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Statement of originality

This document contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

Disclaimer

The information contained in this document is tentative. Its aim is to consult with the market on the PCP scope prior to its publication in the Call for Tenders. The draft information here contained shall be updated if improvements are deemed necessary, specially after the Open Market Consultation.

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Introduction

INCAREHEART is a pre-commercial procurement (PCP) project investing in Research and Development (R&D) services towards innovative ICT-enabled integrated care solutions to advance multidisciplinary health and care for patients with chronic heart failure. It brings together 8 partners from 8 countries, presenting a vital mix of public procurers: Region of Jämtland Härjedalen (Sweden), Università degli Studi di Napoli Federico II (Italy), Region of Central Macedonia (Greece), Santa Casa da Misericordia da Amadora (Portugal) and Ministry of Health (Turkey), and three supporting partners (Empirica, Ticbiomed and the International Foundation for Integrated Care). Get to know more about us.

As part of the Open Market Consultation (OMC), this document describes the scope and use cases of the INCAREHEART PCP. The OMC represents a specific phase during the overall PCP methodology, aiming to actively approach the market when the identified needs by the procurers must be communicated openly and clearly to all potentially interested bidders. Market players get the unique opportunity to give feedback on the requirements of the foreseen pre-commercial tender.

In this document you will find the following sections:

- INCAREHEART overview
- Requirements
- Use cases
- Pre-commercial Procurement

INCAREHEART Overview

The prevalence of chronic conditions and multimorbidity is rapidly increasing in Europe and worldwide, leading to a steadily increasing demand for health, social care, and support services and intensifying pressures on health and care systems. An area of substantial opportunity for health and care providers is to overcome fragmentation in care provision for people with complex health and support needs. Provision and management of care and support for **patients with Chronic Heart Failure (CHF)** requires a multifaceted effort across settings for which multiple challenges remain, partly caused by existing fractures in systems and service delivery that currently lead to individuals "*falling through the gaps*"[1]. With care and support needs managed by different providers, often through many unconnected and uncoordinated episodes of care, adverse impact on care experiences and care outcomes for patients, inefficiencies on a system level and poor workforce satisfaction are inevitable.

Health and social care systems in Europe have been moving towards a more integrated approach of care service delivery over recent years. In essence, integrated care approaches are expected to improve patient experience, outcomes of care, effectiveness of health systems and provider wellbeing (known as the "quadruple aim" of integrated care) and to confront the complexity of different services which patients and their caregivers are expected to navigate under current condition in most systems across Europe. Although the debate on integrated care has been a significant driver in efforts directed towards developing better and more cost-effective health and social care systems in Europe for some years now, this concept has not yet been consequently applied in day-to-day practice. Yet, service delivery has developed in ways that have tended to fragment care, both within and between sectors as well as between providers and the patients/clients (the latter often being referred to as "formal-informal divide"). As a result, patients are surrounded by uncoordinated '*Islands of Excellence'*, when what is needed is integrated and coordinated care[2].

One aspect adding complexity to bringing such products to international markets concerns the general requirement for interoperability with a range of ICT legacy infrastructures prevailing in national and regional health care systems and at the level of local or regional service provider organisations.

The five procurers represented in the INCAREHEART consortium share the sense of urgency to ***radically improve integrated care for patients with CHF***. They are willing and ready to adopt an innovative integrated care solution that overcome fragmented health and care service provision. INCAREHEART will jointly procure R&D services to shape an ICT-enabled integrated care solution supporting the implementation of a comprehensive multidisciplinary and cross-organisational care and support model for people living with CHF across a fully integrated patient pathway.

The INCAREHEART solution will enable procurers to provide better health and care for CHF patients with a special focus on:

- Radical improvement of the hospital discharge processes and other care transitions,
- Profound increase of collaboration efficiency and improvement of patient experiences of the care system,
- Tailored provision of secondary prevention measures,
- Digitally enabled real patient-empowerment and self-management support,
- Innovative performance monitoring, including for example new ways of PREMs and PROMs collection.

As most services can also contribute to integrated care service delivery to people living with other chronic conditions, INCAREHEART welcomes, in line with procurer interests and market demand, suppliers with an integrated care solution easily adaptable to conditions also prioritised by the procurers such as respiratory, metabolic, other cardiovascular events, or cancer. Furthermore, it is of value to INCAREHEART procurers should the new platform be also reusable for a more integrated management of other prevalent resource-consuming long-term conditions such as dementia or frailty.

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1 https://www.kingsfund.org.uk/sites/default/files/Evidence-base-integrated-care2.pdf.

2 Rigby, M. et al. (2013). Developing a New Understanding of Enabling Health and Wellbeing in Europe - Harmonising Health and Social Care Delivery and Informatics Support to Ensure Holistic Care. Paper presented at the Standing Committee for the Social Sciences. London, UK, p.42.

INCAREHEART stakeholders' profile

Patients

Patients can be both male and female adults who have a clinical diagnosis of Chronic Heart Failure - at most stages of the condition. They are end users of Procurers' Organisation or from a Partner´s Organisation; community-dwellers, who are willing to use the INCAREHEART solution.

Since the INCAREHEART solution cannot realistically cover all aspects, complications, and stages of CHF care, as this would be over ambitious and an overburden of both suppliers and procurers, the aim is to call for a solution that treats most patients, as those in Class IV will be very ill and least likely to engage in ICT-solutions. Furthermore, focusing on the first 3 levels will enable people with CHF to remain well for longer and reduce the numbers of people being categorised as Class IV, but will not exclude people in this Class if they are digitally literate. The following stratification of the patient population illustrates the INCAREHEART target population:

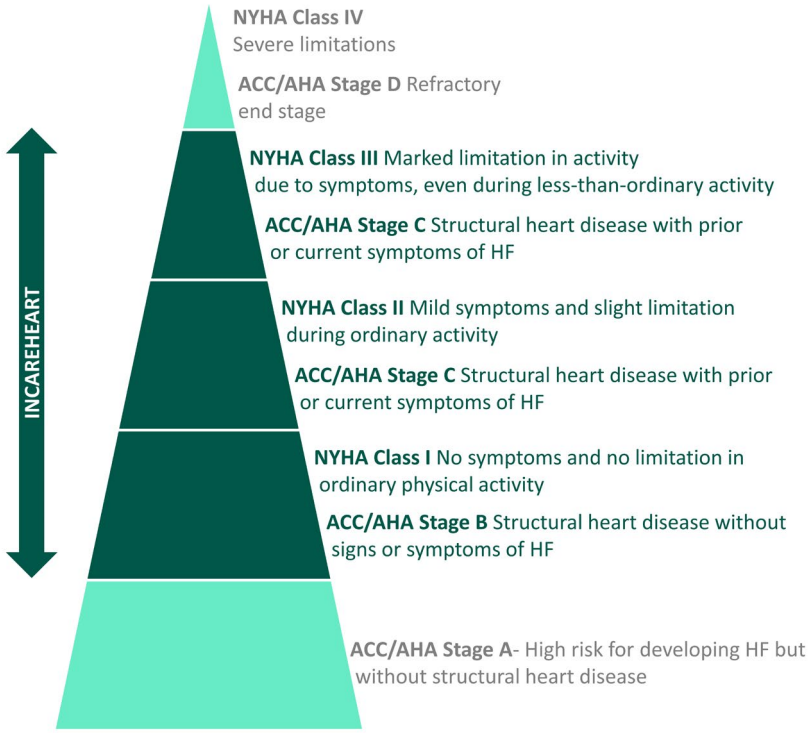

Figure 1. Stratification of the heart failure population (NYHA classification[3] and ACC/AHA[4])

Family Carers

Caregivers are male and female adults that provide informal care to a service user and are willing to use the INCAREHEART solution.

Health and social care professionals

Professionals are male and female adults that provide healthcare treatment and/or social support, based on a formal background training and experience, with track record on research in healthcare or social sectors.

Decision Makers

Decision makers are the individuals who can make the authoritative decisions on behalf of the care

[3] https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure

[4] https://www.acc.org/guidelines

provider organisation or a specific department. They are often managers, executives, directors, presidents, etc.

Co-design and requirements elicitation framework

Key stakeholders (patients, informal carers, health and care professionals, and decision makers) were involved through focus groups and/or individual Interviews to elicit their needs, preferences, expectations, and improvement suggestions. The care delivery shortcoming identified through this exercise will lead to ***the elicitation of both functional and non-functional requirements*** based on the building blocks described in Figure 2 below.

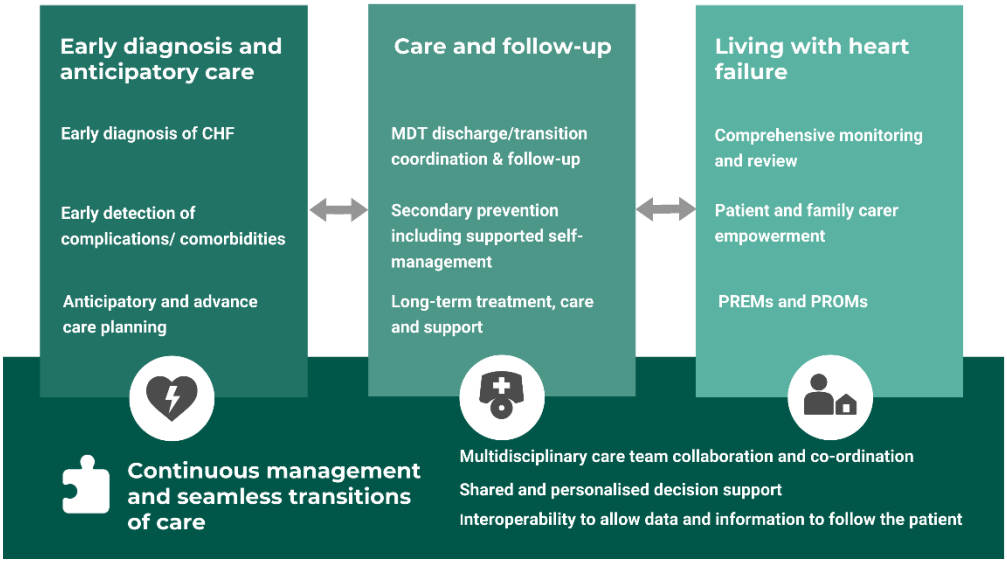

Figure 2. INCAREHEART building blocks

In parallel, ***organisational, and legal/regulatory requirements*** will be identified in a systematic manner. Further to this, any sectoral and/or occupational codes of practice that may exist in the participating regions and/or service provider organisations will be identified. Results of the requirements analysis build the basis for the development of a comprehensive and systematic requirements catalogue for inclusion in the Call for Tenders.

In a next step, a ***use case approach*** will be applied, which has proven to be highly effective and efficient in comparable contexts, especially when involving all relevant types of INCAREHEART users. For the purposes of INCAREHEART, a use case is understood as a structured textual description of a specific example of care service use following a dedicated pathway, thereby focusing on activities by all stakeholders involved and outputs to each user, not only of the ICT solution, but of any part of the so-called socio-technical system. Further to this, INCAREHEART ***organisational & service processes*** will be modelled and documented. Here, a key step will be to model the socio-technical system (STS), in which services are to be delivered. In an STS, service delivery incorporates several elements in addition to ICT. Service models describe the operation of the complete STS, along with the roles to be played by the patient and different categories of staff from involved provider organisations. Service models are set up based on use case generation and validation.

The initial use cases and service process models will, together with the outcomes of the requirements analysis, become part of the Call for Tenders and its supportive material (Challenge brief). Use cases and service process models will be further developed at the end of each of the three main PCP phases, based on the outcomes received from the suppliers.

Last, an overall ***framework*** for the conduction of ***change management*** will be developed for application in the INCAREHEART pilots and later use by future procurers.

INCAREHEART Scope

Building blocks

1 Multidisciplinary care team collaboration and coordination

Rationale:

- CHF is a complex chronic condition with high prevalence of co-morbidities.
- Multidisciplinary care management programmes are one of the central recommendations in the ESC guidelines.
- ICT is key for patient-centred MDT coordination, which itself is a key feature of effective care models.

Shortcomings:

- CHF care is still fragmented, there is little coordination for a true whole patient approach.
- Lack of an integrated and efficient way of planning care, communicating results, and solving problems dynamically.
- Current solutions often appear to be add-ons not well integrated with the public health and care system and its EHRs.

Planned Progress:

The solution will:

- support a streamlined team-based approach to heart failure care which is patient-centred and cuts across all stakeholders who are typically involved in CHF care.
- enable pro-active health and care,
- A care platform for the development, execution, and monitoring of personalised care plans
- support to co-ordinate the delivery of the person's care plan with the patient as an active partner
- include clear presentation of the care plan for the patients as well as their care team.
- include an easy-to-use messaging system to connect health and care professionals with patients as well as with each other
- enable the collection, management, and provision of information between individuals, services, and other relevant organisations.
- include voice messaging as an optional medium.

2 Shared and personalised decision support

Rationale:

- Continuous monitoring of health and other parameters, along with data from EHRs, mobile apps and data actively provided by patients, provide rich input for offering personalised support to patients.
- Personalised decision support can indicate prevention and treatment options that take different factors into account, such as patients' age and health status, adverse effects of medications, co-morbidities, etc.
- Advice and medication reminders, prompts for recommended physical activity, other lifestyle interventions, planned appointments, test (results), etc. are ideally integrated into decision support tools for patients.
- Efforts in ICT supported integrated care build upon individualised care plans and shared decision making between MDT and patients as well as informal carers, such as family members, thereby regularly monitoring and modifying set goals and prescribed activities.

- Patients are provided access to their care plan and advice on treatment modification can be given directly to them, if they are empowered through tailored education for self-management of their condition.
- Decision support systems (DSS) support the complex decision-making processes of diagnosis, prognosis, and therapy planning, reduce unnecessary mistakes and costs, as well as improve patient outcomes.
- In the context of CHF, a major role of a DSS is to predict and prevent destabilisation episodes during stable times. Tested algorithms and AI techniques are increasingly available, which can be applied to CHF care.

Shortcomings:

- No decision support tools are available on the market that satisfy the demands of the INCAREHEART procurers of providing a dynamic decision support tool that takes into account real time data collected from EHRs, devices including data from monitoring wearables, and also leverages data and observations otherwise uninterpretable by humans.
- Available DSS do not fully interoperate with the heterogenous data sources, which severely limits their efficiency, existing information that could help to further stratify the patients is lost due to semantic and syntactic misunderstandings.
- So far, no tools exist that incorporate patients' treatment preferences into the clinical decision-making process.
- Time-consuming operations by patients caused by a lack of usability of ICT tools seem to prevent regular use of patient-interfacing tools.

Planned Progress:

The solution will:

- include a data dashboard accessible based on defined roles.
- include a DSS system used by both patients and professionals that establishes the personalised care plan based on patient preferences and clinical parameters.
- include AI processing of monitoring data and the data available from the EHR and other sources.
- include easy to use interfaces while guaranteeing an appropriate level of functionality.

3 Interoperability to allow data and information to follow the patient

Rationale:

- Exchange of information between different health and care providers is of paramount importance for care and treatment of CHF, as information must frequently be exchanged between a multitude of stakeholders.
- Information must be recorded electronically, managed, governed, regulated, linked, and made available through one or more interconnected applications. This requires effective interoperability, enabling different information systems (and devices) to communicate and exchange usable data and information, allowing professionals and patients to have timely access to relevant data and information.
- Access to and interconnectivity with legacy systems is crucial for integrated, ICT-supported heart failure care provision enabling seamless exchange of information generated between newly developed applications and existing digital infrastructures. To enable ICT tools for CHF patients to be effective, interoperability needs to support every step of the care pathway.
- ML or AI can detect deterioration or developments of co-morbidities early, to efficiently manage polypharmacy patterns and interactions or power decision support systems. Such algorithms must be provided with clear data structure and semantics, which can only be achieved by interoperability.

Shortcomings:

- The products available often cover only a few aspects of CHF management and their inter-operability is poor.
- Frequently, data is not exchanged timely enough or in a format that lies outside the clinician's workflow.

Planned Progress:

- A patient-interfacing empowerment platform to involve the patient in self-monitoring and individual goal setting.
- A system characterised by an open architecture and the use of standard protocols to achieve organisational, semantic, syntactic as well as technical interoperability.
- to reduce administrative costs for manual workflows, improve efficiency and reduce errors.

4 Early diagnosis of CHF

Rationale:

- Early, reliable, and precise diagnosis of CHF is an essential element for successful treatment and thus also crucial for reducing mortality, improving quality of life and lowering societal costs.
- Heart failure is slow in showing symptoms at onset, making integrated efforts to early detection and diagnosis extremely important.
- In early stages it is difficult to recognise for patients because many symptoms and signs, such as swelling of the ankles, breathlessness, or fatigue, are not specific to CHF and are often considered a normal part of the ageing process.
- The lack of recognition of symptoms is also considered to explain the long delay between the onset of symptoms and seeking medical care in CHF patients.
- Patients experience harmful misdiagnosis and delays in diagnosis, with most patients only being diagnosed at the later symptomatic stage or at moments of acute decompensation episodes characterised by massive fluid congestion or breathlessness, leading to E&A admission.
- Diagnosis of heart failure is complex, and primary care access to appropriate objective tests often delayed. Consequently, many cases go undiagnosed.

Shortcomings:

- No convincing solution available to answer the question how to sensitise persons at risk for heart failure.
- Many risk assessments tools today do not take real advantage of ICT
- Available online tools are usually limited to a single language domain, and not integrated even with local health records, risking the loss of valuable information and data.
- A survey of the state of the art in the market also showed no interface with health systems either to pull risk parameters or deliver assessment results back to the relevant systems.

Planned Progress:

INCAREHEART will:

- fully leverage EHR longitudinal data (where available) and sharing of patient history, beyond the traditional clinical and health economic domain
- include full support to patient-system interaction for early diagnosis.
- exploit the value of sharing (real-time) data and information across settings.
- link the assessment results with an interface to professionals.
- put a special focus on services to reach rural and deprived areas.

5 Early detection of complications and co-morbidities

Rationale:

- Co-morbidities make management more complex for patients and care professionals, as they can contribute to disease progression and alter the response to treatment, partly as polypharmacy is inevitable.
- Co-morbidities contribute to non-compliance, which in turn leads to higher rates of hospitalisation, re-admissions, and ultimately death.
- Early detection of co-morbidities is particularly critical in CHF patients with preserved ejection fraction who are older and often affected by multimorbidity.
- Possible explanations include underutilisation of effective CHF treatments in the presence of other conditions due to safety concerns, patients' inability to remember complex medication regimens, inadequate post-discharge care, lack of social support and failure to seek immediate medical attention if symptoms recur.

Shortcomings:

- ineffective data collection and coding undermine the possibilities for a comprehensive response.
- measures to detect complications and the development of co-morbidities have so far mainly consisted of educating and training patients to early recognise the signs and symptoms of impending decompensation. However, this is only a subjective approach that depends heavily on the patient's level of education and ability to follow these instructions.
- depression and anxiety in CHF patients often remain underdiagnosed.

Planned Progress:

INCAREHEART will:

- facilitate a regular comprehensive assessment (incl. e.g., depression assessment) of patients to help inform shared decision-making with caregivers
- include personalised risk calculation and therapeutic recommendation tools.
- address data sharing and infrastructure needs such as integrating highly heterogeneous multi-scale data sources or integrating imaging data.
- provide multiple channels to establish bi-directional communication of text, images, voices, video.
- improve the training of patients on the implications of an acute decompensation episode or potential co-morbidities,
- provide transparent information on parameter significance via easy-to-use ICT-enabled tools.
- integrate cloud-based appointment booking, including a functionality to add symptoms before appointments.
- enable patients to set their own health goals.
- allow the integration of gaming tools.

6 Anticipatory and advance care planning

Rationale:

Anticipatory Care Planning (ACP) can help the individual to be more in control and able to manage any changes in its health and wellbeing. Especially in conditions that are complex and with high mortality rates, anticipatory care planning is to be included early in the patient's care journey. ACP refers to a timely exchange between patient and carers on the patient's preferences for possible advanced stages of the disease, as well as the end-of-life phase. Nominating a healthcare proxy, deciding on preferred place of care as well as a place to decease are relevant aspects in that regard and need to be addressed before a patient may lack the competences to take these decisions on their own.

The approach is largely recommended to improve the patient's quality of life and end-of-life satisfaction, as well as to reduce the surviving family members' stress. Regarding heart failure, advance care planning might involve resuscitation preferences in case of a cardiac arrest, the deactivation of an implantable cardioverter-defibrillator or artificial hydration. Multidisciplinary care has a special role in this context. In a recent study, it was one of the factors associated with especially positive outcomes. This could include trained ACP facilitators, nurses assisting patients in defining their wishes as well as doctors educated in communicating ACP. Ideally, specialised heart failure nurses should be involved in or coordinate the team. This has been demonstrated to improve care cohesion and clinical outcomes. MDTs are also crucial to determine when the end-of-life-phase in a patient is reached, so that this evaluation does not depend on one speciality's viewpoint.

Shortcomings:

- no tools are available to integrate the whole of social and health information, patients' and their social network's capacity and capability to face the treatment burden
- no tools available that offer a holistic overview of patients' situation nowadays to inform an appropriate ACP approach.
- the fragmentation of risk stratification processes, which are disease-specific or excluding the social component does not offer enough information to develop an adequate and anticipatory care plan
- clinicians are often reluctant to bring up the topic, for considering it a type of "professional failure", however, many patients wait for the doctor to start this discussion, because they do not understand or prefer to ignore the magnitude of the diagnosis.
- most heart failure doctors and cardiologists are not trained in communicating ACP with patients and accordingly lack crucial communication skills.
- heart failure is not sufficiently integrated into palliative medicine and its institutions
- palliative specialists are often involved too late in the process
- hospices were originally designed for cancer patients and often do not have expertise in heart failure care
- healthcare providers struggle to identify the right moment to initiate ACP as heart failure often has a quite unpredictable trajectory
- physicians often do not actively identify CHF patients likely to be in their last year of life to enhance the chance to have this conversation in time, making it difficult to support patients in their wishes in the last phase.

Planned Progress:

INCAREHEART will:

- offer tools that help with the identification of the point at which patients enter the end-of-life phase and at which a definitive ACP conversation would be in order.
- involve a training module for clinicians on how to conduct ACP conversations.
- involve a safe and secure digitally enabled "Advance Care Directory" exploring the patient's values and preference for good quality of life.

7 MDT discharge/transition coordination and follow-up

Rationale:

- The period following discharge from hospital is recognised as a particularly vulnerable time
- Interventions targeted at improving health and care provider communication during transition periods (e.g., from hospital to the community or vice versa) focus on improving the quality of information shared between different stakeholders involved, improving co-ordination and continuity of care, and reducing healthcare utilisation.
- Transitional care can have a major impact on patient outcomes following discharge and may include medicines reconciliation, electronic tools to generate a structured discharge summary, shared

involvement in follow-up between hospital and community, web-based access to discharge information for general practitioners, early follow-up, and the communication of follow-up appointments ahead of hospital discharge.

- Transitional integrated care should ideally involve a programme designed to provide a structured MDT discharge plan and follow-up through patient education, medication optimisation, psychosocial support, and improved access to care.
- The concrete staffing should ideally comprise internists, cardiologists, CHF nurses, general practitioners, and other experts, including pharmacists, dieticians, physiotherapists, psychologists, and social workers, working in close collaboration.
- This role of the multidisciplinary team in the continuing management of heart failure patients is crucial, as stated by all the principal guidelines on CHF management. More explicitly, multidisciplinary care management has a class I A recommendation to reducing hospital readmission and mortality by the European Society of Cardiology.
- Apart from aerobic exercise, it is the only non-medication and non-device intervention proven to improve morbidity, mortality, and quality of life in heart failure patients[5]. A meta-analysis of 30 trials (> 7000 patients) employing multidisciplinary intervention and follow-up in heart failure discovered e.g., a reduction in all-cause hospital admission rates in 14%, heart failure admission rate in 30% and all-cause mortality in 20%[6].

Shortcomings:

- patients often do leave the hospital with not all crucial prescriptions.
- many patients do not receive proper follow-up after discharge, and the discharge process is burdensome for many patients
- Many discharged patients do not receive a visit from a doctor in the period they stay at home.
- there seems to be a lack of downstream support from specialist services to facilitate referral[7], as well as a lack of coordination and communication between hospitalists and primary care physicians[8].
- Primary care physicians too often do not receive discharge summaries[9], and when they do, the summaries often lack appropriate documentation of medication indication and advice for follow-up. It is therefore difficult for physicians to plan an appropriate follow-up after hospital discharge[10].
- in the immediate time after discharge, crucial information is often lost, which might lead to an interrupted care chain and to a more frequent re-admission of the patient[11].

Planned Progress:

INCAREHEART will:

- implement a Digital Discharge pathway allowing effective information sharing across health and care providers/professionals
- improve care team communication during transitions,

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5 Ponikowski et. al. (2016). 2016 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure. Available at: https://bit.ly/3cmlZKF.

6 Frankenstein et. Al. (2015): Multidisciplinary approach for patients hospitalized with heart failure. https://bit.ly/3gCLoD6.

7 Heart Failure Policy Network (2018). The handbook of multidisciplinary and integrated heart failure care, available at: https://bit.ly/3cj1Wg1

8 Jones CD, Vu MB, O'Donnell CM, et al. A failure to communicate: a qualitative exploration of care coordination between hospitalists and primary care providers around patient hospitalizations. J Gen Intern Med. 2015;30(4):417–442.

9 McMillan A, Trompeter J, Havrda D, Fox J. Continuity of care between family practice physicians and hospitalist services. J Healthc Qual. 2013;35(1):41–49.

10 Tan B, Mulo B, Skinner M. Transition from hospital to primary care: an audit of discharge summary—medication changes and follow-up expectations. Intern Med J. 2014;44(11):1124–1127.

11 Lorenzini et. Al. (2016): Integrated care for heart failure in primary care. https://bit.ly/3deRlV1.

- develop and use standardised processes for leveraging and transferring data from EHRs, ensuring timely and accurate information transfer after discharge.
- consider a more regular review of the patient progress after an exacerbation period through daily multidisciplinary "Situation Reports", mapping between different EHR systems (GP, outpatient clinics, hospitals)

8 Secondary prevention including supported self-management

Rationale:

- Inhibiting or delaying heart failure is the goal of secondary prevention.
- Patients already diagnosed with CHF are likely to already have reached a serious level of co-morbidity
- Secondary prevention deals with reducing the impact of the condition on the patient, such as preventing extremely serious events like sudden cardiac deaths.
- Cardiac rehabilitation (CR) has, for many years, been a highly recommended approach to secondary prevention for patients recovering after a heart attack or heart surgery traditionally delivered from a hospital outpatient centre. Despite demonstrated benefits and guideline recommendations, CR utilisation has been poor, particularly in women, older patients, and ethnic minority groups.
- Some commercial platforms facilitating remote rehabilitation with a focus on exercises have emerged in recent years, albeit with a lack of CHF focus. The major benefits of such platforms are the ability to deliver these interventions without ongoing face-to-face contact, which provides an opportunity to reach large numbers of people, and the convenience of selecting the timing of cardiovascular disease management sessions.
- There is a need to identify development issues that can hamper the implementation of the interventions outside controlled trial settings systems, which may require new computing infrastructures, specific clinical responsibilities, time for training, and development and openness to new ways of doing things[12].

Shortcomings:

- low adherence in cardiac (tele-)rehabilitation
- thin line between tailored guidance and top-down instructions, the latter might be perceived as unwarranted intrusion and lead to less adherence
- little transparency in information sharing and the option for the patient to set their own health goals.
- lack of maintaining productive habits acquired in hospital, the patient might not receive enough coaching in the transition phase.
- Mature solutions enabling to flexibly tailor blended approaches are rare
- Most activity trackers lack the accuracy necessary for medical decision making and lack integration with EHRs or medical records
- Current approaches specifically focussing on nutrition are often based on single advice without lasting support.
- nutritional support is mainly stand-alone and not yet well integrated with day-to-day activities.
- the optimal combination of core components for mobile-delivered cardiac rehabilitation is unknown.

Planned Progress:

INCAREHEART will:

[12] Karunanithi, M., & Varnfield, M. (2015). Information and communication technology-based cardiac rehabilitation homecare programs. Smart Homecare Technology and TeleHealth, 69. doi:10.2147/shtt.s75395

- enable comprehensive, multi-component CR and self-management with a primary focus on CHF patients
- probably include an exergaming component integrated with the sensor system to create a powerful combination of telemonitoring and rehabilitation.
- include personalised intervention strategies

9 Long-term treatment, care, and support

Rationale:

- Ongoing treatment after a definitive diagnosis consists of controlling the condition, preventing acute episodes, and offering the necessary support
- The main goal of ongoing treatment is to improve the patient's clinical status, functional capacity, and quality of life
- Ongoing treatment and support also aim to prevent or mitigate exacerbations[13]
- Heart failure patients are primarily treated with medication that help manage the main symptoms: fluid congestion and fatigue.
- While general lifestyle measures, patient education, and close follow-up should be followed by all patients, the level of medication depends on the stage of disease progression[14].

Shortcomings:

- polypharmacy management is an underappreciated issue in the management of CHF patients
- The use of non-prescription medications is common as well, adding further complexity to the medication therapy regimens of patients with heart failure.

Planned Progress:

INCAREHEART will:

- provide a solution effectively supporting medication reminders, polypharmacy management and adherence feedback.
- Include a solution supporting a multidisciplinary approach to polypharmacy management, involving GPs, specialists, nurses, pharmacists, and patients.
- include a patient-facing tool summarising medication regimen, to allow, e.g., pharmacists better counselling and avoid adverse effects of OTC medications
- consider innovative AI algorithms as they have the potential to improve prescribing and minimise the risks from polypharmacy.

10 Comprehensive monitoring and review

Rationale:

- The primary goal in monitoring and follow-up is to detect possible decompensation and prescribe appropriate therapy as early as possible achieved through consultation in a heath care facility, via telephone or, more recently, with mobile health (mHealth) packages.
- Patients should be monitored to keep track of the process of CHF as well as co-morbidities, requiring integrated pathways, which is also recommended in the guidelines.

[13] Ibid.

[14] Lorenzini et. Al. (2016): Integrated care for heart failure in primary care. https://bit.ly/3deRlV1.

- Telemonitoring enables a healthcare professional to remotely interpret the data necessary for the patient's medical follow-up to make decisions about their care.
- Data is collected through a connected device or questionnaires to monitor vital parameters and symptoms at home daily
- patient interfaces on smartphone apps are a crucial element in helping patients keep track of various facts they need to consider as part of their disease management, including weight, medication, fluid and food intake, and symptoms (e.g., breathlessness, fatigue, ankle swelling, orthopnoea, reduced exercise tolerance).
- Using telemonitoring in combination with AI can help to further stratify the patient cohort. Due to the high level of co-morbidities, this is a challenging task. As machine learning excels at recognizing patterns, it might help developing more tailored treatments for different types of patients.
- For advanced stages of heart failure, there are now many implantable devices that allow early detection of clinical changes in biological parameters and provide alarms that lead to therapeutic interventions. This data is often generated by proprietary solutions that relay the information to a service centre.

Shortcomings:

- An adequate approach to systems integration and interoperability is rare in current solutions, threatening vendor lock-in, even obstructing re-use of collected data
- Uncertainty about data quality makes it difficult for clinicians to use, given the liability they are subject to
- an integrated comprehensive low-cost sensor system for effectively monitoring patients with heart failure at home seems to be missing on the market
- connectivity is another issue with most products on the market. Even if connectivity is available, it is mostly unidirectional and only supports the transmission of values out of the device. Any input, including adaptation to therapy parameters, needs to be set manually
- innovative, medical grade devices tend to be costly and therefore only suited for research use rather than widespread adoption

Planned Progress:

INCAREHEART will:

- explore the potential of machine learning to recognise patterns and provide decision support for healthcare professionals
- include a solution that supports and incorporates patient held devices. Captured health status data will be reported back to the patient and to the healthcare professional so that both can interpret it and act accordingly.
- analyse the data to generate advice to both parties, as targeted decision support

11 Patient and family carer empowerment

Rationale:

- empowerment is at the very core of integrated care and refers to the patients' ability to plan care with people who collaborate to understand them, allow them control, and bring together services to achieve outcomes they consider important[15]
- empowerment implies better access to understandable information/education, like the patients' individual health records, to achieve a higher level of health literacy in general, especially regarding their condition

[15] Goodwin et. Al. (2016): Understanding Integrated Care. https://www.ijic.org/articles/10.5334/ijic.2530/.

- shared decision making and self-management transform the patient from being a passive receiver of treatment to becoming actively engaged in their own care[16]
- mobile and digital technologies can empower patients by reducing their dependence on health care professionals for information
- The shared information access possibilities of ICT platforms can potentially transform the relationship between patient and carer from a paternalistic one to a co-creation situation
- it is crucial for family carers to be involved in the management and decision-making regarding their relative's disease; empowering this carer group can enhance a pivotal point in the care system

Shortcomings:

- patients are often completely reliant on health care providers, face difficulties navigating between health and social system and receive interventions only upon fully manifested (severe) symptoms
- Systems that share and actively provide (health) data to patients to support self-management are still underused, especially for complex patients[17]
- much of the high-quality information available (e.g., on government websites) exceeds the reading level of many people with low health literacy[18].
- ICT solutions are not necessarily empowering per se. On the patient's end, for making those solutions work they need to wear the sensor-equipped devices, actively collect data like weight or use the smartphone app regularly. Ideally, genuine empowerment through ICT applications should go beyond employing patients as data collection clerks.
- while existing telehealth solutions transmit immense amounts of data to healthcare providers, there is often no option to share them with family carers and fellow heart failure patients.
- Technology-enabled care tools have a huge potential in supporting the development of online patient portals and communities, as shown by PumpingMarvellous and PatientsLikeMe. None of the studied solutions include an integration with an online peer community or the option to donate data to them, fostering community empowerment.

Planned Progress:

INCAREHEART will:

- provide integrated ICT-services including but not limited to:
    - Providing static advice for self-management for different health and support issues
    - Access to the Personal Electronic Health Record from the professionals
    - Chat-based interaction between patient and professionals
    - Virtual online video consultations
    - Education programs for patients as agreed with professionals
    - Peer-patient support
- visualise collected data for patients in appealing graphics with explanations in lay language, enabling them to not depend on clinical contact to monitor and understand deterioration signs that occur before the actual symptom.
- Include an option to share these visualisations (possibly complemented by other information) with family carers as well (upon consent), empowering them to understand their relative's position better.
- Include esthetical behavioural prompts, since a big part of managing heart failure comes down to lifestyle adjustment.

[16] European Patients Forum (2017): Toolkit for patient organisations on patient empowerment. https://bit.ly/2Bg0GOb.

[17] Melchiorre, M.G. et al (2018). eHealth for people with multimorbidity: Results from the ICARE4EU project and insights from the "10e's"by Gunther Eysenbach.

[18] OECD Health Policy Studies 2019. Health in the 21st Century.

- focus on innovative measures little explored until now, like virtual physician/nurse avatars or serious gaming. Employing engaging tools that distract the patient a little form the "teaching" aspect and have the patient acting might enhance patient's adherence.
- offer digital integration into patient peer groups and the option to donate data to patient organisations.
- for informal carers, include an option to digitally connect to a peer support group
- offer a solution that allows patients to have the option to share their data with their relatives, keep an online diary and set their own goals for rehabilitation.

12 Patient reported experiences and outcome measures (PREMs and PROMs) collection

Rationale:

- Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs) are both enablers for integrated care provision and quality adherence/improvements, and thus increasingly recognised as providing valuable and essential information for achieving health and care system objectives.
- Whereas PROMs report the feedback on (clinical) outcomes and impacts of individual care (e.g., Quality of life, symptoms, distress, functional ability self-efficacy), PREMs capture a person's perception of their experience with health care or service (e.g., access to and ability to navigate services, involvement in decision making, knowledge of care plan and pathways, quality of communication), and are a good indicator for the quality of care and support provided during the intervention.
- Patients can point out the bottlenecks and areas of improvement within the health and care sector, this way providing complementary information to traditional outcome measures, enabling a more comprehensive understanding of outcomes and effectiveness.

Shortcomings:

- lack of patient reported data tends to lead to ineffectiveness in measuring outcomes and evaluating the CHF care provided.
- the development of mechanisms to promote meaningful data linkage across care transitions is essential.
- development and use of PREMs (and thus the knowledge about it) are still limited[19], not to mention the availability of mature ePREMs tools.
- quality and outcome reporting still tend to be subject to tedious data collection efforts, often happening "offline" through questionnaires individual healthcare providers are required to complete.
- The resulting data is often late, largely disconnected, not of high quality and rarely detailed enough from an integrated care perspective (i.e., which steps of the care process went well in the patient's opinion and what steps still have room for improvement).

Planned Progress:

- Suppliers of the INCAREHEART solution must provide procurers with weekly analyses and summaries of care provided and its outcomes.
- Analysis is to be provided of medical and organisational quality parameters alongside assessment of the efficiency of care, thereby relying on effective data linkage across care transitions

[19] OECD. Recommendations to OECD ministers of health from the high-level reflection group on the future of health statistics. Strengthening the international comparison of health system performance through patient-reported indicators. Paris: OECD; 2017.

- Suppliers are also required to advance ePREMs and ePROMs collection on patients' view of the service delivery process along the care pathway to produce valuable data on the overall impact of an intervention or treatment.
- ePROMs and ePREMs collection should be integrated into the existing electronic health record system of the user to allow for the flow of information. Data should be collected at a pre-specified time points, with a focus for PREMs on care transitions such as hospital discharge, (re)admission or detection of exacerbations.

Preliminary non-functional requirements

Non-functional requirements will include, among others:

- **Servers – pilots**. The INCAREHEART solution shall be hosted on servers physically located within the geographic regions of the five pilots. The INCAREHEART solution shall be able to exchange information (read and write data) with the systems of the 5 procurers' pilots.
- **Languages**. The INCAREHEART solution and all supporting materials (e.g., user manuals, videos) shall be available in local languages and in English.
- **Instantiating**. The INCAREHEART solution shall be able to be reproduced in a similar setting in form of a new instance (e.g., another hospital).
- **Reproducibility**. The INCAREHEART solution shall be easily reproducible/replicable to large amounts of users across different geographic regions.
- **User levels**. The INCAREHEART solution shall differentiate among patients, health, and care professionals (and between different roles of health professionals: GPs, nurses, specialists like cardiologist, endocrinologist, nephrologist, neurologist, ophthalmologist) and caregivers/relatives. The system shall provide a role-based user access control mechanism.
- **Interfaces.** The INCAREHEART solution shall provide the necessary interfaces based on the different user levels, as a minimum:
    - patient/family carer interface
    - health and care professional interface (incl. sub-interfaces for different specialists)
    - administrative interface: designed for the use of non-clinical healthcare providers such as hospital administrators, administrative managers, financial managers, etc. No personal information will be available in the administrative interface, only anonymised statistics, and real-time data about the pilot.

Preliminary legal and regulatory requirements

Legal and regulatory requirements will include, among others:

- **GDPR**. The INCAREHEART solutions shall be fully GDPR compliant.
- **Access Control.** The service will govern access to the service by username and secure password (in compliance with regional/national/European data protection legislation).
- **Security Policy**. The service will develop a security policy with respect to the processing of personal data.

Preliminary operational, staff and business requirements

Operational, staff and business requirements will include, among others:

- **Installation of prototypes.** The INCAREHEART solution developer will install the necessary prototype system v1 and v2 at the premises of each of the five procurers. Alternatively, the developer will provide access to a lab environment to test the prototype by at least 15 users of each of the five procurers.
- **Introduction of pilot system.** The INCAREHEART solution developer will introduce the pilot system at the premises of each of the five procurers in close collaboration with procurer representatives. System introduction includes installation of the solution and preparation of user

devices for rollout. On-site testing will be done to reveal and resolve any issues that prevent the system from working properly at the premise.

- **Helpdesk provision and technical maintenance**. The INCAREHEART solution developer will set-up and operate a help service and maintenance response team to address problems faced by end-users (patients, informal carers, health and care professionals and other staff involved at the sites). This service will be provided at each of the five sites.
- **Change management**. The INCAREHEART solution developers shall provide a change management strategy describing the approach to change management the developers will follow and execute during the pilot operation phase. Appropriate materials development and where necessary events organisation shall be planned as part of the strategy.
- **Business strategy.** The INCAREHEART solution developers shall provide a business strategy describing the approach for commercialising the solution (including market expansion plans, business models, etc.).
- **Total cost of ownership.** INCAREHEART suppliers need to deliver models to quantify total cost of ownership and total cost of care related to the services and products they are offering.

INCAREHEART Draft Use cases

1.1 Use case 1 "CHF early detection"

ID	UC1
Title	CHF early detection
Summary	INCAREHEART needs to support health and care systems in the early(ier) identification of CHF patients. There must be an approach for early detection of CHF/case finding using algorithms mainly and proper follow-up must be ensured.
Actors	• Patients • GPs • Specialists • Screening/secondary prevention campaign facilitators (e.g. GPs, physicians, nurses, volunteers) • System administrator
Key functionalities	• Interoperable access to EHR longitudinal unstructured and structured data (where available) and sharing of patient history, beyond the traditional clinical and health economic domain • Interoperability to practice information system of the primary care physician to identify risk factors and follow up recommendations • Patient Data Analytics for personalised profiling, and recommendations • Use of data (EHR data, questionnaires) • Data visualisation and advice • Case finding/detection • Storage of MDT needs assessment results
Integrated care aspect	• Comprehensive and holistic MDT assessments of needs after diagnosis, not only including the pure medical view • Better linkage of data and information to ensure continuity of care
Integrated care functionalities covered	☒ Shared care plan ☐ Remote monitoring ☒ Data dashboard

1.2 Use case 2 "Enrolling people with CHF, the MDT care team and carers/family members"

ID	UC2
Title	Enrolling people with CHF, the MDT care team and carers/family members
Summary	The INCAREHEART solution shall be able to differentiate user types and include new users in the system – GPs, specialists, patients, their informal carers, social carers, and other healthcare specialist professionals whose services are required regularly or occasionally.

	Each procurer will have an overall administrator who can create new professional/practitioner accounts. Health and care professionals will enrol new patients and their informal caregivers into INCAREHEART, as well as include specialist colleagues. The system shall re-use existing information (e.g., EHR) and local authentication techniques as much as possible and these will be used throughout the INCAREHEART service, including access of the Shared Care Plan and the envisioned patient empowerment platform.
Actors	• Patients • GPs • Specialists • Screening/secondary prevention campaign facilitators (e.g. GPs, physicians, nurses, volunteers) • System administrator
Key functionalities	• Enrolling new physicians and other healthcare professionals • Enrolling new patients • Enrolling new specialists • Enrolling family carers • Role-based access control • Automatic creation of template for “Shared Care Plan” and data dashboard • MDT Data access and information sharing Initiate virtual assistant that guides the patient in case this is necessary
Integrated care aspect	• Inclusion of all actors involved in the journey of a CHF patient • Set-up of a shared care plan used by all stakeholders involved
Integrated care functionalities covered	☒ Shared care plan ☐ Remote monitoring ☒ Data dashboard

1.3 Use case 3 “Supporting empowerment and self-management of the person living with CHF and their family carers”

ID	UC3
Title	Supporting empowerment and self-management of the person living with CHF and their family carers
Summary	INCAREHEART intends to provide the patient and family carers with access to and easy-to-understand summaries of health information and data, educational materials, the Shared Care Plan, and the ability to share information with health and care professionals involved along the care journey. By involving patients in their own health and care and ensuring they are properly prepared and supported by health and care professionals and appropriate educational material, patients can be empowered to take an active role in the management of their own health. The INCAREHEART solution should improve the capacity building of patients and family carers on the implications of an acute decompensation episode or potential co-morbidities (cf. UC10),

	providing transparent information on parameter significance via easy-to-use ICT-enabled tools. INCAREHEART enabled patients will have the opportunity to be coached on physical activity, nutrition, and other lifestyles (such as smoking, drinking, drug abuse and others) in line with personal preferences. Harmful effects (such as intolerances, allergies, and undesired food-drug interactions) can be avoided and the patient can receive comprehensive long-term coaching. The coaching process will begin in hospital and continue beyond the immediate discharge.
Actors	• Patients • Family carers • GPs • OTs, PTs, dieticians • System administrator

Key functionalities	• Patient accesses empowerment platform
	  ○ Easy to use and understand data dashboard
	  ○ Patients sets own goals
	  ○ Patient receives medication reminders,
	  ○ Patient-facing tool summarising medication regimen, to allow e.g. pharmacists better counselling and avoid adverse effects of OTC medications
	  ○ Messages on lifestyle changes
	  ○ Contact with a virtual assistant, who alerts the doctor if necessary
	  ○ Symptoms tracker that can be analysed in combination with patient data
	  ○ Chat-based interaction between patient and professionals
	  ○ Education material and coaching programs for patients as agreed with professionals
	  ○ Intelligent feedback about how lifestyle changes influence BP, weight etc.
	• Automatic integration of data derived from apps (e.g., activity trackers, nutrition tracking) into INCAREHEART platform
	• Automatic integration of data derived from wearables into INCAREHEART platform
	• Shared Care Plan access for MDT as well as patients
	• Training of patients on the implications of an acute decompensation episode or potential co-morbidities, providing transparent information on parameter significance via easy-to-use ICT-enabled tools.

Integrated care aspect	• Patient access to a shared care plan • Integration of various data into one platform and person-centred visualisation of information and interpretation support
Integrated care functionalities covered	☒ Shared care plan ☒ Remote monitoring ☒ Data dashboard

1.4 Use case 4 "Optimising cardiac rehabilitation and treatment adherence"

ID	UC4
Title	Optimising cardiac rehabilitation and treatment adherence
Summary	This use case aims to optimise the CHF medication therapy and polypharmacy management in the health systems of the INCAREHEART procurers by 1) shortening the time of finding the optimal treatment and by 2) increasing adherence to the medication therapy. Optimising drug therapy relies on good treatment decisions, and these require a range of patient data, including age, sex, lab results, and co-morbidities such as depression, diabetes and comorbidities-related treatments. Continuous monitoring of newly diagnosed CHF patients should enable the healthcare professionals to more rapidly identify the optimal medication treatment for their patients, primarily by providing immediate (timely) follow-up. The solutions should ensure that professionals are properly supported in identifying the best medication or combination of medications, and dose, in adherence with the compelling evidence of the guidelines. This support will take account of the specific patient profile (age, sex, co-morbidities, etc.). According to the new ESC/ESH guidelines, early discontinuation of treatment and suboptimal daily use of the prescribed regimens have proven to be the most common facets of poor adherence. After six months, more than one-third, and after one year, about one-half of patients may stop their initial treatment. New ICT devices should be included in the prototype that remind/motivate the patient to adhere to drug therapy.
Actors	• Patient, • Health Care Provider • Family carer

Key functionalities	• Comprehensive Polypharmacy Management
	  ○ Medication regimen is documented in the Shared Care Plan accessible to all stakeholders of the pathway (types of medication, timeframes, scheduling of follow ups)
	  ○ Provide the patient with customised alerts and reminders, supported by ICT devices (smart button, ePill boxes). The solutions should enable a feedback and confirmation loop
	  ○ Patient-facing tool summarising medication regimen
	• Shared Care Plan access for MDT as well as patients
	• Virtual visits
	• Remote Cardiac Rehabilitation at home
	  ○ Comprehensive, multi-component CR and self-management with a primary focus on CHF patients
	  ○ Choices will be offered in terms of psychological strategies such as quick wins, like trophies celebrating the small successes or competitions
	  ○ Combination of telemonitoring and rehabilitation
	  ○ Personalised exergaming
	• Automatically display BP and other measurements (daily weights, heart rate and rhythm, oxygen saturations and a self-rated health status) performed remotely as well as data from

	remote monitoring by the patient into the system (e.g. a dashboard in the SCP), allowing the health and care professional in charge of treatment to review and correct the therapy • Devices that allow to monitor and document the exact behaviour of the patients towards therapy adherence should be included (electronic pill boxes, smart button, etc). During a visit, the professional should be able to review medications, update the medication plan and communicate this to the patient. • Data should be visualised to patients in an appealing and easy-to-understand manner and users should be trained in coaching session to interpret them and relate them to the risk of hospitalisation • The remote monitoring should be integrated seamlessly, allowing for a measured value to be immediately transferred through the system (e.g., via Wi-Fi, Bluetooth, etc.), and to be available to the health professional. This will facilitate the latter identifying the best medication or combination of medications, and dose, in a shorter period compared to manual visits. • Optimised adherence to the prescribed therapy: This part of the solution focuses on empowering the patient to adhere to the defined treatment plan in the SCP. Based on the continuous data collected (BP measurements, physical activity, calory intake, other clinical data) the patient is provided with customised alerts and reminders, supported by ICT devices (smart button, ePill boxes). The solutions should enable a feedback and confirmation loop. Poor adherence data should aim to engage the user more, e.g. by providing extra materials, engaging in a relevant community, etc.
Integrated care aspect	• Concordant prescribing where professionals and patients need to engage in shared decision-making about therapeutic option
Integrated care functionalities covered	☒ Shared care plan ☒ Remote monitoring ☒ Data dashboard

1.5 Use case 5 “Ensuring seamless transitions of care and support”

ID	UC5
Title	Ensuring seamless transitions of care and support
Summary	A Digital Discharge pathway will be implemented allowing effective information sharing across health and care providers/professionals, improving the accuracy, efficiency and reliability to support hospital discharge and other transitions in the CHF pathway. The INCAREHEART solution improves care team communication during transitions, develop and use standardised processes for leveraging and transferring data from EHRs, ensuring timely and accurate information transfer after discharge. Features suppliers are requested to include in the solution are: a) Discharge summary, b) Medication documentation, c) Care and treatment plan, and d) Self-care advice. When it comes to following-up CHF patients after hospital discharge, the INCAREHEART solution should consider a more regular review of the patient progress after an exacerbation period through daily

	multidisciplinary “Situation Reports”, mapping between different EHR systems (GP, outpatient clinics, hospitals), enabling different views for the different professionals, making summary notifications, identifying potential adverse drug events etc.
Actors	• Patients • Family carers • GPs • Nurses • Hospital doctors • Internist • Cardiologist • OTs, PTs, dieticians System administrator

Key functionalities	• Patient about to be referred to specialist by GP
	• Patient data can be accessed by specialists
	• Specialist accesses Shared Care Plan and revises/adapts (incl. patient goal setting)
	• GP can access Shared Care Plan
	• Patient about to be discharged from hospital
	• Digital Discharge Pathway initiated in the INCAREHEART system
	  ○ Discharge Summary
	  ○ Shared Care Plan developed/adapted incl. patient
	  ○ Tracking of pain level
	  ○ Remote CR
	  ○ Simplified digital run through of post-acute care option
	  ○ Self-care advice
	  ○ Daily multidisciplinary Situation reports compilation, mapping between different EHR systems (GP, outpatient clinics, hospitals), enabling different views for the different professionals, making summary notifications, identifying potential adverse drug events
	• Discharge Summaries shared with GP and specialists

Integrated care aspect	• Transitional care is improved, especially the discharge process • MDT access is granted to a Shared Care Plan
Integrated care functionalities covered	☒ Shared care plan ☒ Remote monitoring ☒ Data dashboard

1.6 Use case 6 “Treatment adjustment”

ID	UC6
Title	Treatment adjustment
Summary	The treatment, including intervention strategies, of the patient should be adjustable. This can happen both automatically (algorithm-based) as well as manually by a healthcare professional. Automated adjustments should be accompanied by clear explanations on why the adjustment was done and what outcomes are envisaged.

	Clear, universal algorithms/ protocols and cut-off points that could trigger the automated adjustments system should be established. However, they should be customizable in order to allow the health care professional to set certain cut-off points and targets for a certain patient based on previous treatment experience with that patient. All automated adjustments should be alerted to the health care professional to approve them or not. The health care professional should be also able to monitor all baseline parameters of the patient (clinical, labs) and receive alerts about any changes to manually and on-time adjust the treatment in order to avoid complications and prevent re-hospitalizations. Treatment adjustment should be also elective as planned by the healthcare professional (up titrating the dose of a certain drug or quitting a certain drug) and these planned adjustments should be alerted to the patient (reminders). Treatment adjustment may also be needed when a new condition/ disease (except heart failure) is diagnosed that has to be managed by another specialty. Addition of any new medication should be alerted to the health care professional to make any appropriate adjustments (e.g., type of painkillers that could be prescribed by an orthopaedic surgeon for back pain in a heart failure patient with atrial fibrillation receiving anticoagulants)
Actors	• Patients • Caregivers • Health care providers (GPs, cardiologists, nurses)
Key functionalities	• Access to Shared Care plan • Platform to record baseline patient parameters • Platform to record current patient status • System to detect changes and alert health care providers • System to propose automated treatment adjustments • System to allow health care professional to check current patient status/ changes/ treatment adjustment options and make final decisions • System to alert patient about treatment adjustment and provide feedback to the health care professionals • PREMS and PROMS are continuously recorded and updated • An automated Decision Support System Is activated • The generated information is automatically saved onto a cloud allowing clinicians to adjust treatment in response to early signals of e.g., fluid accumulation.
Integrated care aspect	• Data from baseline parameters are compared with current patient data (manually entered or through sensors), changes are detected and automated and manual treatment adjustments are applied. • Concordant prescribing
Integrated care functionalities covered	☒ Shared care plan ☒ Remote monitoring ☒ Data dashboard

1.7 Use case 7 “Slow or no internet connection”

ID	UC7

Title	Slow or no internet connection
Summary	If the user does not have an internet connection, or the speed of the internet connection is very slow, the INCAREHEART solution shall still work with cached data. This includes access to the shared care plan, medication alerts or a basic analysis of new data from medical devices. Data entered (either manually or from sensors via Bluetooth/NFC) should be cached and uploaded to the servers when an internet connection is available. More general, the INCAREHEART solution should not require large bandwidths to work properly.
Actors	• Patient • Family carer • Health and care professionals
Key functionalities	• Offline mode, • Low bandwidth usage, • Asynchronous data exchange
Integrated care aspect	n/a
Integrated care functionalities covered	☐ Shared care plan ☐ Remote monitoring ☐ Data dashboard

1.8 Use case 8 "Regular MDT assessment"

ID	UC8
Title	Regular Multidisciplinary team assessment
Summary	The solution shall be leveraged by an online system that facilitate a regular comprehensive Multidisciplinary team assessment of patient's biopsychosocial needs, preferences, expectations, and limits to support care practitioners shared decision-making (UC9)
Actors	• Person living with CHF • Caregiver and/or family member • Primary Health Care professional • Care coordinator • Social worker
Key functionalities	• Access to Shared Care plan • Manual data input for patients report ePREMs and ePROMs, as well as for care professionals' data collection of patient's history, biopsychosocial status, parameters and PHR. • Automatic data input from wearables and mobile apps continuous monitoring of health and other parameters, along with data from EHRs, including support for medication and treatment exchange. • View, generate and export/print reports - The system is expected to be able to produce a standardized output in form of a report, for care professionals. Suitable reports for patients should also be available, using user-friendly design and understandable language and graphics. There should be different export options available (minimum: PDF, HTML), as well as a printing option.

	• Care professional collects patient's history and biopsychosocial status, to support:
	  ○ the assessment onset and progression of Patient's different conditions ; the changes in autonomy and the support that is or will be needed; the treatment effectiveness; the existence of potential precipitants; the burden of care on family carers, etc
	• Shared care plan is checked for compliance and recorded accordingly in EHR. Patient's current medication and treatments changes are recorded in EHR
	• ePROMS data are collected through validated tools and integrated in the EHRs to support:
	  ○ the assessment of patients' biopsychosocial status (quality of life, symptoms, distress, functional ability, self-efficacy, etc)
	• ePREMS data are collected through validated surveys/questionnaires and integrated in the EHRs to support:
	  ○ the assessment of integration of care, as well as the efficiency and quality of care across care transitions the patient experience
	• If relevant, data from wearables and/or mobile apps are extracted to the EHR

Integrated care aspect	• Enhanced patient experience • Personalised and individualised care • Patient activation and empowerment • Patient access and ownership of health and care information • Improve provider satisfaction and care team well-being • Promote better informed decisions by the care team • Reduce cost and/or increase value of the intervention • Integration of Digital solutions and electronic health records • Transparency of progress, results and impact
Integrated care functionalities covered	☒ Shared care plan ☒ Remote monitoring ☒ Data dashboard

1.9 Use case 9 "MDT decision support"

ID	UC9
Title	Multidisciplinary team decision support
Summary	The approach to decision support in INCAREHEART centres on a care plan shared between health and social care professionals and patients, as well as a data dashboard accessible based on defined roles. The INCAREHEART solution will provide with a Decision Support System (DSS) to be used by both patients and professionals that establishes the personalised care plan based on patient preferences, clinical parameters, and other relevant determinants avoiding fragmented decision-making. Decision support systems should be envisaged that integrate a combination of various outcomes to facilitate the treatment decision, predict exacerbations and to share information between patients,

	primary care specialists, and health insurance companies or health authorities. The INCAREHEART solution will include AI processing of monitoring data and the data available from the Electronic Health Record and other sources.
Actors	• People living with CHF • Carers and family members • Primary Health Care • Care coordinator • Social care • Community link worker • Specialists • Other community care settings: care homes, rehabilitation centres, hospital at home, etc. • Counselling, psychological support, mental health • Nutritionist • Cognitive and dependency assessment and support services • Rehabilitation • Administration: provider, insurance company or health authority
Key functionalities	• The INCAREHEART telemonitoring solution should explore the potential of machine learning to recognise patterns and provide decision support for healthcare professionals. • DSS linked to automated development/adjustment of a Shared Care Plan • Interoperability with heterogenous data sources • DSS system used by both patients and professionals that establishes the personalised care plan based on patient preferences and clinical parameters, avoiding fragmented decision-making • The solutions are to include AI processing of monitoring data and the data available from the Electronic Health Record and other sources. To meet liability obligations, procurer clinicians must be enabled to override AI-generated results. • Linking extensive datasets to actionable tasks to streamline the physicians' care delivery and support the clinical decision-making at the point of care • The system should also be usable in physical meetings and show the alignment or deviation of patient data from the shared goals, e.g., through cloud-based solutions. • Therapeutic recommendation tools should be personalised, addressing data sharing and infrastructure needs such as integrating highly heterogeneous multi-scale data sources or integrating imaging data. • ePROMs and ePREMs collection should be integrated into the existing electronic health record system of the user to allow for the flow of information. Data should be collected at a pre-specified time points, with a focus for PREMs on care transitions such as hospital discharge, (re)admission or detection of exacerbations. • Information collected will include but are not limited to a) Communication and information, b) Care received (e.g., time spent waiting, knowledge of care plan), c) Physical and

	emotional support, d) Shared decision-making and d) Consideration of family & home environment. • Advice and medication reminders as well as prompts for recommended physical activity, other lifestyle interventions, planned appointments, test (results), etc. are ideally integrated into decision support tools for patients.
Integrated care aspect	• Enhanced patient experience • Personalised and individualised care • Patient activation and empowerment • Health and digital literacy • Patient access and ownership of health and care information • Improve provider satisfaction and care team well-being • Improve patient safety • Reduce cost and/or increase value of the intervention • Better outcomes • Digital solutions and electronic health records • System wide governance • Support for aligned payment systems • Transparency of progress, results and impact
Integrated care functionalities covered	☒ Shared care plan ☒ Remote monitoring ☒ Data dashboard

1.10 Use case 10 "Early detection of complications and co-morbidities"

ID	UC10
Title	Early detection of complications and co-morbidities
Summary	
Actors	

Key functionalities	• Automated, cloud-based decision-support
	• A functionality to add symptoms before appointments to enable a faster diagnosis of co-morbidities or the nature of an exacerbation during visits.
	• System regularly initiates a co-morbidity check (based on data analytics, algorithms and preferably validate questionnaires)
	• Assessment results stored:
	  ○ Onset and progression of their different conditions,
	  ○ Existence of potential precipitants, such as infection or adverse effects of medicines comorbidity,
	  ○ Treatment effectiveness,
	  ○ Impact on their ability to remain independent and changes in patient's autonomy,
	  ○ Burden of care on family carers,
	  ○ Additional prevention strategies to anticipate the support that will be needed in the future.

	• The solution shall make assessment results available to the GP for early diagnosis of CHF and co-morbidities. • Monitor heart rate, heart rhythm, respiratory rate, activity, amongst others • Algorithm determines a normal baseline for each patient. When data deviates from the baseline, the system triggers an alert
Integrated care aspect	• MDT assessments considering the complete patient history, situation and living conditions • Assessment results accessible to MDT and patient/family carer • Comprehensive, integrated monitoring for complex patients • MDT access is granted to a Shared Care Plan • Better linkage of data and information to ensure continuity of care
Integrated care functionalities covered	☒ Shared care plan ☒ Remote monitoring ☒ Data dashboard

1.11 Use case 11 "Interoperability"

ID	UC11
Title	Interoperability
Summary	A key requirement for the INCAREHEART solution is that it is interoperable with existing systems and with other devices which are necessary to capture certain clinical parameters. The selection of parameters depends very much on the characteristics of the proposed solution and the data it requires for its algorithms. Patient data generated by continuous monitoring linked to the physicians escalates the quality of care. Integrated CHF management solutions must have access to existing data in the health and care system as well as to data from mobile applications. A data integration platform which ensures interoperability is required. Health data should be held independently. EHR systems, clinical decision support systems and analytic tools need to compute on coherent health data. Health data should be easily accessible.
Actors	• Physician • GP • Specialists • Family carer • Patient • System administrator
Key functionalities	• Integrating data from different sources. • Automatic data upload will be the preferred choice for any data that the patient must handle (such as Blood Pressure). Depending on the proposed solution, developers will have to define what data they need to ensure that it is included in the system. For example, if they identify that BMI measurements are central for their solution, they need to ensure that BMI measurements are captured (e.g. by providing patients or physicians with smart scales during the testing phase of the project).

	• All data should be gathered, transformed, and stored using an international data standard format (example: IEEE 11073 PHD, LOINC and/or SNOMED) as is possible by the data type. Data exchange protocols with a future perspective such as HL7/FHIR should be implemented in a separate and exchangeable interoperability layer.
Integrated care aspect	
Integrated care functionalities covered	☒ Shared care plan ☒ Remote monitoring ☒ Data dashboard

INCAREHEART Pre-Commercial Procurement

Why innovation procurement

Innovation procurement happens when public procurers procure the development (PCP) or deployment (PPI) of pioneering innovative solutions to address specific mid-to-long-term public-sector needs. This approach has different advantages, for both public, private parties and for the intended users. It helps to:

- encourage and focus innovation by the private sector
- support breakthrough innovation, in collaboration with the end users.
- facilitate the smoother adoption of innovations
- speed up the creation of customer benefits from innovation.
- share risk-benefit under market conditions between public buyers and private parties
- use public expenditure more effectively.

Pre-Commercial Procurement (PCP) is the procurement of R&D of pioneering innovative solutions before they are commercially available.

Competitive development in phases

Pre-Commercial Procurement (PCP) is a specific approach to procure R&D services that involves competitive development in phases, risk-benefit sharing under market conditions, and where there is a clear separation between the PCP and the deployment of commercial volumes of end-products (potential follow-up PPI).

Evaluation per phase

A PCP consists of 3 competitive phases of solution design, prototype and piloting. To deliver the R&D services, suppliers/technology vendors are awarded a public framework agreement and phase contracts. Only those suppliers/technology vendors evaluated as successful after each phase will be requested a proposal for the next phase. Those suppliers/technology vendors who are evaluated as satisfactory or lower will not pass to the next PCP phase, thus their framework agreement will be terminated.

Each PCP phase has a maximum budget allocated and payments are made based upon the results of an evaluation after each phase, by an evaluation committee. In the last phase, ideally a minimum of two solutions will be tested and demonstrated in an operational environment.

Follow-up of a PCP

When a PCP is completed successfully, the developed solution can be procured during phase 4. This is a separate step that requires a new tender which is open again for all technology vendors.

Procurement process in INCAREHEART

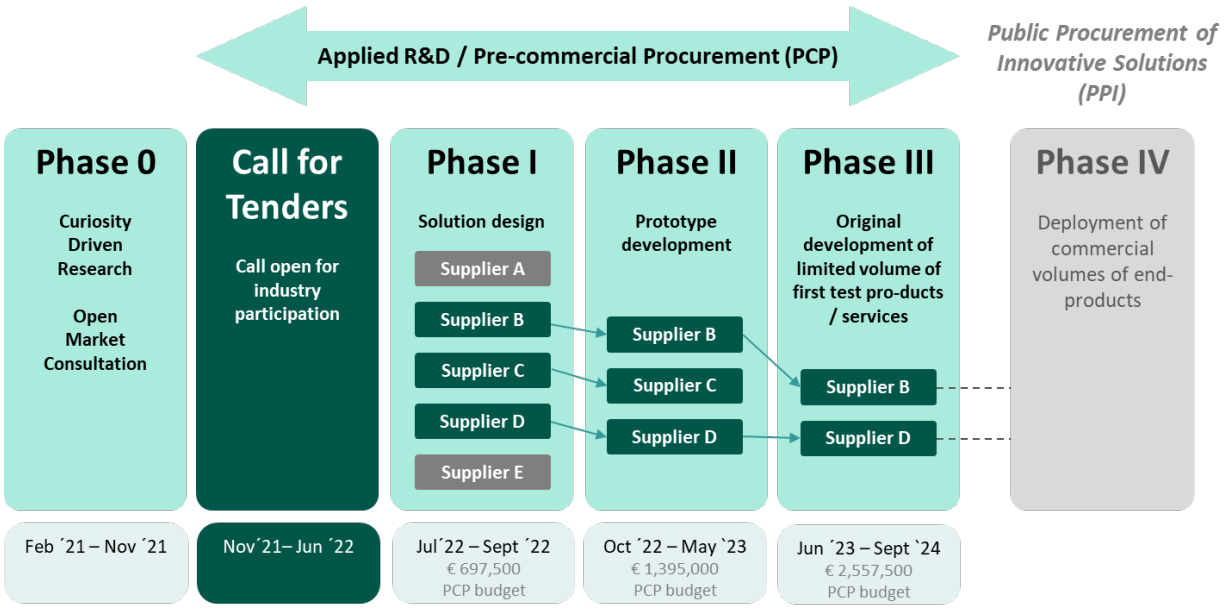

Figure 3. INCAREHEART PCP Phases

PCP-phase 0: Open Market Consultation

An OMC aims to:

- inform potential suppliers (industry) about the INCAREHEART pre-commercial procurement opportunities.
- explain in detail the pre-commercial procurement process
- open a dialogue with market stakeholders about the scope of procurement envisaged in the project, including technical specifications
- facilitate matchmaking among potential suppliers in need of support in the building of consortia capable of addressing the needs of the INCAREHEART procurers in full.

The Open Market Consultation is organised in the form of different activities that are available in the INCAREHEART website:

- **Local events**. Each procurer will hold an OMC event in their local language to engage with country stakeholders.
- **International webinar**. In addition, an international OMC webinar will be organised in English to welcome participants from any location. Besides, an added value of the international webinar will be a pitching session for market players interested in finding partners for a joint tender. In a parallel session, external procurers are invited to provide feedback on the requirements and use cases, in a way that the procured solution represents the interests of a larger number of demand-side organisations.

PROCURER	DAY	LANGUAGE	FORMAT F2F/Digital
Region Jämtland Härjedalen	JUNE 10	English	Blended
Ministry of Health of Turkey	JUNE 15	Turkish	Online
Università degli Studi di Napoli Federico II	JUNE 15	Italian	Online
Region of Central Macedonia	JUNE 17	Greek	Online
Santa Casa Da Misericordia Da Amadora	JUNE 18	Portuguese	Online
International webinar	JUNE 29	English	Online

Table 1. List of OMC webinars

- **OMC online questionnaire**. Organisations related to INCAREHEART are invited to fill in an online questionnaire to let us know about their experience, existing solutions and further feedback on the PCP scope. The questionnaire will be open until the 31st of August.
- **Matchmaking tool**. Many PCP tenderers choose to apply together with international partners in a joint tender (consortium) to be able to fulfil all the requirements. A tool to facilitate matchmaking is available on the website.
- **Management of FAQs**. The questions that might arise during the OMC will be published anonymously in the INCAREHEART website with clear answers for any interested party.

Call for Tenders

- **Tentative launch**: last quarter of 2021
- **Submission**: electronic (via email)
- **Proposal sections**:
  - ADMINISTRATIVE
  - TECHNICAL
  - FINANCIAL
- Official language is ENGLISH
- **Eligibility criteria**
  - Open to all types of operators (companies or other type of legal entities) regardless of their size or governance structure.
  - Single entity or joint tender offer (consortia)
  - The organisation or consortia of organisations must be able to cover all the requirements unless stated otherwise
- **Evaluation criteria**
  - Exclusion, Selection, Compliance and Award criteria are yet to be developed.
  - Quality-price ratio will put a focus on quality.
- **Intellectual Property Rights**
  - Suppliers keeps ownership of the IPRs attached to the results generated during the PCP implementation.
  - A **financial compensation** is calculated in the financial section of the tender, valuing the allocation of ownership of the IPRs by giving an absolute value for the price reduction between the price offered in the tender (actual price) compared to the exclusive development price (market price) to ensure compliance with the EU R&D&I state aid framework. The **actual price** is the price quoted by the bidder considering that they are retaining the IPR on the outcomes in accordance with the framework agreement to be signed and that they can exploit the developed project knowledge in the market. The **market price** is the price that the bidder would have quoted if the project IPR on the outcomes were fully retained by the contracting authority and the bidder did not have the possibility of exploiting the intellectual property (knowledge developed within the PCP).

PCP-phase 1: Solution Design

To develop an overall conceptual architecture and technical specifications for each of the system components and their interfaces based on the requirements, use cases and service process models.

- **Expected output**: detailed report describing the solution and a detailed plan for the prototyping and testing activities in Phases II & III.
- **Duration**: 3 months

- **Maximum phase total budget**: €697,500
- The offers are ranked according to quality – price ratio
- For phase 1, **5 contracts are expected to be awarded** [**minimum of 3]** is expected to be awarded. Contracts are awarded until the remaining budget for that phase is insufficient to fund the next best tender.

PCP-phase 2: Prototype Development

To develop and test prototypes in two iterations. Iteration 1aims at developing non- or partly functional prototypes of key systems components. Test outcomes will be collected and analysed for design, to serve as input for the suppliers' development of the second iteration. These are now envisaged to be functional prototypes, demonstrating component behaviour and system-wide interaction.

- **Expected output**:
  - Prototype specification
  - Prototype demonstration
  - Plan for development of a limited volume of solutions for field-testing
  - Updated cost/benefits forecast including a preliminary business plan
- **Duration**: 8 months
- **Maximum phase total budget**: €1,395,000
- The offers are ranked according to quality – price ratio
- For phase 2, **4 contracts are expected to be awarded** [**minimum of 3]** is expected to be awarded. Contracts are awarded until the remaining budget for that phase is insufficient to fund the next best tender.

PCP-phase 3: Testing of pilot systems

Further development of the selected prototype solutions to a state where they can be piloted under real-life conditions, involving patients, informal carers, and health professionals.

- **Expected output:**
  - Implementation in the 5 testing sites involving patients, informal carers and health professionals
  - Overall assessment and success verification
  - Updated cost/benefits forecast, including a preliminary business plan
- **Duration**: 16 months
- **Maximum phase total budget**: €2,557,000
- A **minimum of 2 contracts** are expected to be awarded.