Ministero della Salute Direzione Generale della Ricerca Sanitaria e Biomedica e della Vigilanza sugli Enti **BANDO RICERCA FINALIZZATA 2018** **esercizio finanziario anni 2016-2017**	**Project Title:** Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization:TELEMECHRON study
Project Code: NET-2018-12367206	**Principal Investigator:** Bianchi Stefano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Toscana

Project Type: Network Project/Progetti di Rete

Major Diagnostic Category*: Nefrologia e Urologia

Project Classification IRG: Healthcare Delivery and Methodologies

Project Classification SS: Biomedical Computing and Health Informatics - BCHI

Project Keyword 1: Application of human-centered computing (human-machine interfaces), intelligent systems, virtual environments, computer-assisted diagnosis and treatment systems with data including imaging data and telemedicine to biomedical and clinical systems, including the study of collaboration to engineer-usable effective software systems.

Project Keyword 2: Chronic diseases, Telemedicine, telemonitoring, ehealth, mhealth, health-related quality of life; medical decision-making

Project Keyword 3: Case Manager, clinical manager, chronic disease management

Project duration (months): 36

Project Request: **Animals:** ☐ **Humans:** ☒ **Clinical trial:** ☐

The object/s of this application is/are under patent copyright Y/N: ☐

Operative Units / WP

	INSTITUTION	Department/Division/Lavoratory	Role in the project
1	Toscana	Unità Operativa di Nefrologia e Dialisi di Livorno e Livorno Sud, ASLNO.	Stefano Bianchi has the role to coordinate the components of the project and to arrange the study of WP1
2	Istituto Superiore di Sanita'	Centro nazionale TISP-Tecnologie innovative in sanità pubblica	Assessment of the entire process, promoting clinical governance, quality and legal regulation and guidelines
3	Regione Lombardia - Direzione Generale Sanità	Istituti Clinici Scientifici Maugeri IRCCS	To design and to test and evaluate innovative models to a better management of patients with chronic conditions
4	Provincia autonoma Trento	Azienda Provinciale per i Servizi Sanitari	Building a more sustainable health system concerning a new model of care for patients with type 2 diabetes with the use of smart technologies.

Overall Summary

The telemedicine (TM) intervention in chronic disease management promises to involve patients (pts) in their own care, provides continuous monitoring by their healthcare providers, identifies early symptoms, and responds promptly to exacerbations in their illnesses. This project is aimed to analyze three current healthcare services in order to introduce into them adequate changes to improve the management of three chronic diseases: congestive heart failure (CHF), type 2 diabetes mellitus (T1-2DM), and chronic kidney disease (CKD). Innovative strategies to improve quality of care and optimize resource utilization of TM in home-based services will be designed, verified and promoted over the territory of three Italian regions.

Background / State of Art

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The current trend in aging population will likely result in a future increase of chronic diseases occurrences as well as a future increase of chronic diseases comorbidities. System fragmentation, discontinuities in patient care, and serious inefficiencies in the financing and delivery of care as well as the prevalence of unhealthy lifestyles have all exacerbated the problem, especially among those suffering from chronic illness. Hence, the focus of this project is on the capabilities of health Information and communication Technology (ICT) not only in extending the reach of clinical resources to serve a widely dispersed and underserved patient population, but more importantly, in improving the efficiency, effectiveness, coordination, and continuity of care with active patient participation in the management of chronic illness.In this context, telemedicine can improve the management of these diseases by using information and communication technologies. The advantages cover more regular follow-ups and fewer unnecessary travels and hospitalization and a more appropriate delivery of care . To guarantee quality in the patient's care, a typical telemedicine application combines three systems: the patient system for the medical monitoring, the data transmission system between the two structures (e.g., the patient's home and a healthcare facility) and the data processing and archiving system, which is generally located in the hospital.
In this project, we focus on three main chronic diseases, i.e. cardiovascular diseases, diabetes, and kidney diseases.

It's available a Systematic Review on this topic? Si

It's available as publication please report bibliographic data? Si

Bibliographic data (DOI): 10.1016/j.irbm.2015.01.009/

Hyphotesis and Specific AIMS

Hyphotesis and Significance:
This project is aimed to analyze the current models and to design innovative strategies to improve quality of care and optimise resource utilization of TM in home-based management for the global care of three chronic diseases: CHF, T1-2DM, CKD. The main focus is on the prevention of complications, recurrence of instabilizations and optimal therapy for the global management of chronic pts through TM and e-Health.
Reducing avoidable/unnecessary hospitalisation of pts with chronic conditions, through the effective implementation of a health care network, offering integrated care programs and applying chronic disease management models, should ultimately contribute to the improved efficiency of health systems.

Preliminary Data:
In a previous Project, financed by the Ministry of Health of Italy "Development of a service interface method (WebService) between family care physicians operating in a primary care setting and nephrologists , for the prevention, diagnosis and treatment of kidney damage in patients with type II diabetes mellitus" (n. Project RF-2011-02346990, 2014-2017, PI Stefano Bianchi) a shared clinical chart has been established between family physicians and nephrologists, aimed at determining the early diagnosis and staging of chronic kidney disease in 6142 patients with type 2 diabetes mellitus, followed up in a primary clinical setting. In these patients the evidence-based therapies established by the National and International Guidelines have been strongly implemented. The clinical chart shared on the web has allowed a constant interactive dialogue between family physicians and nephrologists, and is currently being examined to evaluate if this shared diagnostic and therapeutic approach has allowed to slow the progression of kidney damage in these patients, a reduction in the number of hospitalizations and complications related to diabetes and chrocic kidney disease and the costs of diagnostic examinations, medications and global care sustained by the National Healthcare System.

Picture to support preliminary data:

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Specific Aim 1:

To identify, analyse and compare current models of TM applied to patients with chronic conditions across the participating regions, with special attention to the following elements:
- target population
- setting
- relationship with other modalities and components of healthcare
- process and delivery of care
- outcome measurement
- economic evaluation.

Specific Aim 2:

To design, test and evaluate innovative models for applying TM to the management of pts with chronic diseases . New models will be characterized by the followings:
- flexible adaptation to pts subgroups/ individual pts characteristics, including pts (and caregivers) expectation and willingness to participate actively in the process of care
- identification of technical components which are essential, accessory, useful or futile for different pts subgroups, including evaluation of pts abilities and preferences.
- definition of the team of care and the roles and responsibilities of each components: case manager, clinical manager etc
- pre-definition of outcome measures, that should include at least the evaluation of quality of life, perceived quality of care by the pts and caregivers, number and duration of hospitalizations.
- definition of Quality Assurance (QA) derived indicators related to risk and performance of TM implementation where needed

Specific Aim 3:

To collect a set of data allowing to analyse and validate the care model and to measure the patient adherence to the care plan as well as measure the performance of the predictive models based on this data.

Experimental Design Aim 1:
- Definition of a more trans-disciplinary approach to the management and treatment of chronic diseases, by offering patient-centered solutions adapted to the specific needs and built upon their feedbacks and requests.
- Definition of a scalable, flexible and secure system architecture integrating wireless wearable and non-wearable sensors to enable patients to autonomously monitor their health status and track their daily activity, a hub device for local data processing, an APP for user interaction with the system and cloud services for data storage, analysis and reasoning.
- Identification of a solution combining data acquisition, processing and transmission, enabling autonomous interactions among the system components

Experimental Design Aim 2:
-Development and integration of the defined system building blocks. The compliance with the defined system requirements will be verified by testing each single component and by performing integration tests to validate the main functionalities of the proposed system.

-Identification and detailed definition of the "Virtual Tutor" solution for enhancing health and re-inclusion. A user friendly App for an interactive patient remote monitoring will be designed and developed.
-Detailed definition of the main technical components of the system: the sensors, the hub device, the data processing short-term and long-term algorithms, the communication modules and the interfaces among the different subsystems and cloud application for service provisioning.
-Design of a multi-technology wireless network to support efficiently the data exchanges among the sensors, the hub device (local data processing engine) and the cloud data center.

Experimental Design Aim 3:
Definition of the case studies for the system innovative features and the potentialities demonstration. Pts attending home peritoneal or hemo dialysis , pts on clinical pre-dialysis, pts with T1-2 TM and pts with CHF will be considered to validate the proposed solutions.
Demonstration of the system capabilities to address the specific requirements of the identified case studies, by its flexibility to self-adapt to different patients needs
The main components for the development of the proposed innovative system will be:
1 a smart chair, able to perform dialysis at home
2 body unobtrusive wearable sensors, which measure bio-parameters to define the state of the disease in patients with pre-dialysis stage of CKD, T1-2 DM and CHF
3 a hub device (e.g., smartphone) with a specifically design APP which collects the data from the body sensors and from the smart armchair; the hub makes a short-term analysis of the data for early warnings related to the state of the disease
4 an APP which acts like a Virtual Tutor, interacting with the patient, reminding a correct life style (food, activities, etc.), as well as collecting manually inserted data from the patient (mood, food eaten, exercises, questions for doctors/caregivers, etc.);
5 a cloud repository which collects all the data for long-term storage and analysis of the disease; the repository can be accessed by the medical staff and caregivers;
6 a secure ICT cross-segments infrastructure assures the movement of information from the patient (chair, body sensors) to the hub and to the cloud.

Metodologies and statistical analyses:
We identified four tasks.
Task 1 User requirements
This task is responsible for identifying: (i) clinical and biological parameters to be retrieved during the session, with accompanying timescales and measurement units, (ii) clinical parameters to be monitored during and in between treatments (iii) patients clinical, structural and psychological requirements for undertaking a home clinical management (iv) environmental data.
Task 2 System requirements
This task starts from the analysis of the identified user requirements. As an example functional, network, security, privacy, operational requirements will be identified. Moreover, based on the result of the surveys addressed to pts, caregivers and clinicians, the project team will identify the technical, ergonomic and aesthetic requirements of all different devices allowing patients to be easily monitored at home in complete autonomy and independence, and physicians and caregivers to assist and monitor the entire process in a safe, comfortable and efficient fashion.
Task 3 Case studies
The objective of this task will be to define the number of cases to be submitted to the experimental protocol.

The clinical characteristics of the pts and his skills (as well as the caregivers) to fully understand and collaborate with the aim of the investigation will be thoroughly evaluated
The acceptance of people not on dialysis, but with advanced CKD, Type 1-2 DM and CHF to live, at least for a part of the day, with wearable devices, will be carefully taken into account.

Expected outcomes:

- Prevention: Reduced admissions and days spent in hospitals, and improvements in the daily activities and quality of life
- Reduced demands on general pratictioner visits as pts have a better understanding of their condition and self management of that condition improves.
- Patient and carergiver Quality of Life and Self Management: Reduced stress on the patient and carers through better understanding of natural cycles of the impact of the impairment. Incentive to take ownership of medication and Improved compliance with rehabilitation program, resulting in higher quality of life.
- Robust evidence based on health and social care outcomes, quality of life and care efficiency. Pts will be able to wear multi-functional, unobtrusive intelligent sensors with high data encryption to promote their health.
- The real-time quality data provided by this project will provide seamless and secure information exchange among all those involved in health, social and care services.
- Patient Public Involvement will be crucial in the exchange and acceptability of such a device and is a fundamental part of this project technological development. Pts participation in care is emerging as a growing movement wherein patients are assuming more responsibility for the prevention, detection and treatment of health problems in a manner that supplements or substitutes for professional services.
- This project will provide an advance interaction between pts and their carers, and more active participation of pts and their relatives or other informal care givers in care pathway.
- Reinforced medical knowledge with respect to management of chronical disease.
- The remote monitoring and treatment is expected to reduce both direct and indirect healthcare costs
- Adherence to the therapy and continuous check-ups are both required to improve the effectiveness of the therapy with a subsequent reduction of unplanned hospital admission, urgency calls, mistreatment or waste of unused drugs that are all sources of extra cost for National Healthcare Systems.

Risk analysis, possible problems and solutions:

A formal risk plan will be developed and maintained by the coordinator, as part of normal project management activities. Risks would be identified during project preparation, and mitigations considered.
Personnel: a risk is connected to the timely hiring of personnel for performing the work-plan, according to scientific excellence and gender balance. That is mitigated by the strong permanent staff pool of all the partners, but some specific competences might require long advertisement of the hiring and selection time. Effective advertisement by the communication actions will further mitigate the problem.
Activities: all tasks are subject to the typical risks connected to scope change over time. The risk is in incurring delays or extra costs. This will managed by WP PI and it is mitigated by the ability to reallocate tasks or efforts within the careful project monitoring and control.
Adoption of services: the successful adoption of services depends on their successful and timely deployment and this can be mitigated by good communication with potential users and other stakeholders to maintain the engagement and understanding.
Conflict Resolution : conflicts will be solved at the lowest level possible, and preferably amicably. In case of conflicting

views, the decisions will be taken by voting in the schedule meetings.

Significance and Innovation

The interactive education and training facilities designed to facilitate self-monitoring of the different aspects of the care plan and awareness raising in the patient, will facilitate the empowerment of the patient and the adoption of a proactive approach towards the treatment of the disease. These achievements are likely to affect the patients ability and willingness to remain active both in their private and professional life.
The use of mobile sensors will increase the set of data retrieved and processed by the system, and provide an exhaustive overview of the treatment outcomes. A wider set of data will also facilitate decision-making both for physicians and patients.

Description of the complementary and sinergy research team

A Steering Committee, made up of WPs PI and CoPI, will be established at the beginning of the operative phase of the project and will meet every year. Procedures will be provided in the Working Groups Agreement to be signed by the partners before the start of the project. This document will formalize the rights, obligations, relationships and procedures within the consortium, as well as any other relevant issue.
Dott Bianchi will coordinate, supervise the specific activities of the different WPs. The WP PI will report on the WP status to the Coordinator, and is responsible for each WPs progress.
Dott Bianchi is responsible for Quality and Risk Management as well as for the exploitation strategy. He is also responsible, together with Istituto Superiore di Sanità of dissemination, impact, sustainability and business model of Virtual Tutor. The majority of partners have long-lasting collaborations in previous projects, what built mutual confidence and trust. All the partners have developed many scientific projects and have long-lasting collaborations in previous projects, what built mutual confidence and trust. In this project they will be pooling their efforts around a common objective, which is of the utmost interest for all of them and this is a guarantee of excellent collaboration within the project.

Training and tutorial activities

We anticipate doctors and nurses training for consultancy and tutoring activities dedicated to health care professional to achieve effective and efficient clinical practices related to the treatment of patients with different chronic diseases
We provide professional learning expertise to drive a culture of chronic care, among patients and family doctors and nurses, applying the principles of Therapeutic Education and Medical Humanities.
We anticipate the use of the instruments and coordinate chronic care specialist team, with activities across the region and facilitate best practice sharing; sustain and reinforce ethics and compliance principles to achieve effective and efficient clinical practices related to the treatment of patients with chronic illnesses

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Bibliography

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2) Stevens PE. J Nephrol 2010;23:23-32.
3) Fox CH. J Am Board Fam Med 2008;21:522-530.
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11) Bruno G. Diabetologia 2007;50:941-948.
12)Walker T. Am J Kidney Dis. 2015;65(3):451-463.
13)Tong A. Am J Kidney Dis. 2015 Aug; 66(2):212-22.
14) Jose A. Blood Purif 2006;24:22¿27.
15) Hanson CS. Nephrology (Carlton). 2017 Aug; 22(8):631-641.

Timeline / Deliverables / Payable Milestones

Each partner will report project progress to the Coordinator on a three- monthly basis. This will cover technical progress, results, deliverables and compliance with the WP, as well as the monitoring and updating of the possible identified risks. Progress of the task will be reported in terms of percentage of completion and estimated time to completion, deviations from agreed time scales and corrective actions.

Milestones 18 month

User requirements
System requirements
Overall system architecture design
Platform Service design
Wireless sensors (wearable and chair sensors)
Communication chain (sensor-body, body-hub, hub-cloud)
Data protection (secure ICT)
Case studies and User Acceptance
Design and execution of the field trails

Milestones 36 month

Virtual Tutor -User and -Cloud Interface
ICT solution and cloud analysis

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Overall architecture of the trail system (Interfaces)
Integration of patient-side and cloud components
Data analysis and validation of the trail results

Gantt chart

overallGANTT.pdf

Equipment and resources available

WP1 has an excellent track record of clinical studies that have resulted in important publications in the fields of nephrology and progression of kidney disease. It has been active in diagnostic procedures and treatment of CDK and its progression .WP1 has an excellent reputation in Medical and Health Informatics. It runs extremely large databases, including a number of patient registries on chronic renal insufficiency.
ASLNO adopts and follows, for all the aspects of its clinical and research activity, a Code of Ethics in line with the ethical and social principles of its mission, its own tradition of correctness and transparency in the conduct of every health and research activities and with the purposes of the regional mandate. ASLNO adopts and follows a Code of Privacy aimed to protect everyone rights to be protected about personal data.
WP4 guarantees an existing electronic health record . In addition to this, the use of available apps is already implemented and validated. In terms of facilities, informatics and electronic tools to monitor the required data are in many cases piloted and therefore they are representing a solid basis for the development of the present project.
WP3 has a regional administrative database already available and a large amount of devices to support this research and regional personal health record of the pts already present and use by all the hospitals and GPs
WP2 guarantees fast calculation resources, software for analysis, sofware platform for web based application such as data base or cloud computing
SUBCONTRACTS
WP3:A specialized external support needed throughout the project for the coordination of technical activities. A senior professional, supported by a team of eHealth and mHealth specialists, will:
-collaborate with the research teams in the evaluation and choice of the most suitable solution for implementing an electronic version of the cards that the pts will use for self-assessment
-supervise the regional guidelines regarding Digital Ecosystems opportunities that
WP4: Subcontracting will be used mainly for reporting or technical services . This is to improve reporting quality and if needed technical services as foreseen in the present proposal.

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Translational relevance and impact for the National Health System (SSN)

The adoption of new care models enabled by the use of technology might create a new paradigm of care for treating chronic diseases aiming at supporting health care staff in efficiently taking care and monitoring the health status and at fostering patient self-management. The project might provide the unique opportunity to pilot a new care model, potentially transferrable to other regions/provinces, allowing to improve the quality of care and to reduce the risk of complications and variation in the completion of care processes. In addition, the aggregations and analysis of the dataset may allow the review of the care plan and the measurement of Key Performance Indicators in order to assess, for instance the effectiveness of the therapy. The new care model may reduce the number of hospitalisations and consequently health care costs for the Health Care System , thanks to a telemonitoring system and/or structured virtual support.

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PRINCIPAL INVESTIGATOR PROFILE

Name		
Bianchi Stefano	Institution	Toscana
	Department/Unit	Department of Medicine, UOC Nephrology and Dialysis, Livorno SudASL nordovest, Toscana, Italy
	Position Title	Principal Investigator

Personal Statement

This project is aimed to design innovative strategies to improve quality of care and optimise resource utilization of telemedicine in home-based management for the global care of three chronic diseases: congestive heart failure , type 2 diabetes mellitus , and chronic kidney disease.
Dott Bianchi is the coordinator and has successfully completed a series of projects under these responsibilities . Dott Bianchi is responsible for Quality and Risk Management as well as for the exploitation strategy and together with dott Grigioni (ISS) of dissemination, impact, sustainability and business model of Virtual Tutor.
Dott Scalvini is in charge of the recruitment and management of pts with heart failure.
Dott Piffer is in charge of the recruitment and management of pts with diabetes.

Education/Training - Institution and Location	Degree	Year(s)	Field of study
Institute of Medical Pathology, Santa Chiara Hospital, University of Pisa, Pisa, Italy	Clinical Fellowship in Internal Medicine	2	Internal Medicine
Division of Nephrology, Santa Chiara Hospital, University of Pisa, Pisa, Italy	Clinical fellowship in Nephrology	2	Nephrology
Postgraduate School of Nephrology, University of Pisa, Pisa, Italy	Certified specialist in Nephrology	4	Nephrology
Institute of Medical Pathology and Enviromental Diseases, University of Pisa, Pisa, Italy	Certified specialist in enviromental diseases	2	Enviromental Diseases
Division of Nephrology, Los Angeles County Hospital, Keck School of Medicine, University of Southern California, Los Angeles, USA	Felloship in Nephrology	2	Nephrology
Institute of Respiratory Diseases, University of Siena, Siena, Italy	Certified specialist in Respiratory Diseases	4	Respiratory Diseases

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Positions

Institution	Division / Research group	Location	Position	From year	To year
University of Parma, Italy	Post Graduate School of nephrology	University of Parma, Italy	Professor of Nephrology	2017	2018
Local Health Unit, Hospital of Livorno, Livorno, Italy	Division of Nephrology	Hospital of Livorno, Livorno Italy	Medical assistant	1979	1994
Local Health Unit, Hospital of Livorno, Livorno, Italy	Division of Nephrology	Hospital of Livorno, Livorno, Italy	Chief assistant	1994	2001
Local Health Unit, Hospital of Livorno, Livorno, Italy	Division of Nephrology	Hospital of Livorno, Livorno, Italy	Chief, Hypertension and Kidney Diseases Unit	2001	2008
San Donato Hospital of Arezzo, Arezzo, Italy	Division of Nephrology	Hospital of Arezzo, Arezzo, Italy	Chief of Nephrology	2008	2011
Local Health Unit, Hospitals of Piombino-Cecina-Portoferraio, Livorno, Italy	Division of Nephrology	Hospitals of Piombino-Cecina-Portoferraio, Livorno, Italy	Chief of Nephrology	2011	2018
Local Health Unit of Livorno, Hospitals of Livorno-Piombino-Cecina-Portoferraio, Livorno, Italy	Department of Nephrology, Cardiology and Diabetology, Local Health Unit of Livorno	Hospitals of Livorno-Piombino-Cecina-Portoferraio, Livorno, Italy	Chief of Department	2011	2018
University of Siena, Siena, Italy	Postgraduate School of Nephrology	University of Siena, Siena, Italy	Professor of Nephrology	2008	2013

Official H index: 22.0 (autocertificated)

Source: Scopus **Scopus Author Id:** 55618330900

ORCID ID: 0000-0003-3981-6325 **RESEARCH ID:** J-9962-2016

Awards and Honors:

1995Recipient American-Italian Society of Nephrology grant with the project of study titled "Microalbuminuria as a marker of kidney damage in patients with essential hypertension"
2002 Invited Member Commettee " Proteinuria and other marker of kidney disease". NIDDKD/NHI/NKF
2003-currentMember Committee of Tuscany Region for the prevention, diagnosis and treatment of diabetic nephropathy
2008-2012Member,Italian Society of Nephrology Commettee "Clinical research and international relationships".

Other CV Informations:

Visiting Professor at Henry Ford Hospital, Detroit, USA (2003); Yale University, New Haven,USA (2002); Hopital Broussais, Paris, France; (2001) Northwestern and Rush University Chicago, USA (2001)
Reviewer of Diabetologia, Nutrition Metabolism and Cardiovascular Diseases, Journal of Nephrology, American Journal Kidney Disease, Nephrology, Dialysis and Transplantation, and Cochrane Library
N° of communications to scientific meetings: 250;chapters in books 14; N° of citations more than 4100
2018-current Secretary of the Italian Society of Nephrology.

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Selected peer-reviewed publications of the PI

Valid for PI minimum expertise level

Title	DOI	PMID	Cit. **	P.*
Insulin resistance, metabolic syndrome and endothelial dysfunction Bigazzi, R., Bianchi, S. 2007 Journal of Nephrology		17347967	9	L
Intensive Versus Conventional Therapy to Slow the Progression of Idiopathic Glomerular Diseases Bianchi, S., Bigazzi, R., Campese, V.M. 2010 American Journal of Kidney Diseases	10.1053/j.ajkd.2009.1	20097461	22	F
Do HMG-CoA reductase inhibitors improve kidney function? The saga continues Campese, V.M., Ku, E., Bigazzi, R., Bianchi, S. 2011 Journal of Nephrology	10.5301/jn.5000024	21887675	9	L
The renal effects of mineralocorticoid receptor antagonists Bianchi, S., Batini, V., Bigazzi, R. 2015 International Journal of Cardiology	10.1016/j.ijcard.2015.05.125	26049733	6	F
Statins and lipid-lowering strategies in cardiorenal patients S Bianchi, D Grimaldi, R Bigazzi - Contributions to Nephrology, 2011	10.1159/000327139	21625103	5	F
Hyperinsulinemia, circadian variation of blood pressure and end-organ damage in hypertension. S Bianchi, R Bigazzi, R Nenci, VM Campese - Journal of nephrology, 1997		9442446	11	F
Microalbuminuria in essential hypertension. S Bianchi, R Bigazzi, VM Campese - Journal of nephrology, 1997		9377730	14	F
Altered circadian blood pressure profile and renal damage. S Bianchi, R Bigazzi, VM Campese - Blood pressure monitoring, 1997		10234137	13	F
Silent ischemia is more prevalent among hypertensive patients with microalbuminuria and salt sensitivity S Bianchi, R Bigazzi, A Amoroso, VM Campese - Journal of human hypertension, 2003	10.1038/sj.jhh.10014	12571612	16	F
Diurnal variations of blood pressure and microalbuminuria in essential hypertension S Bianchi, R Bigazzi, G Baldari, G Sgherri, VM Campese - American journal of hypertension, 1994	10.1093/ajh/7.1.23	8136107	330	F
Long-term effects of enalapril and nicardipine on urinary albumin excretion in patients with chronic renal insufficiency: A 1-year follow-up Bianchi, S., Bigazzi, R., Baldari, G., Campese, V.M. 1991 American Journal of Nephrology 37	10.1159/000168289	1951474	37	F
Microalbuminuria in patients with essential hypertension effects of an angiotensin converting enzyme inhibitor and of a calcium channel blocker Bianchi, S., Bigazzi, R., Baldari, G., Campese, V.M. 1991 American Journal of Hypertension	10.1093/ajh/4.4.291	2059393	44	F
Microalbuminuria in patients with essential hypertension: Effects of several antihypertensive drugs Bianchi, S., Bigazzi, R., Baldari, G., Campese, V.M. 1992 The American Journal of Medicine	10.1016/0002-9343(92)90580-5	1442855	73	F
Insulin resistance in microalbuminuric hypertension: Sites and mechanisms Bianchi, S., Bigazzi, R., Galvan, A.Q., (...), Ferrannini, E., Natali, A. 1995 Hypertension	10.1161/01.HYP.26.5.789	7591019	89	F
Elevated serum insulin levels in patients with essential hypertension and microalbuminuria Bianchi, S., Bigazzi, R., Valtriani, C.,Chiapponi I., Sgherri G.,Baldari G., Natali A., Ferrannini, E., Campese, V.M. 1994 Hypertension	10.1161/01.HYP.23.6.681	8206563	95	F

Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization:TELEMECHRON study

Project Code: NET-2018-12367206

Principal Investigator: Bianchi Stefano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Toscana

Project Type: Network Project/Progetti di Rete

Title	DOI	PMID	Cit. **	P.*
Antagonists of aldosterone and proteinuria in patients with CKD: An uncontrolled pilot study Bianchi, S., Bigazzi, R., Campese, V.M. 2005 American Journal of Kidney Diseases	10.1053/j.ajkd.2005.03.007	15983956	106	F
Microalbuminuria in essential hypertension: Significance, pathophysiology, and therapeutic implications Bianchi, S., Bigazzi, R., Campese, V.M. 1999 American Journal of Kidney Diseases	10.1016/S0272-6386(99)70002-8	10585306	154	F
Long-term effects of spironolactone on proteinuria and kidney function in patients with chronic kidney disease. Bianchi, S., Bigazzi, R., Campese, V.M.; 2006, Kidney International	10.1038/sj.ki.5001854	17035949	202	F
A controlled, prospective study of the effects of atorvastatin on proteinuria and progression of kidney disease. 2003 American Journal of Kidney Diseases; Bianchi, S., Bigazzi, R., Caiazza, A., Campese, V.M.	10.1053/ajkd.2003.50140	12612979	300	F

* Position: F=First L=Last C=Corrispondent

** Autocertificated

Project Title:
Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization:TELEMECHRON study

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Applicant Institution: Toscana

Project Type: Network Project/Progetti di Rete

For evaluation CV

Title	DOI	PMID	Cit. *
Is microalbuminuria a predictor of cardiovascular and renal disease in patients with essential hypertension? Campese, V.M., Bianchi, S., Bigazzi, R. 2000 Current Opinion in Nephrology and Hypertension	10.1097/00041552-200003000-00008	10757219	28
Metabolic risk factors and markers of cardiovascular and renal damage in overweight subjects Bigazzi, R., Bianchi, S., Batini, V., Guzzo, D., Campese, V.M. 2006 American Journal of Hypertension	10.1016/j.amjhyper.2005.10.002	16580581	11
Increased cardiovascular events in hypertensive patients with insulin resistance: A 13-year follow-up Bigazzi, R., Bianchi, S., Buoncristiani, E., Campese, V.M. 2008 Nutrition, Metabolism and Cardiovascular Diseases	10.1016/j.numecd.2006.11.001	17368007	5
A Delphi consensus panel on nutritional therapy in chronic kidney disease Bellizzi, V., Bianchi, S., Bolasco, P., (...), Santoro, D., Santoro, A. 2016 Journal of Nephrology	10.1007/s40620-016-0323-4	27324914	3
Increased thickness of the carotid artery in patients with essential hypertension and microalbuminuria Bigazzi, R., Bianchi, S., Nenci, R., (...), Baldari, G., Campese, V.M. 1995 Journal of Human Hypertension		8576899	116
Prevalence of microalbuminuria in a large population of patients with mild to moderate essential hypertension R Bigazzi, S Bianchi, VM Campese, G Baldari - Nephron, 1992	10.1159/000186842	1528348	153
Microalbuminuria in salt-sensitive patients. A marker for renal and cardiovascular risk factors. R Bigazzi, S Bianchi, D Baldari, G Sgherri, G Baldari¿ - Hypertension, 1994	10.1161/01.HYP.23.2.195	8307628	211
Effect of insulin on renal sodium and uric acid handling in essential hypertension E Muscelli, A Natali, S Bianchi, R Bigazzi¿ - American journal of hypertension, 1996	10.1016/0895-7061(96)00098-2	8862220	207
Microalbuminuria predicts cardiovascular events and renal insufficiency in patients with essential hypertension R Bigazzi, S Bianchi, D Baldari, VM Campese - Journal of hypertension, 1998	10.1097/00004872-199816090-00014	9746120	263

* Autocertificated

	Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization:TELEMECHRON study
Project Code: NET-2018-12367206	**Principal Investigator:** Bianchi Stefano
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Project Type: Network Project/Progetti di Rete

Grant

Funded Institution / Country	Year	Title	Position in Projects
Tuscany Region, Italy	2016	Prevenzione, diagnosi precoce e cura dell'insufficienza Renale Cronica nel dipartimento di Leon. Fase 2. DGR 697 del 19/07/2016, PIR Decreto 7722 del 05/06/2017	Coordinator
Tuscany Region, Italy	1993	Expert System for the remote control of the dialysis session (1993-1996)	Coordinator
Tuscany Region, Italy	2014	Emergenza IRC nel dipartimento di Leon. Ricerca epidemiologica e promozione della salute. DGR N. 277 DEL 07/04/2014 Codice Pratica 2014AD00000007153(2015-2019)	Coordinator
Ministry of Health,Italy	2011	New Strategies for diagnostic,therapeutic and clinical care in Metabolism disorders and cardiovascular disease. RF-2011-02347356 (2014-2019)	Collaborator
Ministry of Health, Italy	2011	Hypertension in high school students: Genetic and Environmental Factors. RF-PE- 2011-02346988 (2014-2019)	Collaborator
Ministry of Health, Italy	2011	Development of a service interface method (WebService) between family care physicians operating in a primary care setting and nephrologists, for the prevention,diagnosis and treatment of kidney damage in patients with type II diabetes mellitus (RF-2011-02346990)(2014-2019)	Coordinator

Employment contract extension:

Project Title:
Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization:TELEMECHRON study

Project Code: NET-2018-12367206

Principal Investigator: Bianchi Stefano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Toscana

Project Type: Network Project/Progetti di Rete

Total proposed budget (Euro)

Costs	TOTAL BUDGET	Co-Funding	Project costs proposed to funding Organization (no moh request)	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	729.818,00	729.818,00	0,00	not permitted	0,00
1b Researchers' Contracts	979.620,00	0,00	584.000,00	395.620,00	43,97
2 Equipment (Leasing - Rent)	286.680,00	0,00	105.000,00	181.680,00	20,19
3a Supplies	81.100,00	0,00	2.000,00	79.100,00	8,79
3b Model Costs	0,00	0,00	0,00	0,00	0,00
3c Subcontracts	131.100,00	0,00	110.000,00	21.100,00	2,35
3d Patient Costs	25.000,00	0,00	0,00	25.000,00	2,78
4 IT Services and Data Bases	120.000,00	50.000,00	0,00	70.000,00	7,78
5 Publication Costs	13.400,00	0,00	2.000,00	11.400,00	1,27
6 Convegni	16.300,00	0,00	7.900,00	8.400,00	0,93
7 Travels	24.500,00	0,00	10.000,00	14.500,00	1,61
8 Overheads	166.843,00	0,00	78.989,00	87.854,00	9,77
9 Coordination Costs	5.000,00	0,00	0,00	5.000,00	0,56
Total	2.579.361,00	779.818,00	899.889,00	899.654,00	100,00

Report the Co-Funding Contributor:

WP 1 - Toscana
Total cofunding consists exsclusively of the staff salary (hours of service supplied).
Each Nephrologists (tot. 2): 5 hours per week (tot. 52) per 3 years (tot. 780 hours).

WP 2 - Istituto Superiore di Sanita'
total cofunding consists exsclusively of the staff salary, in proportion to the man months devoted to the project.

WP 3 - Regione Lombardia - Direzione Generale Sanità
Staff salary and technology - € 386.000,00 co-financed by the participating in the project

WP 4 - Provincia autonoma Trento
Co-funding contribution includes managing directors/medical doctors/health care staff, project managers, researchers (including IT researchers) already working within the eligible institutions for the Provincia Autonoma di Trento, as indicated in the Bando (Allegato A). The overall contribution is estimated as the 35% roughly of the requested funding.

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Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization:TELEMECHRON study

Project Code: NET-2018-12367206

Principal Investigator: Bianchi Stefano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Toscana

Project Type: Network Project/Progetti di Rete

Working Package summary budget (Euro)

WP	Research Institution	Funding Institution	TOTAL PROGRAMME COSTS	Co-Funding	Project costs proposed to funding Organization	List of costs proposed for funding to the MOH
WP-1	Toscana	Total cofunding consists exsclusively of the staff salary (hours of service supplied). Each Nephrologists (tot. 2): 5 hours per week (tot. 52) per 3 years (tot. 780 hours).	637.484,00	113.818,00	300.000,00	223.666,00
WP-2	Istituto Superiore di Sanita'	total cofunding consists exsclusively of the staff salary, in proportion to the man months devoted to the project.	309.000,00	80.000,00	0,00	229.000,00
WP-3	Regione Lombardia - Direzione Generale Sanità	Staff salary and technology - € 386.000,00 co-financed by the participating in the project	909.655,00	386.000,00	300.000,00	223.655,00
WP-4	Provincia autonoma Trento	Co-funding contribution includes managing directors/medical doctors/health care staff, project managers, researchers (including IT researchers) already working within the eligible institutions for the Provincia Autonoma di Trento, as indicated in the Bando (Allegato A). The overall contribution is estimated as the 35% roughly of the requested funding.	723.222,00	200.000,00	299.889,00	223.333,00

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Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Toscana

Project Type: Network Project/Progetti di Rete

	Project Title: Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.
Project Code: NET-2018-12367206-1	**Principal Investigator:** Bianchi Stefano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Toscana

Project Type: WP PROJECT - 1

Major Diagnostic Category*: Nefrologia e Urologia

Project Classification IRG: Healthcare Delivery and Methodologies

Project Classification SS: Biomedical Computing and Health Informatics - BCHI

Project Keyword 1: Application of human-centered computing (human-machine interfaces), intelligent systems, virtual environments, computer-assisted diagnosis and treatment systems with data including imaging data and telemedicine to biomedical and clinical systems, including the study of collaboration to engineer-usable effective software systems.

Project Keyword 2: Chronic diseases, Telemedicine, telemonitoring, ehealth, mhealth, health-related quality of life; medical decision-making

Project Keyword 3: Case Manager, clinical manager, chronic disease management

Project duration (months): 36

Project Request: **Animals:** ☐ **Humans:** ☒ **Clinical trial:** ☐

The object/s of this application is/are under patent copyright Y/N: ☐

Investigators, Institution and Role in the Project

	Co-PI	Key Personnel	Institution/Org./Pos.	Role in the project	Birth Date
1	X	Bigazzi Roberto	Azienda sanitaria locale Nord Ovest /UOC di Nefrologia e Dialisi /Dirigente medico	Co PI	21/05/1953

Overall Summary

Chronic kidney disease (CKD) is a common and costly disease. Inpatient assistance is the usual healthcare response for these patients (pts). However most of pts like to stay at home rather than moving to hospitals. Service providers wish the outpatient status because of a better cost-efficiency and cost saving program. This opens new views how caring procedures and processes need to be done to enhance the quality of life (QoL) by supporting pts to remain involved in their personal and professional life. A smart system, including a smart dialysis chair, body-area network with on-body sensors and mobile coaching application for personalized care of pts that require dialysis (D) or in clinical pre-D will be designed, developed and tested in a real environment. Three case studies will be defined to validate the proposed solution and highlight the innovative features and the potentialities of this system :1) pts in home peritoneal D 2) pts in home hemoD 3) pts on clinical preD.

Background / State of Art

In Italy there are lot of pts affected by chronic disease including renal insufficiency who like to stay at home as long as possible, rather than moving to any caring institute or hospital and most of them are elderly. Demographic prognosis also shows that the relative portion of elderly people is increasing during the coming years, which opens doors for new innovations. It is also wished from service providers side that people will stay outpatient if they can. Authorities arguments are coming from the cost-efficiency and cost saving that being outpatient brings with. This opens new views how caring procedures and processes need to be organized.

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Applicant Institution: Toscana

Project Type: WP PROJECT - 1

Currently, in Italy, there are around 45.000 patients on D, and only 10.4% of them are already attending a home D program (mainly peritoneal D). Patients beginning home D report low confidence about their own ability to master home D, and fears about being isolated from medical support (1,2,3). Patients also describe home D as being portrayed by educators and clinicians as a complex treatment that was difficult to learn and therefore might be beyond their capabilities, resulting in patients doubting their own ability to perform home D safely (4). The first 3 months of home D are a critical period in determining the success of long-term home D [5,6]. In a previous study, patients established on home D acknowledged these early fears; however, they also spoke of their trepidation being alleviated over time as their confidence increased. Patients cited peer support and clinician recommendation of home D as a better treatment for them and the doctors trust in the patients ability to perform this treatment independently as an encouragement of this treatment choice [7].
Another significant large amount of patients are those who suffer from renal insufficiency but not yet in a dialysis program. Their preD clinical conditions need frequent clinical and laboratory check-ups , to be able to decrease the progression of renal disease, and retard the start of dialysis treatment. Most of them have frequent in-patients and out-patients accesses due to frequent acute complications of their unstable clinical status.
In healthcare field, there is a real need for novel Information and Communications Technology (ICT) tools which are modular, cost-effective, easy to use, and are extremely reliable. These tools need to have flexibility to meet various sets of requirements and also societal expectations. Novel methods and tools need also to be scalable (by the means of simultaneous users) and adaptable (so that they can be used with different kinds of settings) reliable, secure and safe .
New solutions should be easy to use and they should be accepted by end-users; patients, professional health care personnel but also care service providers.
Measurement of vital signs using dedicated solutions, such as wireless body area networks or stand-alone measurement devices, can provide information on the patients medical and activity conditions. Also smart home environment, e.g., a room which has various sets of sensors installed to the building structures etc. can be used to automatically provide valuable supplementary information from the patients living. (8, 9, 10, 11) These sensor devices can also be linked to specific medical treatment device (like the smart dialysis chair) and use to control those. On the other hand, for example the use of sensors for vital signs 24/7 monitoring would open ethical issues, which need to be solved.

Hyphotesis and Specific AIMS

Hyphotesis and Significance:
Patients affected by CKD needs a regular treatment that makes them go frequently to hospitals for attending a D or for frequent check ups .The hyphotesis of this study is that a smart system, including a body-area network with on-body sensors and mobile coaching application for personalized care of pts that require D, designed, developed and tested in a real environment, will be able to to enhance QoL supporting these pts to remain actively involved in their personal and professional life, keeping them at home or at work rather than in any caring structure.
This project proposes a solution that enables pts to perform D at home or at work, with continuous monitoring of their clinical status by providing them with enhanced equipment tailored on their specific needs and designed to facilitate their interaction with the medical and nursing staff.
We will design and develop a smart chair for D, which will be placed at pts home ,where pts can attend D without going to hospitals. Moreover, we proposed a Virtual App, running on a common smartphone, will allow them to be properly assisted, and remote monitored by medical staff. Different type of data gathered by wearable and non-wearable sensors will be the basis for the analysis of the pts health status and for the evaluation of the treatment outcomes, taking into account also behavioural and psychological aspects.
All the data will be stored in a cloud system , and analysed through innovative algorithms for the customization of the long-

term care in the time and ways deemed most suitable and appropriate for both physicians and the pts.
This project proposes a digitalization of the D treatment to be performed at home, with advanced technological solutions. This will: 1)improve the pts health condition 2) delay late-stage progression of the diseases;3) extend pts working career and social life.
Three case studies will be defined to validate the proposed solution and highlight the innovative features and the potentialities of the system. These three case studies will involve: 1) pts attending a home peritoneal D ; 2) pts attending a home hemoD; 3) pts on clinical preD.

Preliminary Data:
See the Preliminary data reported on Overall Project

Specific Aim 1:

Definition of a user-centric system model for enhancing management of renal insufficiency through the integration of innovative ICT solutions. and a reliable connection between the user home and the cloud data centre.

Specific Aim 2:

Definition of the advanced data acquisition, processing and transmission techniques for pts remote monitoring and treatment.

Specific Aim 3:

Development and demonstration of the integrated solutions in three case studies.

Experimental Design Aim 1:
The definition of a more trans-disciplinary approach to the treatment of CKD, by offering pts-centered solutions adapted to the specific needs and built upon their feedbacks and requests. The definition of a scalable, flexible and secure system architecture integrating wireless wearable and non-wearable sensors to enable pts to autonomously monitor their health status and track their daily activity, a hub device for local data processing, an APP (acting as a Virtual Tutor) for user interaction with the system and cloud services for data storage, analysis and reasoning.The identification of a solution combining data acquisition, processing and transmission, enabling autonomous interactionsamong the system componets

Experimental Design Aim 2:
The identification and detailed definition of the Virtual Tutor solution for enhancing health and re-inclusion. A user friendly App for an interactive pts remote monitoring will be designed and developed.
The detailed definition of the main technical components of the system: the sensors, the hub device, the data processing short-term and long-term algorithms, the communication modules and the interfaces among the different subsystems and cloud application for service provisioning.
The design of a multi-technology wireless network to support efficiently the data exchanges among the sensors, the hub device (local data processing engine) and the cloud data centre, also in case of absence of a homogeneous communication infrastructure.

Experimental Design Aim 3:
Development and integration of the defined system building blocks. The compliance with the defined system requirements

will be verified by testing each single component and by performing integration tests, to validate the main functionalities of the proposed system. Definition of the three case studies for the system innovative features and the potentialities demonstration. Pts attending a home peritonealD , pts attending a home hemoD and pts on clinical preD will be considered to validate the proposed solutions. Demonstration of the system capabilities to address the specific requirements of the three identified case studies, by its flexibility to self-adapt to different pts needs

Picture to support preliminary data:
Abstract # 350 Preview.pdf

Metodologies and statistical analyses:
1 This task is responsible for identifying:a) clinical and biological parameters to be retrieved during the session, with accompanying timescales and measurement units, b) clinical parameters to be monitored during and in between treatments c) pts clinical, structural and psychological requirements for undertaking a homeD d) environmental data.
These data will be retrieved consulting the most recent and acknowledged scientific literature in this field, comparing the experience acquired by the clinical partners in implementing homeD , through face-to-face interviews and ad hoc psychological questionnaires addressed to all the actors involved in the process (physicians, nursing staff, patients, caregivers). The data and information gathered will be used to identify the main functions and operations that this system is expected to manage and perform, and, consequently, the quality of service that will be delivered.
2 This task is responsible for the definition the system requirements. Starting from the analysis of the identified user requirements, the service and infrastructure requirements will be defined together with the technical specification of the different components of the system. As an example functional, network, security, privacy, operational requirements will be identified. Moreover, based on the result of the surveys addressed to pts , caregivers, nephrologists, and psychologists, the project team will identify the technical, ergonomic and aesthetic requirements of the smart chair, allowing pts to easily perform hemoD at home in complete autonomy and independence, and physicians and caregivers to assist and monitor the entire process (before, during and after the D session) in a safe, comfortable and efficient fashion.
3 Case studies: In this activity the medical staff involved in the project represents a key element.The objective of this task will be to define the number of cases to be submitted to the experimental protocol, both in relation to the phase in which the smart chair will be used , and in the phase in which the pts will be monitored at home (pts on preD), through the use of appropriate devices designed to monitor pre specified clinical parameters of interest.The identification of case studies will take in account several parameters:
i)the smart chair can be used by more than one person, but not at the same time and because our project will be performed in pts treated with D at home, we will need a smart chair for each patient included.
ii) the clinical characteristics of the pts and his skills (as well as the caregivers) to fully understand and collaborate with the aim of the investigation will be thoroughly evaluated
iii) the acceptance of pts on preD to live, at least for a part of the day, with wearable devices, will be carefully taken into account. The run-in period will last on average 4-6 weeks (used to train the pts and his/her caregiver in performing hemoHD autonomously, using of the devices properly and safely, cleaning and carrying out routine maintenance of the equipment).The duration of the task related to field trials is 14 months, as can be acknowledged from the GANTT. We propose to consider 3 case studies: 2 pts on peritoneal D , 2 Pts on home hemoD and 4 pts attending pre-D clinic .
Classical statistical analysis will be performed on data retrieved in accordance with the characteristics of the data obtained and their interpretation purposes

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Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Toscana

Project Type: WP PROJECT - 1

Expected outcomes:

i)Prevention: reduced admissions and days spent in hospitals, and improvements in the daily activities and QoL of pts through effective use of smart chair and Virtual Tutor, and better coordination and integration of care processes of pts. Reduced demands on general physician visits as pts have a better understanding of their condition and self management of that condition improves.

ii) Pts QoL and Self Management: reduced stress for the pts and caregivers through better understanding of natural cycles of the impairment. Incentive to take ownership of medication and improved compliance with rehabilitation program, resulting in higher quality of life, reduced stress and sickness both for the pts and for their family/carers.

iii) Robust evidence base on health and social care outcomes, QoL and care efficiency. Pts will be able to wear multi-functional, unobtrusive intelligent sensors with high data encryption to promote their health. The real-time quality data provided by this project will provide seamless and secure information exchange among all those involved in health, social and informal care services.

iv)Patient public involvement will be crucial in the exchange and acceptability of such a device and is a fundamental part of this project technological development. Pts participation in care is emerging as a growing movement wherein pts are assuming more responsibility for the prevention, detection and treatment of health problems in a manner that supplements or substitutes for professional services.

v) This project will provide an advance interaction between pts and their carers, and more active participation of pts and their relatives or other informal caregivers in care pathway.

vi)Reinforced medical knowledge with respect to management of chronical disease and co-morbidities.

vii) The remote monitoring and treatment is expected to reduce both direct and indirect healthcare costs of pts that require HD. Demographic change, the ageing of the population and higher longevity, are increasing the prevalence of CKD in the population. Adherence to the therapy and continuous check-ups are both required to improve the effectiveness of the therapy with a subsequent reduction of unplanned hospital admission, urgency calls, mistreatment or waste of unused drugs that are all sources of extra cost for National Healthcare Systems.

Risk analysis, possible problems and solutions:

A formal risk plan will be developed and maintained by the WP1 PI , as part of normal project management activities. Risks would be identified during project preparation, and mitigations considered.

Personnel: a risk is connected to the timely hiring of personnel for performing the work-plan, according to scientific excellence and gender balance. That is mitigated by the strong permanent staff pool of all the partners, but some specific competences might require long advertisement of the hiring and selection time. Effective advertisement by the communication actions will further mitigate the problem.

Activities: all tasks are subject to the typical risks connected to scope change over time. The risk is in incurring delays or extra costs. This will managed by WP PI and it is mitigated by the ability to reallocate tasks or efforts within the careful project monitoring and control.

Adoption of services: the successful adoption of services depends on their successful and timely deployment and this can be mitigated by good communication with potential users and other stakeholders to maintain the engagement and understanding.

Conflict Resolution : conflicts will be solved at the lowest level possible, and preferably amicably. In case of conflicting views, the decisions will be taken by voting in the schedule meetings.

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Project Type: WP PROJECT - 1

Significance and Innovation

The interactive education will facilitate the empowerment of pts and the adoption of a proactive approach treatment of CKD. The use of mobile sensors will increase the set of data retrieved and processed by the system, and provide an exhaustive overview of the treatment outcomes and also facilitate decision-making both for physicians and pts.
The decision to encase and store the equipment needed to do home D in the armrests comfortable chair, is based on the analysis of the results of ad hoc surveys addressed to pts attending home D (7) . The major needs that emerging from the surveys results of are: be comfortable when doing D for 3-4 hours but avoiding the bed ,be able to do other activities in D, and keep working despite the disease
Moreover, the novel results are relating to cross-technology interference (CTI) modelling and mitigation. Due to the trend that everything is going wireless, CTI will be much bigger problem in the future than it is today.

Description of the complementary and sinergy research team

Procedures will be provided in the Working Groups Agreement to be signed by the partners before the start of the project. This document will formalize the rights, obligations, relationships and procedures within the consortium, as well as any other relevant issue.
The workpackage PI (WP PI) will coordinate, supervise and contribute to and perform the specific activities of the different WPs. The WP PI report on the WP status to the Coordinator, and are responsible for each WPs progress set against the planned deliverables and milestones, and assess risks and propose contingency plans.
Dott Bianchi is the Coordinator and has successfully completed a series of projects under these responsibilities . Dott Bianchi is responsible for Quality and Risk Management as well as for the exploitation strategy. He is also responsible, together with Istituto Superiore di Sanità of dissemination, impact, sustainability and business model of Virtual Tutor. The majority of partners have long-lasting collaborations in previous projects, what built mutual confidence and trust. In Virtual Tutor they have pooled their efforts around a common objective, which is of the utmost interest for all of them and this is a guarantee of excellent collaboration within the project.

Training and tutorial activities

We anticipate doctors and nurses training for consultancy and tutoring activities dedicated to health care professional to achieve effective and efficient clinical practices related to the treatment of patients with CKD and/or in replaced treatment as hemodialysis, peritoneal dialysis.
We provide professional learning expertise to drive a culture of chronic care, among patients and family doctors and nurses, applying the principles of Therapeutic Education and Medical Humanities.
We anticipate the use of the instruments and coordinate dialysis specialist team, with activities across the region and facilitate best practice sharing; sustain and reinforce ethics and compliance principles to achieve effective and efficient clinical practices related to the treatment of patients with advance CKD and/or in replaced treatment as hemodialysis, peritoneal dialysis .

Bibliography

1 Walker RC, et al. Am J Kidney Dis.2015;65(3):451463;
2 Tong A, , et al. Am J Kidney Dis. 2015 Aug; 66(2):212-22;
3 Muehrer RJ et al , Clin J Am Soc Nephrol. 2011 Mar; 6(3):489-96.
4 Walker RC, et al Nephrol Dial Transplant. 2015;31(1):133¿141.
5 Hanson CS,et al Nephrology (Carlton). 2017 Aug; 22(8):631-641.
6 Jose A.et al , Blood Purif 2006;24:22-27
7 Young BA,et al ASN Dialysis Advisory Group, ClinJ Am Soc Nephrol. 2012 Dec; 7(12):2023-32.
8 Vartiainen J.et al ., International Conference on Ubiquitous and Future Networks (ICUFN), 2016.
9 Mikhaylov M., et al International Workshop on Smart Wireless Communications, 2016.
10 Mikhaylov M., et al Asian Journal of Control, Jan 2017.
11 Karvonen H., Energy Efficiency Improvements for Wireless Sensor Networks by Using Cross-Layer Analysis,Doctoral dissertation, University of Oulu, March 2015.

Timeline / Deliverables / Payable Milestones

Each partner and WP PI will report project progress to the Project Coordinator on a three-monthly basis. This will cover technical progress, results, deliverables and compliance with the WP, as well as the monitoring and updating of the possible identified risks. Progress of the task will be reported in terms of percentage of completion and estimated time to completion, deviations from agreed time scales and corrective actions.
The coordinator will summarize overall project progress, updating planning charts and manpower records. Project reporting mechanisms will specifically include an internal six monthly financial control report (detailing person-months expended) which will be submitted by each partner to the Coordinator.

Milestones 18 month

User requirements
System requirements
Overall system architecture design
Smart chair design (Environment layer)
Platform Service design (Edge and Cloud layers)
Wireless sensors (wearable and chair sensors)
Communication chain (chair-body, body-hub, hub-cloud)
Data protection (secure ICT)
Case studies and User Acceptance
Design and execution of the field trails

Milestones 36 month

Virtual Tutor -User and -Cloud Interface

	Project Title: Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.
Project Code: NET-2018-12367206-1	**Principal Investigator:** Bianchi Stefano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Toscana

Project Type: WP PROJECT - 1

ICT solution and cloud analysis
Overall architecture of the trail system (Interfaces)
Integration of patient-side and cloud components
Data analysis and validation of the trail results

Gantt chart

GANTT TOSCANA.xlsx

Equipment and resources available

The UOC of Nephrology and Dialysis of ASLNO has an excellent track record of clinical studies that have resulted in important publications in the fields of nephrology and progression of kidney disease. It has been active in diagnostic procedures and treatment of CDK and its progression . The group has performed many international trials.
The UOC of Nephrology and Dialysis ASLNO has an excellent reputation in Medical and Health Informatics. It runs extremely large databases, including a number of patient registries on chronic renal insufficiency.
ASLNO adopts and follows, for all the aspects of its clinical and research activity, a Code of Ethics in line with the ethical and social principles of its mission, its own tradition of correctness and transparency in the conduct of every health and research activities and with the purposes of the regional mandate. With the adoption of the Code of Ethics, ASLNO adopts a set of principles of behaviour and of procedures which, in addition to the internal control system, comply with the objectives and provisions set forth in the Ethic Code itself.
ASLNO adopts and follows a Code of Privacy aimed to protect everyone rights to be protected about personal data. The Privacy Code guarantees that the processing of data is carried out in compliance with freedoms fundamental rights, as well as the dignity of the data subject, ensuring a high level of protection, in respect of the principles of simplification, harmonization and effectiveness of the modalities foreseen for them. The Privacy Code establishs that information systems and computer programs must be configured by minimizing the use of personal and identifying data.

Translational relevance and impact for the National Health System (SSN)

Enhanced health and safety working conditions and QoL .
Potential cost-effectiveness due to enhanced self-care, life- style, age-friendly and skills conducive work environments and socio-economic benefits.
Reduced admissions and days spent in hospitals, and improvements in the daily activities of pts.
The real-time quality data provided by the Virtual Tutor will provide seamless and secure information exchange among all those involved in health, social and informal care services.
Patient participation in care is emerging as a growing movement wherein patients are assuming more responsibility for the prevention, detection and treatment of health problems in a manner that supplements or substitutes for professional services.
Competitive advantage for Italian industry through flexible and sustainable work in the field of health care management of CKD pts.

	Project Title: Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.
Project Code: NET-2018-12367206-1	**Principal Investigator:** Bianchi Stefano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Toscana

Project Type: WP PROJECT - 1

PRINCIPAL INVESTIGATOR PROFILE

Name		
Bianchi Stefano	Institution	Toscana
	Department/Unit	Department of Medicine, UOC Nephrology and Dialysis, Livorno SudASL nordovest, Toscana, Italy
	Position Title	Principal Investigator

Personal Statement

This project is aimed to design innovative strategies to improve quality of care and optimise resource utilization of telemedicine in home-based management for the global care of three chronic diseases: congestive heart failure , type 2 diabetes mellitus , and chronic kidney disease.
Dott Bianchi is the coordinator and has successfully completed a series of projects under these responsibilities . Dott Bianchi is responsible for Quality and Risk Management as well as for the exploitation strategy and together with dott Grigioni (ISS) of dissemination, impact, sustainability and business model of Virtual Tutor.
Dott Scalvini is in charge of the recruitment and management of pts with heart failure.
Dott Piffer is in charge of the recruitment and management of pts with diabetes.

Education/Training - Institution and Location	Degree	Year(s)	Field of study
Institute of Medical Pathology, Santa Chiara Hospital, University of Pisa, Pisa, Italy	Clinical Fellowship in Internal Medicine	2	Internal Medicine
Division of Nephrology, Santa Chiara Hospital, University of Pisa, Pisa, Italy	Clinical fellowship in Nephrology	2	Nephrology
Postgraduate School of Nephrology, University of Pisa, Pisa, Italy	Certified specialist in Nephrology	4	Nephrology
Institute of Medical Pathology and Enviromental Diseases, University of Pisa, Pisa, Italy	Certified specialist in enviromental diseases	2	Enviromental Diseases
Division of Nephrology, Los Angeles County Hospital, Keck School of Medicine, University of Southern California, Los Angeles, USA	Felloship in Nephrology	2	Nephrology
Institute of Respiratory Diseases, University of Siena, Siena, Italy	Certified specialist in Respiratory Diseases	4	Respiratory Diseases

Project Title: Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.

Project Code: NET-2018-12367206-1

Principal Investigator: Bianchi Stefano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Toscana

Project Type: WP PROJECT - 1

Positions

Institution	Division / Research group	Location	Position	From year	To year
University of Parma, Italy	Post Graduate School of nephrology	University of Parma, Italy	Professor of Nephrology	2017	2018
Local Health Unit, Hospital of Livorno, Livorno, Italy	Division of Nephrology	Hospital of Livorno, Livorno Italy	Medical assistant	1979	1994
Local Health Unit, Hospital of Livorno, Livorno, Italy	Division of Nephrology	Hospital of Livorno, Livorno, Italy	Chief assistant	1994	2001
Local Health Unit, Hospital of Livorno, Livorno, Italy	Division of Nephrology	Hospital of Livorno, Livorno, Italy	Chief, Hypertension and Kidney Diseases Unit	2001	2008
San Donato Hospital of Arezzo, Arezzo, Italy	Division of Nephrology	Hospital of Arezzo, Arezzo, Italy	Chief of Nephrology	2008	2011
Local Health Unit, Hospitals of Piombino-Cecina-Portoferraio, Livorno, Italy	Division of Nephrology	Hospitals of Piombino-Cecina-Portoferraio, Livorno, Italy	Chief of Nephrology	2011	2018
Local Health Unit of Livorno, Hospitals of Livorno-Piombino-Cecina-Portoferraio, Livorno, Italy	Department of Nephrology, Cardiology and Diabetology, Local Health Unit of Livorno	Hospitals of Livorno-Piombino-Cecina-Portoferraio, Livorno, Italy	Chief of Department	2011	2018
University of Siena, Siena, Italy	Postgraduate School of Nephrology	University of Siena, Siena, Italy	Professor of Nephrology	2008	2013

Official H index: 22.0 (autocertificated)

Source: Scopus **Scopus Author Id:** 55618330900

ORCID ID: 0000-0003-3981-6325 **RESEARCH ID:** J-9962-2016

Awards and Honors:

1995Recipient American-Italian Society of Nephrology grant with the project of study titled "Microalbuminuria as a marker of kidney damage in patients with essential hypertension"
2002 Invited Member Commettee " Proteinuria and other marker of kidney disease". NIDDKD/NHI/NKF
2003-currentMember Committee of Tuscany Region for the prevention, diagnosis and treatment of diabetic nephropathy
2008-2012Member,Italian Society of Nephrology Commettee "Clinical research and international relationships".

Other CV Informations:

Visiting Professor at Henry Ford Hospital, Detroit, USA (2003); Yale University, New Haven,USA (2002); Hopital Broussais, Paris, France; (2001) Northwestern and Rush University Chicago, USA (2001)
Reviewer of Diabetologia, Nutrition Metabolism and Cardiovascular Diseases, Journal of Nephrology, American Journal Kidney Disease, Nephrology, Dialysis and Transplantation, and Cochrane Library
N° of communications to scientific meetings: 250;chapters in books 14; N° of citations more than 4100
2018-current Secretary of the Italian Society of Nephrology.

Project Title:
Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.

Project Code: NET-2018-12367206-1

Principal Investigator: Bianchi Stefano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Toscana

Project Type: WP PROJECT - 1

Selected peer-reviewed publications of the PI

Valid for PI minimum expertise level

Title	DOI	PMID	Cit. **	P.*
Insulin resistance, metabolic syndrome and endothelial dysfunction Bigazzi, R., Bianchi, S. 2007 Journal of Nephrology		17347967	9	L
Intensive Versus Conventional Therapy to Slow the Progression of Idiopathic Glomerular Diseases Bianchi, S., Bigazzi, R., Campese, V.M. 2010 American Journal of Kidney Diseases	10.1053/j.ajkd.200	20097461	22	F
Do HMG-CoA reductase inhibitors improve kidney function? The saga continues Campese, V.M., Ku, E., Bigazzi, R., Bianchi, S. 2011 Journal of Nephrology	10.5301/jn.500002	21887675	9	L
The renal effects of mineralocorticoid receptor antagonists Bianchi, S., Batini, V., Bigazzi, R. 2015 International Journal of Cardiology	10.1016/j.ijcard.2015.05.125	26049733	6	F
Statins and lipid-lowering strategies in cardiorenal patients S Bianchi, D Grimaldi, R Bigazzi - Contributions to Nephrology, 2011	10.1159/000327139	21625103	5	F
Hyperinsulinemia, circadian variation of blood pressure and end-organ damage in hypertension. S Bianchi, R Bigazzi, R Nenci, VM Campese - Journal of nephrology, 1997		9442446	11	F
Microalbuminuria in essential hypertension. S Bianchi, R Bigazzi, VM Campese - Journal of nephrology, 1997		9377730	14	F
Altered circadian blood pressure profile and renal damage. S Bianchi, R Bigazzi, VM Campese - Blood pressure monitoring, 1997		10234137	13	F
Silent ischemia is more prevalent among hypertensive patients with microalbuminuria and salt sensitivity S Bianchi, R Bigazzi, A Amoroso, VM Campese - Journal of human hypertension, 2003	10.1038/sj.jhh.100	12571612	16	F
Diurnal variations of blood pressure and microalbuminuria in essential hypertension S Bianchi, R Bigazzi, G Baldari, G Sgherri, VM Campese - American journal of hypertension, 1994	10.1093/ajh/7.1.23	8136107	330	F
Long-term effects of enalapril and nicardipine on urinary albumin excretion in patients with chronic renal insufficiency: A 1-year follow-up Bianchi, S., Bigazzi, R., Baldari, G., Campese, V.M. 1991 American Journal of Nephrology 37	10.1159/000168289	1951474	37	F
Microalbuminuria in patients with essential hypertension effects of an angiotensin converting enzyme inhibitor and of a calcium channel blocker Bianchi, S., Bigazzi, R., Baldari, G., Campese, V.M. 1991 American Journal of Hypertension	10.1093/ajh/4.4.291	2059393	44	F
Microalbuminuria in patients with essential hypertension: Effects of several antihypertensive drugs Bianchi, S., Bigazzi, R., Baldari, G., Campese, V.M. 1992 The American Journal of Medicine	10.1016/0002-9343(92)90580-5	1442855	73	F
Insulin resistance in microalbuminuric hypertension: Sites and mechanisms Bianchi, S., Bigazzi, R., Galvan, A.Q., (...), Ferrannini, E., Natali, A. 1995 Hypertension	10.1161/01.HYP.26.5.789	7591019	89	F
Elevated serum insulin levels in patients with essential hypertension and microalbuminuria Bianchi, S., Bigazzi, R., Valtriani, C.,Chiapponi I., Sgherri G.,Baldari G., Natali A., Ferrannini, E., Campese, V.M. 1994 Hypertension	10.1161/01.HYP.23.6.681	8206563	95	F

Project Title:
Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.

Project Code: NET-2018-12367206-1

Principal Investigator: Bianchi Stefano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Toscana

Project Type: WP PROJECT - 1

Title	DOI	PMID	Cit. **	P.*
Antagonists of aldosterone and proteinuria in patients with CKD: An uncontrolled pilot study Bianchi, S., Bigazzi, R., Campese, V.M. 2005 American Journal of Kidney Diseases	10.1053/j.ajkd.2005.03.007	15983956	106	F
Microalbuminuria in essential hypertension: Significance, pathophysiology, and therapeutic implications Bianchi, S., Bigazzi, R., Campese, V.M. 1999 American Journal of Kidney Diseases	10.1016/S0272-6386(99)70002-8	10585306	154	F
Long-term effects of spironolactone on proteinuria and kidney function in patients with chronic kidney disease. Bianchi, S., Bigazzi, R., Campese, V.M.; 2006, Kidney International	10.1038/sj.ki.5001854	17035949	202	F
A controlled, prospective study of the effects of atorvastatin on proteinuria and progression of kidney disease. 2003 American Journal of Kidney Diseases; Bianchi, S., Bigazzi, R., Caiazza, A., Campese, V.M.	10.1053/ajkd.2003.50140	12612979	300	F

* Position: F=First L=Last C=Corrispondent

** Autocertificated

Project Title:
Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.

Project Code: NET-2018-12367206-1

Principal Investigator: Bianchi Stefano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Toscana

Project Type: WP PROJECT - 1

For evaluation CV

Title	DOI	PMID	Cit. *
Is microalbuminuria a predictor of cardiovascular and renal disease in patients with essential hypertension? Campese, V.M., Bianchi, S., Bigazzi, R. 2000 Current Opinion in Nephrology and Hypertension	10.1097/00041552-200003000-00008	10757219	28
Metabolic risk factors and markers of cardiovascular and renal damage in overweight subjects Bigazzi, R., Bianchi, S., Batini, V., Guzzo, D., Campese, V.M. 2006 American Journal of Hypertension	10.1016/j.amjhyper.2005.10.002	16580581	11
Increased cardiovascular events in hypertensive patients with insulin resistance: A 13-year follow-up Bigazzi, R., Bianchi, S., Buoncristiani, E., Campese, V.M. 2008 Nutrition, Metabolism and Cardiovascular Diseases	10.1016/j.numecd.2006.11.001	17368007	5
A Delphi consensus panel on nutritional therapy in chronic kidney disease Bellizzi, V., Bianchi, S., Bolasco, P., (...), Santoro, D., Santoro, A. 2016 Journal of Nephrology	10.1007/s40620-016-0323-4	27324914	3
Increased thickness of the carotid artery in patients with essential hypertension and microalbuminuria Bigazzi, R., Bianchi, S., Nenci, R., (...), Baldari, G., Campese, V.M. 1995 Journal of Human Hypertension		8576899	116
Prevalence of microalbuminuria in a large population of patients with mild to moderate essential hypertension R Bigazzi, S Bianchi, VM Campese, G Baldari - Nephron, 1992	10.1159/000186842	1528348	153
Microalbuminuria in salt-sensitive patients. A marker for renal and cardiovascular risk factors. R Bigazzi, S Bianchi, D Baldari, G Sgherri, G Baldari¿ - Hypertension, 1994	10.1161/01.HYP.23.2.195	8307628	211
Effect of insulin on renal sodium and uric acid handling in essential hypertension E Muscelli, A Natali, S Bianchi, R Bigazzi¿ - American journal of hypertension, 1996	10.1016/0895-7061(96)00098-2	8862220	207
Microalbuminuria predicts cardiovascular events and renal insufficiency in patients with essential hypertension R Bigazzi, S Bianchi, D Baldari, VM Campese - Journal of hypertension, 1998	10.1097/00004872-199816090-00014	9746120	263

* Autocertificated

	Project Title: Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.
Project Code: NET-2018-12367206-1	**Principal Investigator:** Bianchi Stefano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Toscana

Project Type: WP PROJECT - 1

Grant

Funded Institution / Country	Year	Title	Position in Projects
Tuscany Region, Italy	2016	Prevenzione, diagnosi precoce e cura dell'insufficienza Renale Cronica nel dipartimento di Leon. Fase 2. DGR 697 del 19/07/2016, PIR Decreto 7722 del 05/06/2017	Coordinator
Tuscany Region, Italy	1993	Expert System for the remote control of the dialysis session (1993-1996)	Coordinator
Tuscany Region, Italy	2014	Emergenza IRC nel dipartimento di Leon. Ricerca epidemiologica e promozione della salute. DGR N. 277 DEL 07/04/2014 Codice Pratica 2014AD00000007153(2015-2019)	Coordinator
Ministry of Health,Italy	2011	New Strategies for diagnostic,therapeutic and clinical care in Metabolism disorders and cardiovascular disease. RF-2011-02347356 (2014-2019)	Collaborator
Ministry of Health, Italy	2011	Hypertension in high school students: Genetic and Environmental Factors. RF-PE- 2011-02346988 (2014-2019)	Collaborator
Ministry of Health, Italy	2011	Development of a service interface method (WebService) between family care physicians operating in a primary care setting and nephrologists, for the prevention,diagnosis and treatment of kidney damage in patients with type II diabetes mellitus (RF-2011-02346990)(2014-2019)	Coordinator

Employment contract extension: Dichiarazione estensione contratto PI Bianchi WP1.pdf

Project Title:
Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.

Project Code: NET-2018-12367206-1

Principal Investigator: Bianchi Stefano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Toscana

Project Type: WP PROJECT - 1

Biographical Sketch Contributors 1

Name:
Bigazzi Roberto

Institution: Azienda sanitaria locale Nord Ovest /UOC di Nefrologia e Dialisi /Dirigente medico
Department/Unit: Unità Operativa Nefrologia e Dialisi
Position Title: CO PI

Education/Training - Institution and Location	Degree	Year(s)	Field of study
School of Medicine, University of Pisa	MD	1977	Medicine
Fellowship in Internal Medicine Istituto di patologia Medica, University of Pisa	MD	1978	Internal Medicine
Fellowship, Divisione di Nefrologia, Hospital of Pisa	MD	1979	Nephrology
Fellowship in Nephrology, University of Florence	MD	1980	Nephrolgy
Fellowship in Nephrology, University Southern California, Los Angeles	MD	1989	Nephrology

Personal Statement:

Dr Bigazzi has a long experience in conducting clinical studies involving patients with chronic kidney disease and this is a valuable condition in which this prospective study should be conducted.
Dr. Bigazzi will be in charge for contacting and recruiting patients with chronic kidney disease discussing the purpose of the study. He will explain to groups of students in the classrooms the rationale of this project . He will be responsible for the enrollment of patients with CKD in HO or in preHD status the informed consent and the collection data and sample.
Dr. Bigazzi has a substantial experience, and successful track records, in research projects dealing with health care services and shared ICT technologies, will be the coordinator of three nurses fully involved in this project.

Institution	Division / Research group	Location	Position	From year	To year
Policlinico Modena Hospital	Nephrology	Modena	Assistant	1980	1981
ASL6 Livorno, Toscana	Nephology and Dialysis	Livorno	Assistant	1981	1989
University Southern California	Nephrology	Los Angeles	Fellow	1989	1991
ASL6 , Toscana	Nephrology and Dialysis	Livorno	Chief Assistant	1991	2001
ASL6, Toscana	Nephrology and Dialysis	Livorno	Chief of Division Nephrology and Dialysis	2001	2018
ASL6, Toscana	Nephrology and Dialysis	Livorno	Chief Department of Clinical Medicine	2008	2016
ASLNordOvest, Toscana	Nephrology and Dialysis	Livorno	Chief Department of Medicine	2016	2018

Project Title: Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.

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Applicant Institution: Toscana

Project Type: WP PROJECT - 1

Awards and Honors

Official H index: 28.0 (autocertificated)

Source: Scopus **Scopus Author Id:** 7004591365

ORCID ID: 0000-0001-8466-6173 **RESEARCH ID:** K-2790-2018

Awards and Honors:

Awards: 1992 American Society of Hypertension Best Poster
1990-91 Recipient American-Italian Society of Nephrology grant" Brain Norepinephrine Turnover Rate in Uremic Rats"
2007-current Contract Professor of Nephrology University of Pisa
Member of: Italian Society of Nephrology

Project Title:
Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.

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Applicant Institution: Toscana

Project Type: WP PROJECT - 1

Expertise Research Collaborators

Selected peer-reviewed publications of the Research Group / Collaborators

Collaborator	Title	DOI	PMID	Cit. *
Bigazzi Roberto	Prevalence of microalbuminuria in a large population of patients with mild to moderate essential hypertension R Bigazzi, S Bianchi, VM Campese, G Baldari - Nephron, 1992	10.1159/000186842	1528348	153
Bigazzi Roberto	Microalbuminuria in salt-sensitive patients. A marker for renal and cardiovascular risk factors. R Bigazzi, S Bianchi, D Baldari, G Sgherri, G Baldari, Campese VM - Hypertension, 1994	10.1161/01.HYP.23.2.195	8307628	211
Bigazzi Roberto	Elevated serum insulin levels in patients with essential hypertension and microalbuminuria Bianchi, S., Bigazzi, R., Valtriani, C.,Chiapponi I., Sgherri G.,Baldari G., Natali A., Ferrannini, E., Campese, V.M. 1994 Hypertension	10.1161/01.HYP.23.6 .681	8206563	95
Bigazzi Roberto	Insulin resistance in microalbuminuric hypertension: Sites and mechanisms Bianchi, S., Bigazzi, R., Galvan, A.Q., (...), Ferrannini, E., Natali, A. 1995 Hypertension	10.1161/01.HYP.26.5 .789	7591019	89
Bigazzi Roberto	Effect of insulin on renal sodium and uric acid handling in essential hypertension E Muscelli, A Natali, S Bianchi, R Bigazzi,Galvan AQ, Sironi AM, Frascerra S, Ciociaro D, Ferrannini E. - American journal of hypertension, 1996	10.1016/0895-7061(96)00098-2	8862220	207
Bigazzi Roberto	Microalbuminuria predicts cardiovascular events and renal insufficiency in patients with essential hypertension R Bigazzi, S Bianchi, D Baldari, VM Campese - Journal of hypertension, 1998	10.1097/00004872-199816090-00014	9746120	293
Bigazzi Roberto	Microalbuminuria in essential hypertension: Significance, pathophysiology, and therapeutic implications Bianchi, S., Bigazzi, R., Campese, V.M. 1999 American Journal of Kidney Diseases	10.1016/S0272-6386(99)70002-8	10585306	154
Bigazzi Roberto	A controlled, prospective study of the effects of atorvastatin on proteinuria and progression of kidney disease. 2003 American Journal of Kidney Diseases; Bianchi, S., Bigazzi, R., Caiazza, A., Campese, V.M.	10.1053/ajkd.2003.50 140	12612979	300
Bigazzi Roberto	Antagonists of aldosterone and proteinuria in patients with CKD: An uncontrolled pilot study Bianchi, S., Bigazzi, R., Campese, V.M. 2005 American Journal of Kidney Diseases	10.1053/j.ajkd.2005.0 3.007	15983956	106
Bigazzi Roberto	Long-term effects of spironolactone on proteinuria and kidney function in patients with chronic kidney disease. Bianchi, S., Bigazzi, R., Campese, V.M.; 2006, Kidney International	10.1038/sj.ki.5001854	17035949	200

	Project Title: Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.
Project Code: NET-2018-12367206-1	**Principal Investigator:** Bianchi Stefano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Toscana

Project Type: WP PROJECT - 1

* Autocertificated

Grant

Funded Institution / Country	Year	Title	Position in Projects	Collaborator
Regione Toscana	2016	Prevenzione diagnosi precoce e cura dell'insufficienza renale cronica nel dipartimento di Leon . Fase 2 DGR 697 del 19/07/2016, PIR Decreto 7722 del 05/06/2017	Collaborator	Bigazzi Roberto
Regione Toscana	2014	Emergenza IRC nel dipartimento di León. Ricerca epidemiologica e promozione della salute. DGR N.277 del 07/04/2014 Codice Pratica 2014AD00000007153	Collaborator	Bigazzi Roberto
Ministero della Salute, Italy	2011	Development of a service interface method (WebService) beetween family care physicians operating in a primary care setting and nephrologists , for the prevention, diagnosis and treatment of kidney damage in patients with type II diabetes mellitus .RF-2011-02346990	Collaborator	Bigazzi Roberto
Ministero della Salute, Italy	2011	Pharmacogenomics of hypertension : a new approach for a personalized medicine. RF-2011-02347356	Collaborator	Bigazzi Roberto
Ministero della Salute, Italy (RF-PE-2011-02346988)	2011	Hypertension in high school students: Genetic and Environmental Factors. RF-PE- 2011-02346988	Coordinator	Bigazzi Roberto

Project Title:
Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.

Project Code: NET-2018-12367206-1

Principal Investigator: Bianchi Stefano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Toscana

Project Type: WP PROJECT - 1

Total proposed budget (Euro)

Costs	TOTAL BUDGET	Co-Funding	Project costs proposed to funding Organization (no MOH request)	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	113.818,00	113.818,00	0,00	not permitted	0,00
1b Researchers' Contracts	237.820,00	0,00	179.000,00	58.820,00	26,30
2 Equipment (Leasing - Rent)	207.480,00	0,00	81.000,00	126.480,00	56,55
3a Supplies	0,00	0,00	0,00	0,00	0,00
3b Model Costs	0,00	0,00	0,00	0,00	0,00
3c Subcontracts	0,00	0,00	0,00	0,00	0,00
3d Patient Costs	0,00	0,00	0,00	0,00	0,00
4 IT Services and Data Bases	0,00	0,00	0,00	0,00	0,00
5 Publication Costs	4.400,00	0,00	0,00	4.400,00	1,97
6 Convegni	7.200,00	0,00	5.000,00	2.200,00	0,98
7 Travels	9.400,00	0,00	5.000,00	4.400,00	1,97
8 Overheads	52.366,00	0,00	30.000,00	22.366,00	10,00
9 Coordination Costs	5.000,00	0,00	0,00	5.000,00	2,24
Total	637.484,00	113.818,00	300.000,00	223.666,00	100,00

Report the Co-Funding Contributor:

Total cofunding consists exsclusively of the staff salary (hours of service supplied).
Each Nephrologists (tot. 2): 5 hours per week (tot. 52) per 3 years (tot. 780 hours).

	Project Title: Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.
Project Code: NET-2018-12367206-1	**Principal Investigator:** Bianchi Stefano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Toscana

Project Type: WP PROJECT - 1

Budget Justification	
1a Staff Salary	exclusively co-funding
1b Researchers' Contracts	3 healthcare assistant research contracts for two years (30 hours per week). 1 back office worker research contract for three years (30 hours per week).
2 Equipment (Leasing - Rent)	Leasing for sensors and related infrastructure for remote monitoring. 3 patients per 5 months (1 Smart dialysis armchair device, 2 Body sensors device) - twice (10 months trial).
3a Supplies	NA
3b Model Costs	NA
3c Subcontracts	NA
3d Patient Costs	NA
4 IT Services and Data Bases	NA
5 Publication Costs	1 scientific publication
6 Convegni	Preparation costs and conference fees for 2 people per year
7 Travels	12 national travels for meeting and audits on the field per year
8 Overheads	Azienda USL Toscana Nord Ovest overhead
9 Coordination Costs	Coordination of the whole project and coordination of the own WP per 3 years

	Project Title: Telemedicine for home-based management of patients with chronic kidney diseases and comorbidities: analysis of current models and design of innovative strategies to improve quality of care and optimise resource utilization.
Project Code: NET-2018-12367206-1	**Principal Investigator:** Bianchi Stefano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Toscana

Project Type: WP PROJECT - 1

Project Title: Assessment of implementation strategies of digital innovations for the continuity of care	
Project Code: NET-2018-12367206-2	**Principal Investigator:** grigioni mauro
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Major Diagnostic Category*: Nefrologia e Urologia

Project Classification IRG: Healthcare Delivery and Methodologies

Project Classification SS: Biomedical Computing and Health Informatics - BCHI

Project Keyword 1: Application of human-centered computing (human-machine interfaces), intelligent systems, virtual environments, computer-assisted diagnosis and treatment systems with data including imaging data and telemedicine to biomedical and clinical systems, including the study of collaboration to engineer-usable effective software systems.

Project Keyword 2: Chronic diseases, Telemedicine, telemonitoring, ehealth, mhealth, health-related quality of life; medical decision-making

Project Keyword 3: Case Manager, clinical manager, chronic disease management

Project duration (months): 36

Project Request: **Animals:** ☐ **Humans:** ☒ **Clinical trial:** ☐

The object/s of this application is/are under patent copyright Y/N: ☐

Investigators, Institution and Role in the Project

	Co-PI	Key Personnel	Institution/Org./Pos.	Role in the project	Birth Date
1	X	Giansanti Daniele	ISS	Co PI	09/10/1965
2		Morelli Sandra	ISS	evaluation of adherence; TAM modeling	13/06/1963

Overall Summary

WP 2 is leading by ISS thanks to the collaboration of the National Centre for Technological Innovations in Healthcare and the National Centre for Telemedicine and New Healthcare Technologies, contributing by:
- Performing an analysis of the design of the 3 healthcare services based on Telemedicine solutions and selected for the present research, studying their technologies, organization and medical procedures;
- Monitoring the set of evaluation tools to qualify the above healthcare services as part of regional interventions, related to the selected pathologies, to each territorial characteristics and regional health model.
ISS will audit the selected healthcare services, using the methodology of Quality Assurance, process indicators for the clinical governance and will define key-elements specifically devoted to the analysis of digital healthcare systems, with special focus on the use of Telemedicine for chronic care management of patients as well as the technological innovations.

Background / State of Art

Healthcare systems globally are facing major challenges such as the increasing number of patients with multiple chronic conditions that require a complex response over a prolonged time period, coordinating inputs from a wide range of health professionals, all optimally embedded within a system that promotes patient empowerment. The introduction of eHealth systems for delivering healthcare at a distance has been one of the responses to these pressures. Telemedicine (TM)

includes a growing variety of applications and services using two-way video, smart phones, wireless tools and other forms of telecommunication technology. Abroad, it is possible to find national healthcare systems in which the use of TM has spread rapidly and is now becoming integrated into the ongoing operations of hospitals, specialty departments, home health agencies, private physician offices, as well as consumer¿s homes and workplaces. This evolution of healthcare services appears quite useful to facilitate the diagnosis, monitoring and management of chronic patients cause of TM programs, using information and communication technologies (ICT), enable the remote exchange of data to organize regular contacts between patients and professionals. The European Commission expressed strong support for telemedicine as a solution to the above challenges. The shared aim of remote care is to enable early intervention, prevent a worsening of long-term conditions and reduce the frequency of secondary care use. This is expected to result in better health outcomes and cost savings. However, evidence for the effect of remote care programs on outcomes, utilization and costs is unclear. Similarly, several literature reviews looking at the cost-effectiveness of TM have not provided any conclusive evidence, e.g. Bergmo found that `the majority of the economic evaluations (of TM) were not in accordance with standard evaluation techniques¿. More recently, the results from international literature show similar difficulties to compare cost-effectiveness of TM services. Nevertheless, while scientists and physicians were developing TM solutions to lead the overall intervention on healthcare systems, for a long time the local decision makers supported limited experiences just introducing some digital device as part of the traditional service. As a result, despite the maturity of the technology, TM services are still not widespread in Italy. Small scale services, not integrated into local healthcare systems, dominate the scene. Italian private enterprises working in the field, usually SME, are not able to well address R&D resources and marketing strategies. The quality of TM studies has been questioned in reviews and there is debate about appropriate research methodologies and techniques. Against this background, the EC decided to support the development of guidelines for consistent assessment of the outcomes of telemedicine. In 2009, the EC initiated the MethoTelemed project, aiming to provide a structured framework for assessing the effectiveness and contribution to quality of care provided by TM applications. The framework was to be based on the users¿ need for information for decision making on whether or not to use new TM applications. Simultaneously the framework was to be based on a systematic review of relevant scientific literature. Therefore, as part of the development of MAST, a systematic literature review of reviews on impacts (all types of outcomes included in the reviews) of TM services with the purpose of identifying the ¿state of the art¿ was carried out by Ekeland et al. and recently followed by Elbert et al.

Hyphotesis and Specific AIMS

Hyphotesis and Significance:

The main hypothesis which is the base of contribution from ISS unit can be summarized as follow:
observing along time the different attempts of Authors worldwide to produce TM evaluation tools it is possible to understand how it is important to use for that purpose a multidimensional approach. In short if the objective of an assessment of telemedicine applications is to describe effectiveness and contribution to quality of care and to produce a basis for decision making, then the relevant assessment framework fulfilling this objective is a multidisciplinary process which summarizes and evaluates information about the medical, technological, economic and social/ethical issues leading professionals and managers to the use of TM in a systematic, unbiased, coherent and robust manner.
Telemedicine is not a separate medical specialty. Products and services related to telemedicine are often part of a larger

investment by healthcare institutions in either information technology or the delivery of clinical care.
All that is also the base for the significance of ISS contribution in the project: to help policy makers, professionals, practitioners, payers, and the public understand how to accurately discuss eHealth development and its key components, assessing the results of implementation and management of TM services.
ISS will be also an independent support for regulations and guide lines.

Preliminary Data:
Preliminary data from the regional approaches are to be found in their WPs.

Specific Aim 1:

Requirements retrieval
Therefore, the first AIM of the present study is to implement a methodology capable to extract the essential element common to the different regions promoting an experimental service implementation and improving the process indicators coerently within the SSN framework.

In the first phase of the project the healthcare service of each region will be assumed as a starting point, and requirements to promote TM introduction will be analyzed, togetgher with the identification of the evaluation tools and any technical product to be used. Regulations to be used complement the support to the partners

A Scheme for each service will be realized and also regulatory issues will be highlighted in view of the change promoting activity. This phase for ISS will be the realization of a record of a database of HC Service, useful as in ERMETE project to keep recorded version of this kind of work on TM implementation.

Specific Aim 2:

Design Audits
With reference to each regional model the second AIM of this study is to analyze actual cronic program in order to get further information on factors which influence several parameters such as the adherence to the program, usability and acceptability of the implied technologies, quality of the needed risk management all along the route of the program, process performance indicator (such as in Quality Assurance or Clinical Governance methodologies).

Auditing the design, activities will be devoted to analyze the design of the change, taking into account the goal each partner wish to reach in the project. At this level key elements will be highlighted to set a minimum set of elements common among partners capable to input the methodology for the strategically implementation. The latter will be the results of the second phase thanks to all the information gathered. Where possible, AQ and CI will be proposed for a continuous improvement of part of the service route identified as part capable to be improved year by year providing indices of quality.

Specific Aim 3:

Observational Audits
The third AIM of the present study is to Assess the implementation of the actual program devoted to chronicity of each region, in order to identify the element of success of the TM program implementation to be share in future in other regional contexts.

The third phase will be an observational phase in which any element and parameter will be monitored, some audit will be carried out to follow development and running of the service. ISS will give any relevant advice to the regional activities they need.

Experimental Design Aim 1:
ISS will highlights those essential elements capable to promote the development of actual change in a traslational fashion in all the other Italian regions not participating to the finalized network project, with the aim to gain value and implementation capability from the paradigmatic work of ISS, thanks to the experience of the regions participating to the project.
In the first phase of the project the healthcare service of each region will be assumed as a starting point, and will be analyzed for the components already used, the evaluation tools and any technical product used at the actual level.
A Scheme for each service will be realized and also regulatory issues will be highlighted in view of the change promoting activity. This phase for ISS will be the realization of a record of a database of HC Service, useful as in ERMETE project [ref] to keep recorded version of this kind of work on TM implementation.

Experimental Design Aim 2:
Parameters observed will be the adherence to the program, usability and acceptability of the implied technologies, quality of the needed risk management all along the route of the program, process performance indicator (such as in Quality Assurance or Clinical Governance methodologies).
Auditing the design, activities will be devoted to analyze the design of the change, taking into account each partner's objective in the project. At this level key elements will be highlighted to set a minimum set of elements common among partners capable to input the methodology for the strategical implementation. The latter will be the results of the second phase thanks to all the information gathered. This activity will be shared with experts such as POLIMI. Where possible, AQ and CDI will be proposed for a continuous improvement of part of the service route identified as part capable to be improved year by year providing indices of quality.
Principles of Risk management will be given at the design level.

Experimental Design Aim 3:
The third phase will be an observational phase in which any element and parameter will be monitored, some audit will be carried out to follow development and running of th service. ISS will give any relevant advice to the regional activities they need. Risk Management and regulatory issues will be monitored to verify the safety of the whole health service supported by innovative technologies and TM

Picture to support preliminary data:

Metodologies and statistical analyses:
Main methodologies will be used: in the requirements retrieval, main elements of the TM implementation were identified to be the input of the evaluation tools to be forwarded. Any applicable regulation will be proposed at this level.
Then tools for the usabiliy, acceptance of the technology and adherence were set. The medical procedures of the TM service will be analysed in terms of expected cost-effectiveness/efficacy
At the Design Audit level, process parameters and quality indicators to be used for AQ were set

Project Title: Assessment of implementation strategies of digital innovations for the continuity of care

Project Code: NET-2018-12367206-2

Principal Investigator: grigioni mauro

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

At the Observational level, audits were the main tool for monitoring
Classical statistical analysis were performed on data retrieved

Expected outcomes:
Improvements in the efficacy, effectiveness and quality of life of patients are expected to be carried out thanks to a rationale use of innovative technologies and TM at the regional level; appropriate indicators set proposed will be useful to realize a model set for future traslation between regions.

Risk analysis, possible problems and solutions:
Risk management is essential when technologies are used, especially Medical Devices and ICT. These issues are tobe followed by ISS thanks to the knowledge on MD regulation, IT Standards and Cyber Security Working Group Issued at ISS site. Mostly several issues will be solved or mitigated by design.

Significance and Innovation

It has to be highlighted that the extraction of a model from three different regional approaches and models for chronic care, and different pathologies call for an in depth study of the common route for TM implementation.
Essential parameters set could be extracted thanks to standardised procedures offered by a central indipendent national institution. The risk management of the entire clinical, organizational and technological isssues of the healthcare service model, starting from regulatory laws and harmonised standard guide lines, render the model highly significant for any national health service as a startegic driving tool for traslational telemedicine

Description of the complementary and sinergy research team

The technical and medical expertise of the ISS unit, carried out since many decades from the application of regulations, standards, and assesment tools to the clinical environment and biomedical industry guarantee tha capacity of the team to interface itself with clinical, administrative and technical staffes of the other project units
Moreover the previous collaborations of several project units in previous EU and IT research projects witness the synergy capability of the actual teams in this program

Training and tutorial activities

Any needed formal training or information session will be gathered in favour of the partners during the audits phases, especially on the regulation and guide lines

Bibliography

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Timeline / Deliverables / Payable Milestones

month 6 - Requirements retrieval doc
month 8 - Audit design
month 11 - report audit 1
month 17 - report audit 2
month 27 - report audit 3
month 33 - report audit 4
month 36 - final report

Milestones 18 month

Evaluation tools for the healthcare service using TM and innovative technologies.
(Usability, technology acceptance model, adherence tool, Quality assurance indicators)

Milestones 36 month

	Project Title: Assessment of implementation strategies of digital innovations for the continuity of care
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Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Assessment of 3 healthcare service using TM and innovative technologies

Gantt chart

Copia di Area 5_Cronicità_WP ISS.pdf

Equipment and resources available

Fast calculation resources, software for analysis, sofware platform for web based application such as data base or cloud computing.

Translational relevance and impact for the National Health System (SSN)

Starting from common elements capable to drive the build up of the program not as a copy, but with the function of driving factors, to promote the development of the program, taking into account the specific carachteristics of involved patology and the territorial difficulties, if any, coerently within each regional applied health model, with the aim to consolidate clinical, organisational and functional improvements and therefore providing improvement on "quality of life, efficacy and effectiveness" of the program, starting from the experiences already gained fom the literature and the real world in favour of the national vision of ISS as central institution.

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Project Type: WP PROJECT - 2

PRINCIPAL INVESTIGATOR PROFILE

Name		
grigioni mauro	Institution	Istituto Superiore di Sanita'
	Department/Unit	National Center for Innovative technologies in Public Health (TISP), ISS
	Position Title	Director

Personal Statement

Goals are: assessment of the entire process of change promoting by using clinical governance, quality assurance and legal regulation and guidelines

Education/Training - Institution and Location	Degree	Year(s)	Field of study
La Sapienza University of Rome	MSc (Laurea) in Electronic Engineering	1985	Biomedical Engineering and Telecommunications

Positions

Institution	Division / Research group	Location	Position	From year	To year
ISS	Technology and health Department	Rome, Viale regina elena 299, 00161	Director of the Unit Biomechanics and Rehabilitative Technologies	2007	2016
ISS	National Center for Innovative Technologies in Public Health	Rome Viale Regina Elena 299, 00161	Director	2017	2018

Official H index: 21.0 (autocertificated)

Source: Web of Science **Scopus Author Id:** 7004215150

ORCID ID: https://orcid.org/0000-0002-8231-8156 **RESEARCH ID:** J-8744-2016

Awards and Honors:

Senior member of IEEE (USA)
Reviewer for several International Journals and Scientific Projects
Member of Scientific Commettee of Centro Protesi of Vigorso di Budrio (INAIL)

Other CV Informations:

Dal 2007 Dirigente di Ricerca, dirige il reparto ¿Biomeccanica e Tecnologie Riabilitative¿ con interessi nella locomozione e telemedicina con applicazioni delle tecnologie wireless ai Dispositivi Medici in ambito mHealth e eHealth (valigette con tecnologie wifi e percorsi strumentati per la riabilitazione).
Si occupa di riabilitazione, teleriabilitazione, realtà virtuale e tecnologie assistive per la gestione di persone fragili, pazienti cronici, malattie rare e polimorbidità.
Ha curato la implementazione di modelli di cura per la cronicità (Programma ISS-NIH - paz. con Ictus) (ASL Roma D - programma CCM -pazienti BPCO) (Progetto europeo per la teleriabilitazione diffusa), applicazioni cliniche innovative (ambienti collaborativi olografici in chirurgia, superfici tattili riabilitative)

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Applicant Institution: Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Selected peer-reviewed publications of the PI

Valid for PI minimum expertise level

Title	DOI	PMID	Cit. **	P.*
Optical vibrocardiography: A novel tool for the optical monitoring of cardiac activity	10.1007/s10439-006-9202-9	17082980	49	L
Optimal planning of sensor networks for asset tracking in hospital environments	10.1016/j.dss.2013.01.031		16	L
3-D simulation of the St. Jude Medical Bileaflet valve opening process: Fluid-structure interaction study and experimental validation		15473484	25	L
Evaluation of the surface-averaged load exerted on a blood element by the Reynolds shear stress field provided by artificial cardiovascular devices	10.1016/S0021-9290(02)00234-8		19	F
A discussion on the threshold limit for hemolysis related to Reynolds shear stress		10476849	56	F
Laser Doppler anemometry study of bidimensional flows downstream of three 19 mm bileaflet valves in the mitral position, under kinematic similarity	10.1114/1.244		18	F
On the monodimensional approach to the estimation of the highest Reynolds shear stress in a turbulent flow	10.1016/S0021-9290(99)00230-4		18	F
Particle image velocimetry analysis of the flow field in the total cavopulmonary connection	10.1046/j.1525-1594.2000.06613.x		22	F
The influence of the leaflets' curvature on the flow field in two bileaflet prosthetic heart valves	10.1016/S0021-9290(00)00240-2		41	F
Computational model of the fluid dynamics of a cannula inserted in a vessel: incidence of the presence of side holes in blood flow	10.1016/S0021-9290(02)00231-2		38	F
The power-law mathematical model for blood damage prediction: Analytical developments and physical inconsistencies	10.1111/j.1525-1594.2004.00015.x		67	F
Innovative technologies for the assessment of cardiovascular medical devices: state-of-the-art techniques for artificial heart valve testing	10.1586/17434440.1.1.81		16	F
Three-dimensional numeric simulation of flow through an aortic bileaflet valve in a realistic model of aortic root	10.1097/01.MAT.0000159384.36271.2c		24	F
A mathematical description of blood spiral flow in vessels: application to a numerical study of flow in arterial bending	10.1016/j.jbiomech.2004.06.028		53	F
Prosthetic heart valves' mechanical loading of red blood cells in patients with hereditary membrane defects	10.1016/j.jbiomech.2004.11.020		15	F
A novel formulation for blood trauma prediction by a modified power-law mathematical model	10.1007/s10237-005-0005-y		62	F

* Position: F=First L=Last C=Corrispondent

Project Title: Assessment of implementation strategies of digital innovations for the continuity of care

Project Code: NET-2018-12367206-2

Principal Investigator: grigioni mauro

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

** Autocertificated

For evaluation CV

Title	DOI	PMID	Cit. *
Ten years of telerehabilitation: A literature overview of technologies and clinical applications	10.3233/NRE-2010-0612		44
Structural characterization and cell response evaluation of electrospun PCL membranes: Micrometric versus submicrometric fibers	10.1002/jbm.a.32048		39
Numerical simulation of the dynamics of a bileaflet prosthetic heart valve using a fluid-structure interaction approach	10.1016/j.jbiomech.2008.05.004		63
Helical flow as fluid dynamic signature for atherogenesis risk in aortocoronary bypass. A numeric study	10.1016/j.jbiomech.2006.02.017		106
Optical vibrocardiography: A novel tool for the optical monitoring of cardiac activity	10.1007/s10439-006-9202-9		50
A novel formulation for blood trauma prediction by a modified power-law mathematical model	10.1007/s10237-005-0005-y		62
A mathematical description of blood spiral flow in vessels: application to a numerical study of flow in arterial bending	10.1016/j.jbiomech.2004.06.028		53
The power-law mathematical model for blood damage prediction: Analytical developments and physical inconsistencies	10.1111/j.1525-1594.2004.00015.x		67
The influence of the leaflets' curvature on the flow field in two bileaflet prosthetic heart valves		11311702	41
A discussion on the threshold limit for hemolysis related to Reynolds shear stress		10476849	56

* Autocertificated

	Project Title: Assessment of implementation strategies of digital innovations for the continuity of care
Project Code: NET-2018-12367206-2	**Principal Investigator:** grigioni mauro
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Grant

Funded Institution / Country	Year	Title	Position in Projects
European Commission (Horizon 2020)	2015-2020	¿¿CONCERT-European Joint Programme for the Integration of Radiation Protection Research¿ (Funded under: Horizon 2020), http://www.concert-h2020.eu/	Collaborator
European Commission (FP7-EURATOM-FISSION - EURATOM: Nuclear fission and radiation protection)	2013-2017	¿OPERRA, ¿Open Project for the European Radiation Research Area¿ (Project ID: 604984¿, Funded under: FP7-EURATOM-FISSION http://cordis.europa.eu/project/rcn/109481_en.html	Collaborator
European Commission (FP7-PEOPLE - Specific programme "People" implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013))	2013	¿MEDDICA, ¿Medical Devices Design in Cardiovascular Applications¿ (Project ID: 238113, Funded under: FP7-PEOPLE), FP7-PEOPLE-ITN-2008 - Marie Curie Action: "Networks for Initial Training" http://cordis.europa.eu/project/rcn/92473_en.html	Collaborator
European Commission (FP7-ICT)	2013	¿MindWalker "Mind Controlled Orthosis and Virtual Reality Training Environment for Walk Empowering" (Project ID: 247959, Funded under: FP7-ICT FP7) http://cordis.europa.eu/project/rcn/93837_en.html	Collaborator
European Commission (CIP - Competitiveness and innovation framework programme (CIP)(2007-2013))	2012	¿CLEAR, ¿Clinical Leading Environment for the Assessment and validation of Rehabilitation Protocols for home care¿ (Project ID: 224985, Funded under: CIP) http://cordis.europa.eu/project/rcn/191697_en.html	Collaborator
European Community (programme eTEN (2005-2007))	2007	¿HelloDoc, ¿Healthcare service linking tele-rehabilitation to disabled people and clinicians¿. Funded under European Community programme eTEN (2005-2007)	Collaborator
European Commission (FP6-IST - Information Society Technologies: thematic priority under the specific programme "Integrating and strengthening the European research area" (2002-2006))	2007	¿Coherent, ¿Collaborative Holographic Environments for Networked Tasks¿ (Project ID: 510166, Funded under: FP6-IST), http://cordis.europa.eu/project/rcn/71166_en.html	Collaborator
European Commission (FP5-IST - Programme for research, technological development and demonstration on a "User-friendly information society, 1998-2002")	2005	¿Smart-PIV, ¿Development Of An Interactive Integrated P.I.V. System Based On Miniaturised Optical Sensor Technology For Implantable Biomedical Devices Design¿ (Project ID: IST-2001-37548, Funded under: FP5-IST), http://cordis.europa.eu/project/rcn/63039_en.html	Collaborator

Employment contract extension:

(Data changed during the moratorium period)

Project Title: Assessment of implementation strategies of digital innovations for the continuity of care

Project Code: NET-2018-12367206-2

Principal Investigator: grigioni mauro

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Biographical Sketch Contributors 1

Name: Giansanti Daniele

Institution: ISS
Department/Unit: National Center of Innovative Technologies in Public Health
Position Title: Senior researcher

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University La Sapienza, Roma	Master's Degree in Electronic Engineering (duration 5 years)	1991	Electronics
Univ. Tor Vergata, Rome	PHD in Telecommunications and Microelectronics engineering	1997	Microelectronics engineering
University La Sapienza, Rome	Specialization in Cognitive Specialization in Cognitive Psychology and Neural networks ay 1996/1997, (duration 1 year)	1997	Cognitive Psychology and Neural networks
ANGQ, Rome	Assessor of Quality Systems, exam at the ANGQ after the course CEPAS	2003	Quality Systems and Assurance
University La Sapienza, Roma	Academic Specialization in Medical Physics (duration 2 years)	2005	Medical Physics
Competent Ministry, Rome	Qualified Expert in radioprotection level 3	2008	Radioprotection

Personal Statement:

The contribution of the key person will be focused to the assessment of the aspects that concur to achieve the quality of telemedicine applications involved in the Project. In particular in collaboration with the other subjects in the same OU and the partners He will: (A)Design procedures for Telemedicine Quality Control to furnish tools to assess telemedicine products and/or services. (B) Apply this procedures to the telemedicine applications in the project.(C)Collect information though an appropriate data-mining.(D)Extract useful information and indications for the partners and the stake-holders. As a part of these tools a Questionnaire a Classification Form and a Quality Assessment Checklist will be proposed in the project specifically for the assessment process

Project Title: Assessment of implementation strategies of digital innovations for the continuity of care

Project Code: NET-2018-12367206-2

Principal Investigator: grigioni mauro

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Institution	Division / Research group	Location	Position	From year	To year
Univ. Tor Vergata	Faculty of Engineering	Roma	Researcher (PHD achievement)	1991	1997
Elettronica spa		Rome	CAE CAD CAM System Manager & Design Engineer	1992	2000
ISS	TESA (last Dept.)	Rome	Researcher Level 3 (Ricercatore)	2000	2006
ISS	TISP (Last Department)	Rome	Researcher Level 2 (Primo Ricercatore)	2007	2018

Awards and Honors

Official H index: 15.0 (autocertificated)

Source: Scopus **Scopus Author Id:** 9846620600

ORCID ID: https://orcid.org/0000-0002-8904-0847 **RESEARCH ID:**

Awards and Honors:

Board Editor in Telemedicine and e-Health journal since 2011
Associated Editor BMC Medical Informatics and decision making 2014-2016
Past Member of ATA (American Association of Telemedicine)

Project Title: Assessment of implementation strategies of digital innovations for the continuity of care

Project Code: NET-2018-12367206-2

Principal Investigator: grigioni mauro

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Biographical Sketch Contributors 2

Name:
Morelli Sandra

Institution: ISS
Department/Unit: National Center of Innovative Technologies in Public Health
Position Title: Researcher

Education/Training - Institution and Location	Degree	Year(s)	Field of study
"La Sapienza" University, Roma	MSc Degree in Electronic Engineering (5 yrs)	1995	Electronics and biomedical engineering
"La Sapienza" University, Roma	Post-graduate Course in "Methods for the analysis of biomedical signals and images" (1 yr)	1997	Acquisition and processing of biomedical signals and images
University of L'Aquila, L'Aquila	Specialization School in Clinical Engineering (2 yrs)	2004	Design and application of medical instrumentation

Personal Statement:

A) Analysis of the 3 telemedicine services selected for the research project and definition of a set of process indicators which can deserve to evaluate the safety (from the regulatory point of view) of a TM-based HC service and the technical quality (such as in Quality Assurance or Clinical Governance methodologies).

B) In order to get further information on factors which influence the adherence to the program, usability and acceptability of the implied technologies will be examined and evaluated, by means of standard or customized methodologies and corresponding statistical analysis.

C) Monitoring of results from Aim 1 and 2 and results of the clinical outcomes and definition of the methodology for supporting the usefully implementation of TM program in other regional contexts.

	Project Title: Assessment of implementation strategies of digital innovations for the continuity of care
Project Code: NET-2018-12367206-2	**Principal Investigator:** grigioni mauro
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Institution	Division / Research group	Location	Position	From year	To year
Istituto Superiore di Sanità	Laboratory of Biomedical Engineering/ Diagnostics and Functional Monitoring	Rome, Italy	Investigator Fellow	1996	1997
Istituto Superiore di Sanità	Laboratory of Biomedical Engineering/ Diagnostics and Functional Monitoring	Rome, Italy	Researcher	1998	2000
Istituto Superiore di Sanità	Laboratory of Biomedical Engineering /Therapeutic and Rehabilitation Technologies	Rome, Italy	Researcher	2001	2004
Istituto Superiore di Sanità	Department of Technology and Health/Biomechanics and Rehabilitation Technologies	Rome, Italy	Researcher	2004	2016
Istituto Superiore di Sanità	National Center for Innovative Technologies in Public Health	Rome, Italy	Researcher	2017	2018

Awards and Honors

Official H index: 8.0 (autocertificated)

Source: Web of Science **Scopus Author Id:** 7005712570

ORCID ID: http://orcid.org/0000-0001-9497-6810 **RESEARCH ID:**

Awards and Honors:

Referee of: Computer in Biology and Medicine; BMC Medical Informatics and Decision Making; JMIR Rehabilitation and Assistive Technologies

Teachings at "La Sapienza" University of Rome:
Systems of information processing (2006-2014) - Bachelors Degree in Nursing; Data processing and signals (2007-2011), Computer Science III (2008-2011), Computer Science II (2008-2010) - Bachelors Degree in Techniques of Neurophysiology;
Foundations of Computer Science (2007-2008) - Master Degree in Philosophy.

Project Title: Assessment of implementation strategies of digital innovations for the continuity of care

Project Code: NET-2018-12367206-2

Principal Investigator: grigioni mauro

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Expertise Research Collaborators

Selected peer-reviewed publications of the Research Group / Collaborators

Collaborator	Title	DOI	PMID	Cit. *
Giansanti Daniele	Virtual microscopy and digital cytology: state of the art	10.4415/ANN_10_02_03	20567061	13
Giansanti Daniele	Web based health technology assessment in tele-echocardiography: the experience within an Italian project.		20061659	3
Morelli Sandra	Routine tests for both planning and evaluating image quality in tele-echocardiography.		20061658	3
Morelli Sandra	Digital tele-echocardiography: a look inside		20061655	3
Giansanti Daniele	Validation of an automatic tool for the assessment of image quality in digital tele-echocardiography	10.1258/jtt.2008.007004	18852313	3
Morelli Sandra	Health technology assessment of a homecare device for telemonitoring and telerehabilitation for patients after hand transplantation	10.1089/tmj.2007.0023	18328027	4
Giansanti Daniele	A protocol for the assessment of diagnostic accuracy in tele-echocardiography imaging.		17848108	7
Morelli Sandra	Telemedicine technology assessment part I: setup and validation of a quality control system		17489698	14
Giansanti Daniele	Telemedicine technology assessment part II: tools for a quality control system		17489699.	10
Morelli Sandra	Quality assessment and cataloguing of telemedicine applications. J Telemed Telecare. 2006;12(4):189-93. PubMed PMID: 16774700. CIndex: 6		16774700	6

* Autocertificated

Project Title:
Assessment of implementation strategies of digital innovations for the continuity of care

Project Code: NET-2018-12367206-2

Principal Investigator: grigioni mauro

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Grant

Funded Institution / Country	Year	Title	Position in Projects	Collaborator
Italian MoH		"Strumentazione e metodi per la valutazione funzionale della mano nel trapianto di organo prelevato da cadavere"	Collaborator	Morelli Sandra
Italian MoH		"e.R.ME.TE. Regioni per la medicina telematica. Modelli di riferimento interregionale per prodotti e servizi di telemedicina"	Collaborator	Morelli Sandra
Italian MoH		"Tele-ecocardiografia sul territorio: studio di fattibilità, accuratezza diagnostica e analisi del rapporto costo/efficacia"	Collaborator	Morelli Sandra
Italian MoH		"Il trattamento del soggetto parkinsoniano: integrazione tra aspetti diagnostici, valutativi e terapeutici per l'ottimizzazione dell'efficacia riabilitativa globale"	Collaborator	Morelli Sandra
Italian MoH, Ricerca Finalizzata 2013	2016-2019	¿High-end and Low-End Virtual Reality Systems for the Rehabilitation of Friality in the Elderly¿	Collaborator	Morelli Sandra
European Commission	2010-2013	European Project "Mind-Controlled Orthosisand Virtual Reality Training Environment for Walk Empowering Mind Walker"	Collaborator	Giansanti Daniele
MIUR	30 months	Linea di Ricerca "Sistema di rieducazione neuromotoria al cammino basato sull' uso di percorsi tra parallele o su scale" nel Progetto MIUR "Messa a punto di nuove metodologie per la teleriabilitazione neuromotoria" in collaborazione con IRCSS Fondazione S. Maugeri Durata 30 mesi	Coordinator	Giansanti Daniele
Ente Finanziatore Ministero della Salute, Ricerca Finalizzata	30 months	Progetto"Caratteristiche precliniche e modelli di trattamento non farmacologico dei disturbi cognitivi e motori della malattia di Parkinson"	Collaborator	Giansanti Daniele
Italian MoH, Ricerca Finalizzata		Progetto Nazionale "Fattori di rischio per patologie neuromuscoloscheletriche in operatori a videoterminale"	Collaborator	Giansanti Daniele
INAIL	2017-2019	Sviluppo e validazione di una piattaforma robotica per la riabilitazione motoria e il coordinamento visuomotorio degli arti superiori con scenari di realtà virtuale relativi ad attività di vita quotidiana	Collaborator	Giansanti Daniele

Project Title:
Assessment of implementation strategies of digital innovations for the continuity of care

Project Code: NET-2018-12367206-2

Principal Investigator: grigioni mauro

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Total proposed budget (Euro)

Costs	TOTAL BUDGET	Co-Funding	Project costs proposed to funding Organization (no MOH request)	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	80.000,00	80.000,00	0,00	not permitted	0,00
1b Researchers' Contracts	114.000,00	0,00	0,00	114.000,00	49,78
2 Equipment (Leasing - Rent)	40.000,00	0,00	0,00	40.000,00	17,47
3a Supplies	46.100,00	0,00	0,00	46.100,00	20,13
3b Model Costs	0,00	0,00	0,00	0,00	0,00
3c Subcontracts	0,00	0,00	0,00	0,00	0,00
3d Patient Costs	0,00	0,00	0,00	0,00	0,00
4 IT Services and Data Bases	0,00	0,00	0,00	0,00	0,00
5 Publication Costs	0,00	0,00	0,00	0,00	0,00
6 Convegni	2.000,00	0,00	0,00	2.000,00	0,87
7 Travels	4.000,00	0,00	0,00	4.000,00	1,75
8 Overheads	22.900,00	0,00	0,00	22.900,00	10,00
9 Coordination Costs	0,00	0,00	0,00	0,00	0,00
Total	309.000,00	80.000,00	0,00	229.000,00	100,00

Report the Co-Funding Contributor:

total cofunding consists exsclusively of the staff salary, in proportion to the man months devoted to the project.

	Project Title: Assessment of implementation strategies of digital innovations for the continuity of care
Project Code: NET-2018-12367206-2	**Principal Investigator:** grigioni mauro
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Budget Justification	
1a Staff Salary	exclusively co-funding
1b Researchers' Contracts	1 research contract for three years, partially funded by the Moh compensative funding for ISS (see page 4 of the call)
2 Equipment (Leasing - Rent)	computational resources (i.e. workstations with GPU for high performance computing, network storage systems and remote management control)
3a Supplies	software licences (i.e. network data base sw, simulation and statistical packages)
3b Model Costs	NA
3c Subcontracts	NA
3d Patient Costs	NA
4 IT Services and Data Bases	NA
5 Publication Costs	NA
6 Convegni	Conference organization (at ISS premises) for the presentation of the project approach and metodology
7 Travels	National travels for periodical audits on the field in the three regions and coordination meetings (at least the Kick off meeting and the Final Conference)
8 Overheads	ISS overhead
9 Coordination Costs	NA

(Data changed during the moratorium period)

	Project Title: Assessment of implementation strategies of digital innovations for the continuity of care
Project Code: NET-2018-12367206-2	**Principal Investigator:** grigioni mauro
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Istituto Superiore di Sanita'

Project Type: WP PROJECT - 2

Project Title:
Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.

Project Code: NET-2018-12367206-3

Principal Investigator: Scalvini Simonetta

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Major Diagnostic Category*: Nefrologia e Urologia

Project Classification IRG: Healthcare Delivery and Methodologies

Project Classification SS: Biomedical Computing and Health Informatics - BCHI

Project Keyword 1: Application of human-centered computing (human-machine interfaces), intelligent systems, virtual environments, computer-assisted diagnosis and treatment systems with data including imaging data and telemedicine to biomedical and clinical systems, including the study of collaboration to engineer-usable effective software systems.

Project Keyword 2: Chronic diseases, Telemedicine, telemonitoring, ehealth, mhealth, health-related quality of life; medical decision-making

Project Keyword 3: Case Manager, clinical manager, chronic disease management

Project duration (months): 36

Project Request: **Animals:** ☐ **Humans:** ☒ **Clinical trial:** ☐

The object/s of this application is/are under patent copyright Y/N: ☐

Investigators, Institution and Role in the Project

	Co-PI	Key Personnel	Institution/Org./Pos.	Role in the project	Birth Date
1	X	Bernocchi Palmira	Istituti Clinici Scientifici Maugeri Spa Società benefit / Continuity Care Unit/ Responsible of coordination of activities related to taking charge of chronic disease.	As CoPI my role will be to help PI in the scientific coordination, in the phases organisation of the patients enrolment and training of nurses.	11/03/1965
2		Bertolaia Patrizia	ASST GOM NIGUARDA / Department of Servizi Territoriali / Head of Department	As research collaborator my role will be to contribute with my expertise to the project managment and clinical component	23/11/1958
3		Trevisan Roberto	ASST Bergamo / Unit for Endocrine Diseases and Diabetology / Head	As research collaborator my role will be to contribute with my expertise to the project managment and clinical component	24/10/1957

Overall Summary

The new regional chronic care model represents a hard stimulus to evaluate innovative strategies for cooperation between GPs and specialists.
Lombardy will trigger a "Steering Board" in order to define what can be recommended based on a critical review of current experiences in different realities. -To design and to test and evaluate innovative models for applying TM and in particular mobile health and Apps to the management of patients with chronic conditions and comorbidities.- To design, to form and to insert the Case manager in the new care model.
Expert will participate in the Lombardy Steering Board and surveys will be done to assess the different realities;
Forty patients with chronic disease will experiment a new App on a smartphone to increase the interaction with case manager, while 40 patients will serve as control group.
Ten nurses will be formed, trained and insert in GPs¿ cooperative and in the hospital to participate to the new care model.

Project Title:	Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.
Project Code: NET-2018-12367206-3	**Principal Investigator:** Scalvini Simonetta
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Background / State of Art

In industrialized countries, the number of people suffering from multiple chronic conditions continues to increase. The collaboration between hospital and territory with integrated communication tools and the monitoring of the patient with the appropriate instruments, including telemedicine (TM), are fundamental to ensure both the continuity of care and the sustainability of the health system.
TM applications targeted to pts with multiple pathologies can support territorial models that, starting from primary care in its various forms of association, come to involve specialized hospitals. Experiences and TM projects are increasing in the country, but their distribution is fragmented, limited to specific areas and duration. A number of studies prove that TM has a positive impact on the management of chronic patients. Recent meta-analysis showed that telemonitoring and/or structured telephone support are effective in reducing mortality and hospitalizations for chronic heart failure, contribute to improve the QALYs and reduce health care costs. However, randomized studies have yielded conflicting results, probably due to differences in the models used and to the choice of target population. Also in other areas such as hypertension, arrhythmias, diabetes, respiratory failure, data are not yet enough to clarify the clinical benefits and/or cost-effectiveness. Chronic diseases are a good setting for new healthcare delivery modalities, to improve quality of care and outcome, control costs and better interaction between primary and hospital care. Hospitalizations are the main determinant of costs of care. Optimized therapy, self monitoring and appropriate lifestyle may reduce or delay deterioration of heart function, worsening of symptoms, and need for hospitalizations, and ultimately improve survival. Specialized care is needed at first diagnosis, in case of definite worsening, and in advanced disease. Moreover, GPs know the general picture of their patients in terms of comorbidities, adherence to therapy, social status and expectations. In Lombardy there are 1) favorable experiences in telemanagement, 2) new modalities for GPs-provided integrated services to patients with chronic conditions, 3) an electronic patient record that can be shared between GPs and hospitals, and 4) a new regional chronic care model which represents an innovative strategy for applying new technologies for cooperation between GPs and specialists. The first official document was a systematic health population management exercise, clustering all patients in 65 different disease types, each one diversified along three levels of severity (DGR X/6164 of 30/01/2017). The second planning document designed the governance architecture of the health care system both for public and private providers. Providers could put forward their candidature to become `case-managing organizations¿ and `commissioning organizations¿ for chronic patient (DGR X/6551 of 04/05/2017). The third official act defined the required modalities and contractual forms and obligations that health care organizations had to adopt in order to establish the integrated care networks able to take care of the patient (DGR X/7038 of 3/8/2017). Finally, the operational start-up of the chronic care model is present in this document (DGR X/7655 of 28.12.17) In light of these new regional documents and of the national chronicity plan, new type of services could be implemented. In this scenario, a structured physician-directed, nurse-managed service using ICT and Mhealth, could be an efficient management for a growing number of complex patients and could promote a real integration between hospital-based care and home care. In a very close future the patient¿s home, where clinicians can combine old-fashioned sensibilities and care with the application of new technologies, could respond to major demographic, epidemiologic, and health care trend.

Hyphotesis and Specific AIMS

Hyphotesis and Significance:
There are many good practice in Lombardy on the management of chronic condition with different type of telemedicine and monitoring services, but these are confined on the local level and often not known; a regional central point -where all information could be found- would be useful to promote the best practices. Actually a complete census on regional system

on integrated care of chronic disease with telemonitoring is not present. Moreover, papers already published suggests that the next step in chronic disease management could involve a combination of wearable devices and mHealth apps that focus on improving health conditions. Such devices are in wide use. The pervasiveness of mobile technologies promises much in the search to increase efficiency. The use of this technology is done not only by the patient but could be a support for the case manager. In the new Lombardy reform, case manager is one of the most important figure in the management of chronic patients. We need to prepare nurses to afford this new role so important in chronic disease management.

Preliminary Data:

So far, in Lombardy telemedicine has been used mostly by specialists. The main experiences in chronic patients consist of 1) projects developed for HF, COPD and post-cardiac surgery patients, which led to the teleassistance service provided by regional healthcare system 2) telemonitoring of pts with implanted electric devices (pacemakers/defibrillators); 3) second opinion for GPs, Many publications were done on this basis; for this reason, on December 2016 Lombardy Region become a 4 stars Reference Sites, that are inspirational ecosystems, delivering creative and workable solutions that improve the lives and health of older people.

Specific Aim 1:

To identify, analyze and compare current models of TM applied to patients with chronic conditions in Lombardy region, with special attention to the following elements:
- target population
- setting
- relationship with other modalities and components of healthcare
- process and delivery of care
- outcome measurement
- economic evaluation.

Specific Aim 2:

Aim 2: To design and to test and evaluate innovative models for applying TM to the management of patients with chronic conditions and comorbidities. New models will be characterized by the followings:
- flexible adaptation to patient subgroups/ individual patient characteristics, including caregivers
- expectation and willingness to participate actively in the process of care (empowerment)
- application of new devices and/or mobile apps
- pre-definition of outcome measures, that should include at least the evaluation of quality of life, perceived quality of care by the patients and caregivers, number and duration of hospitalizations.

Specific Aim 3:

Aim 3: To design the role of the Case manager
- Definition of the team of care and of the roles and responsibilities of each component with particular attention to case manager
- Education programs and training introducing the case manager figure in the management of chronic patient, whit an innovative holistic approach to the patients in order to tackle the chronic condition challenge.
- Evaluation through Learning Questionnaire of the improvement in education and practical activities of the case manager
- Improving ambulatory care nurses¿ perceptions of competency

Experimental Design Aim 1:

Project Title:	Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.
Project Code: NET-2018-12367206-3	**Principal Investigator:** Scalvini Simonetta
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Lombardy will trigger a "WP Board" in order to define what can be recommended based on a critical review of current experiences in different realities. Key persons with significant experience in the field of telemedicine and care of patients will be identified among regional leaders and scientific experts. The researchers of this project are available to help Steering Board in all the actions of the Region on this theme.
In 12140_DGR2017_7600_regole_2018, there is mentioned widespread medicine, understood as a set of methods of assistance to the home of the patient who make use of new technologies; In this sense, it is envisaged the establishment of a working table on the application of the National Guidelines on Telemedicine, with the following objectives:
- catalog all the telemedicine projects active in the Region, (Census);
- fill out for each of the active telemedicine projects, a standard card, to allow the detection of all the parameters useful for the calculation of the indicators proposed by the Guidelines;
- identify some critical issues of an organizational and technical nature;
- develop an analysis of the potential need for telemedicine services in Lombardy;
- define a nomenclature of the services and the requirements of accreditation;
- to define experimentally the remuneration system.
The Working Table will also monitor the impacts of the tools of diffused medicine in terms of improvement of outcome and recovery of efficiency.

Experimental Design Aim 2:
Forty patients with chronic heart failure and comorbidities (Hypertension, diabetes, and COPD) will be enrolled and 40 patients will serve as control group. During the last days of hospitalization, or during an ambulatory visit the patient is randomized to a Group1 (telemedicine service and App) and Group 2 (control group). In this project Group 1 adopt a multidisciplinary approach with Structured Telephone Support + Telemonitoring with mHealth referring to clinical and case manager interventions. Card is a clinical score used during the follow-up telephone contact to assess any clinical variation from the baseline status. A specific App, containing the card, could be download on the mobile phone of the patients. Once at home and according to their symptoms, the patients were invited to fill in the card two times a week, early in the morning, for 4 consecutive months. In the case of variation by 3 points of this score from the baseline value, the case manager had to contact the patient for consultation. Additionally, biological signals invoice with telemedicine, scheduled appointments with case Manager and clinical manager if needed will be present.
The models will be focused on the Case Manager and the Clinical Manager activities as main referral for the patient, and will include: patient informed consent, electronic medical records, shared clinical pathways, risk profile, definition of the objective and of the plan of care and definition of minimum data set, remote monitoring with mHealth and criteria for outcome and process quality evaluation.The evaluation and the choice of the app will keep in mind the experience gathered by Formit on the heath-app (http://www.appsanitarie.it/). Indicators of the success of the project are: 1- compliance of the patient (more than 70% of cards inserted in the App; 2- exacerbation and hospitalizations during the follow-up. Given the heterogeneity of the actors participating in the system, the project aims to define an innovative reference model of collaboration between them, based on the emerging ¿Digital Ecosystem¿ approach already successfully used in other areas (i.e. E015 Digital Ecosystem www.e015.regione.lombardia.it).

Experimental Design Aim 3:
To define the role of case manager, an audit with experts will be organized.
Ten experienced Nurses will be enrolled, formed for 3 months and trained to become case managers through programs in nursing case management. for 1 months and then inserted in the GPs cooperatives (ATS Val Padana) and Hospitals (ICS Maugeri, ASST Niguarda, ASST Bergamo, Auxologico) with the role of case manager.
Coursework may focus on health care and social field; the programs is designed to develop students' critical thinking,

planning and decision-making skills in order to prepare them to become effective case manager.
The course topics will include: -Effective case management of chronic conditions and comorbidities in the community and in healthcare systems -Physical and psychological factors -Developing strategies to manage chronic populations; -Leadership; -Role of the ICT in helping case manager and in particular Mobile Apps and Mobile device in use to the case manager or to the patients. At the end of the course, an evaluation through Learning Questionnaire of the improvement in education and practical activities of the case manager will adopted. Still at the end, all the nurses will undergo the Utrecht Work Engagement scale, to assess nurse engagement.

Picture to support preliminary data:
RF-2018- WP3_Network Project_ePreliminary Data Lombardia_.pdf

Metodologies and statistical analyses:
Respect aim 1: we will be performed a survey (Computer Assisted Web Interviewing and Computer Assisted Personal Interviewing) using standardized method addressed to all public and private facility in Lombardy to catalog all the active telemedicine projects (second opinion, teleconsultation, health tele-cooperation); if some projects/services for chronic patients are already present, we need to identify the number of users, the administrative and technical issues. Administrative data queries could be utilize to have a detailed situation on services present in Lombardy.

Respect aim 2: Patients will be recruited consecutively from the hospitals involved in the project. Consenting eligible patients will be randomized to either an intervention or a control group.
The following clinical data and minimum data set of project will be collected at the beginning (T0) and after 4 months (T1). Data will be descriptively analyzed and presented as percentage or mean ± standard deviation for all clinical variables, median ± interquartile (IQ)
range for variables without a normal distribution, and percentage for categorical and binary variables. Distribution and normality of variables will be tested by the Kolmogorov-Smirnov test. To compare groups at T0, Student¿s t test or the Mann-Whitney-Wilcoxon test for continuous variables, and the chi-squared test for categorical variables, will be used.
The effects of use of the patient's cards will be analyzed by two-way analysis of variance (ANOVA) for repeated measures (time and group). A post hoc analysis will be conducted when the ANOVA F ratio is significant for Student's
t test among times and groups, and Bonferroni¿s correction will be applied.
Also, predictive analysis will be performed to detect the characteristics of improvers and non-improvers using multivariate logistic regression.
The level of significance will be set at $p < 0.05$.

Respect to Aim 3 = Learning Questionnaire will be performed at the beginning and at the end of the training. Utrecht Work Engagement scale will be performed after the inclusion of the nurses in a chronic disease management services.

Expected outcomes:
Referred to AIM 1: The region will have the elements for deliberate on common technology standards, the required modalities and contractual forms and obligations for telemedicine services
Referred to AIM 2: An Increase of use and adherence of the card on a App; increase in the interaction with device and mhealth; empowerment of the patient; increase in quality of life; reduce of exacerbation and hospitalization in the treated group in comparison with the control group.
Referred to AIM 3: Understand the real role of case manager and his potentiality; create a training for nurses to become a

case manager; increase in the interaction with new devices and mhealth; increase in the interaction among case manager, clinical manager, specialists and patients. Through the use of problem-based learning and simulation, nurses may be able to more efficiently and effectively develop the necessary skills to provide effective case management of chronic disease.

Risk analysis, possible problems and solutions:
Referred to aim1 = Delay in the activation of the Steering Board/ push for responsible people in Lombardy.
Referred to Aim 2 = Delay in the enrollment of the patients/activated the four recruiting hospitals
Referred to Aim 3 = Delay in the enrollment of the nurses/activated the four recruiting hospitals and ATS Valpadana.

Significance and Innovation

At the end of this project, the Region could set up a system in the regional territory of widespread medicine, by defining accreditation requirements and a remuneration system, respecting the application of the National Guidelines on Telemedicine.
At a second point, from a clinical point of view, the project aims to improve patient empowerment and the integration with the case manager and clinical manager. From a technological point of view, the innovation of the project consists in the use of app dedicated to the patient that allow an appropriate information return to the patient himself. Furthermore, the data governance, through the digital ecosystem model, is extremely important for the scalability and interoperability of the system.
At the end, the figure of case manager is totally innovative both at regional and national level.

Description of the complementary and sinergy research team

The project has an operating team in Lombardy, so they are accustomed to use the same electronic medical record and shared clinical pathway; indeed they previously participated together to regional and national projects and in particular to the 'New Health Network' sharing an innovative telemedicine services for chronic heart failure and COPD. Each of them will bring their complementary expertise and tools for the success of the project. In particular the " Istituti Clinici Scientifici Maugeri IRCCS " will assure the scientific coordination and will contribute to define pilot site.
The possible patient recruitment center are: ASST Niguarda, IRCCS Auxologico, ASST Bergamo, Istituti Clinici Scientifici Maugeri IRCCS;
The ASST Niguarda, ASST Bergamo, Istituti Clinici Scientifici Maugeri IRCCS and ATS Valpadana will contribute to define the role of case manager to form and to test them.
Cefriel will contribute as sub-contractors to support technical aspect of the project.

Training and tutorial activities

(Aim 1): not requested
(Aim 2): Young fellowship positions will be required for the project. Candidates will be selected by the study curriculum and on specific skill and competences acquired during their previous education. They will undergo a specific training in the management of chronic conditions of about three months providing all clinical competences necessary to determinate the clinical skills required for the project and allow them to reach an adequate level of self-sufficiency. Besides their active role in the experimental phases of the project, fellows will be involved in data collection and in management and in all the different phases of the paper publications.
(AIM 3): Training and tutorial activities are part of the project.

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8. Bernocchi P, Scalvini S, Tridico C, et al. Healthcare continuity from hospital to territory in lombardy: TELEMACO project. Am J Manag Care. 2012;18(3):e101-e108.
9. Zanaboni P, Scalvini, S, Bernocchi P, et al. Teleconsultation service to improve healthcare in rural areas: acceptance, organizational impact and appropriateness. BMC Health Service Research 2009;9:238. DOI: 10.1186/1472-6963-9-238.
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Timeline / Deliverables / Payable Milestones

In the phase 1 the project will start with the setup and start of the working group that will last 3 and 4 months;
In the same time Lombardy region will organize the Steering Board on Telemedicine Services. Within this time, PI and collaborator will prepare clinical protocol for aim 2 and work protocol for aim 3 that will last two and three months respectively.

In the phase 2: for aim 1 there will be some Boarding Meetings; for aim 2 the presentation of the protocol to the Ethic Committees and the beginning of the patients' enrolment; for the aim 3 the Course dedicated to Case managers will done

In the phase3: for aim 1 a final meeting will be done; for aim 2, we will finish the patients follow-up and for aim 3 the Case managers will engage in hospitals and in GP's cooperative.
At the end, data analysis, final conference and final report will be done.

Milestones 18 month

The main milestones expected in the first half of the project are: the Kick off meeting, and the regional working group setup, the work protocol setup for aims 2 and 3, the clinical protocol approval by the ethics committee, the delivery of courses dedicated to Case managers, the nurses engagement and patients enrollment.
A project meeting will be held around the 12th month.

Project Title:	Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.
Project Code: NET-2018-12367206-3	**Principal Investigator:** Scalvini Simonetta
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Milestones 36 month

In the last 18 months we expect to engage case managers in hospital and GP's cooperative. We will formalize the needs of peripheral users (specialists, GPs, hospitals). Data collection and analysis will be concluded and we will organize a second meeting and local and regional conferences to present the project results.

Gantt chart

RF 2018 - WP3_network Project_ Lombardia Gantt.pdf

Equipment and resources available

Facilities Available

Regard to Aim 1: regional administrative database;
Regard to Aim 2: Echocardiography, ECG, Holter monitoring (for CHF patient), pletismography (for COPD patients) (Holter AP monitoring (for Hypertensive patient) and blood examination (for all the patients in particular diabetic patient) in each center will be able to support this research as part of the usual clinical practice. The economic value of these examinations and time staff time consumption will be covered by the single institution.
Devices: personal smartphone of the patient, if he/her prefer to use this for the project. Device for transferring biological signal (as ECG), saturimetry, glucometry already present in hospitals to give to the patients.
Regional personal health record of the patients (fascicolo sanitario eletronico) already present and use by all the hospitals and GPs
Regard to Aim 3: Informative material already published

Subcontract - (Explain Reason for Subcontract)
A subcontract related to services that can not be carried out by the WP will consist in a specialized external support needed throughout the project for the coordination of technical activities. A senior professional, supported by a team of eHealth and mHealth specialists, will:
-collaborate with the research teams in the evaluation and choice of the most suitable solution for implementing an electronic version of the 'cards' that the patient will use for self-assessment
-supervise the regional guidelines regarding Digital Ecosystems opportunities that can be found in the project, both in using existing external APIs and exposing APIs potentially needed by external actors.

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Project Type: WP PROJECT - 3

Translational relevance and impact for the National Health System (SSN)

The project identifies good practices and indicates the technological standards and the models of the best care pathways: these indications can be acquired at both regional and national level. Similarly, the definition of rules and procedures for accessing data in ecosystem mode is a contribution that can be valorized at regional and national level.
In addition, developing mobile Apps and integrated them in a care model for chronic condition could be relevant in early recording a possible instabilization of the disease.
The project will contribute significantly to an effective and timely definition of the figure of the case manager also present in the national plan of chronicity, but actually with a different role in the territorial realities. The centrality of this functional figure is also highlighted in the innovative Lombard model of taking care of the chronic patient as a new paradigm of care.

Project Title:
Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.

Project Code: NET-2018-12367206-3

Principal Investigator: Scalvini Simonetta

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

PRINCIPAL INVESTIGATOR PROFILE

Name	Institution	Regione Lombardia - Direzione Generale Sanità
Scalvini Simonetta	Department/Unit	Istituti Clinici Scientifici Maugeri IRCSS
	Position Title	Head of cardiac Rehabilitation Unit, Head of continuity Care Unit

Personal Statement

The principal investigator Dr. Scalvini prepared the present project. She proposed to join expertise in the current consortium dedicated to chronic patients and will be responsible of coordinate and monitor the activities among partners, to contact and organize meeting with partners and relationships with the subcontractors.
For the goal of the study Dr. Scalvini will assume the scientific coordination and will contribute to realize the different phases of the project.

Education/Training - Institution and Location	Degree	Year(s)	Field of study
C.S.G. srl (Consulenza Strategica Gestionale) for Regione Lombardia IREFs	Revalidation of the certificate Managerial Training	2013	Manager of Complex stuctures
Regione Lombardia IREF (University of Brescia)	Training for Managers of High Level Hospital - Regione Lombardia.	2005	Manager of Complex Structures
University of Brescia, Italy	Specialization	1992	Cardiology
University of Pavia, Italy	Specialization	1988	Respiratory Physiopathology and Physiokinesis-therapy
University of Brescia, Italy	Medical Degree certificate and Medical Qualifying examination	1985	Medicine and Surgery

Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.

Project Code: NET-2018-12367206-3

Principal Investigator: Scalvini Simonetta

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Positions

Institution	Division / Research group	Location	Position	From year	To year
Istituti Clinici Scientifici Maugeri IRCCS Spa Società Benefit	Cardiac Rehabilitation Unit, Continuity Care Unit, Directions of Institute	Lumezzane, Bs, Italy	Head of Cardiac Rehabilitation and Care Continuity Units, Scientific Director of Institute	2016	2018
IRCCS Fondazione Salvatore Maugeri	Directions of Istitute	Lumezzane, Bs, Italy	Scientific Director of Institute	2014	2016
IRCCS Fondazione Salvatore Maugeri	Directions of Istitute	Lumezzane, Bs, Italy	Scientific Director of Institute	2006	2012
IRCCS Fondazione Salvatore Maugeri	Cardiac Rehabilitation Unit	Lumezzane, Bs, Italy	Head	2014	2016
IRCCS Fondazione Salvatore Maugeri	Cardiac Rehabilitation Unit	Lumezzane, Bs, Italy	Manager of Second Level	2003	2014
IRCCS Fondazione Salvatore Maugeri	Continuity Care Unit and Telemedicine Service	Lumezzane, BS, Italy	Head	2003	2016
IRCCS Fondazione Salvatore Maugeri	Cardiac Rehabilitation Unit	Gussago, BS, Italy	Clinical Assistant and Manager of First Level	1994	2003
IRCCS Fondazione Salvatore Maugeri	Cardiac Rehabilitation Unit	Gussago, BS, Italy	Clinical Assistant	1986	1994

Official H index: 23.0 (autocertificated)

Source: Scopus **Scopus Author Id:** 7004295712

ORCID ID: 0000-0001-7387-505X **RESEARCH ID:** NA

Awards and Honors:

1. Awards and Honorable mention 'Europe Awards in e-Health'; European Commission 2003 Brussels 'The contribution of ICT to eHealth' Telemedicine and Homecare eHealth Applications
2. eEurope Awards in eHealth' 'Good Practices for Developing a Country's eHealth Action Plan' High Level conference and Exibition; Malaga Spain 10-12 Maggio 2006
3. From 2013 up to now expert in the European Innovation Partnership (EIP) on Active and Healthy Ageing in the Action Group B3 on Integrated Care.

Other CV Informations:

For several years (1989- 1998) her activity has been concentred and organized on clinical aspects related to heart failure disease and management in the field of rehabilitation under chronic conditions. Since 1998, Dr Simonetta Scalvini developed interest for new technology to help patients to take better care of their health. Indeed, she participates to manage and develop the 'Telemedicine Unit' in Fondazione Salvatore Maugeri.
Current work concerns studies on integrated care with the application of ICT-enabled new models in chronic diseases; design of telehealth service to provide practical support, both clinical and technical and managing Chronic Disease and Care of the Elderly.

Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.

Project Code: NET-2018-12367206-3

Principal Investigator: Scalvini Simonetta

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Selected peer-reviewed publications of the PI

Valid for PI minimum expertise level

Title	DOI	PMID	Cit. **	P.*
Trends in heart failure hospitalizations, patient characteristics, in-hospital and 1-year mortality: A population study, from 2000 to 2012 in Lombardy	10.1016/j.ijcard.2017.02.052	28262349	1	L
Maugeri Centre for Telehealth and Telecare: A real-life integrated experience in chronic patients	10.1177/1357633X17710827	28537509	2	F
Heart failure: Optimal postdischarge management of chronic HF	10.1038/nrcardio.2012.161	23165075	5	F
Tele-assistance respiratory card: Feasibility of self-reporting in patients with severe COPD	10.1089/tmj.2012.0089	23230820	1	L
Home-based versus in-hospital cardiac rehabilitation after cardiac surgery: A nonrandomized controlled study	10.2522/ptj.20120212	23599353	16	F
Home-based telemanagement in chronic heart failure: An 8-year single-site experience	10.1258/jtt.2011.110201	21979603	10	L
A pilot trial of telemedicine-assisted, integrated care for patients with advanced amyotrophic lateral sclerosis and their caregivers	10.1258/jtt.2009.090604	20139136	31	L
Socio-technical and organizational challenges to wider e-Health implementation	10.1177/1479972309102805	19411570	43	L
The SUMMA project: A feasibility study on telemedicine in selected Italian Areas	10.1089/tmj.2008.0109	19382864	8	F
Tele-assistance in chronic respiratory failure patients: A randomised clinical trial	10.1183/09031936.00005608	18799512	157	L
Multicenter randomised trial on home-based telemanagement to prevent hospital readmission of patients with chronic heart failure	10.1016/j.ijcard.2007.10.027	18222552	122	C
Wireless-accessible sensor populations for monitoring biological variables	10.1258/jtt.2008.003010	18430280	14	C
Chronic heart failure home-based management with a telecardiology system: A comparison between patients followed by general practitioners and by a cardiology department	10.1258/135763306777978461	16884578	10	F
Incidence of atrial fibrillation in an Italian population followed by their GPs through a telecardiology service	10.1016/j.ijcard.2003.12.005	15686770	18	F
Telecardiology: One-lead electrocardiogram monitoring and nurse triage in chronic heart failure	10.1258/135763305446175 0	16035981	21	F
Effect of home-based telecardiology on chronic heart failure: Costs and outcomes	10.1258/135763305446168 8	16035980	60	F

Project Title:
Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.

Project Code: NET-2018-12367206-3

Principal Investigator: Scalvini Simonetta

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Title	DOI	PMID	Cit. **	P.*
A pilot study of nurse-led, home-based telecardiology for patients with chronic heart failure	10.1258/1357633047733915 76	15068649	42	F
Assessment of prehospital chest pain using telecardiology	10.1258/1357633023202722 11	12217107	34	F
Telecardiology community: a new approach to take care of cardiac patients. "Boario Home-Care" Investigators.		10630052	32	F

* Position: F=First L=Last C=Corrispondent

** Autocertificated

For evaluation CV

Title	DOI	PMID	Cit. *
Socio-technical and organizational challenges to wider e-Health implementation	10.1177/147997230910280 5	19411570	43
Tele-assistance in chronic respiratory failure patients: A randomised clinical trial	10.1183/09031936.00005608	18799512	157
Multicenter randomised trial on home-based telemanagement to prevent hospital readmission of patients with chronic heart failure	10.1016/j.ijcard.2007.10.027	18222552	122
Effect of home-based telecardiology on chronic heart failure: Costs and outcomes	10.1258/1357633054461688	16035980	60
A pilot study of nurse-led, home-based telecardiology for patients with chronic heart failure	10.1258/1357633047733915 76	15068649	42
Effects of oxygen on autonomic nervous system dysfunction in patients with chronic obstructive pulmonary disease	10.1183/09031936.99.13111999	10836335	43
Experience from controlled trials of physical training in chronic heart failure. Protocol and patient factors in effectiveness in the improvement in exercise tolerance	10.1053/euhj.1997.0736	9568451	204
Decreased heart rate variability in patients with chronic obstructive pulmonary disease	10.1378/chest.106.5.1432	7956396	126
Non-invasive modalities of positive pressure ventilation improve the outcome of acute exacerbations in COLD patients	10.1007/BF01711086	8294627	186
Acute exacerbations in severe COLD patients; Treatment using positive pressure ventilation by nasal mask	10.1378/chest.101.6.1533	1600770	99

* Autocertificated

	Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.
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Project Type: WP PROJECT - 3

Grant

Funded Institution / Country	Year	Title	Position in Projects
Ministero della Salute	2010	Feasibility and cost-effectiveness of a multidisciplinary home-telehealth intervention programme to reduce falls among elderly discharged from hospital: a pilot randomized controlled trial	Collaborator
Ministero della Salute	2009	Blood pressure control and cardiovascular risk management in high risk hypertensive patients. Clinical efficacy of home telemonitoring.	Collaborator
Ministero della Salute	2007	Assessment of biological parameter changes induced by the rehabilitation program in elderly patients with congestive heart failure	Collaborator
Ministero della Salute	2006	Sviluppo e applicazione di tecnologie web-based per il monitoraggio e la teleriabilitazione cognitiva e motoria di pazienti affetti da patologie croniche del sistema nervoso centrale	Collaborator
Ministero della Salute	2005	Arcipelago Salute	Collaborator
Ministero della Salute	2004	Integrazione dei servizi sanitari del territorio 'Isolato'	Collaborator
Ministero della Salute	2003	SUMMA - Second opinion Unificata per Medici di Medicina generale Associati e valore aggiunto delle nuove forme organizzative	Collaborator
Ministero della Salute	2002	CRITERIA - Confronti fra Reti Integrate TEcnologiche per gestire al domicilio pazienti post acuti e cronici - RIcerca Applicata	Collaborator

Employment contract extension:

(Data changed during the moratorium period)

	Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.
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Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Biographical Sketch Contributors 1

Name:
Bernocchi Palmira

Institution	Istituti Clinici Scientifici Maugeri Spa Società benefit / Continuity Care Unit/ Responsible of coordination of activities related to taking charge of chronic disease.
Department/Unit	Continuity Care Unit
Position Title	Responsible of coordination of activities related to taking charge of chronic disease.

Education/Training - Institution and Location	Degree	Year(s)	Field of study
Ministero dell'Università e della Ricerca Scientifica e Tecnologica	Ph. D	1997	Experimental and Applied Medicine
University of Milan, Italy)	Biological Degree certificate	1992	Biological Sciences

Personal Statement:

As CoPI Dr Bernocchi is responsible with PI to coordinate WP. For the goal of the study Dr. Bernocchi will plan in accordance with group the increase of use of the apps for the patients and she will identify nurses to partecipate to the training to become case manager. In particular Dr. Bernocchi will help PI to assure the scientific coordination and to contribute to define pilot site.
In addition Dr. Bernocchi will coordinate the organisation phases of the patients enrolment and training of nurses.

Institution	Division / Research group	Location	Position	From year	To year
Istituti Clinici Scientifici Maugeri IRCCS Spa Società Benefit	Continuity Care Unit and Telemedicine Service	Lumezzane, Bs, Italy	Responsible for taking chronic patients for the Institute	2018	2018
Istituti Clinici Scientifici Maugeri IRCCS Spa Società Benefit	Continuity Care Unit and Telemedicine Service	Lumezzane, Bs, Italy	Responsible of clinical studies. Internal Quality Responsible.	2016	2018
IRCCS Fondazione Salvatore Maugeri	Continuity care Unit and Telemedicine Service	Lumezzane, Bs, Italy	Responsible of clinical studies. Internal quality responsible.	2007	2016
IRCCS Fondazione Salvatore Maugeri	Coordination Centre of the Cardiovascular Pathophysiology Centre	Gussago, Bs, Italy	Quality manager, audit and project manager for clinical trials. She managed direct relationship with the Sponsor, Investigators, Government of the hospitals and ASL.	2001	2007
IRCCS Fondazione Salvatore Maugeri, IRCCS -	Cardiovascular Pathophysiology Centre	Gussago, Bs, Italy	Researcher	1992	2001

Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.	
Project Code: NET-2018-12367206-3	**Principal Investigator:** Scalvini Simonetta
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Awards and Honors

Official H index: 16.0 (autocertificated)

Source: Scopus **Scopus Author Id:** 6603741618

ORCID ID: 0000-0003-0875-2007 **RESEARCH ID:** NA

Awards and Honors:

JOINT commission Italian network "Premio Qualità" 2016: "Programma di Intervento Multidisciplinare di telesorveglianza e teleriabilitazione domiciliare per la riduzione delle cadute nella popolazione anziana dopo la dimissione ospedaliera: studio randomizzato e controllato": second finalist.

Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.

Project Code: NET-2018-12367206-3

Principal Investigator: Scalvini Simonetta

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Biographical Sketch Contributors 2

Name: Bertolaia Patrizia

Institution	ASST GOM NIGUARDA / Department of Servizi Territoriali / Head of Department
Department/Unit	Department of Servizi Territoriali
Position Title	Head of Department

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Milan, Italy	Specialisation	1993	Hygiene and Preventive Medicine
University of Milan, Italy	Specialization	1989	psychiatry
University of Milan, Italy	Medical Degree certificate	1985	Medicine and Surgery

Personal Statement:

As chief of the Department of Servizi Territoriali and Research Collaborator in this project, dr Bertolaia will support to PI in the activities related to taking charge of chronic patients .

For the goal of the study Dr. Bertolaia will plan in accordance with group the increase of use of the apps for the patients and she will identify nurses to partecipate to the training to become case manager.

Institution	Division / Research group	Location	Position	From year	To year
ASST GOM NIGUARDA	Social health management, Complex Structure Continuity Hospital Territory and Department of territorial services	Milan, Italy	Head	2017	2018
ATS METROPOLITAN CITY OF MILAN	Social management - department of integrated health and social activities (ASSI), Complex Structure Domiciliary (first home care)	Milan, Italy	Head	2011	2017
ASL MILANO	General Direction	Complex Structure District 5, Milan, italy	Head	2008	2009
ASL Milano (before CITTA' DI MILANO)	Social management - department of integrated health and social activities (ASSI)	Complex ADI and Older Structure, Milan, Italy	Head	1998	2008

Awards and Honors

Official H index: 0.0 (autocertificated)

Source: Scopus **Scopus Author Id:** NA

ORCID ID: NA **RESEARCH ID:** NA

	Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.
Project Code: NET-2018-12367206-3	**Principal Investigator:** Scalvini Simonetta
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Awards and Honors:

1. INTERNATIONAL COMPETITION BALINT 1985: Report on the doctor-patient relationship - Second classified
2. ASL CITY OF MILAN 2007 QUALITY AWARD: Report on the implementation of the network of social and health services for the elderly: involvement of the Healthcare Residences (RSA) in activities open to the district - Second classified
3. GIMBE AWARD 2012: Report on risk management in home care: what is the relationship between clinical and management errors? - ASL of Milan first classified

Project Title:
Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.

Project Code: NET-2018-12367206-3

Principal Investigator: Scalvini Simonetta

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Biographical Sketch Contributors 3

Name:
Trevisan Roberto

Institution: ASST Bergamo / Unit for Endocrine Diseases and Diabetology / Head
Department/Unit: Unit for Endocrine Diseases and Diabetology
Position Title: Head

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Padova, Italy	Specialisation	2001	Internal Medicine
Ministero dell'Università e della Ricerca Scientifica e Tecnologica	Ph. D	1990	ENDOCRINOLOGICAL AND METABOLIC SCIENCES
University of Padova, Italy	Specialisation	1985	Diabetology
University of Padova, Italy	Medical Degree certificate	1982	Medicine and Surgery

Personal Statement:

As chief of theUnit for Endocrine Diseases and Diabetology and Research Collaborator in this project, dr Trevisan will support to PI in the activities related to taking charge of chronic patients .
For the goal of the study Dr. Trevisan will plan in accordance with group the increase of use of the apps for the patients and she will identify nurses to partecipate to the training to become case manager.

Institution	Division / Research group	Location	Position	From year	To year
ASST Papa Giovanni XXIII di Bergamo	Unit for Endocrine Diseases and Diabetology	Bergamo, Italy	Head	2017	2018
ASST-PAPA GIOVANNI XXIIII	Unit for Endocrine Diseases and Diabetology	Bergamo, Italy	Head	2012	2017
Ospedali Riuniti di Bergamo	Division of Diabetology	Bergamo, italy	Head	2000	2012
Hospital of Padova	Unit of Endocrinology	Padova, italy	Manager I Level	1993	2000
Hospital of Padova	Division of Endocrinology	padova, Italy	Assistant Doctor	1989	1993
Guy's Hospital, London	Unit of Metabolic Medicine	London, UK	Research fellow	1988	1990
Hospital of Padova	Endocrino-Metabolic Laboratory and Division of Diabetology	Padova, Italy	Medical Researcher	1982	1988

Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.

Project Code: NET-2018-12367206-3

Principal Investigator: Scalvini Simonetta

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Awards and Honors

Official H index: 38.0 (autocertificated)

Source: Scopus **Scopus Author Id:** 7005070706

ORCID ID: 0000-0003-0420-4468 **RESEARCH ID:** Q-8706-2016

Awards and Honors:

Not available

	Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.
Project Code: NET-2018-12367206-3	**Principal Investigator:** Scalvini Simonetta
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Expertise Research Collaborators

Selected peer-reviewed publications of the Research Group / Collaborators

Collaborator	Title	DOI	PMID	Cit. *
Trevisan Roberto	Efficacy of self-monitoring blood glucose as a key component of a chronic care model versus usual care in type 2 diabetes patients treated with oral agents: results of a randomized trial	10.1007/s00592-017-1072-0	29138925	0
Bernocchi Palmira	A multidisciplinary telehealth program in patients with combined chronic obstructive pulmonary disease and chronic heart failure: study protocol for a randomized controlled trial.	10.1186/s13063-016-1584-x	27659741	12
Bernocchi Palmira	Home based telemedicine intervention for patients with uncontrolled hypertension: - A real life - Non-randomized study	10.1186/1472-6947-14-52	24920046	12
Bernocchi Palmira	Healthcare continuity from hospital to territory in Lombardy: TELEMACO project		22435961	12
Bernocchi Palmira	Teleconsultation service to improve healthcare in rural areas: acceptance, organizational impact and appropriateness.	10.1186/1472-6963-9-238	20021651	24

* Autocertificated

Grant

Funded Institution / Country	Year	Title	Position in Projects	Collaborator
Ministero della Salute	2009	Outpatient Day Service (ODS): a technological integrated innovative health care modality for the secondary prevention in subjects with diabetes mellitus	Collaborator	Trevisan Roberto
MIUR e Regione Lombardia	2011	Gloreha Home TC (Progetto di ricerca Industriale e sviluppo sperimentale nei settori strategici di Regione Lombardia e MIUR N. 7128 del 29 luglio 2011)	Collaborator	Bernocchi Palmira

Project Title:
Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.

Project Code: NET-2018-12367206-3

Principal Investigator: Scalvini Simonetta

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Total proposed budget (Euro)

Costs	TOTAL BUDGET	Co-Funding	Project costs proposed to funding Organization (no MOH request)	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	336.000,00	336.000,00	0,00	not permitted	0,00
1b Researchers' Contracts	316.800,00	0,00	205.000,00	111.800,00	49,99
2 Equipment (Leasing - Rent)	26.200,00	0,00	11.000,00	15.200,00	6,80
3a Supplies	0,00	0,00	0,00	0,00	0,00
3b Model Costs	0,00	0,00	0,00	0,00	0,00
3c Subcontracts	71.100,00	0,00	60.000,00	11.100,00	4,96
3d Patient Costs	0,00	0,00	0,00	0,00	0,00
4 IT Services and Data Bases	105.000,00	50.000,00	0,00	55.000,00	24,59
5 Publication Costs	4.000,00	0,00	0,00	4.000,00	1,79
6 Convegni	2.200,00	0,00	0,00	2.200,00	0,98
7 Travels	3.100,00	0,00	0,00	3.100,00	1,39
8 Overheads	45.255,00	0,00	24.000,00	21.255,00	9,50
9 Coordination Costs	0,00	0,00	0,00	0,00	0,00
Total	909.655,00	386.000,00	300.000,00	223.655,00	100,00

Report the Co-Funding Contributor:

Staff salary and technology - € 386.000,00 co-financed by the participating in the project

	Project Title: Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.
Project Code: NET-2018-12367206-3	**Principal Investigator:** Scalvini Simonetta
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Budget Justification	
1a Staff Salary	Three-year salaries of permanent staff involved in the project working in Maugeri, Niguarda, Bergamo
1b Researchers' Contracts	Need to acquire temporary staff or consultants on the project, for integrate the project activities
2 Equipment (Leasing - Rent)	Equipment used for the project - Trainign and tuning of software and programs to fit the proposed analysis.
3a Supplies	no
3b Model Costs	no
3c Subcontracts	Purchase of specific services (i.e. web site and customers survey ....) to achieve the results
3d Patient Costs	no
4 IT Services and Data Bases	Services to support the integration, extraction and analysis of data and use DB
5 Publication Costs	Publications related to the project
6 Convegni	Conferences related to the project
7 Travels	Travel expenses for meetings and dissemination project's outcomes
8 Overheads	Three-years overheads
9 Coordination Costs	no

Project Title:
Telemedicine for home-based management of patients with chronic diseases and comorbidities: analysis of current models, design of innovative strategies for the determinant role of the case manager.

Project Code:	NET-2018-12367206-3	**Principal Investigator:**	Scalvini Simonetta
Research Type:	a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:**	Regione Lombardia - Direzione Generale Sanità

Project Type: WP PROJECT - 3

Ministero della Salute Direzione Generale della Ricerca Sanitaria e Biomedica e della Vigilanza sugli Enti **BANDO RICERCA FINALIZZATA 2018** **esercizio finanziario anni 2016-2017**	**Project Title:** Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.
Project Code: NET-2018-12367206-4	**Principal Investigator:** Piffer Silvano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Provincia autonoma Trento

Project Type: WP PROJECT - 4

Major Diagnostic Category*: Nefrologia e Urologia

Project Classification IRG: Healthcare Delivery and Methodologies

Project Classification SS: Biomedical Computing and Health Informatics - BCHI

Project Keyword 1: Application of human-centered computing (human-machine interfaces), intelligent systems, virtual environments, computer-assisted diagnosis and treatment systems with data including imaging data and telemedicine to biomedical and clinical systems, including the study of collaboration to engineer-usable effective software systems.

Project Keyword 2: Chronic diseases, Telemedicine, telemonitoring, ehealth, mhealth, health-related quality of life; medical decision-making

Project Keyword 3: Case Manager, clinical manager, chronic disease management

Project duration (months): 36

Project Request: **Animals:** ☐ **Humans:** ☒ **Clinical trial:** ☐

The object/s of this application is/are under patent copyright Y/N: ☐

Investigators, Institution and Role in the Project

	Co-PI	Key Personnel	Institution/Org./Pos.	Role in the project	Birth Date
1	X	Inchiostro sandro	APSS	Advise on the clinical content of the new care model and supervise the project according to my role as Co PI.	22/11/1959
2		Mastellaro Marina	APSS	My role as research collaborator will be to contribute with my expertise to the project managment and clinical component	12/07/1960
3		Gentilini Maria Adalgisa	APSS	My role as research collaborator will be to contribute with my expertise to the statistical component of the study and in developing a predictive models	28/07/1966

Overall Summary

The objective of the present WP is to test and validate a new care and assistance model for patients with type 1 and/or 2 diabetes, in order to improve the quality of care and to offer a more sustainable healthcare system, centred on the patient empowerment and promoting patient self-management.
The model is enabled by the use of artificial intelligence (AI) platforms and digital tools (apps).
The app system is based on the stepped-care concept, in which the required intervention by the healthcare professional is strategically supported by a virtual assistant. AI algorithms (in part already validated) will assist risk evaluation based on patient trajectories and predictive models.
The design of the app includes:
(i) patients' personal records (physical activity, glycaemia levels, etc.) and education programmes aiming to support self-care process;
(ii) electronic reports and an alert system that inform GPs on patients critical health status ("prescribed" telemonitoring system).

Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.

Project Code:	NET-2018-12367206-4	**Principal Investigator:**	Piffer Silvano
Research Type:	a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:**	Provincia autonoma Trento

Project Type: WP PROJECT - 4

Background / State of Art

In recent years, advancement of AI methods, specifically Deep Learning (Osmani et al., 2018) have created immense opportunities to automatically process clinical and behavioural data of patients and establish models of patients trajectories and sub-groups. These models then are used to automatically estimate the risk of patients developing Diabetes or for patients already diagnosed with Diabetes, estimate the risk of developing diabetes-related complications, including retinopathy, hypertension or peripheral neuropathy. Patient trajectories and subgroups then allow delivery of personalised care based on the estimated risk, including preventative measures (Osmani Venet, Li Li, Matteo Danieletto, Benjamin Glicksberg, Joel Dudley, Oscar Mayora "Automatic processing of Electronic Health Records (EHR) using Deep Learning" ACM proceedings of Pervasive Health 2018 conference, Mount Sinai Hospital, New York, May 2018).
Research focusing on the so-called mobile-Health systems (M-Health) and personal health management systems (P-Health) is rapidly expanding. The area of chronic care is of special interest mainly because patients with such diseases might particularly benefit from easy-to-use day-to-day monitoring and assistance systems and because, for chronic care, clinicians need to properly monitor patient adherence to treatment and to healthy lifestyles.
In terms of service delivery, such M-Health systems can assist the health care staff in delivering more tailored and effective services,
based on the on-going data collection and information on the specific patient. In addition, this technological system might reduce the need of face-to-face clinical examination or visits, therefore optimising the involvement of health care staff and the management/use of internal resources. This system might be of particular help in case of Diabetes patients, considering the characteristics of the diseases management process and considering that the number of such patients is continuously increasing (worldwide the number of patients is estimated to increase to 552 million people by 2030 - International Diabetes Federation Diabetes Atlas).
The Province of Trento has a strong expertise relating to e-health especially in terms of developing new predictive models on web-mobile platforms in order to identify trajectories of care, machine learning methods, dynamical processes, software engineering and research algorithms, and data & knowledge management. In the last years, the Province of Trento has been developing a living lab of pilot projects in the context of M-Health and P-Health. Those initiatives are embedded in the 'TreC' project, which has the objective to design, implement and validate on field an ecosystem of web and mobile applications to support citizens in their self-care management process and to support health care staff in providing high-standard quality services, through systems of monitoring and personalised care programmes. For instance, there are pilot projetcs in the field of chronic diseases (Miele, F, Eccher C; Piras EM. Using a Mobile App to Manage Type 1 Diabetes: The Case of TreC Diabetes. In Proceedings of the 5th International Conference on Digital Health 2015, pp.113-114), obesity, home-diagnose hypertension, etc. Examples of apps include: TreC_Lifestyle for smartphone, TreC_Lab Hypertension, TreC_Lab Oncology Diary, and others.

Hyphotesis and Specific AIMS

Hyphotesis and Significance:
The new care model for diabetes, based on the support of the mobile app, will help patients to effectively adopt healthier life-style and to adhere to the therapy plan. Moreover, the 'ad hoc' intervention of the virtual assistant will support patients and health care staff in the problem-solving process and in managing potential mental health issues as well as other potential co-morbidities

	Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.
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Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Provincia autonoma Trento

Project Type: WP PROJECT - 4

The characteristics of the Trento Province (Azienda Provincial per i Servizi Sanitari APSS) manages all the health care services: b. adhesion to the 'FSE' 'electronic health record' is from 100% of the health care staff, including GPs, so the amount of data available is wide) foster the implementation of the mobile app, that might provide the unique opportunity to pilot a new care model, aiming at empowering the patient and allowing general practitioners (GPs) to efficiently take care of patients.
In addition, the analysis of the dataset, collected through the app, may allow the review of the care plan and the measure of Key performance indicators, in order to assess, for instance the adherence to the care plan. Lastly automatic analysis of both clinical (FSE) and behaviour data (from the app) will allow establishment of patient trajectories and patient subtypes, providing further input to devise personalised care plans based on predictive modelling.

Preliminary Data:
Recently published literature available is on national/International chronic plan (e.g. 'Piano nazionale cronicità'), or national guidelines (e.g.: "Linee nazionali di indirizzo telemedicina"), whilst EU document are highlighting the need of telemedicine application for patients (e.g.: Communication from the EU on telemedicine for the benefits of patients, healthcare systems, and society - COM 2008-2009).

For the Province of Trento, several documents/guidelines have been developed on this matter. Recently published literature available provides data and clustered information (gender, age, etc.) on 28.000 cases of people with diabetes, that represent 5,0% of the total population of about 560,000 people in the Province of Trento (Rapporto Arno Diabete Trentino 2016, Rapporto Arno 2017).
In addition, through the existing "FSE"- electronic health record and the usage of available apps (TreC embedded apps), the Province of Trento has a wide set of data flow on laboratory/clinic-based information, clinical parameters and patient's daily behaviours and lifestyles.

Specific Aim 1:

The first study aim is to identify a sample of potential patients with diabetes to be enrolled in the study (convenience sampling). The identified sample will be involved in the piloting phase of the APP / new service provision procedures, in view of a clinical trial.

Specific Aim 2:

The second aim of the study is to design both the APP and the service provision according to the so-called Chronic Disease Management (formerly Enhanced Primary Care or EPC) procedure, that is, with the Percorsi Diagnostico-Terapeutici Assistenziali (PDTA)

Specific Aim 3:

To collect a set of data allowing to analyse and validate the care model and to measure the patient adherence to the care plan as well as measure the performance of the predictive models based on this data.

Experimental Design Aim 1:
he first aim will be reached by (i) an extended engagement of experts (Clinical and IT); (ii) engagement of patients with diabetes, members of known Associations, GPs, patients and citizen, through focus groups, in order to collect needs and feedback on the app-model.

Project Type: WP PROJECT - 4

Experimental Design Aim 2:
The content of the app is designed on the basis of the care plan guidelines and patient assessment, including the definition of "patient-tailored" education programmes (nutrition, physical information etc.) and on a fine-tuned set of clinical parameters defined with the support of a selected group of specialists, aligned with the care plan.

Experimental Design Aim 3:
The third aim will be based on a care plan review, through the definition of key performance indicators (KPI) allowing to measure the patient adherence to the care plan/therapy and to in efficiently assess the care pathway implemented from the general practitioner. In addition, this phase will also include measures of performance of the predictive models in both risk estimation and patient subtype detection.

Picture to support preliminary data:

Metodologies and statistical analyses:
Methods for the app design and data analysis will include:
- mapping of the existing patient care flow ("AS IS"), for those entrusted to specialised center;
- identifying needs and collect feedback both from patients and doctors, through focus groups and the engagement of associations and meetings with specialists;
- designing the "TO BE" care pathway for the diabetic patient according to the care plan guidelines;
- designing the technical features and app functionalities through the support of experts (IT, Big data experts etc.) in order to engage patient in the use of the app and to support the GP his/her activity;
- collecting and analysing a large-set of data and defining a method of care pattern, process mining and predictive models;
- setting KPI in order to measure patient adherence to the care plan and GP's performance.

Expected outcomes:
Through the project implementation, it is expected to design a new care model reaching the following outcomes:
- Improving the management of diabetes, supporting the GP, empowering the patient and fostering a self-care process and awareness of the disease;
- Reducing the variation in completion of care processes and the risk of complications;
- Analysing and reviewing the care plan pathway through a set of KPI.

Risk analysis, possible problems and solutions:
Difficulties in engaging patients and GPs.
Solution: active engagement of patients and clinical staff since the beginning of the project, through the involvement of target associations and a user friendly and engaging design of the app;

Difficulties in collecting and managing data.
Solution: active involvement IT and clinical staff since the beginning of the project and process will be monitored by the FBK team, considering the relevant experience in data management;

Failure to comply with deadlines and milestones.
Solution: Strict monitoring of project implementation;

Insufficient budgetary resources.
Solution: Strict monitoring of project implementation.

Significance and Innovation

The significance of the project is embedded in the new care and assistance model, centered on the patient empowerment and self-care of the diabetes. The model, enabled by the use of artificial intelligence and digital tools, (e.g.: telemonitoring system and patients virtual assistance), might effectively reduce mortality and hospitalisations for HF and contribute to improve the quality of services delivered. The innovation is represented by the use mainly of AI and digital tools to manage the disease and, through the collection of a wide set of data / and definition of standard KPI, the app is a tool to measure and review the patient adherence to the care plan therapy. Moreover, the new care model can allow to re-design the role and the relationship of the providers of primary care and of specialised/hospital care on the basis of patient needs along individual and tailored disease trajectories.

Description of the complementary and sinergy research team

Each region will contribute to the WP according to the specific interest and regional priorities.
As the Province of Trento institutions will be the leading institutions to manage the majority of the actions in terms of app development, each region will contribute and support this specific action.
From a scientific viewpoint, the teams from different regions involved in this WP have specific and scientifically robust background in their specific field, whilst the specific competences of FBK guarantee a top-quality experience in the field of H-Health. In this context, the WP partners represent an ideal complementary team, mixing clinical and M-Health expertise.
In terms of synergy, the WP leader will work on diabetes, whilst the other participating regions may explore potential use of the same structure on different diseases (e.g. cardiology, nephrology). This will ensure on one side that each region will focus on local relevant diseases, and on the other side this will ensure a multi-faced approach, allowing the validation exercise of the APP/service structure on potentially different diseases.
In addition, each region can participate in the actions/piloting carried out from other regions, contributing to the project cohesions and maximization of the results.

The data sharing and know-how sharing will also contribute to a more robust and valid project results.

Training and tutorial activities

To enable the use of the app, training sessions among clinical staff and patients will be planned, also supported by the use of a booklet and in-app training tutorial.
To promote the exchange of experiences / know-how and to ensure a strict common background in terms of analytic / clinical transferability of the project results, training sessions will be planned - if in line with the participating regions priorities.
Training sessions will be strategically delivered during project implementation to maximise knowledge and know-how sharing and improvement among app users and project partners. Considering budget issues, both training components can be either remote-training or on-site (physical meeting) training.

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Project Code: NET-2018-12367206-4	**Principal Investigator:** Piffer Silvano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Provincia autonoma Trento

Project Type: WP PROJECT - 4

Bibliography

- Osmani, Venet, Li Li, Matteo Danieletto, Benjamin Glicksberg, Joel Dudley, Oscar Mayora "Automatic processing of Electronic Health Records (EHR) using Deep Learning" ACM proceedings of Pervasive Health 2018 conference, Mount Sinai Hospital, New York, May 2018
- Ministero della Salute (2017). Piano nazionale cronicità. Accordo tra lo Stato, le Regioni e le Province Autonome di Trento e di Bolzano del 15 settembre 2016.
- Ministero della Salute. Linee nazionali di indirizzo telemedicina (available at http://www.salute.gov.it/imgs/C_17_pubblicazioni_2129_allegato.pdf)
- European Commission. Communication from the EU on telemedicine for the benefits of patients, healthcare systems, and society (COM 2008-2009
Osservatorio ARNO diabete, Cineca. Rapporto Arno Diabete Trentino 2016 e 2017

Timeline / Deliverables / Payable Milestones

The project consists of 3 phases. The i phase is a preparatory step: protocols will be refined and ethics committee approval for the study will be obtained. During the phase ii, the piloting of the app/system will be implemented and monitored, to assess performance and acceptability of the system. In phase iii, the results from the preliminary steps and piloting will be assessed and an updated system will be delivered (phase 'practice'). At the end the phase iii, preliminary results will be delivered in the context of a final conference, where inputs and feedback will be collected to fine-tune analysis and final reporting. In terms of final deliverables, Recommendations Reports will be delivered summarizing the core outputs of the project and methodological insights.

Milestones 18 month

M1: kick off meeting
M1-3: fine tuning of the study design, to be organized in line with partners needs and local contexts
M3-5: protocols finalisation
M6: ethics committe approval (Milestone), to allow study implementation
M6-7: enrollment of participants for the piloting phase
M7-18: period of data collection (piloting phase), data monitoring
M12: 1st interim meeting (Milestone) to access the status of the project implementation in line with agreed research protocols

Milestones 36 month

M18-19: evaluation exercise
M19-20: fine tuning of the procedures to be implemented in the ii stage of the project (practice)
M21-28: implementation of the ii stage (practice)
M28: 2nd interim meeting (Milestone) to assess implementation and preliminary outcomes
M28-34: data analysis, based on agreed data analysis plan and data collected (practice)
M34: final conference, to validate/disseminate results
M34-26: reports drafting

Project Type: WP PROJECT - 4

M36: recommendations
M36: final reports

Gantt chart

GANTT WP4.pdf

Equipment and resources available

Facilities Available

In the Province of Trento, a specific system is already in place to electronically collected specific information, that is, the existing 'FSE'- electronic health record. In addition to this, the use of available apps (TreC embedded apps) is already implemented and validated. In terms of facilities, informatics and electronic tools to monitor the required data are ' in many cases ' piloted and therefore they are representing a solid basis for the development of the present project. In addition, the Province of Trento has a wide set of data flow on laboratory/clinic-based information, clinical parameters and patient's daily behaviours and lifestyles.

Subcontract (explain Reasons for Subcontract)
Subcontracting will be used mainly (but not only) for reporting or technical services (and not for research purposes, as indicated in the funding rules). This is to improve reporting quality and ' if needed ' technical services as foreseen in the present proposal.

Translational relevance and impact for the National Health System (SSN)

The adoption of new care models enabled by the use of technology might create a new paradigm of care for treating chronic diseases such as diabetes, aiming at supporting health care staff in efficiently taking care and monitoring the health status and at fostering patient self-management. The project might provide the unique opportunity to pilot a new care model, potentially transferrable to other regions/provinces, allowing to improve the quality of care and to reduce the risk of complications and variation in the completion of care processes. In addition, the aggregations and analysis of the dataset, collected through the app usage, may allow the review of the care plan and the measurement of Key Performance Indicators (KPI) in order to assess, for instance the effectiveness of the therapy. The new care model may reduce the number of hospitalisations and consequently health care costs for the SSN, thanks to a telemonitoring system and/or structured telephone or virtual support.

	Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.
Project Code: NET-2018-12367206-4	**Principal Investigator:** Piffer Silvano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Provincia autonoma Trento

Project Type: WP PROJECT - 4

PRINCIPAL INVESTIGATOR PROFILE

Name		
Piffer Silvano	Institution	Provincia autonoma Trento
	Department/Unit	Servizio Epidemiologia Clinica e Valutativa
	Position Title	Dirigente Medico di Secondo Livello

Personal Statement

My role as PI, concerning a new model of care for patients with type 2 diabetes, will be to conduct the WP and monitor the correct running of all activities. I will deal with the creation and coordination of the working group, with the definition of the methodological protocol. Through the construction of a path monitoring system I will deal with the evaluation of the effectiveness and efficiency of the level of assistance, patient compliance and its perception of the quality of care received. The outcome of the WP will be aimed at building a more sustainable and equitable health system focused on the empowerment of the patient, also with the use of smart technologies.

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Pavia	Speciality	1993	Health Statistics
University of Pavia	Speciality	1989	Oncology
University of Verona	Speciality	1985	Hygiene - Public Health Guidance
University of Padova	Medical Degree	1981	Medicine and Surgery

Positions

Institution	Division / Research group	Location	Position	From year	To year
Azienda Provinciale per i Servizi Sanitari	Servizio Epidemiologia Clinica e Valutativa	Trento	Director	2011	2018
Azienda Provinciale per i Servizi Sanitari	Osservatorio Epidemiologico	Trento	Director	1995	2010
Unità Sanitaria locale Valle dell'Adige	Unità Sanitaria Locale	Trento	Coadjutor of health	1988	1995

Official H index: 33.0 (autocertificated)

Source: Scopus **Scopus Author Id:** 6701787093

ORCID ID: NA **RESEARCH ID:** NA

Awards and Honors:

Provincia Autonoma di Trento, 2009, Cancer atlas. Practical methods of predictive oncological risk from environmental factors, Coordinator unit 2 (Funds: 75.000).
2009 - present Member of (RIAP) - ISS
2003 - present Provincial representative of the Italian network Observes Health
1998 - present member of the Italian Association of Tumor Registries

2004 - present Member of the editorial board of the Journal Epidemiologia e Prevenzione (IF 1.966)

Other CV Informations:

2012 -2017 local coordinator of the SENTIERI project: epidemiological studies in the sites polluted by national interest
2008 - 2011, local coordinator of the Okkio Health project
2009 -2012, local coordinator of the HBSC project
2008 - 2011, local coordinator of the project Sidria 3 - Italian Study on Childhood Respiratory Disorders Environment: "Long-term effects of air pollution-study of cohort of adults and children".
2001 -2003, local coordinator of the project Sidria 2
1995 -1998, local coordinator of the project Sidria 1
1997 -2007 Member of the Vaccine Ministerial Commission
2004 - 2008 Provincial representative in the Technical Committee of the CCM of the Ministry of Health

Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.

Project Code: NET-2018-12367206-4

Principal Investigator: Piffer Silvano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Provincia autonoma Trento

Project Type: WP PROJECT - 4

Selected peer-reviewed publications of the PI

Valid for PI minimum expertise level

Title	DOI	PMID	Cit. **	P.*
[Nursing aspects in men with urinary catheters at the Nursing Service of the District of Trento]. Agostini M, Ventura I, Kaisermann D, Piffer S. Riv Inferm. 1997 Apr-Jun;16(2):98-103. Italian.	NA	9305159	0	L
Descriptive epidemiology of head injury in Romagna and Trentino. Comparison between two geographically different Italian regions. Servadei F, Verlicchi A, Soldano F, Zanotti B, Piffer S. Neuroepidemiology. 2002 Nov-Dec;21(6):297-304.	10.1159/000065523	12411733	0	L
Respiratory tract cancers: lung and mesothelioma. Crosignani P, Piffer S.Epidemiol Prev. 2004 Mar-Apr;28(2 Suppl):48-56. English, Italian.	NA	15281606	0	L
[Customer satisfaction analysis in women attending an organized mammographic screening. Pilot study at Trento]. Della Sala W, Tognotti F, Pellegrini M, Bernardi D, Gentilini M, Piffer S. Ann Ig. 2005 Sep-Oct;17(5):433-40	NA	16353680	0	L
Gardner's syndrome and thyroid cancer--a case report and review of the literature. Acta Oncol. 1988;27(4):413-5. Review	10.3109/02841868809093564	3060152	0	F
Skeletal scintigraphy and physical examination in the staging of early breast cancer	10.3109/02841868809090313	3365350	0	F
Diagnosis and prognosis of malignant mesothelioma. A description of 8 clinical cases	0	2725943	0	F
Knowledge and attitudes on cancer prevention in the female population. A sampling study in Trento	0	8766308	0	F
A thorough study of mesothelioma cases. The role of the National Health Service statistics	0	9789373	0	L
The impact of parental smoking on asthma and wheezing. SIDRIA Collaborative Group. Studi Italiani sui Disturbi Respiratori nell'Infanzia e l'Ambiente.	10.1097/00001648-199911000-00008	10535782	0	L
Estimates of cancer burden in Trentino-Alto Adige	10.1700/1334.14793	24158058	0	F
Antenatal course attendance among primiparous mothers, with physiological pregnancy and birth at term in Trentino (Northern Italy): characteristics of non-attender women and benefits among attender women in pregnancy behaviours, type of birth delivery and neonatal outcomes	10.1007/s00431-017-3035-4	26036737	0	L
Breastfeeding during the first year of life: estimates using records generated in general paediatrics.	0	276529932	0	L
Coverage and outcomes of antenatal tests for infections: a population based survey in the Province of Trento, Italy.	10.1080/14767058.2018.1424822	29243192	1	L

Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.

Project Code: NET-2018-12367206-4

Principal Investigator: Piffer Silvano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Provincia autonoma Trento

Project Type: WP PROJECT - 4

Title	DOI	PMID	Cit. **	P.*
Length of stay for childbirth in Trentino (North-East of Italy): the impact of maternal characteristics and organizational features of the maternity unit on the probability of early discharge of healthy, term infants	10.1007/s00431-017-3035-4	29116396	0	L

* Position: F=First L=Last C=Corrispondent

** Autocertificated

For evaluation CV

Title	DOI	PMID	Cit. *
Skeletal scintigraphy and physical examination in the staging of early breast cancer	10.3109/02841868809090313	3365350	0
Diagnosis and prognosis of malignant mesothelioma. A description of 8 clinical cases	0	2725943	0
Knowledge and attitudes on cancer prevention in the female population. A sampling study in Trento	0	8766308	0
A thorough study of mesothelioma cases. The role of the National Health Service statistics	0	9789373	0
The impact of parental smoking on asthma and wheezing. SIDRIA Collaborative Group. Studi Italiani sui Disturbi Respiratori nell'Infanzia e l'Ambiente.	10.1097/00001648-199911000-00008	10535782	0
Estimates of cancer burden in Trentino-Alto Adige	10.1700/1334.14793	24158058	0
Antenatal course attendance among primiparous mothers, with physiological pregnancy and birth at term in Trentino (Northern Italy): characteristics of non-attender women and benefits among attender women in pregnancy behaviours, type of birth delivery and neonatal outcomes	0	26036737	0
Breastfeeding during the first year of life: estimates using records generated in general paediatrics.	0	276529932	0
Coverage and outcomes of antenatal tests for infections: a population based survey in the Province of Trento, Italy.	10.1080/14767058.2018.1424822	29243192	0
Length of stay for childbirth in Trentino (North-East of Italy): the impact of maternal characteristics and organizational features of the maternity unit on the probability of early discharge of healthy, term infants	10.1007/s00431-017-3035-4	29116396	0

* Autocertificated

Grant

Funded Institution / Country	Year	Title	Position in Projects
Provincia Autonoma di Trento	2009	Provincia Autonoma di Trento, 2009, Cancer atlas. Practical methods of predictive oncological risk from environmental factors, Coordinator unit 2 (Funds: 75.000).	Coordinator

Employment contract extension:

	Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.
Project Code: NET-2018-12367206-4	**Principal Investigator:** Piffer Silvano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Provincia autonoma Trento

Project Type: WP PROJECT - 4

(Data changed during the moratorium period)

Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.

Project Code: NET-2018-12367206-4

Principal Investigator: Piffer Silvano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Provincia autonoma Trento

Project Type: WP PROJECT - 4

Biographical Sketch Contributors 1

Name:
Inchiostro sandro

Institution	APSS
Department/Unit	U.O Medicina
Position Title	MD

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Trento	Master	3	Healthcare Management
University of Verona	Specialised Master	5	Medicina Interna
University of Padova	Specialise master	5	Cardiology
University of Verona	Specialise master	3	Diabetologia e Malattie del Metabolismo
University of Padova	Medical degree	6	Medicine and Surgery

Personal Statement:

My role as research collaborator will be to contribute, according to my expertise, to the clinical content of the new model of care for patients with type 2 diabetes. In the past, I have been co-author of the document "Consenso Italiano" relating to the screening and treatment of cardiopathic ischemia in the diabetic patient (2010), promoted by SID-AMD and I have been referee for the scientific magazines: Circulation, Atherosclerosis, Diabetic Medicine, Nutrition, Metabolism and Cardiovascular Disease, Journal of Diabetic Complications. I am partner of the "Società Italiana di Diabetologia (SID)"and the "Associazione Medici Diabetologi (AMD)". Today I am council member of the Triveneta Section of the "Società Italiana per lo Studio dell' Aterosclerosi".

Institution	Division / Research group	Location	Position	From year	To year
Azienda Provinciale per i Servizi Sanitari	Medicina e Pronto Soccorso	Borgo (Trento)	Direttore	2012	2018
Azienda provinciale per i Servizi Sanitari	Medicina	Trento	Dirigente	1998	2012
ASI Pordenone	Diabetology	Pordenone	Assistant	1991	1998

Awards and Honors

Official H index: 19.0 (autocertificated)

Source: Scopus **Scopus Author Id:** n.a

ORCID ID: n.a **RESEARCH ID:** n.a

Awards and Honors:

The research activity has been awarded in six different situations from the "Società Italiana of Diabetologia". Section "Veneto Trentino Alto Adige"(1987, 2001, 2004, 2006, 2008, 2012, 2014), at a National level (Boehringer MannHeim Italia 1995 award). An award relating to a healthcare research programme for the year 2007-2008 has been obtained and

promoted from the Province of Trento: "Il profilo di rischio di malattia cardiovascolare e di microangiopatia della popolazione diabetica trentina".

Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.

Project Code: NET-2018-12367206-4

Principal Investigator: Piffer Silvano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Provincia autonoma Trento

Project Type: WP PROJECT - 4

Biographical Sketch Contributors 2

Name: Mastellaro Marina

Institution: APSS
Department/Unit: Servizio Governance Clinica
Position Title: MD

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Padova	Master's degree	5	Hygiene - Public Health Guidance
University of Padova	Medical degree	6	Medicine and Surgery

Personal Statement:

My role as research collaborator will be to contribute with my expertise to the project managment and clinical component, as I have expertise in the chronic area.

Institution	Division / Research group	Location	Position	From year	To year
Azienda Provinciale per i Servizi Sanitari	Servizi Governance Clinica	Trento	Dirigente medico	2005	2018

Awards and Honors

Official H index: 0.0 (autocertificated)

Source: Scopus **Scopus Author Id:** N.A

ORCID ID: N.A **RESEARCH ID:** N.A

Awards and Honors:

N.A

Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.

Project Code: NET-2018-12367206-4

Principal Investigator: Piffer Silvano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Provincia autonoma Trento

Project Type: WP PROJECT - 4

Biographical Sketch Contributors 3

Name: Gentilini Maria Adalgisa

Institution: APSS
Department/Unit: Servizio Epidemiologia Clinica e Valutativa
Position Title: MD

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Padova	Degree in Statistics (obtained in 1996)	5	Statistics and demography

Personal Statement:

My role as research collaborator will be to contribute with my expertise to the project, in relation to the collection and analysis of data. My expertise includes the collection, data quality and elaboration of data of birth and abortion data of Trento province and the development of a predictive model to identify frail elderly. Moreover, from 1998 ongoing, I have been carrying out statistical-epidemiological activities related to cancer screening, to oncological epidemiology, to the population cancer registry, to health information flows, to mortality and hospitalization, to APSS projects, to ad hoc studies.

Institution	Division / Research group	Location	Position	From year	To year
Azienda Provinciale per i Servizi Sanitari	Servizio epidemiologia clinica e valutativa	Trento	Statistical manager	2010	2018
Azienda Provinciale per i Servizi Sanitari	Osservatorio Epidemiologico	Trento	Statistical manager	2002	2010
Azienda Provinciale per i Servizi Sanitari	Osservatorio Epidemiologico	Trento	Statistic	1996	2002

Awards and Honors

Official H index: 0.0 (autocertificated)

Source: Scopus **Scopus Author Id:** -

ORCID ID: - **RESEARCH ID:** -

Awards and Honors:

1996: Award for the thesis about Demographic analysis with 1991 census population data of the municipality of Padova.

	Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.
Project Code: NET-2018-12367206-4	**Principal Investigator:** Piffer Silvano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Provincia autonoma Trento

Project Type: WP PROJECT - 4

Expertise Research Collaborators

Selected peer-reviewed publications of the Research Group / Collaborators

Collaborator	Title	DOI	PMID	Cit. *
Inchiostro sandro	How can we monitor glycaemic variability in the clinical setting?	10.1111/dom.12142	24034515	0
Inchiostro sandro	Is the metabolic syndrome a cardiovascular risk factor beyond its specific components?	n.a	17599611	0
Inchiostro sandro	Prevalence of diabetes and/or ischaemic heart disease in classes of increasing carotid artery atherosclerosis: an ultrasonographic study.	n.a	12873297	0

* Autocertificated

Grant

Funded Institution / Country	Year	Title	Position in Projects	Collaborator
n.a	n.a	n.a	Collaborator	Inchiostro sandro

Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.

Project Code: NET-2018-12367206-4

Principal Investigator: Piffer Silvano

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Provincia autonoma Trento

Project Type: WP PROJECT - 4

Total proposed budget (Euro)

Costs	TOTAL BUDGET	Co-Funding	Project costs proposed to funding Organization (no MOH request)	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	200.000,00	200.000,00	0,00	not permitted	0,00
1b Researchers' Contracts	311.000,00	0,00	200.000,00	111.000,00	49,70
2 Equipment (Leasing - Rent)	13.000,00	0,00	13.000,00	0,00	0,00
3a Supplies	35.000,00	0,00	2.000,00	33.000,00	14,78
3b Model Costs	0,00	0,00	0,00	0,00	0,00
3c Subcontracts	60.000,00	0,00	50.000,00	10.000,00	4,48
3d Patient Costs	25.000,00	0,00	0,00	25.000,00	11,19
4 IT Services and Data Bases	15.000,00	0,00	0,00	15.000,00	6,72
5 Publication Costs	5.000,00	0,00	2.000,00	3.000,00	1,34
6 Convegni	4.900,00	0,00	2.900,00	2.000,00	0,90
7 Travels	8.000,00	0,00	5.000,00	3.000,00	1,34
8 Overheads	46.322,00	0,00	24.989,00	21.333,00	9,55
9 Coordination Costs	0,00	0,00	0,00	0,00	0,00
Total	723.222,00	200.000,00	299.889,00	223.333,00	100,00

Report the Co-Funding Contributor:

Co-funding contribution includes managing directors/medical doctors/health care staff, project managers, researchers (including IT researchers) already working within the eligible institutions for the Provincia Autonoma di Trento, as indicated in the Bando (Allegato A). The overall contribution is estimated as the 35% roughly of the requested funding.

	Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.
Project Code: NET-2018-12367206-4	**Principal Investigator:** Piffer Silvano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Provincia autonoma Trento

Project Type: WP PROJECT - 4

Budget Justification	
1a Staff Salary	Staff' Salary includes Project Managers, MD/health care staff, researchers (including IT)
1b Researchers' Contracts	Researchers' contracts include health-care staff, project managers and reserchers (including IT) to implement project's activities
2 Equipment (Leasing - Rent)	Costs include IT equipment
3a Supplies	Supplies include consumables and health care service delivery, in line with the eligible costs as per project requirements
3b Model Costs	None
3c Subcontracts	Subcontracts are included for reporting and/or technical services
3d Patient Costs	Patient costs include medical examination/visits and follow-up visits, in line with the eligible costs as per project requirements
4 IT Services and Data Bases	Costs include software licenses and database
5 Publication Costs	Publication costs are foreseen to cover reports costs, submission/publication fees in peer reviewed and/or scientific journals, including open-access (if appropriate)
6 Convegni	Costs cover expenditures for training sessions (as per WP proposal) and dissemination
7 Travels	Travels includes costst for participation to meetings/scientific conferences
8 Overheads	Overheads (automatically calculated) inlcude fixed and indirect costs
9 Coordination Costs	None

Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.	
Project Code: NET-2018-12367206-4	**Principal Investigator:** Piffer Silvano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Provincia autonoma Trento

Project Type: WP PROJECT - 4

Principal Investigator Data - Working package 1 Code: NET-2018-12367206-1

Cognome: Bianchi
Nome: Stefano
Codice fiscale: BNCSFN52E02E625V
Documento: Passaporto, Numero: AA2693220
Data di nascita: 02/05/1952
Luogo di nascita: Livorno
Provincia di nascita: LI
Indirizzo lavorativo: Via Forlanini 1
Città: Piombino
CAP: 57025
Provincia: LI
Email: stefano2.bianchi@uslnordovest.toscana.it
Altra email: stefano.bianchi1952@libero.it
Telefono: 0586614383
Altro telefono: 056567283
Fax: 0586614383
Qualifica: Direttore
Struttura: UOC Nefrologia e Dialisi
Istituzione: ASL Nordovest, Regione Toscana

Principal Investigator Data - Working package 2 Code: NET-2018-12367206-2

Cognome: grigioni
Nome: mauro
Codice fiscale: GRGMRA58D22H501S
Documento: Carta d'identità, Numero: AS 8845285
Data di nascita: 22/04/1958
Luogo di nascita: Roma
Provincia di nascita: RM
Indirizzo lavorativo: Viale Regina Rlena 299
Città: Roma
CAP: 00161
Provincia: RM
Email: grigioni@iss.it
Altra email: mauro.grigioni@iss.it
Telefono: 0649903097
Altro telefono: 0649902855
Fax: 0649903096
Qualifica: Dirigente di Ricerca

	Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.
Project Code: NET-2018-12367206-4	**Principal Investigator:** Piffer Silvano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Provincia autonoma Trento

Project Type: WP PROJECT - 4

Struttura: Centro Nazionale Tecnologie Innovative in Sanità Pubblica (TISP)
Istituzione: Istituto Superiore Sanità

Principal Investigator Data - Working package 3 Code: NET-2018-12367206-3

Cognome: Scalvini
Nome: Simonetta
Codice fiscale: SCLSNT59D49B157W
Documento: Carta d'identità, Numero: AT 6113441
Data di nascita: 09/04/1959
Luogo di nascita: Brescia
Provincia di nascita: BS
Indirizzo lavorativo: Via Maugeri 4
Città: Pavia
CAP: 27100
Provincia: PV
Email: simonetta.scalvini@fsm.it
Altra email: simonetta.scalvini@icsmaugeri.it
Telefono: +390308253183
Altro telefono: +393356348844
Fax: +390308253189
Qualifica: Specialista Cardiologo
Struttura: Unità Operativa di Continuità Assiestenziale e Unità Operativa di Cardiologia, Istituto di Lumezzane (BS)
Istituzione: IRCCS Istituti Clinici Scientifici Maugeri Spa ¿ Società benefit

Principal Investigator Data - Working package 4 Code: NET-2018-12367206-4

Cognome: Piffer
Nome: Silvano
Codice fiscale: PFFSVN55S07L378X
Documento: Carta d'identità, Numero: AU2096917
Data di nascita: 07/11/1955
Luogo di nascita: Mattarello /trento)
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	Project Title: Innovative care models for patients with diabetes to improve the quality of care, empower patients, and optimise resource utilisation.
Project Code: NET-2018-12367206-4	**Principal Investigator:** Piffer Silvano
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	**Applicant Institution:** Provincia autonoma Trento

Project Type: WP PROJECT - 4

Qualifica: Dirigente Medico d Secondo LIvello
Struttura: Servizio Epidemiologia Clinica e Vautativa
Istituzione: Azienda Provinciale per i Servizi Sanitari