A Proposal of Case-Based Approach to Clinical Pathway Modeling Support

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***Abstract*—In this work, we analyze the formalization and the role of the Clinical Pathway (CP): it is growing up as a main instrument for the implementation of clinical guidelines and evidence-based medicine. Its primary objective is the improvement of the care process monitoring the unjustified variations in clinical practices to reach faster the best fit care and to reduce the costs of the health system. In a generalized context of an aging population and the ever-increasing diffusion of chronic diseases, we introduce a CP methodological and technological approach with the aim to improve the way patients are monitored during their pathway, to help physicians to read the clinical picture in the best and fast way and to reduce the general clinical complexity.**

***Index Terms*—Case Management, Clinical Pathway, Machine Learning, BPM, Recommender System, Blockchain.**

I. Introduction

In the development of digital services for supporting clinical-health and care processes, it is possible to identify some areas of innovation in charge of the Regional Health Services. The one that is attracting the most attention is related to the digital management of Clinical Pathways (CPs) [1].

CPs are emerging as a main tool for the implementation of clinical guidelines and evidence-based medicine. Their primary objective is the optimization of care, reducing unjustified variations in clinical practice and the costs of the health system, thanks to its interfunctional and multidisciplinary nature, and its integrated and cooperative coverage of the hospital and extra-hospital settings [2] [3].

CPs are also functional to containing clinical complexity, in a generalized context of an aging population and the ever-greater diffusion of chronic diseases linked to unhealthy lifestyles and improper eating habits: the elderly and/or chronic patient typically presents a difficult to read clinical picture and a high diagnostic and therapeutic complexity.

New ways to mitigate the cognitive overload for the clinician have to be investigated. Starting from decision support to medical prescription using predictive analysis, it is possible to guide the clinicians in dealing with complex pathology cases as depicted in Figure 1. Providing clinicians a guide that helps them to follow the best care pathway can reduce variations from the ideal pathway, which affects medical spending.

Despite the development of CPs offers increasingly broad and qualitatively satisfying coverage of clinical cases (both in the diagnostic and therapeutic fields, as well as in the treatment of chronic diseases), their adoption in treatment centers is still slowed down by human, cognitive, organizational and technological barriers.

The increasing computerization of clinical/health workflows and medical records offers a significant opportunity to reduce these barriers. However, the same computerization of clinical practices has generated new problems - mainly due to a large technological and informative fragmentation - that generally make the progress in the dissemination of evidence-based medical practice sub-optimal, and reduce the contribution of information technology to this progress.

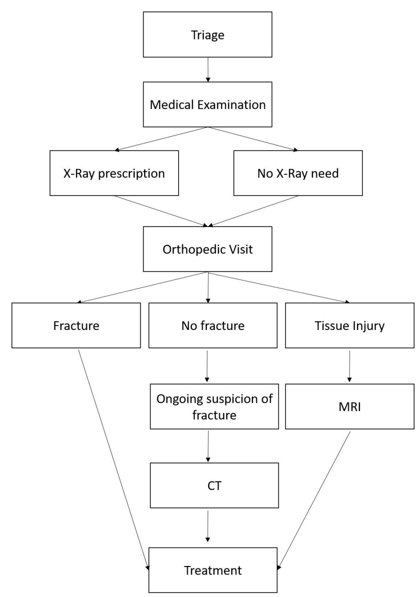

Fig. 1. Example of Clinical Pathway

In many sectors, ICT is gaining momentum due to the consolidation of technologies and methods for process automation and the availability of very large transactional and historical data and tools able to exploit its volume and heterogeneity for creating a prescriptive and predictive value. These techniques, which go under the name of predictive analytics, are successfully applied in areas such as marketing, customer

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relations, fraud or financial risk. Unfortunately, especially in Italy, they are weakly exploited in the clinical-health context, although characterized by the presence of enormous amounts of information, both structured and textual.

The progressive computerization of clinical practice processes in care centers is in fact, leading to the accumulation of an extraordinary amount of data whose value in terms of support to medical decision (both for care and secondary uses - such as health administration/government and scientific research) is huge and, to a large extent, unexpressed.

The exploitation of these broad masses of health data is promoted by another strategic area of the healthcare sector: the development of models and solutions for Clinical Governance that boost interoperability between various databases, also to improve resource management and for evidence-based governance.

In summary, the current scenario offers wide space for creating value to support clinical trials and health governance, in response to the urgent need to:

1) design interventions and policies to optimize treatment, improve prevention, epidemiological surveillance and expenditure restructuring, especially with reference to the growing incidence of high-risk and high-cost patients;
2) accelerate the diffusion of CPs, so exploiting its benefits in terms of quality and continuity of care, of prescriptive appropriateness and containment of health spending;
3) mitigate the cognitive and managerial overload of the healthcare staff in the treatment of highly complex patients.

II. Related Work

In the health sector, significant efforts are made to create a level of interoperability and exchange of information between different systems. Furthermore, the biggest challenge is to represent information streams to try to extract clinical path information from this scattered dataset.

An integrated clinical pathway management has been proposed by Li et al. [4]. This approach is based on a semiotically inspired system architecture which aims to embed pathway knowledge into treatment processes and existing hospital information systems. With the aim of supporting later analysis, Caron et al. [5] proposed a process mining-based approach that enables the extraction of valuable organisational and medical information on past CP executions from the event logs of healthcare information systems.

A contribution to the possibility of managing in a personalized and dynamic way comes from Schlieter et al. [6], who proposed personalized dynamic pathways and a reference architecture for integrating them into existing inter-organizational healthcare information systems. In all the works cited above, the authors's aim is to extract information from a series of heterogeneous systems to build a chain of events that, in a second phase, will be formalized as a concrete pathway.

III. Addressed Problems

The main problems that this work wants to face are related to the fragmentary nature of the care system, to the inadequacy of the notations for the formal definition of CPs, to the information overload of clinicians and to the limited possibility of using many of the available clinical data (especially those recorded on paper forms). Thus, we can identify four main problems:

1) fragmentation of IT support in healthcare;
2) expressive limitations of formalisms;
3) information overload for physicians and care managers;
4) low exploitation of clinical data.

A. Fragmentation of IT support in healthcare

The adoption of CPs in health facilities and health districts is experiencing rapid diffusion in Italy as a tool for rationalizing clinical guidelines and organizing the treatment of complex pathologies and chronic diseases such as diabetes, Chronic Obstructive Pulmonary Disease (COPD), rheumatoid arthritis and heart failure. Some regions are implementing CPs as an extension of the Electronic Health Record, and there are many CP automation initiatives by individual local health agencies.

The prevailing direction is a ”low automation” approach of the CP, e.g. a support in the form of an ”open” electronic document (Care Coordination) [7] shared among the clinicians involved in the patient's journey, and coordinated/managed by the so-called case manager. From this point of view, the electronic tracking document of a CP arises as an additional ”informational debt” along with the traditional clinical documents such as the specialist report, the first aid report and the hospital discharge letter.

However, the real potential of CPs, compared to clinical guidelines (which have a substantially descriptive/narrative nature), is in the wider possibilities offered by ”high automation”. This work aims to lay the foundations for the next evolutionary step of CP automation, with a broad integration with the well-established IT support tools such as document repositories, electronic medical records, electronic prescription systems, booking systems and with the overall hospital context.

The main technological barriers limiting the diffusion of IT tools for care continuity are the plurality of poorly interoperable software tools supporting clinical workflows, as well as the need of involving multi-disciplinary specialists and having many contacts with the patients when developing the systems assisting in the treatment of diseases [8] [9].

B. Expressive limits of formalisms

According to the definition of Edward Shortliffe, a learning health system is a system that *”is capable both of assuring that every decision is made with complete information and ensuring that every care instance can contribute a deeper understanding of care for individuals and populations”* [10].

Clinical/health workflows in general, and CP in particular, show a reduced level of causality. They do not guarantee to obtain the same outcome from the identical repetition of a very complex scheme of actions, but on the contrary they are based on a principle of specificity of each individual "case", the uniqueness of the symptomatic, diagnostic, prognostic, etiological and therapeutic response of each patient [11] [12].

A critical success factor for CP automation is the availability of a CP expression notation that overcomes the rigidity of process automation formalisms such as Business Process Model and Notation (BPMN) [13], incorporating by design uncertainty, late choice, exception and non-motivated adherence, as we can see in Figure 2.

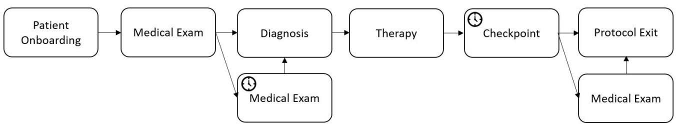

Fig. 2. Healthcare process in BPMN

C. Information overload for physicians

The management of patients with high clinical complexity (meaning not only patients with complex pathologies and chronicity but also patients in comorbid conditions) and the increasing availability of data entail new problems of information overload for the clinicians.

Computer Science and in particular, the recent machine learning research line, known as data-driven phenotyping or computational phenotyping [14], offers interesting possibilities of development of risk stratification techniques and their application to the clinical domain. For risk stratification we mean the process of statistical determination of detectable characteristics associated with an increase in the occurrence probability of a pathology [15], and of similarity with other patients and therefore of prognostic prediction. This, together with the possibility to elaborate highly visual and interactive patient syntheses, constitutes an excellent opportunity to create a technological tool for mitigating the clinicians and managers cognitive overhead.

D. Low usage of clinical data

The progressive spread of high-risk and high-cost populations is creating new challenges for the health government, both locally and regionally, in an already difficult scenario of a constant reduction of public funding for health spending.

In this scenario, it would help the availability of data-driven clinical intelligence tools that allow statistical analyses, based not only on the services provided and hospitalization, but which can go into the details of the single treatment or clinical observation. This allows putting in evidence and performing more detailed analyses of, for example, latent patterns in the demographic and / or temporal distribution of a pathology, or spotting the emergence of hidden risk factors corresponding to syndromes or pathological conditions of high social significance [16].

Although much of the data-generating streams are already digitized, and despite the existence of technological and regulatory devices of standardization and centralized storage, such as the Electronic Health Record (EHR) and Pathology Networks, the population's clinical and health data are often confined to heterogeneous silos and in forms that limit their aggregability, prompt availability and analysability.

In particular, a substantial portion of the data digitally available is documentary or narrative. In order to make the information contained in a report or a hospital-discharge letter useful in an analytical context that also includes patient-structured data (such as hemato-chemistry, reports of pathological anatomy, structured anamnesis and measurements taken from diagnostics for images). It is essential that text documents are treated with semantic classifiers, i.e., with techniques that recognize and extract information, such as diagnoses, measurements, observations, and therapeutic indications.

On the other hand, the wide availability of clinical data relating to a sample of patients (considering all the clinical specialties and the temporal dimension) identifies new problems of:

- conceptual modeling of the person (in the clinical sense);
- population (in epidemiological and health governance);
- technological management of masses of data that exceed the storage and processing capacity of traditional computer architectures.

IV. Approach

The research presented in this paper aims at developing a tool that supports the definition, the management and implementation of a broader meaning of CP called Diagnostic Therapeutic Care Pathway (DTCP). This tool is intended for care and assistance centers according to a highly-automated and highly-integrated model capable of transforming the body of available data in the knowledge that can be used to support physicians and health authorities.

Specifically, this research aims at creating value for the following perspective:

1) support to design and maintenance of DTCP schemas, by developing a formal notation and a specific process automation platform for the clinical/health domain;
2) support to medical diagnostic, by developing a tool recommending clinically similar cases;
3) operative and cooperative support to the implementation of DTCP in care and assistance points, by developing a platform for application integration, which uniforms the operational management of the patient under DTCP.

The architecture proposed to reach these goals is composed of two main layers: the *Patient Engagement Layer* and the *Medical Supervisor Layer*.

The Patient Engagement Layer includes all the software systems used in healthcare facilities. One of the components of this layer is the Healthcare Information System (HIS) where it is possible to acquire information regarding flows in a hospital, such as accesses to the emergency room. The main component is the Electronic Medical Record (EMR), which contains all the information related to a patient's care and to his overall clinical picture, such as drug therapies or vital signs. Another important component is the booking system: it allows us to know the tests that the patient has to carry out, the timing and the related waiting lists. Other pieces of the system are represented by RIS/PACS, where reports and imaging are stored, and by telemedicine systems that allow patient management at home as if they are inside a hospital ward. Accesses to the emergency room, vital parameters, therapies, exam booking, reports, are all outputs of heterogeneous systems that put together feed a system capable of tracking the patient during the clinical pathway.

To reduce the fragmentation of information in healthcare, it is necessary to introduce an integration layer. This level must necessarily have a high degree of flexibility to guarantee interoperability with all the different types of possible systems located in the different places with different levels of granularity and goals. The Medical Supervisor Layer "consumes" the information collected in the Patient Engagement Layer.

Among the elements in this level, the Notation Layer manages notations and formalisms in a mixed and hybrid way, thus solving the limitations related to using only one formalism.

A process mining module in the architecture enable it building a clinical pathway. Moreover, this module is also responsible of conformance check and calculate the performance of clinical pathway.

From the doctor's point of view, the presence of a Recommender System module makes it possible to analyze clinical pictures of patients and receive clinical recommendations in the drug prescription task and compare similar cases. This part can be consider an entry point of a more complex Clinical Decision Support System (CDSS).

Finally, the Predictive Analytics module enables predicting if and when patients will undergo significant changes in their health conditions, which is a challenging task for the medical staff but that would avoid the consequences of a late intervention. The system, therefore, is able to identify in advance the patient's health decline, allowing physicians to intervene in a timely and systematic way.

All the module in the Medical Supervisor Layer work together to verify the patient journey and helps doctors keep a high number of patients under control in every step of their care path and gives the patient the perception of being followed and guided towards the best care.

The proposed approach is based on using Case Management Model And Notation (CMMN) or Decision Model And Notation (DMN), specializing them for clinical/health domains, noting that they are suitable to shaping human uncertainty and arbitrariness during the implementation of a path [17]. These formalisms will be extended with new syntactic constructs through which DTCP models can be expressed in terms of both procedures and goals. The two notations are partially integrated by some already available engines, in which some discretional fragments of a model case are procedural in nature, namely, they obey specific and non-discretionary dependencies between tasks. This is a model of clinical cases in which a decision period is followed by a specific examination.

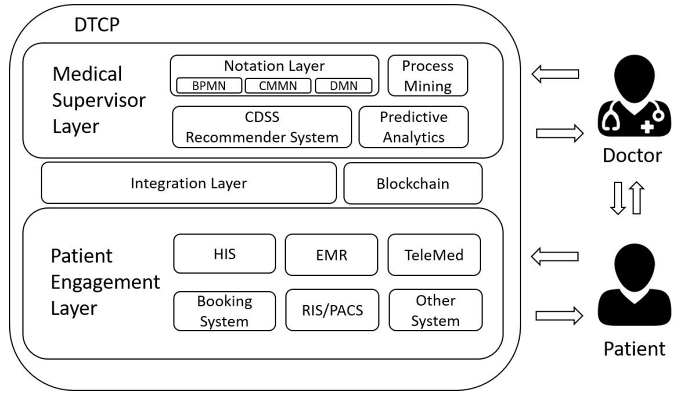

Fig. 3. Architecture of DTCP

The declarative nature of CMMN and its ability to incorporate procedural portions in BPMN make it a very good candidate formalism for modeling and running DTCP. The extensibility of CMMN with domain-specific constructs and the availability of an open-source engine are further advantages in terms of integrity, flexibility, and opportunities for research and innovation, as we can see in Figure 4.

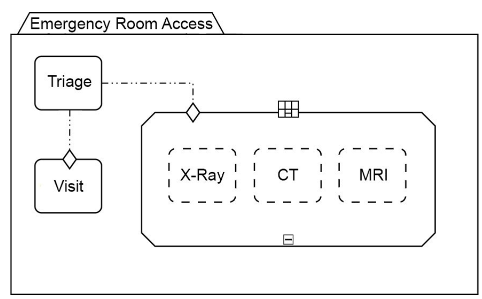

Fig. 4. Healthcare process in CMMN

In order to enrich the support to the execution of DTCP, it is also necessary to develop techniques to aid repair, realignment, suspension, recovery, and abortion of DTCP. This will provide an additional environment of "motivated violation", by the doctor, of the DTCP in place.

Furthermore, the system uses Blockchain technology to verify the patient's identity, track prescriptions, or to address the correct application of protocols. This technology combines widespread peer-to-peer control with the most advanced encryption to make information collection and tracking extremely secure [18] [19].
One of its possible uses in DCTP is to verify the patient's digital identity, keep track of prescription history, drug administration and treatment history more safely and reliably.

V. Future Work

One of the possible future implementations that aim to make the clinical path management system safer and more reliable lies in introducing a Blockchain system. As far as the use of Blockchain in DCTP is concerned, an evolution of the system may concern the application of therapeutic protocols and certified medical devices. In this way, by introducing the use of the smart contract, healthcare organizations have the opportunity to strengthen the system, as smart contracts are performed automatically when certain conditions are met and allow the safe and unchangeable tracking of information, while at the same time being able to track the correct functioning of medical devices. The use of the Blockchain can serve as the basis for more elaborate healthcare applications, including prior authorization and automatic data processing. This technology uses algorithms to fully customize the conditions that determine when to exchange value, transfer information or trigger events, recording them in a secure and unchangeable way.

VI. Conclusion

Big data processing platforms are born to manage huge quantities of data, without requiring a radical reconstruction of existing IT architectures. At the same time, big data processing times allow transformations, modeling, and processing that are also very sophisticated, including both historical data (batch ingest) and the most recent clinical inputs (event ingest).

The clinical analytics architecture proposed in this work aims at bringing the fundamental principles of big data processing into the health domain, offering an open and scalable tool of ingestion, metabolization and data analysis. This tool would be able to integrate, through connectors, a multitude of existing software components already available in healthcare organizations. Furthermore, it would produce a series of advanced, interconnected, extensible and integrable tools to support clinical care and governance. This suite is organized into three functional areas:

1) the management of clinical big data;
2) the implementation of DTCP;
3) predictive analysis for preventive, diagnostic, prognostic, therapeutic, epidemiological and health governance.

The system will be deployed, under strict clinical supervision, in the context of two cardiovascular diseases with a high social impact: ischemic heart disease and heart failure. For both the considered pathologies, the diagnostic, prescriptive, prognostic and analytical characteristics will be developed through the automation of the DTCP, the automatic stratification of the cardiovascular risk and the therapeutic recommendations, the search for epidemiological correlations and the retrospective monitoring/validation of the clinical adequacy in the cardiovascular context. The development of greater skills in the modeling of welfare processes at a local level, with advanced techniques and tools that use innovative machine learning, big data, and multichannel technologies, enable obtaining a significant competitive advantage through a better understanding of the functioning of these processes and the exploration of opportunities to improve the effectiveness of their execution. By intervening in the processes and thanks to the adoption of specific DTCP, it is possible to obtain a reduction in associated costs and an improvement in quality for chronic patients, creating further opportunities for using technologies and greater advantages.

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