TELe-Health

Series Editors: Fabio Capello · Giovanni Rinaldi · Giovanna Gatti

Giovanni Rinaldi *Editor*

New Perspectives in Medical Records

Meeting the Needs of Patients and Practitioners

Springer

TELe-Health

Series editors:
Fabio Capello
Cumberland Infirmary
North Cumbria University Hospitals
Carlisle
United Kingdom

Giovanni Rinaldi
Ospedali Riuniti Marche Nord
Pesaro
Italy

Giovanna Gatti
European Institute of Oncology (IEO)
Milan
Italy

Recent advances in technology and medicine are rapidly changing the face of health care. A revolution is occurring in diagnosis and treatment thanks to the implementation of instrumentation and techniques deriving from engineering and research. In addition, a cultural conversion is taking place in which geographical and social boundaries are about to be overcome, resulting in enhanced availability and quality of care. Telemedicine has been considered a possible means of improving health care worldwide that is likely to change the way in which doctors deal with patients and diseases. While various restraints continue to limit the application of telemedicine in different settings and different areas of health, the innovations emerging from eHealth and telecare could stimulate a great leap forward for medicine, provided that some basic rules are taken into consideration and followed. In this series, diverse aspects of tele-health – preventive, promotive, and curative – will be covered by leading experts in the field with the aim of realizing the full potential of the new and exciting technological solutions at our disposal.

Giovanni Rinaldi
Editor

New Perspectives in Medical Records

Meeting the Needs of Patients and Practitioners

Springer

Editor
Giovanni Rinaldi
Ospedali Riuniti Marche Nord
Pesaro
Italy

ISSN 2198-6037 ISSN 2198-6045 (electronic)
TELe-Health
ISBN 978-3-319-28659-4 ISBN 978-3-319-28661-7 (eBook)
DOI 10.1007/978-3-319-28661-7

Library of Congress Control Number: 2016958442

Printed on acid-free paper

This Springer imprint is published by Springer Nature
The registered company is Springer International Publishing AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

Preface

For a long time, governments and regional authorities have set up projects on the use of medical records for different needs: longitudinal and omni-inclusive, specialists for each medical discipline, synthetics, and for emergencies. In this context, the industry has provided its expertise and has proposed solutions to the different needs.

But, despite the enthusiastic expectations of the initiatives by governments and regional authorities, in the literature, we find criticisms, problems, and lack of understanding; the question is whether these initiatives have improved services, reduced costs, and improved care to citizens. The technology has reached a high degree of maturity, and in this context, there are users with different needs, and each of them wants to be the driver of the actions related to the production, management, processing, and use of medical records.

So, whereas policy makers (with the reason on their side) believe that technology can make improvements and they produce rules and regulations that in some cases are accompanied by incentives, the industry, however, continues to produce solutions to solve temporary needs, always looking for new initiatives imposed by politicians or health managers. Doctors (they are the main users of these systems – not to be forgotten) have gained skills and needs that must be taken into account. If you did not, from their point of view, the creation of clinical tools and applications is not in line with the care needs.

In this context, for some years, patients enter the medical record world, and they correctly pretend that their needs must be taken into consideration. They are not only users but also the protagonists of the process of care. In the technological workflow, patients want a role in the management of clinical information – they claim as their own – and as part of privacy context. They want access to information and, in some cases, to complete clinical and social data, they search for "collaboration" with other patients through social applications, and they need interaction with the doctors and health staff.

And finally, we must not forget the many initiatives proposed by the European Commission, in terms of investments in innovation and improvement of technologies in the health sector. These projects have improved communication between researchers, the technology, and the needs of those who use these tools.

It is hard not to take into account all the needs expressed by the various components involved in this complex, articulated ecosystem. But it seems that it is not enough. The result, according to the literature, remains the same: close to some clear successes, in some cases, there is disaffection and disinterest and in other cases frustrations and tensions. According to some authors, national programs have not always kept their promises; they do not always document cost reduction and the improvements of clinical results are not always well proved from surveys. When cases of success are documented, they are often accompanied by delays, higher costs, and lower results.

Web 2.0 has brought innovative concepts in the ICT landscape, and also in the health context, we note the entrance of solutions driven by these concepts: sharing, collaboration, open source, pervasive computing, user engagement, distribute knowledge, pervasive and participative actions, and networks of communities.

But around users' needs and to the novelty brought by technology, new clinical models are appearing, such as precision medicine, system medicine, cross-border care, access to international centers of clinical excellence, networks of pathology, and care of chronic disease, and we wonder how can traditional medical records face the complexity of this rich ecosystem?

Perhaps we need to rethink what has been done, not forgetting the good practices and the countless progress. We have to consider that many medical records are affected by an old design although there have been many advances. These advances should be combined with the proposed innovations: creating medical records starting with the doctor-patient relationship, improving the understanding and usability of clinical information provided to patients, and enhancing and promoting infrastructures as really federative in which collaboration between the actors is the norm.

Medical records are complex living objects. They require new impulses according to the new demands made by the actors of the eHealth ecosystem.

Traditional medical records do not meet the new requirements expressed by new clinical models and by the advent of new technologies. The result is amply demonstrated and discussed in many articles published in specialized magazines.

We want this collection of contributions to be the first step toward a new way of thinking about the design and development of medical records: it is a provocation for further discussions.

The book is an opportunity for the reflection, the discussion, and the understanding that can inspire new attitudes, modify directions, improve the vision, and propose ideas for a concrete and fruitful work.

Next to traditional solutions, we will also explore new concepts and new models that are more responsive to the changing needs of the actors of the health system.

And it is these traditional experiences that have worked so well until now that due to the advent of these new features, they require themselves to change direction. We argue that medical records must be designed from the doctor-patient relationship and that the concepts of sharing, collaboration, and pervasive knowledge should be taken into account.

Moreover, the needs of the patients must be taken into account also; the patient empowerment concept must be supported by suitable tools (unfortunately still missing), tools that can present clinical data to patients in a way that they can understand them.

New medical models like precision medicine and system medicine need to treat a large amount of data; therefore mathematical algorithms must be used in order to extract knowledge from data.

At last, in the complex clinical pathways that the new medical models require, a set of different agencies and medical institutions are engaged in working together, so medical records must respond to the requirements expressed by a multiagency environment.

These reasons impose the choice of new infrastructure and push toward models of federative architecture.

Pesaro, Italy Giovanni Rinaldi

Introduction. Medical Records: Are We at the Top? Is There Still Room for Innovation?

In literature, there are a lot of publications about medical records or health IT [1, 2]. On the one hand, we note the presentation of standard applications and architectures, also very often accompanied by evidence of few successes especially as it regards the major national projects, but on the other side, we note that there are emerging new ideas and new concepts that are being born and are taking new roads.

What I would say is that there is a world still very overwhelmed that communicates not always and not just through academic journals but through "informal" communication, blogs, tweets, and so on. I think it is more correct to call the area they are treating as Health 2.0 or eHealth [3].

In the last years, it seems we are attending at a new era of health IT. In it, we note great emphasis in innovation and new paradigms are tested and proposed. Often this novelty is drawn by the world called Web 2.0 [4] (transported in the health world, the correct term is Health 2.0) in which the concepts of sharing, open source, collaboration, user engagement, pervasive computing, distribute knowledge, pervasive and participative actions, and network of communities are enhanced.

Obviously also new devices and hardware have contributed to this further ICT revolution especially as regards the opportunity offered by mobile devices and telemedicine instruments: with those devices and applications, "everyone" can claim or monitor health status, manage clinical workflow, and treat medical data.

Whereas before it was about checking and analyzing the processes (through software and hardware) according to the standard medical applications proposed by the software industry, now the paradigm seems changed: emphasis is posed on the users such as what counts, what is useful, and what is needed, and all of that are through new technologies that allow the passage of the focus from the processes to the users.

User needs and user expectations produce relationships, and these are mediated and in some cases enhanced by the technology; for this reason, it is much more than a "system," and we are speaking about a health information space: an "ecosystem."

In this ecosystem, medical data are driven by the mechanism of publication–brokerage–delivery: publication consists in the actions for which the doctor managing the clinical data of a patient allows access to other clinicians who need to access them for care reasons; brokerage allows to drive the information according to the care right for the patient, and it has a meaning of setting the rules of technical functions in the usage of clinical data; delivery consists in the need to access information according to different meanings (medical care, social care, health education, etc.) driven by different needs according to the patient, the doctors, the health researcher, and the policy maker.

But all of this makes sense if it is governed: privacy must assure the patients and not stop or complicate the care; the concept of data property in health assumes a different concept compared to the management of money in Internet banking procedures or journey booking and entertainment online.

In the ecosystem, information (as actor relationship) has value and is transacted in the delivery of care, so the development of services and the deployment of clinical capabilities and practice through the conversational relationships among the actors produce and enrich the medical information value chain, but inevitably, they are recognized as a cooperation of a set of roles that came with their own responsibilities, performing publication, brokerage, and delivery of clinical information.

We inscribe the complex relationships among the actors in an environment supporting the operation and governance of a dynamic and participative ecosystem of care, in which many actors, belonging to different institutions, agencies, and organizations, depend on each other and interact and transact in complex ways over the infrastructure and in the real, face-to-face world where resources and policies emerge and evolve, but because there are hard limits on capacities and resources, optimization and rationing are realities that must be faced, while costs and demand are managed.

Clinical information is constructed upon relationships between the actors. The value-adding chain, on which health transactions are based in health information economy, is founded on these acts of communication, and it collects a set of roles and interactions working together to create and deliver a service, in which each element provides its own contribution for the benefit of the users adding "value" inside the ecosystem.

So the construction of information according to the roles and its interpretation assumes a fundamental role in the design of the medical record.

Clinical information produced in this ecosystem fosters collaboration among users and can be intentional or accidental, because it is based on the meaning of the information created: social collaboration among health actors is based on voluntary traditional clinical information sharing, but there is a great amount of medical information produced for some scopes that can be reused, revealing hidden connection among data. This promotes accidental collaboration, unthinkable in the past.

But the ecosystem described, wherein the relationships among the actors belonging to different organizations, institutions, and agencies live and are nurtured (even if they want to continue to express their ethos in the collaborative work that a medical job requires), gives rise to new technology architectures and promotes the realization of federative platforms, in which clinical information and services are shared, fostering also collaboration and the inclusion in the care workflow of all the actors including the "empowered" patient.

So the first concept of this innovation is a new look at how the clinical data is composed, starting from the relationship among the actors and based on the set of rules depending on the different agencies where the actors belong. In a clear manner, the role of the actors assumes an important function in the ecosystem and needs to be governed. Let us take a look at the process of care describing the access to a medical excellence center as study case [5]. The patient accessing the medical excellence center brings with him all the referrals, reports, results, and medical notes made in different medical centers obviously in different electronic formats. During access in the center, clinicians will record clinical data (in different formats we presume), and when the patient is discharged, the follow-up done by the local health organization must maintain the contact with the specialized doctors in the excellence center. The main intuition is to exchange data in different formats, but very often, the software procedures are not standard and, even if these are declared as standard, in reality they are "dialects" of the standard.

The process of data exchanging is more complicated if the medical excellence center is abroad.

In this workflow, organizational processes done in different organizations that inevitably must meet the patients are well defined, but what about the information? What about the needs of the patients, doctors, and researchers? What about the empowerment of the patient? Can the patient communicate easily with all the doctors involved in the care? While it is considering the valid organizational and economic considerations, we agree that something is missing.

Let us think also of the network of pathologies or the management of chronic disease: the processes are different to that described, but the need of sharing clinical data is the same.

While the clinical processes listed now are made of relations that produce information and require the sharing of information, the creation of a network, and real patient engagement, we wonder how is it possible with the current tools?

These concepts introduce the idea of the actors. There is no relationship without the actors. Whereas, as said, the traditional medical records are based on the processes in the health system and finalized within the walls of the organization, strong emphasis must be posed on the actors: clinicians (including nurses and other medical operators), patients and their families, researchers, and policy makers. Each of them is part of the ecosystem, each of them produces information that must be shared for the benefit of all, and each of them has their own needs and requirements.

Could the focus on the clinical data based on relationships and the attention to the clinical narrative be enough?

What can the actors (doctors, patients, researchers, policy makers) do about this amount of data?

We are subject to a kind of "pollution caused by data." But it is better to get information rather than not have them. The point is how can we use them profitably?

There is in literature a great emphasis on big data and also in medicine. But what is most remarkable is that very often, in medicine, paradigms of use of big data typical of other areas are assumed.

In the ecosystem described, a lot of clinical and medical-social data are produced. Moreover the new paradigms brought by Health 2.0 foster the production of information by all the actors. Mobile devices, the instrument for communication in telemedicine (the m-Health area), produce information that must be analyzed; the empowerment of the patient produces information; the accessing of all the actors to specific social networks produces information; the new medical instruments used for monitoring or providing diagnosis produce information; the recent advances in genomics and the connection with the diagnosis formulation or care processes produce information.

So that this amount of "different" types of information could be fruitful, it is not enough to be shared in the ecosystem (as we described so far), but it must be provided suitable algorithms and methodologies to make the information useful.

We are not just thinking about the usage of algorithms but also, for example, the presentation of the data to the actors.

It is common practice in health to exchange data as they are generated. So referrals are presented to patients in the form that they are analyzed by doctors. In many situations, it can be difficult for patients to catch what counts for them.

By the way this is another mismatching about the property of data; certainly the medical document or the referral is the property of the patient but what can be the aim if it is not understood?

We are not asserting that it is not convenient to show the referrals to the patient but just to present them in a way that is understandable. Fortunately researchers [6, 7] and institutions are studying opportunities and instruments to make the clinical data comprehensible to patients. It is the case of the challenge supported by Health Design Challenge [8, 9].

In the site, almost 40 projects in which clinical data are presented to the patient in a comprehensible way are shown. The results are very remarkable.

The TedMed conference by Thomas Goetz by the title "It Is Time to Redesign Medical Data" is another example in which the concept of promoting broadens patient participation through a clear and understandable vision of the patient's own clinical data with the aim of arranging well-organized medical strategies and enhancing suitable health education [10].

He affirms that "Your medical chart: it's hard to access, impossible to read – and full of information that could make you healthier if you just knew how to use it."

This is the point of view of the patient; I think it is essential for patient empowerment.

But what about the point of view of the researcher or the clinician?

In recent years, precision medicine and system medicine have been proposed as new medical models. Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person [11].

These approaches are based on the systems perspective in order to consider the holistic and composite characteristics of a clinical problem and evaluate the problem with the use of computational and mathematical tools [12, 13].

For this reason, a coordinated approach across disciplines and across research and industry and among all the relevant stakeholders is required. The underlying concept regards the creation of a network in which system biology, practice information, and environmental information are shared in a broader system biology and clinical community.

Those medical models are based on the idea that the treatments are driven by data and each patient is unique so treatment must be personalized [14].

In these models, the concepts already treated previously about the collaboration between doctors and researchers through the creation of networks, a new vision about the usage and inclusion of genetic data and the integration with clinical data and environmental data, and a new look to the relationship between patients and doctors by considering also narrative medicine as intentional information are enhanced; in addition, as we said previously, this information reveals hidden correlations among data, and this promotes accidental collaboration previously unimaginable to study. Then at last it becomes necessary to the implementation of suitable algorithms for analyzing and extracting useful information by the great amount of data.

We wonder: could precision medicine be fruitful, nurtured, and enhanced using the current medical record?

Big data in medicine therefore is not just management of a great amount of data but also algorithms and methodologies of analysis.

In conclusion, these concepts are the base of the ecosystem we are describing: the relationship between the actors of the ecosystem; the role of each of them also belonging to different agencies; the creation of networks between the actors; the social interactions; the medical doctor relationship and the approach to the narrative medicine; the need of personalized care; the integration between genetic data, practice data, and environmental data; the need to make information accessible and comprehensible; the complexity of the voluntary and accidental collaboration; and the usage of complex algorithms in order to analyze data.

They are supported by the concepts of sharing, collaboration, publication, brokerage, delivery, and governance.

And so that these needs can be accepted, it is necessary to have a new vision about medical data in order to face the challenge that modern healthcare requires: system medicine, precision medicine, pathology networks, chronic disease care, the access to medical excellence centers, and cross-border care.

Pesaro, Italy Giovanni Rinaldi

References

1. Greenhalgh T, Potts HW, Wong G, Bark P, Swinglehurst D (2009) Tensions and paradoxes in electronic patient record research: a systematic literature review using the meta-narrative method. Milbank Q 87(4):729–788. doi:10.1111/j.1468-0009.2009.00578.x
2. Hayrinen K, Saranto K, Nykanen P (2008) Definition, structure, content, use and impacts of electronic health records: a review of the research literature. Int J Med Inform 77:291–304
3. Van De Belt TH, Engelen LJ, Berben SAA, Schoonhoven L (2010) Definition of Health 2.0 and Medicine 2.0: a systematic review. J Med Internet Res 12(2):e18
4. O'Reilly T. What is Web 2.0? O'Reilly Media. [Online] Available from http://oreilly.com/web2/archive/what-is-web-20.html. Accessed 9 Oct 2015

5. Rinaldi G (2014) An introduction to the technological basis of eHealth. In: Gaddi A et al (eds) eHealth, care and quality of life. Springer, Italia, pp 31–67. doi:10.1007/978-88-470-5253-6_3
6. Blake Lesselroth J, Pieczkiewicz DS (2012) Data visualization strategies for the electronic health record. In: Berhardt Leon V (ed) Advances in medicine and biology, vol 16. Nova Science Publishers, Inc. Hauppauge NY USA
7. VAHC (2013) Proceedings of the 2013 workshop on visual analytics in healthcare. Washington, DC. www.visualanalyticshealthcare.org
8. http://healthdesign.devpost.com/
9. http://healthdesignchallenge.com/
10. http://www.ted.com/talks/thomas_goetz_it_s_time_to_redesign_medical_data
11. National Academy of Science (2011) Toward precision medicine: building a knowledge network for biomedical research and a new taxonomy of disease. The National Academies Press, Washington, DC
12. Ahn AC, Tewari M, Poon CS, Phillips RS (2006) The limits of reductionism in medicine: could systems biology offer an alternative? PLoS Med 3(6):e208. doi:10.1371/journal.pmed.0030208
13. Ahn AC, Tewari M, Poon CS, Phillips RS (2006) The clinical applications of a systems approach. PLoS Med 3(7):e209. doi:10.1371/journal. pmed.0030209
14. Collins FS, Varmus H (2015) A new initiative on precision medicine. N Engl J Med 372:793–795. doi:10.1056/NEJMp1500523

Contents

1 EHR, EPR, PS, PHR: Different Medical Records for Different Aims: Roles of Doctors, Patients, and Institutions

Giovanni Rinaldi

1.1 Introduction

It seems we are approaching a new information and communications technology (ICT) era in the health context: we note that new ideas are emerging and new concepts are being born. These innovations come in two types, strictly linked together: hardware and software.

The web2.0 has brought about innovative concepts in the ICT framework, and also in the health context we note the arrival of solutions driven by these concepts, such as sharing, collaboration, open source, pervasive computing, user engagement, distributed knowledge, pervasive and participative actions, and networks of communities.

Obviously, the introduction of new devices has also contributed to this revolution, especially in regard to the opportunities offered by mobile devices and telemedicine instruments. With these devices everyone can claim access to clinical data and require access to clinical pathways, then being able to send to professionals the data sourced from telemedicine instruments for monitoring their own health status [1].

In a recent post Eric Topol declares http://www.huffingtonpost.com/eric-j-topol-md/health-technology_b_1610684.html "Take your electrocardiogram on your smartphone and send it to your doctor. Have a suspicious skin lesion that might be cancer? Just take a picture with your smartphone and you can have a quick test back in minutes. Does your child have an ear infection? Just get the scope attachment to your smartphone and get a 10× magnified high-resolution view of your child's eardrums and send them for automatic detection of whether antibiotics will be needed. Worried about glaucoma? You can get a contact lens with an embedded chip that continuously measures eye pressure and transmits data to your phone. These are just

---

G. Rinaldi
Ospedali Riuniti Marche Nord, Pesaro, Italy
e-mail: rinaldi8giovanni@gmail.com

G. Rinaldi (ed.), *New Perspectives in Medical Records*, TELe-Health,
DOI 10.1007/978-3-319-28661-7_1

a few examples of the innovative smartphone software and hardware that have been developed and will soon be available for broad use." Moreover, in the book "The patient will see you now" [2] Topol affirms that we are moving in a new direction towards a world in which each individual will have all their own medical data and the computer power to process it in the context of their own world, and there will be comprehensive medical information about a person that is easily accessible, analyzable, and transferable. People engaged in the medical process (both professionals and patients) can produce much clinical data, and can access information on worldwide networks.

In the digitally connected world, smart devices and applications are ubiquitous, and we wonder whether this pervasive digitalization will lead to better healthcare for people.

These advances encourage new approaches to clinical practice, medical research, and medicine; generally speaking, they prompt professional collaboration and patient engagement, but they also raise questions and pose challenges for existing healthcare delivery systems.

On the other hand, we are also witnessing the introduction of new clinical models. Two such models are precision medicine and system medicine.

Precision medicine "refers to the tailoring of medical treatment to the individual characteristics of each patient. It does not literally mean the creation of drugs or medical devices that are unique to a patient, but rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventive or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not" [3].

System medicine is prospective medicine that will be predictive, personalized, preventive, and participatory [4], and that will take into account the multiple components of the healthcare system, including disease outcomes as reported by the patients themselves, and as reported by public and private organizations involved in healthcare management [5]. System medicine is beginning to explore medicine beyond linear relationships and single parameters, and involves multiple parameters obtained across multiple time points and spatial conditions to achieve a holistic perspective of an individual [6].

System medicine provides the best available care for each individual, and it also requires that researchers and healthcare providers have access to large sets of health- and disease-related data linked to individual patients [7].

In the same way, precision medicine is designed to provide the best accessible care for each individual; however, this is not achievable without a massive reorientation of the information systems on which researchers and healthcare providers depend: these systems, like the medicine they wish to support, must be individualized.

So precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.

These medical models are based on the idea that the treatments are driven by data, and as each patient is unique so the treatment must be personalized.

These medical models tend to overcome the traditional reductionism in medicine (in which treatments are focused on components where information about time, space, and context can be lost) in favor of a system of medicine where emphasis is placed on the interrelationships between dynamic and individualized multidimensional medical treatments.

The necessity for treating huge amounts of information (molecular information, lifestyle, environment, clinical data) with adequate mathematical instruments and algorithms emerges clearly from these new medical models.

Research in the medical context in the past decade has made important steps in the identification of better methods for the care of patients, and has produced strong specialization to cope with different pathologies.

From a medical-organizational point of view, this specialization has brought about the realization of medical centers of excellence. These centers are especially focused on clinical specialties and inevitably have become centers of attraction for patients from different locations (also from abroad); so they are also centers of attraction for the best doctors and for the most innovative medical technologies. To access medical centers of excellence, patients must make many specific visits and undergo a number of diagnostic investigations to verify their possible access to the center. Often during this workflow the patient feels alone, and at discharge time the return home is fraught with anxieties, fears, and questions, and the follow-up risks may not be clearly explained. The context of the provision of these highly specialized clinical services is, by nature, very dynamic and requires the partnership of various bodies—including mixed public-private-voluntary organizations—which should be based on collaborative work among stakeholders from different agencies and different levels of specialization.

The context of cross-border care presents the same challenges; although the European Commission [8] wants to promote cooperation between member states on healthcare matters and has proposed directives to guarantee the safety, quality, and efficiency of care that a patient will receive in another European Union member state, the principles concerning cooperation between the organizations responsible for medical records in cross-border care seem dated and inadequate. And so it seems that the European networks of disease control and the European networks for the treatment of chronic diseases suffer from the inadequacies of the current technical systems and their inability to exchange clinical information.

In these medical models clinical information is fragmented in different organizations; each of them collects the information needed for the execution of their part of the workflow and only in some cases are clinical data exchanged through actions allowing the duplication of information.

The organizational workflows depicted above are characterized by strong collaboration between the professionals belonging to different health organizations, hospitals, and patient agencies (also including social workers, patients, and their families); they have distinct organizational aims and different infrastructures, and very often clinical data are locked in silos. In this landscape, despite the request for "working together", the dispersive vision of care predominates, tied to territorial assistance. It seems more appropriate that a clinical network organization should be really patient-centric and focused on a medical community of stakeholders belonging to different hospital or health organizations, based on the sharing of clinical information and online services.

Beyond the good intentions, the entire system does not seem prepared to address these challenges from a technical point of view; thus, instead of the innovations and the new technology era increasing collaboration, it seems that these factors increase confusion.

What is emerging in the encounter between the new technologies—in which the concepts of collaboration between the actors and the pervasive knowledge are enhanced —and the new medical models—in which communities of actors are created who share information and who will utilize huge amounts of structured and unstructured data—is the complexity of clinical information. Clinical information is a thriving entity created, managed, and nurtured by a community of users with a set of needs emerging from their access to it. We cannot allow clinical information to exist as a structured database with low-level communication tools.

It is here that we need to introduce the notion of a health ecosystem. This ecosystem is based on clear concepts, such as the plurality of actors and their relationships, and specifically the doctor-patient relationship, produces value. The utility of data in such an ecosystem depends on the users' ability and capacity to interpret it and propose conclusions; therefore, before taking any actions, it is necessary to know the value of the ecosystem: the clinical information.

1.2 The eHealth Ecosystem and Its Intrinsic Value

The complex ecosystem we have partially described consists of a set of actors belonging to different agencies governed by different aims and with their own culture and ethos.

The ecosystem comprises a set of roles and interactions working together to create and deliver services, in which each element provides its own contribution for the benefit of the users, adding "value" inside the ecosystem.

User needs and user expectations produce relationships and these are mediated and in some cases enhanced by the technology; for this reason, more than "system" we are speaking about a health information space: an "ecosystem".

The ecosystem is founded on the voluntary acts of relationship generating information; the transactions of the ecosystem are the relationships between the actors, and mainly the doctor-patient relationship.

The value of this ecosystem is the information.

The ecosystem exists and is nurtured in the information space, in which the clinical information value chain consists of voluntary acts of "publication, brokerage, and delivery". These acts, on which clinical information is based, are necessary for making available medical records and for creating a virtual community of actors, creating effective and real collaboration among the individuals interested in the healthcare context, including the patient.

We refer to "publication" because the longitudinal, holistic, comprehensive clinical information referring to a patient consists of various acts of relationship between doctor and patient and also between doctors and doctors on behalf of the patient; the outcomes of these acts must be available.

We refer to "brokerage" intending the term to mean the mechanism of making available the needed information, for the care aim, to different actors who need to use it inside the ecosystem, with ethical intent.

We refer to "delivery" in the context of establishing a network of service supply relationships of many different sorts with significant elements of trust and dependence [9].

Information consists of a set of "pieces" obtained from relationships, ordered according to the meaning of the connection between the actors.

These transactions form the relationships among the actors, and produce value and enrich the whole information ecosystem, in which actors, institutions, agencies, and organizations share medical information, build collaborations, and create virtual communities. And we should not forget that these opportunities and challenges, unthinkable some years ago, are now made possible by the new developments in technology. These developments allow pervasive computing, shared information, and distributed knowledge; collaborative tools that make available sophisticated and complex algorithms for information analysis. All of this, across agencies, institutions, and nations, empowers the creation of communities of actors engaged in the treatment of clinical information for the individual.

But at the same time, we are also aware that certain uses of technology can lead to a drift, making possible the use of incorrect forms of "do-it-yourself healthcare". For this reason, technology must be governed in the healthcare context, and this assertion is not contrary to the new development of technology.

This issue of governance is related to the concept of what are the basic clinical data units, or, in other words, the extent to which the narrative of the record can be safely broken down into such units. This seems to contrast with the database concept of real facts translated into entities, and their attributes, in the traditional data model. Moreover, all clinical observations that are recorded are situated in the context of some health problems that are being treated through the sequence of clinical encounters, conversations, relationships, and explanations of data obtained from clinical services.

This view is based on the practice of primary care, where the doctor-patient conversation, and the generated narrative, are central. This picture is somewhat different in a hospital-based acute care encounter, where the execution of medical services and the generation of clinical data are common. Here, at the clinical level, the assumption is that this relationship is episodic; it has a beginning (the hospital admission) and it will end in the patient's discharge.

So, at last, clinical information produced in the ecosystem fosters collaboration among users. This can be intentional or accidental, because it is based on the meaning of the information created: social collaboration among health actors is based on the voluntary sharing of traditional clinical information, but a great amount of medical information produced for some purposes can be reused. In addition, this information reveals connections among data, and this promotes accidental collaboration that was previously unthinkable.

The relationship between the actors produces information that is constituted by sign and meaning. A sign is always connected to a meaning. All human beings use a mechanism to make sense of the world; by means of this they give a sense to things, and when something has a meaning, that something becomes a sign for us. Sign and meaning, therefore, are strictly connected and must be considered as combined [10].

But semiotics is not just the study of signs; it is the study of signs and meanings joined together. Thus, a system of signs (a semiotic system) is always made up of at least two distinct bodies: a system of entities that we call signs and a body of features that represent their meanings.

The conversation between the actors in the ecosystem produces signs and their meanings, but the link between sign and meaning, consecutively, creates a new entity, which is their relationship.

A sign has some degree of independence and stands for something that is other than itself, i.e., there is no deterministic relationship between sign and meaning. If we consider human languages we find that often they give different names to the same object, precisely because there is no necessary connection between names and objects.

Therefore, in the ecosystem we are describing, the connection between signs and meanings is not necessarily linked. The connection can be established only by conventional rules; the rules of a code. Two independent entities—signs and meanings—are connected by the conventional rules of a code.

There is always an agent that produces signs, meanings, and conventions; we are introducing the concept of coding; in other words, the rules of the code are defined by the actors involved.

The clinical conversation is relatively simple. Two or more actors enter a relationship and exchange signs, which have meanings through the conventional rules of a code. We can document sets of relationships. The doctor-patient relationship is the main one, but in the ecosystem, the clinical information is a result of the relationships of other actors. The doctor-doctor relationship is another possibility on behalf of a patient. Three other possibilities are patient-researcher and doctor-researcher relationships in a medical research context, and policy maker-doctor in the context of an organization and the managing of resources. And, finally there is the patient-patient relationship. Obviously many other stakeholder relationships are possible, but they are not mentioned here.

Each of these relationships has the power to produce information in the ecosystem, and each of them has rules and is developed in a different way; each relationship has clear features, and for each of them we can have different signs, meanings, and codes. But all contribute to a unique purpose: patient care.

When two actors in the ecosystem enter a relationship they exchange (in reality) data (with meaning) and concepts, expressed in a narrative way or in a dialogue.

During a relationship between doctor and patient, the doctor exchanges data and concepts: signs and meanings joined by a code, whereas the patient exchanges concepts in a narrative way or in a dialogue, with these concepts inevitably having a different basis from those of the doctor. The doctor translates through their own code, eliminating possible redundancies.

This exchange differs in different cultures and depends on the ethos of the actors, with the patient-patient relationship being governed by a different code from that used in the doctor-doctor relationship. In these relationships, as predicted by the mathematician C.E. Shannon in his theory of information [11], we have to consider the entropy generated as the upper limit of the information treated, and we are also faced with a kind of noise. But we are invited to overcome the noise and maintain entropy within acceptable limits in order to recover the original information.

In the eHealth ecosystem, information is generated and interpreted in the context of determined conversations in relationships of care. By this we mean actors with roles, responsibilities, and relationships interacting and transacting in order to perform those roles and discharge those responsibilities.

The result is a complex web of conversations that take place over space and time and generate units of information that can have different meanings and significances in the different contexts and in different relationships between the actors. The conversation not only has different purposes but different sorts of purposes, such as care, management, collaboration, charity, governance, and research.

If the conversation is constrained in a set of data governed by traditional data schema, there is the risk of a loss of the meaning of the relationship. However, the power of the narrative introduces important considerations: the relationship is a voluntary act that generates information that is immediately usable, and it is collaborative, but in the narrative involuntary knowledge is hidden and it can be used in the future for other opportunities for the patient's care.

This is the limit observed in the traditional frameworks, in that so-called middleware tools can exchange data, but not clinical information.

We know that there is a necessity to group data extracted by information, but we know that this action is subject to the noise and entropy described by Shannon; this action responds to a reductionist concept of medicine, but it really works immediately.

But we should not preclude the opportunity to go to the bottom, as suggested by Richard Feynman: "There is plenty of room at the bottom" he asserted, and even if this suggestion was originally made in relation to the immense possibilities offered by miniaturization, this idea of Feynman's is should also be taken into account in the theory of information [12].

These concerns lead us to consider the narrative as the unit of information in the ecosystem more appropriate than the traditional approach and to open new opportunities.

The relationships between the actors produce intentional collaboration and intentional information. However, informational collaboration is accidental: it is obtained when clinical information created for one purpose is found and used, or when such information influences another purpose (within the limits imposed by ethics and inherent to patient care). We have introduced the concept of the act of publication to render this repurposing of clinical information as ethical under the principles of consent. This commits us to the building of an environment where the re-use of information for medical research and practice is consistently enabled and where collaboration among the stakeholders—across time, experience, and context—becomes the norm.

In the theory of clinical conversation we have pointed out that when new medical models are practiced, different medical professionals come into play in the care of the patient, and very often they belong to different organizations. In this space different relationships are introduced that create a set of conversations that produce clinical information.

1.3 The Actors and Their Needs

In the traditional design and implementation of software instruments in the health context, including medical records, the focus is placed on the organization of the services. In order to manage resources, what counts is the description and management of each step of the organizational workflow. This is the aim of enterprise resource planning (ERP), born in the commercial or industrial context; the healthcare area also has taken inspiration from these models. Obviously, during the medical workflow clinical data are stored, retrieved, and managed.

Special applications, such as patient management, patient logistics, hospital finance, and general management of the organization, have been developed and integrated so that the ERP system fits with the hospital situation and requests.

This software facilitates the integration of all the functional information flows across the organization into a single package with a common database, including the clinical data collected during patient care and now also accessible by a patient menu.

Therefore, ERP in the clinical context or in medical record applications manages the information referring to the health state of the patient according the concept of patient-centered design, in which the data are structured according to the patient's needs.

So, inside the same health organization, or in a network of health centers, or inside a region in which hospitals use the same software system (e.g., ERP, medical records) the patient data could be managed in a centralized way (or exchanged without problems), achieving what is often claimed as the desired purpose: a patient-centered system.

According to the definition provided by the Institute of Medicine (IOM), patient-centered care concerns "Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions" [13].

We want to emphasize that the meaning that technicians offer for the term "patient-centered" is regarded as not far from the meaning assumed by clinicians.