To all those who think they cannot do it.
To my Family, Margherita my little flower, it's all thanks to you; and my sweet grandparents, Francesco and Celestina always warming my heart. I got it as I promised!

"…*You are my sunshine, my only sunshine*
You make me happy when skies are grey
You'll never know, how much I love you
Please don't take my sunshine away..."

Jamie Davis,You are my sunshine, 1940

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Dipartimento di Sanità Pubblica e Medicina Preventiva
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An innovative approach for health care delivery to obese patients: from health needs identification to service integration

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Adknwoledges

Many disasters occurred during my PhD, and sometimes I would have wanted to give up, quit. But I did not. I was not sure how much more I could take after putting up with so many almost. I spent three years and a half of perseverance, hard work, heartbreak, panic attack, sobs, COVID-19 pandemic lockdown in Germany, and laughter. For this, I would like to thank a few people who made me smile, supported me, and brought me joy.

I would like to thank Prof. Annamaria Colao, Prof. Rosario Pivonello, especially Dr Claudia Pivonello, my mentors for about nine years, always by my side. There aren't enough words to be grateful for.

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I cannot express my gratitude and love to my big family. To my parents for all the love, support, encouragement and prayers they have sent on my way along this journey. Your unconditional love and support have meant the world to me. I hope I have made you proud. To my siblings Antonio, Anna and Concetta without your love and efforts, I wouldn't have made it. To my sweetest and lovely niece, Margherita, you are my sunshine, my source of pure joy. I wouldn't have been more blessed without you.

Finally, what else is there left to say? I got it! I close another chapter of my life.

“I want to talk fast because I might start crying. You know, I have never elected the homecoming queen or anything, but I sure feel like one now!” Madonna said to thousands of fans during the Virgin Tour in Detroit in 1985.

Nothing comes easy in life; you must strive and hustle to be where you always dreamt of being.

Be brave and move on

List of abbreviation

AG Action Group

AHA Active and Healthy Ageing

BMI Body Mass Index

CSUQ Computer System Usability Questionnaire

DXA Dual Energy X-Ray Absorptiometry (DXA)

EBP Evidence-Based Prevention

EC European Commission

EHR Eletronic Health Record

EIP European Innovation Partnership

EU European Union

HMHM Home & Mobile Health Monitoring

I2M Innovation To Market Plan

IHSD integrated health services delivery

KP Kaiser Permanente

MAFEIP Monitoring and Assessment Framework

NCD Non-Communicable Diseases

NHS National Health System

NIECR Northern Ireland Electronic Care Record

NUTS Nomenclature of territorial units for statistics

OPERA Obesity, Programmes of nutrition, Education, Research and Assessment of the best treatment

PCMH patient-centred medical home

QoL Quality of Life

RS Reference Site

RSCN Reference Site Collaborative Network

SDOH Social Determinatns Of Health

VHA Veterans Health Administration

WHO World Health Organization

WOF World Obesity Federation

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empirica Kommunikations- und Technologieforschung GmbH is a private research and consulting company that supports innovation in several fields: digital health research and innovation, eCare & the Aging Society, eSkills & Work and Energy.

Paginemediche.it, is an Italian digital health platform, aimed to connect physicians and patients by offering personalized health paths, that fosters the relationship with the patients through interactive and innovative digital services, and provides users with the ability to register for free to the platform and access to their own personal dashboard. At the same time, it allows physicians to have an online visibility profile and a suite of free and paid services to improve and optimize their professional activities.

Excecutive Summary

In Europe, more than half of the population is overweight or obese, and effort to design, validate, and implement innovative approaches is required to address social and health unmet needs of obese patients in terms of health promotion, disease prevention, and integration of services. The challenge is improving the collaboration between the different health and care stakeholders involved in the lives of obese patients, changing the socio-cultural attitude towards food intake and other behaviours leading to a negative impact on their health-related quality of life. The digital transformation of health and care can support changes in healthcare systems, healthy policy, and approaches to patient care and better implementation of the different health promotion and disease prevention strategies between all the stakeholders and support obese patients.

Based on the previously experience adopted by Blueprint Partners with the Blueprint persona and user scenario in the context of models of care and prevention, health policies and analysis of risk factors affecting health and quality of life of obese subjects, the study aimed to simulate an integrated care pathway, through a multidisciplinary approach, developing and applying solutions and good clinical practices addressing the social and health unmet needs of obese patients. A pilot study assessed the quality of life (QoL), adherence to the Mediterranean diet, efficacy and interoperability of a digital health platform, Paginemediche. it. A qualitative approach has been adopted to identify and specify key digital solutions and high-impact user scenarios in Active and Healthy Ageing (AHA). To achieve a successful result, an iterative and collaborative approach has been followed to develop a user-centred perspective to the identification of solutions addressing health needs with different complexity along the entire life-course. Four initial key topic areas were chosen and used to identify different digital solutions that may meet the needs of the population segments defined by both age and the complexity of their health status. All data, derived from the industry representatives in the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA), were collected via a survey to how digital solutions best met the needs of the various population segments represented by personas. Subsequently, innovative solutions were designed based on how a user from a target group interacts with technologies, developing "personas" belonging to specific "population segments" with different conditions and needs. Then, a high-impact user scenario, based on the correlation of personas' needs, good clinical practices and digital solutions available targeting needs which playing a role in the health and care delivery for the persona, has been developed. In the end, to evaluate how digital solutions and technologies can support obese patients during their

weight loss or management of their related comorbidities in current service provision, ten obese patients were enrolled to evaluate a Digital Health platform, paginemediche.it, developed.

Matilde, the Blueprint persona developed, highlighted some of the main needs (social support, development of a health-friendly environment and educational program on healthy nutrition and physical activity) that may be addressed by integrating innovative solutions in the care of obese patients. Based on her profile, a high-impact user scenario diagram correlates health and social needs with digital solutions and can help key actors in the creation of a well-integrated care approach. Moreover, the evaluation of the digital platform, paginemediche.it, demonstrated how digital solutions can motivate and support obese patients in changing habits towards a healthy lifestyle, although no further statistical significance has been identified in the quality of life assessment because of the limited number of the patients, and short period of observation.

Overweight or obese patients tend to be marginalized and the subject of a real social stigma. Digital solutions may be useful to overcome psychological factors that prevent obese patients from starting their journey for a lifestyle change. The suggested approach, which considers health needs, IT skills, socioeconomic context, interoperability, and integration gaps that may influence the adoption of innovative solutions tailored to improve health outcomes is person-centred, and identify what is important for obese patients. The implementation of a persona and user scenario approach may also be useful for the early involvement of end-users in solutions' design and adaptation, increasing adherence, and the effectiveness of digital solutions. Persona profiles, the user scenario, and the related digital solution also consider the potential benefits that can derive for both patients and health system in term of reduced emergency room admissions, waiting lists, and health related expenditures.

1. Introduction

Current challenges for European health and social system

1.1 How old is the European population?

Aging should not represent an issue for the National Health Systems (NHS), but a new challenge and/or a new land to better explore to make the population age healthily, as good health represents the most important factor to live independly in old age. A better understanding of aging processes, the prevention of age-related illnesses and healthcare strategies are the principals to have people healthy and active in the course of their lives. In the last decades, older people (aged > 85 years) increased representing one of the most vulnerable and susceptible to diseases and disability portion of the population (Figure 1); as consequence of this fenomenon an increase of total ageing cost, including retirement, health care, long-term care and education expenditure, is expected in the next decades (3, 4) (Figure 2).

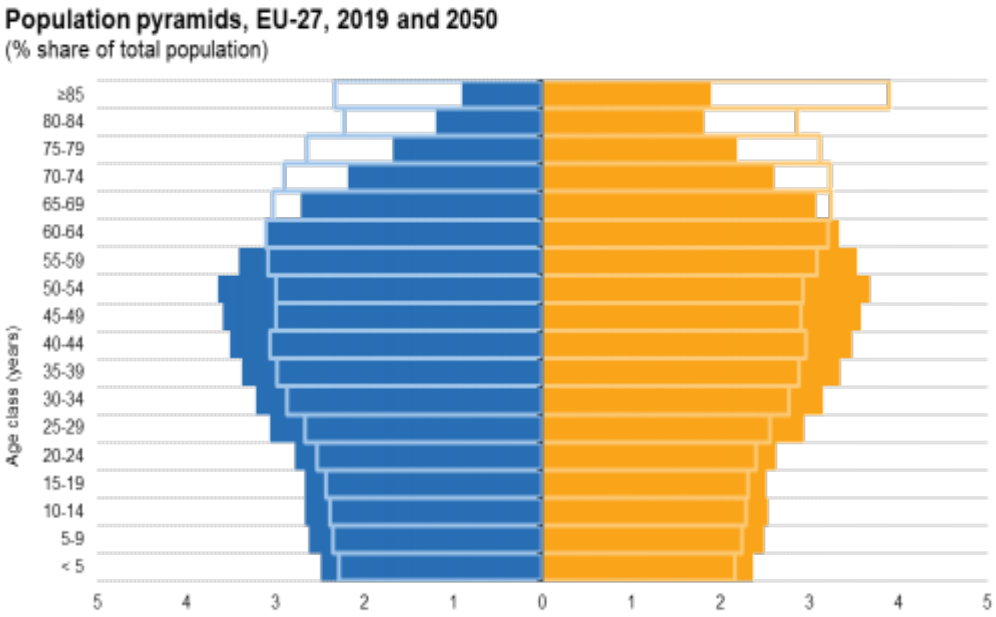


Figure 1 Population pyramids, representing the demographic transition across EUn the next three decades.Eu-27, 2019 (solid bars) and 2050 (bars with borders). All data as of 1st Jenuary 2019, estimated and provisional 2050 population according to the 2019 projections baseline variant (2) . Man: *Blue bars; Women: orange bars.*

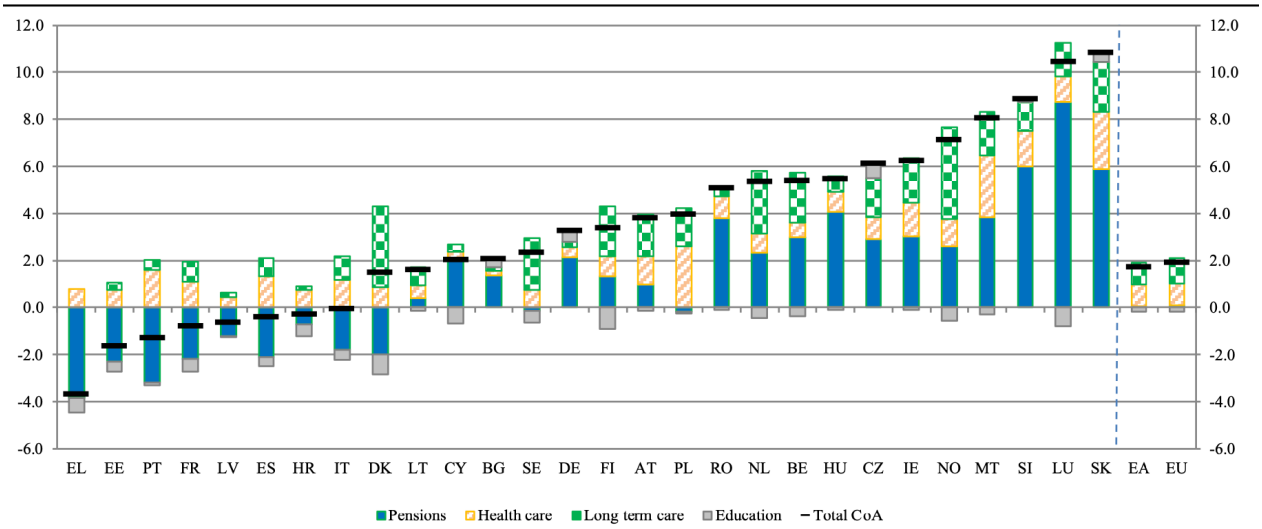


Figure 2 Projected change in age-related expenditure (2019-2070) (3)

Conceivable explanations of population ageing relate to increased life expectancy, paralleled by a drop in fertility rates. This fenomenon, defined as demographic ageing, means that the proportion of people of working age in the European Union (EU) is reducing, while the number of older people is rising (2) (Figure 3)

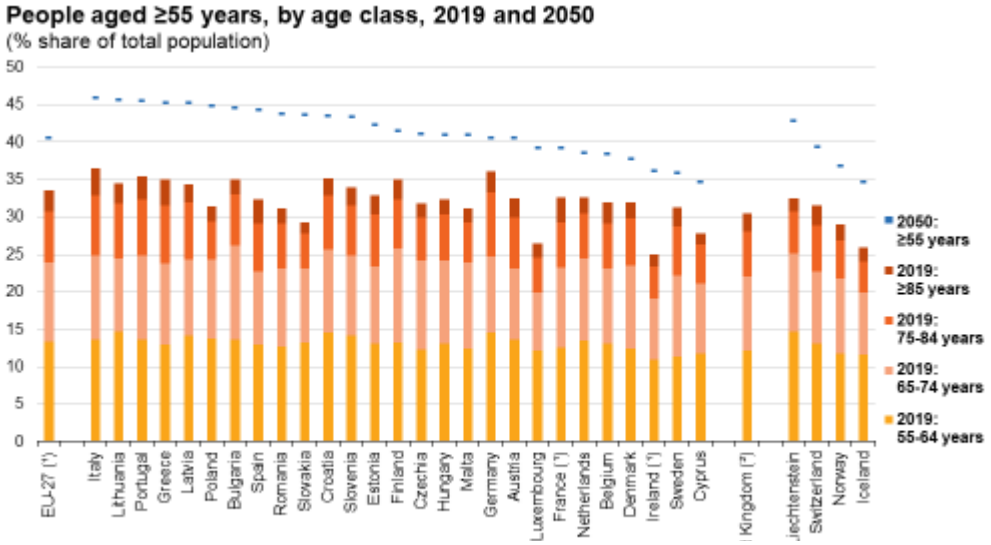


Figure 3 People aged ≥55 years, by age class, 2019 and 2050 (% share of total population). Ranked on the projection share aged ≥55 years in the total number of inhabitants in 2050, according to the 2019 projections. (2)

Indeed, it has been expected a boost of the European population from 446.8 million in 2019 to 449.3 million during the period 2026-2029, followed by a fall to 441.9 million by 2050. In particular, the working-age population (people aged between 15 and 64 years) will decrease from 333 million in

2016 to 292 million in 2070 (5), and older people will increase from 90.5 million at the start of 2019 to reach 129.8 million by 2050. As a result the median age is expected to rise by 4.5 years between 2019 and 2050, to reach 48.2 years by 2050, (Figure 4) (2) . Among the EU Member States, in particular Poland, Slovakia and Malta, the median age of the population is expected to increase by more than 8.0 years; Italy the median age is projected to increase by 6.3 years; France, Belgium, the Netherlands and Denmark their median age are projected to increase by 3.0-4.0 years; in Sweden is projected to increase by 2.6 years and Germany of 1.2 years (2, 6).

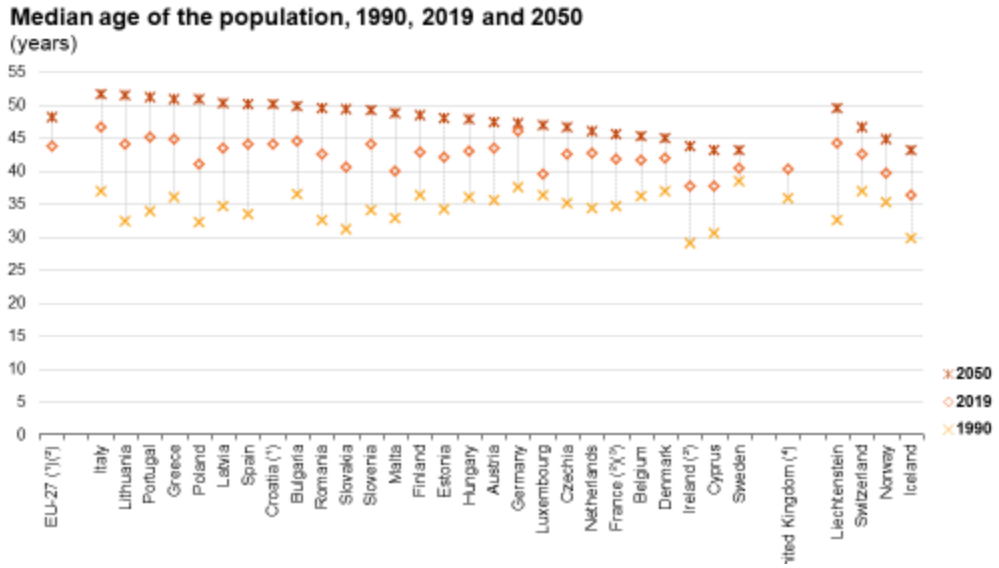


Figure 4 Median age of the population, 1990, 2019 and 2050 (2)

Older people living in rural area, especially those with reduced mobility, illness or social exclusion, are exposed to a lack of services, although these locations could represent a good place to retire. On the other hand, those living in urban areas are advantaged by a better access to public transport, public, commercial, and health care services. Older people accounted for a high share of the population in eastern Germany, northern Italy, and north-western Greece (28.9%, 28.5%, and 27%, respectively) (Figure 5)

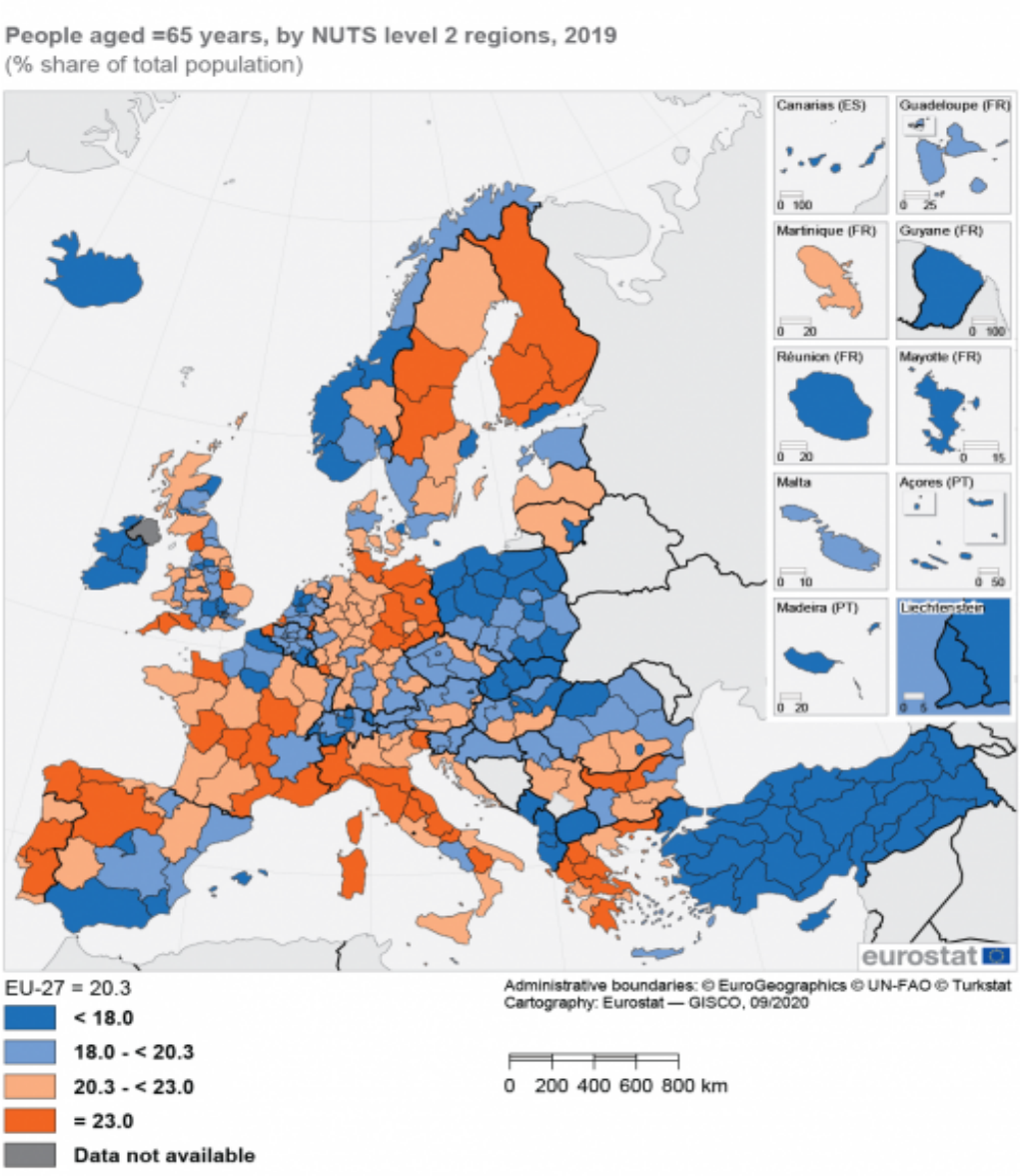


Figure 5 People aged ≥65 years, by Nomenclature of territorial units for statistics (NUTS) 2019 (% share of total population)(2).

Such developments will have profound implications, not only for individuals, but also for governments, business and civil society, impacting, among others: health and social care systems, labour markets, public finances and pension entitlements (7, 8) .

The 2021 Ageing Report, published every three years, showed that in the next decades the total costs associated with pensions, health care, long-term care, education and unemployed benefits are expected to rise by 0.4 percentage point than projected for the same period (1.7 percentage points to 26,7) by the 2018 Ageing Report between 2016 and 2070 as European citizens continues to age

significantly (3, 5). Consequently, the aging-related costs will be different among the Member States, and they will drop down in eight Member States (Greece, Croatia, France, Latvia, Estonia, Italy, Lithuania, and Spain); will increase by up to 3 percentage points in ten Member States (Portugal, Denmark, Cyprus, Poland, Sweden, Romania, Bulgaria, Finland, Hungary and Slovakia); and will rising by more than 3 percentage points in the remaining ten Member States (Netherlands, Austria, Ireland, Germany, United Kingdom, Belgium, Czech Republic, Slovakia,
Malta and Luxembourg) (3, 5) (Figure 6 A-B).

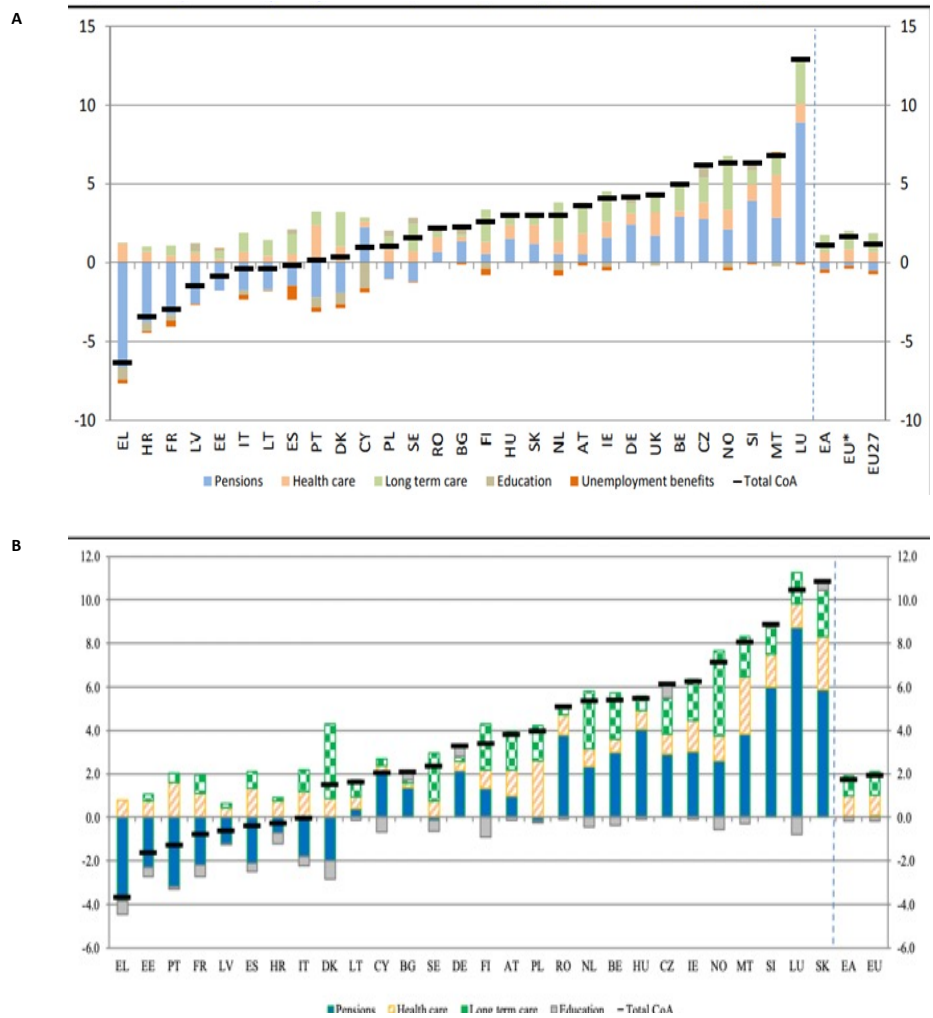


Figure 6 Projected change in age-related expenditure A) 2016-7 (2); B) 2019-2070 (3)

1.2 Ages and Health

Life from childhood to adulthood might be understood like a physical, emotional, social, psychological and biological change, but when these changes refer to people with complex health and care needs every day life leads to real and daily challenges (9, 10). Complex care needs refer to all of those related to multiple chronic conditions, that may determine functional and cognitive impairments, thus posing challenges for mental health, independency and wellbeing, and contribute to social vulnerability which significantly impacts on quality of life and relationships (9, 11). The biological process of ageing is very complex and irreversible, characterized by a wide variety of molecular and cellular changes most related to metabolic and cell cycle impairements, structural and functional tissues changes (9, 10). This biological changes lead to a reduction mental and physical reserve, increasing the risk of illness (12). On the other hand, social dimensions like homes, communities, sex, ethnicity and socioeconomics status also affect aging since early stages of life: more in detail, the place where people live as a child, personal behaviour, eating habits, physical activities, use of tobacco and alcohol impact and modify how people age.Despite the percentage of people with diseases and multiple chronic conditions rising over the years, there is the need to empowerpeople towards the different dimains of healthy aging, such as, healthy nutrition, physical activities, preservation of cognitive function. To achive this goal it is important to set up safe, equal, accessible, supportive, and integrated health care and social systems where none is socially isolated but all their needs are addressed (12).

In accordance with a recent World Health Organisation (WHO) Resolution (67/13), a comprehensive **Global Strategy and Action Plan on Ageing and Health** is being developed in collaboration with Member States and other partners. The Strategy and Action Plan draws on the evidence of the **World report on ageing and health** and builds on existing activities to address 5 priority areas for action (13).

1. **Commitment to Healthy Ageing.** Awareness of the value of Healthy Ageing, sustained commitments and actions are required to formulate evidence-based policies that strengthen the individual abilities of older persons.
2. **Aligning health systems with the needs of older populations.** Health systems need to be better organized around older people's needs and preferences, in order to enhance older peoples intrinsic capacity, and integrated services across settings and care providers. Actions in this area are closely aligned with other WHO initiatives to strengthen universal healthcare and people-centred and integrated health services.

3. **Developing systems for providing long-term care.** Long-term care are needed in all countries to meet the needs of older people. This requires developing governance systems, infrastructure and workforce capacity. WHO effort on long-term care (including palliative care) contributesto enhance universal health coverage, addressing non-communicable diseases, and developing people-centred and integrated health services.
4. **Creating age-friendly environments.** Actions are needed to combat ageism, enable autonomy and support Healthy Ageing in all policies and at all levels of government. These activities build on the WHO work implemented during the past decade to develop age-friendly cities and communities, including the development of the Global Network of Age Friendly Cities and Communities and an interactive information sharing platform for an Age-friendly World.
5. **Improving measurement, monitoring and understanding.** Research, new indicators and analytical methods are needed for a wide range of ageing issues. This work builds on the extensive work WHO has done in improving health statistics and information, for example through the WHO Study on global AGEing and adult health (SAGE)

In 2012 the WHO Regional Office for Europe published 4 strategies and action plans for healthy aging in Europe 2012-2020 (14). The first objective named "Healthy ageing over the life course", is the delivering of health promotion and disease prevention services for healthy ageing by some actions in particular for persons aged ≥ 50 years, developing instruments for evaluation and monitoring of the implementation of policies for healthy ageing, supporting reporting systems and research to monitor the successful of the health system. The second objective named "Supportive environments" aims to engage communities in developing strategies for becoming more age-friendly, by supporting older people to play an active role in their social context. The third objective named "People-centered health and long-term care systems fit for aging populations" are the response of health systems to aging through high-quality services and social protection by contributing to research, documentation, and spreading of good practices related to new models of healthcare delivery and access to information (including e-Health). Moreover, health literacy is emphasized, as well as supporting home care and disease management programs, promoting policies for financial protection to guarantee universal access to health and social care (e.g. cost-sharing regulations), strengthening primary care interventions and promoting a proactive approach to chronic diseases prevention (primary, secondary and tertiary) beside an integrated healthcare approach. The fourth objective named "Strengthening the

evidence base and research" aims to strengthen the capacity to assess and monitor older adults health and functional status and to improve accessibility to social and health care services.

Actions by the Member States mostly refer to monitor the health and social care services and their utilization and accessibility by older adults, by improving the system's capacity to monitor the demographic, social and health conditions, along with the creation of excellence centers for research on healthy aging policies (15). Therefore, the European Commission aimed to promote:

- Physical activity
- Falls preventions, to reduce accidental falls and linked diseases among older adults through exercise programs, physical therapy, and home safety assessment and by specific programs addressing the risk factors related to disease conditions.
- Reduction in the gaps in vaccination against common infectious diseases that bring older people to have health risks (morbidity and mortality).
- Support for informal caregivers and older patients in home care, and self-care. This means making informal care sustainable and improving health and well-being of those in need of care and their caregivers..

1.3 The shift from acute-centered to integrated care

Increasing chronicity and multi-morbidity across the EU is leading to growing demand for integrated care (16). *Integrated care* means a close collaboration and shared information between health professionals, patients, health organisations and specialties, aimed to improve health, well-being and indipendence of patients, containing the economicand social burden of diseases (17, 18) (Figure 6). These concepts are likely to be shaped by the views and expectations of various stakeholders in a specific health system: hence the need to review the concepts, types of integration, models of care, and cost available in literature, to better understand the potential and benefits of adopting an integrated care system, and customise the approach to implementation.

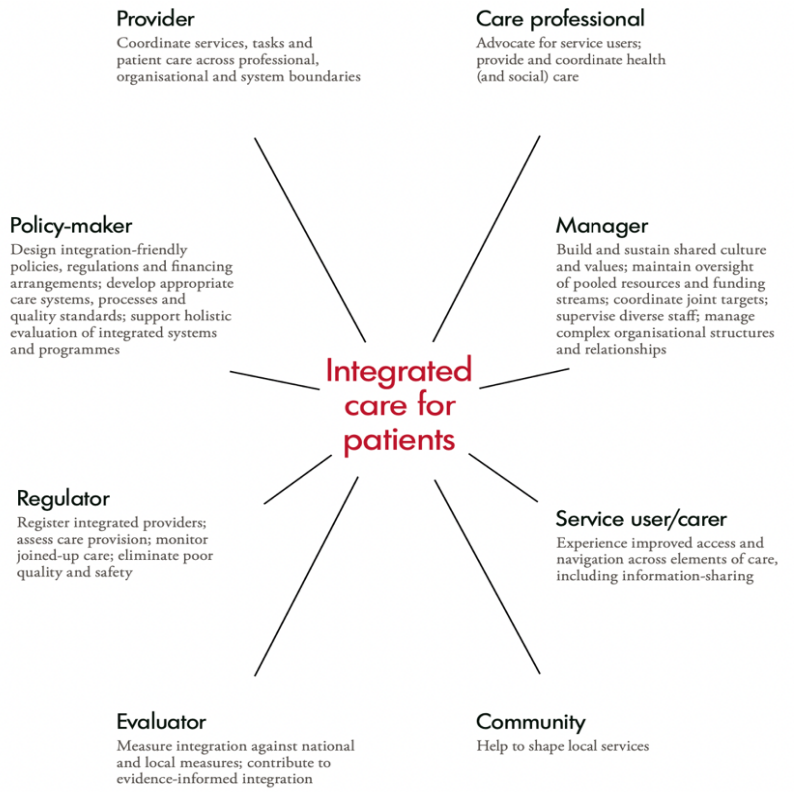


Figure 7 Perspectives shaping integrated care (18)

Three different approaches can be identified (15) focusing on patients, familes and community needs:

1. **A process-based definition to understand the different components of integrated care.**
   The focus of this approach is to identify and reach the best care model and life-styles, and service integration in order to improve population well-being.
2. **A user-centered definition ofintegrated care strategies at all levels of the system.**
   The Government of England represent a practical example of this concept, where the frame of integrated care is defined by the population themselves throuthg a patients representive; This approach highlights the importance of patient involment in the development, implementation and evaluation of integrated care model(19).
3. **A health system-based definition, as adopted by WHO Regional Office for Europe.**
   The WHO Regional Office promotes the "integrated health services delivery" (IHSD) to strengthen people-centred health through the collaboration and shared information in the entire health system and stakeholders involvement in the disease management(15, 20).

Moreover, to achieve a good integration of services four types of integration can be adopted:

Organizational integration is represented by close collaboration between organization through networks; *Fuctional integration* refers to an integration combined with ICT solutions, for example Eletronic Health Record (EHR); *Service integration* refers to the establishment of multidisciplinary teams; *Clinal integration* refers toshared guidelines and protocols among professionals (15, 19);

A wide range of integrated care models form individual to disease-specific model are available (15). More in detail, an individual integrated care models is often reliable to the patient with multimorbidity and/or long-term conditions by creating a multidisciplinary team (21) (i.e case management, individual care planning (22), a patient-centred medical home (PCMH) (23) and personal health budgets (24). These care plans are expensive and intensive. Patients' health literacy is necessary tounderstand the care plans and to adhere to the constant change based on patients feed-back and periodic assessment (15).

Group and diseases specific models are mostly dedicated to older adults and frail older adults, as they are aimed at sustaining functional independency (i.e. *PRISMA* the Canadian model (25)), and i management of chronic disease(26). The population-based model include examples of integrated care services adopted in a EU Member State and in USA, such as the Kaiser Permanente (KP)(27), Veterans Health Administration (VHA)(28) and Integrated care in Basque country (29). The KP and VHA are typical USA models based on stratification of the population based on their health and social needs, and the supply of different type of services according to needs, in an integrated way. Moreover, KP model is based on the promotion and prevention services, assessing the risk factors exposure, while VHA is aimed to enabling patient self-management (27, 28). Integrated care in Basque country aimed to remodel health care service in order to enhance care provision for patient with chronic disease through a collaboration among primary care, social services and hospitals, to achieve better outcomes (29).

As the prevalence of chronic diseases is rising due to the increased ageing population across the countries, governments are challenged both to ensure a better quality of life and diseaseself-management, and to counteract the elevated cost of universal healthcare provision(2, 5, 30, 31). Handling a patient with multiple clinical conditions raises an issue of both clinical and social. By following separated guidelines for the management of different disease, service overlapping happens in the management of common symptoms at diagnostic-therapeutic and social level (32).

How can governments strenghen the integration of health services for care and cure? This is not an easy goal to persue, and a lot needs to be done both at clinical and social level across the countries.

The Members of the Committee on Integrating Social Needs Care into the Delivery of Health Care to Improve the Nation's Health, Washington (USA), analyzed the social determinatns of health (SDOH) which could affect pisitively or negatively people's health, and indentifed five activities (awareness, adjustment, assistance, alignment, and advocacy) to strengthen integration, taking in consideration not only the type of infrastucture and indivudual needs, but also the social determinants of health (the conditions in which people are born, grow, live, work and age) acting on their community (Figure 8A,B) (33). The specific activities adopted differs across and whithin the health care system, according to the social needs addressed. More in details, *adjustment and assistance* aim to improve care delivery to patients based on their social condition that could reduce or defeat a risk; *alignment and advocacy* aim to optimize procurement and investment on social care resourses (Figure 8B). Each activity depends on the level of maturity,including digital innovation and financing models (33).

Evidence on how SDOH impact on health led to a greater awareness that improving health and reducing health inequalities depend on improving social conditions. In this context, the combination of diseasae prevention and health promotion, with subsequent improvement of health and related outcomes of the population rather than just delivery of services, are needed to boost health care system at social and clinical level. The results of this combination, of course, depends on the ability of the health systems to link the needs of patients (clinical and social) to policy-makers and relevant stakeholders (33) (Figure 8A).

A

Social Determinant of Health	Examples of Underlying Factors
Economic stability	Employment Food insecurity Housing instability Poverty
Education	Early childhood education and development Enrollment in higher education High school graduation Language and literacy
Social and community context	Civic participation Discrimination Incarceration Social cohesion
Health and health care	Access to health care Access to primary care Health literacy
Neighborhood and built environment	Access to foods that support healthy eating patterns Crime and violence Environmental conditions Quality of housing

B

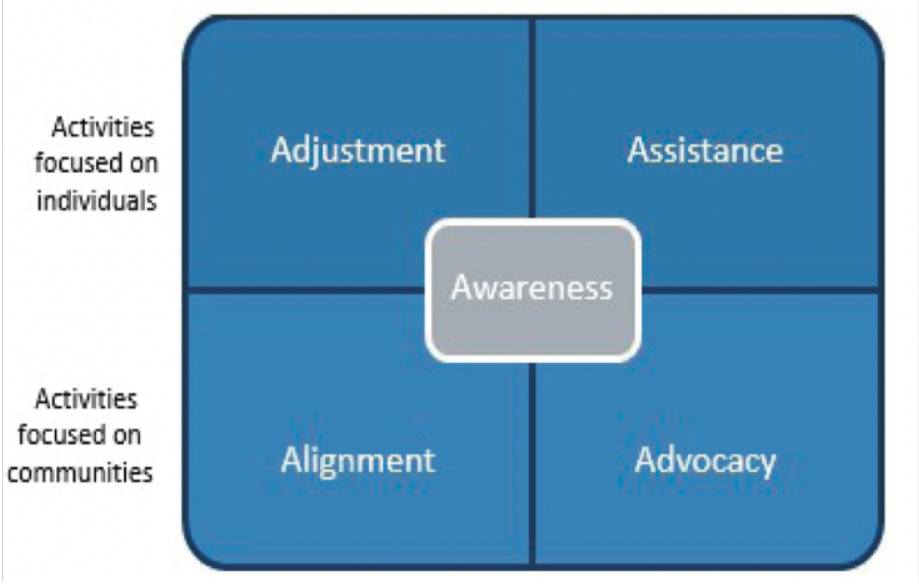


Figure 8 A) Social determinatns of health (SDOH) wich could affect positively or negatively people's health; **(B)** Health care system activities to strength social health care integration (33)

The development and adoption of digital tools allows to find new answers to traditional problems of health and medicine, and to improve the integration of services by strengthening the collaboration between the different professionals involved. Furthermore, digitally-supported services improve accessibility and ensure equity. The advantages of the new models based on ICT supported integrated care is represented by a potential rationalization of social and health processes with a possible impact on the containment of health expenditure, reducing the social cost of diseases. If correctly used, ICT based integrated services can contribute to a transformation of the health sector and a substantial change in the underpinning business models. Hence there is an urgent need to validate new approaches and solutions, through large-scale pilot studies, measuring the impact and barriers to the adoption of patient-centered care models, capable of providing both continuities of hospital-territory care and the integration of social and health care.

1.4 European Innovation Partnership on Active and Healthy Ageing

The European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) was created in 2011, bythe European Commission, to promote innovation and digital transformation in active and healthy aging (1). The partnership, includes members from academia, public authorities, industries, health and care organizations, investors and patient's organizations belonging to different European Member States (MS) (1). The European population is ageing rapidly and the number of people over 65 and 80 years will double in the next 50 years (2). In this way, the European population life expectancy will increase, but living longer does not mean living a healthy life, instead people have to deal with an unhealthy life often characterized by chronic diseases, polytherapy, multimorbidity, exposure to risk factors (clinical and social) representing almost 20% of years of our life (1). The EIP on AHA provided to all the European MS and regional ecosystems a chance to ensure to their older adults a healthy ageing, and to the younger generations the promotion of a healthy and active lifestyle by providing innovative solutions with the aim to reduce comorbidity in older age, and icrease the average healthy life of European population of 2 years (1). Based on these evidence, the EIP on AHA has been promoting an action focused on three general objectives (1, 34):

1. Enhancing European population life promoting a healthy life style during ageing;
2. Supporting sustainability and efficiency of health and social care systems;

Scaling up of good practices in digital health to improve the EU competitiveness. To achieve these goals, the EIP on AHA has been acting along two main pillars: Action Group (AG) and Reference Sites (RS) (1).

In 2013, 500 commitments were submitted from organisations to contribute to the objectives identified in thestrategic implementation plan, and 32 RS were recognised as excellence sites for innovation in AHA (1, 34). Subsequently, 2 further calls were issued by the European Commission, in 2016 and 20219,to broaden the community of the EIPonAHA, that engaged 113 Reference Sites, currently joined in a network: the Reference Site Collaborative Network (RSCN) (35).

The Action Groups are communities of partners working together on specific topics, to improve active and healthy aging and promoting healthy and indipendent lifes in a smart, healthy and age friendly environment (SHAFE) (36). This main objective can be achieved by the identification of people needs to address, and sharing knowledge and experience on good practices with other colleagues across the EU. Different stakeholders like academics, industry, health care organization and citizens are involved at local, ragional, national and European level in an ecosystem characterized by an open innovation quadruple helix model. The EIP on AHA AGs from 2013 to 2020 have been working on six main topics:

A1 Adherence to prescription and medical plans.

- A1 AG aims to strengthen the adherence to polytherapy prescrition and management of multimorbidity, through an integrated approach to medication review, supported by innovative digital tools and service models. A lot of actions, initiatives, and research projectshave been performed inEuropean countries between 2016-2018 to identify factors affecting adherence to polytherapy in 65 years older patients, and their prevalence. (37).

A2 Fall Prevention

The A2 Action Group focuses on good practices to prevent falls in older adults. Falls represent the main cause of disability in people over aged 65 (34, 38). Recent data demonstrated that less then half of persons who fall consult a physician; almost 30% of falls needs a medical treatment, 5% and 1% of falls induced fractures and hip injuries, respectively (34, 39, 40).

The A2 Action Group activities identified new tools supporting evidence-based fall prevention approaches to promote local, regional and/or national level fall prevention and risk assessment services and policies.

A3 Lifespan Health Promotion & Prevention of Age-Related Frailty and Disease

The A3 Action Group of EIP on AHA aims to prevent functional decline and frailty by improving the adherenceto healthy lifestyles, along the entire life, in order to improve health outcomes in older adultspopulation. Their work was focused on four domains: Food and Nutrition, Physical Activity, Frailty, and Cognitive decline (1). Different tools have been developed by all stakeholders involved,

for the screening of frailty and its determinants (SUNFRAIL commitment), Common definition of frailty and prevention campaigns (ADVANTAGE Joint Action); managing cognitive decline (i-PROGNOSIS Personalized Game Suite approach); digital solution to support and monitor older patients at home (Aicare platform) (1, 41).

B3 integrated care for chronic diseases

The B3 AG focuses on the implementation of integrated caremodels in the health systems, to improve continuity of service provision, and reduce unnecessary hospitalization. The stakeholders involved in this group have been able to develop self-assessment tools to help patients in the diseases management; guidelines for integrated management of respiratory diseases; analysis of the risk of stratification to sharpen the focus of the health care system services (1).

C2 Independent living solutions

(4), The C2 AG objective is to develop independent living solutions to improve the so called Healthy Life Years (HLY) as well as disability-free life expectancy (1).

D4 Age friendly environments

D4 AG aims to develop age-friendly environments to support AHA inmore inclusive societies.Tha D4 Action Group developed initiatives and good practices for empowerment of older adults in the use of digital solution, and to involvement of local, ragional and national authorities (1) to enhance Smart, Health and Age-Friendly Environments (36).

The **Reference Site (RS) of the EIP on AHA** are innovation ecosystems delivering creative and workable approaches and solutions that improve the lives and health of older adults and the whole community, including relevant stakeholders from a regional and local level. The RSs arebased on a Quadruple Helix model, including stakeholders form Academia, Health Authorities, Business and Patients organisations, and aim to identify, develop and test innovative solutions addressing AHA at local level and to transfer innovation across the EU (42). In 2019, 113 RS were indentified in Europe, and more than 200 innovative and good practices on digital transformation have been published (1, 43)

The EIP on AHA Action Groups and Reference Sites joined forces to contribute to the implementation of three coherent initiatives supporting development and transfer of innovation on AHA: the *Blueprint for the digital transformation of health and care,* the *Innovation To Market Plan* (*I2M),* and the *Monitoring and Assessment Framework* (*MAFEIP*) (Figure 9) (1).

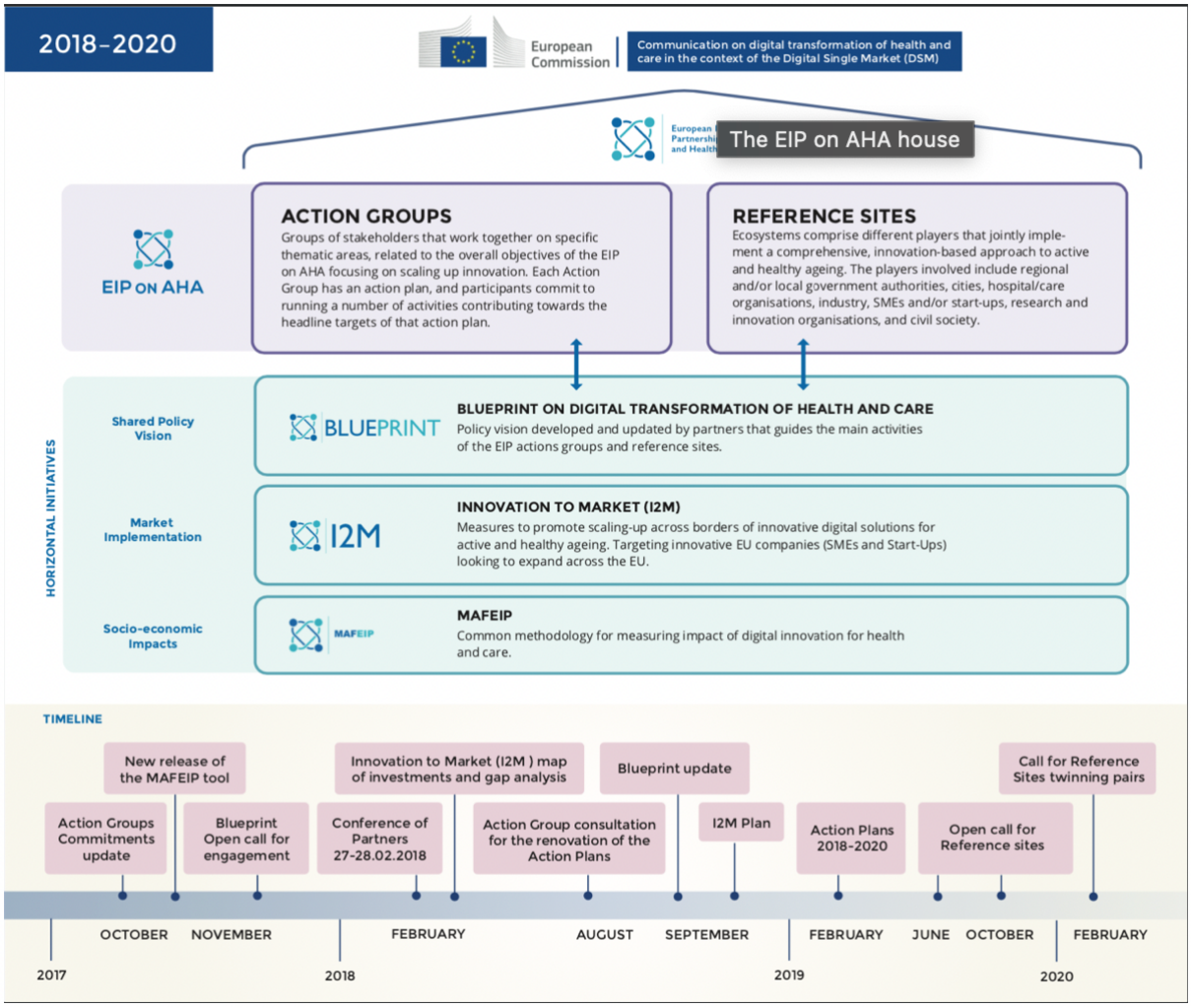


Figure 9 European Innovation Partnership on Active and Healthy Ageing (1)

1.5 European Blueprint on Digital Transformation of Health and Care for the Ageing Society

The European Blueprint on Digital Transformation of Health and Care for the Ageing Society (Blueprint) was presented for the first time at the EIP on AHA (1) Conference in December 2016. In the first update in 2017, it was efined as a shared policy vision by different stakeholders, incluging policy makers, civil society, professional organisations and industry, it represents a new approach in mobilising investments and commitments in the digital transformation of health and care (44).

The Blueprint aimed to involve relevant stakeholders and support regions in investing in innovative digital solutions accessible to be transferred at European level. The Blueprint identified user scenarios

for large-scale application of innovative solutions in AHA. More in details, the Coordination & Support Action " WE4AHA" facilitated EIP on AHA participants to invest in new digital solution for AHA, achieving the following mailstones (45, 46) (Figure 10):

- reach out to more than 50 regions that will invest in the implementation and/or deployment of large scale, sustainable, digital solutions for active and health ageing;
- reach a total of € 500 million of investments in digital innovation for health & care;
- reach an additional 4 million people in Europe who will benefit from digital innovations in active and health ageing (46) (47).

The WE4AHA project belongs to H2020 Programme. It is focused on development of support and promotion activitiess for a better large-scale dissemination of Digital Innovation for Active and Healthy Ageing (48).

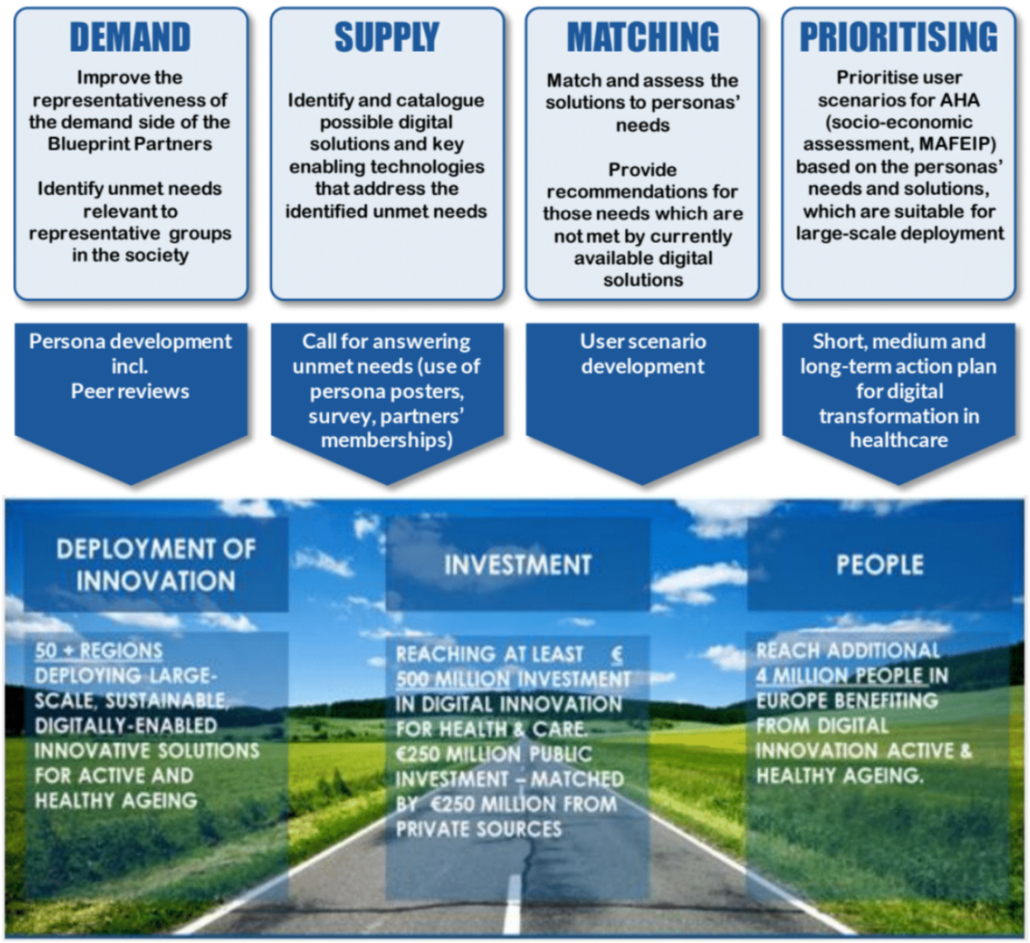


Figure 10 Overview of tasks in relation to overall Blueprint goals (47)

Four main priority topics have been identified to achieve these objectives (Figure 11):

1. **Data analytics for predictive risk stratification and prevention**, to support health management. Difficulties in this area were represented by the lack ofICT solutions able to collect and aggregate data, and help in the management of care plan.
2. **Proactive prevention through empowerment, self-management, monitoring, and coaching,** to promote primary and secondary population prevention through programs on citizen/patient empowerment, self-management, monitoring, and coaching.
3. **Digital solutions for connected health**, to enable people stay at home and be supported by connected services for chronic care management. Connected health promotes both the self-management of long-term conditions and the delivery of continuous health across the population.
4. **Digital support for integrated care**, to involve multidisciplinary team work and care coordination among carers (health and social care services); to promote interoperable exchange of health and clinical data among care providers, delivery of services along a health and care pathway, and the provision of patient- centred service.

An example of the avaibility of tools and model for patients and care professionals for a better self-care management by enabling digital tools for health literacy, care pathways management communication, workforce management, can be represented by the Home & Mobile Health Monitoring (HMHM) Citizens Enabled program supporting patients with complex needs, as long-term chronic conditions in Scotland.

Subesequenlty, with the second update in 2018, the document discrebed the Blueprint Partners' work and recommendations on the four health and care priority topic areas, but also the identification of population health and care needs using a "personas" approach, and to develop/adapt ICT solutions able to adrees patients' needs (49). The rational was to develop *personas*, *use case*, and *user scenario* and understand how people interact with the ICT technology(47) (Figure 10). A persona defined a single, specific hypothetical/fictitious person who represents a segment of the user population (50-53). with a realistic name, a face, and a description of their character (needs, goals, hopes, dreams, and attitudes). The Blueprint persona descriptions, developed by the Blueprint Partners, include also behavioral characteristics, which could affect both short-term and long-term success with interventions directed toward managing a disease or adopting wellness (53, 54), for example, a persona's trust or lack of trust in care professionals, their self-management capabilities, and specific details about their character (e.g., being prone to aggressive behavior or having the tendency to reject outside support).

Use case defined typically daily persona action and identify which type of digital solution or services fit with the action identified (55).

A user scenario based on the interaction between the persona actions and needs, and ICT solutions identified, analysed the effects of the expected health outcomes. For example, the effects of the Artificial Intelligence (AI) on preventine healthcare can be analysed in a user scenario (47).

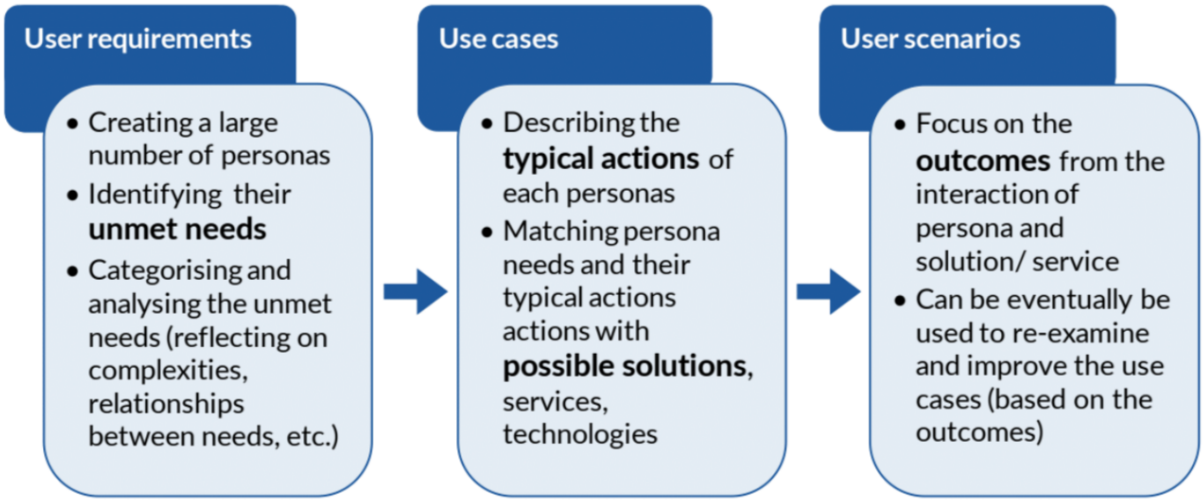


Figure 11 Possible IT developmentstrategy adapted to the Blueprint context (47)

1.6 Obesity

Obesity has become a global challenge, and its prevalence has tripled worldwide since 1975 (56) and has been defined by the WHO as the largest global chronic disease (57). Overweight and obesity are associated with increased morbidity, mortality, and health care expenditures, with a significant negative impact on health-related quality of life (58-60). It has been estimated that in 2016 1.9 billion adults of 18 years and older were overweight, of these over 650 million were obese and at least 2.8 million people die each year worldwide as a result of overweight or conditions related to obesity (61). Initially considered only a problem for high-income countries, overweight and obesity are dramatically increasing in low- and middle-income countries too, particularly in urban settings.

In Europe, more than half of the population is overweight and obese (62), reporting that in 2015 the overall obesity rate among adults is 21.5% in males and 24.5% in females (63).

WHO and the World Obesity Federation (WOF) define overweight and obesity as a chronic, relapsing, progressive, and multifactorial disease related to several conditions, characterized by an abnormal or excessive fat accumulation with a dramatic impact on economic and social costs (64-67) in terms of both healthcare expenditures and premature morbidity and mortality (60). An adult is classified as obese or overweight when his weight is higher then a healthy adult weight based on Body Mass Index (BMI), although it doesn't correlate directly with fat accumulation but with other body measurements like skin fold thickness measurements, bioelectrical impedance, underwater weighing, dual energy x-ray absorptiometry (DXA) (40). A BMI ranged between 18.5 and 24.9 Kg/m^2 defines a healthy condition; a BMI ranged between 25 and 29.9 Kg/m^2 define an overweight condition; while a BMI $\geq$ 30 Kg/m^2 define an obese condition. Consequently, there are three stages of obesity: Class 1 (BMI between 30 and 34.9) mild condition, Class 2 (BMI between 35 and 39.9) moderate condition, and Class 3 (BMI >40) considerate as extreme /severe condition (40, 57, 68, 69).

Obesity is caused by an energy imbalance due to a higher intake compared to energy expended (67). People prefer "energy-dense" foods and drinks, associated with modest or poor physical activity (70). Paradoxically, an obese patient presents a clinical picture of malnutrition or nutrition deficiencies because of the effect of the so-called "obesogenic diet" rich in refined sugar, saturated fat, and sodium and deficient in folate, copper, iron, calcium, protein, and vitamins (64, 65) and decreased muscle mass, weakness, edema, and/or an impaired immune respons (71-74). Lower levels of Vitamin A, B, and C are associated, for example, with moderately elevated C-reactive protein (CRP) concentration, which means a higher inflammation status, eventually leading to the development of different chronic

diseases (CD) (75, 76); whereas low levels of Vitamin D (Vit.D), very common in obese patients with prevalence rates as high as 90% (64, 65), correlate with the incidence of type 2 diabetes mellitus (T2DM). Micronutrient deficit such as lower blood iron, zinc (77-79), and magnesium (80-82) levels could represent the possible cause for some clinical conditions such as anemia (45% of obese patients) (83-85), metabolic syndrome (86), or a reduced magnesium intestinal absorption (86) as demonstrated in some studies in obese patients before bariatric surgery (86-88).

Healthy dietary habits represent a common issue among different society, and need a multisectoral, multi-disciplinary, and cultural approach to be changed (67). Indeed, unhealthy diets and physical inactivity are major risk factors for chronic diseases, and for this reason the WHO promotes healthy dietary habits giving some tips such as:

1. achieve energy balance and a healthy weight
2. limit energy intake from total fats and shift fat consumption away from saturated fats to unsaturated fats and towards the elimination of trans-fatty acids
3. increase consumption of fruits and vegetables, and legumes, whole grains and nuts
4. limit the intake of free sugars
5. limit salt (sodium) consumption from all sources and ensure that salt is iodized

Overweight and obesity have a high impact on multiple physical and psychological parameters.

Chronic stress, as well as discrimination, play a role not only in the development but also in the persistence of obesity (89), and it has a deep psychological and physical impact resulting in eating behavioral changes, psychosocial stress, and indirect effects on social relationships (90-92). Some researchers have defined obesity as a "neuropsychological disease" (93) because, apart from the impact on the impairment of physical functioning, health perceptions, and vitality, the scientific evidence suggests a link with mental disorders such as depression, anxiety, panic disorders or mood disturbances. In turn, psychiatric disorders can also cause obesity as a result of drugs' effects or hormone imbalances, leading to mental illness as a result of poor self-image and physical conditions (94-97). Indeed, a history of mental illness may increase the risk of developing obesity, while obesity may increase an individual's chances of developing a psychiatric disorder (98). Men and women present a different link between mental health and obesity (99, 100). Obese adolescent and adult females have a higher probability of developing depression than obese male counterparts (101-104). Surprisingly, some interesting data have demonstrated that symptoms of depression, anxiety, and stress started to drop significantly after adopting a Mediterranean lifestyle for three weeks (105), or

participants stated they feel better emotionally and physically after participating in dietary counseling sessions that made them feel they had better control over their disease (68).

Several studies provide clear indications that all Western countries, including Italy, are witnessing real epidemics of adult and childhood obesity and Non-Communicable Diseases (NCDs), mostly because of the dramatic changes that have occurred in both food systems and consumer eating habits and behaviors globally (106, 107). A balanced healthy diet is not the same for every individual – while the principles may be the same, several factors influence the results: age, gender, lifestyle and degree of physical activity, cultural context, locally available foods, and dietary habits (108-110). In this framework, the Mediterranean lifestyle represents an example of an effective approach to counteract obesity, and might be effective in the treatment of some chronic conditions such as diabetes, metabolic syndrome, and cardiovascular diseases (111-120).

Lifestyle modification programs based on weight loss interventions, self-monitoring, and coaching represent the first-line approach in the treatment of obesity (121, 122). These programs however are not always applicable and difficult to use because of the time required to run the programs, lack of expertise from healthcare providers, the financial burden to patients, or issues with the insurance companies (123).

Digital health solutions have the potential to represent a new tool to manage patients on health interventions through mobile apps, wearable devices, telemedicine, or video games (124, 125). Mobile apps can promote a healthy lifestyle, encourage to be more active and healthy as well as smartphone-based physical activity coaching interventions; indeed users started to feel better and healthier by using it (125), suggesting that digital health solutions are capable to improve physical activity levels (44). In this highly fragmented and complicated context, there is an urgent need to develop appropriate policies, programs, and campaigns for nutritional counseling and education of citizens based on scientific, solid evidence and shared verifiable information. The Mediterranean Diet represents a primary food approach that is tailored to the local sociocultural context and may be adapted to become a sustainable intervention to integrate with service providers for specific persona types.

1.7 Digital Health solution supporting integrated care in obese patients: the WHO and European vision

The World Health Organization (WHO) is carrying out new strategies to promote digital health solutions to decrease the obesity rate in all countries by 2025 (126). Despite progress, many countries still require support to develop national digital health strategies. The Global Strategy on digital health 2020-2025 aims to enhance the digital health networks, promote higher standards for health services and their accessibility, and to integrate financial, organizational, human, and technological resources for the best use of digital services (127, 128). In this framework, the health-related sustainable development goals (SDGs) and the Thirteenth General Programme of Work (GPW13) play an important role in supporting the development of digital solutions ensuring healthy lives and promoting well-being at all ages (129, 130). Digital health indeed provides concrete and valuable options to enhance health and well-being supporting the development of national programs to improve health care delivery and strategies, to ensure universal health coverage and availability of good health data and reporting related to SDGs (127, 131), and identifies digital services to promote equitable and universal access to health for all related to GPW13 (130).

In line with WHO, Europe promotes a smart and inclusive health approach with the EU's 10-year economic-growth strategy in order to keep people healthy and active for longer and make the healthcare sector more sustainable (132). Among the different actions promoted by the EU's 10-year economic-growth strategy, the Innovation Union and Digital Agenda for Europe are the most relevant. The Innovation Union objectives push for new innovative approaches to achieve an Active and Healthy Aging (AHA) across the European countries (44, 132). For this purpose, in 2011 a pilot European Innovation Partnership on Active and Healthy Ageing was launched, of which Blueprint on Digital Transformation of Health and Care for the Ageing Society represents a model of application (44, 133), aiming to improve the average healthy lifespan in the EU. To achieve this set goal, the telated pilot aim at improving the efficacy and sustainability of the healthcare system by innovative products and services that respond to the aging challenges, and contribute to EU citizens' health literacy to ensure them an AHA (45).

The Digital Agenda for Europe aims to enable the use of digital application or services across the European Countries in order to achieve a better quality of life and care by promoting independent living among sick citizen or citizens with disabilities, importantly also reducing medical costs (44, 45,

134). For this purpose, ensuring online access to their medical health data or taking the chance to develop telemedicine fostering interoperability and eHealth certification in all the EU Member State is a real challenge to achieve (44, 45, 135).

In particular, the European Commission (136, 137) is trying to respond to the global rise of overweight and obesity by adopting the White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity-related Health issues (138). Indeed, the EIP on AHA Action Group A3 on Food and Nutrition developed an innovative approach to malnutrition in older adults, which links assessment to adequate interventions (primary/secondary/tertiary levels) and aims to implement innovative tools for effective measures of prevention, detection, and treatment of obesity and malnutrition (139), while the "Blueprint on Digital Transformation of Health and Care for the Ageing Society" deals with the challenging aspects on how innovation can transform health and care provision in our aging society in key health and care topic areas which benefit from digital transformation using a life-course approach (44). (See Table 1).

The European Commission is working to provide its citizens access to safe and top-quality digital services in health and care in different ways. The digital transformation of health care will benefit people, health care systems, and the economy: indeed, digital technologies such as 4G/5G mobile communication, artificial intelligence, or supercomputing offer new opportunities to transform health and care service by enabling innovative approaches to independent living or integrated health and social care. Health data and advanced data analytics can help accelerate scientific research, personalized medicine, early diagnosis of diseases, and more effective treatments [84].

The Digital Single Market (DSM) designates the strategy of the European Commission for the best access to the online world for individuals and businesses. A DSM is one in which persons, services, capital, individuals, and businesses can access and engage in online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence (134).

PUBLIC HEALTH is a Best Practice Portal, a "one-stop-shop" for consulting good and best practices collected in actions co-funded under the Health Programmes and for submitting practices for assessment (140). The Directorate-General for Health and Food Safety (DG SANTE) aimed to identify, disseminate and transfer best practices to progress in health promotion and NCD prevention and management in Europe, and to reduce premature mortality from NCD by one-third by 2030, through prevention and treatment (140). An example of a good approach to this topic comes from Ireland. Little Bites, a one-stop-shop for food safety, food allergen, and healthy eating advice for all

early childcare providers, developed in collaboration with Early Childhood Ireland (141) and Safefood (142) represent a hub that provides excellent downloadable resources, recipes and some lovely videos and photos of children enjoying their dining experiences in Irish early childhood settings.

1.8 The Italian approach to obesity

Obesity rate is rising across the European Countries, with a significant impact on people physical and mental health, and health related costs (56, 57). Governments are not fully prepared to handle the consequences, in terms of services provided, and knowledge of obesity and overweight prevalence. Several conflicting studies estimated the annual cost related to obesity. More in details, International Association for the Study of Obesity (IASO) (143), estimated that the annual costs represented 6.7% of public health care expenditure (cardiovascular diseases, diabetes, dietician) at around €8.3 billion year; whereas Butland et al. report suggested higher estimated cost around €28.2 billion per year (hospitalization, diagnostic, and pharmaceutical costs) and by 2025 they will increase of 45% (144). In Italy it has been demonstrated that 10.3% and 36.5% of adults population is obese or overweight, respectively; whereas the incidence of obese children is higher in the South of the country compared to the North, especially in Calabria Region (49% of children are overweight or obese) compared to Bolzano (15% of children are obesy or overweight), and between gender. Probably, the main cause of the gap between Northen and Southern Italy has been related to the the different school educational level and/or health literacy (69). Taking a look at the Italian National Prevention Plan 2020-2025 (145) focusing on NCD and healthy lifestyle promotion, we can ascertain that no specific National Plan handling obesity has been included. The National Prevention Plan mentions obesity prevention programs aiming at increasing skills in the sector and exchanging experiences through the promotion of knowledge based on training activities on the best obesity prevention practices; identifying and disseminating effective methods related to obesity prevention, through a repository based on Evidence-Based Prevention (EBP); sharing good clinical practices, through a webspace dedicated to the dissemination of the most significant documents in the literature, sharing intervention protocols, strategies for evaluating interventions and results, and supporting local prevention interventions (145). On the other hands, the National Plan for Chronic Diseases instead, aims to improve the protection of patients with chronic diseases; reduce the burden on the individual, their family, and the social context; improve the quality of life; make health services more effective and efficient in terms of prevention and assistance, and fair access for citizens. The Plan identifies a list of chronic diseases for which there is no specific plan yet available at the national level by using epidemiological studies on their

severity, invalidity, welfare and economic weight, the difficulty of diagnosis, and access to treatment. One of the main objectives is to promote a healthy lifestyle in people at risk, to prevent chronic diseases. The Plan is implemented by the different Italian Regions based on their economic resources (146).

Among Italian Regions, Campania Region joined the "OKkio" health surveillance system in 2008, which aims at assessing and monitoring the evolution of the nutritional situation of primary school children (age 8 years) and their school environment, focusing on correct nutrition and physical activity. The protocol is based on a population surveillance approach carried out in a primary school population (147). In 2010 Campania Region also joined the PASSI d'Argento (Silver steps) surveillance system (148) focused on a healthy lifestyle in over 64-year-olds with disabilities or at risk of disability. In addition, for all those people at risk of chronic diseases, Campania Region has developed a preventive plan promoting physical activity (149). Noteworthy is the "Obesity Programmes of nutrition, Education, Research and Assessment" of the best treatment programs, so-called OPERA prevention project, part of the Federico II UNESCO Chair on Health Education and Sustainable Development in Napoli, and Campus 3S (Health, Sport and Solidarity) event that since 2010 moves from Naples to other large Italian squares (150, 151). The OPERA prevention project represents a preventive campaign against obesity, that provides free medical examination, athletic advices to push obese patients toward an active life, teaching obese patients healthy ccoking by perfoming show-cooking, taste and olfactory assessment, and psychological test assessment and support to evaluate which are the obstacles to overcome to start a new healthy lifepath (Figure 12)(150).

Figure 12 The OPERA PREVENTION PROJECT steps (150).

The Agency for Digital Italy (AgID) is intended to ensure the achievement of the objectives of the Italian digital agenda, to contribute to the dissemination of information and communication technologies, and to help the uptake of innovation and economic growth (152).

The Digital Healthcare System refers to all the interventions undertaken by central, regional, and local Administrations to promote digital innovation of healthcare processes . The interventions targeted at the digital healthcare system aim to improve healthcare services promoting healthy behavior among patients; health monitoring and disease prevention and management; limit waste and inefficiencies, improve the quality-price ratio of healthcare services and reduce the differences among regions (153). Smart Health, for example, represents an innovative service for home telemonitoring and remote diagnosis support. Using a medical kit available to patients at home, consisting of a device for sending data in real-time to the doctor and of a set of medical devices (to control blood pressure, blood glucose, heart rate or digital pill dispenser capable of issuing alarms and signals, etc.) and a digital platform, it will be possible to send their clinical data to medical staff in real-time and to be monitored remotely reducing the inconvenience and costs of traveling for visits and controls at health facilities. In this way, it is possible to monitor patient parameters and the effectiveness of treatments (154). IPPOCRATE AS is a software house specialized in the development of eHealth and smart healthcare solutions. It consists of a set of services and digital tools for health and medical care. The software

house uses information and telecommunication technologies (ICT) to improve activities such as prevention, diagnosis, and treatment, as well as to improve the monitoring and management of health and lifestyles. IPPOCRATE AS is involved in both Italian and European research and development consortia with a long experience in obtaining research funds by drawing on the agencies of the European Commission, Ministries, and Regions (155).

Move your health provides an integrated path towards the prevention and management of overweight and obesity-promoting healthy lifestyles in the Autonomous Province of Trento. It proposes tools and initiatives aimed at helping families to choose healthier lifestyles and reducing health inequalities associated with outreach activities, involving migrant or socioeconomically disadvantaged families (156).

Campania is committed to supporting the digitization of processes and services in the healthcare sector. Technological innovation represents one of the most important topics in the health policy strategies of the Region to improve the quality level of health services for its citizens.

Cambiovita is a built-in pathway to curing obesity. The program developed by Cardarelli Hospital, in Napoli, in collaboration with the patient's association 'Insieme amici obesi' (obese friends together). The main role is played by the patient who tells his story, exposes his doubts, his difficulties (157).

2. Aim of the study

Obesity is a chronic and multifactorial disease with a high impact on multiple physical and psychological parameters, requiring a multidisciplinary approach. The disease prevalence has been increasing in the general population and represents a risk factor for the development of several chronic non- Communicable Diseases (NCD). The challenge is to provide an integrated service provision, that implies the management of patients, his/her interaction with the health professional and the digitally-supported inter-connection with the multisectoral professionals involved.

Aim of the study is the design and testing of an innovative and digitally-enabled healthcare service grounded on the health needs of obese patients, including the different elements for a successful personalised intervention strategy. The study is based on the previous collaborative experience implemented by the European Blueprint on Digital Transformation of Health and Care for the Ageing Society focusing on personas and user scenario. It adopts a multidisciplinary approach to:

- outline an innovative care pathway that can be personalized according to the social and health unmet needs of obese patients;
- assess the efficacy and interoperability of a digital health platform supporting such pathway, Paginemediche.it, through a pilot study focusing on specific parameters such as quality of life (QoL), adherence to the Mediterranean diet, weight loss, chronotype, and sleep.

3.Methodology

3.1 Co-creation methodology

In this study, a co-design methodology has been applied to involve different professionals, and specific activities to reach out the goal.

A qualitative and iterative approach has been adopted in the current study to identify and specify key digital solutions and high-impact user scenarios in AHA, and to develop a user-centered perspective for the identification of suitable solutions addressing health needs with different complexity, expressed along the entire life course. This ensured the development of the persona matrix and profiles.

Based on the tools identified in the forth initial key topic areas highlighted jointly by European Partners on both the demand and supply sides of the market, a compendium of the different digital solutions available that may meet the needs of varied population segments defined by both age and the complexity of their health status, has been created. This compendium was assembled through a general consultation, several informal multidisciplinary and multistakeholder focus groups, and two workshops with groups of representatives from the variety of fields described above, taking place in the period November 2017 – November 2020 as part of events organized within the framework of the EIP on AHA ("the Partnership"). With the Partnership's reach to over 1,000 stakeholders across Europe, this approach ensured inclusiveness collecting inputs from a diversity of European geographical and cultural backgrounds. To strengthen the widest involvement possible (beyond inputs of events attendees), in a second step data were collected via a survey, mainly targeting the industry representatives in the Partnership as to how well this compendium of digital solutions best met the needs of the various population segments represented by personas. 70 survey responses were submitted by health tech industry representatives of both large and small and medium enterprises (SMEs), providing information about their existing good practices and how they matched the needs of the population segments.

Two calls for engagement have been performed (between October 2017 and September 2019) to capture capacity for engagement from a wide spectrum of stakeholders where interested parties were encouraged to apply using an online application form (see S1, S2). The calls have been supported by additional engagement and dissemination activities such as through collaboration with the EIP on AHA stakeholders, collaboration with DigitalHealthEurope (DHE), SHAFE, AAL and other

organisations. Various means of outreach have taken place either digitally or through face-to-face meetings.

The first call sought activate participation of demand side representatives (e.g., regional authorities, health and care providers) who have been investing in or implementing digital health and care solutions at scale between November 2017 and end of 2018 and to establish 4 Working Groups (WGs) with 5-7 experts in each that would advance the 4 identified priority topic areas by working on:

- Mapping of specific investments in the 4 areas identified.
- Outlining existing specific barriers to large scale deployment such as:
    - Unresolved interoperability/standards issues
    - Specific skills and training issues as well as organisational aspects
    - Impact metrics/evidence (generic methods, MAFEIP etc.)

The second call for Blueprint stakeholders has been promoted during the Blueprint joint workshop in Aarhus, Denmark, published in the 2nd EIP on AHA newsletter, and as a news item on EIP on AHA website .

The objective of the call was to enlarge the Blueprint community and diversify the types of stakeholders, contributors or endorsers, engaging in Blueprint work and activities. Contributors, worked "on request" supporting the Blueprint partners' work for short periods on topics where they expertise. Endorsers , represented stakeholders supporting the Blueprint work and promote its results. They have been consulted for further improvements on key topics and recommended actions.

The stakeholders profile included those were actively involved in digital health and care services at a national, regional or local levels, provided good practices and knowledge on key topics related to the three priorities areas:

- citizens' secure access to and sharing of health data across borders
- better data to advance research, disease prevention and personalised health and care
- digital tools for citizen empowerment and person-centred care

Data were compiled by the Blueprint Partners into a detailed picture of the different needs in Europe that were addressed by the identified innovative good practices. The overview was shared with the EIP on AHA partners and welcomed by the demand-side stakeholder groups (e.g. healthcare providers), to better understand the needs of their populations, and by supply-side stakeholder groups (e.g. industry) who can inform the development of their innovative practices and tailor them better to the expectations of the demand side. An overview of key ICT-enabling technologies available and

barriers to scaling up is also provided, in order to promote innovation, make health and care systems sustainable, and achieve economic growth in Europe.

3.2 The Blueprint persona approach: Matilde

The Blueprint approach to identify high-impact user scenarios in AHA is adopted in different settings, such as in the software industry and the health and care sectors. With this approach, innovative solutions are designed based on how a user from a target group will interact with technologies (51) by starting to develop "personas".

Based on the twelve Bluprint personas developed, a so-called spin-off persona (158)had been created, including all the Blueprint personas developed later. They are inspired by the original Blueprint personas, following the Blueprint format and key information categories, but with specific needs missing in the original twelve personas. Among the twelve Blueprint persona, some of them are characterize by overweight, psycological diseases, social condition and/or isolation as diseases-related conditions. Mathilde was born precisely from the need to include an example of a specific profile of an obese patient, including all these conditions. A persona template (see S3) to create a new persona , Matilde, was filled in following some tips (159):

Be consistent about the information given.

Be succinct so as to increase the readability and usability of the persona.

Keep the information as concise as possible (avoid repetitive descriptions).

Keep the vocabulary simple: avoid using medical terminology or provide a glossary of terms.

Under the section “Needs”, describe the reasons behind the persona’s needs.

Once the specific Matilde’s needs have been defined and the persona accepted by the Blueprint partners, an officially poster and a graphic facial representation has been developed.

3.3 Use case and service scenario: Matilde’s scenario

Following the development of Matildes’ profiles and identification of needs to address, existing ICT solutions that can target one or more of the Matilde personas’ unmet needs, based on key digital health technologies previously identified and classified by the Blueprint partners, have been taken into consideration (Table 1-2) (47).

Table 1 Suggested ICT solution categories targeting identified personas' needs (47)

Persona / Unmet need	Generally well				Chronic conditions and/or social needs				Complex needs			
	Rose	*Leila*	*Randolph*	*Teresa*	*Millie*	*Nikos*	*Eleni*	*Maria*	*Ben*	*Antonio*	*Procolo*	*Jacqueline*
ICT support to health & wellbeing, health & social care delivery / EHRs, management of health data / health information exchange		■	■		■	■	■	■	■	■	■	■
Telehealth / Telecare / Home care / Tele-monitoring		■		■	■	■	■	■	■	■	■	■
Education, including gamification or serious games; health and digital health literacy, empowerment	■	■	■	■	■	■	■		■	■	■	■
Smart homes and age-friendly environments (e.g., home sensors, Internet of Things (IoT), Ambient Assisted Living (AAL), Independent Living (IL) solutions)		■	■				■		■			
Social or peer support / social networks, messaging	■		■		■		■		■	■	■	■
Other: Assistive technology/wearable robotics (exoskeleton)										■		

Table 2 ICT categories based on personas' needs and example ICT solutions

ICT solution category	Examples of ICT solutions / tools / services
ICT support to health & wellbeing, health & social care delivery / EHRs, management of health data / health information exchange	Interoperable Electronic Health Records (EHRs), Patient Portals Electronic consultations and appointments Secure and reliable search portals for health information Booking solutions for care support Health data management solutions Personal health folder apps 24/7 eHealth call centre (e.g., run by nurses) ICT for integrated care supporting e.g., shared care plan, multi-disciplinary team (MDT), etc.
Telehealth / Telecare / Home care / Tele-monitoring	Teleconsultations with child and mental health services Monitoring of health parameters (weight, blood pressure, blood glucose, etc.) Internet of (medical) Things Telecare personal alarms • Panic button service • Medication reminders / smart medication dispensers • Access to assistance during emergencies Vibrating carer alerts linked to movement sensors in the house Electronic diary with visual and auditory reminders Physical training solutions e.g., to monitor running or other sports or activities Self-monitoring of frailty Tele-assistance subscription service – supervising daily activity trends of elderly people, notifications of potential risk situations Wearables

ICT solution category	Examples of ICT solutions / tools / services
Education, including gamification or serious games; health and digital health literacy, empowerment	Web platform for digital and health literacy Massive Open Online Courses (MOOCs) Information on relevant support infrastructures in the region Healthier lifestyle management • Games for physical exercise • Computerised anger management • Management of chronic conditions Healthy cooking and eating (including fun apps targeting children) Tutorials (for e.g., dancing, fashion, lifestyle, music, and other hobbies) Educational tools (memory exercises, reading, speech and languages) Online libraries (e.g., for reading newspapers) Virtual reality (e.g., virtual museum visits for people with mobility difficulties)
Smart homes and age-friendly environments (e.g., home sensors, IoT, AAL, IL)	Home or property sensors Internet of (non-medical) Things Regulated heating systems Food shopping support Home health / wellbeing monitoring (see also Telehealth) Support for daily routines Wearables
Social or peer support / social networks, messaging	Networking apps (e.g., sports or cooking clubs, social events, healthy lifestyle groups) Discussion fora (e.g., to exchange similar experiences) Easy phone / video connections (e.g., to connect with children or neighbours) Platforms to put care givers and patients in touch (e.g., in case of urgent needs) Online services e.g., shopping, banking, meal delivery, travel
Other	Assistive technology / wearable robotics – exoskeletons

A template characterized by guiding question has been used as starting point to create the scenario. The questions helped to describe different aspect of the scenario, i.e. triggering factors; key actors; interactions among key actors; data needs; transitions; ICT tools; interoperability; changes in health status; and other element (Table 3).

Table 3 Guiding questions template for the Blueprint scenario development

Scenario focus / Event / Episode description *Please describe a scenario related to a chronic condition (for example, resulting from the acute event or related to other chronic conditions/social needs of the persona)*
What factors likely caused, triggered or led to the event? *Examples: Environmental factors? e.g. poor air quality* *Did the persona forget to take medication? (due to health e.g. dementia or lifestyle e.g. too busy? Too stressed with work?)* *No access to a [preventive] ICT tool or service? Cannot afford, lives too far away, etc?* *No access to other key actors? E.g. informal carers, GPs, pulmonary specialist, etc.*

Low digital health literacy?
Key actors involved and their roles *Who are the key actors involved in this scenario? What are their roles?*
Data/information exchange needs *Please describe the types of data/ information needed from your persona within this scenario:* *What data are needed? By whom? With whom are the data shared? Please describe the flow of data. How will ICT support this?*
Managing transition(s) *Please describe how the persona transitions e.g., from one care provider to another? Between hospital and home-care?*
ICT tools or services supporting the scenario elements above *What types of ICT tools or services will the persona and/or key actors need to interact with to improve their situation? Who will be using the tools? (Persona, carers, health and care providers, etc.)*
Suspected changes in health state during this scenario and follow-up needs (if any)

3.3 Pilot Study: digital health platform assessment, Paginemediche.it

The digital health platform paginemediche.it interface was designed by a multidisciplinary team including two endocrinology specialist, a biologist, a nutritionist, a GP, and a computer scientist. The team focused on developing a user interface design that would be easy to use among utents with low ICT literacy. The interface was characterized by a simple language and layout. Graphical representations have been included to make the digital platform easier and more intuitive to use. Briefly, the digital health platform has been modified in such a way as to allow obese patients attending the outpatient clinic of the Policlinico II of Napoli to access their own reserved area and be able to enter their personal and anamnestic data (name, surname, age, sex, weight, height and

waist circumference), and/or connect wearable devices in order to record sleep hours and pedometer or enable the receipt of notifications with small tips on how to follow a healthy diet, e.g. avoid skipping meals, respect the total calories to be taken per day and stay hydrated during the day (Figure13), after signing informed consent.

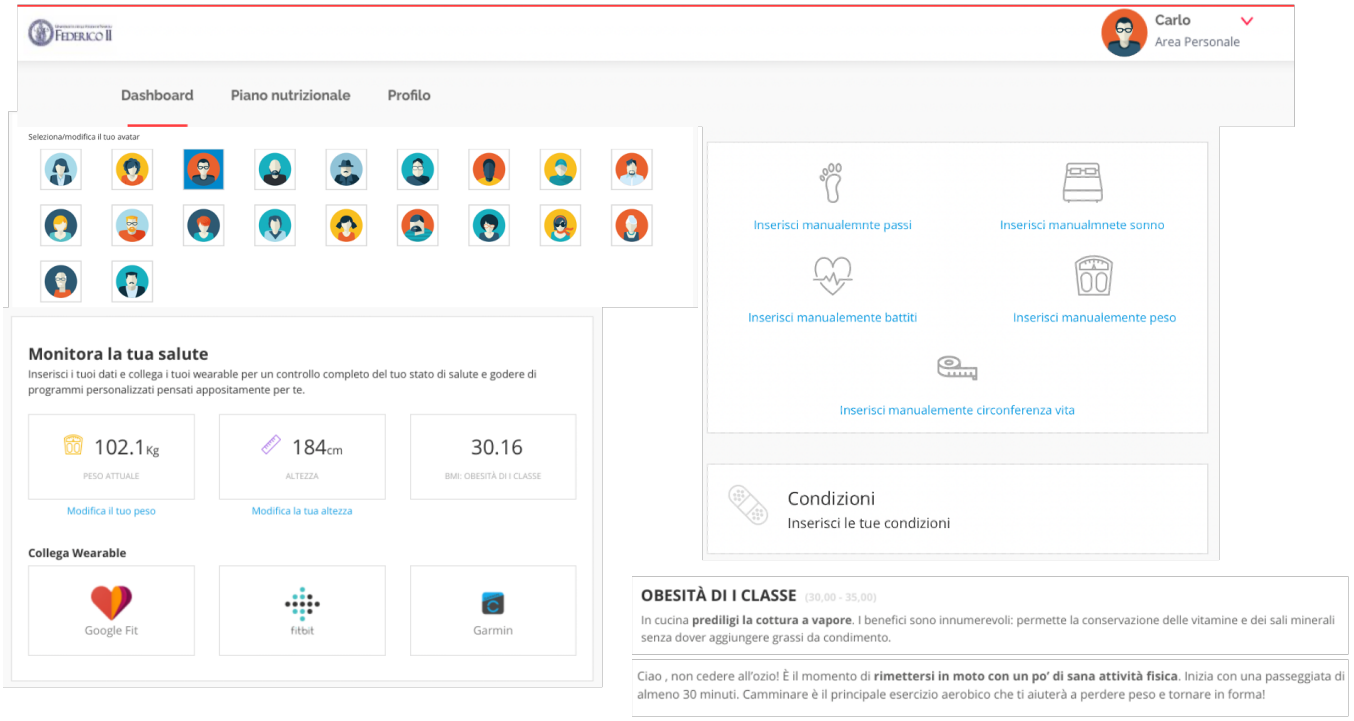


Figure 13 Overview of the main activities available for the obese patients on the digital platform, paginemediche.it, developed.

Patients: 10 patients (aged 38,83± 3,28 years) with an established diagnosis of overweight or obesity and 10 healthy subjects (aged 31,67± 1,08 years) as control group were enrolled in the study. The study was performed in accordance with the ethical standards of the Declaration of Helsinki, and it was approved by the Ethics Committee of the University Federico II of Naples (EC 360/18, date of approval 21th November 2019) . Healthy volunteers were recruited from staff and the faculty population of University Federico II of Naples (Italy). Healthy volunteers did not have any complaints regarding their health and did not have signs or symptoms indicative of overweight or obesity. All enrolled subjects provided a signed informed consent.

Nutritional assessment: The adherence to the MD was assessed using PREDIMED questionnaire, consisting of 14 items administered this questionnaire during a face-to-face interview. A score 1 and 0 for each item, PREDIMED score was calculated, as follows: 0–5, lowest adherence; score 6–9, average adherence; score ≥10, highest adherence (160).

Sleep quality assessment: The Pittsburgh Sleep Quality Index (PSQI) was used to measure the quality and patterns of sleep over the last month. The PSQI is the gold standard questionnaire for assessing subjective sleep quality and has been validated in both obese patients and healthy subjects. The questions analyze seven factors including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction. The scores from each component are added to give a sum score, also called a global score (range 0–21). Combined, these numerical scores provide the clinician with an efficient overall summary of a patient's quality of sleep and sleep health (161).

Quality of life assessment: Participants completed by self-administration the Short Form-12 Health Survey (SF-12), a measure of general health status. The SF-12 consists of 12 items that assess 8 dimensions of health: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. The SF-12 measures various aspects of physical and mental health from which physical and mental summary scores can be calculated (162, 163).

Morningness–eveningness score: Chronotype, morningness- eveningness, was assessed using a questionnaire of 19-item. Four choices of answer are given, indicating: definite morning type, moderate morning type, moderate evening type, and defmite evening type. A time scale is employed for a few questions. The scores are added, and the sum converted into a five-point morningness-eveningness scale (Table 4) (164).

Table 4 Morningness-eveningness score

Morningness-eveningness score	
Definitely Morning type	**70-86**
Moderately morning type	**59-69**
Neither type	**42-58**
Moderately evening type	**31-41**
Definitely evening type	**16-30**

Computer System Usability Questionnaire

Participants completed a standard Computer System Usability Questionnaire (CSUQ) (165) to measure user satisfaction with computer system usability. The questions analyze four factors such

as usefulness, ease of use, ease of learning, and satisfaction; a score from 1 to 7 have been given to each question, for a total of 30 questions.

Statistical analysis

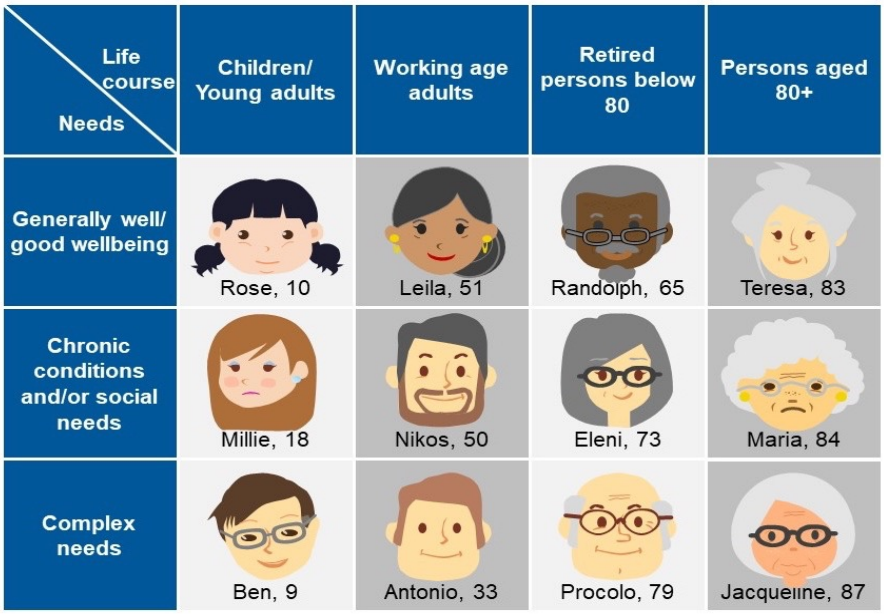
The analysis of difference between the study's groups was performed using test t-student and Mann Whitney (GraphPad Prims version 6 software). We considered a Pvalue to be significant at < 0.05 with a 95% confidence interval (CI).

4. Results

4.1 The Blueprint personas approach

To identify how a user belonging to a particular target group was able to interact with technologies, twelve personas were developed by the Blueprint partners. The twelve developed personas represent different "population segments" and were categorized by age (children/young adults, working-age adults, retirees under 80, persons over 80) and their corresponding well-being as well as health and care needs (good well-being, chronic conditions and/or social needs, complex needs (Figure 14). Data were compiled by the Blueprint Partners into a detailed picture of the different needs in Europe that were addressed by the identified innovative good practices. The overview was shared with the EIP on AHA partners and welcomed by the demand-side stakeholder groups (e.g. healthcare providers), to better understand the needs of their populations, and by supply-side stakeholder groups (e.g. industry) who can inform the development of their innovative practices and tailor them better to the expectations of the demand side.

A



B

Needs / Life course	Generally well / good wellbeing	Chronic conditions and / or social needs	Complex needs
Children / young people	Rose, 10 Social isolation, Inappropriate food intake, overweight Occasional aggressive behaviour Emotional eating	Millie, 18 Pre-diabetes, Attention deficit hyperactivity disorder (ADHD), Aggressive outbursts, Obesity, Worried about being teased due to obesity, wants an independent, fulfilled life while being supported with her conditions, Asperger's syndrome, echolalia	Ben, 9 Cataracts, hearing loss, delayed motor skills, Goes to respite care centre, Unhealthy diet, eating too much, Change or unpredictability negatively affects his behaviour, visual learner Down's syndrome
Working age adults	Leila, 51 Worsening eyesight, Light back pain, Provides support for own children and an elderly female neighbour, Due to her various family responsibilities, she may overlook her own needs, She may be experiencing "winter depression" (SAD), which is as yet undiagnosed	Nikos, 50 Metabolic syndrome (diabetes, hyper-tension), mild chronic obstructive pulmonary disease (COPD), Unable to afford professional lifestyle support services, work routine goes against healthy lifestyle intervention, Trying to stop smoking Stressed due to economic and health issues	Antonio, 33 Diabetes, hypertension, below-waist paralysis Strong support by girlfriend, rejects social support, Heavy alcohol and tobacco use, Fear of losing his job and social connections, Depression
Retired persons below 80	Randolph, 65 Worsening eyesight, Strong peer group, cares for and supports his wife (who has early stage dementia), aware of and concerned about his wife's growing needs and wants to do something about them	Eleni, 73 Hypertension, Poor medication adherence, Lives alone, lack of nearby family members, Stressed due to challenges of dementia and worried about having accidents alone at home Early stage dementia	Procolo, 79 Sight and balance problems, benign prostate hypertrophy, hypertension, diabetes, bladder epithelium cancer, Needs attendance, goes to work via taxi, Diet to avoid hyperglycaemia Fear of hospitals, trust issues towards care professionals
Persons aged 80+	Teresa, 83 Occasional joint pain Difficulty climbing stairs Heavily supporting her husband Scared of being alone and not being able to live an active life	Maria, 84 Diabetes, retinopathy, heart failure, atrial fibrillation, chronic kidney disease (CKD), osteoarthritis: currently under control, occasional relapses. Feels isolated (no friends), huge financial struggles, poor adherence & hygiene, fear of being sent to nursing home, leaving family unprotected	Jacqueline, 87 Chronic obstructive pulmonary disease (COPD), hypertension, falls, osteoarthritis, osteoporosis, incontinence, rejects social support, only by stressed husband, will need oxygen at home, memory, cognitive disorders, hallucinations, mixed dementia, fears visitors, suspects people stealing her

Legend: Health issues | Social & economic aspects | Lifestyle risks | Personality aspects | Mental issues

Figure 14 A) The Blueprint persona matrix, developed by Blueprint Partners; **B)** Key points of Blueprint personas representing different needs, aspirations, attitudes, dreams, disease-related characteristics, care needs of certain groups in the society, and identification of what is important to them.(46, 166)

4.2 Appling the Blueprint persona approach: Matilde

Matilde's persona developed embodies all the recurring issues and needs in an obese patient, including assessment of the quality of life (QoL) and identification of Digital Health models for an intervention strategy.

The persona poster is divided into 5 main areas (Figure 15, S4):

- Basic information related to personal information as name, age, country, life-course, clinical condition (i.e. chronic condition and social needs)
- Relevant ICT Skills, assessment of ability and availability to interact with digital solution (mobile device skills and/or digital health literacy)
- Summary section includes all the relevant personal and clinical event have been characterized the life of the Matilde, to better understand what needs to be address.
- Contextual Topics in which the clinical picture, personal and social context, have been taken into consideration
- Personas need section includes the need identified and need to be met.

Figure 15 Matilde's persona poster and its five main area of interest analyzed.

Matilde, a 60-year-old woman suffering from a severe state of depression that does not allow her to fully understand the risks she runs by being obese and not changing her lifestyle.

In this case, not only the clinical history of the patient was taken into consideration but also the personal and social aspects, the ability to interact with different computer devices, and what needs to be met to be able to help Matilde towards a radical change in her lifestyle through an integrated approach. Three main needs were identified to be met to improve Matilde's lifestyle:

1. Lack of motivation and risk information associated with her current health status.
2. Due to obesity, patients are often unable to take care of themselves (cooking, showering, cleaning the house).

   Access to weight loss programs and psychological support.

4.3 Use case and service scenario: Matilde's scenario

Based on the key points highlighted in the persona poster, as the clinical picture and in relation to Matilde's social condition, it has been possible to identify gaps to implement into the care pathway taking in consideration several aspects:

1. close collaboration and bilateral communication between the multidisciplinary team and Matilde;
2. sharing of data among the various actors involved;
3. development of programs and campaigns for evidence-based nutrition counseling and education;
4. developing a health-friendly environment and programs of psychological support and help in managing feelings and emotions in order to help these patients overcome their state of depression and social isolation;
5. maintain a positive mental state through social activities;
6. reduce ever-increasing health care costs and over time lower premature mortality rates.

To facilitate the development of the user scenario and improve the care pathway a scenario diagram has been created (Figure 16), based on the scenario created by the guiding question template (table 1). As demonstrated, the diagram clearly showed how complex are connections, communications and usability of the health services and gaps to implement.

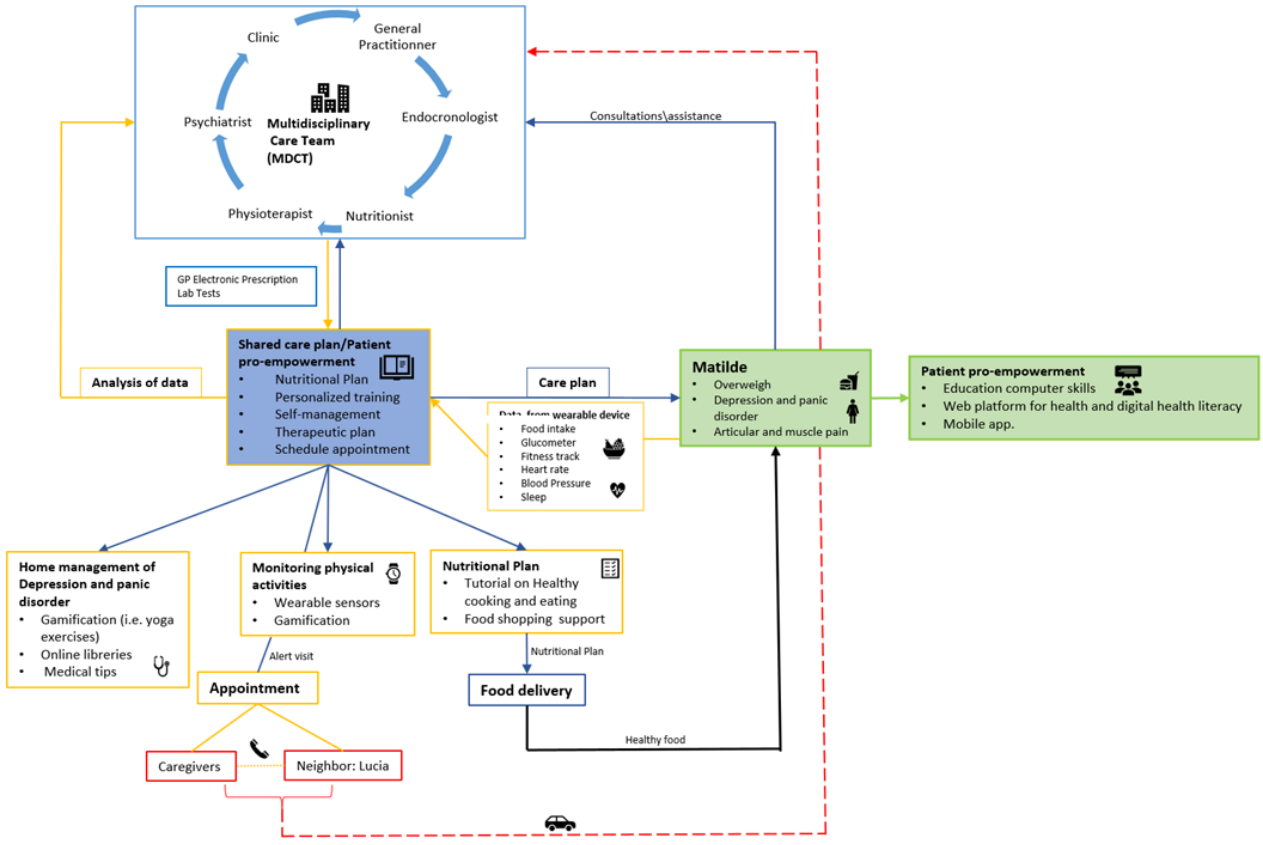


Figure 16 Scenario diagram presenting the possible connections, solutions and services

A shared care plan or a Personalized Care Plan associated with different ICT solution identified to improve Matilde's health care plan could represent an excellent digital tool to imporove the efficacy of the health services by improving communication among professionals, patients management, reducing outpatient waiting lists, and the health related costs expenditure. In this way, it can be possible for the multidisciplinary team monitor Matilde by update her health date directly from home device provided, while Matilde can manage her medical appointments, nutritional plan, physiotherapy and psychotherapy sessions from home by staying in touch with the professionals (Figure 17)

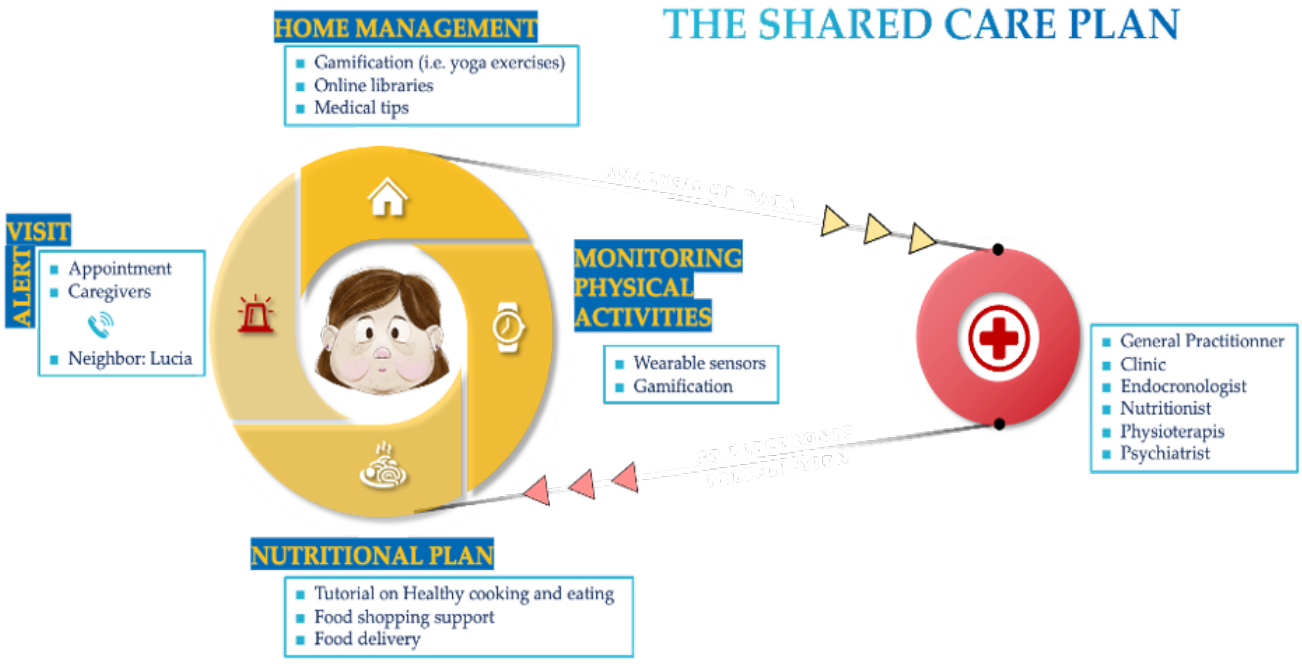


Figure 17 Overview of Matilde's user scenario: integration of services

4.4 Pilot Study: digital health platform assessment Paginemediche.it

A pilot study assessing how technology can support of obese patients during their weight loss has been conducted using the Digital Health platform, paginemediche.it. A total of 10 obese patients have been enrolled in the study (Table 5).

Table 5 Patients' characteristics: anthropometric data and adherence to Mediterranean diet

	Control Group *Mean±SEM n= 10*	Obese Patients T0 *Mean±SEM n= 10*	Obese Patients T1 *Mean±SEM n= 10*	*pvalue Vs Control Group*	*pvalue Vs Obese Patients*
			Lifestyle Habits		
Age (years)	31,67± 1,08	38,83± 3,28	38,83± 3,28	0,0693	
			Anthropometric measurements		
BMI (kg/m2)	21,37± 2,41	37,47± 5.9	32,12± 2,66	**0,006**	
Normal weight	56,33± 9,57				
Obesity I		105,73± 2,87	93,753± 6,85	0,093	>0,9999
Obesity II		112,3± 21,68		0,0324	
			Adherence to the MD		
PREDIMED score	6,5± 0,95	4,3± 0,66	7,1± 0,3	0,2449; >0.9999	**0,0318**
Low adherence	4± 1	3,8± 0,48	n.a.	>0,9999	
Average adherence	7± 0	7± 0	7± 0,3	>0,9999,>0,9999	>0,9999
High adherence	1± 0	n.a.	n.a.		

Results of the study showed that after two months of healthy diet and moderate physical activities the adherence to the MD and morning-eveningness type was improved (p=0,0318, and p=0,0137 respectively) demonstrating a change in the nutritional habits (Figure 18).

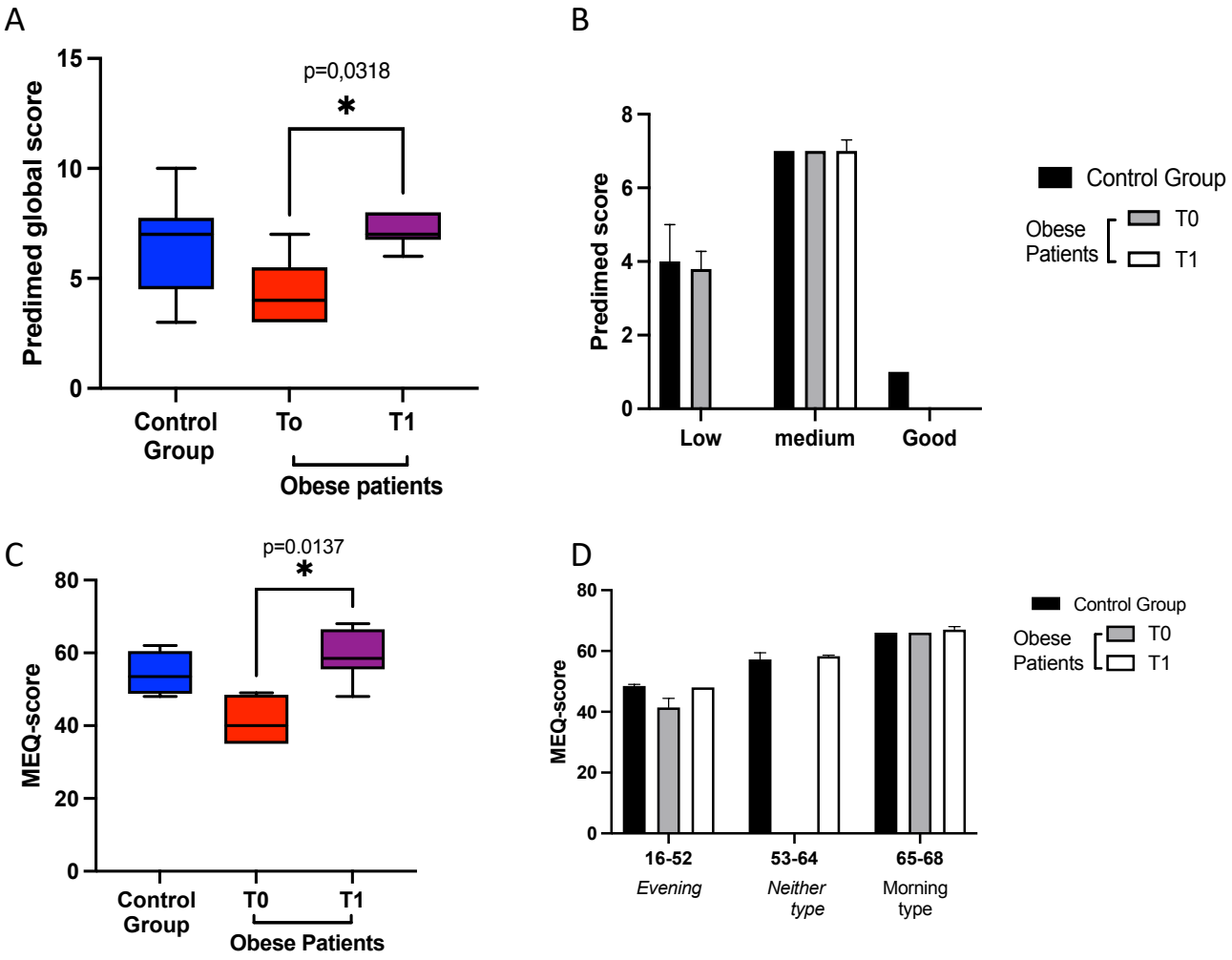


Figure 18 A-B) Aherence to MD, **C-D)** MEQ scores in obese patients at baseline (T0) and after using the digital health platform for two months (T1) and control group (* T0 Vs T1). Data are expressed as mean ±SEM

Unhealthy habits change reflect on sleep time per day as patient slept less than the healthy subject (p=0.0299) at the beginning of the study. After two months of a healthy diet was observed an increase of the sleep time, almost equal to the control group, although it wasn't statistically significant compared to the obese patient's group at the baseline (Figure 19).

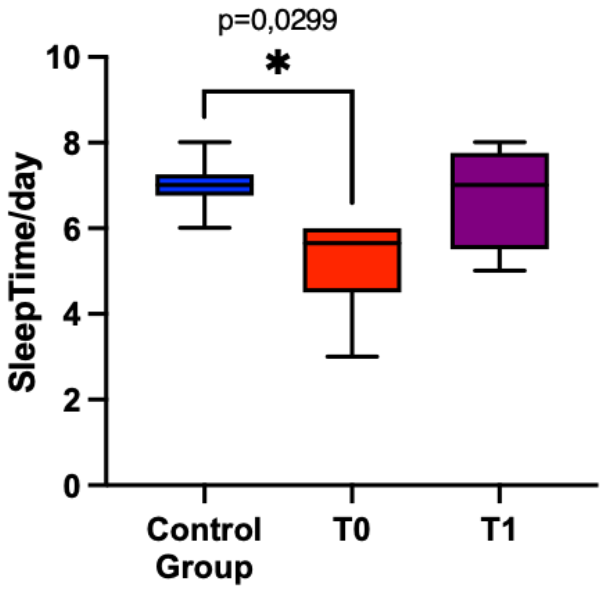


Figure 19 Sleep time per day (hrs) in obese patients at baseline (T0) and after using the digital health platform for two months (T1) and control group (* Control group Vs T0). Data are expressed as mean ±SEM

No statistically significant evidence has been showed in the quality and patterns of sleep analysis, and physical and mental functions although slightly improvement can be observed (Figure 20-21).

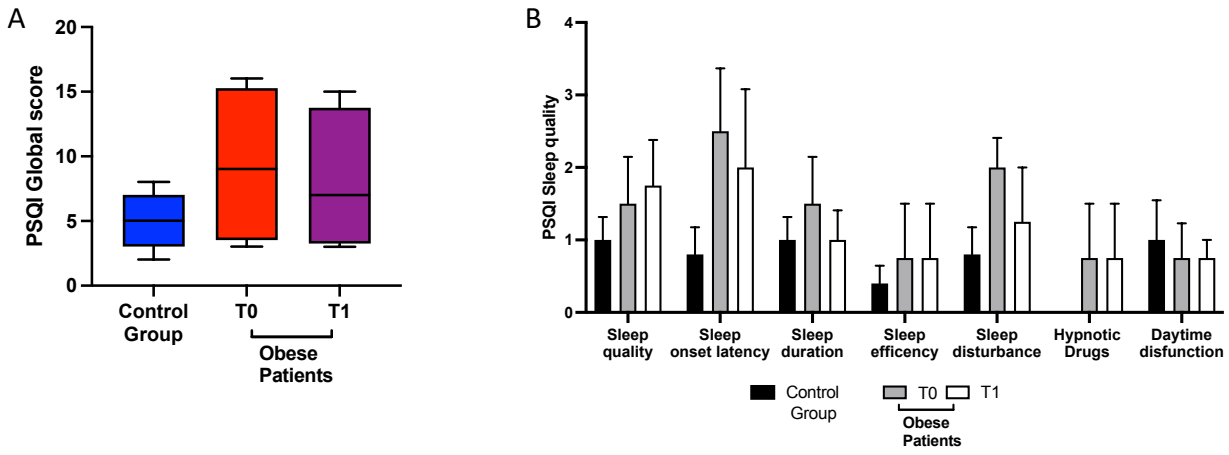


Figure 20 PSQI global score and sleep quality; and SF-12 global score in in obese patients at baseline (T0) and after using the digital health platform for two months (T1) and control group. Data are expressed as mean ±SEM.

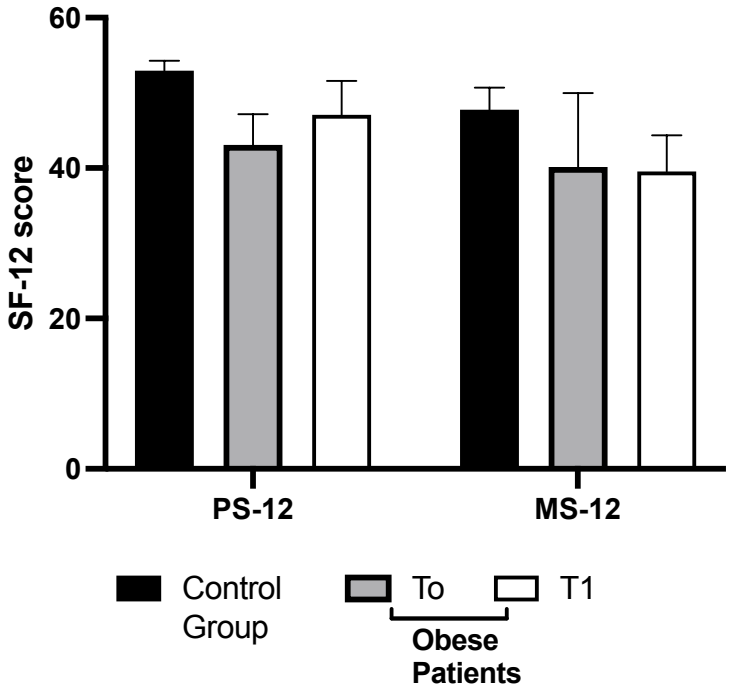


Figure 21 SF-12 global score in in obese patients at baseline (T0) and after using the digital health platform for two months (T1) and control group. Data are expressed as mean ±SEM.

All the partecipants completed the usability evaluation squestionnaire. The questionnaire included 30 questions ranging from 1 (“strongly disagree”) to 7 (“strongly agree”) to measure user satisfaction.. The mean CSUQ scores on the four factors about system usefulness, ease of use, ease of learning, and satisfaction were 4,19, 4,28, 5,6, and 3,40 , respectively (Figure 22).

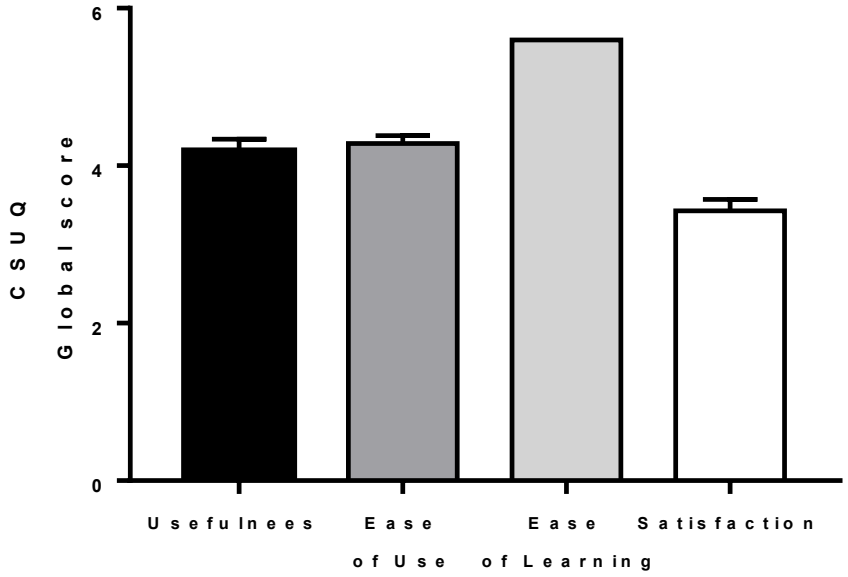


Figure 22 CSUQ global scores in obese patients after two months of interaction with the digital health platform, paginemediche,it. Data are espressed as mean mean ±SEM.

The questionnaire revealed that 32% of patients easily learned how to interact with the platform; 25% considered it easy to use while 24% of patients considered it useful because it gave them more control over their life activities; although only 19% of patients were overall satisfied with the use of this ICT solution.

5. Discussion

Several factors increase the risk of obesity in different settings, such as family, school, community, and working places; and for these reasons WHO's Member States are carrying out programs to promote healthy diets trying to act on both social and economic factors such as income, food prices, individual preferences, cultural traditions, and geographical and environmental aspects (including accessible tourism, climate change and built environment) involving multiple sectors and stakeholders likewise government, and the public and private sectors. The central role in creating a healthy food environment is played by governments who enable people in adopting and maintaining a healthy lifestyle, by creating coherence in national policies and investment plans including trade, food, and agricultural policies and promoting a healthy diet and protect public health.

Recent studies, developed personas representing potential users to support a patient-centred design. The 'users' represented patients with heart failure who would use a mHealth application for heart failure self-management (167); or involve users towards innovation, how it can address unmeet needs, and gives all participants equal involvement (168).

The European Innovation and Knowledge mHealth Hub (169) is a project established by the European Commission, in partnership with the WHO and International Telecommunication Union (ITU) to support the integration of mHealth programmes and services into the health systems of European countries or regions. The project provided a knowledge tool for the iterative development of national or large-scale programs for the prevention and management of type 2 diabetes, supported by mobile solutions, using a person-centered approach. The Hub approach is based on the Blueprint personas, to identify unmet needs to be addressed, linked to solutions available on the market through an innovative algorithm (170).

According to Matilde's persona, and in line with all the Blueprint personas, social support, development of a health-friendly environment and educational program on healthy nutrition and physical activity result of great help in managing relationships with food and psychological well-being, maintaining positive mental health through social and/or outdoor activities. While the persona profiles aim at facilitating the identification of health needs that may be addressed integrating innovative solutions in their care and cure describing a persona's personal experiences, the scenarios provide more details on needs and interactions involving not just the personas, but also the health and care ecosystem (GP, nurses, care providers, social carers); available best practices; experience in

providing digital solutions to patients at local and/or national level; interoperability; and depicts topics that are important for advancing better person-centred health and care delivery. These topics may either be specific to the scenario or applicable to multiple scenarios. User scenario represent a useful tools to understand how answer at its best to unmeet needs, improve interoperability, and usability solution. In this way, it has been possibly creating a methodology able to connect persona with scenario and ICT solutions in different segment of life and deep understand the better way to how to get them to interact improving users' experience and health care.

Such an approach facilitates an interdisciplinary, "user-centered" design of digital solutions, allowing their adaptation. Evidence emerges that the addition of digital tools may indeed facilitate patient behaviour change of unhealthy lifestyle, integrating positive psychology practices and possibly leading to a larger proportion of patients accessing structured interventions for healthy lifestyle promotion (171-173). The implementation of a Persona approach might also be useful for the early involvement of end-users in solutions design and adaptation, increasing adherence, and hence the effectiveness of digital solutions (41). Persona profiles also consider the potential benefits that can derive from digital resources for the patient and associated stakeholders such as careers (informal or formal), healthcare professionals, healthcare providers. Intersectoral, cross-cutting approaches between policies proved their effectiveness in preventing obesity and reducing related risks for health while ensuring monitoring and surveillance. Nonetheless, sustainability issues hinder the scale-up of such approaches to impact obesity at the population level (139). In this perspective, the development of paginemediche.it with the pilot study run, closely related to the Blueprint persona. The digital solution suggested takes into consideration all the social and clinical needs identified in the Blueprint persona.

Digital health solutions, focused on health promotion, adherence to the Mediterranean diet and weight loss in obese patients, are increasing dramatically, demonstrating their efficacy(174, 175)..

A systematic review examined digital self-monitoring in weight loss interventions ≥ 12 weeks, weight outcomes ≥ 6 months, and outcomes on self-monitoring engagement and their relationship to weight loss among overweight or obese patients from 2009 to 2019. A self-monitoring was associated to a higher weight loss in 74% of obese patients treated. As well as, a remote weight-loss program combining mobile applications, daily self-weighing, and calorie restriction via meal replacement resulted in dramatic weight loss among obese patients enrolled in the study after 120 days (mean weight loss 14 kg, 13% total body weight loss from baseline) (175); or the adherence to the Mediterranean diet assessed by digital intervention was higher after 12 months of intervention (176).

According to the literature, the current study demonstrated that digital health support has been sufficient to reduce the weight loss, to improve the adherence to the Mediterraen diet and daily habits in obese patients after 2 months of intervention.

Sleep, and physical and mental functions should not be underestimated in obese patients. Nightly sleep, in terms of quality and quantity, has been associated with a higher risk to develop obesity and overweight along with dysfunctional eating behaviors, decreased physical activity, and metabolic changes (177, 178). Many factors as dyslipidemia, metabolic syndrome, insulin/leptin dysregulation, and inflammation affect cognition and motor behaviours, affecting brain functions and the musculoskeletal system (179, 180). The current study showed that changing unhealthy habits towards healthier nutrition can improve the nightly sleep duration, similar to the control group, as well as a slight improvement of the quality and patterns of sleep analysis, and physical and mental functions have been observed after two months of intervention.

Results of this study demonstrated that 2 months of intervention in dietary and habits behaviours improve the lives of obese patients, although some limitations might have prevented a better outcome. The COVID19 pandemic represented a huge obstacle in the enrollment, involvement and support of the patients. Obese patients have found difficulties in follow a nutritional plan and stay active during this period. Because of the lockdown they have been forced in spending most of the time at home. For all these reasons, the digital platform developed also needs some changes to better monitoring obese patients in terms of usability, interoperability, support, and motivation.

The collaborative ecosystem of the EIP on AHA has been supporting the stakeholder's engagement along a quadruple helix of innovation, which is pivotal to align investments between international, national, and international levels. In Italy, the ProMIS network for the internationalization of the regional health system has been a key enabler to speed up large scale adoption of innovative good practices (181).. At the regional level, the commitment to support the digitization of processes and services in the healthcare sector has been translated into the establishment of dedicated agencies for technological innovation. Still, there is an inadequate structured engagement of the no-profit sector, which is pivotal to ensure citizen involvement and need assessment at scale and strengthening the link between public and private sectors. The participatory design of digital solutions in which the end-user is no longer the passive recipient of a new tool but is an integral part of the design and the innovation process would allow to evaluate of the care experience that is held only by the patient. Furthermore, a joint effort should be undertaken, between key stakeholders involved in training and education to

ensure multidisciplinary approaches that extend their reach towards citizens literacy and empowerment (181).

6. Conclusions

Personas could be defined as successful approaches that enable stakeholders from different sectors, public or private organisations, to understand their potential users better by considering their needs, aspirations, attitudes, dreams, and other relevant characteristics, and identify what is important to each individual. This approach is person-centred focused on specific target groups and useful for identifying ICT solutions to address unmet health needs, taking in accout IT skills, socio-economic context, interoperability, and integration gaps that may influence the adoption of innovative solutions. Personas and user scenario emcopass a wide range of different issues, conditions, and possible solutions with potential uses in education sector where the end-user could be citizen, patient and/or health professionals. As overweight or obese patients tend to be marginalized and subjected to a real social stigma (91, 182), digital solutions could represent a useful tool to help obese patients overcoming all the factors that preventing start lifestyle changing (183). In particular, within the digitally supported patient empowerment and self-monitoring, persona will be helpful to identify different unmet needs and to monitor health status through a multidisciplinary team, sharing data; while regarding the health professionals, the use of persona could be helpful to improve and make easier his job and to teach and educate patient toward an healthy lifestyle, setting goals and monitoring progress. Within the context of the Blueprint work and objectives, personas were developed to enable the EIP on AHA to envision realistic health and care needs of certain groups in the society and share them with other stakeholders. Such a framework will help to identify gaps and inform other developments in the future (e.g., digital transformation). The digital transformation of health and care provides several validated, innovative solutions supporting health promotion, disease prevention, and integration of health services that facilitate the collaboration between all involved stakeholders. Nonetheless, there is a need to concretely implement the Blueprint's shared vision, towards specific objectives; and the purpose of the pilot study, closely correlated in delivering services the persona needs, has been focused on that. This was possible by literally transferring the information contained in the persona into the daily practice, both updating paginemediche and testing the solution in a pilot study.

Artificial Intelligence could provide personalized information or recommendations to the patient/citizen, health professionals involved in prevention and care paths, and health authorities to develop targeted intervention strategies. IT integration and interoperability among data systems would allow designing an innovative model for decision support, based on clinical and lab results of

groups of the patient, including data derived from self-monitoring (wearable), lifestyle monitoring (nutrition, physical exercise), socialization, drug interactions, and OMIC data.

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Supplementary Materials

S 1 Fisrt Blueprint Call for engagement form

WE4AHA Call for Blueprint Partners

The aim of this call is to enlarge the group of contributors to the Blueprint's further development and strengthen the demand side representation. We seek to activate participation of demand side representatives who are investing in or implementing digital health and care solutions at scale between now and end of 2018.
The current Blueprint Champions and the EIP on AHA Reference Sites are kindly invited to suggest candidates from demand side organisations (e.g., regional authorities, health and care providers, etc.) using the current online application form.

* Required

Name and Surname *

Your answer

Organisation *

Your answer

e-mail address *

Your answer

Region/Country *

Your answer

Has your organisation/region implemented at scale any digital health solutions in AHA? *

- ○ Yes
- ○ No

Please describe *

Your answer

Has your organisation/region made any investment in digital health solutions in AHA or has planned to do it before the end of 2018? *

- ○ Yes
- ○ No

Please describe *

Your answer

Concrete expertise of the candidate. Please describe *

Your answer

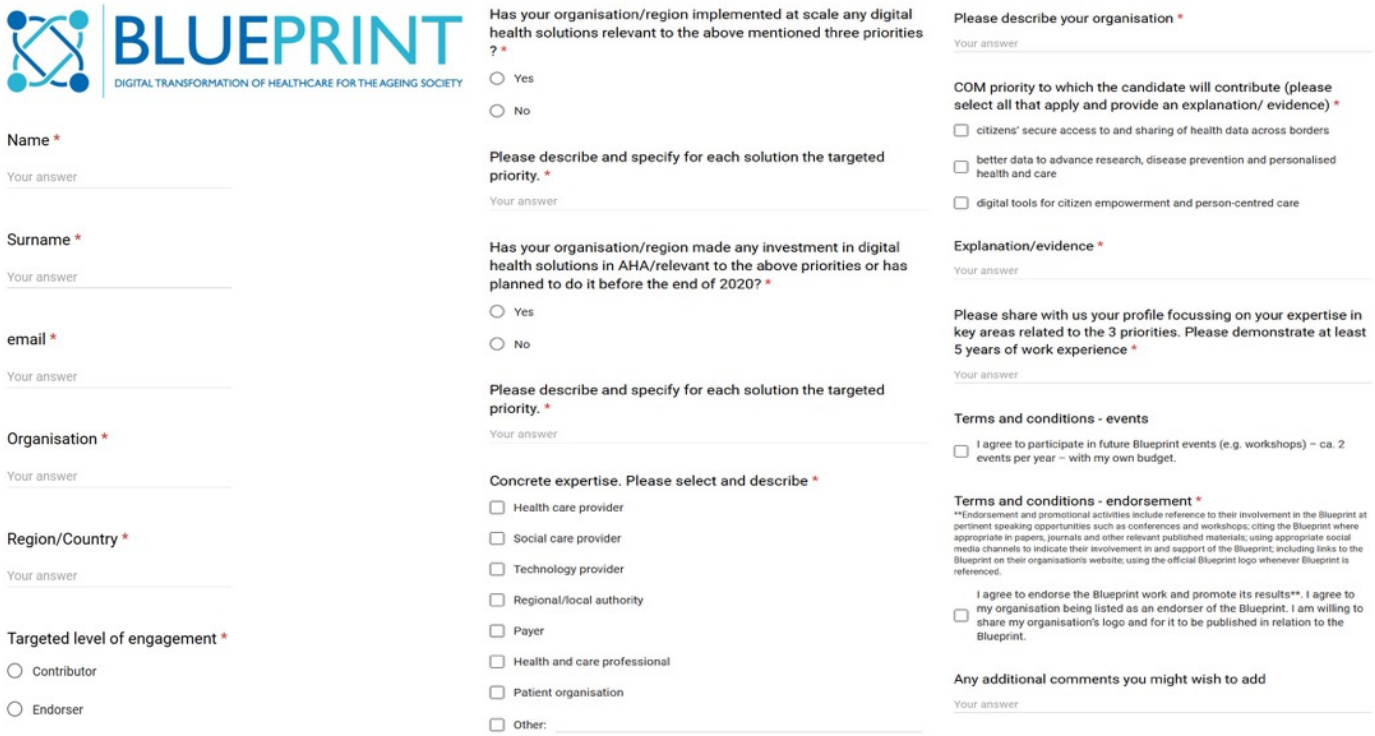
Topic area to which the candidate will contribute (please choose only one option) *

- ○ Big data for predictive risk stratification and prevention
- ○ Proactive prevention though patient empowerment, self-management, monitoring and coaching
- ○ Digital solutions for connected care
- ○ Integrated care (digital solutions to improve information sharing and collaboration)

Additional comments *

Your answer

S 2 Second BlueprintCall for engagement form



BLUEPRINT
DIGITAL TRANSFORMATION OF HEALTHCARE FOR THE AGEING SOCIETY

Name *
Your answer

Surname *
Your answer

email *
Your answer

Organisation *
Your answer

Region/Country *
Your answer

Targeted level of engagement *
- Contributor
- Endorser

Has your organisation/region implemented at scale any digital health solutions relevant to the above mentioned three priorities ? *
- Yes
- No

Please describe and specify for each solution the targeted priority. *
Your answer

Has your organisation/region made any investment in digital health solutions in AHA/relevant to the above priorities or has planned to do it before the end of 2020? *
- Yes
- No

Please describe and specify for each solution the targeted priority. *
Your answer

Concrete expertise. Please select and describe *
- Health care provider
- Social care provider
- Technology provider
- Regional/local authority
- Payer
- Health and care professional
- Patient organisation
- Other:

Please describe your organisation *
Your answer

COM priority to which the candidate will contribute (please select all that apply and provide an explanation/ evidence) *
- citizens' secure access to and sharing of health data across borders
- better data to advance research, disease prevention and personalised health and care
- digital tools for citizen empowerment and person-centred care

Explanation/evidence *
Your answer

Please share with us your profile focussing on your expertise in key areas related to the 3 priorities. Please demonstrate at least 5 years of work experience *
Your answer

Terms and conditions - events
- I agree to participate in future Blueprint events (e.g. workshops) – ca. 2 events per year – with my own budget.

Terms and conditions - endorsement *
**Endorsement and promotional activities include reference to their involvement in the Blueprint at pertinent speaking opportunities such as conferences and workshops; citing the Blueprint where appropriate in papers, journals and other relevant published materials; using appropriate social media channels to indicate their involvement in and support of the Blueprint; including links to the Blueprint on their organisation's website; using the official Blueprint logo whenever Blueprint is referenced.
- I agree to endorse the Blueprint work and promote its results**. I agree to my organisation being listed as an endorser of the Blueprint. I am willing to share my organisation's logo and for it to be published in relation to the Blueprint.

Any additional comments you might wish to add
Your answer

S 3 Blueprint persona template

Template for personas in the health and care needs over the life course framework and matrix*

**Matrix found at the end of the document*

Instructions:

Below is a template for the personas based on the Jim persona under the following link:

https://www.thinklocalactpersonal.org.uk/personalised-care-and-support-planning-tool/jim/

***Please provide a name** for your persona and fill in the corresponding textbox below.*

***Hint:** Be sure to check the "Overview of personas" matrix below or in the Dropbox folder to make sure that the name you provided has not been taken yet.*

'Life course' and 'Need' items can be selected through the dropdown box and are based on the 'health and care needs over the life course framework and matrix'.

***Please fill in the boxes in grey** as well as any guiding questions found in the template. As an example and for your reference only, many items from the template below are filled in with details of Jim (in blue box).*

Headings may differ depending on the characteristics of each persona. Feel free to edit as necessary. There are also additional, untitled boxes at the end of the table for your convenience.

For inspiration, please check the contributions to the matrix (ANNEX IV) or the Dropbox folder labelled "For inspiration".

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Name:	**Age:**

Life course: **Please select one**

Need: **Please select as appropriate**

Profile Summary

(Age, situation, personal life, hobbies, health concerns, etc)

Insert text here
…
…

Example: Jim is 80 years old and was previously married to Mary, who died nine months ago. He has two daughters who are both married and live a few counties away and they have three children between them.

Although now retired, Jim used to work as a fitter in a local engineering firm. When he was younger he loved bikes, DIY and family trips. He is a member of the local church, having once been a lay preacher. He was admitted to hospital with a stroke four weeks ago.

Jim is discharged after a stroke which has left him unable to use his left - non dominant arm, using a stick and unable to get upstairs. His daughter is staying with him temporality until more support is available.
Personal care and support planning is initiated by the social worker in the re-ablement team, who has put some emergency support in place. S/he asks the GP-based multi-disciplinary team to initiate care and support planning to look at Jim's health and social care needs together.

What's Important to Jim

- Please list
- Please list
- …
- …

Example
- Loves his cat, which reminds him of Mary

Own Resources & Assets / Support (not ICT-based)

What forms of support (not ICT-based) does your persona already have access to?
(Examples are:
- housing;
-support from family, friends, professionals (medical, legal, anyone who can help);
-personal assets/attributes e.g. being friendly and polite, sense of humour;

- Doesn't want to go into a home or be a burden on his family
- Going on family holidays
- Spiritual well being and getting to chapel once a week
- Personal hygiene and a smart appearance

-social life incl. membership in organizations, etc)
- <u>ability or willingness to self-care</u>

- Please insert
- Please insert
- ...
- ...
- ...
- ...

Example
- Jim has a son in law, who does small jobs around the house such as fitting a ramp and a hand rail for garden access
- Jim is also a practical problem solver
- His family previously bought a mobility scooter but it remains unused in the shed.
- Has worked out he could get a bath at a local home
- Friends from chapel come and offer support and communion at home

Daily living

- Please insert
- Please insert
- ...
- ...
- ...
- ...

Example
- Less-able to get around and do things
- Not going out as much as he has a fear of falling

Health concerns

- Please insert
- Please insert
- ...
- ...
- ...
- ...

Example
- COPD
- Heart Failure /CKD stage 3
- Atrial Fibrillation
- Falls and leg ulcers

- Has his shopping delivered or uses ready meals
- Sleeps badly since Mary died and is often woken by shortness of breath
- Can't manage to dress or bathe by himself since his stroke

- Osteoarthritis
- Ex smoker: teetotal
- District nurse visits to do dressings and occasional blood tests
- Attends cardiology clinic since diagnoses with heart disease three years ago

Events, issues and personal concerns

- Please insert
- Please insert
- ...
- ...
- ...
- ...

Example

- Shortness of breath
- Pain
- Poor sleep
- "Taking all these medicines"
- Falls happening more frequently
- Feeling "up and down"
- Poor use of left hand and uses a stick to get around the house
- Feeling "useless"

Treatment: medications, therapies, etc

- Please insert
- Please insert
- ...
- ...
- ...
- ...

Examples:
-Offence-related therapy with input from psychology and psychiatry
-Support from a speech and language therapist because of chewing and swallowing difficulties
-Chemotherapy
-On 12 different medications including:

- Six pills for his heart
- Three inhalers
- Two pain killers
- Warfarin to thin the blood

Health tests

- Please insert
- Please insert
- ...
- ...
- ...
- ...

Example

Care professional concerns

- Please insert
- Please insert
- ...
- ...
- ...
- ...

- Tests are annual
- Pulse oximetry
- Peak flow
- Spirometry
- Blood pressure
- Cholesterol
- INR
- Smoking status
- Depression screening
- MRC scale
- MUST/FRAT scores
- Frailty index
- Blood tests; LFTs. Uand Es, FBC, TFT, glucose
- ECG
- Chest examination

Social care

- Please insert
- Please insert
- ...
- ...
- ...
- ...

Employment concerns

- Please insert
- Please insert
- ...
- ...
- ...
- ...

Example from Sarah

- Employment – Sarah was able to be finically independent working as a decorator but now is reliant on her husband's benefits to bring in an income to pay for her additional support
- Social Network- Sarah had previously socialised within her work connections and spent time with her family only.
- Family contact Sarah's role within the family was that she was the "head" and her sons and husband relied her to keep their lives in order. She was a carer for her husband. Sarah is now independent on her family to support

her and she is unable to talk to them about how she feels.

- Daily living -Sarah is struggling to maintain her independence and trying to be strong for her family, she feels the roles have reversed
- Sarah's sons and husband are struggling to accept outside support although the community nurse has started to build up a relationship with the family, even although they are becoming increasingly tired caring for her. Personal care is being provided by her daughter-in-law

Technology-related resources

(incl. access to and availability of such resources, capability to use them, etc)

Please answer the following guiding questions (7 in total):

Does the persona…

1. Have broadband access? Yes/No
2. Have a smart phone or tablet? Yes/No
3. Feel comfortable using the internet? Yes/No

On a scale of 0 – 5, please rate (approx.) degree of comfort **(5 means very comfortable, no need for external support)**

Rating: ____

4. Feel comfortable using a smart phone or tablet? Yes/No

On a scale of 0 – 5, please rate (approx.) degree of comfort. **Rating:** ____

5. Feel comfortable with learning how to use a new gadget? Yes/No

On a scale of 0 – 5, please rate (approx.) degree of comfort.

Rating: ____

Educational interventions / concerns

- Please insert
- Please insert
- …
- …
- …
- …

6. **Overall digital health literacy* - Please rate (approx.) [scale of 0 -5; 5 as high literacy].**
   Rating: ____

**Digital health literacy definition: the ability to seek, find, understand and appraise health information from electronic resources and apply the knowledge gained to addressing or solving a health problem. (Source: Norman and Skinner, 2006 DOI:10.2196/jmir.8.2.e)*

7. Does persona have someone who will assist them in using the internet, tablet, etc when needed? Yes/No

Optional: Please insert any additional comments in the pink box below:
e.g. "not comfortable with smartphone now but is willing to try/learn";
"comfortable, but only with assistance of carer"

Technology-based solutions incl. ICT

Please list any other forms of ICT-based support not mentioned above that would provide better health and care for the persona / target the needs of the persona.
Examples from contributors:

- *Digital support to speed up overcoming the language barrier*
- *Computerised anger management*
- *Medication reminders with associated self management education*

- Please insert your text here
- Please insert yoir text here
- ...
- ...
- ...
- ...

Identified unmet needs

- Please insert your text here
- Please insert yoir text here
- ...

- ...
- ...
- ...

Reminder:

The boxes below may be used to describe particular aspects of your persona in more detail.

Examples of possible additional fields/boxes: *socio-economic context, transportation, housing services, other concerns that are not health-related, etc*

Other (please specify) • Please insert • Please insert • ... • ... • ...	**Other (please specify)** • Please insert • Please insert • ... • ... • ...
Other (please specify) • Please insert • Please insert • ... • ... • ...	**Other (please specify)** • Please insert • Please insert • ... • ... • ...
Other (please specify) • Please insert • Please insert • ... • ... • ...	**Other (please specify)** • Please insert • Please insert • ... • ... • ...

Health and care needs over the life course framework and matrix

Last Update: 13th of June 2018. 12:34

Life course / **Need**	*(Babies)/children/ young people*	*Working age adults*	*Retired people*	*Very old people 80+*
Generally well / good wellbeing	Maddalena, Michael (incl. carer aspect) **(Rose, 10 Mohammed, 16)**	Diane, Soo (incl. carer aspect)	Joost (incl. carer aspect)	Elisio (incl. carer aspect) **(Maria, 83)**
Chronic conditions and/or social needs	Donna, Leo, Michael **(Millie, 18)**	George **(Nikos, 50)**	George **(Eleni, 73)**	Esteban **(Maria García, 84)**
Complex needs	Donna, Leo, Michael **(Ben, 15)**	Elisio	Guido **(Procolo, 82)**	Anne-Sophie **(Jacqueline, 87)**

BLUEPRINT
DIGITAL TRANSFORMATION OF HEALTHCARE FOR THE AGEING SOCIETY

S 4 Matilde's persona poster

BLUEPRINT
DIGITAL TRANSFORMATION OF HEALTHCARE FOR THE AGEING SOCIETY

Web: https://ec.europa.eu/eip/ageing/blueprint_en
Contact: WE4AHA@empirica.com

Meet Matilde

Name: Matilde **Country:** Italy
Age: 60 **Area:** Suburn of city
Life course: Retired people
Need: Chronic condition and social needs
Connectivity: broadband, smart phone

Internet usage	Low	High
Mobile device skills	Low	High
Affinity to new tech	Low	High
Digital Health Literacy	Low	High
Assistance (ICT use)	No	Yes

Matilde is 60 years old, lives alone in a small apartment sites in a working class area of the city with no family living nearby. She is already retired because she is unable to work since two years as janitor because she is overweight. She practiced sport in her childhood but during adolescence she was abused by her mother´s new partner. Starting from this episode she fell in a state of depression and she felt better only eating in uncontrollably way and in few years she was overweight. She tried to react moving in another city at 26 years old to find a job but her unhealthy lifestyle got worse because she was completely alone. She fell in love with Andrea, a bricklayer, who tried to help her. Unfortunately after 10 years of relationship Andrea died for an untreated pneumonia and Matilde falls in a deep state of depression which affected again her weight. She is no longer able to take care of herself as to dress or bathe. Matilda would like to be self-sufficient, to be able to return to her family and take part to city´s activities as guided tour in museum, local festival, or social event organized to help other young people with similar problems. She would like to move in new apartment nearby the centre of the city

What's important to Matilde

- ✓ Staying in good health
- ✓ Being active and come back e to walk by the sea or in a park
- ✓ Staying in touch online with her family and going to visit them.
- ✓ Being able to be auto-sufficient
- ✓ Being able to be part of social events, guided tour in museum, local festival
- ✓ Being not anymore depressed.
- ✓ Find a new comfortable apartment nearby the centre of the city

Daily living

- ✓ She eats ready meals several time in a week
- ✓ She sleeps badly and has shortness of breath
- ✓ She can't manage to dress or bathe by herself
- ✓ She has muscle and bone pains when she tries to move
- ✓ She spend many hours of the day watching tv series in bed

Own resources & assets / support

- ✓ Small apartment in suburbs;
- ✓ Support from family, but it isn´t enough because they live far away.
- ✓ Lucia, her neighbour, tries to help and bring her to all the appointment with own car.

Events, issues and personal concerns

- ✓ unable to take care of herself
- ✓ She is depressed for her past and because she´s alone and warried about her recurring panic attack
- ✓ Feeling stressed about your health and scared to be not able to change her lifestyle
- ✓ Daily muscles and articular pains

Health concerns

- ✓ Obesity
- ✓ Depression and panic disorder
- ✓ Mild Sleep apnea syndrome (SAS)
- ✓ Risk of heart failure and stroke
- ✓ Muscle and bone pains, skin rash
- ✓ Polycystic ovary syndrome (PCOS)

Health tests

- ✓ Monthly routine tests: Blood cells count, lipid profile, glucose, renal and hepatic function, hormonal levels (PG,estrogen, PRL, total testosterone and androgens)
- ✓ Vitamin levels: Vitamin E, C, B12, D every six months
- ✓ Blood pressure every week
- ✓ Test for body weight every 3 months
- ✓ Evaluation of Bone mineral Density (BMD) with MOC DEXA every three years
- ✓ ECG every six months

Treatment: medications, therapies, etc.

- ✓ 1 pill three times week of Calcium supplements
- ✓ 50000U.I./5ml once a month of Vitamin D supplements
- ✓ 1 contraceptive pill/day for 28 days each month
- ✓ Psychotherapy meeting once a week and anti-depressive once a day
- ✓ Physiotherapy 3 times a week
- ✓ Improve her personal hygiene to reduce skin rush and apply a cream twice a day
- ✓ Try to be more active as starting to walk around the house more often
- ✓ She needs to change her lifestyle and follow a healthy diet.

Care professional / educator concerns

- ✓ Matilde sometimes skips medical appointments with specialist because Lucia cannot be with her
- ✓ She is unable to follow her diet because she is not very good at cooking and she has a poor motivation

Needs

(1) Matilda cannot manage to lose weight due to the lack of motivation and understanding of her health risks
(2) Matilda is having more difficult to take care of herself (cooking, hygiene, looking after her apartment)
(3) Matilda would like to access nutritional and psychological programs or other types of support that can help her

This persona was developed by Roberta Patalano, Maddalena Illario and her team, A.O.U Policlinico II of Napoli, with the kind support of the WE4AHA Blueprint and expert team.

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