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PITES: TELEMEDICINE AND E-HEALTH INNOVATION PLATFORM

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CONTENTS

Prólogo

La atención a los pacientes crónicos constituye uno de los temas más críticos al que se enfrentan los sistemas sanitarios hoy día. Esta situación se refleja en el interés hacia nuevos modelos organizativos de los procesos asistenciales y su implementación usando las capacidades de tecnologías de Internet, comunicaciones móviles y dispositivos biomédicos personales. Su introducción y difusión extendida en la práctica asistencial no es trivial ya que involucra tareas complejas de cambios de organización y de culturas de trabajo tales como las implicadas en la coordinación entre niveles asistenciales y con los servicios sociosanitarios, Por otra parte, desde el lado tecnológico también hay que abordar soluciones para la interoperabilidad; la seguridad, y otras cuestiones emergentes de ingeniería para grandes sistemas digitales.

La gran mayoría de la actividad de I+D+i relacionada con estos temas ha estado impulsada fundamentalmente desde la tecnología. Este libro aporta una experiencia innovadora difícil de encontrar en la literatura. Contiene cinco contribuciones sobre trabajos de I+D+i en nuevos modelos para la atención a pacientes crónicos utilizando sistemas de telemedicina que han sido producidos por grupos de investigación inmersos en el propio Sistema Nacional de Salud. Cada uno atiende a su contexto local y al diseño de un escenario de intervención propio pero dentro del marco común del Proyecto Coordinado *PITES* (Plataforma de Innovación para Telemedicina). *PITES* sigue un modelo de innovación abierta liderado desde el conocimiento de los profesionales sanitarios desarrollando aplicaciones de ecosistemas digitales de telesalud seguros, accesibles e interoperables basados en estándares abiertos con flexibilidad para que cada proyecto tenga la libertad para diseñar e implementar sus protocolos en su contexto local.

El primero de los cinco artículos incluidos en el libro se refiere al Proyecto Coordinador principal de *PITES*. Sus autores son componentes del grupo de la Unidad de Investigación en Telemedicina y e-Salud del Instituto de Salud Carlos III de Madrid. Lleva por título ***"PITES:* Innovation platform in new services based on telemedicine and e-health for chronic and dependent patients".** En el mismo se describe la concepción, diseño, realización y evaluación de la plataforma tecnológica y de servicios *PITES*. Esta plataforma está destinada a soportar de forma trasparente proyectos de investigación sobre nuevos modelos emergentes de atención a crónicos, personas mayores frágiles y dependientes. El objetivo ha sido hacer disponible infraestructuras digitales interoperables y abiertas para facilitar y acelerar el desarrollo de aplicaciones de telesalud que de otra forma serían muy difíciles de acceder o muy costosas en tiempo y esfuerzo de diseñar y realizar desde cero para grupos clínicos. Tecnológicamente se basa en la provisión de servicios digitales sobre redes IP utilizando tecnologías Web y SOA así como en la implementación de estándares para la interoperabilidad semántica.

PITES se fundamenta en la experiencia y lecciones aprendidas hace mas de 15 años en el diseño, implementación y uso de aplicaciones de telesalud en diferentes entornos y contextos de aplicación real, soportados por un gran número de proyectos pilotos y ensayos.

La plataforma *PITES* actualmente sirve como infraestructura a distintos proyectos en diferentes sitios de España y participa en la Acción B3 de EIP-AHA (European Innovation Partnership for Active and Healthy Ageing).

El segundo artículo, titulado **"Servicio Aragonés de Salud: Results of *PITES* project on social and health care for chronic dependent elders in Aragón"** tiene por autores a investigadores del Sector Sanitario de Barbastro y corresponde a trabajos desarrollados en uno de los Proyectos Coordinados de *PITES*. En el mismo se describe el diseño, desarrollo y evaluación de un protocolo para la atención integrada sanitaria y social para pacientes mayores crónicos dependientes alineada con la estrategia de promoción de soluciones de telemedicina y de innovación en servicios de e-Salud del Servicio Aragonés de Salud. Un aspecto central del protocolo es la telemonitorización de signos vitales.

La evaluación se ha basado en un estudio de control randomizado para comparar los beneficios del nuevo protocolo con la atención clásica. Se han estudiado cuatro parámetros: impacto en la actividad clínica, calidad de vida, economía, y satisfacción de los usuarios.

El tercer trabajo, bajo el título **"Hospital Clínic de Barcelona: Deployment of Integrated Care Services Supported by Information and Communication Technologies (ICS-ICT) for Chronic Patients",** describe una experiencia de gran interés. Contiene la evaluación del despliegue de cuatro "Servicios de Atención Integrados" soportados

por TIC en un sector sanitario urbano dirigidos a generar eficiencias mediante la trasferencia de la complejidad del hospital a los servicios domiciliarios pilotados por la atención primaria.

Los cuatro escenarios evaluados han sido: i) Bienestar y Rehabilitación con pacientes de EPOC; ii) Atención Potenciada para pacientes frágiles de EPOC; iii) Hospitalización Domiciliaria y alta temprana para una variedad de diagnósticos en servicios reales y, iv) un programa soportando diagnóstico y terapia en diferentes ensayos de control randomizado. Además en el artículo se describe la plataforma Linkcare que ha sido evaluada usando el Modelo de Evaluación de Aplicaciones de Telemedicina (MAST).

El cuarto artículo, bajo el título **"Hospital Universitario Virgen del Rocío: Results in Chronic Obstructive Pulmonary Disease, Multimorbidity and Headache Patients Scenarios",** está realizado por el nodo *PITES* de Sevilla. En esta contribución se describe la definición, desarrollo y validación de nuevos servicios integrados basados en telemedicina en línea con el modelo organizativo para la atención a pacientes crónicos del Sistema Público de Salud de Andalucía.

Tal como se muestra en el título la investigación ha cubierto tres grandes escenarios: EPOC, pacientes con jaquecas, y pacientes con multimorbilidad.

Un aspecto destacado del trabajo es la experiencia desarrollada en el uso de la arquitectura del estándar ISO13606 para la interoperabilidad en la comunicación de registros médicos.

El quinto trabajo, que completa los contenidos del libro, lleva por título: **"Gerencia de Atención primaria de Albacete: Results of a primary-care telemedicine programme for patients with metabolic syndrome".** En este artículo se describe con detalle la experiencia en el uso de la plataforma *PITES* para el seguimiento y control domiciliario de pacientes crónicos con síndrome metabólico en un marco de atención primaria. También se presentan los resultados de evaluación de la aceptación por los pacientes y su grado de satisfacción.

Los diferentes casos que se describen en los cinco artículos del libro representan un esfuerzo coordinado de diferentes nodos de innovación, liderado desde el conocimiento sanitario y haciendo uso de las tecnologías de telemedicina ubicua en red. Estos trabajos aportan una experiencia anticipativa relevante sobre cuestiones críticas para las implantaciones extendidas de los nuevos servicios para crónicos que se pretenden abordar en el Sistema Nacional de Sanidad.

Esperamos que el contenido de este libro pueda servir de referencia para futuras investigaciones en este dominio.

Para finalizar queremos agradecer a todos los autores el esfuerzo en la realización y la calidad de sus contribuciones.

José Luis Monteagudo y Carlos H. Salvador
Madrid, 2014.

Foreword

Chronic-patient care is one of the most crucial matters facing health care systems today. This situation is reflected in the interest expressed in new organisational models of health care processes and their implementation using the capabilities of Internet technologies, mobile communications and personal biomedical devices. Their introduction and widespread diffusion in health care practice is in no way trivial, since it involves complex tasks of changes in organisation and work cultures, such as those implicated in the co-ordination between health care levels and social/health care services. Furthermore, from a technological standpoint, solutions for interoperability must also be addressed, including safety and other emerging engineering issues for large-scale digital systems.

The great majority of Research & Development and Innovation (R&D+I) activity relating to these matters has been essentially spurred by technology. This book provides an innovative experience that is difficult to find in the literature. It contains five contributions about R&D+I work on new chronic-care models, using telemedicine systems produced by research groups embedded in the National Health System itself. Each of these focuses on its local context and the design of an intervention scenario which is both specific and yet comes within the common framework of the *PITES* Co-ordinated Project *(Plataforma de Innovación en nuevos servicios de Telemedicina y e-Salud). PITES* follows an open innovation model inspired by the know-how of health professionals developing applications of safe, accessible and interoperable digital e-health ecosystems based on open standards with flexibility, so that each project enjoys the freedom to design and implement its own protocols in its local context.

The first of the five papers included in the book refers to the principal *PITES* Co-ordinated Project. Its authors are members of the Telemedicine and e-Health Research Unit group at the Carlos III Institute of Health in Madrid. It is entitled ***"PITES:* innovation platform in new services based on telemedicine and e-health for chronic and dependent patients".** It outlines the conception, design, setting-up and assessment of the *PITES* technological and services platform. This platform is aimed at providing transparent back-up and support for research projects entailing new emerging models of chronic care for frail, dependent senior citizens. The goal is to make open, interoperable digital infrastructures available, in order to facilitate and speed up the development of e-health applications that would otherwise be very difficult to access or very costly in terms of time and effort for clinical groups to design and implement by starting from scratch. Technologically it is based on the provision of digital services over IP networks using Web and SOA technologies, as well as the implementation of standards for semantic interoperability.

PITES is based on the experience gained and lessons learnt over more than 15 years in designing, implementing and using e-health applications in different settings and contexts of real application, supported by a great number of pilot projects and trials.

The *PITES* platform currently serves as the infrastructure for various projects at different points around Spain, and participates in Action B3 undertaken by the European Innovation Partnership for Active and Healthy Ageing (EIP-AHA).

The second paper, entitled **"Aragon Health Service: results of *PITES* project on social and health care for chronic dependent elders in Aragon",** was authored by researchers from the Barbastro Health Sector and corresponds to work undertaken on one of the *PITES* Co-ordinated Projects. It describes the design, development and assessment of a protocol for integrated health and social care for chronic, dependent elderly patients, in line with the Aragon Health Service's strategy of promoting telemedicine solutions and innovation in e-health services. A pivotal aspect of this protocol is the telemonitoring of vital signs.

Assessment was based on a randomised control study designed to compare the benefits of the new protocol to classic care. The following four parameters were studied, i.e., impact on clinical activity, quality of life, costs and end-user satisfaction.

The third paper, entitled **"Barcelona Clinic Hospital: deployment of integrated care services supported by information and communication technologies (ICS-ICT) for chronic patients",** describes an experience of great interest. It contains the assessment of the deployment of four ICT-supported "Integrated Care Services" in an urban health sector, targeted at generating efficiency through the transfer of hospital complexity to primary-care piloted hospital-at-home services.

The four scenarios assessed were: i) wellbeing and rehabilitation, with patients suffering from chronic obstructive pulmonary disease (COPD): ii) enhanced care for frail COPD patients; iii) hospital-at-home and early discharge for a variety of diagnoses in real services; and, iv) a programme supporting diagnosis and therapy in different randomised control trials. In addition, the article describes the Linkcare platform, which was assessed using the Telemedicine Application Assessment Model *(Modelo de Evaluación de Aplicaciones de Telemedicine - MAST).*

The fourth paper, entitled **"Virgen del Rocío University Teaching Hospital: results in chronic obstructive pulmonary disease, multimorbidity and headache patients scenarios",** was issued by the *PITES* node in Seville. This contribution describes the definition, development and validation of new telemedicine-based integrated services, in line with the Andalusian Public Health System's organisational model for chronic care.

As indicated in the title, the study covered three major scenarios, namely, COPD, headache patients and those with multimorbidity.

One noteworthy aspect of the work done here was the experiment conducted on the use of the ISO13606-standard architecture for interoperability in the communication of medical records.

The fifth paper, which completes those contained in the book, is entitled **"Albacete Primary Care Authority: results of a primary-care telemedicine programme for patients with metabolic syndrome".** This paper gives a detailed description of an experiment in the use of the *PITES* platform for home-based follow-up and control of chronic patients with metabolic syndrome in a primary-care framework, and reports the results of the researchers' assessment of patients' acceptance and degree of satisfaction.

The different cases described in the five papers of the book represent a co-ordinated effort by different innovation nodes, spearheaded by in-depth knowledge of health care and the use of ubiquitous on-line telemedicine technologies. These papers contribute a relevant anticipatory experience of key issues for widespread implementation of new chronic-care services sought to be addressed by the National Health System.

We trust that the content matter of this book will serve as a reference for future research in this field.

Lastly, we should like to thank all the authors concerned for the tremendous effort made and the quality of their contributions.

José Luis Monteagudo and Carlos H. Salvador.
Madrid, 2014.

CHAPTER 1.

PITES: INNOVATION PLATFORM IN NEW SERVICES BASED ON TELEMEDICINE AND E-HEALTH FOR CHRONIC AND DEPENDENT PATIENTS

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Organisation: *Telemedicine and e-Health Research Unit, Carlos III Institute of Health, Madrid, Spain.*

Index Terms: *Telemedicine, eHealth, chronic diseases, disability, interoperability, innovation platform, health care models, evaluation, archetypes, ISO 13606, ISO 13940.*

ABSTRACT

The Platform of Innovation in Telehealth Systems (PITES) is a stable and public innovation infrastructure oriented at improving the health care of chronic, fragile and dependent patients. It is made up of a technological platform, services and tools, with its use directed at research groups, public or private entities and organizations, with the objective of offering support for the obtaining of evidence on new models for health care provision based on ICT (Telehealth) in scenarios related to chronic illness and dependency.

PITES is directed at broaching two main objectives: a) facilitating and accelerating the development of telehealth applications by making available technological infrastructures which in another way would not be tackled or would have to be designed and constructed from scratch by each project, and b) promote interoperability through the adoption of open standards for the communication of medical data and information.

As an R&D&I platform it has been conceived to be flexible, functionally transparent, secure and with the capacity to evolve and coexist with other platforms —for research or clinical use— by means of technical and semantic operability mechanisms based on standards. Technologically, it is aligned with the current convergence framework for the provision of digital services on IP networks using Web technologies and SOA.

PITES follows an open innovation model promoted from the knowledge of the professional health users for the application of secure, accessible and interoperable telehealth environments using open standards. The PITES digital ecosystem gives each Project the freedom to design and implement its protocols.

1.1 INTRODUCTION

A great deal of R&D&I has been carried out in recent years in the area of telemedicine and e-Health directed at supporting innovative health care models for

people with chronic health conditions such as hypertension, cardiac insufficiency, chronic pulmonary obstruction, asthma, diabetes, cancer, dementia and other ailments [1]. The objective is to implement more appropriate and effective health care models in order to maintain health under everyday conditions, avoiding serious complications and without the need to resort to emergency services and hospital admittances. One priority is to avoid or delay for as long as possible the situation of dependence on the health care system for pluripathological conditions.

It must be borne in mind that telehealth systems and services are in the definition and positioning phase in traditional health care systems and coexist with other systems such as Telecare, Personal Health Systems (PHS), mobile Health (mHealth) and Personal Health Applications (PHAs) and with those that often overlap [2,3].

It is important to consider that innovation in telehealth does not only rest in technological advances. The system of innovation in this domain is very complex and interdependent. A fusion of technology with health care knowledge and the organization of health care systems is necessary together with measures to empower the users and a redefinition of the contact of the professionals with the patients.

PITES stems from experience and lessons learned over 15 years in the design, implementation and use of telehealth applications in different environments and contexts of real application, supported by a large number of pilot projects and trials. PITES currently serves as an infrastructure for diverse projects in different locations in Spain. PITES also forms part of the Accion B3 of the European Innovation Partnership for Active and Healthy Ageing.[4]

The PITES platform supports research or innovation projects, not health care activities nor commercial services. The platform permits different telehealth projects to be implemented in a flexible and transparent manner using different local approximations and contexts of use for both professionals and patients. PITES incorporates the philosophy of separating the applications of the infrastructures that support them.

The structure of this document is as follows: The two goals of the PITES innovation activities are described in section 2, the obtaining of evidence and the interoperability of the clinical information. As regards the obtaining of evidence, we begin by presenting the current context of the evaluation in e-services. The challenges that persist are highlighted, brought about by the intrinsic complexity of the environments in which the evaluations have to be carried out. The methodology designed and proposed in PITES is then described in order to tackle the complexity of the search for evidence on the e-services process. As regards interoperability, we present the fundamental aspects of interoperability in clinical information and the interoperability framework of the platform.

The PITES platform is presented in section 3. Firstly, a conceptual model of the organizational and functional framework is described as a proposal for the reduction in users, resources and its interactions to which the interventions must be adapted to be able to be evaluated with the support of the platform. After that, the architecture of the PITES platform is presented as an open system of distributed services and its advantages in collaborative research and innovation in this field. Finally, some of the services that currently support the platform and which already act as permanent components supporting the projects are described.

1.2 CONTEXT OF INNOVATION WITHIN THE PITES SCENARIO

1.2.1 Evaluation of services based on telemedicine

1.2.1.1 Current context of the evaluation of e-services

One of the permanent challenges facing e-health, and therefore telemedicine and its effects is the obtaining of scientific, generalized and reliable evidence (transferable between different contexts) on it. There are numerous reasons for the evaluation: promotional, pragmatic, ethical, medical-legal, even academic. The objective is to promote and legitimize practices of excellence, evaluate the policies, standards and national legislations on e-health and value its impact in terms of efficiency and technical and clinical effectiveness, impact on the organization, health staff, costs, patient satisfaction and personal ethical health aspects, confidentiality and safety.

The recommendation for evaluation has been endorsed from multiple authorities and international organizations such as the World Health Organization in its "eHealth Program for Health-Care Delivery" (eHCD) [5] and the "Global Observatory for eHealth" [6], which established that services based on e-health will be essential when they demonstrate that they are based on evidence, requiring well-defined agreed specifications and criteria for it, and validated by means of controlled experimental trials or by consensus widely accepted by experts. Also within the ambit of the European Union, by means of eEurope initiatives [7] or i2010 [8], the need to strengthen the aspects of demonstration and evaluation in projects has been made clear to allow the complete analysis of the results to be undertaken and make available the evidence of quality for the drawing up and dissemination of directives on good practices.

Traditionally, the evaluation of e-health services has brought to light significant difficulties giving rise to uncertainties and thus resistance to its implementation by consultants and managers. The belief that the implementation of formal evaluation processes constitutes an obstacle for developers and the commercial and economic context is currently being dismissed. It has come to light through demonstration that the systems are effective, cost-effective safe, robust, accessible, and usable, as well as a source of benefits and knowledge, an aspect which is known in the technological sector as "evidence-based business" [9]. Nevertheless, it is evident that the organizations and health systems determine *a priori* numerous factors that, in evaluation interventions, condition the work frameworks and their implementation, and therefore the potential final results. In this sense, there still remain significant methodological challenges and practical implementations mainly related to two aspects: 1) the interdisciplinary nature of the field of e-health, and 2) the intrinsic complexity of the context in which the evaluations have to be carried out.

As regards the first aspect, it is an obvious fact that e-health constitutes a heterogeneous and interdisciplinary field of science with which two areas of research converge fundamentally (in turn, trans-disciplinary): the computer aspects of health (technological ambit) and research into health services (socio-health ambit). Traditionally, all of them use different languages, cultures, reasons and operating conditions which have generated divergent working templates [10]. These silos of parallel competencies are a cause of additional difficulties in the development of e-health. In the past decades efforts have been directed at achieving a mutual recognition between the respective disciplines and a search for synergies and single paradigms [11].

The second aspect refers to the intrinsic complexity of the context in which the evaluations have to be carried out. During the past two decades, the results achieved

related to the dissemination of the innovation, knowledge and experience in the ambit of health have not all been as satisfactory as was hoped. The cause would have to be sought in some of the work strategies more orientated towards the resolution of complicated problems rather than a complex problem [12]. Starting from this idea, different authors have carried out an approximation of the organizations and health practice from the perspective of complexity theory, contemplating them as adaptive complex systems [13-17]. Parallelisms related to questions such as changing behaviors, interrelated, yet not totally predicable, whose evolution and behavior patterns respond to the relationships between their components on the basis of non-explicit rules, the appearance of emerging behaviors, "attractor patterns", effects of self-organization, the influence of "shadow systems", etc. have come to light. By means of the aforementioned work, it has become possible to explain different aspects of behavior dynamics in relation to clinical care, education, leadership and management in health environments, which have opened up new ways and action strategies related to evaluation, as well as improving the quality and adoption of innovations.

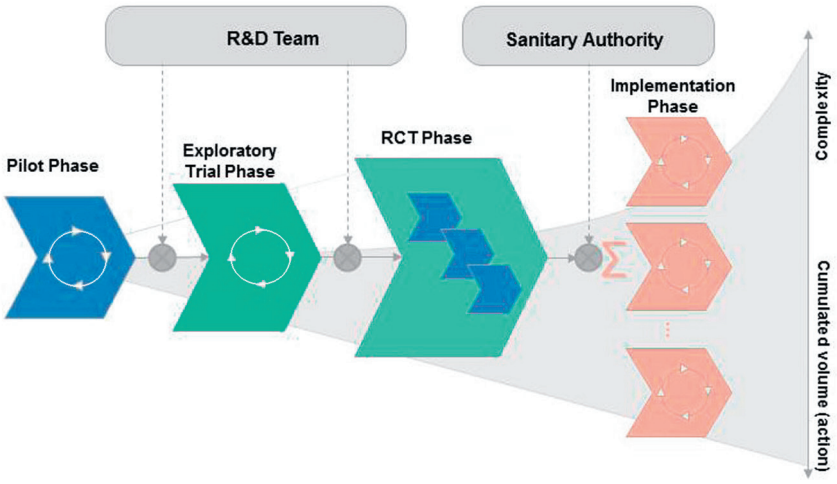
1.2.1.2 Evaluation methodology of e-services in PITES

Within the framework of the PITES platform the specification of an evaluation methodology has been carried out aligned with the hybrid methodologies for the search for evidence [18-22] into the new assistance services based on telemedicine directed at chronic illness.

The PITES evaluation methodology [23] is made up of four consecutive pages (Figure 1): pilot phase, exploratory trial phase, clinical trial phase, and the implementation phase. Responding to the classic sequence in hybrid models, an initial stage related to the evaluation of the concept and the configuration of the intervention prototype (pilot phase), followed by an intermediate step related to the evaluation of the results relative to the impact of the intervention in the innovation in health processes and results (exploratory trial and clinical trial phases), and a third pragmatic evaluation stage related to the long-term impact of the intervention in production environments (implementation phase).

By means of the support of infrastructures and resources that the PITES platform contributes, it is possible to carry out phases 1 to 3 (pilot, exploratory trial and clinical trial) under conditions of "minimum implementation".

Figure 1. The PITES evaluation methodology



The description of the phases is as follows:

Pilot phase

The objective of this phase is the evaluation of the technological prototype that is going to support the intervention as regards the quality and functioning of the prototype, usability, and satisfaction of the users of the prototype. Internally the process involves two consecutive tasks. Firstly, the design and development of the technological prototype under optimal laboratory conditions. This first task has the character of a concept trial, exploratory and iterative until the optimum prototype is configured. For this, it is necessary to carry out a study on the state of the art, available technologies, medical devices, communications, etc. In second place, the carrying out of a feasibility study under controlled practical conditions outside the laboratory. Few participants are required to carry out this initial field trial (It would be valid for the proposal of the basic model to not exceed 20 patients nor more than 5 health professionals), as is the availability of equipment under optimum working conditions, together with well-trained and motivated users. It is not a question of carrying out a comparison study since the focus continues to be on the technological system and its optimization; therefore throughout the development of this phase, proposals for improving the prototype are gathered and then sent to the laboratory. The technological prototype is developed externally to the health organization with the participation of health professionals among which include those belonging to the research group and the resources and infrastructures required are facilitated externally to the health organization by the PITES platform.

To pass from phase 1 to phase 2 a positive evaluation of the results of phase 1 is necessary in relation to: the test of the concept, the technical viability, the acceptability of the health professionals, and the satisfaction of the users of the system. The decision is brought about within the ambit of the research group itself and is made effective by the promoting or financing entity.

Exploratory trial phase

Once the technological prototype has been optimized, it is time to begin the evaluation of the intervention in the health aspect of clinical efficiency. For this and, in agreement with the requirement to maintain a controlled complexity by means of a "minimum implementation" in the health organization, it is necessary to establish the provision model by means of carrying out the intervention emphasizing the resources and infrastructures required that are going to be facilitated externally to the health organization by the PITES platform. To carry out this task the proposed procedure is the carrying out of one or more exploratory trials whose objective is to experiment with the intervention, varying the deferent components and alternatives, to observe the effect of the intervention in its entirety and its consistency in different contexts, viability, participant acceptability, etc. As a result, evidence has to be obtained on the most suitable parameterization of the clinical trial (the following phase), to specify the intervention and the optimum studies.

Aspects such as identifying the key processes and results of the intervention, identifying the mechanisms through which the intervention would lead to an improvement in the results, the identification of the application difficulties or implementation of the intervention, the establishment of the collectives or groups on those that influence the intervention by optimizing its probability of response, the determination of the components and the intensity of the intervention in accordance with the available possibilities and resources, or the evaluation of the learning curve

of the skills of the users are basic aspects to be determined in order to be able to guarantee the performance in the suitable intervention in the clinical trial phase. It is also not necessary to perform an analysis and modeling of the intervention that is required to be evaluated. If it is going to be compared with a practical standard, or an improved practice (for example, the same intervention with and without the support of telemedicine), it will also be necessary to model the comparison intervention which might be the same or even more complex. As well as the modeling process, if it is possible, it may be very interesting to carry out a simulation of the intervention by means of experimenting functional aspects of the scenario, the modeling of components, the statistical and mathematical model, etc.

As regards the methodology of the exploratory trial phase, the same degree of quality of evidence is not demanded as in a controlled randomized clinical trial; while it is inacceptable methodologically to modify an intervention during the course of the controlled randomized clinical trial, a study in this phase may be developed precisely to carry out trials on the variations in the intervention and clarify which are the most appropriate with views to the clinical trial. The criterion is to carry out one or more studies with a more adaptable development especially as regards the rigidity of the protocols and the inclusion of patients. The carrying out of quasi-experimental studies with sample sizes that do not exceed 100 patients and 10 health professionals may be suitable in this phase.

The availability of "Living Labs" as a community experimentation context may result in an appropriate option as it would carry out formal studies in social environments with a controlled complexity. If this is not possible, it would be advisable to carry out an analysis on the context in which the intervention is going to be evaluated since the degrees of complexity which show the different health problems are diverse and dependent on the context. It is recommended to consider aspects related to: the illness itself (risk factors, co-morbidity, prevalence, etc.), the patient (lifestyle, adherence to the treatment, symptoms, etc.), and the social context (social support, socio-economic level, cultural level, etc.).

The support of the exploratory trial and the corresponding interventions (resources, logistics, and infrastructures), is carried out externally of the health organizations involved and counting exclusively on the participation of health professionals belonging to the said organizations and contributing the resources and infrastructures required by the PITES platform.

To pass from phase 2 to phase 3 a positive evaluation of the results of the experimental studies carried out in phase 2 is needed which guarantees the viability of carrying out the controlled randomized clinical trial in order to evaluate the intervention in terms of efficiency. The decision is made within the ambit of the research group itself and put into effect by the promoting or financing entity.

Clinical trial phase

This phase is key to the evaluation of the efficiency of the complex interventions and consists of carrying out a controlled randomized trial with all of the rigor and power required, assuming the standard design aspects that require these types of trial: inclusion and exclusion criteria, sample size, criteria and duration of the intervention, randomization and informed consent of the participants, etc. From the knowledge accumulated in phase 2, definitive decisions must be taken on the nature

of the intervention in order to standardize the intervention going to be evaluated and minimize the biases that limit not only the internal but also the external validity.

During this phase, unlike the previous ones, it is absolutely prohibited to make modifications in the protocol of the intervention. The minimum sample size determines the statistical power of the clinical trial and there must be the possibility of carrying out a replication of the intervention in multiple centers (multicentre trial), maintain its uniformity of implementation to guarantee the internal and external validity of the study and the generalization of the results. The participation of multiple centers contributes an additional value as it makes possible the study in different contexts of established patterns and emerging self-organization behaviors shown by the health professionals that are of doubtable use in phase 4.

The support of the clinical trial and the corresponding interventions (resources, logistics, and infrastructures), are carried out externally to the health organizations involved and counting exclusively on the participation ofhealth professionals belonging to the said organizations and contributing the resources and infrastructures required by the PITES platform. It is essential that the resources and infrastructures external to the health organization do not represent a direct object of evaluation in the clinical trial, and act exclusively as a support to the operational deployment of the intervention.

To pass from phase 3 to phase 4 a positive evaluation of the efficiency of the intervention in the results of the trial, together with a decision from the health authority to adopt, is necessary (for example, an autonomous health service) with the support or endorsement of a Health Technology Evaluation Agency. Therefore, the ambit of the decision is outside the scope of the research group, although its continuity and participation in phase 4 may still be relevant.

Implementation phase

Once the evidence on the efficiency of the health of the intervention is demanded, it is necessary to adapt it to the local contexts in order to deal with two objectives: the full implementation of the intervention in the health organization in its technologic and health ambits, in such a way that it constitutes a health procedure more as regards the provision of all of the resources and infrastructures required at the margin of the external supports, and from that, the carrying out of financial cost studies and long-term studies to determine the efficiency of the intervention.

For this, it is necessary to count on a significant and essential institutional support that promotes and manages the change and the dissemination of the innovation to the health organizations participating in this phase, and preferably from legal and financial instruments that regulate the introduction of new technologies in the National Health System as a factor essential for the progression of the intervention as a routine health procedure.

The total effect of knowledge that would contribute to carrying out the local implementation in different socio-health contexts from the participation of several organizations, would contribute to the convergence of the intervention towards the standardized health procedure. Taking the methods and other knowledge accumulated during the development of phases 2 and 3 as reference, it is necessary to carry out an analysis on the operative feasibility of the service that adapts the intervention in specific health contexts, together with a deployment project and all of them particularized for the conditions of each participating organization. In this process it

would constitute a valuable contribution of the health professionals who would act as active agents of the health process in the previous phases due to their knowledge on the intervention and the health context, and as the promoters of complementary strategies for the dissemination of the innovation.

1.2.2 Interoperability

1.2.2.1 Interoperability of the clinical information

The interoperability of the clinical information is one of the requirements of the health continuity [24]. The current paradigms of the health put the patient at the centre of a process around which are located the organizations and professionals who provide them with their services independently of their geographical or temporary location. For this strategy to be effective it needs the information to flow between the different nodes in such a way that it is automatically interpretable by them. Thus the professionals will have all of the information that they require to carry out their work, avoiding problems of duplicating the test for the patient to increase his/her safety, statistical studies can be carried out more easily on having the normalized information available and are able to plan the action to be carried out automatically.

Also for a platform like the one presented here, or for any other medical telecare service, this question is essential, as one of the problems that usually comes up is that of its isolation as regards other information systems, since on being systems created specifically for carrying out the support work of the service, the possibility of communicating with others is not normally taken into account and the information generated in these services usually stays in their own storage systems, without reaching the patient's records unless a manual introduction of the required data is written [25]. The interoperability of these platforms, therefore, is a fundamental requirement if it is required to integrate into the trends of the health continuity.

With these premises the PITES platform has been provided with an interoperability framework to facilitate the sharing of the information between the different nodes that are connected to the platform, as is its interconnection with other information systems such as the clinical records of the health organizations and for the use of the information for secondary uses.

But, what is interoperability? the ISO (specifically the Information Technology Vocabulary – Fundamental Terms, or ISO/IEC 2382-01) defines the interoperability as the "capacity to communicate, implement applications or transfer data between sever functional units without the user needing to know the particular characteristics of the said units". The definition is fairly clear, but perhaps insufficient. The first thing that has to be specified is that there are several types of interoperability: the classic technical, syntactical and semantic, the organizational has recently been merged, and there are authors that go further and even speak of political interoperability, whose existence depends rather on where the limit of the definition of the organization is placed. Let us see what each of these "interoperabilities" are.

Technical Interoperability: this is the basis on which the connection between systems is supported. Technical interoperability defines the interfaces, both physical and logical, which allow the aforementioned functional definition to be able to exchange information. It is currently well advanced, which is logical, since, evidently, it is not exclusive to the health scenario and its development has been necessary for many other field. Standards such as 802.3, 802.11, TCP/IP, HTTP, the Zigbee Bluetooth

specification, the low levels of the ISO 11073, SOAP family, etc. are those that are used to achieve technical interoperability.

Syntactical Interoperability: Syntactical interoperability is the formats of the exchanged files or of the types of data used, making them able to make translations between formats depending on that used for each system involving the communication. The systems that only provide this type of interoperability act as mere messengers without intervening in the content of the information communicated without being able to react depending on it. This type of interoperability also has a high level of development, although in the health field some evolution is still necessary. Within the range of standards on which they are based so as to achieve syntactical interoperability can be found XML, the specifications for types of data such as TS 14796 from CEN or the ISO 21090, the specifications of messages of versions 2.x of HL7 or the reference models of HL7 V3 or UNE-EN ISO 13606, although the latter are also the basis of the semantic interoperability, as can be seen below.

Semantic Interoperability: according to the definition of the 251 Technical Committee of CEN, it is the state that exists between the two entities-applications when, with respect to a specific task, an application can accept data from the other and carry out this task satisfactorily without the need for the intervention of an external operator. Contrary to what, on occasions, is believed, the use of terminologies to encode the information is not sufficient to achieve semantic interoperability since clinical information consists of much more than just words. At the times of expressing the clinical information the vocabulary is necessary, as well as being able to express the context in which the information has been generated (who, when, with which objective, about whom, the level of viability, etc.) as well as being able to formalize that which must be gathered for each concept handled so that it makes sense (it must contain a summary of the records, a discharge report, the Barthel index, etc.). For the first necessity, the terminologies (SNOMED-CT, CIE-10, LOINC, etc.) can be used to express the context; (UNE-EN ISO 13606:1, RIM, CDA, etc.) reference models are used and there are mechanisms as archetypes to formalize and share the concepts (for example those defined in UNE-EN ISO 13606:2) or the detailed clinical models (DCM).

Organizational Interoperability: summarizing considerably, it may be said that the organizational interoperability is supported by business rules. In order for two organizations to be able to cooperate they must share a common context in their procedures and work flows. It will be difficult to interoperate, for example, if the definitions of the process, health plan or health order are different or incompatibles. The definitions of some of these concepts are currently imposed by the information systems that are used in the different organizations and that the providers have included in their developments without previously formalizing them. Other concepts are established by the health policies developed by the different administrations on which the organizations depend (that is the concept that some political interoperability authors use). There is still much more to be done in this field, although in the environment of standardization there are works such as the EN 12967 HISA (Health Informatics - Service Architecture) norm which, in its first part, deals with the business point of view, and mainly the UNE-EN ISO 13940 norm (system of concepts to give support to the continuity of the health).

1.2.2.2 Definition of the Interoperability Framework of the Platform

The design of the interoperability layer of the PITES platform is dealt with by taking its objective into account (open platform to support e-health services) such as

the special characteristics of the scenario in which its activity is developed, as well as the peculiarities in Spain, where the existence of autonomous regional governments (known as *comunidades autónomas*), with different languages and the health responsibilities transferred, conditions to a large extent the approach to be implemented:

— PITES is an open platform to give support to a large variety of research groups belonging to different organizations.

— The organizations participating in PITES belong to different *comunidades autónomas* with the health powers transferred and with different languages.

— The information systems of the different nodes may be manufactured differently and be based on different models.

— The list of organizations participating in PITES is not closed, but it is envisaged that in future calls new nodes will be incorporated, a question that also forms part of the philosophy of the platform. That is, the solution that is adopted for the interoperability must be capable of incorporating new elements probably based on systems and models different from those that currently exist.

In such a scenario it would be very difficult to establish a rigid framework for the exchange of information to be set, for example, a series of predefined messages to which any user of the platform, present or future should attend, especially in the health field in which the complexity of the information dealt with is a determinant factor at the time of finding satisfactory communications solutions, as is also the speed of changing the domain knowledge.

In this sphere, current trends point to the use of strategies that permit the information to be separated (which is known from a certain entity and is not going to vary over time) from the knowledge (that which is valid for all of the entities of the domain but which is subject to variations as the research advances or new techniques developed). These double-model strategies (information or reference model and knowledge model or archetypes) [26] allow, on the one hand, the variations systems in the knowledge to be protected and, on the other hand, separate the actions of the experts in the technical field (they develop the systems based on the reference model) of the domain experts (the health professionals that define the concepts to be used by means of archetypes). This is the strategy that, for example, the UNE-EN ISO 13606 norm implements.

Interoperability framework: syntactical interoperability

Syntactical interoperability strengthens the use of XML to encode the messages. This is done in accordance with the reference model of the UNE-EN ISO 13606 norm using the type of information defined in ISO 21090. Given that the UNE-EN ISO 13606 norm remains agnostic as regards the technology (and does not define what has to be used to carry out the final encoding), some common XML Schemas are used for the reference model created by Dr. Dipak Kalra's group (leader of the EHRCom task force, that developed the norm), which is being converted into the de facto standard, as they are currently being used in a multitude of both national and international projects.

As regards the types of data specified by ISO 21090 [27], the XML Schema which proposes the norm in its informative part is used. In this case, a reduction has been made in the types available to facilitate the implementation, always maintaining the compatibility with the norm, as well as the possibility of easily adding the new types that are necessary.

Interoperability framework: semantic interoperability

Semantic interoperability is supported on two pillars: the use of terminologies together with the double reference model and archetypes of the UNE-EN ISO 13606 norm [28, 29].

— Use of terminologies

The first basis for the semantic interoperability of the clinical information is the encoding of the terms used in the domain. For this it has become necessary to use the standardized terminologies. The proposed PITES interoperability framework, the use of SNOMED CT and its link with the archetypes defined as one of the means of supporting the semantic interoperability [30]. This is implemented by means of the creation of the corresponding subsets of terms. Equally, in those cases in which the use of SNOMED CT does not cover the terminological necessities, and given that the 13606 norm does not impose any specific terminology, the terminologies suitable for each domain are used.

— Reference models and archetypes

The reference model is in charge of representing the general characteristics of the components of the ECR, how they are organized, and the context information necessary to satisfy the requirements both ethical and legal of the register. The model defines the series of classes that make up the constituent blocks of the register, that is, gather its stable characteristics.

The reference model of the 13606 norm, for example, organizes information in extracts, which are the containers of the information referring to a patient (that is going to be transmitted. This information includes the demographic data, the access policies and the clinical information, which is organized in compositions that store simple statements on observations, evaluations or instructions (entry), which may be grouped together in sections to represent the internal organization of the documents as their headings are made. Finally, the entries contain elements, in each of which a specific datum is stored. The elements may be grouped together in clusters to represent more complex structures of data, such as temporary series or tables.

In order to achieve interoperability, a model such as this one has to be complemented in the knowledge domain with a formal model to transmit and share structures of predefined classes, agreed to by a community, corresponding to fragments of the registry created under specific clinical situations: the archetypes. An archetype is the definition of a hierarchical combination of components or the reference model, to which it restricts (given their names, types of possible data, default values, cardinality, etc.), to model clinical concepts of the knowledge domain. These structures, although sufficiently stable, can be modified or substituted by other through the evolution of clinical practice.

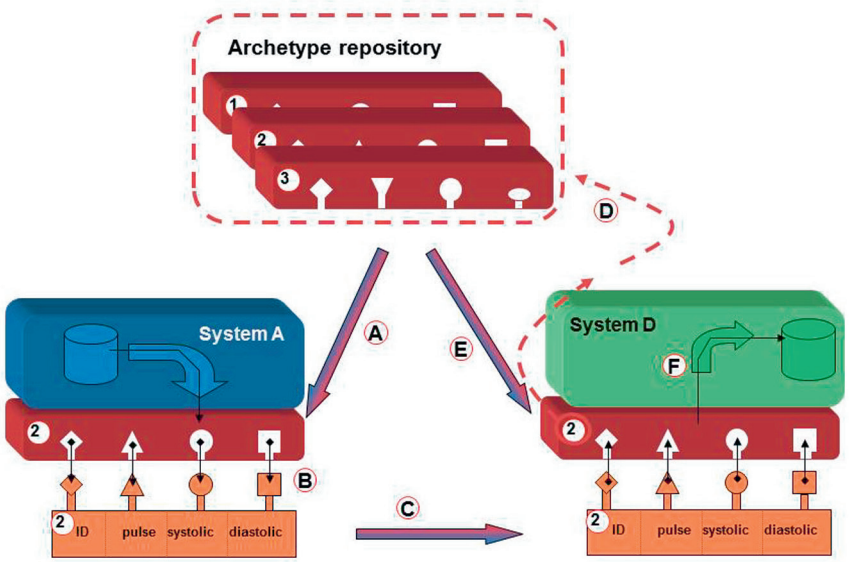
It is worth summarizing that these models (archetypes) can be created at any time, since the systems use them in real time to generate requests for data in accordance with them, they verify the validity of the requests received, interpret them automatically from the semantic point of view, build applications for entering data, etc.

By using this double model, it is not necessary to have a prior total agreement between the organizations participating in the communication, since they have the mechanism of the archetypes as a formalized way of sharing the concepts that are being used and that the receptor is capable of correctly interpreting the information

received automatically. In Figure 2 it can be seen how the communication process would be:

a. When system A is going to send information to system D, it will turn to a repository of archetypes in order to obtain the model corresponding to the concepts that are wished to be sent.
b. Using the corresponding archetype, system A will generate a message in real time.
c. The message is sent to system D, which...
d. ...will check according to which archetype has generated the information and will request it from the corresponding repository (or the organization that sent the information).
e. System D obtains the requested archetype...
f. ...and with it, it correctly interprets the information received to incorporate it automatically into its own storage system.

Figure 2. Communications model with archetypes



— Interoperability framework: organizational interoperability

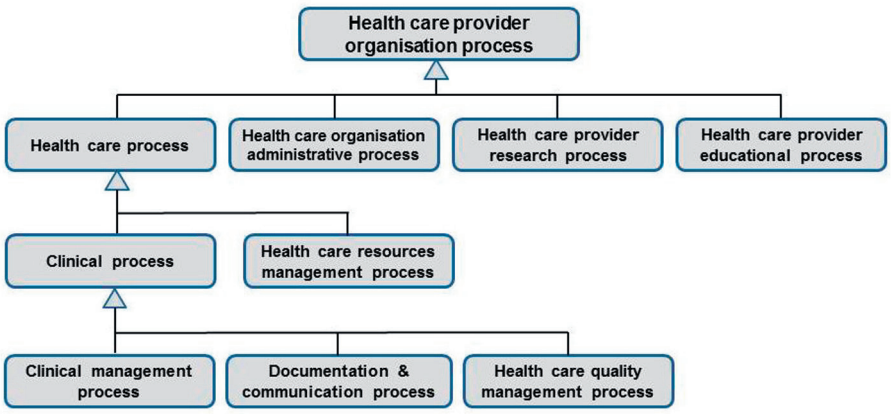
The interoperability of the health information is not only based on syntactical and semantic interoperability. In its COM(2008)3282 recommendation the European Commission recommends that the member states act on different planes, the organizational between themselves, to achieve trans-border interoperability of the health information in Europe [31]. Equally, in the final report of the Semantic Health project, that proposes a road map to achieve the semantic interoperability in Europe, organizational interoperability is cited as of the factors necessary to achieve it [24].

The scenario proposed by the PITES project, in which the participating nodes belong to different autonomous communities, it is proposed to use the UN-EN ISO 13940 norm [32]. The said standard defines the types of concept and the descriptive associations, as regards the health processes with special consideration on the continuity of the care centered on the patient, and the shared care. Its objective is to

carry out a description and formalization of the continuity of the care in the context of the information systems, implying the definition of concepts and descriptive terms that contribute to establishing a common conceptual framework that overcomes national, cultural and professional barriers. That is why a set of concepts is designed to represent the phenomena of the attention process, related to the subject of attention. In this case, the focus is not on the subject in itself but on its condition or state. It applies a modeling technique of the processes in order to identify the objectives of the process, the sub-processes and the activities, also taking into account aspects on the resources, responsibilities and means for patient participation in his or her own care. In those points in which social health is necessary, there activities also appear as well as its work flow.

The standard defines an attention organization as "an organization directly involved in the provision of care". Within an organization of this type, the provision of health services is modeled as a process of organization of the attention (Figure 3). This process will contain one or more attention processes. Similarly, it will also contain an administration process and probably a research process (aimed at improving medical knowledge) and a training process (with the object of improving the capacities of the health professionals by applying medical knowledge).

Figure 3. Components of the organization of the attention process in accordance with EN 13940



1.2.2.3 Summary: the PITES interoperability framework

In summary, in the following Table 1 the interoperability model defined for the PITES project can be specifically seen

Table 1. Specification of the PITES interoperability framework

INTEROPERABILITY	ACTIONS	STANDARDS
Syntactical	• Encoding messages in XML. • Use of a series of types of data proposed by ISO 21090. • Messages in accordance with the 13606 XML Schema as defined by Dipak Kalra's group and that proposed by the computing part of ISO.	• XML. • XML Schema UNE-EN ISO13606.1. • XML Schema ISO 21090.

INTEROPERABILITY	ACTIONS	STANDARDS
Semantic	• Generation of subsets of terms from SNOMED - CT. • Use of other specific terminologies according to need. • Definition of the local concepts by means of archetypes in accordance with UNE-EN ISO 13606. • Linking of the terminologies and the subsets defined with the archetypes.	• UNE-EN ISO 13606.1: Reference model. • UNE-EN ISO 13606.2: Archetype model. • SNOMED-CT. • * Other terminologies.
Organizational	• Definition of a common conceptual framework based on UNE-EN ISO 13940. • Definition of an inter-organizational processes based on UNE-EN ISO 13940. • Definition of inter-organizational work flows based on UNE-EN ISO 13940.	• UNE-EN 13940: System of. • UNE-EN 13940: Processes and work flows.

1.3 DESCRIPTION OF THE PLATFORM

Within the ambit of new services based on telemedicine, the generic overall scenario constitutes a heterogeneous and diverse ecosystem (Figure 4):

— Patients and citizens in different environments, With different health conditions and health care necessities, different degrees of dependence, age and family context, different skills and technological availability, different living and social habits, etc.

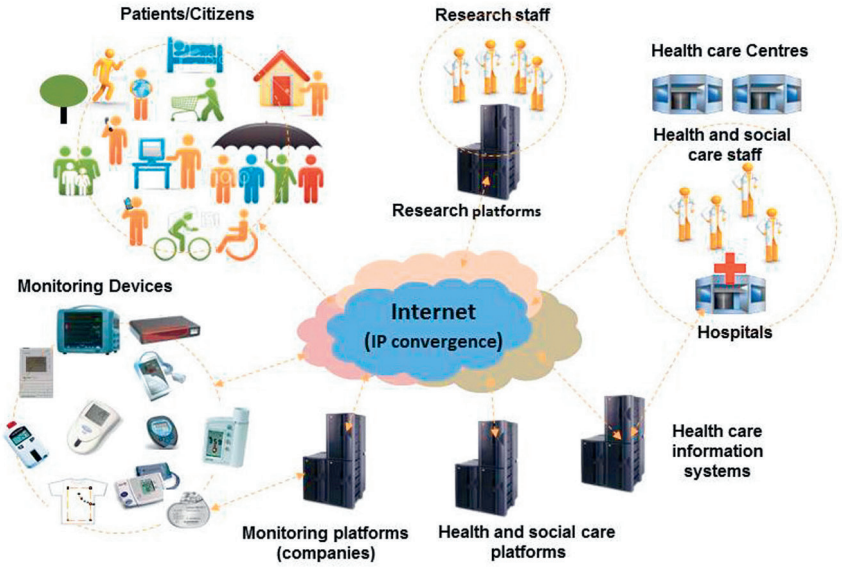
— Health and non-health professionals and with different professional profiles, different skills, attitudes, and technological availability in their environments.

— The world of medical devices, mainly for personal and domestic use, with an enormous diversity, a more and more extensive catalogue becoming even more essential so as to be able to put new health care models into practice, mainly for those whose self-treatment is the main therapeutic option.

— Technological platforms of different types: health platforms, non-platforms, private monitoring platforms, research platforms, etc. These platforms make a ubiquitous access possible and provide personalized services in a complex environment in a solvent manner.

— Some communications networks with a high level of capillarity which makes the Internet possible and with support by means of high-capacity, fixed wireless and digital networks in an environment of convergence and the provision of services on an IP protocol. In this environment, the platforms act as elements of interrelation or an interface between them. The users already have more and more availability to network access technology and are familiarized with it.

Figure 4. Technological environment of the PITES platform



In this complex environment, the PITES platform is constituted as a stable public infrastructure technology, aimed at research groups with innovation nodes located in Health Centers, with the objective making support possible to collaborative research and for the obtaining of evidence on new models for the health care provision based on ICT in scenarios related to chronic illness and dependency.

The design of the platform is sensitive to the complexity of the socio-health system and the difficulties and limitations that the implementation process of e-services has on the organizations. Within the framework of experimental studies, the platform provides support to the first three phases of the aforementioned evaluation methodology of e-services, that is, authorize the resources and infrastructures necessary to deploy interventions with minimum implementation necessities in the socio-health organizations.

The PITES platform is designed to support research projects; not health care activity in "clinical routine". As a research platform it responds to several requirements different from those platforms orientated to "clinical routine". These peculiarities manifest themselves, on the one hand, in a conceptual model of entities that constitute a proposal for a reduction in users, resources and their interactions in the design process of the e-services and, on the other hand, an architecture based on available technologies and those which are nowadays mature such as Web technologies, SOA (Service Oriented Architecture) and the "Cloud Computing" model.

1.3.1 Conceptual entities model

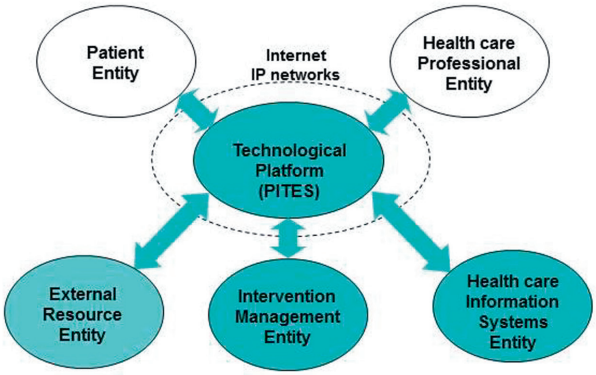
In the context of complex interventions it is fundamental to detect and make clear as soon as possible which agents participate actively in the intervention and its action and interaction mechanisms. Once the said active agents are detected it facilitates the definition, design, development, implementation, and evaluation process of the intervention itself. In this sense, the Chronic Care Model (CCM) [33, 34] from the aspects that propose on the organization, interaction and identification of actors, contributes a good orientation to carry out this initial task.

The CCM has been considered a general reference model on a global level that represents an organizational focus of the health care and tries to act as a guide for the

activities aimed at improving the quality and the management of the chronic health care. It is the most studied model and that which has accumulated the most evidence, in more countries and health systems, illnesses and patient collectives, and which have derived the large part of the organizational models and models for the provision of chronic health care that have been proposed. The CCM establishes that in any chronic patient care scenario three contexts participate or interact: society (with its numerous resources and public and private policies), the health system, and the health professionals and the patients as direct actors of the health care. It is established that the improvements in the results of the chronic health care comes to light by means of productive interactions between some informed and active patients and some prepared health teams together with a proactive attitude, which are promoted by the coordination of additional resources at a social and health level. In this sense, the CCM specifies six categories of resources: the policies and social resources, the organization of the health care, help to self-management, the systems of provision of health care and help in the decision and the clinical information systems. Thus, it implicitly establishes a classification of entities from which it is possible to identify the agents participating in the interventions aimed at an improvement in the chronic health care. The patients and health professionals are always active agents of direct participation in any intervention, and the rest of the resources are agents or optionally active subsystems (they do not need to be present in all of the interventions) that play a support or promoter role.

Taking the focus of the CCM as reference in the design process of the e-services, the PITES platform establishes a conceptual entities model that constitutes a user abstraction proposal, resources and their interactions. The model (Figure 5) is made up of six entities: patient entity, health care professional entity, external resource entity, health care information system entity, intervention management entity and technological platform entity. Each of the conceptual entities of the model represents a view or perspective of the health care provision model that is wished to evaluate by means of the intervention.

Figure 5. PITES conceptual entities



The patient entity encompasses the patient and all of the resources assigned to him or her for the intervention. The patient entity is usually made up of:

— A patient protocol usually consists of periodically carrying out biometric measurements (arterial pressure, weight, pulse, ECG, spirometry, lipid profile, activity, etc.), and replies to questionnaires on symptoms or actions.

— Some biomedical monitoring equipment for personal use (sphygmomanometer, pulse oximeter, scales, thermometer, etc.) or environmental monitoring, to carry out the measurements required by the patient protocol.

— Communications equipment to carry out the periodical sending of protocol information. The equipment must be suitable to interact with the interfaces authorized by the platform.

The health care professional entity represents the perspective of the health professionals and is made up of the series of tools and resources required to carry out the health care protocol established by the intervention. In general, it is applications adapted to the specific patient protocols by means of which the monitoring is carried out including help tools and functionalities that make an indirect communication possible with the patient (advice, warnings, etc.). These applications are usually accessible by means of the Internet with the appropriate access controls. The reply messages to the patients are sent by means of personalized services such as SMS, e-mail, interactive voice systems, etc.

The external resource entity represents any support resource additional to the intervention on the health or community environment. That is health centers, pharmacies, consultations, geriatric residencies, other platforms, etc. The function of this entity is usually to represent any infrastructure that acts as a resource shared between patients, because it supposes some type of logistic advantage (economical, location, etc.). They can act as external resources, for example:

— Residential homes, in which there is the possibility of attending the patients collectively by means of shared equipment, for example, patients with oral anticoagulation therapy who share the INR monitor and the communications equipment. The interfaces with this type of external resource may be applications based on the Web, designed so that a person responsible manages the patient collectives.

— Platforms for external monitoring that receive information of specific patient collectives, for example, a collective of patients with implantable cardioverter-defibrillator (ICD) monitored from a platform that authorizes the company providing the ICD. In these cases, the interface would be based on specific "middleware" that makes it possible to interoperate with the said external platform.

The health care information system entity essentially represents the Electronic Clinical Records of the Patient and the perspective from the health information systems. The function that this entity contributes is that of making it possible to exchange clinical information on the said systems and the ECR essentially summarized clinical information generated by the patients and health professionals during the interventions. The interfaces with the ECR entities are based on "middleware" specific to interoperate with the said information systems in accordance with standards.

The intervention management entity supports a series of roles and resources that are required to carry out the intervention and that are not available or cannot be carried out suitable either by the health system or the community. The services provided by this entity are of two kinds:

— Support to the deployment of the intervention: it provides resources to make it possible to train the health professionals, patients, families; resources for

the maintenance and management of the equipment used; tools for the monitoring of the compliance with patient protocols, etc.

— Support methodology of the experimental evaluation study: it provides resources for the support methodology of the clinical trials and experimental studies. For example, drawing up and management of the documentation (Case Report Forms), applications for the Electronic Data Capture, services for the centralized randomization, recompilation and analysis of results, among others.

The Technological Platform Entity represents the ICT nucleus that supports the functional interfaces, the coordination of activities and finally the telematic infrastructure that require the interventions to be implemented during its evaluation. The services provided by the platform are provided mainly by means of the Internet, digital cellular networks or basic telephone network; the architecture of the platform is described in the following section.

When it is desired to evaluate the health care provision model with the support of the platform, the steps to be followed are as follows: define the intervention that leads to the practice of the health care model and the experimental evaluation study (type of study, variables, measurement instruments, dimension of the study as regards the sample and duration of the intervention, etc.) and define and design the new e-service which will give support to the intervention. To carry out this second stage, the actors involved must be determined (direct and indirect); this datum will establish the entities of the conceptual model that participate. Below, from the perspective of each of the participating entities, we have to establish:

— the specifications of the interfaces, applications and services based on the roles that each participant contributes in the health care process,

— the interactions with the patient as subject of the health care and their environment,

— the temporary aspects of the provision of health care,

— the organization and management of the health care, the aspects of support to the decision and monitoring of the activity, and

— the aspects related to responsibilities, flows and management of the information.

Finally, the provision model establishes an organizational and functional framework to which the intervention and experimental evaluation study must be adapted, to be able to carry out a joint deployment which may be supported by the PITES technological platform, and therefore develop it in the context that establishes that of the evaluation methodology.

1.3.2 Architecture

As has already been said, the PITES platform is a platform or research, not a support to health care activity in “clinical routine”. As a research platform, its design responds to some requirements that are additional to those adopted by the platforms oriented to “clinical routine” and which condition architecture decisions.

The platforms oriented to “clinical routine” must provide greater attention to aspects such as scalability maintainability and availability. The research platforms, also:

— Must be conceived from their basis in order to change, evolve and interoperate;

— Must contemplate intrinsically evaluation mechanisms in the widest sense, and
— Must be capable of coexisting with the "clinical routine" platforms to make the mutual interaction possible together with the progressive implementation of e-services.

Under these conditions, the requisites demanded by the PITES platform and which constitute the references for the design of its architecture, are as follows:

— Functionality independent of the technological infrastructure of the environment in which the e-services are going to be deployed: the platform must guarantee some homogeneous functional deployment conditions during the evaluation of the interventions, especially on those that imply geographical dispersion so as to be more sensitive to this aspect.
— Scalability: the platform must be capable of supporting from small pilot projects and concept trials, up to multi-centered interventions that involve hundreds of users (patients, professionals, etc.).
— Dynamism and flexibility: the platform must have the capacity for rapid adaptation and evolution, the incorporation of new functionalities and the reuse of components, incorporation of technological opportunities, etc.
— Operative transparency in the access and location of the resources: the platform must deploy the services in such a way that they are perceived by the users as incorporated or integrated in the socio-health care. This requirement is of greater relevance during the evaluation phases on clinical effectiveness. In the said phases, the platform must not constitute an element that commits the validity of the studies.
— Interoperability: capacity to interoperate with heterogeneous components, distributions, inherited, other platforms/devices. The interoperability is contemplated in a wide sense (syntactic and semantic level) and tied to the conformity with standards.
— Robustness, safety, maintainability and high availability: just as in a clinical routine use, the platform must maintain operating production conditions in experimental studies whose interventions can be extended for months, even years, as well as having the capacity to support multiple interventions simultaneously.
— Conformity with international standards and developments based on "open-source" software: both as recommendations of the European interoperability framework and of the WHO for e-health [35]. Conformity with standards is an essential element to have generalizable and interoperable solutions, as well as a promoter factor of the success in the implementations and a reduction in costs. Questions related to the standard in the exchange of data (ECR), and the interoperability between platforms/devices must be attended to.

These requirements are currently completely reachable by means of available and mature technologies such as:

— The Web technologies as a series of services associated with the Internet for the provision of e-services to users and interoperability support;

— SOA as an architecture paradigm to implement open systems and distributed services.

— The "Cloud Computing" model, as a paradigm for the provision of services and technologies through the Internet, which in collaborative research environments such as PITES, allows the platform to be able to act as a "hub" for the dynamic provision of services.

— A basic Internet network infrastructure based on the current convergence of the ubiquitous provision of services on IP networks.

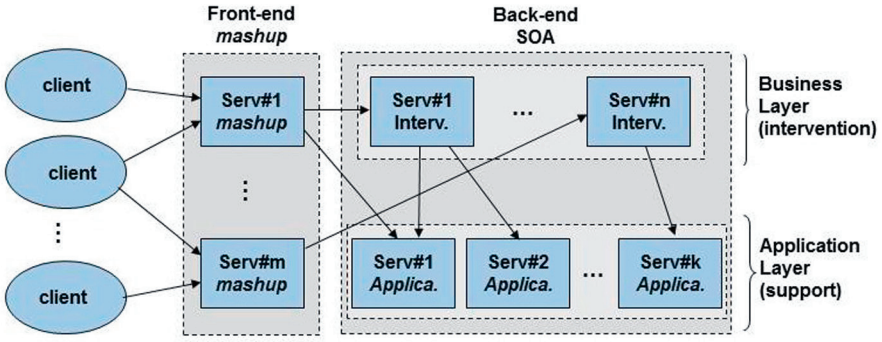
With the support of these technologies and from the requirements, the platform has been designed as an open system of distributed services on communications based on the IP protocol. Any e-service supported by the PITES platform adopts an architecture oriented to services (SOA) and design paradigms established on the web 2.0: weak connection between services, interfaces based on "web-services", "hybrid" web applications (mashups), etc. As additional priority directives, the developments on the PITES platform must be based on "open-source" and obtaining conformity with international standards.

The architecture of the platform is distributed on two levels (see Figure 6):

— the "front-end" of the platform, that encompasses the interaction mechanisms of the platform with the users of the system, that is, the interfaces of the entities (people or other platforms/services), and

— the "back-end", which constitutes the heart of the platform in which the structure has been defined, integration, and interdependence of the internal components of the platform and those of the "front-end" components, that is, the support of the logic of the e-services that support the interventions.

Figure 6. Architecture of the PITES technological platform



The "front-end" interfaces are based on applications, services and protocols based on Internet and digital cellular networks and commutated telephone networks. The platform, has a base services to support these types of intervention by means of content, server, Web SMS gateways, IVR system(Interactive Voice Response), TTS services (Text-to-speech), services ASR (Automatic Voice Recognition), streaming server managers, etc.

The design of the platform in "back-end" adopts an architecture oriented to services in two layers:

— "Business layer", in which the functionalities/services specific to the support of the interventions, the business logic of the applications and services directly

linked to each intervention and which implement the requirements proper to them are deployed.

— "Application layer", where the additional services with functionalities of a special and specialized character and oriented to its use by the services of the "business layer" and of the "front-end" are located. The objective of this layer is to constitute an extendable, diverse and detached series of functionalities that give support to the e-services supported by the platform in the research projects. The provision of these services is transparent and with open interfaces based on "web-services" (SOAP and REST on HTTP/HTTPS protocols). These support services can be made public (beyond the PITES community) by moving the access interface to the "front-end" layer.

From the point of view of the users to whom they are aimed, the support services and applications for the platform are of two types: those directed to the users-person, that is, patients, health professionals, health carers/caretakers or families and support staff for the experimental studies, and those directed to the users-machine, that is, to other platforms, services or monitoring devices.

The architecture adopted for the user-person applications follow a "mashup" model based on three components:

— Client application, in the "front-end" of the platform, based on different technologies: WWW, WAP, J2ME, SMS, VoiceXML, accessible from commercial devices such as PC, conventional or mobile telephones, "smartphones" (Android), IP telephones, etc. These applications are located in the "front-end" of the platform.

— The "mashup" component also in the "front-end", whose function is the addition of information for the creation of enriched content destined for the client applications. These services interact with the providers of the content in the "front-end" and "back-end" by means of open interfaces based on Web services.

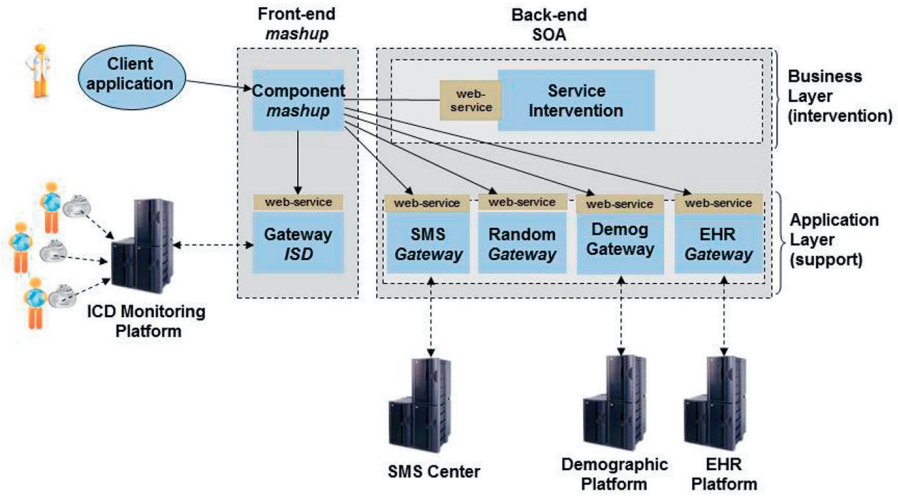
— The providers of the content, made up of the "back-end" services of the platform correspond to the intervention in the "business layer" or services of the "application layer". They may also be other services content providers located in the "front-end".

The services of the platform designed to interact with the user-machines are those directed at monitoring devices and external services platforms (health or non-health). They have a classic "middleware" architecture so as to eliminate heterogeneous points with the external entities, brought about by the manufacturer's or third-party software, networks or different community protocols. The "middleware" is implemented by means of "gateway" type services specific to each case. These "gateway" type services can be assimilated as new "application layer" services in the "back-end", so that in this way they are available to new services in the "business layer" or "front-end" applications and therefore for any e-service that requires it.

The following example is proposed to illustrate the functioning of this architecture, consisting of the architecture required for a remote activity monitoring e-service of ICDs (Figure 7). Imagine that we want to evaluate the clinical effectiveness of a remote ICD monitoring service by means of an experimental study. The objective would be to measure the possible improvement in the health results of a group of patients to whom this type of monitoring is carried out (intervention), as opposed to another group in which a conventional monitoring is based on hospital visits. We

suppose that there is a remote monitoring platform deployed by the manufacturer of the ICD that gathers the information generated by these devices and stores it in its information system (ICD Monitoring Platform). The health professional needs to periodically analyze the activity generated by the ICDs in the patients of the intervention group and combine it with other clinical information through other means. As well as this, the health professional needs to be able to send messages to these patients to give them advice, warnings, etc. As the study is framed within a clinical trial, the health professional needs to be able to carry out a random assignment of the patients in an flexible and safe manner before being included in the study as well as guaranteeing an anonymity of the identification of the patients every time it is necessary to get access to their demographic information by searching the information system of the hospital. Finally the health professional has to periodically send a summary of the clinical activity generated in the study to the ECR of the patients so that it does not become isolated in the platform that supports the intervention.

Figure 7. Example of the ICD e-service monitoring architecture



Within the framework of the architecture of the PITES platform, for the health professional, a client application would be implemented based on the Web to which it would be accessed securely (access control and HTTPS protocol). This application (client application) would be managed by a "mashup", component in the "front-end" of the platform that provides it access to the different sources of distributed data:

— a gateway service at the "front-end" based on "middleware" (Gateway ICD) which has the capacity to access an external monitoring ICD platform in such a way that from the client application client, the health professional can obtain information on the ICD activity of the patients of the intervention group.

— a gateway service in the "application layer" of the "back-end" (SMS Gateway) which permits the sending of SMS messages. This gateway service consists of a "middleware" which manages the transactions with the SMS Center of the mobile telephone provider.

— a gateway service in the "application layer" of the "back-end" (Demog Gateway) which permits access to the demographic information of the patients located in the information system of its organization. On the one hand, the "middleware"

accesses the said system by means of a proprietary protocol and, on the other hand, as regards the platform, it authorizes an interface based on the ISO-UNE 13606 standard that standardizes access to this information.

— a gateway service in the "application layer" of the "back-end" (EHR Gateway) which permits the sending of summaries of the clinical activity generated by the users during the intervention to the ECR of the organization. Once the clinical information is validated by the health professional, the gateway receives an extract in accordance with the a ISO-UNE 13606 standard by means of an interface based on Web services which contains the said information and which the "middleware" sends to the hospital information system through the established protocol.

— a service in the "business layer" of the "back-end" (Service Intervention) that established the operating logic of the intervention managed by means of data bases and processes aspects specific to the intervention.

— a gateway service in the "application layer" of the "back-end" (Random Gateway) which permits access through an interface based on Web services to a centralized randomizing service making the robust distribution of the patients in the two established assignment groups possible.

The application of the health professional has access to a specific service in the "business layer" (service intervention), to a specific service in the "front-end" (ICD gateway) and to four services oriented to general use within the "application layer" of the "back-end" by means of his or her "mashup" component. While the client application together with the "mashup" component´, the service located in the "business layer" and the gateway ICD, are specific to the intervention, the gateway services of the "application layer" are also resources accessible for any other intervention that supports the platform. As an additional element, it is evident that to carry out the implementation of the study, the minimum is to commit resources to be contributed to the structure of the health organization.

The SOA architecture of the PITES platform makes it possible for the services that are initially specified for an intervention to be able to be promoted to services of general use because of its interest, use, and functionality. The weak connection between the services through the Web services interfaces allows functionalities to be added or taken away with relative ease. Following the "cloud computing" paradigm, these services can be used and evolved for future experiments in the PITES community, even making them accessible to the global community. This possibility gives the platform a significant advantage in the promotion of collaborative research in this field as well as being able to put the progressive implementation strategies into practice so that the platform can act as a temporary support to platforms in "clinical routine".

1.3.2.1 Hardware component

The PITES platform has an autonomous functioning (without the need for operators) on a 24x7 regime. The platform is accessible through Internet by means of a redundant link and has the capacity to establish point-to-point VPN with other networks. In order to achieve this demanding working regime, there is a robust telematic infrastructure available in many of its components (communications, storage).

The platform consists at the physical level of a segmented Internet-accessible network including: 9 physical and virtual servers (Xen) on IBM xSeries equipment

over Linux OS (Suse Linux Enterprise); SAN/NAS (IBM N3600) redundant storage networks; backup library systems (TSM and IBM System Storage TS3200 Tape Library).

As basic support for e-services the platform provides a number of different general services: WWW service (Apache), DBMS (MySQL, PostgreSQL), applications managers (Tomcat), content managers (Drupal, LifeRay), "e-learning" server (Moodle), VoiceXML/IVR (VXI*/Asterisk) service, TTS/ASR (Verbio) engines.

The platform includes security elements at different levels: control access (physical and telematic) policies, (storage and communications) redundancy and monitoring tools (Nagios/Cacti).

1.3.3 Services

The specific services currently provided by the platform include

1.3.3.1 Messenger service

Telematic service accessible through the Internet which implements the possibility of sending short SMS messages, usually from the health professionals sent to the patients for notifications, warnings, advice, etc. The service interacts with the SMS Centers of the telephone operators via GSMs available on the platform.

Two conditions are demanded from the SMS service:

— that the SMS messages are delivered to the addressee and if not, get notification that it has not (together with the causes) and

— that the SMS messages are delivered after a certain period of time so that the validly of its content is not indefinite.

Obviously the SMS service offered by the GSM is highly reliable although none of the two conditions demanded can be guaranteed 100%. However, the SMS service has mechanisms available that make it possible to know the current state of the SMS messages together with the occasional incidents that could take place in transit to the destination terminal. The SMS Centers offer the possibility of sending reports to the sender on the progress of the SMS (DLR, Delivery Reports). By means of the DLR request by message, the SMS service of the central station is capable of knowing whether a message is still in transit, has been delivered to the addressee (with time and date of receipt), or not or has been eliminated (together with its cause).

Equally, the SMS service is capable of establishing the period of validity ("validity period") of each message, exceeding which, if it has not been delivered to the addressee, it instructs the SMS Center in order to eliminate the said message from its lists (accompanied by the corresponding DLR report). The period of validity chosen depends on different factors and can vary from just a few hours to several days; its choice for example, in the case of communications to patients, depends on the medical protocol followed in the specific scenario. However, it is not a critical aspect in other types of task, and the default expiry period is not extended.

Another limitation of SMS messages is the nominal limitation in the total number of characters that can be included in each message, and which is fixed at 160. This length is very limiting in the majority of notifications from the doctor to the patient. It is also impractical for the doctor to send consecutive messages to the patient referring to the same matter (one of them might not arrive or arrive in the wrong

order, etc.). However, there is the technical possibility of generating messages that are longer than usual ("long SMS" calls) and which are segmented at the origin and later reassembled by the patient's mobile telephone in a way transparent to the user, and therefore permitting the sending of arbitrarily long messages. This functionality is supported by the SMS service of the platform.

Functionally, access to the SMS messages server is carried out by means of the HTTP/SOAP1.1/1.2. "web-services" interface. In each request to send, the following is indicated: addressee of the message, text of the message, need for confirmation of delivery, period of validity and preferred time period for sending the message (or immediate delivery). Once the request is accepted a univocal identifier is generated with the service applicant and the sending procedure commences with an adjustment of the parameters of the message (establishment of the output queue, internal register, etc). The SMS service is in charge of sending the message through one of the available GSM modems. From the moment of sending the message to the corresponding SMS Center, the progress of the SMS is monitored through to the reception of the corresponding DLR. Before the arrival of each DLR message, the SMS messages server analyzes its content and notifies the state to the corresponding service that requested its sending in such a way that the state of the messages can be known at all times.

By means of a widely available mobile service, this service authorizes, by means of an open interface, a way of indirect communication between health professionals and patients with a high level of security (delivery security and range of validity), and personalization (flexibility in the size of the message and the establishment of the preferred period of time for delivery).

1.3.3.2 Randomizing service

Telematic service accessible through the Internet that implements support to the randomizing process of clinical trials in a centralized way. The service deploys the following functionalities:

— Simultaneous support to randomizing in multiple studies.
— Complete management of the randomizing process by the promoter of the clinical trial.
— Randomizing support in different modalities: simple, by block, stratified, centralized and blind.
— Assignation lists of up to 6 groups with the capacity for self-replication.
— Control of transactions to guarantee the integrity for the applicants of the assignation.
— Generation statistics of the randomizing progress upon request.

The service establishes three levels of privilege (overall administrator, project administrator, project user):

— The "overall administrator" user (level 1), has the capacity to create new projects and administer the functioning of the overall service; each project corresponds to a clinical trial. The process of creating a new project has the aim of authorizing the permission, structures and data necessary for its configuration in the service. Once the new project is created, the figure of the administrator "project administrator" already associated to a specific study is established.

— The "project administrator" (level 2), has the capacity to create the structure of the process of randomizing the clinical trial: total sample, number of assigned groups (identified successively by: A, B, C, D, E, F), variable block sizes (multiples of the number of assignation groups), and the stratification tree (if required). The "project administrator" has the capacity to open/interrupt/close the randomizing process, and request progress statistics on the randomizing (overall, by time intervals, by stratum, etc.)

— The "project user" (level 3), whose function is basically to request the assignments to groups in a specific study.

The service does not establish limits on the studies in relation to the total number of stratification levels. A random assignment list is generated for each stratification branch with as many assignment groups as have been established to guarantee the assignment balance in groups of varying sized blocks. Each randomizing request that the service carries out is associated to a transaction identifier which the service may propose or generated dynamically, in such a way that it is possible to control each assignment individually in relation not only to the activity register but also the recovery in real time of errors in the process. The randomizing service includes internal functionalities for the register of auditing in each clinical trial. In relation to the generation of the project and the assignment tables, the randomizing seed is stored which makes it possible to guarantee the integrity of the assignment lists and their reproduction. It also generates a series of daily files on the degree of activity and functioning of the server, created and updated dynamically by date/time/project/user access/action carried out.

The service is accessible through an interface based on Web services by means of the SOAP (1.1/1.2) protocol and transport on the HTTPS service. This randomizing service has the advantage of basing its functionality on an open interface for the integral management of the process. This approximation makes it possible to promote the clinical trial, design and develop client applications in the measurement of their requirements and resources, incorporating the randomizing process transparently as another element/service in the management of its clinical trial.

1.3.3.3 Clinical information service

Telematic service which stores and retrieves clinical information compliant with the UNE-EN ISO 13606 standard. In is based upon a web services structure with two groups of functionalities: the input of information and its querying/retrieval. The input of information is performed through an interface compliant with part 5 of the standard which accepts extracts codified in XML. The service processes the received information before storing it in order to obtain features which permit to classify it and enable its ulterior querying and retrieval. To do so for one side complete extracts are stored (preserving the integrity of the information) and for the other a relational database is built where the obtained features are kept in order. The querying/retrieval of information presents three options:

— Querying of the information through a graphical interface: the user, after identification, has access to a browser which permits him or her to navigate through the information, but only to that part on which it has permissions depending on his/her role (access control compliant with part 4 of the 13606 standard). This functionality makes use of the archetype server service in order to obtain those used in the generation of the information and be able

to present the data in a complete manner and in the language or using the terminologies desired by the user (if they are defined and mapped in the archetype).

— Retrieval of a patient's information: web service which permits to request a given patient's information using an interface compliant with part 5 of the standard. Through this service the user can request (utilizing other application, service or system) the whole information stored in a person's record or a part of it, obtaining an extract with the requested compositions and complaining the corresponding access restrictions.

— Information queries: the service also offers the possibility to pose specific queries oriented to the statistical processing of the total population in the repository and yielding numerical results about prevalence of diseases or concurrence of problems.

1.3.3.4 Archetype repository service

Telematic service which stores and retrieves archetypes compliant with the model established in the standard: archetypes are transferred in text files codified in the ADL language and using an interface compatible with part 5 of the 13606 standard. The system stores archetypes according the reference model normalized in part 2, which enables to perform searches using any identification data or any state of the archetype and also through the meaning of the nodes (specified as restrictions to the RECORD_COMPONENT class of the reference model of the extracts) defined in it. The retrieval/querying of archetypes permits two possibilities:

— Retrieval of archetypes: following the specifications of the interface defined in part 5 of the standard this automatic service enables to retrieve archetypes through its identifier, concept, terminology, language or those that are specializations or have been specialized by another archetype. This service is oriented to its use by other services, applications or even other external systems.

— Archetype querying: the server offers a web graphical browser for users to navigate through the archetypes repository; to query them through concept or type; see their specializations and download them to be used in their own projects.

Following the philosophy of the double model in the standard, this service permits the archetype querying in an open fashion.

Demographic information service: this service stores and provides demographic information of the entities involved in the clinical information systems. It is based upon the demographic information model included in the reference model of part1 in the standard; this permits to deal with persons (patients and health professionals) and also with organizations or devices and programs in use. This service keeps track of all the identifiers assigned to each entity, including official entities but also those assigned internally by organizations, for instance in specific projects. This working method allows to separate demographic information from the rest of data facilitating to make information anonym. For security reasons this service is not accessible from the outside of the platform so that its possible clients may only be its running applications or other supplied services.

1.3.3.5 Anonymisation service

This service enables to make anonym clinical information to be used in secondary uses such as research or statistics. This service accepts and returns extracts compliant with the standard reference model, codified in XML. Received extracts are analyzed to suppress the identification of the patient including demographic information codified in class IDENTIFIED_ENTITY of the reference model, even though the year of birthday (not including day and month) and the sex of the patient may be preserved for statistical purposes. To do so, a new randomized identifier is assigned and substituted in the extract. This service makes use of the demographic service in order to maintain a record of the identifiers in use so that if further information about the same patient arrives its identifier can be assigned and the health information repository remains coherent. For this reason it is possible to install this service and the demographic service in the client side so that the information about the person does not leave the organization where it was generated and the clinical information is presented anonym to the outside world.

1.4 CONCLUSION

This chapter shows how an infrastructure composed of an open systems technological platform and an interdisciplinary team of technologist researchers and health and social sciences specialists aimed at research groups and public and private organizations and entities as described in the Description section can support simultaneous telemedicine-based services deployment in order to obtain evidence through the execution of experimental studies in chronicity and associated disabilities-related health care provision scenarios such as those presented in the Results section.

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CHAPTER 2.

SERVICIO ARAGONÉS DE SALUD: RESULTS OF PITES PROJECT ON SOCIAL AND HEALTH CARE FOR CHRONIC DEPENDENT ELDERS IN ARAGÓN

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Index terms: Health and social attention, chronics, health innovation, e-health, innovation platform, telemonitoring.

ABSTRACT

Objective: to design, develop and evaluate a protocol for an integrated health and social care for chronic dependent elders living in the Barbastro's Health care Sector geographical area that enhances their quality of life and that is aligned with the Servicio Aragonés de la Salud strategy of promotion of telemedicine solutions and innovation in e-health services.

Methods and Procedures: A randomized control study has been performed to compare the new benefit and with the classical assistance on patients meeting with the inclusion criteria. The evaluation of the service has been carried out according to 4 main pillars: its impact on the clinical activity, quality of life, economic and user's satisfaction.

Results: This mixed, social&health, provision of telemonitorization services has a positive impact on the user's satisfaction and a potential benefit in the subjective user's mental health and health care organization's costs; being the contact centre staff a key factor for the evaluation of the benefits who turn the subjective frequentation into objective. But, longer pilots, bigger participant sample and the empowerment of patients would be needed for a deeper evaluation and stronger conclusions of the impact of these services on the user's quality of life and economic benefits for the organizations.

Conclusions: The inclusion of ICT in health services permits the innovation in new processes and e-health services with a clear improvement of the quality of care perceived, as well as serving the organizations to enhance their systems and services, with an optimization of time and resources that may, under certain conditions, affect to the sustainability of the welfare, social and health systems.

Clinical Impact: The new service using the technological platform permitted us to identify the impact on the clinical status of the chronic patients easing the early

diagnose of decompensations of the pathologies in study (COPD, Diabetes Mellitus, MIA and CVA) and identify new pathological findings thanks to the telemonitorization of vital signs.

2.1 INTRODUCTION

With the rise of the life expectancy and the increase of the number of chronic patients it has become mandatory the emergence of new models of integrated care that enhance the permeability among assistance levels. These models are motivated by new care models (including the control of the quality of the assistance) relying on the possibilities that the Information & Communication Technologies (ICTs) offer; as remote access to clinical records, analysis and visualization tools of clinical data and telemedicine. These new procedures provide collaborative environments for health agents and patients using electronic means that ease the required control of the quality of the services, the continuity of care enhancement, the adherence to treatments, avoid the adverse effects and the economic quantification of the health care costs.

Chronic citizen's requirements have changed in quantity and quality demanding, which forces to adapt the health care organizations to satisfy these new care requests. Moreover, the number of patients with chronic diseases associated to a certain degree of dependency is increasing and requires a special and more specific care to maintain a respectable social life without being marginalized by the society. In addition to these, there are new demands and needs originated by the knowledge improvement and the enhancement of the quality of life.

So far, the health care systems have not tackled, on a specific manner, the attention to chronic dependent patients. The situation is believed as a threat to the system due to the saturation of the services, especially those of the stays at health care centres, instead of a challenge to face offering solutions through a specific basket of services.

Within the Barbastro Health care Sector, the demand of health care attention required by the elder population is enormous, in part as in Spain health is the main worry for elders. The rate of hospital admissions of 60 to 75 years-old people doubles those of the population under that age and it is tripled when over 80 years, confirming that stays are each time longer and the number of readmissions higher. The rate of readmissions sets the evolution after the hospital care, and is therefore an indicator of the quality of the assistance; taking into consideration that programmed admissions or due to other causes not related to the previous admission are not taken into account.

At the same time, in our environment, there is evidence that patients suffering from multiple diseases, including a combination of chronic illnesses and psychosocial conditions, are the ones than frequent most the care services, have more preventive hospitalizations, present more functional limitation in their daily activities, a deterioration of their welfare and quality of life, and report worse health states.

In this framework is placed "PITES T-AYUDA" project which is part of a coordinated nested project of researches in the evaluation of health technologies and e-health services, which has the objective of designing an integrated service of health and social assistance for chronic elder patients. Thanks to the Information and Communication Technologies (ICTs) several technological solutions of personal mobile

telemedicine and e-health support will be developed; which are required for the practical execution of the change towards new models of health care attention for these types of patients. The new integrated social and health assistance is compared against the classical care through the realization of a prospective randomized case-control study (RCT) with ICTs as supplier element. At first, the results expected on the group enjoying the new service are an enhancement of the health status and quality of life together with a decrease in the consumption of the classical care services. Reason of equity in the access to the health resources, sustainability of the public health care system and a search for the excellence in the quality of the services offered have inspired the Barbastro Health care Sector in the design of this project.

2.2 OBJECTIVE

The main goal of the project is to design a service of integrated (social and health) attention targeted to chronic dependent elders through the preparation of a medical and social protocol of the home-telemonitorization service and through the piloting of this new benefit, comparing it with the classical care. Secondary aim is the evaluation of the impact of the service from a clinical, social-economical and user satisfaction points of view; and, as final goal, to enhance the quality of life of chronic dependent elders.

2.3 METHODS AND PROCEDURES

Type of study: To that end, a home telemonitorization of vital signs pilot was designed for a group of patients with the aim of comparing it with the classical assistance, through a randomized case-control study.

Geographical characteristics: Searching for bringing health services to the most disadvantaged environments in terms of communications, two populations were engaged within the geographic area of the SALUD, without continuous direct access to health services. This is the case of the populations Esplus and Albelda, which have health cabinets with intermittent service, depending on the Binéfar & Tamarite de Litera health care centres.

Timeline: The project had a duration of three years to perform the tasks of definition, protocol design and preparation of the new benefit. The pilot was run for 12 months, from February 2012 to February 2013, and the last stage has been dedicated to the evaluation, the comparison of cares and conclusions.

Inclusion/exclusion criteria of patients: Two groups were defined; the intervention group that would enjoy the new care and the control group (with classical assistance.) Groups were formed randomly, given criteria of age, sex, and pathologies suffered. Therefore, 36 patients were recruited for the intervention group and the same number in the control group. Both groups were compliant with the inclusion criteria of being older than 65 years, in a dependency situation, living in the geographic area of Barbastro's Health Sector, and suffering from at least 1 of the following conditions: Diabetes mellitus, heart failure, story of acute myocardial infarction or cerebrovascular accident (CVA) or chronic obstructive pulmonary disease.

Exclusion criteria for participants was the fulfillment of one of the following cases: patients with marked clinical instability (defined by two or more hospital

admissions or three emergency room visits in the three months prior to the trial), patients suffering from any disease that the researchers may believe to be incompatible with the participation on the study, patients with a life expectancy of less than six months or patients that do not provide consent.

Patient's recruitment and size of groups. Drop-outs. The identification of patients was performed by referring to the clinical records through the recommendation of the medical staff of the health centers involved on the pilot.

The intervention group was made up of 36 people (22 women and 14 men). There were six drop-outs during the life of the project due to exitus and were replaced by new entrants. The average age of the group was 85.64 years, with a distribution of the pathologies as follows (15 DM, 29 CI; 11COPD, 16 MI, 12 CVA).

The control group was made up of 33 people, where there were 3 exitus, with an average of 86.9 years. Is was formed of 20 women and 13 men with an equal distribution of pathologies as on the intervention group.

The health care provider. Health care professionals. Contact centre. The Servicio Aragones de Salud- Barbastro Sector, has been the health care provider responsible for the PITES T-AYUDA project and its definition, piloting and evaluation, providing its personnel and infrastructure available for the project. Two Primary care doctors and two nurses from the health care centers of Binéfar and Tamarite de Litera joined the project. The contact center was located at the Emergency's unit at Barbastro's Hospital, and was composed of a dedicated nurse with the responsibility of the alarm management. The Hospital's Emergency Unit and the continuous attention units of the Binéfar and Tamarite health care centres. IT Department of the Hospital was also involved to resolve the technological incidents.

Volunteers and third sector: organization and teams. The socialcare provider has run a key role on the development of the pilot. The Spanish Red Cross participated with the Huesca regional Delegation, involving two local Assemblies located in Tamarite and Binéfar. These assemblies have formed 5 teams of 15 volunteers with polyvalent profile, who have participated in the home visits and constants' taking.

The technology: Technology has been provided for a smoothly operation of the pilot. The pilot service was integrated into the IT infrastructure of the SALUD by sharing the corporative information systems and those of the Barbastro Health care Sector. Furthermore, a telemonitoring portal was developed that permitted the reception and recording of measurements, the parameterization and customization of alarms, and the alarm management. This portal was used as the primary working tool of the Contact Center.

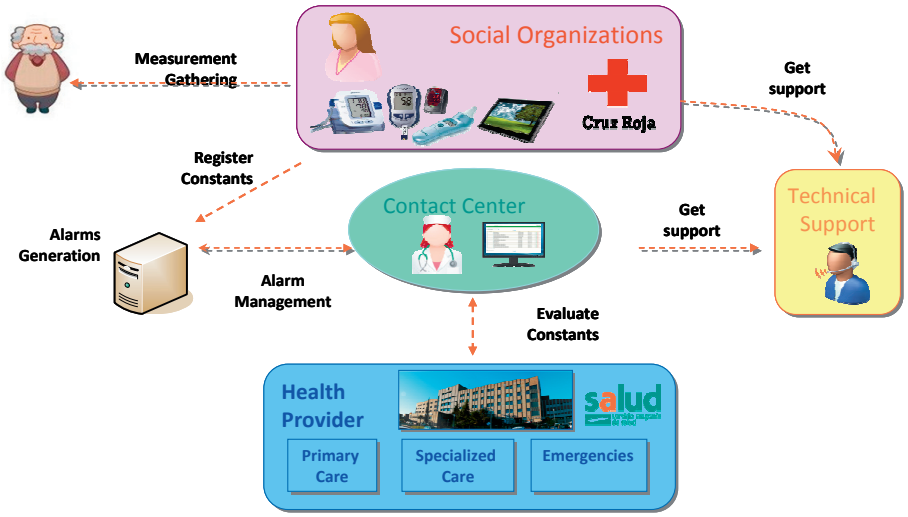
The Red Cross volunteers carried several backpacks with technology and biomedical devices, to help them in the gathering of vital signs. These backpacks contained: a smartphone tablet, a tympanic thermometer for the temperature, a glucometer to measure the glucose in blood, a sphygmomanometer to measure the blood pressure, a pulse oximeter to check the oxygen saturation and an electrocardiograph (ECG) to make electrocardiograms. All these devices are provided with Bluetooth technology.

Methodology or Procedure: Patients were visited on a weekly basis by Spanish Red Cross' volunteers from the villages involved on the pilot (Binéfar and Tamarite) who attended the elders' homes to take their vital signs. These volunteers carried the

backpack with several technological devices. Red Cross volunteers were trained in the use of biomedical devices and good practices in the vital sign taken procedures. Blood pressure measurements, temperature and pulse have been taking on a weekly basis, and an electrocardiogram performed once a month. Capillary blood sugar checks have been made to diabetic patients once a week.

The measurements were transferred through wireless communication technologies to the tablet.

Figure 1. Method



After the reception of the values and the assignment to the patient, these results were sent to a portal where they were recorded.

The platform that registers the data permits to generate alarms based on personal parameters defined by each patient, according to his clinical story and values of normality. Then, if a measure is out of the normal thresholds for a patient, the portal generates an alarm, alert or severe, that will be communicated to the staff in the contact centre, according to its seriousness, via an electronic mail or an SMS.

The contact centre is made up of health care professionals that check the measurements and values taken and the alarms, evaluate them and assess the need of taking additional actions to provide a personalized and immediate attention to the patient; by mobilizing resources, addressing the patient to health care centres or sending ambulances in cases of emergencies. For that intent purpose, the contact centre relies on the conversations with the patient, with the volunteers that took the vital signs and with the staff in Primary Care that are usual health providers for the patient. The contact centre professionals do not substitute, in any case, the patient's health care provider.

2.4 RESULTS

The project was evaluated from the point of view of four main approaches to test the impact on different areas of performance of the pilot. First we evaluated the impact of the new benefit in the clinical activity and the health care services'

consumption. Secondly, we evaluated the pilot users' satisfaction, both patients' and stakeholders' involved in the provision of the new assistance. Then, we assessed the impact on the quality of life of the patients and finally an economic study was carried out to quantify the benefits and costs associated.

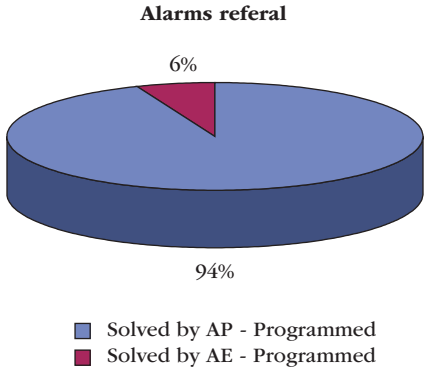
2.4.1 Clinical activity

Patients with multiple comorbidities have a large attendance to health care centers, which automatically results in a high consumption of health services. At the same time, these consumed services are more and more important as the clinical condition of the patients worsens, situation quite foreseeable in patients suffering from multiple pathologies.

One of the first findings was that patients on the intervention case were not always fully stabilized, so thanks to the new provision primary care doctors could achieve the clinical stabilization of their patients. Moreover, during the first period of the pilot there is an increase of the frequentation to primary care services until participants get used to the new model. In order to reduce this initial attendance several aspects are key, as the confidence of patients in the new care, of social agents' in their ability to perform vital constant-taking, and of health professionals' in the technology and in the volunteers who collect the constants. Once that phase of mistrust disappears, that makes patients go to the health center to check if their measurements are correct or distrust of nurses who go to homes to check if volunteers have taken the constants correctly, it has been shown that assistance to primary care reduces. Similarly, patients who regularly visited Primary Care consultations did not need to attend so often, unless they have had decompensations, implying an objective attendance to Primary Care, where the act occurs in cases where the care is really required. This manner the new service permits to filter the activity started only by a subjective perception of need of the patients.

We could also verify the importance of the pathologic profile and condition of the patients in the frequentation, e.g. patients with OAT, whose partial frequentations can not be avoided.

Figure 2. Alarms



With respect to Specialized Attention, it was found out that the number of consultations to specialized care due to the pathologies under study is much lower in the intervention group than those on the control group. For hospitalizations, the number of admissions in the intervention group was slightly lower than the control

group, although longer stays. Instead, the visits to the Emergency unit at Barbastro's Hospital are largely lower in the group with the new provision.

The contact centre has managed 646 alarms in the period of intervention, with a final distribution of 1.59 alarms/day type I (alerts) and 0.18 alarms/day type II (severe alarms). This distribution means 48.41 and 5.34 alarms/month type I and type II respectively. These figures permit a proper planning of resources dedicated to the contact centre. Of these alarms only 64 required attention by the health care services by redirecting patients to primary care centres, with 32 planned acts and 30 urgent. 94% of these alarms have been resolved at Primary Care.

2.4.2 Users satisfaction

To assess satisfaction of the participants in the project we conducted ad-hoc satisfaction surveys to patients, health professionals and volunteers of the Red Cross at the end of the pilot period. These questionnaires were answered by all participants and completed autonomously. The questionnaires collected the opinions regarding the new feature, the technological equipment used and the data-processing portal available for health care professionals.

Results showed a complete satisfaction of the users considering as main benefits the feeling of security to be controlled, reduction of visits and trips to the health centre, and the service provided them sense of tranquility and companionship.

The Red Cross volunteers greatly assessed the service in terms of performing a new care for the elderly, which gives them security. Biomedical devices are considered easy to use and maintain, and have been widely accepted despite acknowledging some initial malfunction. Also it is been highly appreciated the training program performed to teach the equipment use, and the ease of access to the contact point in charge of solving technological troubleshooting.

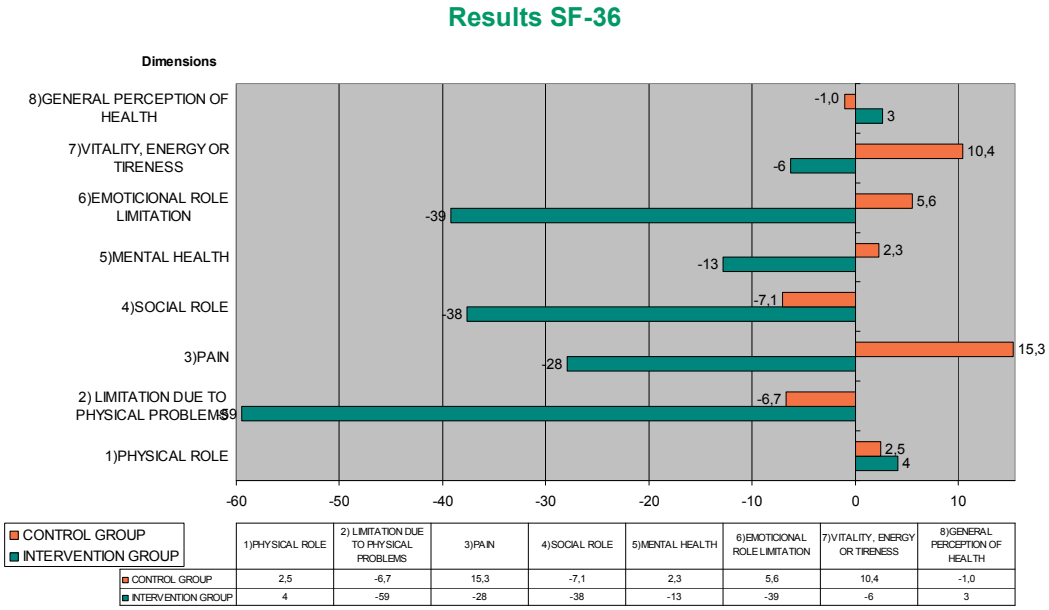
Health care staff valued the service as, primarily, improves the quality of care. It is also appreciated that the service allowed more control over chronic diseases, promoting early detection and intervention of decompensations.

2.4.3 Quality of life

The patient's quality of life was tested by performing health (SF-36) and anxiety and depression (HADS) questionnaires. The results of SF-36 show that, despite there are improving trends in the domains of physical limitation, social role, mental health, bodily pain and vitality & energy in the intervention group, no significant differences could be found statistically between the intervention and control groups. A larger sample would be required and longer piloting periods to obtain clear conclusions.

Regarding to the anxiety and depression status, there is a decrease on the cases of clinical problems in both groups. This decrease can not be attributed to the effect of the introduction of the new benefit, but to the screening performed in all patients at the beginning of the pilot period, since when executing the questionnaires the clinical cases were identified and therefore, treated. In depression, there is an increase in the clinical cases in the control group, which may be attributable to the normal evolution of the patients' mental state due to the usual age deterioration.

Figure 3. Gráficos comparativa SF-36



	1)PHYSICAL ROLE	2) LIMITATION DUE TO PHYSICAL PROBLEMS	3)PAIN	4)SOCIAL ROLE	5)MENTAL HEALTH	6)EMOTICIONAL ROLE LIMITATION	7)VITALITY, ENERGY OR TIRENESS	8)GENERAL PERCEPTION OF HEALTH
CONTROL GROUP	2,5	-6,7	15,3	-7,1	2,3	5,6	10,4	-1,0
INTERVENTION GROUP	4	-59	-28	-38	-13	-39	-6	3

2.4.4 Economical

To evaluate the economic impact on the health organization an analysis of cost / benefit was performed. The costs quantified were those associated to the health services consumption in both groups and the technological investment needed to provide the new benefit for the intervention group.

Figure 4. Detail of health care cost

HEALTHCARE COSTS	Intervention Group	Control Group	Best scenario (Alarms)
Admission costs	59.595,00	54.800,00	59.595,00
Emergency costs	2.448,00	3.536,00	4.080,00 €
GP consultations costs	70.047,18	74.935,53	3.565,62 €
Nurse consultations costs	8.874,21	6.238,42	
Specialized care costs	469,00	2.278,00	469,00
Costes Totales	**141.433,39**	**141.787,95**	**67.709,62**

With regard to the health care costs, the impact on the primary care and specialized care was measured. The table shows a breakdown of costs for each item and it is shown that there are no big differences between the two groups.

Figure 5. Detail of service cost

Service costs		
Technology	**Cost**	**Cost charged to the project**
1 kit (tablet + monitor + licence for 20 patients)	3.900,00	780€ (depreciation)
3 kits (tablet + monitor + licence for 50 patients)	11.875,00	2375 (depreciation)
Bags	216,00	216,00
Call centre-Server	5.000,00	5.000,00
Operative costs		
Glucose stripes (Fb 2013)	254,00	254,00
Glucose stripes (My 2012)	254,00	254,00
Communications	0,00	0,00
Technological incidences	83,44	83,44
Call Centre- Staff	35.721,64	11.907,21
Call centre- User licences	2.520,00	2.520,00
Call centre- Communications	180,44	180,44
Training		
Training (by healthcare professionals)	113,76	113,76
Total Service Costs		**23.683,85€**

To provide the telemonitoring service, the Servicio Aragones de Salud has undertaken the investment in technology for the purchase of equipment, biomedical devices and servers to host the portal. Other costs are the operating costs for the commissioning and maintenance of the call center, licenses, software and consumables. Lastly, the investment in capacitation programs required for the training of Red Cross volunteers. The technological investment is only attributable to the treatment group.

Figure 6. Total costs

Total Costs	Intervention Group	Control Group	Best scenario (Referred Alarms)
Service Costs	23.683,85 €	0,00 €	23.683,85 €
Healthcare Costs	141.433,39 €	141.787,95 €	67.709,62 €
Total Costs	**165.117,24 €**	**141.787,95 €**	**91.393,47 €**
Service Cost per patient	789,46 €	0,00 €	789,46 €
Healthcare cost per patient	4.714,45 €	4.726,27 €	2.256,99 €
Total cost per patient /year	**5.503,91 €**	**4.726,27 €**	**3.046,45 €**

Technology applied to existing health services enables organizations to obtain benefits when the environment is suitable for it to be applied. This environment entails empowered patients in managing their own health and qualified to assume a new active role, with a climate of trust between users, volunteers and health workers, where the demand of health services is objective (filtered by the contact centre) rather than subjective (started by the patient). In these environments an increase of expenses of 16.5% is turned into 35.5% savings per patient per year. The challenge is to create the ideal environment and promote the empowerment of the society.

2.5 DISCUSSION

The realization of the project and the development of the service have permitted to identify the key strengths, strong points and weaknesses to improve on the future. First, the study methodology chosen was a randomized clinical control-cases trial. Although initially the groups are created alike, this homogeneity is lost as the time goes by and the logical worsening of patients occurs. The emergence of other diseases means an imbalance of the groups (affecting the comparability), and has also a clear effect on the health of the patients and the health care services consumed.

The number of participants has been limited, 36 participants in each group, which impedes to obtain clear and convincing conclusions due to the small sample. Likewise, it is been observed that the technology allows, thanks to the constant monitoring, the early diagnose, improves the quality of the care and the stabilization of patients. But, also due to the short duration of the pilot, we could not prove the enhancement of the health outcomes, improvement of the quality of life and impact on the attendance to health services, not reflecting the mid term benefits of the changes of habits and the profitability of the transfer of low value health care tasks to the third sector.

Finally it is important to remark that only direct costs derived from the clinical frequentation have been taken into account on the economic evaluation. Indirect costs that mainly affect the control group have been left out (journeys costs, companion's hours, etc...)

2.6 CONCLUSION

ICTs permit to develop new technological telemedicine solutions that make possible the integration between the social and health attention targeted to chronics and dependent elders.

New health and social services will be supported on three pillars; 1) the monitoring of vital constants and its management by the health care services 2) a proper management by both providers —social and health— of the patient's home-generated information and 3) the adoption of a new more skilled role by socialcare professionals that are currently conducting home visits.

The telemonitoring services, with the participation of the social partners in the vital constants gathering, have allowed the transfer of low-value health competences to the social environment. Thanks to exhaustive monitoring of patients it is been improved their stabilization, promoted the early diagnose and improved the quality of care. The frequentation has moved from subjective to objective and from urgent to scheduled, releasing Specialized Care from consultations and emergencies visits. At the same time, the pilots would need longer periods of testing and bigger samples to quantify the economic impact on the consumption of health services.

In addition, patients and professionals agree when pointing out the improvement of the quality of the care perceived.

2.7 ACKNOWLEDGMENT

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CHAPTER 3.

HOSPITAL CLÍNIC DE BARCELONA: DEPLOYMENT OF INTEGRATED CARE SERVICES SUPPORTED BY INFORMATION AND COMMUNICATION TECHNOLOGIES (ICS-ICT) FOR CHRONIC PATIENTS

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Index Terms: Coordinated Care, Chronic Diseases, Co-morbidity, COPD, CHF, Type II Diabetes, eHealth, Frailty, TeleHealth.

ABSTRACT

Objectives: To assess the deployment of four Integrated Care Services supported by Information and Communication Technologies (ICS-ICT) in a urban health care sector (540,000 inhabitants) aiming at generating efficiencies in chronic care management at health system level through the transfer of complexity from hospital to home-based services driven by primary care. To develop an ICT platform supporting the four ICS-ICTs and to identify strategies for regional deployment of the services.

Methods and Procedures: The four ICS-ICTs assessed were: i) Wellness and Rehabilitation (W&R) with 173 COPD patients included in a pragmatic 2-yrs follow-up study design; ii) Enhanced Care for frail COPD, wherein a total of 950 patients were included in the 3 different protocols (155 of them in one RCT); iii) Home Hospitalization and early discharge, where 2,314 patients presenting acute episodes of a variety of diagnoses were assessed, using a pragmatic approach, as part of a real service; and, iv) a program supporting remote diagnosis and therapy, which included 7,000 patients in 4 different RCTs. Moreover, an open Health Information Sharing platform (i.e. Linkcare®) was developed and evaluated using the Model for ASsessment of Telemedicine applications (MAST).

Results: Efficacy or effectiveness, complementariness and high degree of transferability of the four ICS-ICTs were proven. The ICT platform showed usability, acceptability and efficacy to support the four ICSs. Technological adaptations required for regional deployment and strategies to achieve interoperability at health system level were identified. Novel reimbursement schemes based on bundled payments and shared risks among actors were proposed. The novel business model relies on the potential of ICS-ICT to generate efficiencies at health system level thus facilitating investments on ICT innovation with no further increases in total health care costs.

Conclusions: The positive outcomes of the four ICS-ICTs supports adoption of the coordinated care approach for chronic patients and confirms the role of ICT supporting those services. The results foster regional deployment of the ICS-ICTs assessed in the project.

3.1 INTRODUCTION

Population ageing and changes in lifestyle are central factors in explaining the increasing prevalence of chronic disorders, a trend that it is expected to continue over the coming decades, challenging the sustainability of health care systems worldwide. The toll that Non-Communicable Diseases (NCDs) represents for health care systems in Europe is close to 70% of the total burden and these conditions also have a dominant impact on both mortality and disabilities [1-3].

There is evidence indicating that current fragmentation of care generates avoidable inefficiencies at system level [4], perpetuates a reductionist approach to chronic disorders that precludes management of co-morbidities [5] and does not facilitate future predictive and personalized medicine.

Thus, there is an urgent need to introduce substantial changes in the way we approach delivery of care for chronic patients, as well as its articulation with social support services. This need led the World Health Organization (WHO), in 2002, to launch the Innovative Care for Chronic Conditions initiative (ICCC) [3, 6] formulating basic principles and strategies to enhance management of chronic patients.

The project was conceived to develop the practicalities of the ICCC-WHO [3, 6] acknowledging that Integrated Care Services supported by Information and Communication Technologies (ICS-ICT) [7], as enabling tools, are two core components in the new scenario.

Well-articulated innovative ICS-ICTs are proposed as a more cost-effective solution on the hypothesis that they can improve the care experiences and outcomes for patients by coordinating their care better and simultaneously promote cost-effectiveness through preventing the unnecessary use of complex care services [8-12].

The main objective of the project was to identify proper strategies for future extensive regional deployment and adoption of ICS-ICT aiming at transferring complexity from hospital to primary care and to patient home with a proper integration with community services. The intended service-focused approach adopted in the project has important implications on deployment strategies.

All four ICS-ICTs considered in the project, namely: Wellness and Rehabilitation, Enhanced Care for frail patients, Home Hospitalization and early discharge and Remote Support to primary care for diagnosis and therapy, had been previously assessed through small pilots [13-15]. The four ICS-ICTs cover a wide spectrum of care coordination with a strong focus on prevention and modulation of the disease progress.

The project was designed to explore the five factors classically recognized as barriers for deployment of ICS-ICT, namely: lack of evidence of clinical benefits, technological issues, service reimbursement, regulatory and ethical aspects and organizational factors. A systematic assessment of the results has been carried out following the methodological approach proposed in MAST [16].

In summary, the core hypothesis was that deployment of ICS-ICT may generate efficiencies at health system level that facilitate adoption and sustainability of the services. Finally, the project has contributed to generate specific strategies for extensive deployment of ICS-ICT at regional level, facilitating the generalization of the lessons learnt and contributing to the reshaping of the health systems to successfully face the challenge of chronic conditions.

3.2 METHODS AND PROCEDURES

3.2.1 Material

The site

In Barcelona, the driver of the transfer of complexity is a tertiary public hospital (Hospital Clinic), as part of the process of setting coordinated care into one of the four territorial health sectors (Barcelona-Esquerra – 540,000 inhabitants) of the city of Barcelona. The health sector includes, besides Hospital Clinic, two general hospitals, 18 primary care centers run by different providers, one mental health center, one convalescence center and health transportation systems/organizations.

The project was developed in close coordination with the Department of Health through TIC-SALUT and the Catalan Agency for Health Information, Assessment and Quality (AIAQS) aiming at transferring the lessons learnt in the project to the whole Catalan region [17]. Catalonia has one public payer (CATSALUT) covering health care services for the entire population of 7.2M inhabitants. The services can be delivered by a wide range of public or private (profit and non-profit) organizations.

The ICT platform

An ICT platform, Linkcare®)[18], was conceived and developed to provide organizational interoperability and knowledge sharing among stakeholders involved in coordinated care. All in all, the ICT platform fosters continuity of care and proactive patient care. To address those developments, we adopted enterprise application integration software architectural principles since they provide a common basic set of ICT solutions for integration at site level with potential for scalability. This option allowed integration with external legacy systems by implementing interoperability middlewares using SOAP web services for interoperable machine-to-machine interactions, as well as organizational interoperability between professionals participating in ICS-ICTs by means of a common facade.

3.2.2 The field studies

The four ICS-ICTs deployed in the project were planned to cover a wide spectrum of care coordination with a strong focus on prevention and modulation of the disease progress. We targeted chronic patients with respiratory disorders, mainly Chronic Obstructive Pulmonary Disease (COPD); Chronic Heart Failure (CHF) and type II diabetes. The field studies were designed following different study designs are described below:

3.2.2.1 Wellness and rehabilitation (W&R)

This ICS-ICT aimed at promoting healthy life-styles in clinically stable chronic patients, enhancing their self-management and improving adherence to prescribed

treatments. Main objectives in W&R were to assess the deployment, effectiveness and long-term sustainability of a low-cost community-based cardiopulmonary rehabilitation program supported by mobile technologies in clinically stable chronic patients. Specifically, we were interested on the effects of the intervention on long-term sustainability of training effects over time and on the impact of the training program on patient's daily physical activity and health related quality of life. Due to the complexities of the development of the technology (smartphone with wireless sensors and expanded functionalities, and a personal health folder), the study was designed with a pragmatic approach: non-randomized controlled study with 173 COPD patients allocated either in the intervention or in the usual care group.

The study assessed several dimensions: i) analysis of factors modulating dropouts and adherence [24]; ii) use of ICT in elderly COPD patients compared to the general population [25] and, iii) evaluation of the effects of the intervention on long-term sustainability of physiological training-induced effects, health-related quality of life and on daily physical activity throughout the follow-up period. As alluded to above, the ICT support consisted of a mix of different technological approaches: periodic SMS, use of wireless mobile technology to assess intensity of home-based training and use of the personal health folder.

3.2.2.2 Enhanced Care for frail patients (EC)

This ICS-ICT consisted of 3 different study groups. Firstly, a RCT to assess effectiveness of an intervention to prevent hospital admissions in severe frail COPD patients with history of repeated hospitalizations in the previous year. Secondly, a study design targeting the deployment of a real service for prevention of hospitalizations of severe frail chronic respiratory patients and conducted by the Integrated Care Unit of the Hospital Clinic. Finally, a third group of chronic respiratory patients with Long-Term Oxygen Therapy (LTOT) was established to analyze the service design required for management of frailty and complexity at community level. All in all, this ICS-ICT explored the spectrum of programs needed for management of chronic frail patients in the community.

3.2.2.3 Home Hospitalization and Early Discharge (HH/ED)

This ICS-ICT was extensively deployed as a conventional service at Hospital Clinic wherein patients requiring hospital admission where hospitalized at patient home fully (HH) or partially (ED) substituting in-hospital stay. The personnel attending the patients at home were professionals from the Integrated Care Unit at the Hospital Clinic.

3.2.2.4 Remote Support to primary care for diagnosis and therapy (Support)

It explored the transfer of specialized diagnostic and therapeutic interventions to primary care in 5 different areas of Spain.

3.2.3 Evaluation

Assessment

The project outcomes were evaluated following MAST (Model for ASsessment of Telemedicine applications) [16] because of its focus on multidisciplinary assessment with the purpose to produce a basis for decision making. There are two core

components in MAST: i) Multidisciplinary assessment of the outcomes considering up to 7 domains: safety, clinical effectiveness, patient perspectives, economic aspects, organizational aspects and social aspects, and, ii) transferability assessment.

Cost Analysis and Business Model

The economic evaluation of the four ICS-ICT compared to usual care was addressed to assess costs of the new model of care. A basic option of telemonitoring was included in the analysis of costs for each ICS-ICT, but the relative impact of different modalities/intensities of telemonitoring on the ICS-ICT has been estimated separately. We have also analyzed the impact of the new model of care supported by ICT on the structure of the health value chain.

The team extensively reviewed the literature on reimbursement policies [19-23] taking into account new proposals and consolidated experiences. The potential impact of reimbursement issues in the design of incentives to foster the change has also been considered.

We have elaborated a business case for the take-up of ICS-ICT based on the premises described above. All the analyses were done from a policy maker perspective taking into account that scalability to the whole health system was a must. Interactions between payer(s) and health care providers have been addressed as the central component of the business model without neglecting the interplay among the various actors of the entire value chain.

Ethical and Regulatory Issues

Ethical and legal aspects associated with the deployment of ICS-ICT, including ethical challenges and the lawfulness of the proposed service models, were identified and analyzed. The impact of regulatory issues on equipment was not the focus of the project because our choice was to use commercially available equipment. In contrast, ethical and legal issues, particularly those related to concerns about privacy, consent, responsibility of care and liability related to novel technologies, information sharing, transmission or decentralization of clinical procedures and cross-country services, were considered a core area of activity during the project. We have taken this orientation because privacy becomes a central issue in ICS-ICT, particularly when integrated knowledge sharing becomes a goal.

Data Analysis

The conclusions at project level have been mostly drawn from statistical inference analysis applied separately at site level (paired-t tests, non-parametric analyses, Mixed Model for Repeated Measurements and different models of Multiple Analysis of Variance with contrast analyses).

3.3 RESULTS

The Site

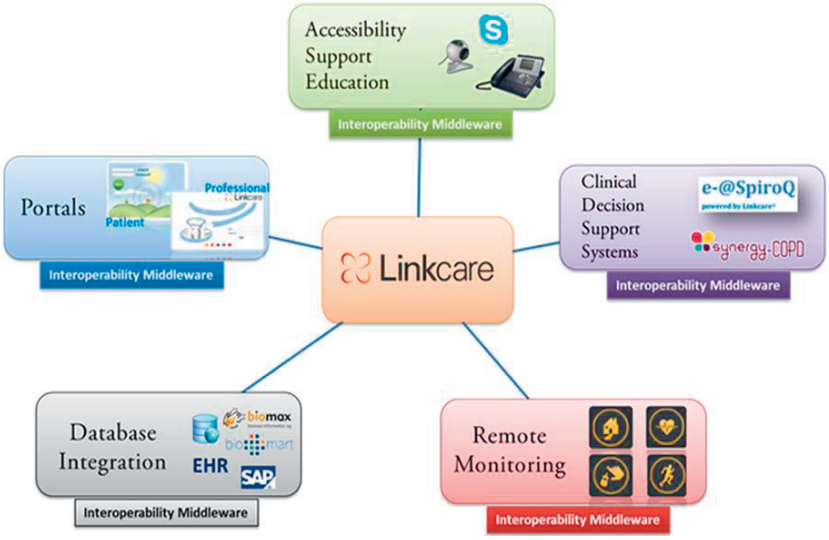
A characteristic feature of the Barcelona setting was that, by design, the project was organized as an independent operation of the workforce reengineering of the territorial care in the health care sector, based on clinical groups. It is of note, however, that productive interactions were generated between the two separate processes:

assessment of the four ICS-ICTs and workforce preparation. The team devoted a substantial amount of activity into fields that were considered as strategic for future deployment, such as the convergence between integrated care and the incipient area of Systems Medicine [5].

Technology

The setting of the ICT dimension of the project [18] (Figure 1) fully served to support the field studies. It is acknowledged that the ICT platform requires further developments before the ICS-ICTs could be successfully deployed at regional level. Those developments are currently ongoing being main priorities: i) the multi-center version of the ICT platform; ii) refinement of functionalities ensuring traceability and data confidentiality; iii) enhancement of interoperability and usability of the mobility solution; and, iv) transition to cloud computing.

Figure 1. Architecture of the ICT Platform, LinkCare®



3.3.1 The field studies

The four ICS-ICTs were deployed within the new service model whose main characteristics are depicted in Figure 2. The four ICS-ICTs assessed in the project cover a wide spectrum of care coordination and they should be considered as complementary interventions to articulate patient-centered care with emphasis on prevention and early disease modulation.

The main characteristics, displayed in Figure 2, are: i) the model of care is addressed to target chronic patients fulfilling the eligibility criteria for one of the ICS-ICT groups; ii) management of the patients is done through programs, being the program a specific formulation of one ICS-ICT (see generic structure of all the programs in Figure 3), iii) each of the programs has well-standardized interventions, iv) a patient-centered care is adopted including management of co-morbid conditions, and, v) an active role of the patient is promoted through the patient's portal and through the call center, including different modalities of telemonitoring.

Figure 2. Depiction of the conceptual integrated care model assessed in the project

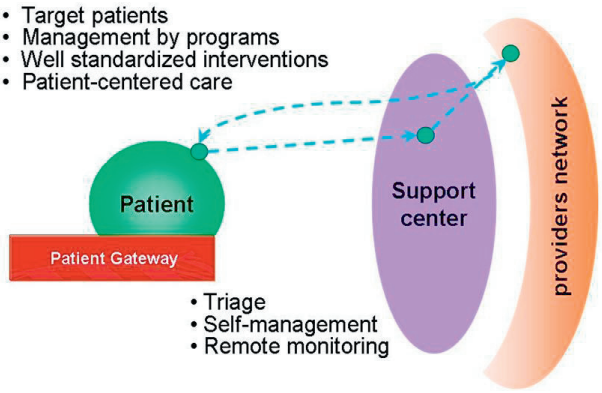
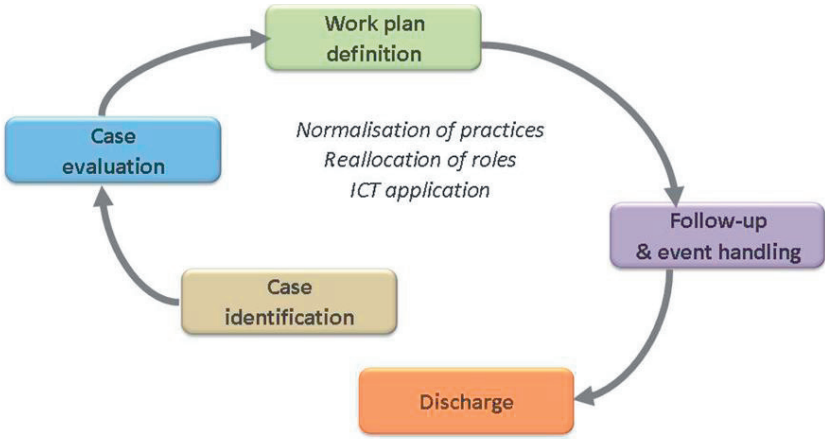


Figure 3. General structure of the Integrated Care Services managed by the core module of the LinkCare® platform



One of the main goals of this model of care is to avoid fragmentation across health care tiers. A key advantage of the approach is that it can provide continuous information on patients, facilitating prevention of crises and knowledge on disease evolution beyond the episodes of exacerbation. Main summary results of the field studies carried out in the project are described below.

3.3.1.1 Wellness and Rehabilitation (W&R)

A total of 173 COPD patients allocated either to intervention or to the control group were studied: i) at baseline measurements, ii) after 8 weeks supervised training, and, iii) after a mean follow-up period of 21 months. The patients from the two groups were trained during 8 weeks. The intervention arm of the study included integrated care with home-based training with ICT support during the follow-up period, whereas the control group followed usual care after the supervised training program. We demonstrated that the ICS-ICT group presented statistical significant effects on long-term sustainability of training-induced increase in aerobic capacity assessed by the six-minute walking test and endurance time; enhanced health-related quality of life; and, importantly, enhanced daily physical activity after the follow-up period.

The study showed very clearly clinical efficacy of the intervention on main outcome variables. Moreover, the results of W&R seem to be transferrable to any other site provided that standardization of the intervention is properly followed. We understand, however, that the results of this ICS-ICT should be interpreted as a feasibility study that must be reproduced in a larger sample size through a multicenter study.

3.3.1.2 Enhanced Care for frail patients (EC)

The first RCT (n=155) was carried out to assess effectiveness this ICS-ICT on prevention of hospitalizations in frail patients with high risk of readmissions. The aim was to explore effectiveness of prevention of hospitalizations by an ICS-ICT across levels of care. EC improved clinical outcomes including survival, significantly reduced unplanned admissions, but not the overall admission rate. The study facilitated identification of key modulators of adoption of ICS-ICT [26]. Appropriate patient stratification and preparation of work force in primary care were identified as key components of success [27-29].

A second step was to initiate the deployment of EC as a real service for severe frail COPD patients (n=250) run by the Integrated Care Unit at Hospital Clinic. This is a transversal unit created for the deployment of specific ICS-ICT and to support the bridging with the community within the process of transfer of complexity from the hospital to primary care. The effectiveness of the EC program as a real service is out of any reasonable doubt. Over the last years, it has completely changed the ecosystem of the Pulmonary Medicine Department in terms of admissions of the subset of frail chronic respiratory patients with previous history of repeated hospitalizations. Moreover, the rate of early readmissions after discharge (30 days) is significantly lower (10%) than those observed in the whole region (15%) and in the recent COPD audits done in Spain (30-35%) and at EU level (30-35%). During the last period of the project, we have run a third protocol on LTOT (n=545) [29] that provided key information to generate a mature service for management of frail and complex patients at community level with interoperability among providers with heterogeneous health information systems. Such a program will be deployed on January 2014.

Within this ICS-ICT, we have shown effectiveness and we have identified a great potential for cost-containment. However, one of the most important achievements has been the design of a suite of EC-specific ICS-ICTs covering: i) transitional care programs, before and after hospital admission; ii) management of frailty/complexity in the community; and, iii) palliative care for end-of-life patients. None of EC-specific ICS-ICTs has a disease-oriented focus, but all of them are patient-oriented dealing with co-morbidities and taking into account environmental, life style and socio-economic factors that influence health.

3.3.1.3 Home Hospitalization and Early Discharge (HH/ED)

The home hospitalization program has been successfully deployed as conventional care in Barcelona by the Integrated Care Unit of the Hospital Clinic. Up to 2,314 patients with criteria for hospital admission in a tertiary care center and covering a broad spectrum of disease conditions were included in the analysis. The program aimed at full (HH) or partial (ED) substitution of in-hospital stay for a short-term home-based hospitalization run by hospital personnel. The results showed safety, acceptability and satisfaction of patients and professionals. Early re- admission rate (hospital and emergency room) and mortality were slightly better than conventional

hospitalization with significant lower costs than conventional care because an average of 5 in-hospital days per patients were saved. The program had a balanced economical outcome and it was highly efficient at health system level.

3.3.1.4 Remote Support to primary care for diagnosis and therapy (Support)

We successfully explored the role of a web-based application to enhance quality of forced spirometry in primary care done by non-specialized professionals. The study (4,500 patients)[30] done in 5 different areas of Spain showed that the rate of high quality spirometries in primary care can be markedly enhanced, during a 12 months follow-up period from 60 to 72% in control and intervention centers, being comparable to the one obtained in specialized settings. Feasibility of the setting for a strategy of case finding for chronic obstructive respiratory diseases in pharmacy offices was also shown [31] and the formal RCT to assess the service is being successfully completed in Barcelona [32]. Moreover, an algorithm for automatic identification of high quality tests has been elaborated showing a high sensibility and specificity of 96 and 95% respectively [33-34].

The total number of patients assessed in this ICS-ICT is above 7.000. The setting has been successfully deployed in approximately 100 primary care units in the Basque Country as a regular service and it will be extended to the whole region during 2014. Likewise, similar steps are taken in Catalonia to achieve full regional deployment in 2015. The final aim is to have high quality forced spirometry testing automatically certified as such and accessible by health care providers across the system. Moreover, the setting shows high degree of transferability to other diagnostic areas.

3.3.2 Evaluation

3.3.2.1 Assessment

In summary, we can state that: i) all four ICS-ICTs showed clinical efficacy and potential for extensive deployment, but W&R may still require further controlled studies; ii) high degree of transferability was observed in all ICS-ICTs except for HH/ED wherein specific factors modulating transferability were identified; iii) high potential for generating efficiencies has been shown in all programs; and, iv) further developments in the current ICT platform is still needed to be ready for successful integration at system level and to support regional deployment of the four ICS-ICTs.

The initial plan to perform RCTs for the different field studies could not be accomplished because of unexpected technological incidences (W&R) and due to the positive clinical outcomes (HH/ED and, partially in EC) prompting deployment of a real service. The main lesson learnt was that the development of the project has required a substantial degree of flexibility involving the application of principles of complex adaptive systems theory [35-37].

3.3.2.2 Cost Analysis and Business Model

The different ICS-ICTs assessed in the project generate a potential favorable cost-effectiveness incremental ratio for sake of reducing hospital care and transferring complexity to primary care and patient home. The project has also identified favorable health outcomes and enhanced use of health care resources, which makes outpatient care a better strategy than use of inpatient services.

To calculate the impact of ICT on costs, the project has adopted a service oriented approach acknowledging that ICT is one of the key enabling components of the novel ICS-ICTs generating efficiencies into the new health care scenario. We distinguished three main components into the ICT associated costs: i) general ICT infrastructure, ii) ICT platform supporting the integrated care services, and, iii) specific telemonitoring initiatives. The current report focuses on the costs associated to ii), including initial investments, update and maintenance, that are embedded into the overall cost of the different ICT-ICTs. The costs of the general ICT infrastructures at regional/country level (i) are beyond the scope of the project. Moreover, we believe that specific telemonitoring initiatives (iii) require Health Technology Assessment in each case to be conducted by each health care provider separately or in conjunction with the payer.

We understand that deployment of ICS-ICTs implies an enrichment of the entire health care value chain with new roles of existing actors and emergence of new actors with novel complexities that may generate opportunities if productive interactions are in place. We propose that the relationships between payer(s) and health care providers covering different health care tiers should be the two core elements of the federated business model. It seems consistent with the service-oriented approach taken in the project that allied actors in the health care value chain, namely: equipment manufacturers, pharmaceutical industry, telecom operators, ICT integrators, etc., which lead to productive interactions through mainstream health care providers.

It is acknowledged the need to define a reimbursement system that represents the interest of the payer to a binding budget constraint such that no additional resources are spent in the health care of the target patients. Moreover, the reimbursement modality must have an additional role as incentive of the actors such that it fosters adoption of ICS-ICT substituting hospital by territorial care, including home care, enabled by a costly ICT implementation. The final scenario should be that invoicing for inpatient services should see a reduction whereas these savings (or less) would be spent in the form of home care and ICT innovation. The overall spending would either be reduced or health care outcomes increased for the same expenditure. We have thoroughly analyzed the expected impact of different modalities on reimbursement, namely: i) paying per activity, ii) paying a capitation, and, iii) a bundled payment, on the deployment of ICS-ICT assessing the effects on the business case, their role as incentives for adoption and their potential for generalization at systems level. Finally, a bundled payment is proposed, as described below.

3.3.3 Deployment Strategies

Specificities of the strategies for extensive deployment of ICS-ICTs in a given area depend on two main factors: i) the profile of the site (defined by the driver of the change and the structural characteristics of the site), and, ii) the domains playing a central role as barriers for deployment.

During the project, the health care sector of Barcelona-Esquerra achieved remarkable results in several dimensions. The parallel deployments of ICS-ICT and reengineering of the site, together with progressive integration and interactions, has shown to be productive in terms of health outcomes. We have identified two major priorities aiming at consolidating deployment at site level. Firstly, they should concentrate on few rather modest operations aiming at generating success stories involving all care tiers. Likely, ICS-ICT supporting frail patients with LTOT will be one of the realistic targets to favor convergence among all health care providers of the area. Secondly, it is now critical

to reinforce governance at site level favoring convergence between reengineering of clinical processes and ICT deployment.

The Catalan Health Plan (2011-15) [17] is a relevant frame for extensive deployment of ICS-ICT at regional level. Major issues to be solved are: i) foster convergence of existing experiences on ICS-ICT, ii) activate novel reimbursement modalities and incentives to enforce deployment, and, iii) governance to rapidly evolve toward territorial care involving integration of all health care providers of a given sector. Existing regional interoperability tools such as the Shared Electronic Health Record (HC3) and the Personal Health Folder (Canal Salut) provide a good basis for a successful regional deployment of ICS-ICTs.

3.4 DISCUSSION

The project was undertaken as an operation to support ongoing process of reshaping health care systems aiming at facing the burden generated by the epidemics of chronic conditions. To this end, it was planned with a service-oriented approach to assess the role of ICT in the health scenario. From the technological standpoint, our interest was to explore the role of the ICT platform (Linkcare®) in two domains. Firstly, covering the concept of organizational interoperability among actors and, secondly, as a support of knowledge management functionalities and Clinical Decision Support Systems. The two aims were fully achieved such that the ICT platform showed efficacy to support the four ICS-ICTs assessed in the project. Moreover, we identified the ongoing additional technological developments needed for regional deployment of the services.

Main achievements of the project have been demonstration of clinical efficacy/effectiveness of the four ICS-ICTs beyond previous pilot experiences. We have identified complementariness among the ICS-ICTs such that they allow an articulation of clinical strategies covering the entire spectrum of patient severity. Moreover, except for home hospitalization, it has been demonstrated a high degree of transferability of the ICS-ICTs provided they are customized to the specificities of each health care system.

MAST has shown to be a valuable tool to guide the assessment of ICT applied to health, but limitations imposed by some key assumptions have been highlighted. Also, we have identified the need for development of new assessment tools that should be valid for continuous evaluation of novel ICS-ICT deployed at systems level. Specific proposals have been elaborated. Finally, we understand that the achievements in business area of the project include several aspects that deserve to be highlighted. Firstly, the business proposals are consistent with the service-oriented approach of the project. Secondly, the business model is sensible to the need for cost containment and accountability of the actors involved. The proposed reimbursement scheme and incentives system is expected to foster care coordination and extensive adoption of ICS-ICT. Last but not least, the project has prompted new business scenarios that constitute a relevant innovation in the field.

The project has been a productive experience, but with no doubt, a very complex one. As main project limitations, we acknowledge weaknesses in two areas that should not necessarily be interpreted as failures of the project. Firstly, the fact that the project began with rather weak technological tools to support the field studies.

However, the final release of the ICT platform has played the expected role throughout most of the lifetime of the project. The necessary technological steps for regional deployment were identified and they are currently being implemented. Secondly, we have accumulated evidence of the potential of the four ICS-ICTs to generate efficiencies into the health care system. But some of the field studies were not developed as RCTs In other words, we have strong and valuable evidence, but such evidence does not fully meet the academic standards supporting cost-effectiveness of all ICS-ICTs.

3.5 CONCLUSIONS

In summary, we understand that the project provides a novel and sustainable approach for the deployment of ICS-ICT in health systems with heterogeneous providers that should foster extensive adoption of integrated care for chronic patients.

3.6 ACKNOWLEDGMENTS

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CHAPTER 4.

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO: RESULTS IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE, MULTIMORBIDITY AND HEADACHE PATIENTS SCENARIOS

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Index Terms: Archetype, Chronic Diseases, Semantic Interoperability, Service Oriented Architecture.

ABSTRACT

Objective: To define, develop and validate a method supported by a technological platform for deployment and evaluation of new integrated services based on telemedicine aligned with the Andalusian Public Health System organizational model for the chronic patient care.

Methods and Procedures: The platform has been designed using a Service Oriented Architecture strategy, and based on the regional software development recommendations. With the aim of separate information and knowledge, the system architecture is based on ISO 13606 standard. The system database includes the classes detailed in the reference model of this standard, and archetypes are stored to model the relation between the stored information and the clinical knowledge. To evaluate the telemedicine services, three health care scenarios have been selected to represent three important health problems: Chronic obstructive pulmonary disease (COPD), Headache, and Multimorbidity patients.

Results: The COPD scenario was piloted using a telemedicine platform of the Linde Healthcare Company because eHealth platform was still in development phase. In the Multimorbidity scenario, a register called Clinical Wall has been developed to support the communication and coordination among health care professionals. In addition, other shared records have been developed in the eHealth platform to support the process of the Headache scenario.

Conclusions: eHealth platform permits us to effectively support investigation, development, and innovation projects in the area of interoperability, eHealth, and telemedicine.

Clinical Impact: The platform allowed us to obtain experiences in the application of new standards and technologies, as well as in new care processes for COPD, headache and multimorbidity patients.

4.1 INTRODUCTION

ITH the rising of life expectancy and increasing number of chronic patients, the identification and deployment of new shared care models between different health

care levels is required [1], [2]. These models are based on new methodologies for care management and quality control that apply Information and Communications Technologies (ICT) tools in order to obtain patient history remote access, analysis and visualization clinical data tools, and personal telemedicine [3].

New processes involve collaborative environments between health care actors and patients, applying technologies that facilitate the needed health care quality control, continuity improvements, treatment adherence, avoidance of adverse events, as well as the quantification of health care costs.

The adoption of a Service Oriented Architecture (SOA) in the development of informatics systems allow us to define reusable and interoperable services obtaining a high scalability and flexibility making possible to easily adapt our systems for changing requisites. Thus, SOA based technologies offer an appropriate response to the design requisites, because of their fundamental attributes: adaptability, reusability, and interoperability based on standards. Their implantation provides value and is accepted in the Health System because they allow systems to adapt to the self-assistance service needs. This architecture represents important challenges in the organizations because they must use standards defined by the ISO 215 technical committee (ISO 12967 Health Informatics Service Architecture) [4] and by HL7 within your project Health Service Specification Project (HSSP) [5]; and thus to prevent past errors. This is the case, for example, of SOA-based implementations that need to find a balance between system costs and agility.

SOA is the formal response to the processes designed under Business Process Model (BPM) standards. BPM is a systematic approach to improve the business process organization. The activities that represent BPM can be grouped in five categories: design, modeling, execution, monitoring, and optimizing. This methodology's effectiveness has been demonstrated in different contexts [6].

The BPM adoption involves benefits within the organization because an increase in visibility and knowledge of the activities occurs. The BPM methodology sets a precise definition of the roles and tasks, facilitating audit tasks. As a consequence, the capacity to identify bottlenecks and define optimization mechanisms is increased [7]. BPM Notation (BPMN) is a standardized graphical notation that allows the modeling of business processes in a workflow format.

The new health services based on telemedicine need to be evaluated rigorously, in terms of security, effectiveness, efficiency, health-related quality of life (HRQoL), health care resources, acceptability, etc.

ICT allow the development of telemedicine technological solutions and eHealth support necessaries for the practical implementation of change towards new health attention models for people with chronic diseases, fragility conditions and dependency.

To evaluate the telemedicine services, 3 health care scenarios that represent three important health problems were selected:

— Chronic obstructive pulmonary disease (COPD): World Health Organization predicts that COPD will become the third leading cause of death [8] and the fifth cause of disability-adjusted life year (DALY) [9] worldwide by 2030.

— Multimorbidity patients are characterized by its high complexity and vulnerability with a large number of symptoms, as well as a large prevalence of functional impairment [10].

— Headache: financial costs of headache to society through lost productivity are enormous [11].

The general objective of this project node has been to define, develop and validate a method supported by a technological platform, to evaluate and deploy new integrated services based on telemedicine aligned with the organizational model of the Andalusian Public Health System for chronic patient care. This platform will have an interoperable SOA to satisfy the necessities and specific care functions of each scenario.

COPD scenario presents the following specific objectives:

— To analyze the effectiveness of a telehealth program in patients with advanced COPD treated with long-term oxygen therapy (LTOT).

— To analyze study participants (patients and health care professionals) satisfaction.

Multimorbidity scenario presents the following specific objectives:

— To support communication and coordination between professionals involved in multimorbidity patient care.

— To analyze acceptance, use and consensus decision between health care professionals.

Headache scenario presents the following specific objectives:

— To analyze the effectiveness of a telehealth system using videoconferences between Primary and Specialized Care to improve headache control and monitoring.

— To realize consensus care between General Practitioner (GP) and neurology specialists.

4.2 METHODS AND PROCEDURES

PITeS project adopts the recommendations established the identification and modeling of services and BPM through the current process identification of "as is" processes as a basis for the future "to be" processes.

Current process identification ("as is"): Include the identification of the business initial functions and objectives supported by the organization, existing systems' inventory (hardware, software, and outsourced services) and quality attributes. This information can allow us to define common functions and to align information systems' resources through the reusable web services definition, which can be useful for the different scenarios. The identified services are the following:

— Patient identification.

— Patient search.

— Access control mechanisms for professionals or patients.

Futures process definition ("to be"): To reduce unplanned redundancies, to maximize the reusability, and to increase the consistency, the defined architecture uses an Enterprise Service Bus (ESB) to manage the communication between the different software components. ESB is an integration platform that includes services such as instances localization, messages/protocols routing, mapping between different specifications, audit, etc. Because ESB is the central node of communications between

the different components, the number of connections between nodes is reduced and access management is facilitated.

In addition to the messaging and communications between components managed by the ESB, a platform called "eHealth platform" has been developed with a few common functionalities for all modules, such as:

— Assigning patients to research projects.

— Creating virtual episodes.

eHealth platform has been designed using an SOA strategy and aligned with the strategy defined by the Health Andalusian Service Information Technologies Sub-direction. This platform develops their communications following a regional infrastructure principle: to avoid information duplicity. This platform uses following existing corporate interoperability services:

— Patients' demographic-data query (User Database).

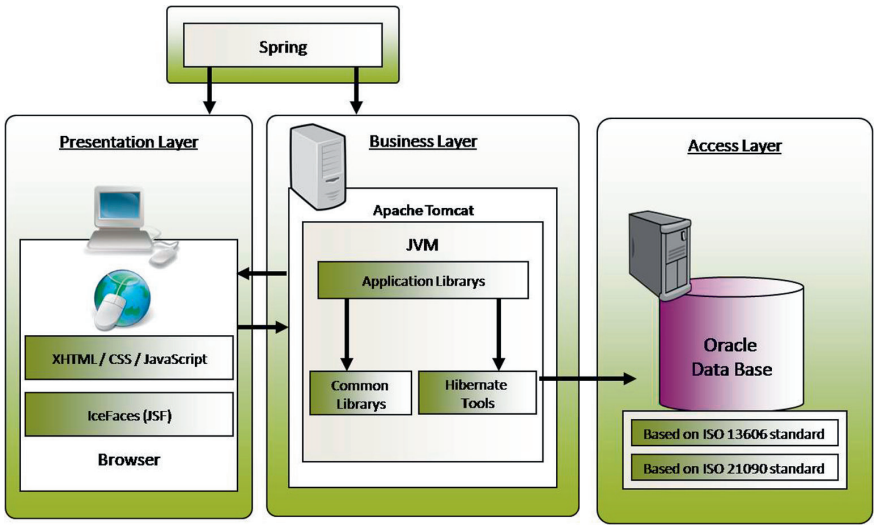
— Professionals' credentials' validation (Centralized Operator Access Module).

With the objective of separating information and knowledge, the system architecture is based on the ISO 13606 standard [12]. The system database includes the detailed classes within the reference model to this standard. Records definition is based on logical structures called archetypes. Archetypes are a formal definition of semantic relationships between concepts defined as a set of restrictions within the underlying reference model. Archetypes are able to define the relationships between clinical concepts as a new layer that allows administration of the evolution of clinical knowledge. In this process we are using LinkEHR-Ed [13] to edit the archetypes. LinkEHR Editor is a platform that allows us to edit multimodes archetypes.

eHealth platform has been designed based on the regional software development recommendations. It incorporates ICEfaces frameworks based on Java Server Faces (JSF), and includes a productive persistence layer based on Hibernate tools. It also uses Model-View-Controller pattern, Oracle database, CSS style sheets, JAVA and JavaScript technologies, Tomcat applications server, Spring framework, etc.

The proposed infrastructure facilitates development of easily scalable systems with semantic interoperability, designed to adapt to changing clinical necessities of the health care professionals.

Figure 1. eHealth platform architecture



4.2.1 COPD scenario

The scenario centered on patients with COPD was the first scenario that was evaluated. It was piloted using a telemedicine platform of the Linde Healthcare Company because eHealth platform was still in the development phase.

The study was designed as a randomized controlled trial during four months. Information about patient enrolment process, inclusion and exclusion criteria, telehealth program, clinical response, and outcome measures have been already published [14]. Patients were randomized into a telehealth group (n = 24) and a control group (n = 21) who received usual care.

The intervention effectiveness was evaluated through a number of accident and emergency department visits and a number of hospital admissions. Satisfaction of Patients and health care professionals was also evaluated.

4.2.2 Multimorbidity scenario

When the PITeS project began, it was decided to start to work in a common architecture that supports the different research and innovation projects that our research group performed. At this moment eHealth platform described above was born. In this platform we have included headache and multimorbidity scenarios.

We conducted a pilot study, during six months, to assess the use and acceptance of the Multimorbidity module (MM) within eHealth platform, by 70 health care professionals belong to the Virgen del Rocío University Hospital (VRUH) and to two Primary Care Centers [15]. MM effectiveness was evaluated through number and type of records, the total number of messages exchanged, and the number of health care professionals who took part. We also defined as main usage indicators the percentage of messages answered and the percentage of records ending in agreements between professionals.

To assess the acceptance of the MM by the health care professionals we prepared a questionnaire based on the theory of the Technology Acceptance Model [16]. The aim of this questionnaire was to analyze the intention of using the MM. The questionnaire has 21 items on the following dimensions: perceived usefulness, perceived ease of use, subjective norm, facilitating conditions and intention of use. Health care professionals were asked to score each item between 1 and 10, with 1 meaning 'totally disagree' and 10 'totally agree'.

4.2.3 Headache scenario

The scenario, centered on patients with headache, is integrated within eHealth platform described above. In this scenario, professionals from different levels of care are involved (primary and specialized care). By this means, in addition to the platform functionalities, it was considered necessary to use a videoconference tool, to allow professionals involved to make a joint exploration without the need to travel. For this aim, Spontania was used (a webconferencing tool from Dialcom Networks).

To evaluate effectiveness in this intervention a longitudinal observational study was proposed, in which: a number of Neurology visits, the telemedicine system effectiveness, quality of life and satisfaction for health care professionals and patients, are analyzed.

4.3 RESULTS

4.3.1 COPD scenario

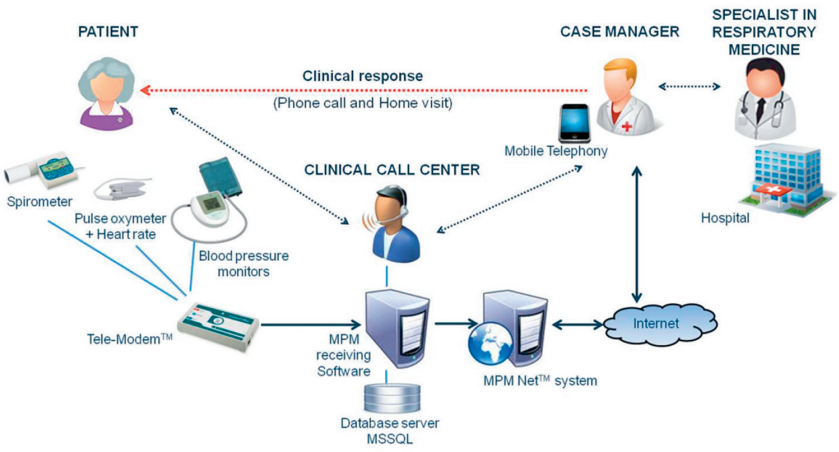
The final service operation is as follows:

Patients measured their vital signs on a set schedule. Vital signs were recorded through the following equipment: a spirometer, a pulse oxymeter, heart rate (Spirotel, MIR), and blood pressure monitors (AND, Model UA-767 BT). Once the patient performed daily measurements, the data were sent via a hub (Tele-ModemTM, Aerotel Medical Systems) connected to the patient's home regular phone line. Tele-ModemTM is an easy-to-use multi-parameter communicator; it can simultaneously transmit data from up to four sensing devices to the Medical Parameters Monitoring (MPM) receiving centre. Tele-ModemTM runs on an external power supply and is especially designed to enable Bluetooth device operation with no limitations.

Once measurements have been recorded into each connected instrument, the user simply presses the "Start" button to activate transmission. Equipped with an internal memory and real-time clock, its automatic data transfer is reliable and minimizes human error.

MPM TM Call Centre (Aerotel Medical Systems) serves as the hub for MPM and disease management. Easy to operate, it can be applied to any standard personal computer equipment. Comprised of a Microsoft SQL (MSSQL) database server and workstations connected in a network configuration, it is designed for long-term use and offers various access and management options. Furthermore, MPM NetTM system (Aerotel Medical Systems) is used to enable authorized users to display MPM data on the Web (Figure 2).

Figure 2. Telehealth service architecture platform



This study's main results were the following [14]:

— Mean number of accident and emergency department visits in the telehealth group was slightly lower than in the control group (0.29 versus 0.43, P=0.25).

— Mean number of hospital admissions was 0.38 in the telehealth group and 0.14 in the control group (P=0.47).

— There were clinically important differences in health-related quality of life in both groups. The mean score on the Saint George Respiratory Questionnaire was 10.9 versus 4.5 in the control group (P=0.53). The EuroQol-5D questionnaire score improved by 0.036 in the telehealth group and by 0.003 in the control group (P=0.68).

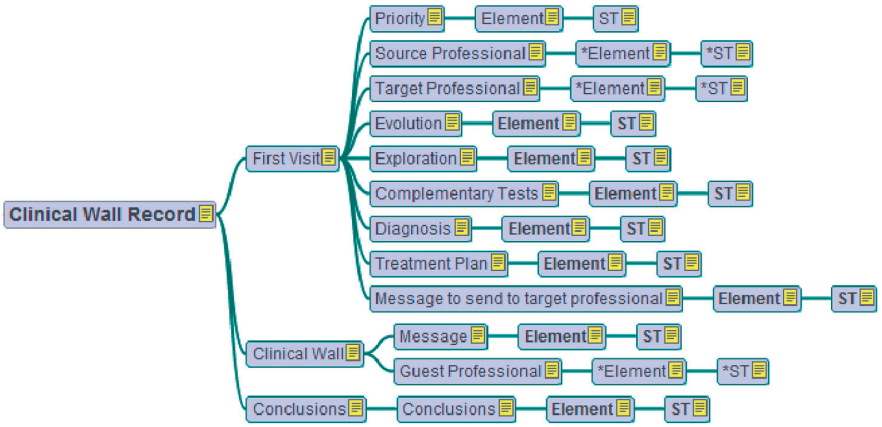
— Both patients and health care professionals showed a high level of satisfaction with the telehealth program. Health care professionals obtained a mean score to 6.75 ± 9.96 (mean ± standard deviation) respecting global satisfaction with the telemedicine system (from 1=very poor to 10=very good). Patients were asked to rate from 1 to 10 the following items: program satisfaction, recommendation of the program to a relative/friend as needed, and whether they would take part in another telehealth program. The mean scores were 9.30 ± 1.10, 9.39 ± 1.95, and 9.61 ± 0.89 respectively.

4.3.2 Multimorbidity scenario

Clinical Wall is the register that has been defined, designed, and implemented within the eHealth platform to support this scenario. When two or more professionals have the need to interchange opinions about a patient's care, they can initiate a conversation in the Clinical Wall. This register allows health care professionals that participate in a patient's care to interchange messages, until they decide some conclusions or final decisions. If any professional that is participating in the Clinical Wall needs another professional opinion, it is possible to invite experts to the conversation to incorporate their clinical experience [17].

All the registers that have been deployed into the eHealth platform have been defined as archetypes. Figure 3 shows the archetype mindmap related to the Clinical Wall. The archetype has been designed by means of a hierarchical structure, with the objective of offering flexibility and reutilization. Although only one mind map is shown relating all the parts, in this case there are 16 archetypes at the level of: Composition, Section, and Entry.

Figure 3. Clinical Wall mindmap



The study's main results were the following [15]:

— 40 of the 70 health care professionals responded to the survey to evaluate the system acceptance. The professionals valued positively all the items in the

questionnaire, with mean values of over 5 points. Grouping items into dimensions, high mean scores were obtained: 7.54 ± 1.53 for perceived usefulness, 7.08 ± 1.64 for perceived ease of use, 7.74 ± 1.35 for subjective norm, 6.85 ± 1.66 for facilitating conditions, and 7.87 ± 1.60 for intention of use.

— A total of 16 reports were created in the Clinical Wall, all of them with high priority. 12 of the 16 records (75%) were answered by the destined health care professionals. Consensual decisions between the health care professionals were related to changes in appointments coordination (50%), diagnosis tests and patients' conditions (25%) and prescription changes and renewal (25%).

4.3.3 Headache scenario

To support this scenario, a three workflows has been defined, creating three registers, which has been designed and implemented within the eHealth platform.

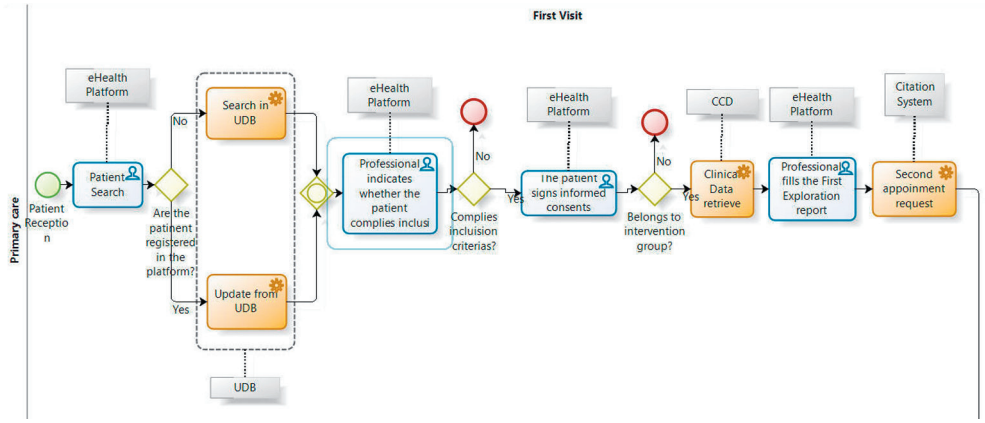
Phase 1. Initial evaluation

The process begin when the GP identify headache symptoms in a patient. He makes an initial evaluation of the patient's situation, filling out the "Initial evaluation report." In this first visit the GP make an appointment with a patient for a future consultation, when the GP and the specialist will make a joint consultation by videoconference.

Initial evaluation report is made up of a total of 10 hierarchical archetypes.

Figure 4 shows the BPMN related to the first phase.

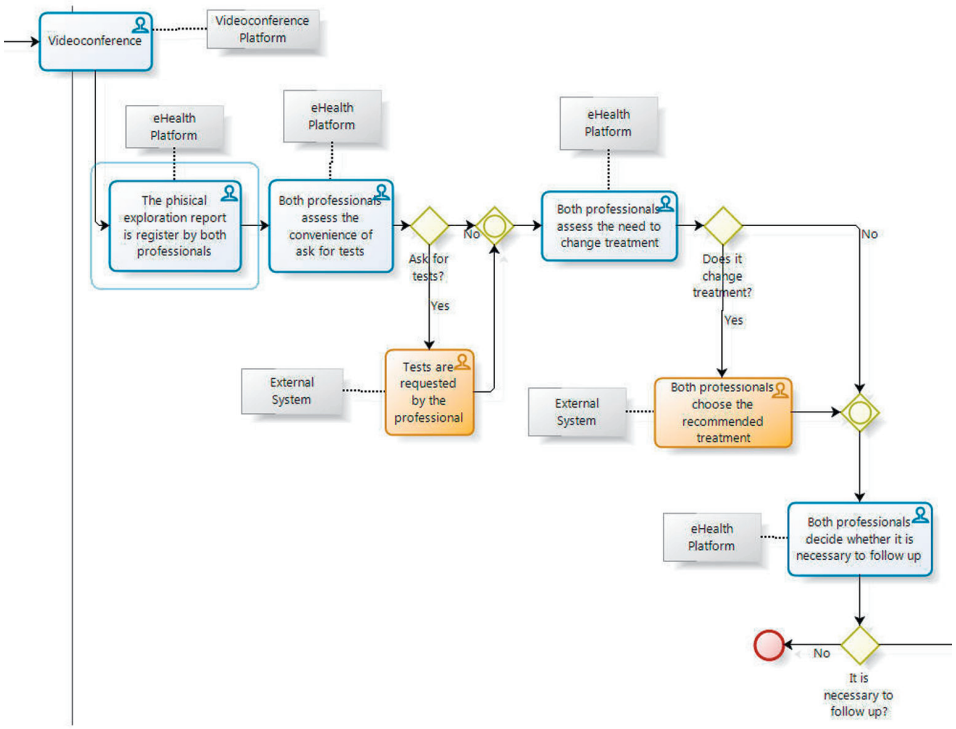
Figure 4. Initial evaluation BPMN within headache process



Phase 2. Exploration

The patient is in the GP office. Both professionals are connected by videoconference. The GP examines the patient (fundus of the eye, etc), with the specialist's supervision. With conventional treatment, this examination could only be done by a specialist. In this new process, the GP has been previously trained to do this examination, and can only perform it with the specialist's supervision. While the GP examines the patient, the specialist completes the "Examination Results Report."

Figure 5. BPMN corresponding to the headache examination process

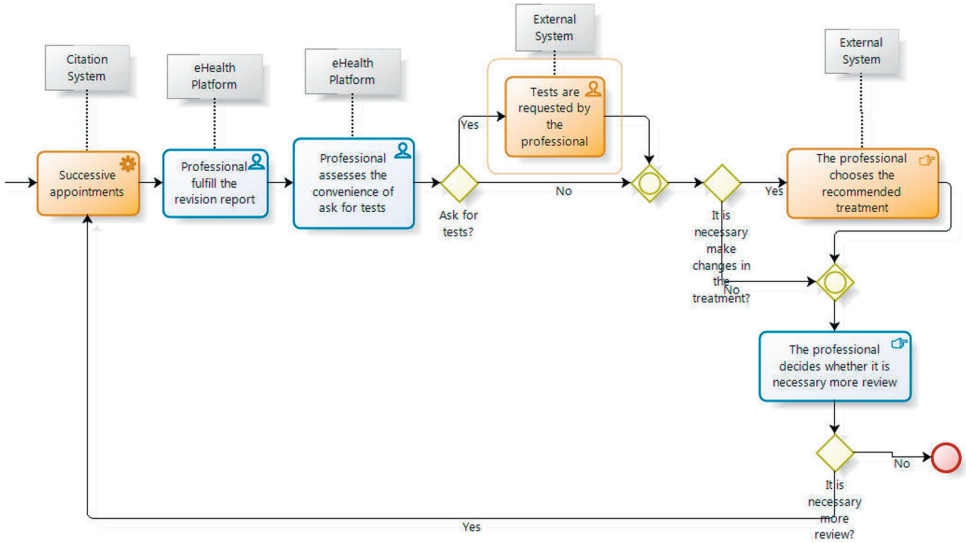


The record corresponding to the examination report is composed of a total of 17 hierarchical archetypes, 9 of which are shared with the Initial Evaluation Report. Figure 5 shows the BPMN related to the second phase.

Phase 3. Revisions

Once the examination is completed, both professionals decide if the patient is going to continue with follow up in any of the following possibilities: standard neurology follow up, join follow up by videoconference or Primary Care follow up. When a follow up session is performed, the professional fills the "Revision Report."

Figure 6. Revision BPMN within headache process



The record corresponding to the Revision Report is composed of a total 9 hierarchical archetypes, of which 3 are shared with the Initial Evaluation Report, and another 3 are shared with the Examination Report. Figure 6 shows the BPMN related to this third phase.

4.4 DISCUSSION

When the phase of requirement definition of the eHealth platform started, we identified the importance of use ISO 13606 standard to allow the interoperability between our platform with external systems. We considered the possibility to align the persistence layer with this standard, but the ISO 13606 specification doesn't cover the implementation in the persistence layer. The references about the design of the persistence model based on this standard were lacking. As a consequence, our database model design mapped this standard reference model is valuable piece of research about new approaches in the implementation of two level modeling.

In the requirement definition stage, we have done a representation to the process using BPMN in order to specify the functionalities covered by each eHealth Platform module. Another future challenge is to use this BPMN by means of BPM System (BPMS) that allow us to exploit the total BPMNs potential.

We also considered that it will be beneficial including generic decision supports tools and services based on standards of the SOA health application. These services will be based on technologies of expert knowledge definition and execution by means of process and rules modeling methodologies.

The knowledge management as a combination of BPMN processes and archetypes will require the definition of a common governance to be able to support evolution in clinical knowledge and processes, and facilitate their common interaction. Finally, in order to support knowledge evolution the capability of being able reproduces which archetype and process was used at the time that clinician made the decision for audit purposes.

Considering the eHealth platform potential we designed a generic connector that allows us to interoperate with any other external system based on multiple standards. Therefore, we have begun to develop such a connector, offering this as an Web service in addition to the existing ones, which will permit us to receive, store, and present (in a basic manner) the documents generated by other systems. At the moment, we have the connector reception part, which is in the trial phase. The platform has the capacity to receive information based on HL7 CDA or ISO 13606 standards.

Moreover, we had obtained initial results in the incorporation of decision support functionalities in eHealth platform [15]. This work applying the opensource tool OpenCDS will lead to provide recommendations for medication and problem interactions, as well as to calculate indexes or scales from validated questionnaires. The combination of Decision Support Services in the telemedicine services developed in PITeS Project will allow clinicians to obtain recommendations provided by the system.

Based on the results obtained by the PITeS project, the VRUH node continues working on the same direction, focusing our efforts in the definition, design, and development of tools in three areas of maximum strategic interest: interoperability,

patient's safety, and decision support. For this propose, we have been given financing in the framework to the PITES-ISA project (code PI12/01571), as one of the coordinated project nodes, in which the majority of PITES nodes also participated.

The developed and installed eHealth platform has been presented to the regional authorities by the Innovation Initiative Evaluation Commission in ICT of the regional health ministry, for evaluation and possible implementation into the real environment of services of Andalusia Public Care System.

4.5 CONCLUSIONS

eHealth platform permits us to effectively support investigation, development, and innovation projects in the area of biomedical informatics, eHealth, and telemedicine.

In the PITeS project framework, the platform has allow us to obtain experiences in the application of new standards and technologies, as well as in new care process for patients with COPD, headache and multimorbidity without impacting in the regional infrastructure.

The development of reusable common components has allowed reducing our development costs for the eHealth platform. With increase experience in the different scenarios, many components have been packaged in Web services to allow other systems to reuse them.

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— Headache scenario: M.D. Jiménez Hernández, M. C. González Oria (Neurology Department).

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CHAPTER 5.

GERENCIA DE ATENCIÓN PRIMARIA DE ALBACETE: RESULTS OF A PRIMARY-CARE TELEMEDICINE PROGRAMME FOR PATIENTS WITH METABOLIC SYNDROME

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Index Terms: *Metabolic Syndrome; Telemedicine; Primary Health Care.*

ABSTRACT

Objective: Telemedicine allows for home control of chronic patients and transmission of clinical data. The aim of this study was; firstly, to assess the result of a primary-care telemedicine programme for the follow-up and control of patients with metabolic syndrome; and secondly, to assess patients' acceptance and degree of satisfaction.

Methods and procedures: Prospective before-and-after study conducted at six health centres, in which 82 patients participated. The telemedicine programme consisted of the periodic teletransmission of analytical and clinical parameters by patients and the corresponding dispatch to them of preventive care guidelines by the research team.

Results: When the parameters obtained during the first quarter were compared to those obtained in the second, no significant differences were observed in blood pressure, lipid profile, capillary glycaemia and waist circumference. At the end of the programme, 93.9% of patients stated that they were satisfied or very satisfied and 87.8% considered the information received useful or very useful but 53.1% reported experiencing technical difficulties.

Conclusions: Although no evidence was found of a reduction in the parameters that define the metabolic syndrome, teletransmission of information and preventive care guidelines proved both viable and highly satisfactory.

Clinical impact: The results show the feasibility of continuous telemonitoring of patients with metabolic syndrome. This experience constitutes a health care innovation in this type of patient. In all likelihood, clinical effectiveness was no lower than that achieved in routine clinical practice, though this is something that remains to be verified by future research.

5.1 INTRODUCTION

Telemedicine consists of the application of new communication technologies to medical and health care activity [1] and can be defined as the application of medicine at a distance [2]. In recent years, the rapid expansion of the use of the World Wide Web and the spectacular deployment of related technologies have together resulted in a fusion of the "Internet world" and the "health world" [3], with the ensuing recognition of the enormous applicability of computerised information systems and new data-transmission technologies to health care tasks, in view of the fact that health professionals need to have information on their patients, including data on the latter's family, social and professional environments [4]. Telemedicine encompasses a number of fields of application ranging from research to the delivery of health care services[5], and there are many medical specialisations that have incorporated telemedicine systems into their daily activities, particularly those, such as radiology or dermatology, which make use of image formats.

In primary care, the introduction of new telemedicine services should be viewed as one of the components of a strategy for transforming the current health-service delivery model, traditionally geared to acute problems, into the type of higher quality, more efficient health care model that adapts best to the needs profile of a population which is constantly growing and affected by numerous chronic health problems [6].

Among the advantages for the telemedicine user is teleassistance, enabling interventions such as home control of chronic patients or transmission of clinical data from the home for evaluation purposes. Remote control of given chronic diseases is one of the most used applications in telemedicine, and computerised information systems exert increasingly more influence on given areas, such as follow-up of patients with chronic heart or renal failure [7,8]. In this way, physicians' knowledge of the results of certain variables remotely transmitted to them by their patients allows for treatment to be fine-tuned, as occurs with glycaemia in the case of diabetic patients.

One instance of a highly prevalent chronic disease is the metabolic syndrome, which constitutes a clustering of risk factors whose association increases cardiovascular risk more than merely additively [9]. This clinical condition has a high prevalence in Western societies (1 out of every 5 adults) and clearly contributes to population morbidity and mortality rates [10]. A recent study conducted in the Albacete Health Area [11] here in Spain showed prevalence to be 20.9% in the population aged 40 to 70 years. The use of telemedicine could have repercussions on the health of those affected, through better control of their blood pressure, glycaemia or lipid levels, and so contribute to further reducing cardiovascular risk.

Despite these advances, the added benefit of the use of telemedicine has been little studied, considering that this is an area where physicians' degree of commitment to and involvement in any given case may vary greatly depending on a wide range of factors [12]. Hence, the costs and benefits of telemedicine versus other alternative forms of health care should now be assessed, since the ultimate aim is to ensure the good of patients and health professionals alike [13]. At the present time, one should still lean towards prudence when considering the real expectations of telemedicine, avoiding unfounded optimism yet also bearing in mind its enormous future potential [3].

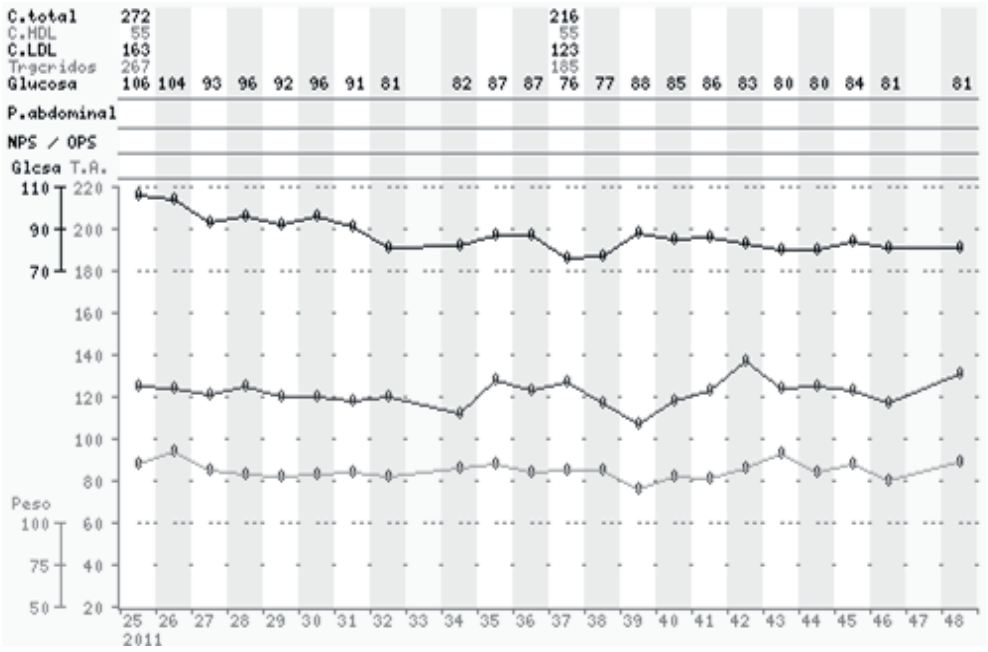
Accordingly, this study sought: firstly, to assess the result of a primary-care telemedicine programme for the follow-up and control of the parameters that define the metabolic syndrome; and secondly, to assess patients' acceptance and degree of satisfaction.

5.2 MATERIALS AND METHODS

We conducted a prospective, before-and-after, intervention study at 6 health centres in the Albacete Health Area. The study subjects comprised 82 patients diagnosed with metabolic syndrome and aged under 65 years, who were required to meet 3 or more of the following Adult Treatment Panel-III (ATP-III) criteria (US National Cholesterol Education Program/NCEP) [14]: abdominal obesity waist circumference greater than 102 cm in men and 88 cm in women); triglycerides, 150 mg/dl or higher; cHDL, less than 40 mg/dl in men and 50 mg/dl in women; systolic blood pressure, 130 mmHg or higher and/or diastolic blood pressure, 85 mmHg or higher (or currently undergoing antihypertensive treatment); and fasting glucose, 100 g/dl or higher (or currently undergoing pharmacological treatment).

The telemedicine programme consisted of periodic (weekly or quarterly) electronic transmission of analytical and clinical parameters by patients via a technological platform for chronic and dependent patients known by its Spanish acronym as *PITES* (*Plataforma de Innovación en nuevos servicios de Telemedicina y e-Salud* - Innovation Platform for New Telemedicine and E-health Services), developed at the Carlos III Institute of Health Telemedicine Unit. Using a broadband Internet connection, this platform enabled data to be transmitted from patients' homes and graphically visualised (Figure 1) for subsequent monitoring by their general practitioners and analysis by the research team. All users underwent practical, face-to-face instruction until proper management was ensured. The programme was co-ordinated by a qualified professional team made up of specialised health care staff and a software technician.

Figure 1. Example of the graphical display of parameters teletransmitted by a patient



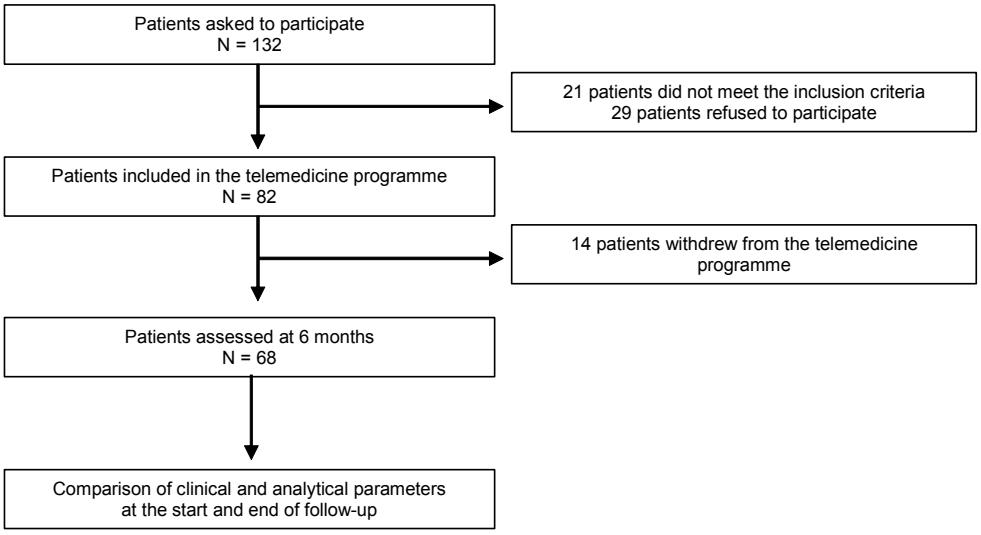
In line with their cardiovascular risk factors, the patients selected were taught to record weekly readings of their blood pressure (home self-measurement with an OMROM M6 Comfort Upper Arm Accurate Blood Pressure Monitor) and capillary glycaemia (using a CardioChek Home Blood Testing Device), and quarterly readings of their lipid profile (home self-measurement with a CardioChek total cholesterol, cHDL, cLDL and triglyceride analyser) and waist circumference (self-measurement with a flexible, unstretchable tape measure). In addition, the research team sent out fortnightly recommendations on healthy lifestyles and habits to the patients, embracing specific recommendations on diet, physical exercise, use of medication, and toxic habits. Furthermore, questionnaires were remotely administered, both at the commencement of the study and again at 6 months to obtain information on sociodemographic variables, toxic habits, level of physical activity (active, partially active or inactive), use of medication, adherence to preventive care guidelines and drug treatment (Morisky-Green questionnaire), and degree of satisfaction with the teleassistance programme.

The study fulfilled the requirements of the Helsinki Declaration and was approved by the Clinical Research Ethics Committee of the Albacete University Teaching Hospital. All participants gave written informed consent.

After completing the data-processing, exploratory analysis and variable categorisation or transformation stages, we compared the information obtained during the first quarter to that obtained during the second using the Student's T-test for paired data. Similarly, we used McNemar's Test of Symmetry to detect differences in qualitative variables between the start and end of patient follow-up. All comparisons were two-way, with a 5% alpha error. Data-analysis was performed using the SPSS v. 19.0 statistics programme.

5.3 RESULTS

Figure 2. Study flow chart



Of the initially proposed total of 132 patients, 21 failed to fulfil the inclusion criteria (15.9%) and 29 refused to participate in the study (22.0%) (Figure 2). The final sample comprised 82 patients, and at the end of 6 months 68 of these (82.9%) continued in the

programme. The main causes of withdrawal were patients' rejection of the telemedicine programme and technical incidents relating to the system. During the follow-up period, patient percentage compliance with self-monitoring was 75.8% for blood pressure, 76.0% for glycaemia, 61.9% for lipid parameters, and 60.9% for waist circumference.

Patients' baseline characteristics are listed in Table 1, and the trend in the different analytical or clinical parameters across follow-up is shown in Table 2. When the parameters obtained during the first quarter were compared to those obtained in the second, no statistically significant differences were observed in mean systolic pressure (123.8 ± 11.2 SD vs. 124.7 ± 9.7 SD), mean diastolic pressure (80.5 ± 6.5 SD vs. 80.5 ± 6.2 SD), total cholesterol (172.1 ± 38.5 SD vs. 177.3 ± 39.1 SD), cHDL (40.5 ± 13.7 SD vs. 38.4 ± 11.1 SD), cLDL (96.9 ± 34.4 SD vs. 109.9 ± 38.2 SD), triglycerides (190.1 ± 103.3 SD vs. 162.4 ± 91.5 SD), capillary glycaemia (117.5 ± 27.0 SD vs. 114.7 ± 22.8 SD) or waist circumference (113.2 ± 13.9 SD vs. 112.8 ± 13.8 SD). Similarly, when the initial data were compared to the final data at the end of follow-up, no statistically significant differences were observed in terms of the proportion of smokers (26.8% vs. 14.3%), risk drinkers (18.3% vs. 20.7%), physically active subjects (28.0% vs. 36.7%) and patient non-compliance with medical treatment (24,4% vs. 23,1%) or dietary recommendations (26.8% vs.18.4%).

Table 1. Patient characteristics

Characteristics	No.	%
Sex		
—Men	61	74.4
—Women	21	25.6
Age		
—34-50 years	37	45.1
—51-65 years	45	54.9
Cardiovascular risk factors		
—Abdominal obesity, dyslipidemia, hypertension and hyperglycaemia	33	40.2
—Abdominal obesity, dyslipidemia and hypertension	18	22.0
—Abdominal obesity, dyslipidemia and hyperglycaemia	12	14.6
—Abdominal obesity, hypertension and hyperglycaemia	11	13.4
—Dyslipidemia, hypertension and hyperglycaemia	8	9.8
Chronic use of medication		
—Yes	77	93.9
—No	5	6.1
Therapeutic compliance		
—Good compliance	56	68,3
—Poor compliance	20	24,4
—Not shown	6	7.3
Smoking		
—Smokers	22	26.8
—Non-smokers	60	73.2
Alcohol consumption		
—Risk drinkers	15	18.3
—Non-risk drinkers	67	81,7

Characteristics	No.	%
Physical activity		
—Active	23	28.0
—Partially active	29	35.4
—Inactive	30	36.6
Adherence to dietary recommendations		
—High	16	19.5
—Medium	44	53.7
—Low	22	26.8

Table 2. Trend in analytical and clinical parameters across follow-up: mean values and standard deviation (in brackets)

Parameters	1st month	2nd month	3rd month	4th month	5th month	6th month
Systolic blood pressure	124.3 (12.8)	124.0 (12.0)	123.7 (11.7)	124.8 (10.7)	124.7 (10.7)	125.0 (10.1)
Diastolic blood pressure	81.3 (6.9)	79.9 (7.0)	80.0 (6.9)	81.0 (6.4)	80.4 (7.1)	80.1 (6.6)
Total cholesterol	175.9 (36.6)	—	—	172.6 (45.4)	—	177.9 (42.8)
HDL cholesterol	40.6 (13.9)	—	—	41.1 (13.8)	—	40.9 (12.0)
LDL cholesterol	103.3 (29.8)	—	—	105.9 (39.8)	—	108.8 (36.1)
Triglycerides	174.6 (106.5)	—	—	183.2 (110.6)	—	161.6 (91.4)
Capillary glycaemia	120.7 (31.3)	119.2 (34.2)	117.2 (26.8)	112.6 (23.9)	114.6 (26.2)	115.0 (21.9)
Waist circumference	113.8 (11.6)	—	—	112.7 (12.2)	—	113.3 (13.4)

After 6 months of participating in the telemedicine programme, 74.5% of patients stated that they were satisfied, 18.4% stated that they were very satisfied, 38.8% considered that their health had improved, and 87.8% ranked the information received as useful or very useful, but 49.0% reported experiencing some technical difficulties and 4.1% reported experiencing many technical difficulties.

5.4 DISCUSSION

These results show that continuous monitoring of patients diagnosed with metabolic syndrome can be conducted using electronic means, which can also be used to provide such patients with preventive care guidelines at regular intervals. Metabolic syndrome is currently recognised as a pathological entity in its own right, essentially because the risk factors constituting the syndrome often occur in a given population simultaneously, their association raises cardiovascular risk, and there is an underlying mechanism for the different components of the syndrome, with insulin resistance being accepted as the common denominator. These circumstances serve to trigger alterations of the metabolism of fats and carbohydrates involved in the development of major disorders plaguing the 21st century, namely, obesity, diabetes and hypertension, all of which are linked to the metabolic syndrome.

One of the main advantages of telemedicine is undoubtedly the health care information it provides, since the new technologies not only open a new field in the transmission of such information to the public in general and patients in particular, but also afford optimal applicability in health education [4]. While the results do not allow one to establish whether the analytical parameters that define the metabolic

syndrome registered a reduction at 6 months of follow-up, the experience nevertheless constitutes a health care innovation in this type of patient, which proved viable and very satisfactory to all those involved. In all likelihood, clinical effectiveness was no lower than that achieved in routine clinical practice, though this is something that remains to be verified by future research.

Telemedicine should probably not be seen as an alternative form of health care delivery in these types of patients, but rather as a complement to ordinary procedures, for the purpose of enhancing accessibility, patient comfort, and speed not only in the sending of information, but also in response times on the part of health professionals. Home telemonitoring can provide continuous monitoring and, at the same time, foster patients' participation in the management of their own illnesses, though unfortunately these new technologies might also heighten inequalities in health care, due to differences in population access [15]. Moreover, telemedicine requires extra health care resources in addition to those usually in place and so, far from relieving health professionals of part of their daily workload, could well represent an additional burden [16]. The principal obstacle to the use of telemedicine could be the great technological dependency involved and the need for the patient's collaboration, which calls for basic knowledge of the management of these new tools (Segura de la Morena, 2004). Then there is also the fact that, at present, telemedicine is not specifically regulated from a legal standpoint. Here in Spain, the legislation applicable is the Personal Data Protection Act (*Ley Orgánica de Protección de datos*/LO 15/1999) and the Patient Autonomy Act (*Ley Orgánica de Autonomía del paciente*/LO 41/2002), and while these statutes do not specifically govern telemedicine, they may be said to be the only point of reference when it comes to a national personal-data privacy policy. In this connection, the European Community urges the health authorities of its Member States to promote the implementation and legislation of telemedicine [16].

In reality, there are few studies about the evidence of clinical benefits in telemonitoring or teleassistance programmes in the case of cardiovascular risk factors, and still fewer about the psychological impact on patients. In the case of diabetic patients, for instance, the use of telemedicine is controversial, since some studies report an improvement in metabolic control [17-21], while others have failed to observe this [22]. Among hypertensive patients, the traditional follow-up system, based on regular medical visits, entails a small number of blood pressure readings, so that telemedicine, aside from reducing the number of visits, also makes for a greater number of readings [23](Pickering, 1999), which are probably of higher quality on being free of the white-coat effect. Different studies on the use of telemedicine in the field of arterial hypertension [24-29] report favourable data on the degree of control of blood pressure figures and adherence to treatment, though these results should be approached with caution, given that these studies were frequently conducted on a small number of patients and the follow-up period was excessively short [30]. One project undertaken in Spain involving the application of telemedicine to the control of cardiovascular risk factors [31] in an internal medicine unit, reported a satisfactory solution to a high percentage of consultations and better management of resources but, as in our case, failed to observe improved control of cardiovascular risk factors across follow-up.

These lines of research will have to be addressed in future, with more randomised clinical trials to be undertaken on the applications of telemedicine. Technological advances in the telecommunications field will logically entail the enthusiastic

implementation of local projects, yet their implementation must be well planned and subject to prior proof of their usefulness from a clinical point or view. To date, moreover, there has been insufficient evidence to decide, in the majority of cases, whether telemedicine applications have an acceptable cost-effectiveness ratio [32,16].

Although the results obtained do not translate as clinical effectiveness in terms of a reduction in the parameters that define the metabolic syndrome, attention should be drawn to patients' good acceptance of and high degree of satisfaction with the telemedicine programme, despite the technical difficulties reported. In the case of diabetes too, telemedicine users report a high degree of satisfaction, consider the system useful, and perceive themselves as having a greater capacity to better manage their own disease [33]. With respect to acceptance by health professionals, studies have conducted surveys of primary care physicians which show that 80% of those surveyed ranked telemedicine as a useful instrument in their routine practice, though these results should be assessed with caution in view of the low response rate obtained [34].

The main limitations of this study are those inherent in the before-and-after design, which rules out any comparison between the trend in the parameters analysed and the results of routine clinical practice. A further limitation on our results is the proportion of withdrawals and the selection of patients, which means that the study population may not represent persons of more advanced age or those that experience more difficulty in managing electronic media. Hence, with respect to the external validity of the conclusions, the characteristics of the study setting (socioeconomic level of participants, lifestyle, etc.) may not be directly extrapolatable to any other setting.

In conclusion, notwithstanding the fact that a telemedicine-based 6-month follow-up produced no evidence of a reduction in the analytical parameters that define the metabolic syndrome, the teletransmission of information by patients and corresponding dispatch of preventive care guidelines by health professionals proved both viable and highly satisfactory. At times like these, when the increase in health care costs makes rationalisation essential, investigation should centre on changes in health care delivery systems which will change the way in which work is structured. There can be no doubt that any new options which bring savings without lowering health care quality will inevitably be linked to these new information and communication technologies.

5.5 ACKNOWLEDGEMENTS

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