Personalized Integrated care for frail seniors within the Pharaon Project: the Italian pilot site.

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Abstract. Technology plays an important role into the life of older people. With the increase of age, they are experiencing physical and cognitive frailties and they require assistance for the management of their daily activities. In this sense, digital technologies could offer a holistic ecosystem which could empower their daily life 24h decreasing the caregiver burden. Multi-domains researchers are joining their efforts to propose a selection of services. In this context, this paper introduces the large scale pilot Pharaon project, pointing out the attention on the Italian pilot site. Within the Italian pilot, a personalized and integrated care service was and will be investigated in the forthcoming years to meet the challenge of older population. Particularly, the paper introduces the methodology and the actions performed to face the covid-19 pandemic which affect the first stage of the process, the service domains, and the methodology applied. Additionally, the paper presents and discusses the key performance indicators related to impact, business, social and clinical domains and how the technology is used within the Italian pilot to support the population during the pandemic emergency.

Keywords: Personalized Care, Pharaon Project, Integrated IoT System, Older Persons, Need Study.

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1 Introduction

1.1 Background

Fast ageing of the population, along with concurrent healthcare and social trends, has in the latest years raised a generalized issue across the whole European Union, to preserve and protect the quality of life (QoL) for a population segment quickly become highly frail and vulnerable (World Health Organization 2015). Most of the countries lack the technical, organizational, and legal instruments to effectively cope with this growing problem. Frailty is the main determinant cause of death, and it is strictly related to the ageing process (Clegg et al. 2013). Timely action during the process that progressively makes a subject disabled could significantly impact the entire social and health system. Life expectancy in Italy is the second in all of Europe, and in Tuscany the average life is 85.4 years for women and 81.3 years for men, whereas in Apulia is 84.8 years for women and 80.6 years for men (Statista 2019). As a result, the number of seniors is growing and leading to a change in the traditional family model.

This evolution was raising challenges for the Italian health-care and welfare system, even before the COVID-19 outbreak, especially relating to seniors with reduced capabilities of independent living, not relying upon a nearby family and/or a habitual relationship network. These people are at potential risk of isolation and protection loss by public institutions. According to a 2017 report from the Italian Statistic Institute (ISTAT 2017), 18% of elderly people perceived around them a weak social support network, and about half of them didn't consider their social protection as "strong". Adding up to this, are the challenges linked to socio-demographic changes (falling ratio between birthrate and average age), limited autonomy (30% of elderly declaring "severe trouble in running household activities"), and the resource cut suffered by the Italian public welfare system in the last decade. Hence, innovative and sustainable solutions for improving the lives of elderly citizens can by all means be paramount for improving their day-by-day status and quality of life.

Digital technologies play a key role in winning this challenge since they can support the extended caregivers' ecosystem in multiple ways. Indeed, on the healthcare side, they allow 24x7, real-time monitoring of older people vital parameters, and promptly detect situations where a direct care intervention must occur. On the assistive side, they can allow an easier contact of older people with their caregivers and keep them in constant connection with their families as well as their friends and the outside world (Mancioppi et al. 2019).

This scenario has become further accelerated by the ongoing COVID-19 crisis, severely when not fully crippling the physical connections, and making digital inclusion a must even for a social segment like the older adults who have at large extent been left out of this societal transformation (Remuzzi and Remuzzi 2020).

The medical, social, and technological research are joining their efforts to find innovative, effective, and widely applicable solutions to overcome seniors frailty and exclusion. The European institutions are making important investments to support these efforts, fostering a tight collaboration of the different professional and scientific

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actors into large multidisciplinary projects, encompassing pilots with real users on a significant scale, prepared by methodologies enabling joint requirement elicitation and co-design. Pharaon is part of this effort within the Horizon 2020 frame-programme, along with other large-scale pilot (LSP) projects tackling the topic from complementary viewpoints, like ACTIVAGE[1], SMART BEAR[2], GATEKEEPER[3], SHAPES[4], ADLIFE[5], InteropEHRate[6], Smart4Health[7]. These projects compose the Large Scale Pilots Health and Care Cluster, defined within the "EU OPEN-DEI" project (GA No. 857065)[8], which is a coordination and support action (CSA) aiming at the creation of common data platforms based on a unified architecture and established standards.

1.2 The Pharaon Project: the Italian Pilot Site

Pharaon (Pilots for Healthy and Active Ageing) is an Innovation Action funded by the European Union's Horizon 2020 programme under the Grant Agreement n°857188 (www.pharaon.eu). This large-scale pilot project involves partners from 12 European countries and aims to achieve smart and active living for Europe's ageing population. Pharaon is creating a set of highly customizable interoperable open platforms to integrate advanced services, devices and tools including IoT, artificial intelligence, robotics, cloud computing, smart wearables, big data, and intelligent analytics. These solutions are going to be widely tested and validated, to respond to the needs of older adults and aim at enhancing the independence, safety, and capabilities of people as they age. The project is a collaboration of 41 organisations, led by the BioRobotics Institute of Scuola Superiore Sant'Anna (SSSA), based in Pisa, Italy, and will last 48 months (from December 2019 to November 2023). Pharaon adopts a user-centric approach and is going to test several digital solutions in 6 different pilots over 5 countries: Italy (Tuscany-Apulia), Spain (Murcia and Andalusia), the Netherlands (Twente), Slovenia (Isola) and Portugal (Coimbra-Amadora).

The Italian pilot is coordinated by SSSA; it includes two pilot sites: Umana Persone Social Enterprise R&D Network (UP) which operates in Tuscany Region, and Ospedale Casa Sollievo della Sofferenza (CSS) located in Apulia Region. Umana Persone is a network contract with legal subjectivity that currently involves ten social cooperatives operating in Tuscany and active in the social welfare services sector. Its mission is to carry out research and development activities for the innovation of the Third Sector[9]. Ospedale Casa Sollievo della Sofferenza[10] is one of the historic and

[1] ACTIVAGE Project official website: https://www.activageproject.eu/
[2] SMART BEAR Project official website: https://www.smart-bear.eu/
[3] GATEKEEPER Project official website: https://www.gatekeeper-project.eu/
[4] SHAPES Project information of EU cordis website: https://cordis.europa.eu/project/id/857159
[5] ADLIFE Project official website: https://adlifeproject.com
[6] InteropEHRate Project official website: https://www.interopehrate.eu/
[7] Smart4Health Project official website: https://www.smart4health.eu/
[8] OPENDEI Project official website: https://www.opendei.eu/
[9] Umana Persone Official website: https://umanapersone.it/
[10] Ospedale Casa Sollievo della Sofferenza official website: https://www.operapadrepio.it/it/

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largest hospitals and research centres in Southern Italy. Its mission is represented by hospital care activities, scientific research, education, and professional training of healthcare personnel. Additionally, the Italian pilot involves three industrial partners: Hewlett Packard Enterprise (HPE) [11], Co-Robotics s.r.l. (CORO)[12], and Orthokey Italia s.r.l. (OKEY)[13].

HPE is a technical partner contributing its expertise and competencies in ICT infrastructure specification, design, and deployment. HPE offers its know-how to make, along with other technical partners, the best choices for what will be the foundational platform developed by the project, on top of which advanced technological components will be integrated and deployed to enable the whole span of innovative care services delivered by Pharaon. CORO is a spin-off company of SSSA and its role in the Italian pilot sites such as in Pharaon project is to provide and to develop technological solutions based on robotic platforms and wearable sensors. Finally, Orthokey core business is the development of innovative solutions for the healthcare sector. OKEY also avails itself of the expertise of Medea, its third party connected to the Pharaon project, which deals with the evaluation of the socio-economic impact of innovation processes and solutions.

2 Challenges of the Italian Pilot

Pharaon is developing open platforms for smart living at home to allow intelligent integration of advanced ICTs from fields such as robotics, IoT, Big Data, or smart wearables. This will effectively enable the European ageing population to face the negative consequences limiting their independence and QoL by cognitive impairment, frailty, and multiple chronic health conditions. Currently, most digital technologies in healthcare are fragmented and utilized only on a small scale. Pharaon wants to contribute to the sustainability and scale-up of existing and future business models, thus reduce the risk of their obsolescence by supporting technological and market scalability and thereby enhancing the competitive supply of good quality services. Through the 6 planned pilots and the activities addressing ecosystem expansion, the Pharaon project wants to demonstrate the suitability of the platforms to integrate digital technologies and the capacity of these technologies to keep people at their homes longer, while using institutional healthcare facilities only when intensive care is needed.

Within the Pharaon project, 10 challenges (PCH) have been identified and are going to be addressed within the 6 pilots. Each pilot has its own challenges. The following table summarizes the challenges of the Italian pilot site. In Italy, Pharaon is focusing on setting up and merging Health and Care at home for older vulnerable subjects or moderately frail individuals. In doing so, the pilot wants to emphasize correct lifestyles (e.g characterized by personalized diets and physical exercise programs, social connectivity) and health status monitoring at home.

[11] HPE official website: https://www.hpe.com/it/it/home.html
[12] Co-Robotics s.r.l. official website: http://www.corobotics.eu/
[13] Orthokey Italia official website: http://www.orthokey.com/

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Table I – Pharaon Challenges (PCHs) of the Italian pilot site.

Name	Description
PCH1: The behaviour and the approach of elderly to friendly technological devices	Through co-creation meetings and interviews with users, experts and consortium members, ideas for useful functions of the system must be collected in a creative atmosphere, visualized in terms of user scenarios, and evaluated for their fit with social and technical requirements.
PCH2: Health status definition and its progress over time	With the Pharaon project, we intend to demonstrate that it is possible to improve the health and wellbeing of patients through 1) their proper categorization, 2) establishing a consensus concerning planned clinical actions among all levels of care for each situation that is supported by a tool noting the entire patient history, 3) transparency that facilitates tracking between all healthcare and social areas, allowing to apply the recommended clinical actions.
PCH4: Promote Social Cohesion	Mobility is a vital factor of social inclusion within society and an important precondition for a satisfying QoL in the old age. Reduced mobility leads to isolation and dependence can have a devastating effect on seniors' self-esteem. Within the Pharaon project, the need to provide alternatives to foster social connectivity is highlighted.
PCH5: Define specific personalized care plan on the basis of user´s needs	Different personalized care plan based on objective evaluations made autonomously by the system would be defined, evaluating its results through a large and comprehensive data collection and analysis.
PCH10 - Support to caregivers towards more efficient and personalized care services	Caregivers are at an increased risk to experience burnout and often eagerly need support. Fortunately, their burden can be reduced considerably by implementing ICT solutions. Pharaon project aims at proposing solutions to reduce the caregiver workload.

3 The Pharaon methodology within the Italian pilot

Pharaon methodology applied to the Italian pilot is composed of five main steps (**Errore. L'origine riferimento non è stata trovata.**). The first step aims at refining, translating, and adapting the Pharaon challenges (Section 2) into the needs of the two Italian pilot sites. The second step aims to refine these scenarios with end-users (i.e. older persons, formal and informal caregivers) to define the goal models such as the final Pharaon scenarios (Lorca et al. 2018). Then, within the third step, these scenarios will be developed following agile co-creation approaches where the end-users will be requested to evaluate the solutions providing advice and feedback at different developmental stages (Fiorini et al. 2019b). Finally, the solution will be pre-validated

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and tested in real scenarios (respectively 4th and 5th steps of the scenario). The following paragraphs detail the first and the second step of this methodology.

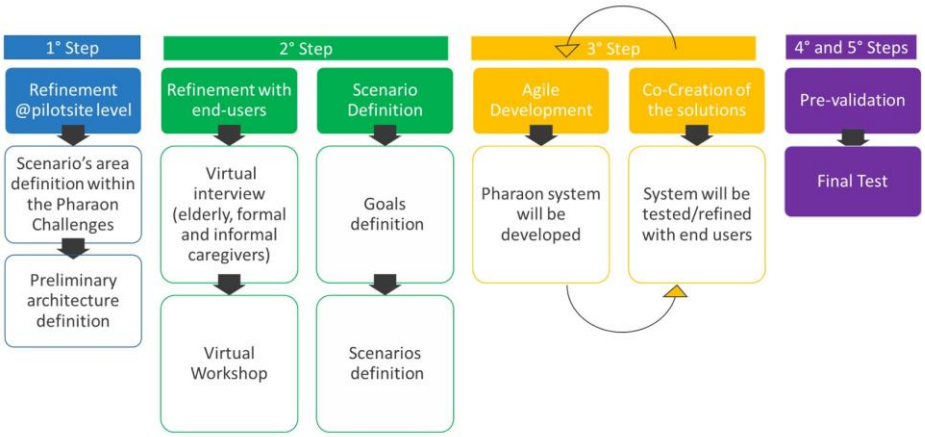

Figure 1 Overview of the Pharaon Methodology applied at Italian Pilot level

4 Target Stakeholders

The Italian Pharaon Pilot Site has planned to recruit and involve a large number of participants, which is currently estimated to be around 700 users, distributed as follows: 300 older adults in fragile condition, mainly with mild dementia, 300 relatives and informal caregivers, 100 healthcare professionals. These participants are going to directly use the Pharaon platforms and technologies, and they will provide enough differences to be a great test field for trials and improvement. Older adults and informal caregivers are involved according to the following processes:

- Active participation in the identification of their needs and suggestions.
- Self-Empowerment in making an informed choice about their health status.
- Use of the digitized Comprehensive Geriatric Assessment (CGA).
- Improve communication with the other actors of the care process.
- Decrease in social isolation.

Furthermore, healthcare professionals are involved in considering the following processes and role:

i) Psychologists and Physicians:
   - Coordinate, training, guidance.
   - Monitor testing.
   - Support the design, development, and refinement of the digitized CGA.

ii) Professional caregivers:
   - Use data and tools to improve the quality and effectiveness of their work,

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decreasing the risk of burnout.

In addition to the main stakeholders described above, other actors can play an important role in achieving the objectives defined for the Italian Pilot. Indeed, volunteering could improve the social connection of older people and can increase communication among the network of stakeholders. Moreover, strict collaboration with Public (local and regional) administration is needed, and local social services should work with the services providers in the recruitment of end-users.

5 1st Step: Scenario refinement at Italian Pilot level

5.1 Scenarios Definition

According to the methodology previously described, the Italian pilot's challenges have been discussed within the consortium to fit the challenges to the two realities (i.e. domiciliary assistance and residential/hospital environment). The following paragraphs summarize the scenario refinement domains such as a preliminary identification of the system requirements.

Health status definition: within this scenario, the Pharaon system aims at measuring and monitoring the CGA domains (Parker et al. 2018). Here, the Pharaon system will be activated by the caregiver/physician (e.g. one possibility could be to trigger the "initialization" phase through a specific vocal command given by the caregiver); then it starts to ask questions to the frail senior about social support network data (e.g. where the patient lives, etc.) and about the clinical data of CGA that clinicians would like to monitor. It is expected that the user is seated and that the care staff have entered basic data into the system such as the patient's name and age that are loaded in the platform at the patient admission in Geriatric Unit. Additionally, the Pharaon system should identify the carers and patient (e.g. using RFID sensors) and it should be able to correctly manage and store the acquired data.

Remote Monitoring: in our vision, the Pharaon system will run a dedicated interface that mainly consists of three modules: the first one includes variables acquired through questionnaires. The second one will collect data regarding vital signs and other domains such as cognitive, functional, social and emotional outcomes of CGA. The third module will collect the data related to the personalized care scenario concerning the monitoring of the level of social inclusion, movements, emotional and mental states. Key aspects of this interface include flexibility and modularity because the active modules depend on the scenario the users are involved in.

Support for Caregiver's Work: caregivers, physicians, and phycologists could access the interface for monitoring patient's health status, providing feedback to personalize the care. Informal caregivers will receive in their own devices (smartphone, tablet, etc.) the information about health and social status of the older persons that

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come out from the platform and will have access to psychological support and counseling through the platform.

Promote social inclusion: social cohesion is related to the action of territorial policies and personal mobility of older persons. Through the Pharaon interfaces, the frail senior could be in contact with the other actors of the care process. Indeed, within Tuscany Region, little groups of 3-4 older people, who live not too far one from each other, will be formed to foster social cooperation and inclusion. A platform could be installed on their TV and through the Pharaon app, they could chat, organize visits, virtually meet and play cards.

Personalized care: through this service, the older person could access the Pharaon system from home which, for instance, suggests him/her physical and cognitive stimulation exercises tailored on the person's profile. The Pharaon system will analyse part of this data using smart algorithms to automatize the care process planning. Additionally, sensors could be installed in the domestic environment. In case of problems, an alert should be sent to formal and informal caregivers. Every person will have "special connections", according to the needs and interests: doctor, friends, relatives, associations, etc. Additionally, as detailed in the previous scenario, seniors could use the Pharaon system to stay in contact with other seniors and play together.

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5.2 Description of the System Components

According to the scenario refinement previously described, an initial list of system components were outlined within the pilot as reported in Tab. II.

Table II Overview of system components.

Service	System Components
Managing and storing health data	• Integrated Care platforms for managing the connection between the devices and the management of data. • Smart AI algorithms for analysing aggregated data.
Remote monitoring	• Robots for automatizing the CGA monitoring service. • Wearable devices and sensors – to monitor the health status of the patients and the parameters of the CGA. • Interfaces to manage data acquisition, test administration, and data visualization.
Facilitating interactions	• Smart TV and Pharaon application to manage the social meetings among peoples of the same community. • Telepresence robot at home to promote the interaction proposing telco with relatives but also with clinicians and psychologists to reduce the social isolation.
Personalized service at seniors' home and in the domestic environment	• A personalized interface where people can access and visualize important data (i.e. include a Smart TV). • Smart solutions to promote personalized care plan including physical and cognitive stimulation (i.e. through games) and teleassistance; • Smart algorithms for decision supporting.

These system components should be refined within Step 2 and then, they should be integrated within the Pharaon architecture.

The Pharaon architecture is under development starting from an initial baseline, represented by a restricted number of existing, potentially suitable platforms best fitting the project's objectives and requirements. By performing a proper analysis and matching of the project's requirements, a Pharaon architectural blueprint will be developed, aimed at creating a superset of the different platforms' capabilities, through proper interoperability mechanisms as well as tighter integrations, according to the results of the design investigation phase. Then, the platform blueprint will be adapted and specialized for each of the project pilots, and the tailored design will be deployed top the pilots' physical infrastructures. For the Italian pilot, this platform will be developed on HPE resources, who, along with the other pilot technical partners, will mainly take care of:

- ensuring that the platform components support the requested data flow, moving information and controls from/to the periphery (IoT devices, wearable devices on patients, robots) into the system intelligent core (e.g., modules executing machine learning algorithms to process data and detect actions);

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- setting up the platform components in charge of elaborating heterogeneous, multi-source data processing, extracting added value information by the combination of data from the person's monitoring, existing care records, and manually input information (by patients as well as caregivers);
- granting data storage in the defined repositories, and data accessibility from the presentation layer making the information available and usable for physicians and caregivers;
- configuring the platform to best meet the non-functional attributes set out by the pilot requirements, in terms of Key Performance Indicators (KPIs) like scalability, elasticity, resilience, reconfigurability;
- developing the platform to be intrinsically secure, resilient to external attacks and safeguarding the privacy of sensitive/PII (Personally Identifiable Information) data moving across the Pharaon system.

6 2nd Step: Scenario Refinement with end-users

According to the Pharaon methodology, the Italian's scenarios should be refined within co-creative sessions. However, the world has suddenly faced a pandemic emergency caused by the COVID-19 virus. Thus, from the beginning of March 2020 several restrictions, including social distances and lockdown, have been applied by the governments in Italy as well as in all the countries involved in the Pharaon project. Consequently, face-to-face meetings have not been allowed and planned workshops have been cancelled. Therefore, Italian co-creators organized a plan to react to the emergency collecting the requested feedback. The contingency methodology proposed to face the COVID-19 situation included a structured interview (through videoconference systems or phone calls) with older people, informal and formal stakeholders such as clinicians, nurses and social operators. Additionally, a virtual workshop has been organized involving Social/Technical workers from the social cooperatives of the Umana Persone's network. Interviews and workshops covered the same topics to easily compared and shared the results.

6.1 Participants

According to the proposed methodology, older persons, informal and formal caregivers have been contacted by phone calls or videoconference systems to refine the scenarios. Moreover, a dedicated virtual workshop has been organized within the Tuscany pilot site to collect additional feedback from the Social/Technical workers, who are in charge to design, manage and coordinate assistive services within the social cooperatives linked to UP.

Users are recruited voluntarily. Inclusion criteria for older people are:

- presence of physical frailty;
- absence or presence of cognitive frailty with a Mini-Mental State Examination (MMSE) ≥24/30;

- absence of sensorial issues (hearing and/or vision).

The professional and informal caregivers have been involved based on their experience with seniors with cognitive and/or physical frailty. The following table summarizes the recruited subjects in the two pilot sites for the scenarios refinement phase.

Table III – Total number of subjects recruited for the refinement of the scenarios

Pilot	Older Adults	Informal caregivers	Professionals				Total
			Social Workers	Clinicians	Technician/ Engineers	Public Social Services	
Apulia	10	10	-	3	2	-	**25**
Tuscany	12	12	8	-	12	4	**48**
Total	**22**	**22**	**8**	**3**	**14**	**4**	**73**

6.2 Interview Guidelines

According to the participants' preferences, the interviews have been conducted by videoconference system (e.g. skype, zoom) or by phone. The videoconference system was the preferred and suggested way because the interviewers could make evidence and observe also non-verbal cues. The proposed interview has been divided into three main parts:

Informed consent acquisition – this part was devoted to the oral acquisition of informed consent. If the participant agreed, the interviewer turned on the video recording and reconfirmed the informed consent orally with the video recorder on (see section 6.4 for more details).

Attitude towards technologies – within this part, the interviewer asked questions related to socio-demographic information (i.e. age, sex, level of education). Then, he/she asked for the attitude toward technologies and to what extent the assistive devices (e.g robots, IoT) could be useful to support daily life. All the technological components listed in Table II were included in the analysis to collect complete feedback. In the end, the Pharaon project and services (see previous sections) have been introduced. If the interview was conducted by phone, the interviewer read a story, whereas if the interview was conducted by a videoconference system, a slide presentation was used.

Interview on Pharaon services – at the end of the presentation, the patient was asked to what extent Pharaon can be useful underlying his/her needs and priorities. The objective was to identify the respondent's needs in terms of physical, cognitive and social assistance, and the acceptance level of technology. Then, the participants were asked to identify the emotional, quality and functional goals (Lorca et al. 2018) of the relevant services identified during the discussion.

The interviews have been fully transcribed to support data analysis.

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6.3 The Virtual Workshop

The virtual workshop has been proposed on the Zoom® video communication platform and divided into 5 main parts:

Pharaon introduction – a general introduction of the project as well as the proposed Italian scenarios was delivered at the beginning of the workshop. It is worth noticing that the same slides used in the interview have been used in this workshop to be aligned with the content.

Attitude towards technologies – Each participant was asked to anonymously answer an online questionnaire. The proposed questionnaire followed the domains proposed also in the interview, i.e. the attitude toward the technology, and the preferences of Pharaon services and domains.

Plenary discussion and service – the results of the questionnaires have been briefly discussed during the plenary session. The three most voted services were identified such as the best three domains. Then, the workshop facilitators asked participants to discuss the service domains proposing some concreate services for their social cooperatives. For instance, if one of the selected domains was the home monitoring, they had to details how they wish to implement that service in their realities. The brainstorming idea has been collected on a virtual shared poster created with Google Presentation®.

NOW, WOW, HOW prioritization – by using a shared virtual poster and virtual post-it created on Google Presentation®, the facilitators asked the participants to rate the ideas according to two parameters: feasibility/implementation and originality following the guidelines presented in (Gamestorming). According to these two parameters, three categories of ideas have been identified into three quadrants as follows:

- *Now*– Normal ideas, easy to implement. These ideas normally result in incremental benefits.
- *How*– Original ideas, impossible to implement. These are breakthrough ideas in terms of impact, but practically impossible to implement right now because of current technology/budget constraints.
- *Wow*– Original ideas, easy to implement. 'Wow' ideas are those with potential for orbit-shifting change and possible to implement within current reality.

The participants had to write the number of the services previously identified on the post-it and move the post-it into one of the three quadrants according to the level of priority assigned. In the end, the three most voted services within the NOW and WOW quadrants were identified.

Scenario description – The participants have been divided into three groups to write down the scenarios. Each group had to develop one of the three scenarios previously identified. A scenario template (using Google Docs) was provided to the group to guide the discussion; the participants were requested to describe the steps of the scenario, such as to identify the goals of the model (i.e. emotional, functional and quality goals) (Lorca et al. 2018).

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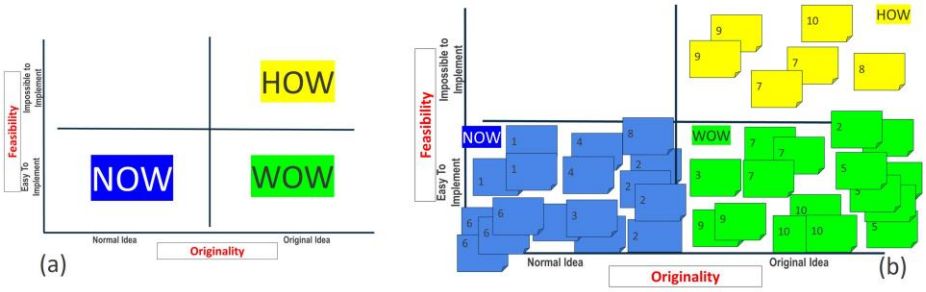

Figure 2 – (a) WOW, NOW, HOW matrix used during the workshop (b) The matrix at the end of the workshop. The participants move the virtual post-it in the poster according to the level of prioritization given.

6.4 Legal and Ethical guidelines for the interviews

The Italian pilot site aims to build a user centered scenario, and it can't be approached without seriously taking into consideration legal and ethical indicators among others. For this reason, the co-creation methodology represents the best way to consider all the domains (i.e. physical, psychological, emotional, environmental, social) – most of them related to legal and ethical risks that tend to increase for aging adults – and ensure that legal and ethical requirements will be effectively respected, adapting solutions case by case.

Another important aspect to point out is that the legal and ethical indicators that have to be considered relevant, are not only those coming from the older adults, but also those from their families – when they do exist -, especially in Mediterranean cultures where the family is the most important social institution. Some useful indications came from the other partners of the Pharaon Consortium who gathered informations about the most relevant risks and threats for elderly in using technologies. At the end, some framework templates (i.e. Informed Consent, Factsheet, Revocation Sheet) were elaborated at project level according to these data and distributed at pilot levels.

Due to the contingency period caused by the Covid-19, pilots had to go ahead modifying the original program from face-to-face interviews/focus groups to phone or video interviews. Strategies were also modified and documents adapted. The interview framework was structured to ensure a balanced relationship between interviewer and interviewed. It was necessary to consider that the role of the interviewer was not only to facilitate dialogue in focus groups, but also to stimulate every single person to express their opinions and needs, ensuring in the meantime people didn't feel influenced or embarrassed. For these reasons, we ensured people felt comfortable with the interviewer, adopting also simple measures such as choosing professionals with specific skills, who would follow the same person until the end.

A very big effort has been also dedicated to the training of professionals in managing interviews, selecting how/when to stress some topics, and leading conversations to collect the most relevant information.

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As we weren't able to stimulate in person the senses of the people interviewed (with pictures, or seeing, touching, trying technological devices), we focused on stimulating their imagination -whenever possible- through images, videos or storytelling (real examples of what a person can do at home with the devices).

Comparing information collected from the questionnaires submitted by other partners, we noticed that privacy and safety were the main concerns of the elderly and their families, so we focused primarily on them.

The main goal since the first contact with the elderly has been the accessibility of information. This meant that some efforts were dedicated to elaborate privacy policy, informed consent documents and some other tools to clearly and easily explain to people (not only the elderly, but also formal and informal caregivers and professionals) the characteristics of the project: what they are asked to do, which kind of data will be elaborated and how-where-until when it will be stored.

We wanted not only to be compliant with the GDPR, but also ensure effective comprehension of the contents. The main measures that were adopted are as follows:

- Simplifying the contents;
- Removal of complicated words, substituting them – whenever possible - with more simple ones;
- Underlining or writing in bold the most important aspects of each part of the content, to focus people's attention on them;
- Providing all these documents and information with plenty of time for the recipient to read them several times.

We also elaborated a sort of "Road Map" for interviewers to guide them through the first part of the interviews. Following the steps of the Road Map, the interviewers ask specific questions in order to verify if the person interviewed fully understands the context. At this stage, people are invited to ask for clarification if needed, and in this case the interviewer should offer the explanation before collecting the consent and proceeding with the interview.

In order to approach ethical problems related to the fundamental human rights (i.e. dignity, freedom, independence, etc…), the interviewers deeply researched the domains of DOING, BEING and FEELING, in order to understand how technologies should operate, and in which way they should make people feel and develop the goal models.

People's perceptions represent the first criteria used to filter technologies in order to be considered ethical. This doesn't rule out refining these technologies and considering different ones in the future, but it means that the implementation of the scenario is based on a cyclic process that starts and finishes with the end-users follow up.

6.5 Data Analysis

The analysis of the data has been conducted in both the pilot sites (UP and CSS). To assure that the data analysis would follow the same procedure both in Tuscany and Apulia, we used the same template to report on the analysis. The proposed data analysis is adapted from (D'Onofrio et al. 2018; Fiorini et al. 2019a).

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The interviews have been fully transcribed in both the pilot sites. After transcription, each interview has been analyzed using the method of Thematic Content Analysis (TCA). The first level of coding was meant to identify themes and units of meaning. In this, we stayed close to the wording used by the respondent. In the second level of coding, we used more theoretical words. Finally, the third level of coding was the actual analysis: looking for recurring themes, coherence and unique cases. In particular, the TCA is divided into two fundamental analyses: 1) Analysis of Vertical content [coding and categorizing by an intra-interview reading (progress of an interview on all codified themes)], and 2) Analysis of Horizontal content [second coding and categorizing on reading inter-interviews (illustration of a theme by all the interviews)]. In particular, the analysis was meant to highlight the similarities and differences between the two pilot sites.

Then, these results have been discussed among the multidisciplinary research team of the Italian pilot, which consists of geriatricians, psychologists, social operators, health service researchers, robotics engineers and biomedical engineers. The objective of this analysis is to bring the data from the two pilot sites (i.e., UP and CSS) together and perform a cross-site synthesis at the Italian pilot level. We aimed at identifying the commonalities and differences between the two sites regarding the goal models and the goal scenarios, related priority services and attitudes towards the technology and the Pharaon services. For this, we looked at both quantitative differences (e.g. the type of support needed, the number of older people positive about the technology) and qualitative differences (e.g. the type of arguments in favour of Pharaon services). Finally, the results have been aggregated to obtain the selected goal models as described in (Lorca et al. 2018).

7 Key Performance Indicators

This section explains the multidimensional framework Key Performance Indicators (KPIs) that we are going to use within the Italian pilot to evaluate the proposed services. Indeed, the proposed KPI domains included: quality goal and performance indicators, social, clinical and emotional indicators, impact and business indicators, and legal and ethical indicators.

7.1 Quality goals and Performance Indicators

The overall pilot evaluation will be driven by a set of indicators relating to the improvement in the delivery of care services, and the achieved leap forward in the life quality of participating older people. Nonetheless, these leading quality goals will have to be achieved also through several technical quality goals, instrumental and enabling to reach the sought outcomes of impact and effectiveness for the end-users. These technical quality goals will involve all the technology layers in the Pharaon system, peripheral/edge components, service platform, vertical applications and technology components. Numerical targets will be set out by Pharaon at a more advanced

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development state. Nevertheless, we can already envisage some qualitative targets that the pilot will have to carefully observe.

For the service platform, the quality goals are expected to include:

- **Technical parameters** affecting the perceived user experience: data availability latency, connection setup latency, system stability; such parameters should be kept under control, to prevent negative reactions from the users, and not spark inefficiencies in the caregivers' operation.
- **System accuracy**: e.g. data leaks along with the acquisition, processing and storage pipes, especially in the flows demanding levels of synchronicity.
- **Scalability and elasticity**: the system must provide, besides the physical capacity, also the functional capability of responding to sudden demand peaks, in line with the specific targets set out for the pilot, by prompt provisioning of additional resources to keep the service fulfillment level.
- **Security and privacy**: the system should be able to avoid unauthorized access to users' data and/or to the own components; data integrity and consistency must be guaranteed; attacks and incidents must be handled and their impact must be kept at the minimum level.

7.2 Social, Clinical and Emotional Indicators

The pilot evaluation will be lead by a indicators set finalized to the improvement of social, clinical and emotional goals as shown below:

- **Clinical Indicators** will consist of the reduction of hospitalization, increasing of pharmacy adherence, increased level of physical activity (monitoring of movements), frailty risk reduction evaluated by the Comprehensive Geriatric Assessment (CGA), cognitive improvement assessed by the Mini-Mental State Examination (MMSE) (Folstein et al. 1975), decrement of the depression symptoms assessed by Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos et al. 1988), improvement of the QoL measured by Quality of Life AD (QOL-AD) (Logsdon et al. 2002), and decreased levels of burnout of caregivers measured by Caregiver Burden Inventory (CBI) (Novak 1989).
- **Social Indicators** will be obtained through the improving level of social connection and perceived social support measured by the Multidimensional Scale of Perceived Social Support (MSPSS) (Zimet et al. 1988).
- **Emotional Indicators** will be modelled with the equal hierarchy to functional and quality goals because the consideration of emotion is fundamental to the development of sociotechnical systems. Different roles may have conflicting emotional goals in response to the same goal. So it is important to distinguish different emotional indicators for each stakeholder category.
  For older frail adults, the main emotional indicators are expected to be:
  - Improved Self-Empowerment and confidence: the system should increase people's ability to take care of themselves, giving feedback about their

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lifestyle.

- Reduced feelings of loneliness: through the Pharaon system seniors should have the sensation of being connected to other people and reaching them easily.
- Improved sense of inclusion in the healthcare chain process due to improved communication.
- Feeling part of something and still "useful" to society: being integrated into a network of positive relationships allow people to find meaning in their existence.
- Easy access to Pharaon service: the system must be perceived as friendly and easy to use.
- Easy access to healthcare data: older people must feel that information about their health status is always available to them.

For professional and informal caregivers the main emotional indicators will include:

- Reduced burden: the system must be a real help in carrying out daily tasks and make them easier.
- Reduced sense of loneliness: the platforms used in the project should allow operators to continuously share information and emotions with colleagues.
- Easy access to important data regarding the health status of the beloved care person.
- Empowerment the management of the diseases: caregivers should increase their confidence in the ability to take care of their family member, increasing their awareness and competence about their disease and care plan.

7.3 Impact Indicators

The impact of digitalisation of health and social services has been profound and is expected to be even more thoughtful in the future. Like for other services, it is important to evaluate the impact of such digital health services. Decisions to adopt, use or reimburse new digital health services, at different levels of the health and social care system, are ideally based on evidence regarding their performance in the light of health system goals.

In order to evaluate this, a broad perspective should be taken. Attainment of the broad health system goals, including quality, accessibility, efficiency and equity, are objectives against which to judge new digital health services. Accordingly, evaluations should be designed and tailored in such a way as to capture all relevant changes in an adequate manner. According to such assumptions, within the *"Personalized Integrated care for frail elderly",* the Italian Pharaon pilot aims at generating impact

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evidence on different dimensions and different stakeholders. In particular, the goal is to generate benefits for:

- End-users;
- Social and healthcare system;
- Public and private health/social care entities

In this regard, a study outcome has been identified. In particular, we foresee that ICT/IoT technologies improve the efficiency of health and care systems with demonstrated added value according to different elements:

- Users QoL;
- Sustainability of the service from an economic point of view and from human resources perspective;
- Efficiency of provided treatments.

In particular, the deployment in the Italian scenario of integrated care platforms able to manage the connection between various devices (wearables, sensors etc.) bound up to the high-quality management of data get the goal to generate noteworthy improvements.

Furthermore, the deployed technologies will be able to generate and analyse a higher volume of data thus allowing the definition of better treatments from caregivers to patients/elderly. Such highly refined and personalized treatments get several cascading goals:

- Seniors/patients improvement of related QoL due to personalised care.
- Health/Social care system's equity improvement through the reduction of out-of-pocket-payments due to personalized treatments thus reducing the users' money waste and improve their access to effective health and social care pathways also thanks to technologies that allow the caregivers and GPs remote monitoring.
- Improvements in health and social care system's capacity to properly allocate human and financial resources according to the real needs of people.

Additionally, the implementation of Pharaon approaches has the goal to improve access to health and social care pathways to a larger population portion by promoting personalized care services. In fact, through technological devices, the goal is to collect and evaluate a large and comprehensive amount of data to define different and personalized care plan suitable to reduce in a short-medium run the use of health services by patients.

According to Italian pilot scenarios, through the help of digital devices, this approach aims at empowering the users to implement healthier behaviours and lifestyles and to improve users' health literacy. According to WHO, "Health Literacy" refers to *"the achievement of a level of knowledge, personal skills and confidence to take action to improve personal and community health by changing personal lifestyles and living conditions. Thus, health literacy means more than being able to read pamphlets and make appointments. By improving people's access to health information, and*

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their capacity to use it effectively, health literacy is critical to empowerment"(World Health Organization 1998).

By the improvement of users' "Health Literacy", Pharaon gets the unique opportunity to promote a deep change, able to alleviate the ever-increasing pressure on the public system, relieve the caregivers from overstating stress and to reduce the waiting list by fostering teleassistance services, stimulate remote control and implementing continuous psychological support to caregivers using chat, telco, and information by the devices.

To analyze data and to generate Italian scenarios outcomes' evidence, statistical approaches will be implemented to ensure outcomes accuracy and reduce bias elements typically included in such type of analysis. In particular, variables statistical description, statistical significance and multivariate statistical analysis will be implemented to generate the best possible evaluation and ensuring the achievements of the aforementioned expected evaluation goals.

7.4 Business Indicators

One of the main declared objectives of the Italian Pharaon pilot is to be sustainable in the medium/long run regardless of the project expiring date. According to European market observers, the IoT market is expected to surpass $241 billion in 2022. The true leader for IoT spending in the forthcoming years will be the consumer segment, with revenues exceeding $32 billion. The largest consumer use cases will be related to the smart home, personal wellness, and connected vehicles. Within smart homes, home automation and smart appliances will both experience strong spending growth over the forecast period and will help make consumer the fastest-growing industry segment overall with a five-year CAGR of 20.0% (IDC 2019).

The Italian IoT market is growing at CAGR rate of 35% with an overall value of 5 billion (2018) (Osservatori 2019). The smart home segment shows the highest annual growth rate (+52%). In this competition, Artificial Intelligence can play a fundamental role in the IoT market, opening up new opportunities for enhancing the data collected to anticipate the needs of companies and consumers. The understanding of the main type of market is fundamental due to the fragmentation and the barriers to entry typical of the IoT market in order to define the proper business model.

According to a preliminary analysis, the business model that will be adopted in Italian Pharaon pilot will be a B2B2C, because services will be never sold directly to the citizens, but they will be always reached through public/private institutions in charge of delivering socio-healthcare services. Therefore, Italian Pharaon pilot target customers are:

- Public healthcare institutions.
- Public insurances.
- Private insurances.

The identified customers will necessarily make the Italian pilot exploitation to be adaptable to the different customers approaches, both from an engagement and selling policy point of views. If the customers are public institutions, it will be necessary to

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answer specific public tenders and adapt the offering to the specific tender needs, even including other kinds of supporting/integration services; in case of private customers, Italian Pharaon pilot will be tailored to very specific needs collected visiting the customers more than once and then the most suitable package and, consequently, the most appropriate selling policy will be jointly created.

On top of this, the aforementioned market represents a huge opportunity to be intercepted. As such, the implemented strategy foresees the setting-up of an interested and key stakeholders ecosystem able to promptly updates needs and translate them into Pharaon local actions. Through this ecosystem, it would be possible to make the best use of the assets generated through constant monitoring of external communities

To set-up this ecosystem, specific webinars are going to be scheduled and key local stakeholders will be invited. Such webinars would have the goal to:

- Present the Italian Pharaon pilot to a wider community.
- Concretely understand stakeholders' needs.
- Involve different stakeholders to create a local network that can be recognizable also at EU level as representative of them.

On top of this, the Italian partners are involved in international EU and extra-EU networks such as the "EU OPEN-DEI" project (GA No. 857065) and the related "Large Scale Pilots Health and Care Cluster" as well as in other relevant international networks such as the "International Collaboration Digital Transformation Healthy Ageing (IDIH)"[14].

These initiatives represent a unique opportunity to leverage the Italian study outcomes and to get visibility in international fora. At this regard, several actions are already on stage (as workshops, webinars and newsletters) and will be further defined with key stakeholders during the project lifespan.

All the initiatives presented will contribute to the definition of the sustainability and replication analysis of the Italian case study according to national and international key players highlighting those elements suitable for Pharaon pilot site replication and scaling-up in different ecosystems than the pilot one. In order to accomplish with such strategy, at the end of the project, specific Italian guidelines will be released containing the analysis about the potential adaptations and enhancements proposed on top of Italian Pharaon case's experimental framework to be considered for future adopters.

8 How the proposed solutions could support during COVID-19 related situation

The current spread of Covid-19 is the latest testimony to the threats to public health that have recently been addressed: 2002: SARS epidemic in China; 2012: MERS outbreak in the Middle East; 2014-2016: Ebola virus in Africa; 2019-2020: Covid-19 outbreak China/rest of the world. In particular, Italy has strongly hit by Covid-19

[14] IDIH, https://idih-global.eu/

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pandemic with a total number of 229.858 of total cases and 32.785 total deaths (last update 24 May 2020).

The disease outbreak affects all segments of the population and is particularly detrimental to members of those social groups in the most vulnerable situations, such as frail people.

Indeed, according to a study released by Istituto Superiore di Sanità (ISS) and Italian Istituto Nazionale di Statistica (ISTAT), those with high risk of dying because of Covid-19 are those belonging to the 60+ age group (ISTAT 2020). Indeed, the mortality rate for male seniors aged over 60 is higher than 30%. Additionally, there seems to be a deadly trend toward mortality with Covid-19 in older patients with specific comorbidities, thus identifying a new "Covid Spiraling Frailty Syndrome" (Abbatecola and Antonelli-Incalzi 2020). According to a recent case-control study conducted by the Agenzia Regionale di Sanità (ARS) Toscana (Paolo et al. 2020), a chronically ill patient has a more than doubled risk of developing symptomatic Covid-19 compared to a healthy subject. Dementia is one of the major risk factors. A chronically ill or oncological patient, with the same gender and age group, has a 56% higher risk of developing symptomatic Covid-19.

Fostering remote care is of paramount importance to limit access to healthcare structures and contain the risk of contagion. In case of emergency, this would allow patients to be monitored by doctors, without any risk to them and without interrupting the service, as, unfortunately, chronic patients following a traditional care pathway are experiencing. Today, indeed, anyone who needs outpatient rehabilitation cannot be guaranteed the service; however, anyone who is an in-patient in a healthcare facility, cannot be visited by his or her relatives, and, as a result, may suffer a negative psychological impact. Older persons are not just struggling with greater health risks but are also likely to be less capable of supporting themselves in isolation (a condition that is dramatically worsened in such a health crisis). Although social distancing is necessary to reduce the spread of the disease, if not implemented correctly, such measures can also lead to the increased social isolation of older persons at a time when they may be at the most need of support.

Therefore, robotics and ICTs in the service of public health could represent a new consolidated model of clinical practice in the management of Covid-19 (Yang et al. 2020). The cooperation between autonomous robotic systems and clinical staff could give rise to new prevention protocols that effectively and promptly counteract the spread, in the future, of infectious diseases capable of putting at risk the public health of our country and the globalized system in which we live.

In this context, the Italian pilot is planning concrete actions aimed at developing a modular robotic and ICT solution that can support and assist healthcare personnel during the Covid-19 emergency, helping to reduce the risk of infection and transmission of the virus. The realization of the described scenario can drastically reduce the contact between health/social workers and patients, proposing teleoperated robotic systems able to support in tasks such as visiting relatives, surveillance, and monitoring the status of the patients. The proposed solutions would be able to significantly mitigate the risks related to epidemic emergencies, promoting new styles of coexist-

ence of humanity with very virulent epidemics. Particularly, the following scenarios have planned to be implemented to meet the Covid-19 challenge:

- **Telepresence service (@Home, @Residential Facility):** a telepresence robot will be used in a semi-automated mode to establish a relationship between the socio-medical operator and patients, particularly for increasing the remote assistance and monitoring of the health status multiple times during the day.
- **Video-consultation (@Home):** the service will allow performing a remote patient examination, i.e video-consultation session between doctors and patients.
- **Patient remote monitoring (@Home**): discharged patients after a hospital stay due to Covid-19 infection should be carefully monitored for a while. Thus, they are asked to daily fill a web-based checklist complete with all the relevant Covid-19 related symptom. Additionally, the system could ask them to insert some physiological measurements such as the body temperature and the oxygen saturation level. This data represents a mix of quality and quantity indicators for the monitoring process, to timely intervene in case of recurrence of the infection symptoms. Gathering such data from the discharged patients can be useful both for monitoring the health of these people, as well as for collecting data to be used for scientific purposes to improve the knowledge about the development of the disease over the time.

For what concerns the experimentation, the telepresence service will be tested within the Tuscany pilot and the other two services will be tested within the Apulia pilot.

9 Conclusion

The proposed paper introduces the personalized integrated care system for frail seniors within the Italian pilot of the Pharaon project. An overview of the Italian pilot is presented such as the used methodology and the identified KPIs. A summary of the results obtained during the first step of the methodology was presented, as well as the methodology proposed for the second step. A total of 73 users (older persons, informal caregivers, and professionals) were involved to refine the scenarios.

The technology could have a great impact on the lives of older persons as much as on the people that support them. However, sometimes research to market barriers are experienced that could be stem from a variety of causes. Indeed, Pharaon project aims to evaluate the services based on multidisciplinary KPIs which aim to give suggestions and improve the services considering issues which could promote and favour the exploitation of these technologies in the real world.

It is worth noticing that technology is playing an important role within the pandemic emergency. This is the reason why the Italian pilot would aim to make the difference proposing three services to face the challenge and supporting the frail older

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adults in managing social distances. These solutions are under test within the UP and CSS pilots.

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