Technological, economic and social issues hampering homecare approaches adoption: challenges and opportunities. Emilia Romagna perspective.

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Abstract

Transition from hospital treatments to homecare approaches needs both behavioral and technological changes and different actors need to be involved (formal and informal caregivers, nurses, patients, doctors, and industrial systems), both private and public stakeholders should be engaged in the process.

Emilia-Romagna Region represents a proper socio – economic ecosystem to develop and implement an appropriate homecare approach, in particular a home hemodialysis (HD) treatment. This work analyses the existing literature about home HD approaches and the regional ecosystem, both from industrial and socio-economic perspective. The aim is to identify open issues and a possible roadmap to home HD implementation involving all different stakeholders needed.

Introduction

Adopting an appropriate homecare approach is a challenging and debated issue; literature is articulated and wide, and terms as "telemedicine, eHealth, …" have been in use since 1990.

Homecare approaches are considered the best solution for facing the future European healthcare systems challenges. Indeed it is foreseen that "*the share of the elderly (65+) and very old (80+) population in the EU is projected to grow respectively from 17.4% in 2010 to 30.0% in 2060 and from 4.7% in 2010 to 12.1% in 2060*" *("eHealth Action Plan 2012-2020-Innovative healthcare for the 21st century"),* and this will led to an increase of the overall number of patients and not-self-sufficient people, often affected by more than one pathology; at the same time, social changes are transforming society and familiar settings (i.e. progressive inclusion of women in the labour market or IT introduction in all aspects of life, regarding both leisure and workplaces (*Vancea et al., 2016*), homecare approaches and new technological solutions could support delivering of much more efficient and effective treatments, reducing hospitalization rate and overall healthcare systems costs.

Preliminary literature analysis permits to underline that each research or study faces different aspects or issues involved in the process needed for homecare approaches implementation, and at European level, there are strong differences in many features *(Genet et al., 2013)* . Moreover main differences between papers regard aspects such as (i) pathology characteristics, (ii) healthcare system analyzed, and (iii) available technologies, but some transversal themes can be identified as keys elements to be in-depth analyzed when a new care models is studied: workforce development and workforce knowledge, stakeholders engagements, cultural ecosystems, etc.

Starting from these background and considering existing literature, our objective is to identify or design a path to be adopted in order to create, develop and implement a favorable ecosystem and a proper model to realize an homecare approach in Emilia-Romagna Region. Indeed, Emilia-Romagna healthcare system is a benchmark both at Italian and European level, but homecare approaches are present only as pilot studies or case studies; moreover, one of the most important regional industrial district is specialized in life science, especially in biomedical sector and it could be involved in this shift from hospital to homecare approaches.

These considerations led us to wonder what are the aspects to be considered and the stakeholders to be involved in order to develop and adopt a proper telemedicine approach. To develop a first model, our work will be focalized on hemodialysis, a particular therapy for patients suffering from end-stage renal disease. Our focus is on hemodialysis because production of systems for hemodialysis treatments is one of the major specialization of biomedical of the Emilia-Romagna industrial system. In particular, Mirandola biomedical district, located in Modena, is one of the major European biomedical district and it is specialized, among other, in the development, production and commercialization of devices for hemodialysis, apheresis and plasmapheresis, etc. Extra-corporeal circulation and related therapies could be considered one of the main focus of the district.

Hence, performing an overview of literature focused on homecare hemodialysis treatments and analyzing Emilia-Romagna healthcare systems and industrial specialization, this work will try to develop a model and a process to be established to develop a first effective pilot of a telemedicine approach, involving all the public and private stakeholders needed. Main stakeholders of these process are medical staff, nurses, families' members, informal caregivers, patients, productive ecosystem, etc.

Once validated and tested in a real environment, a proper eHealth homecare model could be easily transferred /adapted for other therapies or applied in other nations to other chronic diseases.

Literature review

Before starting with literature review, it could be useful to define the correct means of the most frequent terms found in papers and which may generate confusion. Indeed, as anticipated, homecare approaches are largely debated, but it is hard to find shared definition.

For the purpose of this article we can consider these definitions:

- **Homecare**: *"care provided at home"*, in our meaning provided both by professionals and informal care providers after appropriate definition of (i) patients needs and (ii) therapeutic approaches to be adopted. In this definition, *"'Care' means domestic aid services, personal care and supportive, technical and rehabilitative nursing" (Boerma et al., 2013)*

- **eHealth:** *"the use of information and communication technologies (ICT) for health"* as defined by the World Health Organization (WHO) (www.who.int/ehealth/en/)
- **Telemedicine** is *"the use of ICT for health service delivery"* (WHO definition) *(Ryu et al., 2012).*

Literature analysis was focalized in a first step in identifying the main topic to be faced when stakeholders try to develop an homecare approach. As anticipated, some common themes could be identified as key/core -themes when analyzing a telemedicine solution, independently of the papers' purposes (i.e. they underline the needs of skilled workforce, of proper organizational model); whereas, papers differ in:

- **Pathology characteristics**, which have important consequences on patients' needs and health status; i.e. needs of diabetic patients are different for people affected by Chronic Obstructive Pulmonary Disease (COPD) depending on age, pathologies symptoms, patients autonomy, patients overall health status
- **Healthcare system characteristics**, because several are the elements which can differ between nations or regions, such as: reimbursement systems, workforce knowledge and skills, cultural background, habits, etc.
- **Available technologies**, which can depend on the pathologies analyzed or on the article specific purposes (i.e. if it is focalized on patients involvement, the major focus could be on apps and not on devices for therapies administration).

In reviewing literature, we focalized mainly on studies about ***"hemodialysis homecare approaches"*** which represent our area of interest. We integrated this analysis with some consideration collected also from publication about national or international policies, such as European Commission indication or guidelines. Indeed, also at European level, eHealth policies are considered the key elements to overcame the challenges deriving from the ageing of population. Ageing is strictly related with an overall increasing in healthcare costs.

Before starting the description of the **hemodialysis (HD)** homecare approaches' needs, we propose a brief description of current HD treatment in order to better frame therapies and patients characteristics.

Hemodialysis overview

Hemodialysis is a way of removing retained fluid (by ultrafiltration), electrolytes and waste products in peoples suffering from end-stage renal disease (ESRD) *(Ludvigsen et al., 2015)* which can be the consequence of chronic kidney disease (CKD). Patients suffering of ESRD could be treated also with Peritoneal dialysis (PD) (using patient's peritoneum for blood purification), but after 3 / 5 years they needs HD treatments (http://archive.eucomed.org/disease-sectors/community-homecare/dialysis) due to therapies consequences.

ESRD could be considered a socio-economic problem, indeed, despite the overall improvement of CKD treatment and prevention approaches and an overall reduction of cases, elongation of life-expectancy also for people with chronic diseases, causes a challenge for healthcare system (elongation of life expectancy causes also an elongation of the therapy). Indeed it is foreseen that *the number of prevalent dialysis patients is expected to grow (in USA from approximately 451,000 in 2012 to approximately 632,000 in 2025) (Wetmore et al., 2016).* European forecasts established that in 2020, 361.000 patients will be treated with hemodialysis, 32.100 with peritoneal dialysis, and 268.000 with kidney transplants (http://ercpa.eu/facts-figures/).

Simplifying treatment's procedure, during hemodialysis blood is removed from the body and forced to pass through an apposite filter (called dialyzer) which has the purpose of removing cited waste products (i.e.: urea, creatinine, potassium). Then the blood is re-infused in the patient.

The main technologies needed for therapies administration are: electromedical device (or dialysis machine) and disposables, which comprises dialyzer and other key elements such as tubatisms, or particular filter to be added for specific treatments. Moreover, patients parameters are monitored and controlled during all treatment, to avoid complications or adverse reactions. Typically, HD lasts 4 hours and it is repeated 3 times per week.

Dialysis machines are devices able to remove blood from the body through a "pump"; blood is pushed through a Dialyzer. Dialyzer is crossed by blood and dialysate which are separated by a semi-permeable membrane; so blood depuration, liquid retention or administration of substance (as calcium or bicarbonates) happens in the filter. Other specific filters can be added to remove specific molecules. Filter, dialyzer and tubatisms are "disposables" 'cause they are changed and removed after each single treatment.

Patients' parameters are monitored by specific sensors and the main collected information can be grouped in three categories:

1. Efficacy Monitoring: main parameters monitored are urea, ionic dialysance, sodium removal, vascular access
2. Hemodynamic Monitoring: main parameters monitored are blood pressure, blood volume, blood temperature, online hydraulic permeability, online hemoglobin and Biofeedback System
3. Safety monitoring. The "first failure safety" principle is applied, in other words, the dialysis machine should not expose the patient to a risk of damage if one (and only one) machine failure occurs.

Main machine producers worldwide are: Baxter (ARTIS dialysis system, USA), B.Braun (Dialog+ HDF-machine, Germany), Fresenius Medical Care (5008 e 5008S, Germany), Nikkiso (DBB-07, Japan), Nipro (Surdial-X, Japan), Bellco (Flexya, now Medtronic).

Home HD is certainly not a new concept, however it is not a systematic applied procedure, above all in south-Europe Countries.

Homecare HD approaches

It is possible to find some associations which promote the use of homecare HD (https://www.kidney.org/atoz/content/homehemo), such as National Kidney Foundation, an American Foundation, but at least in Italy, eHealth approaches are not a concrete reality; it is hard to find example of well implemented telemedicine approaches.

Hence, considering these aspects and revising literature, common topics can be founded concerning the eHealth approaches for homecare HD administration. In particular, to develop and appropriate homecare model should taken into account:

- **Staff or workforce characteristics**: as explained by Mitra (*Mitra et al., 2015),* workforce development is a challenging issues. In the paper, workforce needed for an effective HD homecare approach comprises: medical figures (physician / nephrologist), nurses, technician, renal social workers (specialist advisors / health care liaisons), administrative figures (as HD managers), dietitian, psychologist or counselor and educators; in addition, they underline the utility of the

"expert patients". Expert patients are needed to improve the adoption of home HD by new patients, to provide guidance and advice. All these figures are needed both to overcame technological or medical risks (as non-adherence, machine faults, …) and to involve patients themselves in their therapies. Indeed, also in other studies (*Young et al., 2012*) could be found that home HD help to increase patients involvement with a reduction of side effects (independence, responsibility and confidence are promoted).

Education: education can be declined in different ways, considering both different roles involved in homecare HD and social-interactions modalities. Concerning roles, it is expected that medical staff (or informal caregivers) have competencies to manage patients and equipment (i.e. nurses may know the correct procedure for cannulation or they may be able of treating comorbidities) or that technicians are able to face possible machine failure. This aspect can be classified as "adequate knowledge" (*Mitra et al., 2015*). A study reports that the main adverse effects in home HD are needle dislodgement or air embolism, so effective workforce training is a key element to ensure patients safety (*Karthik et al., 2016*).

Education is strictly linked to social background, indeed in certain situation language barriers between medical staff and patients can be an issue, another important barrier could be cultural habits. All the staff may be educated to face different cultural settings, especially in a domestic environment. On the other side, social interactions are considered important in order to avoid "treatment burden" or to support patients during therapies administration or in to facilitate the "mind-change" needed for the shift from an hospital to an homecare approach.

HD perception: strictly linked to staff or team characteristic is the perception of HD both from patients' side and formal and informal workforce. Indeed, as anticipated, it is important to favor patients' awareness, and to help them in accepting their situation and conditions. *"Empowerment"* is also one of the main topic and action promoted by European policies. Empowerment is needed also to make patients much more aware and responsible of their condition, "*fear of change or lack of self-confidence or concerns of substandard care*" (*Young et al., 2012*) are considered obstacles in adopting home HD.

HD perception could comprise also some psychological aspects, such as fear of blood, of needles, fear to "be alone" which can affect both patients and informal caregivers (*Kidney Health Australia, 2012*)

- **Therapeutic workflow.** For the purpose of this work, with "therapeutic workflow" we consider all the organizational aspects needed for homecare HD effective program implementation, in other words, all the elements to be taken into account when an home HD is administered. Organizational workflow comprises the steps and the elements to be faced. Starting from Young (*Young et al., 2012*), aspects to be considered are: selection of dialysis machine, prescription of dialysis regimen, selection of the appropriate technologies for remote monitoring of patients safety; in our opinion it is necessary to add other elements **as patients' selection procedure** (considering also socio-psychological aspects)**, therapy effectiveness monitoring and workforce education.**
- **Technological issues** are mainly linked to aspects such as electrical access points, layout of residence (*Young et al., 2012*) which can influence the proper adoption of every telemedicine approaches. Specifically for home HD, water source could be an issue, mainly for the regions where water supplying or water quality are considered a problem; it is important to underline that a dialysis treatment consume liters of waters, needed for the extracorporeal circulation and to favor blood purification.

Continuous therapies' monitoring requires also internet connection or secure modalities to transfer data and real-time information, protecting patients' privacy. Hence, IT infrastructures are a key element which may considered when homecare approaches are implemented.

- **Home situations and geographical context** are other issues to be considered. With the term "home situations" we comprise all those aspects which in literature are described as: social isolation, individual barriers (*Kidney Health Australia, 2012*), and families situations (such as: number of members, education level, etc.); similarly, geographical context can be an issues when patients are dispersed through a territory. Another important aspect is linked to "cultural" consideration, which may influence dialysis approaches adoption. Patients' lifestyle is an element to be considered when preparing a "centered-patients" approach.
- **Comorbidities;** comorbidities can influence home HD management and outcomes; patients in HD are often aged and treated for long time, so it is expected that they are affected by other pathologies than CKD, such as diabetes. A correct home HD treatment may be focalized on patients characteristics (needs and preferences); indeed a "patient-centric prescription" may be adopted (*Diaz-Buxo et al., 2015*). In this patient-center prescription all the aspects linked to the other pathologies need to be carefully evaluated. Other aspects to be considered for home HD prescription are i.e. fluid gain and loss, inflammation, nutrition, etc.
- **Healthcare system and legal framework,** introduction of home HD will require a depth analysis of healthcare system, taking into account reimbursement policies or other specific national or regional characteristics.

Case studies

Literature analysis is also aimed at identifying case studies and international experience to be transferred to Emilia-Romagna. To identifying and selecting case studies / best practices, besides literature analysis, a research was performed also in other repositories, such as the one implemented by European Innovation Action on Active and Healthy Ageing (EIP on AHA).

Concerning literature, in-depth analysis of homecare approaches and treatments demonstrate the efficacy and positive effects of out-center / home HD (*Arkouche et al., 1999 and Saner et al., 2015*) for i.e. in terms of patients survival and quality of life; it is also reported that home HD can also prevent complications.

Out-center HD (*Arkouche et al., 1999*) is a sort of intermediate step in the passage from hospital to home approaches. In these centers, as the ones described by Arkouche, patients can schedule their treatments and have personal instruments (machines) while nurses and medical staff visit patients at regular moments. Similar to these out-center HD, Marshal (*Marshall et al., 2015*) proposes an hemodialysis hub which is the "*organizational structure that will support both patient-facing clinical activities and business processes*".

Other important information for implementing an home HD, is an economic analysis of healthcare system costs. Literature reports:

- "*in Switzerland the annual cost of HHD is estimated as sFr 54 000 compared with sFr 78 000 for CHD*" (*Saner et al., 2005*)
- "*in USA: Overall annual cost of care for in-center, satellite, and home/self-care hemodialysis and peritoneal dialysis were US $51,252 […], $42,057 […], $29,961 […], and $26,959 […]*" (*Lee et al., 2002*)

- In Canada a comparison was performed between frequent home nocturnal hemodialysis (FHNHD) and traditional approaches (in-center conventional hemodialysis – CvHD or home CvHD and peritoneal dialysis) (*Klarenback et al., 2014*). In this study, in addition to costs evaluation, they considered also quality of life; Klarenback demonstrated that "*FHNHD is an attractive option compared with CvHD (…)*" but authors underline that patients selection, out-of-pocket costs or other aspects should influence this evaluation. Moreover, the small size of the sample and the short duration of the study are indicated as work limitations.

Other important case studies to be cited, are strongly linked with enterprises R&D activities. Baxter Healthcare Corporation is developing its dedicated equipment for home HD; in particular Baxter is testing a novel hemodialysis system for homecare approaches (*Bernardo et al., 2017*). Paper reports results of the first clinical tests needed to evaluate efficacy and safety, but the overall aim is to realize a system to be used in homecare approaches. This kind of development path, the design of a new equipment, its validation and its production could be fully implemented in Emilia-Romagna region.

EIP on AHA database was analyzed in order to identify best practice to be implemented in Emilia-Romagna Region or successful case history to be transferred. EIP on AHA is a network of European actors, "*a communication and information hub for all actors involved in Active and Healthy Ageing through Europe; the place to promote news and events, to meet and exchange ideas with peers, to look for potential partners on innovative projects*" (https://ec.europa.eu/eip/ageing/home_en). Using key words (as dialysis, hemodialysis, haemodialysis) in its repository (https://ec.europa.eu/eip/ageing/repository_en) the only result obtained is about an Italian initiative aimed at evaluating an "integrated telemedicine platform for predictive medicine, telemonitoring and empowerment of patient affected by Chronic Kidney Diseases (CKD)" (https://ec.europa.eu/eip/ageing/repository/integrated-telemedicine-platform-predictive-medicine-telemonitoring-and-empowerment_en). In this case, the main focus is not strictly linked to therapy, but to an integrated system able to support patients and monitor his or her status / condition.

Methodology & data analysis

Literature analysis helps to identify the main organizational and technological aspects to considered in developing an homecare HD approach. Thanks to these information we analyzed the specific contest of Emilia-Romagna, to apply a sort of SWOT analysis aimed at identify the strength and the weakness which may be encountered in setting up an HD approaches in this region. In particular, these key elements will be in-depth analyzed: regional healthcare system and industrial framework.

Industrial framework:

Mirandola Biomedical District is a **Compound of Companies** specifically focused on the production of **Medical Devices.** Mirandola is located in the north of Modena municipalities, so in north of the Emilia Romagna Region.

The beginning of the industrial history started in the late 60s, the district hugely developed in the 80s and 90s. Positive economical trend and competence concentration attracted several multinational and global

companies that invested in the area mainly through acquisition (but also "de novo"). Actually, the most important players present in the area are: Baxter, Medtronic, B.Braun Avitum Italy, Fresenius Kabi Italia, Livanova but a plethora of specialized SMEs exist in the area, producing both their own products or acting as subcontractor of big industries.

Different medical therapeutic fields could be found in the district, mainly enterprises are focalized on Apheresis and Plasmapheresis, hemodialysis, Heart surgery, Anesthesia, Gynecology, Infusion, Transfusion, Autotransfusion, Continuous Renal Replacement Therapies, Enteral and Parenteral Nutrition.

Products can be separated in two main categories, which differ for their complexity and application; enterprises are involved in the production of **DISPOSABLE devices and** of biomedical **EQUIPMENT.**

Disposable are mainly plastic components, like tubatisms or the cited filters, whereas equipment are electronic devices, which act as the "active element" of the extracorporeal circulation. Equipment is often provided with the sensors needed for the monitoring of the therapies.

Last available data of Modena Chamber of Commerce (2016 report) reports that in Modena province are present more than 90 enterprises involved in biomedical sector, of these: 50% produce treatment and diagnosis disposable, 42,7% realize equipment or instruments for analysis, and 7,3% realize prosthetic products. These enterprises generate over one billion billions including satellite activities.

Bellco, now a Medtronic company, produces its own dialysis machine, in the same way, Baxter is involved in machines production. On the other side, a lot of SMEs are involved in the production of disposable, so in the district could be founded all the competencies and expertise needed for developing an appropriate home HD: already existing devices could be adapted and revised to respond at the new requirements of an homecare approach.

However, one of the main problem recorded at industrial level is the lacking of collaboration between enterprises; but thanks to some local and regional initiatives this lack is to going to be overcome. Multinational enterprises are maybe the only entities which can support an home HD implementation. Hence an important regional commitment is needed to involve these entities.

Emilia-Romagna Regional healthcare system

Emilia-Romagna regional healthcare system is acknowledged as an Italian reference point for the quality of the services administered. In 2016, Meridiano Sanità Regional Index (*The EUropean House - Ambrosetti, 2016*) reports that Emilia-Romagna has the best performance considering 4 main index: healthcare offer efficiency, quality of supply, population health status and ability of the healthcare system to respond to health needs.

In order to describe in a proper way the regional framework it is important to illustrate some data; following data refer to 2014 and are taken from Emilia-Romagna annual report on healthcare system (Il Servizio sanitario regionale dell'Emilia-Romagna. Le strutture, la spesa, le attività al 31.12.2014).

Regional Health Service expenditure was 8.6 billion euros and per capita spending was 1,940.61 euros. Regional Health System comprises:

- 8 “Aziende USL” – Unità Sanitaria Locale – Local Health Unit: Azienda USL di Parma, Azienda USL di Reggio Emilia, Azienda USL di Modena, Azienda USL di Bologna, Azienda USL di Ferrara, Azienda USL della Romagna, Azienda USL di Imola. Each of these Local Health Units are organized in districts which guarantee for the assistance administration, identify needs and program the actions. Results are evaluated at district level
- 4 “Aziende Ospedaliero-Universitarie” - Hospitals-Universities - : Parma, (Ospedale Maggiore), Modena (Policlinico), Bologna (Policlinico Sant’Orsola-Malpighi), Ferrara (Ospedale Sant’Anna di Cona);
- 1 Azienda Ospedaliera – Hospital agency: Reggio Emilia (Arcispedale Santa Maria Nuova)
- 4 Istituti di ricovero e cura a carattere scientifico (Irccs) - Institutes of hospitalization and care with scientific purposes - : Istituto Ortopedico Rizzoli di Bologna, Istituto delle scienze neurologiche di Bologna (all’interno dell’Azienda Usl di Bologna), Istituto in tecnologie avanzate e modelli assistenziali in oncologia di Reggio Emilia (all’interno dell’Azienda Ospedaliera di Reggio Emilia) e Istituto scientifico romagnolo per lo studio e la cura dei tumori di Meldola (Forlì-Cesena).

Beds in public hospitals are 14,224. Patients assisted through homecare assistance are 102.947 (102.521 in 2013) – 3,1 % of the total regional expenditure. Homecare assistance is administered to non-self-sufficient or to patients at risk of non-self-sufficiency and an evaluation of “social condition” is performed to select adequate patients. This evaluation takes into account aspects as pathologies, living condition and family support. Patients over 90 years old are the ones who benefit more of home care assistance.

Other elements which can be considered as an interesting element to set up a new model for HD administration are the “Casa della Salute” – healthy houses (http://salute.regione.emilia-romagna.it/cure-primarie/case-della-salute). “Case della Salute” are 72 in Emilia-Romagna Region and they are a new organizational model; there are three kind of these structures: “small, medium and large”. The small one guarantees general medicine services for 12 hours per day (from 8 am to 8 pm), nurses’ assistance, homecare assistance coordination, social assistance and counseling with one midwife. Medium and large offer the same service of the small “case della Salute” plus activities related with public health and mental health. Almost the 35% of the regional population could access to these intermediate structures. Casa della Salute are policed at district level.

Concerning investments, Emilia-Romagna healthcare system, from 1991 and 2014 was involved in 650 different activities (related both to technologies and structural networks) with an expenditure of 2,7 billion euros. Of the 2.7 billion euros, 69% of the investments were dedicated to new construction and expansion of the structures, 15% restructuring, 9% in technology, 7% to regulatory adjustments. In 2014, 70% of these investments were concluded.

It is also involved in the development of innovative solutions to improve patients conditions or to promote empowerment, i.e. it is available “health electronic file”; each regional inhabitant can access to its personal information (through appropriate recognition system which guarantees data privacy) and he or she can consult medical reports, appointments, visits, medications’ prescriptions, and pay tickets and book visits and specialist examinations.

For the purpose of the present work, it is important to report specific data about dialytic therapies.

In 2010 patients undergoing dialysis were 3181 of which 2891 was treated with extracorporeal dialysis (90,8%) and 290 (9,11%) with peritoneal dialysis (PD) (in the same year, national ratio was 10,5 % PD and

89,4% HD). Average age of patients undergoing dialysis was 67,8 (±13,3) for HD and 61,3 (±17,1) for PD. Dialysis was administered by hospitals or decentralized centers. The first ones can offer a complete assistance, whereas, decentralized centers can be organized to offer programmed and desultory medical presence or can have a constant medical presence. In 2010, only 39,7% of patients used decentralized centers (Registro regionale emiliano-romagnolo di dialisi e trapianto (RER-DT) Report 2010).

In 2011, 3.600 are patients undergoing a dialytic treatment (8% of regional population) and an overall evaluation of expenditure of each patient undergoing HD is 45.000 euros / year (L'ambulatorio della CKD: l'esperienza dell'Emilia Romagna col progetto PIRP, 2015) (Pontoriero et al., 2007).

In 2013, Emilia-Romagna become reference site for the cited EIP on AHA; reference site are "*coalitions of regions, cities, integrated hospitals or care organisations that aim to provide concrete examples of innovative services with proven added value to citizens and care systems in EU regions. Some of them have contributed to growth and job creation in their areas, many have extended elements of their best practice from local to regional or national level*" (http://europa.eu/rapid/press-release_IP-13-633_en.htm?locale=en).

This overview allows to identify Emilia-Romagna as a proper ecosystem to implement a concrete home HD approach. It is interesting to underline that some attemps was performed; the most interesting is a pilot implemented in Piacenza. This pilot comprised 5 patients, 3 are Housed in a home for older people and 2 lived in their own houses. A new technologically advanced system was given to the patients; in particular, the two patients living at their home, who are self-sufficient had a system which can be easily transported (like a trolley) http://www.ilpiacenza.it/cronaca/emodialisi-a-domicilio-piacenza-parte-con-un-esperienza-pilota-in-emilia-romagna.html . However, this pilot seems to be the only one recorded at regional level.

Discussion

In previous section we presented an overview of literature aspects and a description of Emilia Romagna Region strengths and characteristics in healthcare domain, from a medical and industrial point of view. In this section we trying to summarize our analysis and to propose a possible model for homecare HD approach and the steps to be done to transfer this model from an idea to a concrete experimentation. Moreover this analysis allowed to define some open issues which may be investigated in the future for helping this transition from hospital to "home". An appropriate model would balance quality of the administered service and its cost (sustainability).

Open issues

We would like to start our discussion with a proper description of open issues, themes which may be in-depth analyzed before or during a proper model home HD . Some of these open issues are treated in literature but in specific contexts and/or for specific eHealth application, so they may be in-depth evaluated for an application in Emilia-Romagna Region.

1. Responsibility
   One of the main point which may be treated concerns responsibility aspects, in other worlds it may be established who is responsible of different aspects, spanning from therapies compliance to technical failures, every telemedicine approach (not only home HD) will require this evaluation. In

the first case the main problem is related to patients compliance, indeed, homecare approaches could cause a minor control on patients behavior; if the monitoring activity made by nurses or informal caregiver is not appropriate, patients can be less inclined to respect the scheduled treatments or they can be administered in an inappropriate way. In this case, who has the responsibility of adverse effects? And if any technical failure causes problems, who is responsible? The machine producer or the medical staff? And if the technical failure is linked to the IT connection infrastructure? All these aspects may be proper evaluated and clarified when implementing a home HD. Probably many of these aspects can be overcome with a proper organizational model, through risks assessment and through the adoption of adequate technological solution. Responsibility could be clarified through the adoption of an appropriate regulations.

2. In-depth cost evaluation

   As anticipated, literature analysis provides some information about costs' evaluation connected with an home HD approaches and they agree in claiming that homecare approaches are "cheaper" than a traditional treatment. However, some considerations can be done:

   - cited articles are no so updated, data come from studies not done in recent years and this can have consequences i.e. on available technologies, or in staff wages, …
   - is it not clear how much are considered indirect or out of pocket costs of a therapy, which are not only linked with costs for healthcare system. In order to have an overall estimation could be useful to consider every costs of "traditional" and "home" HD as the one connected to travels (from home to hospital and vice versa) for traditional approaches or the expenses connected to IT infrastructures needed for home HD
   - an appropriate costs' evaluation may take into account the specific ecosystem in which the home HD will be implemented. Indeed, healthcare systems can be organized in different ways and access to technologies and their costs can vary from region to region and from nation to nation
   - costs depend on the organizational model adopted. As described in the previous paragraphs, staff characteristics, technological instruments, medical approaches, … can be structured in different ways influencing costs' structure of home HD

   Related to costs' aspects could be also the private or public funding which would be adopted for home care approaches.

3. Adoption barriers

   With the term "adoption barriers" can be considered different aspects spanning from a mindset change needed at all level to technological problems. Mindset change is well treated in literature, and it is linked with the "fear of change", both medical staff and informal caregivers could not be inclined in adopting a new approach which alters the treatment. Emilia-Romagna will be not saved by this problem. Moreover, taking into account informal staff, older people living at their own home are often assisted by in-home nurses coming from east-Europe; in these cases language and competencies barriers could be an important barrier to be faced.

4. Safety aspects and social implications

   Patients safety and efficacy of the therapies may be always considered. It is expected that it will be pursued through implementation of proper organizational models and technological solution. However, it may be considered also safety of the other figures involved in therapies administration, starting from medical staff to patients family. Moreover, one of the main issue is related to a sort of Life Cycle Assessment (LCA) of home HD; indeed it may be established a proper procedure to

collect, stock and dismiss the wasted materials (i.e. disposables which are used for blood circulation). All this aspects will be evaluated and a proper risks analysis may be scheduled.

Regional roadmap for home HD model design and implementation

These analysis allows definition of some main topics to be defined to implement in Emilia-Romagna Region a home HD, then we are going to propose a series of steps to be developed to reach the scope. To validate an appropriate model could be useful to start a experimentation at local level, with a reduced number of patients. In this way all the organizational and management aspects can be defined. Once implemented and validated the approach can be easily transferred at regional level.

The first step will be the setting up of a working group composed by different figures, both medical ones and organizational. In particular, it will be necessary to involve also administrative and legal personal from hospital, for the evaluation of costs and to overcame the problems mainly related to risks evaluation and responsibility issues. It will be useful to involve actors involved in local healthcare system management, but also at regional level to facilitate the future transfer of the therapeutic approach. Other key partners to be involved will be representatives of organizations (such as cooperatives) which are engaged in healthcare assistance. This kind of organization can mobilize the sufficient critical mass to support the education and involvement of informal caregivers.

This working group will be in charge of clarify all the open issues and to overcame the barriers. Integration of all the home-care services would be faced (as coordination between care providers, informal caregivers, general practitioners, etc.). Another aim of these working group will be to identify all the technological aspects to be updated. In a second phase this working group may involve industrial representatives. In particular, considering Emilia-Romagna Region, organizations developing HD devices or disposables can be involved and encouraged in developing or designing new instruments which respond to medical needs. In collaboration with healthcare system, industries could test and validate their new products or services. Last but not least, researchers should be involved to support the development of proper technologies, considering biomedical and IT aspects, in collaboration with industrial actors.

Technological analysis will involve also other actors who can be telecommunication experts, IT providers, in order to define also all the aspects related to eHealth approach implementation.

In parallel, it will be useful the involvement of experts for assurance aspects and lawyers for privacy matters. Indeed, these figures can be involved in the resolution of the main issues to resolved to develop an appropriate home HD.

Once developed a proper model, it will be vital to verify the if the identified working staff, which will be probably composed by formal and informal workforce, has the appropriate and adequate knowledge to manage a home HD. It is expected that some update of competencies will be needed, so also these activities will be scheduled.

Conclusion

Emilia Romagna Region seems to be a proper socio – economic ecosystem to develop and implement an appropriate HD homecare approach. What is needed is the correct involvement of the stakeholders and an

harmonization of the efforts. Once implemented and validated the model could be applied to treat other pathologies or transferred to other Italian / European regions.

Implementing an appropriate HD homecare approach in Emilia-Romagna Region will be important both from social and economic point of view. Social aspects comprises: an improvement of patients' health condition, a reduction of illness' impact on people life and habits, a major involvement of informal caregivers in health condition improvements. Home HD approach will improve the overall status of patients and their lifestyle.

Economic improvement are linked with a saving of healthcare systems in term of hospitalizations reduction and adverse effect prevention. Considering industrial background is important to an economic point of view, indeed: *"the global telemedicine market has grown from $9.8 billion in 2010 to $11.6 billion in 2011, and is expected to continue to expand to $27.3 billion in 2016, representing a compound annual growth rate of 18.6%" (eHealth Action Plan 2012-2020-Innovative healthcare for the 21st century),* hence, promoting the involvement of local productive ecosystems could promote and overall improvement of social and economic regional ecosystem.

Moreover, regional industrial ecosystem, characterized by a plethora of biomedical industries, will be the proper technological support to implement and realize the technological infrastructure needed for an homecare approaches. Indeed at regional level, mainly in the biomedical district can be found enterprises producing both equipment for HD and disposables needed for its administration. Whereas the regional market could not justify an R&D investment needed for adapting their products to an homecare approach, considering the entire cited telemedicine market, the provisional income deriving from these new treatments could be a sufficient motivation.

This work has the aim of identify some key elements for an home HD implementation and it is acting as a working document which underlines the necessity of establishing a composite working group at regional level to implement a new treatment model. The most appropriate model to be implemented should probably comprise both public and private entities, to guarantee the sustainability of the model and the appropriateness of the home HD.

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