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How Information Availability Changes Healthcare Chronicity Management: Findings from a Pilot Case Study

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Structured Abstract

Purpose - Chronic diseases are a crucial matter for worldwide National Health Systems; they represent one of the first causes of disability, mortality and morbidity, due to their persistency and tendency to develop some degree of disability (WHO, 2013).

To ensure the economic and social sustainability of such diseases, new healthcare business models development should be considered. Accordingly, Chronic Diseases Management shows how patients are enabled to actively take part of their healthcare by taking advantage of Internet of Things (IoT) (Batalden et al., 2018).

This is particularly highlighted in cardiac chronicity: patients enhance their health status, by increasing the participation level (Osborne et al., 2016) on their care pathway, through telemedicine.

Accordingly, the main purpose of this work is to explain how is possible to improve real time medical information exchange between patient and hospital, by using technological infrastructures.

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Just in time information allows the clinical staff to improve the chronicity management. This means: increasing quality of life for patients, optimisation of hospital workload, cost saving.

Design/methodology/approach — It was adopted a pilot case study method (Yin, 2014), classified as "Extreme Case Sampling" (Patton, 2002). Study concerns with the observation of remote management of a group of heart failure (HF) patients that, at moment of discharge, are equipped with: i) electrocardiograph; ii) weight scale; iii) pulse-oximeter; iv) sphygmomanometer. All those medical devices are connected with a mobile transmitter. Thus, according with his/her own clinical protocol, each patient provides both the self-measurement and dispatch of his/her own clinical data. These data are sent on a website platform, where, on a daily basis, cardiology staff check them.

Originality/value – The availability of these biomedical parameters allows medical staff to predict patient's health status evolution. Before a patient's health condition worsens, a predictive model, based on patients' co- production and IoT, allows the medical staff to provide a TRIAGE aimed at promptly manage those troubled patients. Preliminary findings show that: i) patients were managed exclusive by telephone contact ii) no HF relapse, iii) no ER transit; iv) none hospitalization. Also a cost saving was observed.

Practical implications – Empirical experience demonstrates that possibility to share clinical information might change the traditional paradigm (Cahn, 2000) of service providing. As complexity increases, information requirements increase; thus, managerial approaches to healthcare change. Patient's participation and IoT technologies become critical drivers in chronicity management sustainability: operative inputs able to enhance also Social Value of services provided.

Keywords – Chronicity Management, Co-Production, Telemedicine, Sustainability, Internet of Things.

Paper type – Academic Research Paper

1 Introduction

The dynamic environment of the healthcare sector is characterized by pressure on cost reduction, drastic technological changes and new approaches towards patients. In this scenario, in which economic crises and the ageing population are fundamental drivers, National Health Systems (NHS) should consider the adoption of innovative services in order to manage chronic diseases. These pathologies represent one of the first causes of disability, mortality and morbidity, due to their persistency and tendency to develop some degree of disability (WHO, 2013). Accordingly, chronicity is featured by:

- progressive deterioration;
- requests for high integration between health and social services;
- a need for the design and development of integrated facilities within the health district.

In order to ensure the economic and social sustainability of treating such diseases, primary prevention, early diagnosis, appropriate therapy and also patient education and empowerment become important issues in the life-cycle of those pathologies. However, for an effective healthcare care pathway of such chronicity, availability of information is fundamental to precede patients' needs and to actively prevent complications; this requires a cultural change based on the exploitation both of digitalization and its impact on the innovative relationships between patients and healthcare organizations.

Accordingly, Chronic Diseases Management based on new technologies shows how patients are enabled to actively take part in their healthcare by taking advantage of Internet of Things (IoT). This is particularly highlighted in cardiac chronicity (e.g. heart failure and arrhythmias).

By increasing the chronic patients' participation level as well as compliance with adherence to their treatment pathway provided, patients enhance their health status. Telemedicine, such as remote monitoring technologies, is particularly oriented to sustain this transformation, by enabling new relationships between patients and the healthcare structure, in which the patient overcomes the status of a "consumer" by becoming an active "actor" (Bannon, 1991) of the health service.

Starting from these preconditions, the main purpose of this work is to explain how improving chronicity management by improving on real-time medical information exchange between patient and hospital staff, through technological infrastructures. A case study on heart failure (HF) was carried out in order to demonstrate how a higher access to patient's biomedical information could lead to a better management of the disease. Indeed, it allows clinical staff to predict the patient's health status' evolution and to make a *just in time* calibration of therapies.

This brings to: i) improvement quality of life (lower rates of hospitalization mortality and readmission); ii) optimisation of hospital workload (alignment between staff and procedure, reduction of emergency, lower bed occupancy), iii) cost saving (economic as well social).

To achieve its purpose, this paper follows this outline: after this brief introduction, the second section reports a background addressed to the issues of HF, telemedicine, IoT, coproduction and their relationship with the chronicity management; the third section provides insights into the empirical pilot case of HF management in the innovative experience of the Cardiology Department of Policlinico Casilino of Rome. The fourth presents findings of the inquiry from both the clinical and economic points of view.

The last section discusses results obtained and provides some consideration about the innovative service analysed.

2 Background

HF occurs when the heart is unable to pump sufficiently to maintain blood flow to meet the body's needs (Di Lenarda et al. 2010). It is a chronic disease that negatively affects survival, quality of life and independence of patients, causing significant resource consumption.

This pathology could occur at whatever age; its symptoms (shortness of breath, excessive tiredness, and leg swelling) are not clinically evident. In Europe there are more than 15 mln HF patients (2.5% of people, reaching 20% of people > 80); it still remains one of the main causes of death and hospitalization (Epstein et al. 2013). Because HF is associated with high levels of mortality and morbidity (75% incidence of patients >65), it brings long hospitalization periods (Riley et al. 2009); readmission rate within 30 days of 25% (Dharmarajan et al. 2013) that rises to 46% within 180 days (Hasan et al. 2011).

Problems attributed to HF have an economic relevance for worldwide NHS (McMurray et al. 1998). In Italy, HF is responsible for 1.4% of the yearly national expenditure.

A plan for a more efficient HF management should: i) early locate those patients with high risk of developing HF; ii) include HF patient in a specific monitoring pathway aimed at the prevention of severe HF relapse. In particular with regard to this second point, telemedicine can be a crucial driver able to reduce repeated hospitalizations and patients' mortality, also reducing healthcare costs.

Telemedicine, defined as "a new healthcare delivery process, based on innovative technologies, provided when patient and professional are not physically in the same place", is a new way to take over the chronic patients management, "that allows guaranteed continuity of healthcare in far away territories and a better integration between hospital and patient" (Italian Board of Health, 2014, p. 10).

HF patients, who need continuous follow-ups, could actively detect their clinical parameters (such as ECG, weight, blood pressure, etc.) by themselves and then communicate them to the hospital. This makes the patient a crucial factor in exploiting the potential of IoT for the prediction of their clinical condition. Many studies are concerned with the benefits (both clinical and economical) of telemedicine in HF management (Palozzi et al., 2017). However, Black et al. (2015) stated that the patient's adherence to the tele-management protocol is the determiner of success or failure of that kind of intervention.

Current generation of technologies is going to lead to an ever more IoT-based healthcare. This technological advancement plays a leading role in delivering a health service suitable for patients' needs. Although even in the traditional model of medical health outcomes could be considered coproduced (Batalden et al., 2018), the IoT-based healthcare implies a paradigm shift from the once physician-centred environment to a

more patient-oriented healthcare service (Edgren, 2006; Pal et al., 2017). Patients are the only people who are present at all stages during the provision of care (Sutton et al., 2014; Rathert et al., 2011), and, if involved in a "socio-technical network" that supports them in their health activities, they become aware participant in the treatment of their illness. (Oudshoorn 2008).

Good outcomes are more likely recognized if the patient receives help in a timely way, if the clinician and patient communicate effectively, develop a shared understanding of the problem and generate a mutually acceptable evaluation and management plan (Batalden et al., 2018). Moreover, such an approach allows clinicians and researchers to new medical discoveries by identifying previously unknown trends in patient progression through an illness, finding new links between symptoms and conditions, determining new treatments that may be suitable for various conditions (Baker et al., 2017).

Chronic patients, in particular, own information that many healthcare practitioners may not know. Through the engagement of such type of information, the service could be better aligned to patients' requirements (Bovaird, 2007). The users' contribution as coproducers during service providing is not unavoidable but often it is crucial to perform a service (Osborne et al, 2016).

Ostrom (1996) defines co-production as "the process through which inputs are contributed by individuals who are not in the same organization". It is a collaborative development based on the establishment of partnerships between healthcare professionals and patients (Cahn 2000). The relationship between clinicians and patients may be seen as "a meeting of two experts, where clinician has knowledge of diagnosis and treatment options, the client knows about the experience of illness" (Realpe and Wallace 2010). Patients, who play an active role beyond the "traditional feedback approach" (von Hippel 2005), have the opportunity to participate their own services, by integrating their active contribution in a Chronic Care Model (CCM).

CCM and its adaptations are an example of proactive disease management approach whose aim is to manage the no acute chronic conditions of the disease in a cost-effective way (Kadu et al 2015). CCM is designed with the purpose to help practices at improving patient health outcomes by transforming the daily care for patients with chronic illnesses from acute/reactive to proactive: it establishes a combination of effective team care and planned interactions with self-management support (Coleman et al 2009).

This approach seems to be particularly coherent also with the Integrated Care Pathway (ICP) field. An ICP is a tool based on the analysis of critical processes made by the different individuals who are involved in the processes undertaken to treat a specific pathology (Vanhaecht et al., 2010), including physicians and nursing staff.

Previous experiences with HF treatment demonstrated that ICP implementation contributes to reduce the readmissions rate within 30 days.

3 Method and Study Setting

In order to describe and understand a process innovation, we adopted the pilot case study method, a useful technique for the "empirical inquiry that investigates a contemporary phenomenon within its real-life context" (Yin, 2014, p. 16). In order to reach information-rich key informants and critical cases, we used the snowballing technique, by interviewing well-situated and competent people involved with an "Extreme Case Sampling" (Patton, 2002). Moreover, in order to increase our understanding related to the HF process and understand the operational flowcharts, we also collected a huge quantity of information through empirical observation and review of internal documents as well as technical report analyses.

The case study focuses on the new post-discharge process for HF patients' follow-up, designed by the Cardiology Department of the Policlinico Casilino of Rome, whose goal is the introduction of a new CCM finalized to improve the patient's quality of life and consequently to lower the costs for the NHS.

This Cardiology Department, after many years' experience on cardiac markers and patterns (Calò et al., 2016), has developed a model of follow-up for the early detection of HF symptoms that forecast acute HF implication and then future hospitalizations (Chaudhry et al. 2007).

Our target aims at empirically describing and analysing how the hospital has redesigned the management of chronic HF by the *just in time* knowledge of following biomedical data from patients: i) electrocardiograph stream, ii) weight and body fluid accumulation; iii) blood pressure; iv) blood oxygen saturation.

The study is a prospective, randomized, parallel group, controlled trial. It involved a group of "co-participant" patients of their follow-up, by the use of remote monitoring equipment. Exclusion criteria adopted to select eligible HF patient were:

- Inability (e.g. dementia, lacking ability to communicate);
- Age < 18 years;
- State of pregnancy or lactation;
- Implanted cardiac assist system;
- Unstable angina or recent (<2 months) myocardial infarction and/or life expectancy of <1 year and/or complex and uncorrected congenital heart disease;
- Patients scheduled for having undergone cardiac (included CRT or ICD implant) surgery within 90 days or those who are listed for heart transplantation.

Patients assigned to the project (n. 50) received a telemedicine Kit equipped with the following devices:

- Electrocardiograph recorder,
- Weight scale with body fluid accumulation indicator,
- Blood Pressure Meter,

Oxygen Saturation Monitor.

The telemedicine system is based on a wireless Bluetooth system with a personal digital assistant (PDA). Each device is equipped with a Bluetooth chip and connected to the PDA. Patients were instructed to submit daily measurements (automatic transmissions) of all biomedical parameters. The PDA uses the mobile phone network to transmit all data to the e-Health Center (HF-HUB) where the measurements are organized and made available to the trained personnel dedicated on a password-protected and encrypted website. A "nurse-filtered" model has been developed: a reference nurse is responsible for patient training and support; remote transmission checks; phone contacts; administrative activities.

The responsible physician is appointed in making the appropriate decision, based on the interpretation of the submitted reports; A member of the nursing staff contacts the patient (or patient's care-giver) to inform them about any events, interventions, relevant findings from the transmissions and to communicate the necessity for changes to the patient's therapy or follow-up.

Economic information from the healthcare organization were collected by the Time Driven Activity Based Costing (TD-ABC) approach (Keel et al., 2017) in order to understand the full cost (Bertoni et al., 2017) of the service delivered.

4 Results

The HF Remote Management Model (HFRMM) based on IoT gives *just in time* information about patient's health status (stable or deteriorating). Such a predictive model allows the medical staff to provide a physician and nursing TRIAGE aimed at having an early understanding of those patients need to be managed before their health condition worsens. This follow-up method involves three main subjects remotely connected:

- Patient (or his/her caregiver)
- Nurse
- Physician

Following the duties of these HF Healthcare Management actors:

- Patient: according to his/her follow-ups protocol, with a fixed frequency (daily, weekly), he/her provides the self-measurement of the clinical data and transmits them to the HF-HUB.
- ii) Nurse: on daily basis, he/her opens the HF remote monitoring system websites. Priority is given to urgent alert-triggered transmissions. If the transmission contains relevant events, the nurse calls up the patient's medical records and contacts patient by telephone; just in case of need, involve the physician staff.

Physician: he/her receives the alert-triggered cases and related documents. On the basis of this information, he/her sets up the most appropriate medical decision (telephone contact, elective hospitalization, day hospital, drug therapy change).

Figure 1 represents the HF Management Model applied by the Cardiology Department of Policlinico Casilino of Rome.

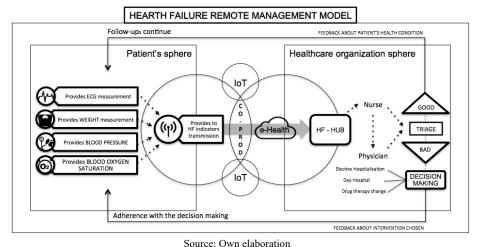


Figure 1 - Heart Failure Remote Management Model

Figure 1 shows that the IoTs connect the patient with the healthcare organization, carrying out a co-produced healthcare service. Patients, through the telemedicine technologies, are able to continually inform medical staff about their health status. Spotted arrows show the "direction" of information from the patient to medical staff for the TRIAGE; filled arrows show the feedback approach provided by the healthcare organization to the patient including the intervention decision taken.

Following sections provide findings concerning the cost of HFRMM and clinical outcomes achieved.

4.1 Clinical Outcomes

From the clinical point of view, the project (that is still in progress) on HF patients has shown the following results:

- high adherence to the healthcare protocol (> 90% average);
- lower bed occupancy, due to early discharge from hospital (2/3 days left);
- lower rate of hospital readmission (in office visit or day hospital), both within 30 days and within 180 days from discharge;
- none hospitalization.

Table 1 shows results before and after HFRMM:

Table 1 – Clinical outcome samples

Patient 1	Female 81 years old NYHA class*: IV Before HFRMM	After HFRMM
	- 4 hospitalization/year average (HF relapses: about 1 every three months) - Average length stay: 10 days	 Monitoring start: 24/02/2017 Adherence to monitoring plan: 99% Alerts: n. 137: 100% for weight increase above the predefined threshold, diuretics dose adjustments were provided Several adjustments of betablockers dose on the basis of heart rhythm HF relapses after monitoring programme: 0 NYHA: III
Patient 2	Female 61 years old NYHA class*: III	
	Before HFRMM	After HFRMM
	- 2 hospitalization/year (HF relapses: about 1 every six months) - Average length stay: 9 days	 Monitoring start: 1/06/2017 Adherence to monitoring plan: 87% Alerts: n 10: 87.5% for weight increase, followed by diuretics dose adjustment; 12.5% for elevated heart rhythm HF relapses after monitoring programme: 0 NYHA: II

*HF severity classification: I (low) – IV (high)

Source: Own elaboration

Both patients, involved with the HFRMM for more than 6 months, drastically reduced the number of hospitalization/year from three (average) to zero. They were completely managed by telephone contact for adjustment of drugs therapy. The health status has enhanced and quality of their life has increased. Thanks to the HFRMM both patients lower their length stay of the last HF caused hospitalization to six days each; hence the average bed occupancy for HF decreases of 2.5 days.

4.2 Full Cost of the service

With regard to financial implication, main expenditures (on annual basis per patient) incurred concern:

- i) Nursing and physician staff;
- ii) Remote monitoring Kit, including the e-health platform;
- iii) Depreciation of office furniture;
- iv) Depreciation of HF-HUB office;
- v) Utilities;
- vi) Maintenance.

The nursing and physician staff costs were computed by the TD-ABD approach. Each daily activity performed by health staff was mapped and measured in term of quantity time spent (Palozzi et al., 2015). Figure 2 summarizes the workload activities related to nurse and physician duties in HFRMM involvement (expressed in average minutes on the basis of the experience on 20 patients simultaneously managed, 20 transmissions/month each). Percentages indicate how many patients (% of the sample in 6 months observation) need both routine and/or alert-triggered activities per day.

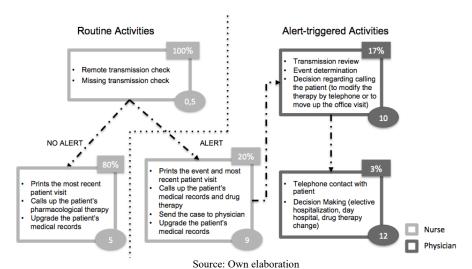


Figure 2 - Heart Failure Remote Management Model: medical staff activities

Staff involvement costs were estimated by multiplying the daily time spent per minute times transmissions/year. The amount of wages per minute (adapted from Calò et al., 2013) was: i) physician - 0,61 €/min; ii) nurse - 0,30 €/min.

The remote monitoring Kit, including e-health platform, has annually rented by an external supplier.

Depreciation of office, utilities and maintenance costs have been computed using the square meters occupied by the HF-HUB room as the cost driver.

Depreciation of office furniture cost was considered as negligible.

Table 2 summarizes the full cost of the HFRMM per patients/year.

Table 2 – Full cost of the HFRMM per patients/year

Cost Item	ϵ	Measurement Method
Physician	301,58	TD-ABC
Nurse	453,60	TD-ABC
Remote monitoring KIT	650,00	Direct tracing
Depreciation of office furniture	NEGLIGIBLE	-
Depreciation of HF-HUB office occupied	3,14	Indirect allocation - cost driver: m ²
Utilities	0,89	Indirect allocation - cost driver: m ²
Maintenance	1,31	Indirect allocation - cost driver: m ²
Full Cost	1.410,52	

Source: Own elaboration

5 Discussion and Conclusion

This work analysed a new approach in the chronic disease management based on the experience of the Cardiology Department of Policlinico Casilino of Rome. The study underlined how the participation of patients in their healthcare can be fostered through the IoT.

Understanding how people could be engaged to adopt innovative technologies and new approaches in delivering health services is critical for a successful implementation of any new treatment. Accordingly, in the contemporary dialogue about patient-centred care, co-produced outcomes are strictly related to the dispositions, capacities and behaviours of both providers and users (Batalden et al., 2018). From healthcare providers' standpoint, innovative approaches based on IoT could be able both to reduce device downtime through the remote provision and to efficiently schedule limited resources by ensuring their best use and service of more patients (Islam et al., 2015). From the point of view of patients, new technologies allow them to a higher participation in the decision-making process and in the provision of information for care management. Acting in their own self-interest, they could adopt behaviours that more completely balance risks and benefits. Moreover, if patients were able to tailor follow-up and management of their disease to their own unique circumstances, through patient-centred information flow management, they could begin to experience continuity of care and accrue the health benefits and cost reductions (Lenert, 2009).

The findings of this study are aligned with those ones from the literature. The HFRMM, indeed, increases: i) the level of clinical outcomes; ii) the patients' quality of life; iii) the patients' experience and awareness. Furthermore, patients are generally satisfied to be remotely monitored, because of they felt safer and their quality of life improved.

Investment effort around 1.400 € patient/year could be covered by the saving due to the 2,5 days reduction of the length of hospitalization. In Italy, for instance, hospitalization for HF costs about 600 €/day. For 1.400 €/pat/year of resource consumption, the remote monitoring of HF patient saves cost for 1.500 €/pat, drastically reducing also the readmission rate.

Accordingly, the HFRMM could be considered a self-coverage and cost-effective service and telemedicine usage in HF management could be the way to provide a better service at a lower cost.

Moreover, IoT-based technologies make patients and healthcare organization directly and continuously connected. Furthermore, patients are ever more involved in the self-management of their care. This way, supported by IoT-based technologies, the patient becomes effectively a voluntary "co-producer" (Osborne et al., 2016) that actively participates in the improvement and the innovation of the healthcare system. As stated by Henrike & Schultz (2013), the combination of a patient-oriented system with an efficient cooperation from healthcare professionals leads to a higher willingness to follow innovative procedures. Hence, managers of health organizations should revisit their outlook on the roles that they and the users should play in public services and begin thinking about users as resource-partners and not mere clients.

However, besides acknowledged benefits, several challenges affect the implementation of an IoT-based healthcare. First of all, both practitioners and users should participate in the overturn of the traditional paradigm of a passive user and an active provider (von Hippel, 2005; Chan, 2000). Then, plenty of issues have to be considered. Security, in particular, is still the key issue has to be addressed. In a healthcare environment, on one hand, it is essential that patient's health information is readily accessible. On the other hand, it is also essential that the patient's sensitive data are kept private (Baker et al., 2017).

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