

REDESIGNING SERVICE DELIVERY FOR HYPERTENSIVE PATIENTS: A METHODOLOGICAL GUIDELINE TO IMPROVE THE MANAGEMENT OF CHRONIC DISEASES

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Abstract - Best care is not necessarily the most expensive, but the most appropriate, and prevention is the most powerful tool to promote health. A novel approach might envision the reduction of hospital admittance (thus meeting a requirement from long term condition patients: they would rather not being hospitalized!) and the enforcement of peripheral (both on the territory and at home) assistance. In this direction, experiences of reshaping new service deliveries towards an integrated disease management, namely clinical pathways, can be observed in Europe and in different parts of the world. Aim of this paper is to provide a methodological guideline to support the management in planning clinical pathways, also outlining the main barriers limiting the process. In particular, we present the results of planning a clinical pathway at the Centre for Hypertension of the Federico II University Hospital (Naples, Italy). The case study showed that the introduction of a similar service impacts on the organisation of the structure. An analysis of organizational processes "as are" and the re-design of processes "to be" are necessary to integrate the clinical pathway into the actual activities.

Keywords: *Non Communicable chronic disease, care pathway, ICT*

I. INTRODUCTION

The clinical pathway is a specific "package" of care instruments enclosing multiple, complex and integrated health services. It designs a specific process of care and focuses on the best management achievable for specific diseases, rather than dealing with acute events. Therefore, it shifts healthcare systems away from the current emphasis on acute care towards improved chronic and long-term care, in response to the transitions generated by epidemiological and demographic change. The aim is the "clinical governance" of the patient, in order to reduce the progression of chronic conditions and enforce their prevention. Prevention includes the efforts and actions aimed at reducing modern pandemics such as obesity, cardiovascular diseases and cancer: i.e. the enforcement of healthy lifestyle policies about nutrition, physical activity, drug, tobacco, sexual health. A consistent and growing body of literature describes how control and prevention of diseases lead to a more efficient use of resources, improves the quality of care and the patient outcomes, and represent the strength of the clinical pathways.

In a study about the implementation of vascular clinical pathways, Calligaro et al.[1] described a reduction in the average length of stay of in-patients and, consequently, a reduction of costs. Flynn [2] reached the same conclusion with a study on the effects of a revised clinical pathway on patients admitted with total hip fracture.

Cost reduction in term of reduced use of

diagnostic services is the theme tackled by Hart [3], Kwan-Gett et al. [4], and Board et al. [5].

Clinical pathways present positive effects also on the quality of care and patient outcomes as demonstrated in a number of studies on different models: Borkowsk [6], in a study on hip and knee replacements pathway, Chang et al.[7], in a study on pathway for radical nephrectomy, and other studies by Gretebeck et al.[8], Ibarra et al.[9], Bultema et al.[10].

The introduction of clinical pathways improves the teamwork in term of conflicts [11-12], better communication [2], improvement of coordination, reduction of delays, reduction of misunderstandings and duplications when more units are involved, as showed in a study on cerebrovascular accident [13]. Legal benefits and reduction of malpractice claims [14-17] are also positive effects of the implementation of the clinical pathways.

Clinical pathways give patients the appropriate method of care, fostering and improving the understanding among doctors and other clinicians about the process of care [18]. Although there are several positive effects of this kind of service [19-21], some studies [22-23] pointed at the doctors as possible cause of failure because of their poor attitudes towards teamwork, their low involvement in the implementation process, their misunderstanding about medical benefits. The adoption of this service spans through innovation and overcoming the embedded conservatism of healthcare structure. Its implementation has a deep impact in changing the nature of current healthcare structures: hospital planners will need to reflect on a new organisational structure, designed to be flexible and to adapt to the driving force of each pathway. Therefore the healthcare structures could have a strategic perspective of management, focused on planning and managing the inter-dependencies between all the different types of assets and organisational units involved in the complex process outlined by care pathways.

Although there is an increasing awareness

of the importance of implementation of care pathways in healthcare, there is little evidence of the organisational and management dimensions being understood and tackled in a systematic way, at micro (single organisational unit) or macro (trajectory of care between several units) level. Some experiences of development and implementation of pathway principles are ongoing in Italy, as showed below. A typical example of clinical pathways is the “Day Service”, which simplifies and improves the performances of regional healthcare systems. The Day Service concerns complex, chronic clinical needs; it allows the effective management of medical examinations, instrumental and therapeutic interventions through a controlled number of accesses for patients who do not need continuous assistance from healthcare providers. The definition of a methodological path to design and introduce such innovation is proposed in the following framework, that takes into account both clinical aspects (such as appropriate care path) and organisational ones (such as process flow) Day Service is already available in other Italian regions, such as Emilia Romagna, Basilicata and Tuscany. Although they are based upon different premises, they all respond to the same need: shorten the time necessary for clinical and instrumental performances of critical diseases, such as the oncological and cardiovascular ones. Through the Day Service, the patient can obtain a diagnosis, restricting to one or few times the accesses to the structure and making all kind of health examinations within the same structure. On the other hand, Day Service allows the healthcare structure to avoid the duplication of unnecessary health examinations, to better schedule health examination, to give a more appropriate diagnosis. In Emilia Romagna, a one year experimental phase led to the definition of guidelines that were necessary to avoid useless and costly duplication of resources. Moreover, the experimental phase offered a number of markers to evaluate the impact of day service on the overall regional healthcare system. Two day services are currently available: departmental and multi-specialist, depending

on the complexity of the required activities. The introduction of a patient into the route depends upon a specialist, who also refers to the general practitioner with the final diagnosis, and only a limited number of accesses are allowed for a given therapy/diagnosis.

II. METHODS

Literature on strategic planning and some “ground rules” to improve integrated services, presented in a recent [24], guided the development of this methodological framework. These ground rules can be summarised in 4 steps:

- A. the definition of a target population;
- B. the definition of clinical pathways for each of the targeted care needs;
- C. the design of assets that are appropriate for those care processes;
- D. the determination of practical ways of moving from existing assets to those that are suited to the desired service delivery methods.

Based on aforementioned references, the methodological approach to the design and to the introduction of a clinical pathway is underpinned on these assumptions:

- A. the innovative change must be driven by external forces (such as customers) and this implies an analysis of external environment;
- B. the innovative change must be integrated in organisational processes, and this concerns an analysis of the internal environment;
- C. the innovative change must be assessed through appropriate methods (such as cost/benefit ratios);
- D. the innovative change must start from the bottom-up, involving progressively physicians, paramedics, office workers and managers.

Starting from these assumptions, the methodology framework is structured in three phases: external analysis, internal analysis, cost-benefit assessment.

An external analysis of the care needs of the population occurs to implement and define the innovation to be introduced. Indeed, the design of the actual pathways focuses on

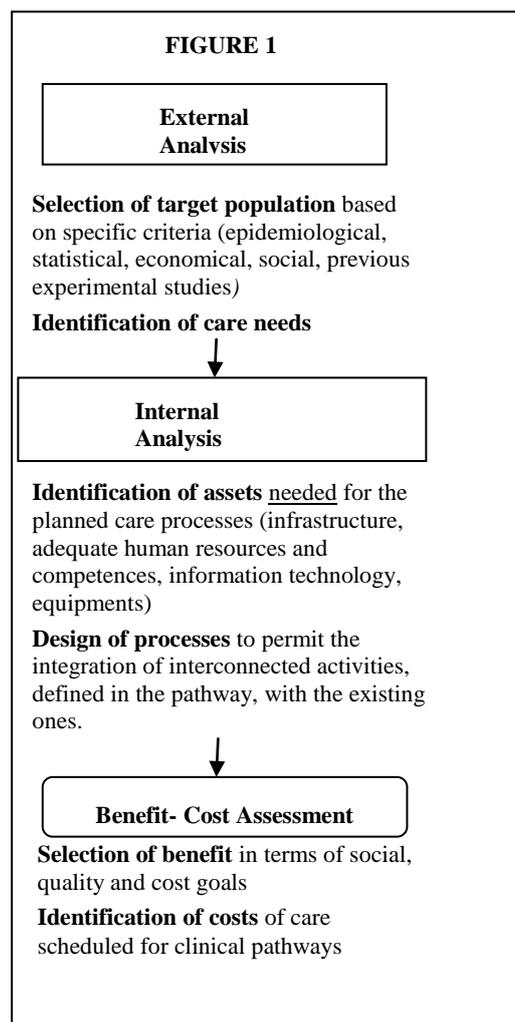
diseases with a high death rate. Epidemiological studies, guidelines of National and European Healthcare Plan drive the choice of the target population, and help in the planning of the care trajectory. As well as any other innovation, the pathway has to integrate into organisational structures through a re-defining of process, behaviours and charges. Flowcharts tools, responsibility matrix, unstructured interviews support the analysis of the process “as is” and the planning of the process “to be”. Furthermore, an analysis of endowment of organization and of assets needs (such as infrastructure, adequate human resources and competences, information technology, equipment) allows the gaining of information about investments needed to implement the pathway. In order to overcome eventual cultural barriers of doctors and healthcare workers, who could cause the failure of innovation, and at the same time, to be more aware of organizational structures (activities carried out, work timetable, delivery timetable, shifts, and so on), all people working in the structure have to be involved in the design and introduction of innovation.

The last phase concerns the benefit-cost analysis: the pathway must positively impact on social goals as well as on cost efficiency. The benefits depend upon the context (examples of benefits are the reduction of deaths, hospitalization, and of the escape index, with an increase of the appeal index), whereas the costs are the total costs of healthcare services foreseen in the pathway. According to benefit-cost analysis, the benefits have to be translated in monetary terms in order to be compared with costs.

Figure 1 summarizes the steps of methodological framework.

The methodological framework has been developed within the Department of Industrial Engineering (DII) and the Centre for Hypertension of Federico II University Hospital). The project is in the planning phase yet, accordingly the findings concern the external analysis. In particular, the external analysis allowed us to identify a clinical pathway, namely Complex and Coordinated

Package



(PACC) for the prevention of cardiovascular diseases.

The case study presented in this paper focuses on the introduction of a clinical governance tool in an organisational unit of the Federico II University Hospital. This clinical governance tool, namely PACC, is organized such as a Day Service and its implementation involves exclusively the organisational unit “Federico II University Centre for Hypertension”.

The Federico II Centre for Hypertension

The Federico II Centre for Hypertension belongs to the Department of Internal Medicine, Immunology and Cardiovascular Sciences. It started in 1980, and is actually among the National Centres of Excellence of the Italian Society of Hypertension. Its

activities concern primary and secondary prevention of cardiovascular diseases, with a special focus on hypertension, whose occurrence among the western population peaks at 60-70 % for certain age groups. The Federico II Centre for Hypertension is based upon the highest levels of competence and efficiency, with driven and updated medical professionals. Moreover, it pioneers the novel frontiers of medicine, such as gene therapy and pharmacogenomics, and the evaluation of the early cardiovascular risk. The mission of the Centre is based upon the concept that cardiovascular diseases require the transfer of prevention activities from the excellence centres to the periphery, to assure the “capillarity” needed to their success. Therefore the centre experimented and implemented the use of Telemedicine, i.e. a controlled, telematics access to a database of clinical records for general physicians, and is inserted into a network of expertise such as interventional cardiology and radiology, endocrinology, nephrology, nuclear medicine, cardiac and vascular surgery [25]. The centre is conveniently connected with the Intensive Cardiac Care Unit (ICCU), offering well-timed access to hypertensive emergencies. The strong orientation of the Centre towards the continuous improvement, and its efforts to increase the appropriateness of diagnosis and care were conjugated with the awareness that instruments such as day-hospitals might not align with the aims of the current National and Regional Healthcare Plan. Therefore, its goal is the introduction of a Day Service to increase the prevention and reduce the progression of cardiovascular diseases, through the improvement of the clinical governance of the hypertensive patient.

The external analysis: Complex and Coordinated Sanitary Package (PACC) as an instrument of clinical governance

According to a number of epidemiological studies, there is a polarization of the most frequent causes of death in Italy, with the prevalence of cardiovascular diseases in the South, and cancer in the North. Among cardiovascular diseases, a pivotal role is

played by hypertension: the adequate control of hypertension by itself would significantly reduce the incidence of major, costly cardiovascular events and of heart failure. Therefore, the efficient prevention of hypertension becomes a critical priority of any western healthcare system. Primary prevention is strictly related to health promotion, as it implies distant and hopefully long lasting results. Screening for high blood pressure, personal habits and family history might be promoted with territory practitioners, taking advantage of the hypertension network, in order to identify subsets of individuals with a higher risk for cardiovascular diseases. Secondary prevention concerns a tighter control of selected populations in order to reduce the occurrence of acute cardiovascular events: a diagnostic route might be proposed, where the first step depends upon the careful examination of the hypertensive patient. The patient could be then introduced into a pathway of controls that are clinically appropriated and timely planned, in order to improve the compliance to therapy. An appropriate control of high blood pressure can be achieved only with careful medical controls, which should be properly scheduled depending upon the risk class of the patient, and after the achievement of therapeutic continuity. Waiting lists and the difficulty to manage complex diagnostic procedures undergo controls with a delay that poses them at risk for acute cardiovascular events. The cost of this situation has both a death toll and an impact in Disability Adjusted Life Years (DALYs), which rebound heavily upon the healthcare system. The introduction of the Day Service would allow the achievement of the aforementioned therapeutic goals, offering the patients the opportunity to enter a route enclosing the appropriate diagnostic instruments required by the physicians, organized in a single solution inside the Federico II Medical Centre. After the selection

of target population, hypertensive patients, the identification of care needs occurs.

The Centre for Hypertension designed a number of Complex and Coordinated Sanitary Packages (PACC), as appropriate diagnostic routes the patient could enter according to his needs and to the requirements of his physician. As the PACC defines a pathway to manage critical diseases, it can be considered a Day Service. Each single package was assembled according to the national and international hypertension guidelines (ESH – European Society of Hypertension – and ESC – European Society of Cardiology).

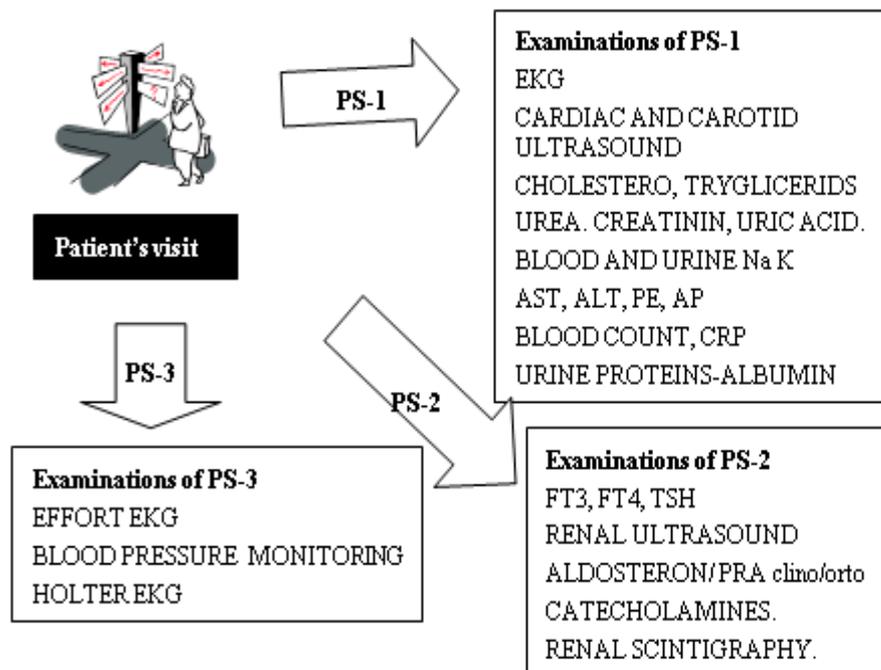
The Centre for Hypertension identified 6 PACCs: 3 for the initial screening and 3 for the follow-up. The 3 screening PACCs are named PS-1, PS-2, PS-3. Their aim is to investigate the “degree” of hypertension and assess the eventual organ damage. The physician will decide the adequate PS based on the first clinical evaluation. Usually, the three PS are independent but, depending upon the severity of hypertension, the physician can decide to combine them. Moving from PS-1 to PS-3, the set of diagnostic tools becomes more complex.

Figure 2 shows diagnostic examinations included in PS-1, PS-2 and PS-3.

The 3 follow-up PACs, named PF-1, PF-2, PF-3, are aimed to monitor the efficacy of the therapy, and the evolution of the disease. The attribution of patients to one of the 3 PFs depends upon the degree of hypertension that has been identified during the screening phase. Depending upon the contemporary presence of the pathological conditions, hypertensive patients can be defined hypertensive, or diabetic hypertensive, or ischemic hypertensive – respectively associated to PF-1, PF-2, and PF-3. Furthermore, the patients are attributed to five categories related to degree of risk (the risk degree refers to the probability to develop an acute cardiovascular event):

In order to implement the PACCs,

Figure 2: Diagnostic pathways for hypertensive patient stadiation

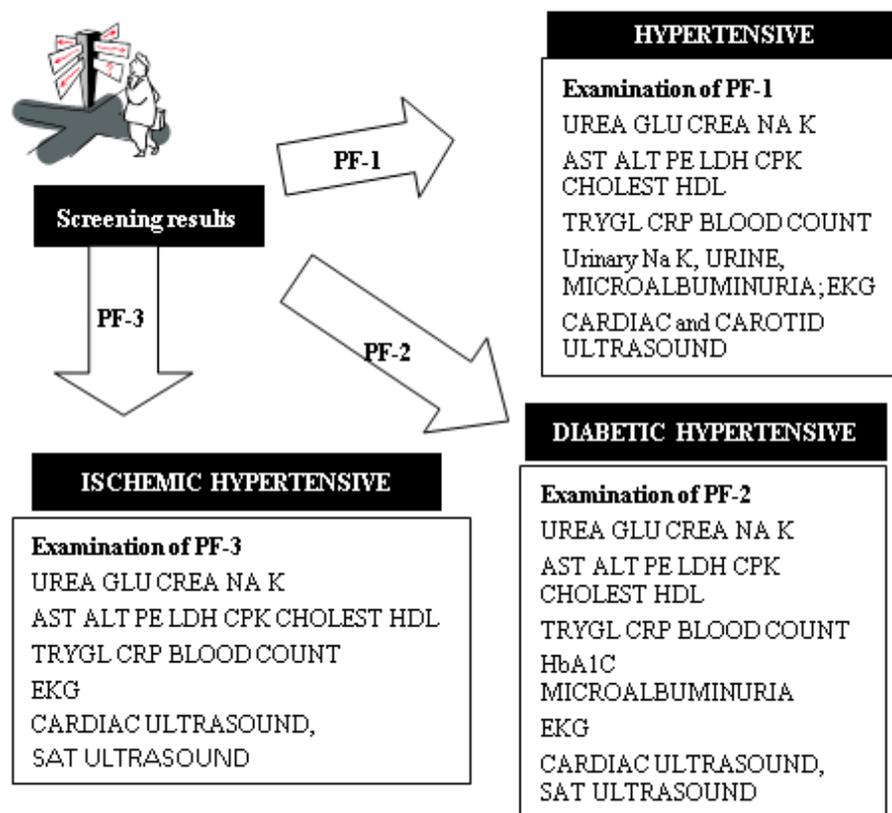


very high risk, high risk, moderate risk, low risk, average risk. Finally, the central aim of PACCs is the achievement of the clinical governance of hypertensive patients by means of a fast, flexible, appropriate (both clinically and economically) and efficient diagnostic and follow-up tool.

The internal analysis: the design of processes at the Federico II Centre for Hypertension

the analysis of assets needs and the re-design of organizational and productive processes are needed. As the present research is in the first stages, the internal analysis focused only on a mapping of actual processes and activities of the Centre for Hypertension. The services offered by the Centre for Hypertension are the followings:

Figure 3: Diagnostic pathways for multimorbid hypertensive patients



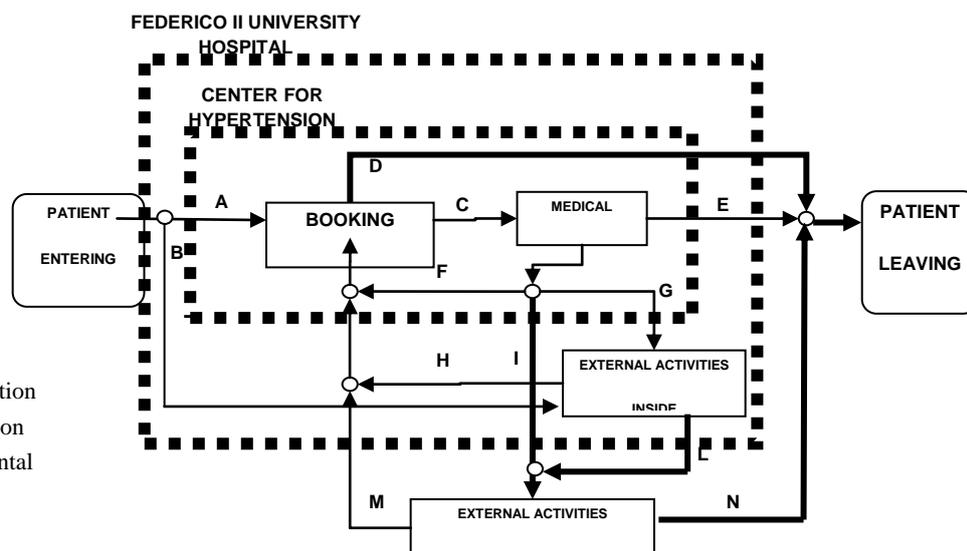
- Cardiac ultrasound
- Cardiac ultrasound following pharmacological stress
- Renal arteries ultrasound
- Carotid ultrasound
- Stress EKG
- Follow-up post-myocardial infarction (MI)
- Emergency follow-up
- 24h EKG monitoring
- 24h Blood pressure monitoring
- First screening examination

In order to re-design the processes, the actual patients' route (macro-process) has been mapped, since they enter the Federico II Medical Centre, through the reservation of the medical service, up to their enrolment into the follow-up (**figure 4**).

The input and the output of the macro-process "patients' route" is the patient. Inside the macro-process, 4 sub-processes are identified:

Figure 4: LEGEND

- A= External Patients Booking
- B= Emergency Patients (118)
- C= Patients Undergoing Examination
- D= Patients Cancelling Booking
- E= Patients Afferent To General Practitioner
- F= Follow-Up Post-Admission
- G= Patients Admitted Post-Examination
- H= Booking Post Admission
- I= Patients Leaving The Hospital After Examination
- L= Patients Leaving The Hospital After Admission
- M= Patients Booking Follow-Up After Instrumental Procedures Outside
- N= Patients Deciding Not To Come Back



1. **Booking**, including all activities related to the application, change or cancellation of the booking for a medical examination;

2. **Medical examination**, concerning all activities related with the actual outpatient examination;

3. **Activities that are external to the Centre for Hypertension but available inside the Federico II hospital**, following hospital admittance either in day hospital, or with regular hospitalization;

4. **Activities external to the Federico II hospital**, not performed inside the Federico II hospital.

As showed by the mapping in **figure 4**, the processes of the Federico II Centre for Hypertension are strictly interconnected with the context of the Federico II University Hospital: a patient enters the hospital to access the Centre, but he can also access the Centre starting from a regular hospitalization in the Federico II University Hospital.

The map of the processes underlines some critical flows. The flow “D” is represented by patients who, after the booking of the visit at Centre for Hypertension Federico II, don’t make the visit due to several reasons, such as too long waiting lists causing organisational bottlenecks. The flow “I” is represented by patients who undergo the examinations at other healthcare structures and, eventually, come back to the Centre only for the specialist visit. This event causes loss of gain for the Federico II University Hospital. The flow “L”

is similar to the flow “I” but it concerns hospitalized patients. Lastly, the flow “N” concerns patients who don’t come back to the Centre after the first visit. The critical reason of this escape could be the long time between the first examination and the second, apparently due to the instrumental exams required by the cardiologists, to be carried out outside the Centre for Hypertension.

The implementation of PACCs could overcome these criticalities. A well-designed clinical pathway would decrease the waiting lists and, furthermore, it might localize the most part of the requested examinations at the Centre for Hypertension, consequently reducing the escapes towards other structures. Of course, a deeper analysis of each of four processes is necessary to re-design the macro-process in order to integrate the PACCs into the actual activity of Federico II Centre for Hypertension. This analysis is one of the activities that we are developing at the Federico II Centre for Hypertension.

III. RESULTS

To achieve effective clinical governance, economical awareness is crucial: this consideration prompted us to evaluate the convenience of the PACCs through a cost-benefit analysis. In this phase of research, we have only defined the benefits: we identified the benefits with respect to the Regional

Healthcare System and the benefits with respect to the Federico II University Hospital.

From the point of view of Campania Region, the benefits, grouped in 4 classes, are:

- B1, that takes in account the death reduction;
- B2, that concerns the hospitalization reduction;
- B3 that refers to the escape rate reduction (percentage of patients going to healthcare structures located in other Italian regions or in different countries);
- B4, the gain due to the appeal rate increase (number of patients coming to healthcare structures situated in the considered region).

On the contrary, from the point of view of the Federico II University Hospital, the benefits concern above all the gain obtained from diagnostic examinations. In fact, the patients following a pathway will do all the examinations at the Centre for the Hypertension and not at any other structures. These benefits, accordingly the gains, have to be spread among the healthcare services offered by Centre. These healthcare services are: specialists' activity, Day Hospital activity, ordinary hospitalisation.

So we identified 3 classes of benefits:

- B1 which expresses the gain for specialists' activity;
- B2 the gain for Day Hospital activities;
- B3 the gain for the hospitalisation activities.

With reference to costs, the lack of an accounting system at Federico II University Hospital made it very difficult to gather the data needed to compute them. The only information available is now the cost of each diagnostic examination based on DRGs (Diagnosis Related Groups) table. DRGs are fixed by National Healthcare System. In this way, we can't underpin the real cost of each PACCs for the Centre.

Further developments of this research will concern the application of Activity-Based Costing to calculate the real costs of PACCs, taking into account the new organizational arrangements of processes surrounding the pathways.

IV. CONCLUSIONS

The Healthcare Systems are focusing on a new way to manage and promote health: the clinical pathway, an integrated disease "management" tool. The pathway outlines that the new mission of a modern Healthcare System is not limited to cure diseases, but is committed to efficiently handle and prevent them. As discussed in the introduction, several studies discuss the clinical implications (how each specific pathway can impact positively on some critical aspects of care, such as cost, quality and patient outcomes), but very few studies focus on the organisational implications (how the pathway can be integrated into the actual activities of a healthcare structure). The present paper contributes to this issue by presenting a methodological framework to manage the design and the implementation of a clinical pathway: both clinical and organisational aspects are taken into account.

The methodological framework has been structured into 3 phases: an analysis of the external environment, an analysis of the internal context and a benefit-cost assessment. Since the presented research, involving the Department of Industrial Engineering (DII) and Federico II Centre for Hypertension, is still in a planning phase, our findings concern above all the external analysis: the description of a specific pathway to manage hypertension, and therefore prevent cardiovascular diseases. This pathway, is delivered under the PACC, a new health care covered service that the Federico II Centre for Hypertension is planning to implement in its organisation.

To a small extent other results can be observed. First of all, the case study shows that the introduction of a similar service impacts on the organisation of the structure. An analysis of organizational processes "as are" and the re-design of processes "to be" are necessary to integrate the clinical pathway into the actual activities. We only presented a map of all processes of the Centre "as are" and their critical flows. But a deeper analysis of each process, concerning its activities, the human

resources involved, the responsibilities requested and the needed changes will occur.

An analysis of required investments to the implementation of PACCs would be necessary as well. To carry out the benefit-cost analysis, a new accounting approach has to be developed. The Federico II University Hospital should introduce a Management Accounting System based on process logic. Finally, the implementation of similar innovations, that impact both on clinical and organizational aspects, requires the intervention of multidisciplinary teams, integrating cardiologists and health care managers.

Further development of this research concerns the internal analysis, in particular the planning of organizational processes “to be” and the investments assessment. With respect to benefit-cost analysis, the lack of an accounting system at Federico II University Hospital could hinder the computation of benefits and costs. However, very preliminary results can be obtained.

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