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Health Care Information Systems: Architectural Models and Governance

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1. Introduction

Health care is an information intensive industry (Rodrigues, 2010), in which reliable and timely information is a critical resource for the planning and monitoring of service provision at all levels of analysis: (i) organizational (Nemeth & Cook, 2007), (ii) regional (Harno, 2010; Pascot et al., 2011), (iii) national (Heeks, 2002; Brown, 2005) and international (Rada, 2008).

As a consequence, *Information and Communication Technologies* (ICTs) have become "indispensables" in the health care sector. The general perception that the use of ICT in health care is ten years behind that of other industrial sectors—such as banking, manufacturing, and the airline industry—is rapidly changing (Raghupathi, 2003).

The adoption of ICT within health care has been characterized by a series of phases evolving since the 1960s (Khoumbati et al., 2009). Health informatics adoption started mainly from financial systems, providing support to the organization's billing, payroll, accounting and reporting systems. Clinical departments launched a major initiative during the 1970s that supported such internal activities as radiology, laboratory and pharmacy (Wickramasinghe & Geisler, 2008), where machinery could support high-volume operations with the implementation of standardized procedures. Financial systems once again became prominent in the 1980s, with major investments in cost accounting and materials management systems (Grimson, 2001). During the 1990s, attention turned towards enterprise-wide clinical systems, including clinical data repositories and visions of a fully computerized *Electronic Medical Record* (EMR) (Bates, 2005).

Systematic reviews (e.g. Wickramasinghe and Geisler, 2008) show that, in most cases, all these ICT-based solutions tended to be uncritically adopted by health care organizations under the pressure of technologically-pushing forces (Burke et al., 2002)—with limited analysis of the organizational consequences during ICT adoption, and limited focus on both the support of the core care processes as well as the improvement of effectiveness (Uphoff and Krane, 1998; Martin et al., 2003; Greenberg et al., 2005). These factors can be linked to an historically low level of emphasis on ICT governance, and determined by an inhomogeneous development of *Health Care Information Systems* (HCISs) (IHCO, 2009e).

In recent years, however, health care providers—faced with an unprecedented era of competition and pressures to improve care quality and effectiveness—are changing this

behaviour (Corso and Gastaldi, 2009), and exploring comprehensive perspectives that allow ICT to improve the quality of health care and of managerial processes, while simultaneously reducing their cost (Anderson, 2009; Christensen et al., 2009; Corso & Gastaldi, 2010b; 2011; Finchman et al., 2011).

This new perspective considers the HCISs made up of different systems as a whole, to be integrated and orchestrated so as to support care in a patient-centric view of organizations and processes. From this viewpoint, HCISs have much to offer to support health care cost management and to improve the quality of care (Kolodner et al., 2008). As a matter of fact, in addition to the embedded role of ICT in clinical and diagnostic equipment (Corso & Gastaldi, 2011), HCISs are uniquely positioned to capture, store, process, and communicate timely information to decision makers for better coordination of health care at all the aforementioned levels of analysis (Finchman et al., 2011).

Over the past decade, the topic of HCIS has flourished, and has germinated an emergent body of theoretical frameworks, empirical research, and practitioner-based literature that has many peculiarities if compared to the traditional streams of research active on information systems (Tan, 2008).

This chapter aims to shed light on this developing research stream—summarizing the status of the research on the topic, pointing out the most interesting aspects that are currently under study, and defining theoretical and empirical gaps to be filled with further analyses.

Consistent with these main intents, the objectives of this chapter are the following:

- Define HCISs as well as the peculiarities that differentiate them from information systems developed and adopted in other industries (§2);
- Describe the architectural models that characterize the HCISs, with a specific emphasis—for their centrality in the creation of value within an health care systems—on Hospital Information Systems (§3);
- Analyse the main challenges that are faced in the governance of HCIS—both inside an health care entity (e.g. a hospital) as well as among the different entities active in the health care sector (§4);
- Outline the gaps that the research on HCISs has to fill in the near future (§5).

All the considerations presented in this chapter are not only rooted in the literature on HCISs but also based on the empirical evidence progressively collected through a permanent research initiative promoted since 2007 by the Politecnico di Milano School of Management, i.e. the *ICT in Health Care Observatory* (IHCO).

The IHCO focuses on the analysis of ICT-driven innovation in the health care industry, with a specific emphasis on HCISs; and the production of actionable knowledge (Mohrman & Lawler, 2011) utilizable by the academics and practitioners who want to implement them (Corso & Gastaldi, 2010a).

The IHCO has traditionally studied the Italian health care industry; however, since 2011, the study of Danish, Swedish and Norwegian health care systems through an annual set of cross-comparative surveys, extensive case studies, periodical and engaging focus groups, and clinical inquiry research projects has been launched. The complete methodology that describes their overall usage is described in Corso and Gastaldi (2011).

Here the main objective is to highlight two characteristics of the research process:

- *The adoption of a collaborative framework to conduct the research*: collaborative implies (Pasmore et al., 2008) research efforts that include the active involvement of practitioners and researchers in: (i) the framing of the research agenda, (ii) the selection and pursuit of the methods to be used, and (iii) the development of implications for action. Through its collaborative framework, the IHCO increases the possibilities of relating its insights to the problems of health care practitioners.
- *The adoption of a multi-company and longitudinal framework to conduct the research*: the idea behind this approach is to reconstruct past contexts, processes, and decisions in order to discover patterns, find underlying mechanisms and triggers, and combine inductive search with deductive reason (Pettigrew, 2003). Through its multi-company and longitudinal framework, the IHCO increase the possibilities of accumulating solid knowledge over time and of generalizing its findings.

2. Health care information systems: definition and peculiarities

Rodrigues (2010) defines HCISs as powerful ICT-based tools able to make health care delivery more effective and efficient. Coherently, Tan (2005) views HCISs as a synergy of three other disciplines—namely, health care management, organization management, and information management. Rada (2008) agrees with these views, and recognises that HCISs are only partly based on the application of management information system concepts to health care. According to his view, HCISs comprise several different applications that support the needs of health care organizations, clinicians, patients and policy makers in collecting and managing all the data related to both clinical and administrative processes.

These data can be used across a number of systems for many different purposes (Wickramasinghe & Geisler, 2008), have to be integrated with the data from other entities in order to be effective (Pascot et al., 2011), and—especially for patient data—must be subject to strict rules in terms of confidentiality and security safeguards (Lobenstein, 2005).

Despite its importance, the health care domain has been underrepresented in the debate on the development of information systems—from both an empirical (Callen et al., 2007) as well as theoretical (Fichman et al., 2011) viewpoint.

Only recently a progressive proliferation of health care information systems research has been pushed by (i) the growing amount of investments made in the sector (World Health Organization, 2009), (ii) the increasing pervasiveness of ICT-based solutions within the health care domain (Stegwee & Spil., 2001), and (iii) the recognized capability of ICT to respond to the double challenge of rationalizing health care costs while, at the same time, increasing the quality of the health care processes (Stebbins et al., 2009).

Reasons behind this evidence have to be linked with the peculiarity that characterized and still characterizes health care industry itself (Anderson, 2009). At a general level, a striking feature of this industry is the level of diversity of (Fichman et al., 2011):

- Its final "customers" (the patients);
- The professional disciplines involved in the process to deliver the health care services (doctors, nurses, administrators, etc.); and

- The various stakeholders with interests in the sector (providers, regulators, etc.).

Fichman et al. (2011) have pointed out the effects of this diversity on the distinctiveness that characterizes the development of an HCIS in comparison to an information system in another industry. Generalizing their view, there are six elements that make HCISs so specific:

1. *The gravity associated with information mismatches*: health care quality is diligently pursued and vigilantly executed, and information systems can facilitate this pursuit by highlighting and monitoring errors at various stages along the continuum of care (Fichman et al., 2011). Even a small error in any one of the various pieces of information stored and used in the HCIS could have dramatic consequences that directly influence the quality of human lives (Aron et al., 2011).
2. *The personal nature of most of the information managed by health information systems*: most of the information transfer between the different health care actors involves risks—both actual and perceived—that the information could fall into the wrong hands. The perception of compromised privacy associated with each information exchange always makes the latter extremely complex in the health domain.
3. *The influence played by regulators and by providers' competition over information management*: health care is a sector highly subjected to regulatory policies on patients' data (World Health Organization, 2009). If one adds to this consideration the difficulties that the providers of ICT-based solutions experience during the exploitation of the advantages associated to their offers (IHCO, 2010; Ozdemir et al., 2011), it is easy to understand why ICT-driven innovation's realization within the health care industry is always so complex.
4. *The professional-driven and hierarchical nature of health care organizations*: one of the barriers to the full exploitation of all the potential associated with health information systems is that powerful actors in care delivery often resist technology (IHCO, 2011; Kane & Labianca, 2011). Given the hierarchical nature of health care (Fichman et al., 2011), aversion to technology by an influential physician is likely to irremediably affect other caregivers' behaviours (Venkatesh et al., 2011; IHCO, 2010).
5. *The multidisciplinarity of the actors who access HCISs*: despite the presence of multiple barriers to the use of ICT in health care, an overall unity in the use of HCISs can emerge because of the interdisciplinary nature of most of the health care services (Oborn et al., 2011). Moreover, the heterogeneity of the health care disciplines makes the pattern of ICT usage complex and entangled—forcing an approach that goes beyond the too simple classification usually performed in other industries between the adoption and the rejection of information systems.
6. *The implications for learning and adaptation associated to the implementation of an HCIS*: the health care delivery setting is characterized by a tension between the need for orderly routines and the need for sensitivity to variation in local conditions (Fichman et al., 2011). This tension magnifies the importance of effective learning and adaptation surrounding HCISs implementation (Goh et al., 2011), because the solutions that work in one specific context can not necessarily work in others .

3. Architectural models for health care information systems

3.1 Overview of health care information systems

From a functional viewpoint, an HCIS supports three main levels of a health care system:

- *Central government at national and regional level*: this comprises central planning capabilities, resources management, the definition of the rules and the procedures to be followed, general controls over financial performance, monitoring of quality and safety. This level is organized differently depending on the model of each national health care system, whose main paradigms can follow the mutual-private model typical in the United States, or the Anglo-Saxon model.
- *Primary Care Health Services*: this level includes all the systems that support the services delivered to the citizens throughout the national or regional territory. It includes all the service providers like general practitioners, local practices, etc.
- *Secondary Care Health Services*: this level refers mainly to the systems that support health care processes among health care providers.

The three levels are usually interconnected only as regards administrative and accounting flows (Locatelli, 2010; Corso & Gastaldi, 2010b), but the potential data exchange among the different layers makes ICTs essential for both the exchange and the manipulation of large sets of clinical data. This evidence provides enormous potential for the future development of health care. As a matter of fact, the ICT-based solutions that are currently present in the health care industry have the ability to not only simplify the relationship between the citizens and the physicians—improving the overall performance of health care services—but also enable a better control of the whole health care system.

For example, in Italy the national health care system is completely public, and provides health care services to all the citizens as a constitutional right. The different Italian HCISs have been based on a set of pillars (Lo Scalzo et al., 2009):

- The digitalization of the information flows at a national and a regional level;
- The development of a national as well as regional social security card;
- The development of a regional infrastructure supporting online services to citizens;
- The development of a strong set of interconnections between health care providers (secondary care) and general practitioners (primary care);
- The creation of a regional *Electronic Health Record* (*EHR*) to be subsequently integrated at a national level;
- The digitalization of the service-delivery processes in secondary care.

As health care is a subject ruled by cooperation between the central government and regions, most of the efforts aim to organize regional activities and to control costs (Corso et al., 2010). On the regional level, central institutions develop plans and projects that address high-level objectives fixed at a national level, and define regional guidelines/policies to be respected by single health care organizations on the territory (e.g. as regards the EHR).

This kind of model is reflected as well by the organization of HCISs, which are powered by a central network dealing with administrative and financial information flows, but have a much more local connotation as regards support to care processes. Moreover, many Regional governments have spent the last ten years creating a pervasive networking infrastructure, digitalizing information flows on activities performed by public providers, developing social health care identification cards, developing at least basic online services (e.g. booking), and activating the key elements for a regional EHR (Lo Scalzo et al., 2009).

If these efforts have proved quite patchy among the different regions, informatisation of health care providers is even more fragmented.

Inside the Italian health care system, it is possible to identify the CRS-SISS, a forward looking project promoted by the regional government of Lombardy, which aims to promote innovation within public health care organizations for an intensive e-health strategy, through the increasing and pervasive usage of ICTs (Corso et al., 2010).

The central elements of the CRS-SISS project are (IHCO, 2011):

- The social security citizen identification card, a powerful tool for citizens to access every health care service in the Lombardy region;
- A pervasive network linking all the health care providers, general practitioners and regional entities;
- The regional EHR, a central database where qualified health care organizations publish digitally signed documents on each clinical episode (e.g. outpatient visit reports, clinical reports, prescriptions, etc.).

The case of Croatia, described in Box 1, is an interesting example of a pervasive initiative driven by ICT and able not only to improve but also to completely redesign the national health care system.

Croatia is a country of about 56,000 square kilometres in Eastern Europe, with a population of 4.5 million inhabitants, of which about 17% are over 65 years.

Among its main initiatives, the Ministry of Health wanted to reduce the administrative burden and bring more transparency into the Croatian health care system. According to this objective, the Ministry launched the Care4U project that not only digitalized the workflows within and among health care organizations, but also integrated on a national scale all the primary care providers.

The project started in 2004, with the involvement of the National Public Health Institute and most of the Croatian health insurance agencies. Since March 2007, the Croatian HCIS operates on a national scale, connects all the offices of the general physicians (about 2,300) spread on the territory, and manages over 4 million citizens. At the end of 2010, a major system upgrade integrated into the system more than 1,100 pharmacies, 100 biochemical analysis laboratories and 66 hospitals.

The features that the HCIS makes available to all these actors are (i) an integrated management of medical records, (ii) the management of the main information exchanges (with electronic prescribing solutions, reservation, drug management, ADT, laboratories management, radiology, etc.), and (iii) the reporting of information flows to the Ministry of Health as well as all the member insurance companies.

The system has led to the achievement of substantial economic benefits—which are mainly related to the reduction in costs of hospitalization—while, at the same time, an increase not only in the effectiveness of the health care processes but also the quality perceived by patients, physicians and nurses. All these advantages have raised Croatia to the third-place ranking in the EuroHealth Consumer Index assessment performed in 2009 on 27 European countries.

Box 1. The National Health Care Information System in Croatia

3.2 Hospital information systems

The core level where ICTs can exploit their full potential both in terms of cost-efficiency as well as quality improvement is that of secondary care, i.e. the health care providers level.

A Hospital Information System (HIS) is a set of organizational structures, information flows and ICT-based solutions that support core and secondary processes of a hospital. HISs are responsible for supporting secondary care, and are the combination of a variety of interconnected systems that manage a huge amount of narrative, structured, coded and multimedia data (Corso and Gastaldi, 2010).

The HIS has not only to manage complex and widespread processes but also to store and make accessible all the information needed by the staff of the hospital.

The organization of the processes of a general health care provider can be described by a classic value-chain model (Caccia, 2008), with two main kinds of processes:

- *Primary (or core) processes*, related to direct patient care:
    - *Admission*: disease prevention, inpatient or outpatient event booking and hospitalization admission;
    - *Anamnesis*: definition of patient's clinical status from a medical and nursing standpoint;
    - *Diagnosis*: definition of patient's therapeutic and care plan;
    - *Care*: therapy, treatment, rehabilitation;
    - *Discharge and follow-up*: patient discharge and possible transfer to outpatient or home care for follow-up activities.
- Secondary (or support) processes:
    - *Strategic services*: strategy, planning and controlling, supervision of regulations;
    - *Administrative services*: administration and accounting, information systems, quality assurance, human resources;
    - *Technology services*: clinical machinery, biotechnologies, building automation, auxiliary systems;
    - *Sourcing and logistics*.

From a technological viewpoint, the concept of HIS includes the technological infrastructure, the organizational components (structures, policies, procedures) and the portfolio of the applications implementing them. Biomedical devices are not considered a part of the HIS, as they should be considered part of the clinical engineering area.

From a functional viewpoint, the main areas of an HIS are (Locatelli, 2010):

- The *administration and management area*, which supports strategic and administrative processes;
- The *front-office area*, which supports the admission of inpatients, outpatients, or emergency/first aid patients;
- The *clinical area*, which supports the core health care processes (the processes through which health care organizations provide treatment to patients).

Typically, these areas implement a number of different systems that have been progressively acquired over a period of years, to later be integrated with the aim of progressively bringing higher levels of process flexibility and organizational coordination.

In the rest of the paragraph the three functional areas will be described, emphasizing their main functional modules and their role in relation to providers' processes. Fig. 1 provides a comprehensive picture of how the different areas interact with each other thanks to a bunch of centralized services and a comprehensive integration layer called "middleware".
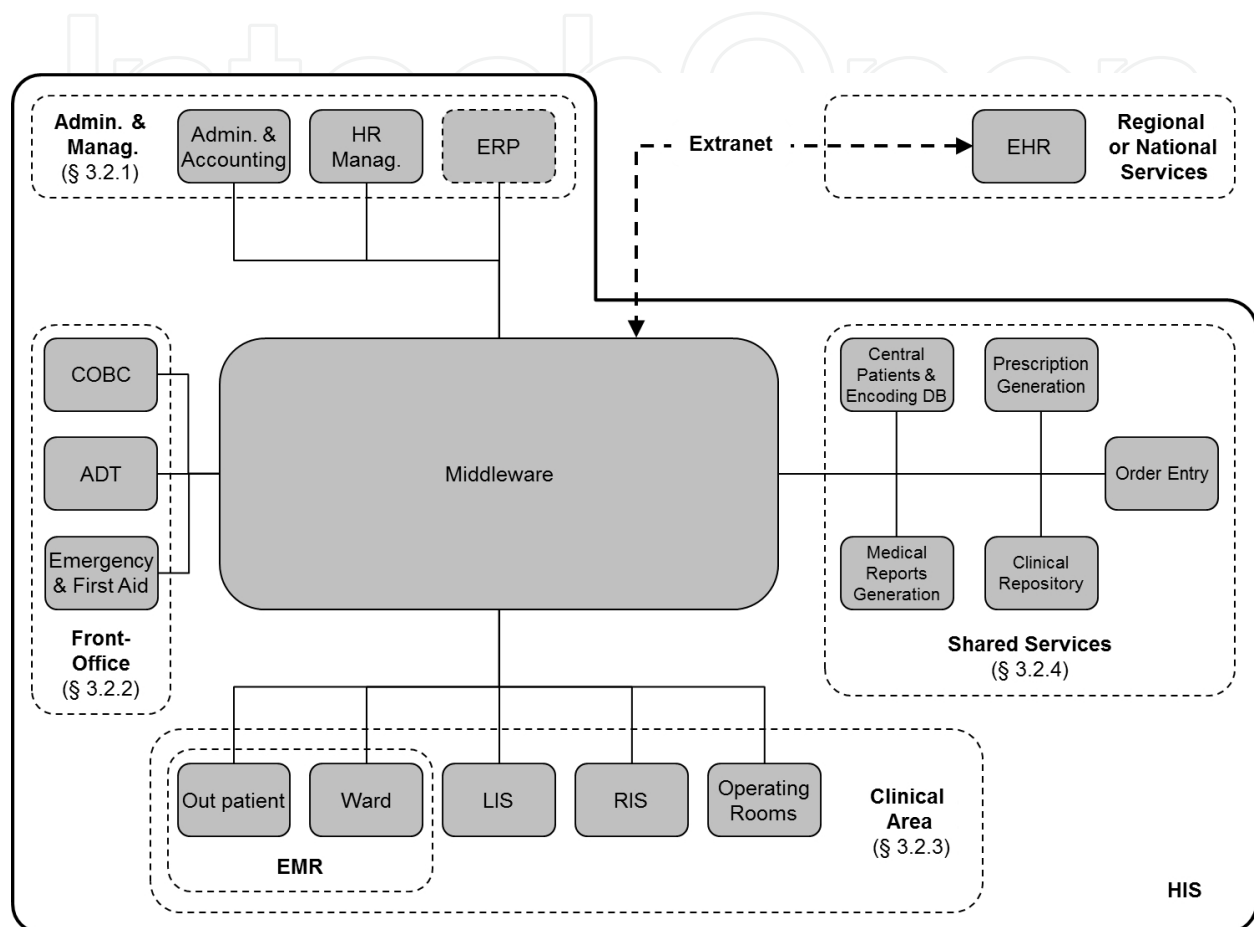

Fig. 1. Conceptual Architecture of a HIS

3.2.1 Administration and management area

The administration and management area supports processes like general administration and procurement, planning and management control, and resource (especially human resources) management (Locatelli, 2010). As administration processes are highly similar across almost all industries, the related systems are technically analogous to the ones used in other industries (Rodrigues, 2010; Tan, 2008; Greenhalgh et al., 2005; Raghupathi, 2003)—even if in health care they have to be slightly modified to better fit the peculiarities of the industry (e.g. its accounting rules).

The components related to this area have the responsibility to support the company in managing the activities of an administrative/accounting nature.

In particular, we typically identify two main components (IHCO, 2009d):

- *Administration and accounting suite*: for the management of accounting and business budget, procurement, storage of assets (general ledger, accounts payable, receivables, payments and bills for treasury management, tax professionals, management of requests for supplier bids, contract management, logistics management department, cost accounting, etc.).
- *Management of human resources*: for legal aspects, economic and security staff (allocation of personnel, analysis and reporting, etc.).

Each one of these components can have its own system that has been historically developed by each department following its own business requirements. Alternatively, the health care organization can implement the so-called *Enterprise Resource Planning* (ERP) suites similar to the ones being used in other industries since the 90s (Umble et al., 2003; Stegwee and Spil, 2001).

Application fragmentation in the administration and management area—added to a similar non-homogeneous configuration of clinical support systems—has led to problems like (i) misalignments and incompleteness of data sources, (ii) data inconsistency, (iii) difficulties in manipulation and aggregation of data, (iv) inconsistency among the results coming from different departments (IHCO, 2011).

For this reason, ERP projects are increasingly becoming frequent in health care—especially starting from the naturally more performance-oriented private providers. In fact, modern ERP platforms have a central data warehouse able to merge information flows from all hospital information sources, and, thus, enable advanced functions—e.g. decision support systems and balanced scorecard tools—that provide managers with up-to-date information on current activities, profit and loss accounts, and general performance indicators of the organization (IHCO, 2009a).

3.2.2 Front-office area

The front office area deals with patient reception, and typically distinguishes between inpatients, outpatients and patients in the emergency unit. These sub-areas are usually supported by enterprise-wide solutions that manage the workflows related to the waiting lists or the appointment management. Common solutions are the *Centralized Outpatient Booking Centre* (COBC) and the procedures related to *Acceptance-Discharge-Transfer* (ADT) (IHCO, 2010). Systems supporting the emergency and first aid wards typically also deal with clinical information (IHCO, 2011).

COBC supports the processes to manage outpatients:

1. The internal agendas for outpatient diagnostic service booking (RIS, LIS, AP), with potential connections to regional booking centres;
2. The communication of work lists to clinical services,
3. The collection and the verification of informed consents;
4. The billing for services and accounting.

The proper functioning of the COBC system is made possible by a front- and back-office service, responsible for programming functions and access management, as outlined below. Back-office cares for the maintenance and planning/preparation for the

reservation of extraordinary activities. These activities are grouped into the main functions of management and planning the agenda reservation, supporting the booking and delivery point, and monitoring the management of waiting lists. The COBC is composed of several channels that allow access to the booking process, and handle different types of interaction.

ADT systems manage the processes related to hospitalized inpatients. In accordance with the hospital's organization (Lo Scalzo et al., 2009), ADT systems can provide the services in (i) centralized mode, (ii) distributed in the wards, or even (iii) in mixed mode (e.g. acceptance can be centralized while transfers and dismissals can be handled by wards).

Specifically, ADT systems support the following activities:

- The management of waiting lists, through integration with the cross-booking management service;
- The management of pre-admission;
- The registration of patient informed consent;
- The management of post-admission;
- The admission, the discharge and the transfers of patients within the hospital.

Emergency and first aid systems are made up by the process for both the organizational aspects of emergency events as well as the direct impact on citizens who request services considered essential for their health.

In this context, not only the impact of operational functions (use of informatics tool in an emergency context) but also the organization of the process (priority based on seriousness of the case) is highly important. These systems must also be able to support the doctor in requesting diagnostic support (e.g. analysis, consulting) as well as in making decisions as quickly and safely as possible (Corso et al., 2010; Locatelli et al., 2010).

The most important features are the following:

- The management of all the organizational aspects in the emergency and/or first aid department;
- The management of triage;
- The management of the EMR and the patient summary specialist folder (for the functions or the activities of both the physicians and the nurses);
- The management of the requests of consultations and examinations;
- The management of clinical and legal documents for both the patient as well as the authorities;
- The management of drug prescriptions;
- The transfer of data to the ADT system, in the case of a transfer to inpatient wards;
- The management of all the first aid discharge activities, including reporting.

3.2.3 Clinical area

The third key block of an HIS is the clinical area, which is the most complex and most delicate area due to its broad support to all the core processes of a hospital. It is also the most challenging area in terms of management, due on the one side to the involvement of critical patient data, and on the other side, to pre-existing systems implemented

independently by each department or ward in different periods—usually without a consistent strategic direction by the *Chief Information Officers* (CIOs) (IHCO, 2011).

Clinical systems are mainly (i) departmental systems or (ii) *Electronic Medical Records* (EMRs). The former support both clinical and administrative tasks in diagnostic services (e.g. anatomical pathology), and are fed by the requests coming from wards or outpatient offices. The latter should be responsible for the digitally-integrated management of clinical information flows to support care, and—acting as a unique bedside working tool—for the role as the unique point of reference for clinical decisions (Locatelli et al., 2010).

Departmental systems receive requests from COBC or from the order management systems in the wards, they support the execution phases of tests, notify the application regarding the execution of the examination, and produce reports that are stored in the clinical repository.

The most common departmental systems are (IHCO, 2009d; Locatelli, 2010):

- The *Radiology Information Systems* (RIS), which manage the acquisition of radiological images, their analysis and the relative reporting. These systems are often linked to Picture Archiving and Communication Systems (PACSs), which acquire, store and distribute images and videos.
- The *Laboratory Information Systems* (LIS), which automatically manage the exam requests from the clinical units and the auto-analyser connected to the LIS, supporting sophisticated controls with validation of the results.
- The a*pplications for the operating room*, which are dedicated to the management of the interventions, to the logging of both the events and the data relevant to surgery and to the production of clinical surgery documentation.

The *Electronic Medical Record* (EMR) is the central element of the HIS. The fundamental function of an EMR is to collect information on the clinical history of patients during hospitalization—acting as a tool to support the multidisciplinary communication between professionals, operations management and decisions.

Literature (e.g. Handler & Hieb, 2007; IHCO, 2009d; Locatelli et al., 2010) allows the identification of five functional areas that characterize EMRs:

- The *ADT Area*: often integrated with the ADT system, this area manages patient admissions, discharges and transfers within the hospital, as well as vital statistics and administrative documentation (e.g. informed consent);
- The *Diagnostic Area*: the features in this area allow the requests of exams and the delivery of reports to/from wards;
- The *Clinical Dossier*: this area embraces the management of all medical and nursing sheets, including initial assessment, automated vital signs monitoring, anaesthesiology documents, OR reports, etc.;
- *Therapy management*: this area includes support to prescription and administration of drugs, transfusions, nutrition, etc.;
- *Out-patient management*: this area manages admission and medical reporting for out-patients, and feeds the patient's EMR with information like preliminary reports or follow-up examinations.

As depicted in Fig. 2, the most diffused functions of an EMR are inpatient ADT (80%), diagnostic procedure management (with electronic clinical exam requirements and reports

available in 80% of cases) and outpatient management (67%). Even if clinical dossier and therapy management are the less diffused areas, at the same time, they are also the ones with the greatest expected growth for the future. Hindrances are mainly related to the difficulties in change management, in the migration of therapy procedures from paper to digital forms, in the needs of smart bedside support, and in legal constraints to digital data management.
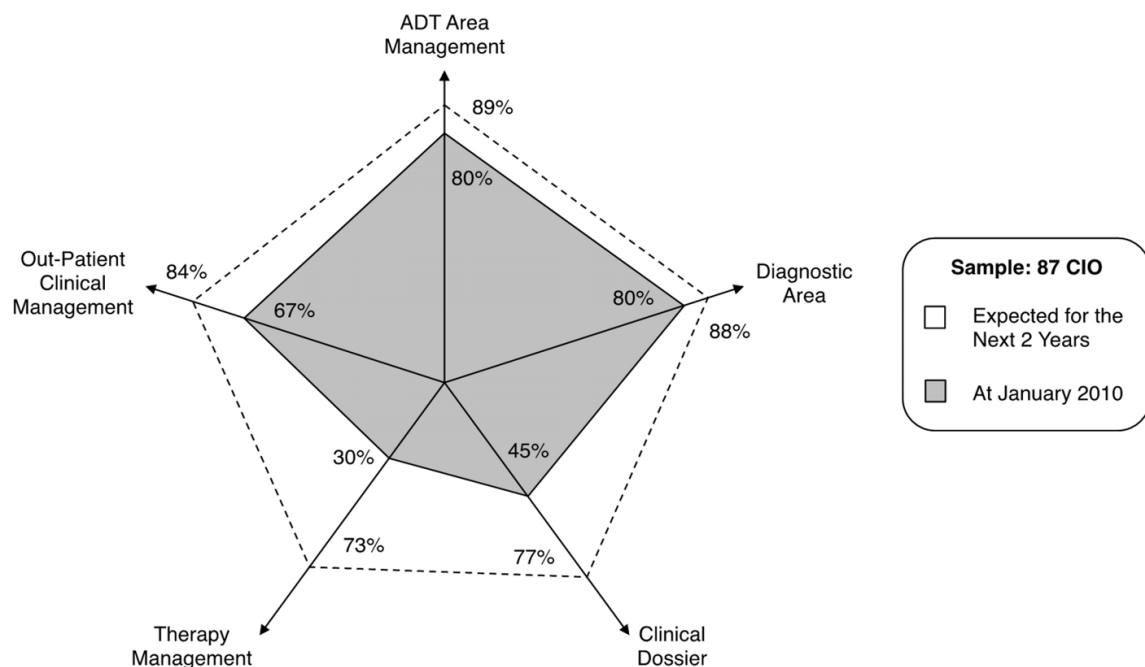

Fig. 2. *The Expected Diffusion* of Functional EMR Areas (ICHO, 2010)

Unfortunately these last areas not only have a key impact on clinical activities, but also are the ones that need higher levels of integration in order to allow the EMR to become a truly useful clinical tool. Case studies performed by the IHCO have confirmed that the lack of integration with the rest of the HIS and the absence of an enterprise-wide approach are the main limitations of current EMR projects. However, many efforts are made not only to standardize the EMR architecture, but also to drive its evolution towards a mature tool able to comprehensively support all the health care processes (IHCO, 2009d).

Another important opportunity coming from digitalization of clinical processes regards the opportunity to feed researchers with first-hand, complete and highly reliable datasets on clinical cases collected in the EMR during daily care and then filtered for clinical research purposes. The case of the Istituto Besta (see Box 2) briefly highlights how this can happen.

Fondazione IRCCS Istituto Neurologico "Carlo Besta" is a centre of excellence for care and scientific research on neurological diseases. Recently, a collaboration was started with the hospital A.O. Ospedale Niguarda "Ca'Granda" and Fondazione Politecnico di Milano, with the aim of transforming Niguarda's web EMR into a "clinical-scientific" portal to not only support patients' management during their entire care process, but also to feed scientific research with key information gathered during each clinical event.

Due to its open architecture, the portal was conceived as a unique access point to the HIS, based on a centralized patient reference registry. The first scientific features were

provided in October 2008 supporting complete outpatient workflow and encoding pathological diagnoses according to international standards. Since 2009, most features of an EMR were also implemented to support inpatient management. This means that admission, anamnesis, diagnosis, clinical diaries, speciality neurology sheets have been standardized, reengineered and digitalized. Clinicians use RFId badges to access the clinical dossier on WiFi laptops fixed on mobile trays than can roll to bedside.

The most innovative feature of this system is however that the clinical portal's EMR is conceived to structure digital information both to support ward activities as well as to feed scientific research. Starting from the general EMR, specific design was done in order to satisfy the requirements of physicians and researchers working in the area of myasthenia gravis and peripheral neuropathy. A procedure was identified to enrich and structure usual clinical datasets, so that high quality data could be gathered by physicians during the clinical event and then it could also be used by the research area. Once the diffusion of the EMR reaches high coverage in wards, stored data are also made available to a clinical decision support system, through which users will directly access clinical and scientific indicators, improve the correctness of diagnosis and identify specific pathological patterns.

This approach at Istituto Besta is also applied to the Epilepsy Pathology Network of the Lombardy Region (EpiNetwork), introducing automatic feeds as a part of its clinical-scientific-epidemiological EMR. Here, the compliance of all organizations' HISs to syntactic and semantic standards is essential to feed the EpiNetwork, thereby increasing the amount and quality of available data.

Box 2. The EMR in Fondazione IRCCS Istituto Neurologico "Carlo Besta" (Milan, Italy)

Besides supporting clinical operations, over time the clinical information systems have assumed a growing role in risk management, e.g. as concerns the automated execution of critical tasks (e.g. laboratory examinations, drug dilution robotization), ensuring timely data gathering to clinical decision makers, automating patient monitoring and alerting upon inconsistencies, and so on (Chauldry, 2006).

Crosswise all systems and all applications, *Mobile & Wireless* (M&W) technologies emerge as a key element to close the bedside safety loop—filling the gap left by the traditional HIS. In fact, M&W technologies can on one hand deliver functionalities like decision-making support directly to the bedside, and on the other, they can strengthen the safe implementation of *Automatic Identification and Data Capture* systems (Bates, 2000). From this viewpoint, Box 3 describes an important example, as regards risk management as well.

The Fondazione IRCCS Istituto Nazionale dei Tumori in Milan (henceforth Istituto Tumori) is recognized as a top Scientific Research and Treatment Institution in Oncology.

Throughout the last decade the Istituto Tumori has implemented a state-of-the-art HIS based on a solid technical infrastructure and international standards (most of all HL7), effectively integrating information systems amongst each other. Regarding the five main functional EMR areas, in the Istituto Tumori ADT, Out-patient management and Diagnostics are the most historically consolidated.

As regards therapy management and bedside operations, the Istituto has recognized that lack of ICT support for bedside operations may be dangerous for patient safety. Therefore the Istituto is pervasively implementing M&W and Radio Frequency Identification (RFId) technologies in order to avoid errors and enhance patient safety and care quality of care at bedside.

An RFId enterprise platform, made of a set of process-tailored mobile applications and RFId devices integrated to the HIS applications, now enables traceability and process control (e.g. patient-to-treatment cross matches and workflow checks) as regards transfusions, radiotherapy treatments, radiology, surgical operation check and tissue samples. Traceability data are collected on mobile devices and gathered to the appropriate subsystem of the HIS, allowing specialists in departments (e.g. the Transfusion Service) to monitor ward activities.

An interesting project regards chemotherapy process reorganization, where the Istituto is leading the project "Towards a complete competence framework and an integrated solution for patient safety in chemotherapy" funded by the Italian Ministry of Health. Results and knowledge (in terms of risk analysis, process diagnosis evidences, workflow recommendations, and an ICT pilot system, …) are now being applied with the design of an enterprise-wide therapy management system and a centralized lab to issue chemotherapy treatments for all wards. Here, RFId will be used to track all critical steps of preparation and administration at bedside, securing patient and drug identification and process monitoring.

Box 3. Therapy Management and Wireless Traceability at Fondazione IRCCS Istituto Nazionale dei Tumori (Milan, Italy)

In fact, to assess the potential impact and the convenience of digitalization in terms of risk management, many new methodologies have supported traditional *Business Process Reengineering* (BPR) theories (e.g. Davenport, 1993) and process-related risk management theories. The peculiarity of these approaches is that ICT is seen not only as a means to reduce process risk, but also as a potential source of new weaknesses in processes. The *Healthcare Failure Mode, Criticality and Effect Analysis* (HFMEA) is a recognized technique that has increasingly been adopted in practice (DeRosier, 2002).

3.2.4 Shared services of a hospital information system

Supporting the main aforementioned areas, there are other components that complement the HIS architecture. The best practices show that the architectural model of an HIS should be based on a common infrastructure, made of central services and a comprehensive integration middleware. More in detail, the shared services are (Locatelli, 2010):

- *Central Patients and Encoding Database:* this service has the responsibility to centrally manage patient identifiers (Master Patient Index, MPI) to make them available to other components of the HIS, and to manage clinical encodings shared among applications (e.g. encodings nomenclature or pharmaceutical handbook);
- *Prescriptions Generation:* this service allows the preparation, digital signature and issue of all prescriptions to be used outside the hospital;
- *Order Entry:* this service manages ward requests for internal exams and second opinion consultations;

- *Medical Reports Generation:* this module supports the issue of legally compliant medical reports for all hospital services;
- *Clinical Repository:* this is a central archive of (i) all kinds of digitally-signed medical reports, (ii) structured data, (iii) patient events (e.g. transfusions, surgery) and (iv) many others, from exam requests to therapy prescriptions. The clinical repository is a core component because it is the central collector of patient data, that all other systems can consult to retrieve official documents and data on past episodes. This component is also responsible for feeding the regional health record, via a dedicated network link (extranet)

Crosswise, the central middleware is responsible for linking all HIS components using standards, such as *Health Level Seven* (HL7). The importance of an infrastructural backbone can be fully understood with the example of St. Olav's Digital Hospital, described in Box 3. This is only one case amongst many (e.g. the Orbis Medisch Group hospitals, in Denmark, and the Julius-Maximilians University Hospital of Würzburg, in Germany) in which a pervasive infrastructure enables the implementation of an integrated technological platform aimed at digitalizing both management activities and clinical processes. A strong technological partner has proved essential in all cases.

4. Governance of health care information systems

HCISs are developed, maintained and innovated by a *complex ecology* of multiple agents that share knowledge (as well as other resources) in often previously unknown interaction paths (Simon, 1996; Anderson, 1999; IHCO, 2011). If, as a result of this complex process, HCISs emerge almost unpredictably over considerable time periods—as various agents in the ecology interact with and react to the actions of others—their governance is naturally characterized by a *shared and multilevel nature* (IHCO, 2010; 2011).

The challenge, in this case, concerns how to foster the necessary collaboration among many diverse organisations over long and uncertain time periods, while, at the same time, continuing to develop internal solutions able to respond to the specific necessities of the health care organisations' different lines of business (IHCO, 2010).

St. Olav 's of Trondheim (www.stolav.no) is the largest hospital in Norway, with 950 beds and 8,000 employees. The willingness to restructure the campus has given the opportunity for a pilot project whose goal is the realization of a completely digital hospital.

Three intervention pillars existed: (i) the review of information flows and clinical documentation for their complete dematerialization, (ii) the multichannel and continuous access to systems and information clinics, and (iii) the advanced infrastructure enabler.

The third pillar is the real basis of a digital hospital design, and it is made of a communication and integration infrastructure mainly based on IP and XML protocols. The main innovative element is on one side the infrastructure's pervasiveness, and on the other side the integration of the HIS—including clinical systems, remote control systems, telecommunications equipment support, building automation systems, asset management

applications, automatic guided vehicles transports, and environment sensors.

The experience of St. Olav's is a case of excellence in terms of a state-of-the art infrastructure enabling a truly paperless organization. In fact, the communication infrastructure and the integration platform can support various application modules: the electronic medical record, the departmental systems, biomedical equipment, bedside entertainment, and so on.

As an example, pocket PCs are used to both replace cell phones, pagers, and terminals for patient entertainment as well as use EMR in mobility, also fed with vital sign data as well as by reports of departmental applications.

Box 4. St. Olav 's Digital Hospital (Trondheim, Norway)

As a matter of fact, the problem is that most of the theoretical and empirical research on information systems management is mainly focusing on firms and their performance (Hunter, 2009)—paying little attention to both the interaction among the different actors inside a specific sector as well as the development of shared solutions like the ones currently needed by the health care industry (Corso & Gastaldi, 2010b).

A comprehensive governance model must, thus, not only focus on what should be done inside each organization of the health care industry to make ICT-based solutions efficient and effective, but also (and especially) consider the decisions that each one of these organizations has to make during the interaction with the other actors in the sector. To simplify the discourse and make it a bit more effective, it is possible to talk about *the internal and external governance* of HCISs (IHCO, 2009e).

4.1 Internal governance

By the term *internal governance of HCISs* we mean the system of policies, processes, decisions and rules that set the way through which HCISs are run, managed and developed inside an health care organization (Corso and Gastaldi, 2009).

Empirical evidence (IHCO, 2008; 2009e; 2010; 2011) as well as literature (Corso et al., 2010; Venkatesh et al., 2011) emphasize that the low levels of formalization of the governance models of the HISs are greatly affecting the development of the HISs themselves. Low financial support—often pointed out as the main problem by health care CIOs —is mainly a reflection of the low commitment by the majority of the strategic board, which often neither has a clear idea about how ICT can have an impact that goes beyond mere efficiency, nor fosters the pursuit of a clear ICT strategy (Callen et al., 2007). The real reasons for a lack of effectiveness in the implementation of the HISs are multiple, and range from the lack of a technological perspective on the part of Chief Executive Officers (CEOs), Chief Financial Officers (CFOs) and Chief Medical Officers (CMOs), and the inability of CIOs to clearly propose all the advantages tied to ICT solutions, to the need to reach concrete organizational results for achieving higher investments in HISs.

As regards the ICT department, very few learning processes are launched to enhance the technical skills of employees, above all in the public sector. Leadership programs are practically inexistent. The turnover rate is very low, and many difficulties are found in attracting professionals from other sectors. CIOs tend to ascribe all these criticalities to

exogenous causes, rather than internal inadequacy, and to blame operational workload instead of their own inability to face it. The CIO himself often has a narrow strategic view that hinders an open approach to innovation. This is due to: (i) a low level of managerial capabilities, (ii) a difficult alignment with corporate strategies, and (iii) an overuse of technical language in strategic board interactions.

ICT supplier involvement is almost always operational or consultancy-oriented, and in the few cases in which the relation is continuative, CIOs fail to sufficiently delegate—working along-side the ICT supplier, even in highly outsourced operations.

To solve this set of problems, CIOs need first to work on their capabilities, as already done in other sectors (Broadbent and Kitzis, 2005). The research conducted by IHCO (2008; 2009e, 2010) shows an operative role for 65% of health care CIOs. With these values it is impossible to manage the effective development of HISs, and, thus, their innovation. It is true that organizations could first work on the ICT department team, but getting out of the operative vicious circle without a true C-Level director is often a challenge (Smaltz et al., 2006).

Obviously, this simply is not enough: having CIOs with more capabilities does not necessarily simplify the development or the management of HISs. Real innovation will not be attained until the ICT department develops a deep knowledge of clinical processes, relational and change management capabilities, and the ability to exploit external knowledge, while working alongside medical offices (IHCO, 2008). Thus, internal governance models have to direct their attention to core health care businesses, redesigning the ICT unit's skills on three main pillars:

- *Demand management*: reconciling the needs expressed by clinical units (and often anticipating them) with the overall ICT strategy of the organization.
- *Project management*: applying process reengineering and change management methodologies to govern projects, face unexpected events, assure success.
- *Supply management*: implementing rigorous procedures for vendor selection and establishing long-term relationships with key vendors able to support innovation.

A possible solution that combines these aspects is the change from a vertical to a horizontal governance model of HISs. The former is completely focused on a hierarchical relationship with the strategic board—forced as ineffective, because of the CIO having historically an operative profile. The latter directs its attentions to the core of care, establishes the ICT department as the main interface between the supply and the demand of the health care organization, and more easily achieves the systemic innovations, the effectiveness, the confidence and the leadership necessary to play a strategic role in health care organizations.

In the most advanced situations studied by the IHCO (2008; 2009e; 2010), CIOs confirmed that good horizontal governance implied increased objectives-sharing and thus, not only more integration between departments, but also a more innovative HCIS.

Reasonably, the change in ICT governance style will expose the CIO and the ICT department to greater interaction with internal (as well as external) organizational actors. In order to not lose focus in these difficult tasks—which imply adapting to very different business needs—a project priority framework is needed (Corso and Gastaldi, 2009).

4.2 External governance

By *external governance of HCISs,* we mean the set of decisions that allow the development of the information system adopted in a health care organization to be coordinated with the other information systems used in the health care sector (IHCO, 2009e).

As opposed to other sectors, within health care, most of the value that an organization brings to its customers is highly dependent on the information localized in other organizations—e.g. those health care organizations in which the patients previously received treatments. From this viewpoint, the cooperation among the different organizations in the health care industry is core and, thus, there is an high emphasis in the development of external governance models able to align the different interests in the sector.

Working on Dougherty and Dunne (2011), and considering the empirical evidences collected by the IHCO (2011), is it possible to state that all the models that allow the achievement of good external governance of HCISs are characterized by three dynamics:

- The development of sufficient connections among health care agents;
- The development of sufficient deviation-amplifying activities that stretch the overall health care industry toward integrated solutions with a positive social impact;
- The development of coordinating mechanisms that recombine, reuse, and recreate existing solutions, slow down amplifications and keep the system under control.

The first dynamic regards the development of sufficient connections among health care agents (Anderson, 1999). The presence of these connections is the most basic condition necessary to allows the emergence as well as the progressive comparison of new patterns and new solutions in the governance of HCISs (IHCO, 2010; 2011).

The process through which these connection are constructed is initiated by a variety of fluctuations that occur outside the norm, so the various agents need to interact and react to feedback about the action of others (Lichtenstein & Plowman, 2009). More specifically, the research of the IHCO (2011) points out that each actor has to strive towards specific behaviours in order to create solid connections with the rest of the health care industry:

- *Involvement and listening of lower level actors*: e.g. a regional council has to continuously develop channels that allow it to be in contact with its hospitals;
- *Proactivity and availability toward higher level actors*: e.g. a physician has to be able to overcome his natural tendency toward localism, offering himself as an open interlocutor in the dialogues with his referring hospital;
- *Comparison and collaboration with the actors of the same level*: e.g. all the hospitals that share the same geographical area should maintain a continuous dialogue that would allow them to coordinate their tasks and learn from other experiences.

The second dynamic is composed of deviation-amplifying activities, such as positive feedback, that move the overall health care system toward a new kind of order (Dougherty & Dunne, 2011) that—being characterized by higher levels of integration among the different health information systems—is comprehensively better in terms of social impact (IHCO, 2011).

Floricel and Dougherty (2007) suggest that reciprocal value can be created and can persist if each actor enables the heterogeneity of the possible outputs to be explored and

experimented through time. More specifically, the analysis performed with the Italian health care practitioners by the researchers of the IHCO (2011) points out that each stakeholder has to work locally in order to set and solve problems of orchestrating knowledge and capabilities across the health care ecology—fostering each potential form of strategizing across the whole health care industry in order to create shared IS applications.

The third dynamic enables new order to come into being and comprises coordinating mechanisms that recombine and recreate existing solutions, that slow down amplifications, and keep the new system persistent and under control (Lichtenstein & Plowman, 2009).

This dynamic relies mostly on the development of public policies and standardization choices that embrace the potential ambiguities that arise in the progressive development of shared HCISs. Even if currently research (Mahoney et al., 2009) tends to emphasize regulations as factors that constrain firms, rather than shaping collective action, public policies and standardization provide an overall direction to bundle knowledge and mitigate risks as well as provide the long-term continuity necessary to allow the new possibilities to emerge.

5. Future trends in health care information systems

According to the latest literature on HCISs (e.g. Fichman et al., 2011) as well as to the evidences collected by the IHCO (2010; 2011), there are three areas where major ICT-based advances are opening promising scenarios to further developments:

- Evidence Based Medicine;
- Health care analytics;
- Social Media in Health care.

Evidence-Based Medicine (EBM) is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients (Sackett et al., 1996). Recently, EBM has gained increasing attention as a tool to address the concerns about health care cost and quality—allowing earlier and more precise diagnoses, producing cheaper and more effective treatments, and minimizing the side effects associated to each treatment (Glaser et al., 2008; Christensen et al., 2009).

If the barriers to the widespread use of EBM are substantial, HCISs can play an important counteracting role. Generalising Fichman et al. (2011), there are four potential ways through which the research on HCISs can foster the adoption of EBM inside the health care industry:

- *Depth of knowledge about the efficacy of many common treatments*: the rise of digital storage of personal medical information gives researchers opportunities to discover precise knowledge about the links between treatments and outcomes;
- *Producing and sharing actionable knowledge*: health information systems researchers can study the antecedents and the consequences of sharing actionable knowledge through digital media in order to better influence practice;
- *Overcoming practitioner resistance*: health information systems can be used to promote education of all the health care stakeholders on the efficacy of diagnostic and treatment options so that they can hold caregivers more accountable;
- *Focusing on the implications that EBM brings in the field of HCISs:* both in terms of privacy as well as security.

Health care analytics is a rapidly evolving field of HCISs that makes extensive use of data, computer technologies, statistical and qualitative analyses, and explanatory and predictive modelling to solve problems that generally affect the entire health care sector.

The difference between analytics and EBM lies in the scale of the problems tackled by the two different solutions. If both of them focus on extracting knowledge from the amounts of digital data available in the health care industry, EBM maintains a focus on the individual while analytics impacts on a larger scale—analysing retrospective population datasets across multiple clinical conditions with models involving extensive computation. Common applications of analytics include the statistical analysis performed to understand historical patterns and, thus, predict and improve future treatments (Davenport, 2006).

According to the analyses conducted by the IHCO, there are three main behaviours that health care organizations have to adopt in order to increase the exploitation as well as the effectiveness of analytics in their industry:

- *Designing for consumability*: it will be progressively necessary to take into account the specific context, user, device and intended purpose of each quantitative analysis;
- *Exploiting natural variations in task performance as an "experimental test bed"*: as long as contextual variables are captured, variations in task performance across the enterprise will be progressively used as experiments to draw causal conclusions;
- *Building capacity and instrumentation to capture and use "external" data*: through the integration and the analysis of the data coming from (i) RFID tags on patients and providers, (ii) patient personal health record data, (iii) patient mobile device sensor data, (iv) data from other organizations, (v) social media data, etc.

Social media communities have been particularly active in the health care domain (Kane et al., 2009)—though with highly different rates across the different countries (IHCO, 2009c). The primary driver of value, in these communities, is a commons-based peer production of knowledge (Benkler, 2002) in which individuals, in a spontaneous way, collaborate on a large scale to produce work products without hierarchical control (firms) or market exchanges (price, contracts) to guide them (a famous example is *www.patientslikeme.com*).

Generalizing Fichman et al. (2011), it is possible to propose a set of the main interesting questions at the intersection between the new social media and the traditional information systems currently present in the health care sector:

- What conditions lead to the formation of health-oriented social media communities, and what is their impact on traditional health information systems?
- Which kinds of information are these communities going to share with the traditional health information systems?
- What are the most effective design rules for the platforms supporting these communities? How can they be seamlessly integrated with the traditional health information systems?
- What posture should large providers of ICT-based solutions be taking with regard to these natural developing platforms?

The conclusive case study presented in this chapter, in Box 4, is paradigmatic of the new horizons ICTs can nowadays open to health care organizations and public decision-makers.

Of course, a mixture of managerial skills, technological knowledge, commitment to innovate, and adequate resources is needed. However, the cases like the one of the University of Pittsburgh Medical Centre suggest that the continuous innovation of HISs and HCIS provides great results both in terms of efficiency and effectiveness in delivering care.

The University of Pittsburgh Medical Centre (UPMC) is a 9 billion USD health care organization affiliated with the University of Pittsburgh Schools of the Health Sciences. UPMC counts more than 54,000 employees, over 20 hospitals, and 400 doctors' offices.

UPMC is a top tier case as regards the integration of ICTs in health care processes. Since 2006 the company has invested 1,45 billion USD to: (i) review its infrastructural backbone, (ii) digitalize diagnostic services, (iii) implement a complete EMR, (iv) ensure widespread use of use of M&W devices (laptops, pagers, smartphones, etc.), and (vi) create a unified communications workspace for staff.

UPMC's current strategy for ICT is focused on three areas: (i) new telemedicine services, (ii) analytics development, and (iii) smart human-computer interfaces.

The first area regards the development of a set of telemedicine services. In this case technology allows the widespread application of new service models like telepathology, teleradiology, remote second opinion, remote monitoring for chronic patients. An interesting example, in this case, is the experimental pediatrics TeleICU project that the health care organizations is developing in partnership with the Mediterranean Institute for Transplantation and High Specialization Therapies (ISMETT). The project provides ISMETT surgeons with the virtual and real time support of Pittsburgh physicians.

The second frontier is analytics, seen as a tool for supporting both managerial governance (mainly in terms of financial control, outcome assessments, and process monitoring) and EBM. In the first case the HIS of UPMC generates key performance indicators that are provided to managers at different levels. In the second case interesting results have been achieved in profiling patients and in supporting clinicians with context-aware tools that display proper protocols, generate reference cases related to patient's condition, predict a treatment's expected outcome, and analyse in real time the history of similar cases stored in a centralized database.

The third area in which UPMC is working, in order to develop its HIS, is an innovative concept of a human-computer interface able to simplify and encourage the use of the HIS by the physicians. For example UPMC has created a new access to the Clinical Repository, where the whole patient history is graphically summarized, and key data from each clinical episode are characterized by graphical landmarks. This interface works as a launch point for all clinical applications, and allows semantic searches from multiple data sources.

Box 5. University of Pittsburgh Medical Centre (USA)

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