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FROM IMPROVISATION TO STANDARDIZATION FOR ACHIEVING A BETTER QUALITY OF CARE: A COUNTER- INTUITIVE INTERPRETATION OF DISEASE MANAGEMENT AND ITS IMPLICATION ON HEALTHCARE INFORMATION SYSTEMS

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In this paper the main assumption and components of the Disease Management approach and programmes are discussed and interpreted on the basis on the classical theory of J.D. Thompson.

Such interpretation would allow to highlight a counter-intuitive aspect of the approach: in a sector usually considered as the prototype of the intensive technology, the DM promises to shift to mediating technologies introducing a tighter, standard regulation allowing not only cost-cuttings, but also higher quality perceived by patients. These considerations will be instrumental to discuss the implication of Disease Management strategies in action in respect with the functional aspects of Healthcare Information Systems. Adopting the classification of the core capabilities of an EHR-S provided by Tang, the specific features of DM-S, suitable to properly exploit the ICT to support DM programs, will be highlighted. Some consideration on the current stage of the IGEA project, i.e. the sole nationwide Disease Management program being conducting in Italy, will conclude the paper.

Keywords: Disease Management, eHealth, Healthcare Information System.

1 INTRODUCTION

During the last few years the economic sustainability of the health sector have been in danger. The need for greater efficiency and an increasing demand for responsiveness to the citizens' health conditions raised, in many countries, the imperative for healthcare systems reforms. The demographic aging of population and the consequent growing burden of chronic diseases, the escalating costs of care, more demanding citizens as well as evident failures in medicine represent, indeed, a recurring scenario in several industrialized countries. Focusing on chronic diseases, such as diabetes, cancer, or cardiovascular disease just to name few, the need for strategies aiming to prevent and control them becomes, steadily, more compelling. These pathologies represent the most common cause of mortality or disability throughout the world (WHO, 2005) and are responsible for almost the 78% of healthcare expenditures (Holman, 2004). In a recent report edited by the World Health Organization, comprehensive and integrated actions for chronic care management have been defined as "vital investments" (WHO 2005).

An effective management of chronic conditions requires a significant evolution of healthcare systems, moving away from traditional models focused on acute disease towards a coordinated and proactive organization of care. The main conceptual frameworks promoting this orientation are the Chronic Care Model (Bodenheimer et al. 2002) and the Innovative Care for Chronic Conditions (WHO, 2002), an adaptation of the former with a more global perspective. These frameworks focus on the continuity of care (Haggerty et al., 2003), emphasizing the local dimension of healthcare and promoting the integration among some representative basic building blocks of high quality chronic disease care, namely healthcare policy, community support, healthcare organization and patients and families. With the increase in complexity of patients needs and in specialization of medicine, integrated healthcare models are thus getting the scene, and new trends in healthcare service management commonly relies on multidisciplinary care-team involved in treatment, as well prevention and monitoring programmes, behavioural education and counselling (Wagner, 2002).

In this context the Disease Management (DM) emerged as a healthcare management strategy for chronically ill patients. It promotes the redesign of the healthcare service supply via a multi-component and Evidence-Based-Medicine-inspired approach. According to it, healthcare systems, jointly persecuting the economic efficiency and the quality of the delivered service, proactively acts with the aim to prevent, or at least control and delay, the more severe and complex stage of certain pathologies. For each of the ill citizens, the DM aims to achieve a continuity of care over time and across multiple points of care, in which the multiplicity and variety of players and technical acts are harmonized together.

As follows, in section 2 the main assumption and components of DM approach and programmes are discussed. In section 3 a counter-intuitive interpretation of the DM using the lens of the classical contribution of J.D. Thompson is discussed. In section 4 an overview of the current state of art of Healthcare Information Systems is provided, while some implications of the Disease Management strategies enactment in respect of Healthcare Information Systems capabilities are presented in section 5. Some further considerations conclude the paper in section 6.

2 THE DISEASE MANAGEMENT APPROACH

The Disease Management originated in the mid-1990 in USA. Aiming to reduce the total cost of healthcare services with no loss on quality, DM fostered the sell and supply of standardized care packages, properly tailored for specific disease on the basis on an in-depth knowledge of the pathology evolution as well as statistical consideration on possible risks to incur in expensive degenerations or comorbidities. Appeared on the scene with a cost-saving inspiration, in some of the following conceptualizations, the DM has been considered as a possible response to a set of open issues, like the fragmentation of care, the lack of coordination, the bias towards acute treatments and poor emphasis to

preventive care (Hunter et al., 1997), that, with different extent, have been shared by many healthcare systems.

Due to its twofold orientation to economic efficiency and clinical efficacy, the DM approach has been diffused and partly reinterpreted abroad, even in some European Countries. In particular, in some nationalized healthcare systems, as in UK and in Italy, the wider conceptualization of DM has been strongly influenced by the Clinical Governance movement (Department of Health, 1998). Following this perspective, DM have assumed a holistic scope, bringing together managerial, organizational and clinical perspectives in order to pursue a timely delivery of appropriate healthcare services on accurately defined patients' categories. More in details, in institutionalized healthcare systems, in which the autonomy, the geographical scope, and the publicly providable services of the healthcare organizations are ruled, DM has being considered as a viable way to facilitate the integration between primary and secondary care (i.e. the IGEA project in Italy). According to this perspective, the conceptualization of DM evolves from being a strategy driving the definition of commercial healthcare packages to an approach and a process for organizational change.

Literature lacks of a univocal definition of Disease Management: every statement or components description provide only a partial vision of the approach. At first glance, DM is a population based management strategy for chronically ill citizens, aiming to combine cost saving and quality improvement throughout the redesign of the healthcare delivery system according to an integrated, pro-active and multi-factorial approach.

DM aims to define interventions for the entire spectrum of a disease adding proactive intervention (as prevention and screening programmes to reduce the risk of exacerbations and complications) to traditional reactive action (as diagnosis, treatment and rehabilitation). An essential DM assumption is that proactively provided preventive services and patients monitoring might downsize the clinical uncertainty in needs and the complexity of care, thus producing positive effects on care efficacy and economic sustainability.

The promotion of proactive and preventive interventions involves a redefinition of professionals' and patients' roles. In this sense, DM contributes to the evolution of the traditional relationship between caregivers and patients, promoting patient's awareness, informed and participated decisions related to possible clinical strategies and behavioural changes to enable self-managed care. Taking into account the importance of educational and coaching interventions to contrast improper lifestyles and the need to balance together health and social needs, patient empowerment is, therefore, a key component of DM.

DM advocates the standardization of healthcare services via evidence-based integrated care pathways (Contenti, Barbini, Albano, 2007). More specifically, according to a population-based approach, typical of public health services, healthcare systems have called to rearrange the delivery of appropriate care for well defined categories of high-risk patients, likely candidates to incur in expensive complications (Harris, 1996). The orientation to the standardization of care implies that the more suitable diseases for DM implementation are those in which variability and uncertainty are reduced by the availability of large part of the knowledge on the disease, its evolution and effective intervention techniques (Epstein and Sherwood, 1996).

According to Hunter and Fairfield (1997), DM adopts a patient-centric view of healthcare provision. DM effective enactment actually requires to shift from an individual, fragmented and episodic care to new paradigms based on integration and coordination of medical resources, along the disease continuum and across the entire healthcare delivery system (BCG, 1995). The integration process is based on the definition of *care pathways* (Campbell et al., 1998) shared among players involved in the healthcare delivery processes. According to the Evidence Based Health Care conceptualization (Rosemberg et al., 1995), that together with the Clinical Governance have strongly influenced the evolution of DM, care pathways define optimal sequences of services, and for each intervention the minimal professional competences involved as well as the more suitable settings, evaluated on the basis of the best clinical evidence and on the local availability of financial, professional and infrastructural resources. While clinical practice guidelines (Woolf, 1990) are devoted to supports professional decision-making and life-long learning, care pathways are tools for planning, monitoring

and measuring the healthcare services each player have to deliver. In the case of community care, they are jointly developed by different healthcare organizations, who decide to cooperate together in order to prevent that part of inefficiencies that may be raised by overlapping of concerns, ambiguities, unprotected rights and conflicts.

Lastly, DM advocates a continuous quality improvement approach in respect to healthcare outcomes, resources management and clinical technology. In this aspect, another relevant component of the DM approach cover the definition of measurable outcomes, process and organization parameters (Donabedian, 1982), and the enactment of effective procedures to track and assess cost and quality performances, by which administrative and clinical audits are performed. In the next section an interpretation of the Disease Management approach capturing some organizational aspects is provided.

3 INTERPRETING THE DISEASE MANAGEMENT APPROACH

Basing on the classical theory of J.D. Thompson (1967), the DM can be considered as an efficient method to reduce the complexity of the medical and healthcare technology. The medical and healthcare technology is generally considered as the prototype of intensive technology: a variety of techniques is drawn upon in order to achieve a change in some specific objects; the selection, combination, and order of application are determined by feedback from the object itself.

In the healthcare sector, in particular, it is important that the physician would be able to assess the health condition, to highlight the most relevant patient's peculiarities, and to manage all the basic techniques of treatment. Then, the physician should be able to define a care strategy, combining the basic techniques of treatment, on the basis of the patient's most urgent needs and preferences. In addition, during the treatment, the physician should control the evolution of the health problem and, if necessary, modify the care strategy defined for the patient itself. The evolution and the outcomes of the care process cannot be foreseen a priori, neither predefined, since it is exposed to a large number of contingencies.

On the other side, even considering the relevant efforts aimed at limiting the discretion of physicians, it is not possible to develop a process of care not based on intensive technology. The DM, in its general definition, is based on a mediating technology: the process starts with the identification of homogeneous groups of subjects (profiling), then, for each category, standardized intervention strategies and education activities are outlined. After the standard sequences of intervention are designed, the responsibility for each of the acts is attributed to any of the health workers categories relevant for the disease in object. Finally, the process of care is applied following the agreed standards.

The mediating technology, operating in standardized ways, and extensively, allows a more efficient planning of the interventions to be carried out, and an improved capability to share resources. As long as the mediating technology can be applied on homogeneous cases behaving in foreseeable way, it succeeds in achieving higher efficiency than the intensive technology. However, when the mediating technology has to deal with heterogeneous and highly variable cases, it easily become strongly inefficient. Hence, the efficiency of the application of DM techniques is depending from the capability to identify and highlight the non-routine cases, in order to treat them with the traditional (intensive) technology. When the single patient shows particular, unintended signs and symptoms, the application of the general rules is suspended and he is transferred to more traditional clinical processes (performed in conditions of intensive technology).

From this point of view, then, the DM may be considered as a strategy aiming at introducing a "module" operating with a mediating technology within the national healthcare system. Such module would be able to treat the patient before the actual insurgence of more dramatic effects of the pathology, in order to prevent the surcharge for the global healthcare system and, at the end, to improve both the satisfaction of patients and the efficiency of the care system.

Surprisingly, this shift from intensive to mediating technologies would end not only in cost-cuttings, but also in higher quality perceived by patients. In other words, the DM may allow the healthcare system to achieve two fundamental but contrasting objectives: the improvement of the value of the

service supplied to the patient (by means of DM, in fact, the patient can prevent or delay the actual appearance of degenerations or comorbidities), and the reduction of the costs related with healthcare (the mediating technology is less expensive than the intensive one). In fact, by identifying homogeneous classes of chronic patients and by treating them before the onset of worsening, the healthcare system is allowed to predefine standard rules of care (also basing on consolidated clinical guidelines), to plan in advance the interdependences among the medical actors involved in the care process, and to develop closer interactions with the patients (also by training and empowering them).

In particular, with reference to the coordination choices, the policy-makers decided to privilege the adoption of standard rules and routines as primary coordination methods. Such decision is coherent with the nature of the DM services, designed to efficiently treat pathologic, homogeneous cases.

The decision to adopt a basic coordination strategy is also motivated by the fact that the physicians working in the DM process are requested to behave in orderly and integrated way, but they don't need to interact and to communicate with each other for the care of the patient: they are in conditions of pooled interdependence (Thompson, 1967). Finally, such decisions are coherent with the DM's focus on economic efficiency and viability, in fact standardization requires less interactions and direct communications among the team members than other coordination strategies.

4 HEALTHCARE INFORMATION SYSTEMS

Disease management has a great potential to improve the care of people with chronic illnesses, and Information and Communication Technology (ICT) is an effective tool in fostering the adoption of this approach to care. Indeed, computerized information processing facilities related to statistical analysis on the distribution of resources consumed in healthcare, is one of the historical precursor to the raise of the DM approach (Coughlin et al., 2006).

Even if with some delay in respect with other information-intensive sectors (e.g. finance), the role of ICT for the innovation and the sustainability of the healthcare industry, as a whole, is increasingly being promoted and recommended worldwide (IOM, 2001, CEC 2004). Over time many terms have been adopted to refer to technical standards, software infrastructures and applications adopted in this specific domain; the branch of "Medical Informatics" and "Telemedicine" are now part of the more general domain of eHealth.

In the academic community several efforts to define e-Health and its scope have been provided (Eysenbach, 2001; Oh et al., 2005; Pagliari et al., 2005; Jones et al., 2005). However a general and comprehensive definition that may be adopted here is the one provided by the Europe's Information Society ICT for Health Unit, according to which e-Health "describes the application of information and communications technologies across the whole range of functions that affect the health sector, from the doctor to the hospital manager, via nurses, data processing specialists, social security administrators and - of course - the patients". Consistently with this definition, e-Health applications and systems are becoming pervasive, being designed, implemented and adopted to support, from time to time, an interdependent set of clinical, administrative, managerial, epidemiological and relational needs and processes. In details, in (Pagliari et al., 2005) e-Health domain is structured in four areas: (i) Professional Clinical Informatics related to functionalities and technologies for healthcare professionals; (ii) Consumer Health Informatics devoted to patients' information, education and empowerment aspects; (iii) Healthcare Business Management dealing with billing, tracking and assessing issues; and (iv) Electronic Health Records (EHR). While the former three directly refer to well identified categories of users, the last represents, in a patient-centric view of healthcare service delivery, the core element for Healthcare Information System.

More precisely, since 1998, Iakovidis (1998) put in evidence the distinction between EHR, assumed as electronic containers of medical documentations, and EHR Systems (EHR-S) operating on them. Whereas dealing with tightly connected issues, the former is related with medical terms coding and classification, patients' information representation and data structures; the latter with software systems capabilities, i.e. functional and non functional aspects of EHR-S. In networked community care environments, EHR-S can be seen as multifaceted "infrastructures" in which geographically distributed

and heterogeneous sources of information and data are dynamically integrated, filtered, and composed to assist particular needs of specific players. Actually, according to the analysis on primary and secondary use of EHR-S discussed in (Tang, 2003), they must support the delivery of personal health care services, including care delivery (e.g., care processes), care management, care support processes, administrative processes as well as education, regulation (e.g., credentialing), clinical and health services research, public health, and policy making.

Neglecting here non-functional requirements, related to dependable aspects of software platforms (Laprie, 1992), the core capabilities of an EHR-S may be described by the eight categories depicted in the following table (Tang, 2003).

<i>Health information and data</i>	Capabilities of processing a wide variety of structured or unstructured, textual or multimedia datasets and documents (e.g. demographics, medication list, allergies, laboratory test results and clinical narratives). They also include manual and/or automated data capture and visualization facilities
<i>Results management</i>	Facilities for the notification and transfer to the point of care of computerized laboratory test results, radiology procedure results reports, etc
<i>Order entry and management</i>	Support for electronically streamline workflow processes related to administrative aspects of healthcare services provision, but also to automatically prevent medical errors as for instance in the case of drug-drug interaction monitoring support in e-prescribing
<i>Decision support management</i>	Computer-assisted diagnosis and other computerized decision support systems, as for instance processing and editing capabilities for standardized and ad-hoc care pathways, and disease treatment and management
<i>Electronic communication and connectivity</i>	Electronic facilities to support the relational needs among care partners involved in multidisciplinary and multisetting teams of care, and between professionals and patients
<i>Patient support</i>	Electronic facilities for patients education and distance monitoring
<i>Administrative processes</i>	Computerized support for administrative processes, including electronic scheduling systems for hospital admissions, inpatient and outpatient procedures and visits
<i>Reporting and population health management</i>	Computerized facilities related to hierarchical reporting requirements at the national and local levels for reimbursing, patient safety and quality, as well as for public health

Table 1: Core capabilities of an EHR-S elaborated from (Tang, 2003)

These categories will be discussed further in the following section in which specific implication of Disease Management strategies enactment in respect of Healthcare Information Systems capabilities will be pointed out.

5 ENACTMENT IMPLICATION OF THE DISEASE MANAGEMENT APPROACH

The adoption of Healthcare Information Systems, and EHR-S in particular, generally offers a number of benefits, including higher quality of care, better patient safety, more efficient information processing, and lower administrative costs (Poissant et al., 2005). Nevertheless in these systems, quite often, the information management tends to be more oriented to individual patients care supports, and several are the reasons.

Formerly EHR-S are comprehensive information systems fostering the ability to manage, across the entire continuum of care, all patients and not just those who are chronically ill. They provide facility for enter and access to real-time clinical data and complete documentation of all patient encounters, enabling also electronic communication among all players and streamlining the healthcare service

provision workflow throughout multiple settings. Also, modern interoperable EHR-S, interconnecting multiple point of care, interoperate and are historically derived by Electronic Medical Record (EMR), local to isolated care delivery organizations. Looking at the clinical and administrative information managed by these systems, whereas the latter have been traditionally processed as structured dataset, being related to natively structured information (demographics, agendas and working plan scheduling, billing, etc), the former were originally captured only as electronic copy of scanned version of paper based documents. According to this original purpose of archiving and tracing legal records of what happened to patients during their encounter, the lack of computer interpretable representation of information limited the possible exploitation of narrative reports to human consultation, relying on few documents' description metadata, entered for the sole purpose to support the indexing and retrieval features of some electronic document management systems. For these reason aggregate evaluation of homogeneous categories of patients often resulted difficult, with a low granularity and scarcely significant.

Besides, DM is a systemic approach in which not only clinical acts are relevant, but also organizational rules and procedures for patient profiling, preventive initiatives, and more in general standardization processes focused to ensure that evidence-based and population-based appropriate interventions are timely delivered in the adequate settings. Although with a patient-centric view in term of healthcare system delivery, in the DM approach the focus is on disease or condition rather than on individual patients. The standardization of services and delivery processes, peculiar of care management approaches, calls for specific information processing and management, both in the operational environment as well as in respect with quality management, outcomes measurements and reporting, and public health disease surveillance.

As a peculiar instance of multidisciplinary and multisettings healthcare services, DM approaches in action implies partly overlapping and partly additional functional requirements for Healthcare Information Systems. Actually, the core capabilities of a Disease Management Systems (DM-S) would be somehow different from those of an EHR-S. In respect with the 8 categories introduced in the section above some of the differences result as follow:

- In respect with *health information and data* DM-S manage more structured data. This is due to the fact that, in DM, not only health information related to individual patient is relevant, but also complete and effective view related to single disease affecting a certain population. Actually important features for DM-S are patients profiling capabilities using key demographics and clinical data, i.e. a chronicle disease diagnostic code, with algorithms to automatically identify all patients who have the same medical condition and stratification tools for risks and severity;
- For *result management* and *order entry and management* no specific needs can be highlighted for DM-S even if, of course, the presence of these capabilities could have positive impacts on the coordination among several different players;
- For what concern *decision support management* in the operational environment, built-in care pathways templates support for patient management play a central role, being relevant not only for the clinical acts but also in order to (semi-)automate the schedule of interventions. Referring to clinical aspects, ad hoc features (i.e. charting) for promptly monitoring the progress of the disease on individual patients are important. Also capturing the proactive approach of DM, DM-S should include reminders and alerts support, at the point of care, related to upcoming and overdue visits and services for the assisted population. Besides editing features for ad hoc specifications goals and activities for individual patient care appear as being not so relevant for the specific purposes of DM-S;
- In respect with *electronic communication and connectivity*, the requirements appear as being not so tight. Actually as pointed out in section 3, the standard rules and routines embedded in the care pathways results as being an effective basic coordination strategy among healthcare professionals until patients conditions remain stable and consistent with the a priori adopted stages of diseases classification;
- In term of *patient support*, whereas distance monitoring capabilities may greatly vary from disease to disease, a peculiar aspect of DM approach is related to patients' empowerment and coaching for behavioral changes. In this respect DM-S should include facilities to easily manage and communicate patient-education materials as well as specific patient-clinicians relationship support;

- According to the DM approach, *administrative processes* refers not only to the traditional organization of the point of care, but also to population-based healthcare service delivery, rather typical of public health programs. More specifically, DM-S should include outreach tools, such as call-back lists and reminder letters, as well as facilities to generate mailing labels and letters to remind patients of upcoming and overdue visits, so that providers may print batches of letters at specified intervals, and lists of patients who need follow-up;
- Lastly, referring to *reporting and population health management* support, the aspects of DM related to a continuous quality improvement approach with a population managing scope, implies, as additional capabilities for the DM-S, robust and easy to use standard and ad hoc reporting functions, both patient-specific (patient summary sheet) and population-focused, as well as sophisticated ready to use tools for tracking chronic disease outcomes. Intuitively these features heavily rely on the capabilities to properly define and manage adequate patients dataset, emphasizing the relevance of collecting, storing and processing structured, and not narrative, clinical information.

6 FURTHER CONSIDERATION AND CONCLUSION

In terms of DM programs' outcomes, there is evidence on substantial quality improvement, but cost savings have still to be proven (e.g. (Velasco-Garrido et al., 2003)); it could be justified by the fact that it is still in its early stage. Apart from this, one important consideration is that, although there is no single model of DM to be applied everywhere, the DM approach has been playing an important role in the redesign of healthcare services toward the integration of primary and secondary care, as for instance in the Italian IGEA project (<http://www.epicentro.iss.it/igea/diabete.asp>).

The IGEA project was launched in 2006 within the Italian NHS, with the aim to define, coordinate and harmonize a shared nationwide DM strategy for diabetes. As a former step in the project enactment, the upcoming alliance between primary and secondary care implies the establishment of networked collaborative working environments. This revealed particularly important in the Italian NHS, where the efforts of coordination and harmonization had to be oriented towards two different directions: on one side to redesign the healthcare system delivery for the specific disease, i.e. identifying and explicitly assigning specific responsibility respectively to community care workers and secondary care physicians; on the other to harmonize the regional initiative autonomously conducted in a institutionalized healthcare system that, although federated, assumes the equal access to services for all the citizens as a fundamental constituent principle.

Considering the number of stakeholders involved in the process, these tasks revealed particularly complex and it is mostly for this reason that the project is still in its early stage. In particular the definition of a complete and well defined shared care pathway for the diabetes, as well as effective performance indicators for auditing and continuous process improvement purposes was particularly challenging.

From this, an important lesson learned observing the project evolution is that, although the key capabilities of Healthcare Information Systems enabled to support Disease Management strategies may be clearly stated a priori, the actual design, development and adoption of a DM-S is heavily influenced by the specific peculiarities and objectives related to the particular disease targeted and to the environment in which it is enacted. Actually we tried to highlight in the previous section the key role played in the DM-S by structured data processing capabilities. Nevertheless a part from technical details related to computer-interpretable and interoperable representation of data, the identification of appropriate data elements and dataset rather concerns the healthcare processes that are intended to be supported and the performance measurements to perform. For this reason future contributions in this domain will be oriented to investigate appropriate methodologies and best practices directed to the identification and definition of the key data elements, in terms of captured aspects and granularity, suitable to support both primary and secondary use of clinical information on routine healthcare.

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