conservazione

I dati personali saranno conservati per il tempo necessario al raggiungimento delle finalità del trattamento indicate al punto n.1 delle presenti Informazioni privacy e/o comunque per il periodo previsto dal Prontuario di scarto, salvo il tempo più lungo necessario per adempiere agli obblighi di legge e/o a quanto richiesto dalle Autorità competenti.

In ogni caso, i dati raccolti potranno essere conservati illimitatamente se anonimizzati e, dunque, non più riconducibili irreversibilmente all'interessato.

5. Accesso ai dati personali

I dati sono trattati dal personale e dai collaboratori e professionisti sanitari di Next Care. In particolare, alcune informazioni sul suo stato di salute saranno disponibili per la consultazione da parte del personale di Next Care per l'aggiornamento dei servizi e del relativo calendario, nonché dai medici e operatori sanitari incaricati del servizio di Telemedicina.

Qualora il Professionista prescelto lo ritenga necessario od opportuno, potrà coinvolgere, tramite la Piattaforma di Telemedicina, altri professionisti, anch'essi registrati alla Piattaforma di Telemedicina – appartenenti ad altre aree tematiche di specialità, laddove dovesse ritenere che la richiesta di consulto che gli è stata presentata richieda l'intervento congiunto di più specialisti (consulto multidisciplinare).

I dati personali potranno inoltre essere trattati da terzi, quali i partner di Next Care, le farmacie presso cui è possibile attivare i servizi, o i fornitori di servizi esterni, che agiscano per conto o a nome di Next Care, e che tratteranno i dati unicamente in conformità allo scopo per cui essi sono stati in origine raccolti, come ad esempio per fornirle alcuni servizi di assistenza sanitaria o assistenza tecnica/informatica sui sistemi Next Care.

In particolare, la piattaforma tecnologica denominata Fleexi. Health utilizzata per il servizio di Telemedicina e i relativi servizi sono forniti da Fleexi Health Tech SRL, che tratterà i dati personali in qualità di sub-responsabile del trattamento.

I dati potranno essere comunicati nell'ambito delle finalità sopra indicate al punto 2(i) a: (i) organismi sanitari pubblici (ASL di competenza, altri enti pubblici in ambito sanitario), (ii) organismi sanitari privati (cliniche, laboratori di analisi, etc.) o esercenti le professioni sanitarie (medici specialisti, farmacisti, personale della Telemedicina etc.), limitatamente a quei dati ed operazioni indispensabili per perseguire le finalità di cui al punto 2(i) o ove previsto dalla legge o da regolamenti. I dati potranno inoltre essere comunicati al data center previsto a livello regionale e nazionale, per rendere possibile l'interscambio dei dati previsto dalla normativa applicabile sulla Telemedicina, secondo i tempi di attuazione da essa previsti.

6. Diritti dell'interessato

Il proprietario dei dati personali, nella sua qualità di interessato, dispone di tutti i diritti di cui all'art. 15 GDPR e ss., più precisamente diritto di accesso, diritto di rettifica, diritto alla cancellazione, diritto di limitazione di trattamento, diritto alla portabilità dei dati, diritto di opposizione, nonché il diritto di proporre reclamo all'Autorità Garante (art. 77 GDPR e 141 Codice Privacy ss.mm.ii).

L'interessato ha diritto a revocare il proprio consenso, precedentemente prestato, in ogni momento e con la facilità con cui lo ha conferito, ai sensi dell'art. 17, par.1, lett. b) GDPR.

Tuttavia, tale revoca non pregiudica la liceità del trattamento svolto sulla base del consenso precedentemente prestato e avrà come unico effetto la cessazione del trattamento dei dati personali dell'interessato per il futuro.

7. Modalità di esercizio dei diritti

Il soggetto interessato potrà in qualsiasi momento esercitare i propri diritti inviando apposita comunicazione ai seguenti indirizzi PEC del Titolare del trattamento:

- **L'Azienda Sanitaria Locale Roma 1** con sede legale in Via Borgo Santo 3, 00193 Roma, in persona del commissario straordinario Dott. Giuseppe Quintavalle,
- protocollo@pec.aslroma1.it

8. Identità e dati di contatto del:

- **Titolare del trattamento – AZIENDA SANITARIA LOCALE ROMA 1**

In persona del commissario straordinario Dott. Giuseppe Quintavalle,

- E-mail: ufficioprivacy@aslroma1.it
- PEC: protocollo@aslroma1.it

- DPO (RPD) dell'Azienda Sanitaria Locale Roma 1 – Scudoprivacy S.r.l.

E-mail: dpo@aslroma1.it

PEC: scudoprivacy@legalmail.it

**CONSENSO AL TRATTAMENTO DEI DATI PERSONALI
PER L'UTILIZZO DELL'APP MEDICA "FLEEXI.HEALTH"**

*ai sensi degli artt. 6, par. 1 lett. a) e 9 par. 2 lett. a) del Regolamento Generale sulla Protezione dei
Dati (GDPR)*

Io sottoscritto/a _____ nato/a _____

il ___/___/_____ residente a _____

via/piazza _____

domicilio (se diverso dalla residenza) _____

Dati di contatto: cell. _____ email (facoltativa) _____@_____

In qualità di

diretto interessato

esercitante la responsabilità genitoriale del minore (è necessario il consenso congiunto di entrambi i genitori)

Genitore 1 _____, nato a _____, il _____, residente a _____
via/piazza _____

Genitore 2 _____, nata a _____, il _____, residente a _____
via/piazza _____

amministratore di sostegno o tutore dell'incapace naturale/rappresentante legale del

Sig. _____, nato a _____, il _____, residente a _____

_____ con atto del Tribunale del _____

DICHIARO

- di comprendere e accettare esplicitamente che i miei dati personali saranno trattati per l'utilizzo dell'App Medica "FLEEXI.HEALTH" nelle modalità descritte in dettaglio nelle presenti Informazioni Privacy, ai sensi dell'art. 13 del Regolamento generale sulla protezione dei dati;
- di comprendere e accettare esplicitamente che, se revocherò il mio consenso non verranno raccolti e trattati ulteriormente i miei dati personali.
- di aver compreso che per qualsiasi mia esigenza in relazione al trattamento dei miei dati personali, nonché al fine di poter esercitare i miei diritti, con riguardo a questo studio, potrò utilizzare i dati di contatto del Titolare e del DPO dell'ASL Roma 1.

ESPRIMO di

- Dare il mio consenso esplicito al trattamento dei miei dati personali, per le finalità e nei modi descritti nelle Informazioni privacy, facente parte di questo consenso, della quale mi è stata consegnata una copia

- ☐ Dare il consenso esplicito al trattamento dei dati personali del minore o dell'amministrato, per le finalità e nei modi descritti nelle Informazioni privacy, facente parte di questo consenso, della quale è stata consegnata una copia.

Il Partecipante al Progetto/I genitori del minore/ Legale rappresentante [es. Amministratore di sostegno, tutore, ecc.]

Data_____ Firma leggibile_____

Data_____ Firma leggibile_____

Annex 4: Socio-technological eligibility form

DATI PAZIENTE	
COGNOME	
NOME	
C.F.	
E-mail	

A. Capacità Digitali	Non autonomo / impossibile senza caregiver	autonomo / richiede supporto	2 Autonomo
A1. Sa accendere e usare lo smartphone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A2. Sa aprire un'app, leggere notifiche, seguire istruzioni	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A3. Sa effettuare una videochiamata	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A4. Sa collegare un dispositivo Bluetooth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A5. Non presenta difficoltà motorie che impediscono l'uso	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A6. Non presenta deficit visivi/uditivi che limitano l'uso	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B. Disponibilità Tecnologica	0 Non disponibile	1 Disponibile ma instabile	2 Disponibile e stabile
B1. Connessione internet stabile (WiFi/4G)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B2. Smartphone compatibile (iOS ≥ 14 / Android ≥ 7)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B3. Bluetooth funzionante	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B4. Fotocamera funzionante	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B5. Presa elettrica adeguata e accessibile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B6. Spazio idoneo per installare e usare i device	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C. Contesto Socio-Assistenziale	0 Assente	1 Parziale	2 Completo
C1. Caregiver disponibile ≥ 3 volte/settimana	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C2. Caregiver in grado di usare i dispositivi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C3. Rete familiare attivabile in caso di necessità	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C4. Paziente autonomo nelle attività di base (ADL)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

D. Idoneità Abitativa / Ambientale	0 Non idoneo	1 Parzialmente Totalmente idoneo	2 idoneo
D1. Postazione sicura per effettuare le misurazioni	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D2. Illuminazione adeguata	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D3. Ambiente sufficientemente silenzioso	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D4. Possibilità di posizionare correttamente i device	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D5. Nessun rischio elettrico evidente (cavi, prese, ecc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PUNTEGGIO TOTALE:

A + B + C + D = _____ / 44

≥ 32 punti IDONEO al Telemonitoraggio

24–31 punti IDONEO CON SUPPORTO (caregiver obbligatorio)

< 24 punti NON IDONEO

Data: ___/___/_____

Valutatore:

Annex 5: Welcome letter accompanying the device inside the package delivered to the patient's home by Next Care logistics

Gentile assistita/o,

nel ringraziarla per aver aderito al progetto propositole e per la fiducia accordata, le porgiamo il benvenuto nella nostra Piattaforma di Telemedicina offrendole alcune informazioni iniziali, che potranno esserle utili durante l'intero percorso sanitario.

Logisticamente la Centrale Operativa di Telemedicina Next Care è situata in Via Filippo Bernardini 10 - Roma, è raggiungibile telefonicamente al numero 06/88793505 dotato di più linee passanti e all'indirizzo email: telemedicina@nextcaretelemedicina.it.

La Centrale è gestita da personale sanitario dedicato che opera dal lunedì alla domenica dalle ore 8.00 alle ore

20.00. Negli orari di chiusura della centrale si dovrà rivolgere ai consueti servizi di emergenza-urgenza, secondo necessità.

Al nostri Operatori sono affidate le attività sanitarie comprese nel suo Piano di Monitoraggio e saremo al suo fianco per sostenerla durante l'intero percorso.

Lei ha appena ricevuto il device (dispositivo medico) correlato al suo piano di monitoraggio e a breve verrà contattato telefonicamente (al recapito telefonico da lei indicato al suo Medico di Medicina Generale) dal nostro Operatore di Centrale, che la supporterà nelle azioni utili a scaricare, attivare e rendere operativo il suo profilo all'interno della APP con cui la nostra Centrale dialogherà con lei per la gestione del suo stato di salute.

Sarà altresì affiancato dal nostro Operatore durante la formazione utile al buon funzionamento del device e alla corretta rilevazione dei diversi parametri. All'interno della scatola che le è stata consegnata troverà in ogni caso un breve manuale riepilogativo per il corretto uso del suo dispositivo, che potrà consultare per qualsiasi dubbio.

Le chiediamo di attenersi scrupolosamente al Piano di Monitoraggio assegnatole, effettuando la rilevazione dei parametri nei tempi concordati e indicati. La invitiamo altresì a mantenere il cellulare disponibile in modalità chiamata e a rispondere tempestivamente alle telefonate provenienti dalla Centrale di Telemedicina, così da facilitare l'interazione e il perseguimento efficace del suo percorso assistenziale.

Le evidenziamo infine la necessità di mantenere il device e i suoi accessori, unitamente alla scatola che lo contiene, con diligenza, poiché è lo strumento che ci consente di monitorare puntualmente il suo stato di salute. Il device, ricollocato con tutti i componenti forniti all'interno della scatola, dovrà essere restituito alla conclusione del suo percorso assistenziale.

Annex 6: Customer Satisfaction questionnaire

AREA ANAGRAFICA

1. TITOLO DI STUDIO

Licenza elementare	
licenza di scuola media o avviamento professionale	
Scuola dell'obbligo (biennio di scuola media superiore)	
Diploma di scuola media superiore	
Laurea	

AREA INDAGINE QUALITÀ GENERALE PERCEPITA

2. Chi le ha indicato il Telemonitoraggio domiciliare eseguito da remoto da una Centrale di Telemedicina come forma di assistenza clinica utile?

Il medico che mi cura per la patologia cronica	
Il medico che mi ha seguito durante il ricovero	
Il mio Medico di Famiglia	

3. Come valuta la presa in carico effettuata dagli operatori della Centrale? (questa domanda contempla il primo contatto, l'intervista con l'operatore, le informazioni fornite relativamente ai servizi e la pianificazione concordata)

Superficiale ed insufficiente	
Complessa e poco chiara	
Articolata e sufficientemente chiara	
Chiara ed esaustiva	

4. Come valuta l'analisi condotta sul suo stato di salute/benessere fisico e psichico e realizzata tramite i questionari riferiti alla presa in carico globale dei problemi di salute?

Superficiale ed insufficiente	
Complessa e poco chiara	
Articolata e ben condotta	
Eccellente e professionale	

5. Come valuta la consegna dei dispositivi medici, le informazioni ricevute per il loro corretto utilizzo, il tutoring effettuato dagli operatori di centrale per la prima attivazione?

Superficiale ed insufficiente	
Complesso e poco chiaro	
Articolato e sufficientemente chiaro	

AREA INDAGINE QUALITÀ PERCEPITA ATTIVITÀ TELEMEDICINA PER PATOLOGIE CRONICHE

8. Come valuta complessivamente l'adeguatezza delle prestazioni di telemedicina (tele monitoraggio, tele assistenza, tele consulto medico e piano di monitoraggio)

Insufficiente	
Accettabile	
Sufficiente	
Discreta	
Eccellente	

9. Come valuta complessivamente i devices (dispositivi medici) da Lei utilizzati per il monitoraggio dei parametri, relativamente a semplicità di utilizzo, di conservazione e affidabilità?

Insufficienti	
Accettabili	
Sufficienti	
Discreti	
Eccellenti	

10. Come valuta complessivamente la sua soddisfazione relativa al rapporto instaurato con gli Operatori della Centrale? (tempestività nella risposta, facilità ed esaustività nella comunicazione, semplicità nello stabilire un contatto telefonico)

Insufficiente	
Accettabile	
Sufficiente	
Discreta	
Eccellente	

11. Come valuta complessivamente la sua soddisfazione relativa al rapporto instaurato con Il suo medico di riferimento? (tempestività, facilità ed esaustività nella comunicazione clinico/terapeutica)

Insufficiente	
Accettabile	
Sufficiente	
Discreta	
Eccellente	

12. Come valuta complessivamente la capacità degli Operatori della Centrale nella gestione dei problemi da Lei segnalati?

Insufficiente	
Accettabile	
Sufficiente	
Discreta	
Eccellente	

13. In una scala da 1 a 10, nel periodo in cui ha scelto di affidare la sua salute ai servizi offerti dalla Centrale di Telemedicina, quanto si è sentito/a in “mani sicure”, tale da non provare alcuna preoccupazione?

Valore compreso tra 1-4	Inadeguatamente	
Valore compreso tra 5-7	sufficientemente	
Valore compreso tra 8-9	Discretamente	
Valore compreso tra 10	Eccellentemente	

14. Quanto ritiene sia stato utile partecipare a un progetto di Telemonitoraggio in termini di consapevolezza del proprio stato di salute?

Inutile	0-2	
Scarsamente utile	3-5	
Sufficiente utile	6-7	
Discretamente utile	8-9	
Eccellentemente utile	10	

15. Alla luce dell'esperienza maturata, ritiene che il telemonitoraggio possa essere uno strumento utile per dare un supporto ai pazienti e ai caregivers, tanto da consigliarne l'utilizzo ad altri pazienti?

Inutile	0-2	
Scarsamente utile	3-5	
Sufficiente utile	6-7	
Discretamente utile	8-9	

Eccellentemente utile	10	
-----------------------	----	--

16. Alla luce dell'esperienza maturata, ritiene che la durata della sua presa in carico ovvero dell'intero progetto sia stata appropriata relativamente al suo stato di salute?

Insufficiente	
Appena sufficiente	
Assolutamente appropriata	

17. Per noi è importante percorrere la strada del miglioramento continuo, favorendo la partecipazione dei nostri assistiti. Se ci fossero altre cose che vorrebbe segnalare e/o evidenziare può farlo utilizzando lo spazio sottostante
