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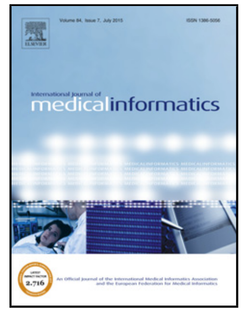

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Sharing health data among general practitioners: The Nu.Sa. project

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Abstract

Today, e-health has entered the everyday work flow in the form of a variety of healthcare providers. General practitioners (GPs) are the largest category in the public sanitary service, with about 60.000 GPs throughout Italy. Here, we present the Nu.Sa. project, operating in Italy, which has established one of the first GP healthcare information systems based on heterogeneous data sources. This system connects all providers and provides full access to clinical and health-related data. This goal is achieved through a novel technological infrastructure for data sharing based on interoperability specifications recognised at the national level for messages transmitted from GP providers to the central domain. All data standards are publicly available and subjected to continuous improvement. Currently, the system manages more than 5.000 GPs with about 5.500.000 patients in total, with 4.700.000 pharmacological e-prescriptions and 1.700.000 e-prescriptions for laboratory exams per month. Hence, the Nu.Sa. healthcare system that has the capacity to to gather standardised data from 16 different form of GP software, connecting patients, GPs, healthcare organisations, and healthcare professionals across a large and heterogeneous territory through the implementation of data standards with a strong focus on cybersecurity. Results show that the application of this scenario at a national level, with novel metrics on the architecture's scalability and the software's usability, affect the sanitary system and on GPs' professional activities.

Keywords: Electronic health record, cybersecurity, privacy, cloud, information sharing, general practitioners, e-health

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1. Introduction

GPs play a fundamental role in providing services to people who need primary care, and they are essential for effective chronic disease management strategies. A novel computer science architecture for GP data sharing is necessary for several reasons.

The first is the need for territorial functional aggregation (TFA), a new health care model able to follow patients on a 24-hours basis, every day of the year, with a team of GPs sharing patients over an entire territory. TFAs require a tool that helps them overcome the limitation resulting from the use of different forms of ambulatory software (about 16 different systems are currently available for Italian GPs) which have widely differing physical and logical data architectures.

The second is that many healthcare providers use information technology to facilitate everyday work independently of each other [1, 2, 3], and this independence is the cause of interoperability problems between different information systems [4, 5, 6, 7]. Therefore, interoperability, which enables the exchange of medical data, is made difficult through the lack of a defined standard [8, 9], especially in the GP scenario.

In response this scenario, in order to facilitate the sharing of health data easy as well as to coordinate data flow, the Nu.Sa. Foundation has been established, in cooperation between FIMMG (the Italian Federation of GPs) and Federsanità ANCI (the Italian Federation of Public Health Agencies [FsA]), with the aim of achieving a digitalisation and cloud computing project for e-health data sharing. The importance of practitioners' ability to share healthcare data under a common system standard is underlined by many papers [11, 12, 13, 14, 15] that use cloud computing system to allow the sharing of medical images in a hospital, data sharing policy or service oriented architectures. The relevance of confidentiality for e-health data systems is highlighted by recent studies such as those dealing with security frameworks [16, 17, 4] and the restriction of access to and privatisation of medical data [18]. Sahama et al. in [19], mantain that by considering social, legal, and technology issues during the creation of e-health systems, privacy and security for data sharing can be ensured.

Moving forward from the actual state of the art, this paper presents a service oriented architecture (SOA) based on the data derived from 16 different forms of ambulatory software, SOA has the ability to add to the actual Italian state of the art all the features described in Table 1 on a nationwide test case with relevant novelties. The main contributions of the architecture presented here include the high standard of data security, the data-sharing data work flow, and the quality of data gathered by heterogeneous systems. The results of the application of this scenario at a national level have a significant impact on the sanitary system and on a GPs' every day professional activities, with a strong increase in efficiency and a reduction of social costs. The interoperability and data-sharing standard is based mainly on data normalisation and data quality, with a major focus on data security and privacy. The data layer description is publicly available and documented online [20].

The effectiveness of the proposed approach is described in the results section from different points of view: a technical account of efficiency and quality of results; a usability test, conducted with a set of 30 users divided between GPs and patients; a comparative analysis with respect to the actual state of the art of Italian GPs in terms of actions and use cases that can or cannot be performed on the Nu.Sa. platform; an extensive survey of about 700 Italian GPs to demonstrate the necessity of such a system and the GPs preferences and main impressions regarding data-sharing platforms; an example of data quality and care quality self-audit for diabetic patients to show how this data-driven care model can strongly improve the quality of chronic care. In the same scenario, FIMMG targets the rise of GP expertise levels using better-quality clinical data, as well as an increased level of data security resulting mainly from data sharing among several GPs, to support the perspective of process reinforcement in the e-health field, designing a system very accessible to their work.

Integration with the FsA has directed special attention to the issue of chronic-diseases management. For many such diseases (diabetes in particular), integrated management initiatives (care networks) and territory-

Figure 1: An example of the MEDIREC interface, accessible from tablets using an app or PCs using a browser, in the process of sharing diagnostic investigations and laboratory exams between specialists and GPs.

hospitals are generally implemented in the Nu.Sa. (Fig. 1).

2. Nu.Sa. Cloud System Architecture

Nu.Sa. provides and manages a cloud computing system that makes available to GPs a range of services and utilities designed to encourage and facilitate their professional activities (Table 1). Further, Nu.Sa. deals with the cloud-based replication of the different ambulatory data structures of a given GPs who join the initiative, using a standardised data layer [20]. GPs can remotely access patient data using both PCs and mobile devices (smartphones and tablets). The database also has "transverse" interoperability with other colleagues who need to provide continuity of care to the same patient as well as "vertical" interoperability with other databases and national health service (NHS) operators.

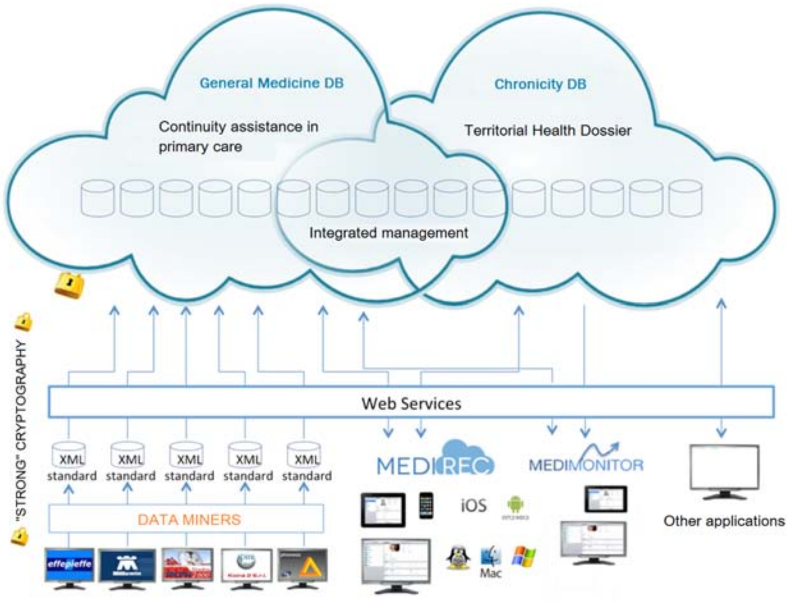

Figure 2: Nu.Sa. cloud integration scheme between GPs and heath specialists for chronic care models.

Through the web services description language (WSDL), a number of services and applications communicate (interface) with the database (DB). The performances of the DB enables the online sharing of healthcare data, even among professionals who normally use different forms of ambulatory management: in fact, it is a web source with reading and editing functions, allowing for complete interoperability with respect to healthcare data that needs to be shared (team work in TFA). Data backup and disaster recovery systems ensure that the interests of professionals and patients as well as business continuity are safeguarded (Figure 3).

Table 1: **Novel Services and Utilities in Nu.Sa.**

Network medicine (also allowing the so-called “mixed network”)
Connection to EHRs through web and mobile interfaces
Sharing data online with 24-hour assistance (continuity)
Mentoring of the GPs’ data quality with self-audit targets and dashboards to ensure a common level of quality among shared data
Conferment of data subject to agreements on report activities through web services (WS) directly from the cloud
Data backup e-disaster recovery for every GP with encryption and cybersecurity layers
Compliance with regulations for sharing patient summaries
Provision at the “point of care” of evidence based medicine and clinical recommendations contextualised to the data of a specific clinical case
Realisation of tele-medicine initiatives through the sending of reports
Integration Specialist-GPs for patients suffering from chronic diseases, using specific computerised healthcare data sheets
Patient-centred approach, sharing of responsibility, and empowerment in the healthcare process
Accessibility to additional web applications, able to interact through WS with the DB in cloud (i.e. patient privacy area, self-audit dashboard, etc.)

2.1. Data Extractors

Nu.Sa. has 16 extractors (termed data miners in the project scheme) devoted to exporting data from the most popular electronic health records (EHR) management software present in the national territory. Listed in Table 2, they cover about the 98% of the total GPs’ software in Italy. At this level, a data normalisation is performed to ensure full interoperability among different forms of software.

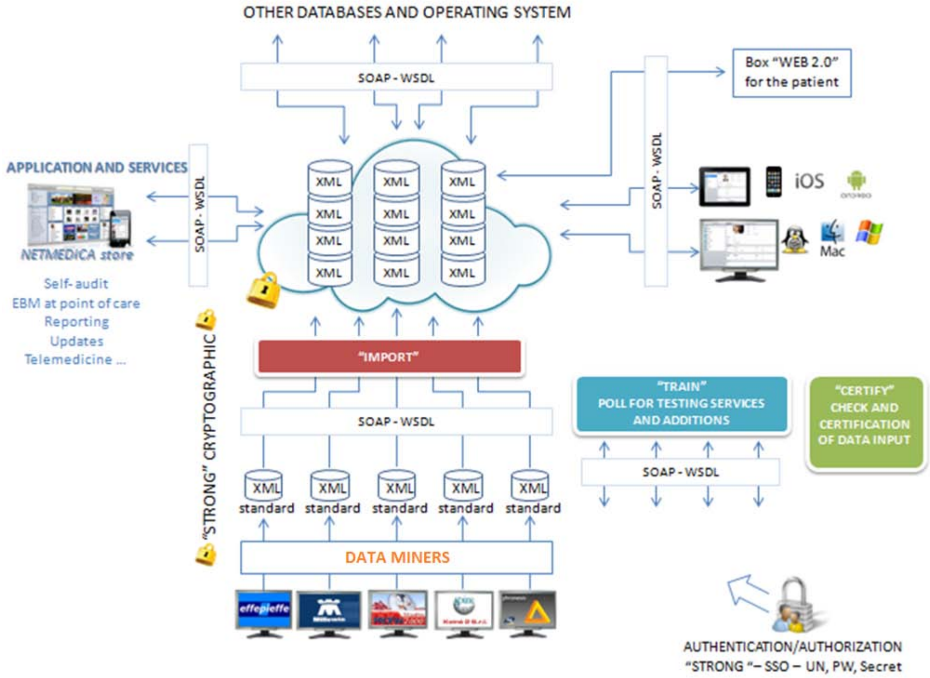

Figure 3: Logical scheme of the Nu.Sa. project and its architecture

Table 2: **GPs' EHR management software**

BASIC^{TM}	MEDICO2000^{TM}
DFD^{TM}	MEDICO2000-V.6^{TM}
EFFEPIEFFE^{TM}	MILLEWIN^{TM}
EUMED^{TM}	MIRAPICO^{TM}
KAPPAMED^{TM}	PERSEO^{TM}
IATROS^{TM}	PROFIM2000^{TM}
MDF^{TM}	PHRONESIS^{TM}
MEDB2000^{TM}	VENERE^{TM}

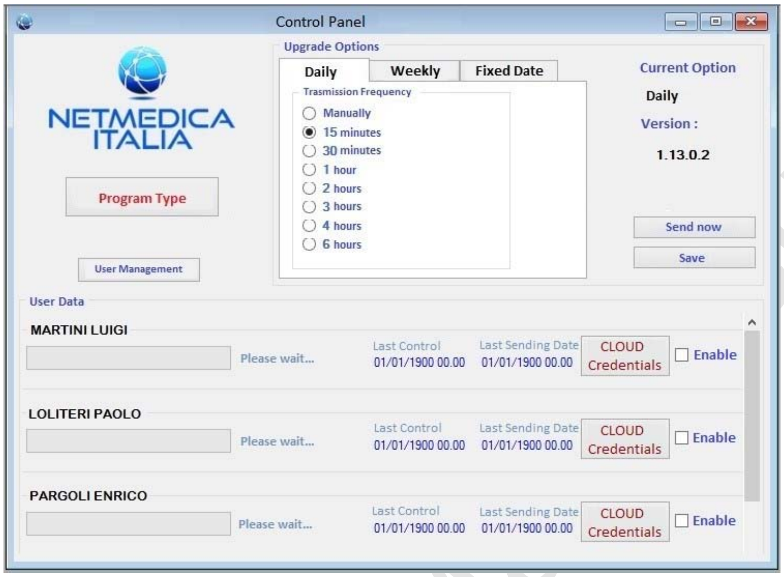

Figure 4: Interface of Nu.Sa. Portal: Control Panel

They are medical applications that can be automatically installed through NetDesk (a management programme for the extractors), which works in the background and is responsible for exporting the data according to the XML language using a standard protocol (Figure 5). The extraction process occurs in two steps: massive extraction of data and extractions according to incremental logic. Data miners are one of the most powerful tools of the proposed architecture, because they allow every GPs to maintain his or her own software and to start the interoperability process directly from the ambulatory EHR management systems. To the best of our knowledge, this is the only on going project to adopt this kind of open architecture (all EHR software can apply to partecipate in the Nu.Sa. network).

Figure 5: Interface of Nu.Sa. Portal: Users Management

2.2. Data Platform

The relational database for the storage and management of data is configured according to a structure optimised in terms of performance and zero data redundancy.

The organisation of data occurs in a patient-centred manner: a table of personal data is defined, containing representative information for the patient, suitably encrypted according to a key confidentially assigned to the physician for his or her exclusive use. Other tables, containing the patient's health data, are related to the personal table (Figure6).

Every EHR record is joined with one or more problems (to be intended as pathology) with its ICD9 code[1].

[1]http://www.icd9data.com

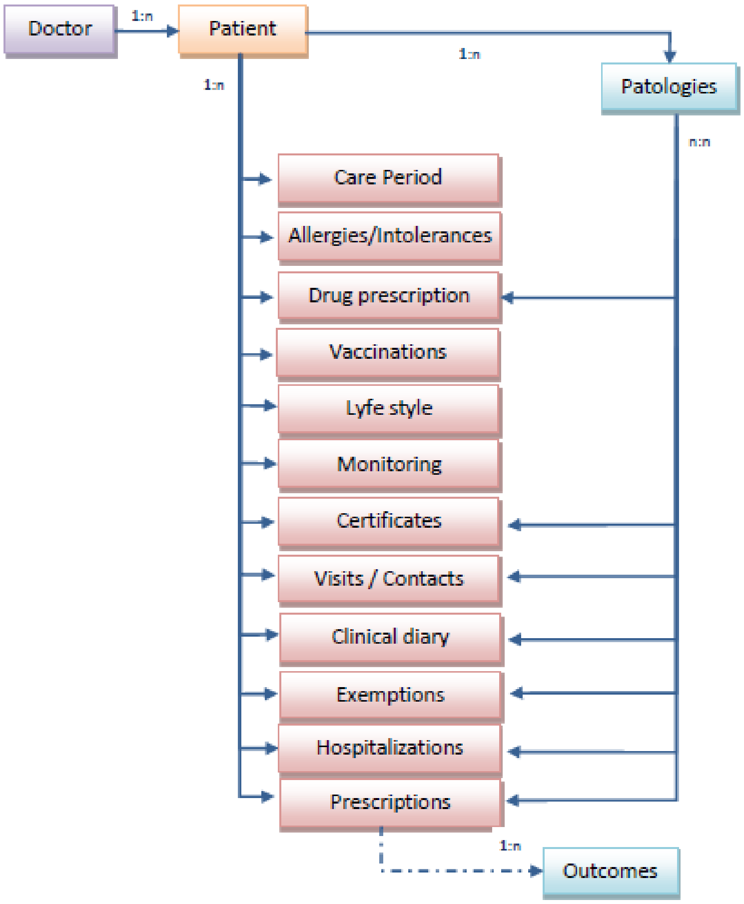

Figure 6: Nu.Sa. database architecture and main contents

3. Cybersecurity, Authorisations, and Privacy Policy

The Nu.Sa. data security infrastructure is of the type described in [21]. Such a solution leverages symmetric encryption algorithms and secure transfer protocols to provide for authorisation and encryption functions. The main advantage of this approach is that, in contrast to the identity-based and attribute-based encryption schemes, it does not require the presence of any centralised, key authority for the management of doctors' credentials.

In the Nu.Sa. architecture, authentication is ensured by a system of single sign on. In the system, an algorithm is defined to establish the authorisation in relation to the management of the groups (pool) for access to data clusters. The generation of credentials can be activated from the Nu.Sa. website, where one can also access the procedures for password renewal.

Such credentials are provided during registration and are activated after the physician has agreed to a procedure sent via email. The credentials allow access to the database in the cloud and its interoperability, using tools made available by Nu.Sa. Physicians, belonging to the same network, group, and TFA, or any form of association that provides the institutional authorisation to access individual patient data for medical-health reasons, are invited by a group coordinator to share data with other physicians of the same group (Figure 7). Shared access to the database will take place only as a consequence of the "head to head" completion mechanism of call-acceptance (with the possibility of nonacceptance).

Nu.Sa. also provides a system that enables the authentication of the assisted patient, permitting direct involvement of the user and aimed at encouraging co-responsibility and empowerment policies. The patient will be provided with authentication credentials to access an area of the database in the cloud that is functionally correlated with the record of care. In this area, there is a section dedicated to the consultation of specific health records made available to the patient directly by the physician, one dedicated to the inputting of data, and a third in which patients can manage their Patient Summary (authorisation/concealment of individual items). All the architec-

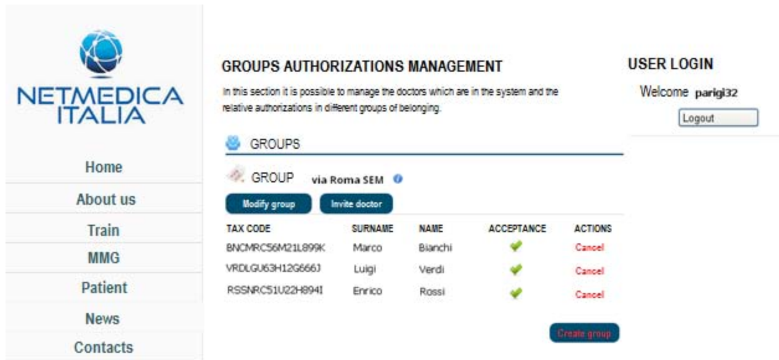

Figure 7: Groups authorisation management: data sharing starts with the mutual acknowledgement of all stakeholders of an AFT.

ture is in full conformity with EU regulations in terms of security and privacy and was officially approved at the national level.

4. Evaluation of the system

4.1. Results: from scalability and technical performances, to usability, state-of-the-art improvements and GPs' needs

The effectiveness of the proposed approach is described in the results section from different points of view:

- a technical account of the efficiency and quality of results;
- a usability test, conducted with a set of 30 users divided into GPs and patients;
- a comparative analysis with respect to the actual state of the art of Italian GPs in terms of actions and use cases that can or cannot be performed on the Nu.Sa. platform;

- an extensive survey of about 700 Italian GPs to demonstrate the need for such a system and their GPs' preferences and main impressions regarding data-sharing platforms;
- an example of data quality and healthcare quality self-auditing for diabetic patients to show how this data-driven care model can strongly improve the chronic care quality.

Finally, a general discussion on the results will be presented, together with conclusions and recommendations for future research.

4.2. System performance and scalability

Tables 3 and 4 present, respectively, the database performance with regard to traffic and connections, and Table 5 shows the overall of the query statistics. The results can be considered indicative, because the experiments were conducted on the basis of data collection spanning an entire year of use (2015) in a real-world scenario in which the specific service was utilised to transmit and receive EHR data.

Table 3: **Nu.Sa. Traffic: Average Traffic per Hour over One Year (2017)**

Traffic	**MByte per hour**
Received	432
Sent	791

We also tested the system with a simulated load test to demonstrate the scalability of the proposed architecture. Nu.Sa. SOA software was tested

Table 4: **Nu.Sa. Database Connections: Average Connections per Hour over One Year (2017)**

Connections	**Value per hour**
Max contemporary connections	178
Failed connection attempts	$0, 2$

Table 5: **Nu.Sa. Queries: Average Queries per Hour over One Year (2017)**

Queries	**per hour**
select	12771
insert	1768
update	576
delete	127

using SOAPUI[2] load testing interfaces. In particular, we performed the tests reported in Table 6.

A stress test with an LT of 970ms and an ST of more than 1200 contemporary requests is acceptable for the purposes of the system and for the actual number of users, and it proves that the system is robust and strongly scalable. The actual Nu.Sa. architecture is also acceptable for the at least twice the number of actual users accessing the cloud-based web interfaces on a daily basis.

4.3. Usability: GPs and patients

In the first phase of usability testing, the participants (20 GPs and 10 patients only for the privacy settings and personal healthcare data views)

[2]https://www.soapui.org

were invited to a computer room in our university lab. A researcher from our group was paired with a participant.

A short survey on participant demographics and familiarity with technology was completed by every participant before the testing. The participants were then given the website name and asked to explore the web-based Nu.Sa. system on their own. Our researchers sat behind the participants and gave no instruction unless a participant could not proceed after repeated efforts. The participant was also encouraged to make comments during the navigation. The researcher recorded the participant's behaviour and comments using observation metrics and took detailed notes. The metrics included 15 tasks to complete on the website (only five for patients), the time needed to complete each task, and whether a task was performed without error, with error, or with assistance. The results showed a very good usability impact, and some comments, mainly on button positioning and icons meanings, are currently used for the new version of Nu.Sa. On average, all usability tests were performed with no assistance. The average time needed to complete a single task was of about 26 seconds. The longest task was the e-prescription task, which took participants over 45 seconds to complete on average. Patients were able to complete their tasks, which were in general simpler than the GPs' task, in about 14 seconds. The main final survey results showed no significant differences between patients and GPs, with more that 85% of final usability surveys. In the survey, 76% of users affirmed that a tablet is the preferred device with which to access the next generation of data-sharing systems.

4.4. GPs' needs and Nu.Sa. solutions: A survey

The survey was conducted by DoxaPharma and Polimi [22] together with FIMMG with a set of 656 GPs from all areas of Italy. About 70% of them work in a group of GPs, and about 50% of them are over 60 years old. They are a representative statistical sample of the Italian GP population. They all use an EHR management system that is compatible with the Nu.Sa. system. The sample has an average expense per year on information and communications technology (ICT) services of around 1500,00 euro, with a projection over the entire GP population of a total expense of more than 72 millions euro per year, with an increase of over 2 millions euro with respect to the previous year's survey. This is a clear inclination of the increasing need for quality ICT solutions tailored to GPs' needs.

The most relevant questions were about the list of GPs' priority needs. The list of the proposed priorities, with very high appreciation percentages decreasing from 93% down to 84%, is presented in Table 7.

Nu.Sa. is going in the direction of covering all these needs, with a particular focus on the first two priorities. This prove also the willingness of the GPs majority to quickly move forward towards a group medicine where data sharing, a correct approach on privacy and cybersecurity, a set of tools for data quality assessment and self-audit, will be the core of the future EHR management systems.

About half (52%) of the survey participants identified the items listed in Table 8 as principal barriers for the rapid expansion of the Nu.Sa. approach to all Italian GPs.

The survey also captured GPs' extensive use of nonintegrated communication systems, from emails and WhatsApp chats to mobile SMS messages and Skype instant messaging.

4.5. Data quality evaluation for self-audit purposes: How to measure a healthcare quality improvement

A final evaluation of the proposed system is in an example of self-audit metrics to define quality key performance indicator (KPI). In Table 9 a real-world of two different GPs with respect to the AFT average (all GPs belonging to the same group) is reported to show how Nu.Sa. is capable of providing data quality measures and comparisons in the same ATF to ensure data quality and GPs' empowerment.

The example is performed only on diabetes metrics and is available in Nu.Sa. for every chronic disease, assuming that these pathologies are the most relevant in primary care and in the new chronic care model that uses AFT as the main assistance level.

The example shows that GP1 is not reaching a high data quality on diabetes chronic care quality; he or she is probably focused only on a few more critical patients. The self-audit evaluation should help GP1 better manage diabetes patients and their data, also ensuring higher-quality, data sharing and procedure homogenisation inside the same AFT.

4.6. Result discussion

All previously described results shows the effectiveness of the proposed approach from different point of view; here following a discussion of the main points and novelties are discussed:

- Technical view on efficiency and quality of results: i) tests on the actual architecture show sufficient performances to scale-up the system up to a nation-wide amount of patients of about 50 million patients; ii) the proposed infrastructure allow also the integration of other heterogeneous data sources with high impact on the integration of the proposed infrastructure with public health data services; iii) the data management system is able to use effectively data in a secure and privacy compliant way, with a novel data anonymization process compliant with the self-audit procedures and with a low increase of computational time.

- Usability test, conducted over a set of 30 users divided in GPs and patients: i) the level of usability is very high with a not standard interface that facilitate action discovery and time needed to complete an action; ii) 85% of the total users judged the web interface as very good confirming theeffect of the life-long improvement of the interface based on user-centered design.

- Survey on about 700 Italian GPs to prove the needs for such a system and their preferences and main impressions on data sharing platforms: i) results show that the proposed system goes on the direction of novel and useful data sharing services, described as the highest priority service by the 93,2% of GPs; ii) the main barriers are still the low level of economic resources and the lack of digital capabilities among GPs and patients.

- Data quality and care quality self audit for diabetic patients to show how this data driven care model can strongly improve the chronic care quality: this application example is relevant with respect to the state of the art of GPs data sharing systems mainly because this is the first system in Europe able to extensively deploy a service to compare performances of different GPs using heterogeneous data sources and data structures.

The impact and novelties of the proposed solutions is extensive and further comments can be done on the data normalization process and on the extensive cryptography methods that is not only limited to identification data.

5. Conclusions

In this paper, we presented the Nu.Sa. architecture, the aim of which is to create a project of digitalisation and cloud computing in order to facilitate the sharing of healthcare data.

The effectiveness of the proposed approach is demonstrated from different points of view: a technical account of the efficiency and quality of the results, showing the high quality of the proposed architecture in terms of performances and scalability; a usability test conducted with a set of 30 users divided into GPs and patients, proving the effectiveness of the graphic user interface (GUI) with respect both to PC and tablet scenarios; a comparative analysis with respect to the actual state of the art of Italian GPs in terms of actions and use cases that can or cannot be performed on the Nu.Sa. platform; and an extensive survey of about 700 Italian GPs to demonstrate the need for such a system and GPs' preferences and main impressions regarding data sharing platforms.

The results of the application of this scenario at the national level indicated a significant impact on the sanitary system and on a GP's everyday professional activities, with a strong improvement of care efficiency and effectiveness and a reduction of the social costs of public care.

Future research in the field should investigate the highest standard of data security (using ABE encryption), a novel architecture for privacy consensus collection, and a novel big-data architecture to ensure scalability and insight analysis.

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Table 6: **Nu.Sa. Load Testing**

Test	**Result**
Baseline testing (BT): this can be defined as pure performance testing; BT examines how a system performs under expected or normal load and creates a baseline against which the other types of tests can be compared.	Average response time for SOA patient-search service with Rossi surname.
Goal: find response time metrics for system performance under normal load. Tests are performed on a complex search among patients of a test GP during a normal, day-to-day usage, tested on all days of week.	350ms
Load testing (LT): LT includes increasing the load and observing how the system behaves under a higher load. During LT, we monitored response times and server conditions. However, the goal of LT is not to break the target environment.	Average response time for SOA patient-search service with Rossi surname.
Goal: find metrics for system performance under high load. Tests are performed on a complex search among patients of a test GP simulating about 900 contemporaneous searches. This high load brings server conditions at about 70% of its maximum performances in terms of CPU and memory usage.	970ms
Stress testing (ST): the goal of ST is to find the exact load volume at which the system actually breaks or comes close to breaking. ST was performed during the night.	Using the same configuration of previous tests, ST brings to server timeout after a certain number of contemporaneous searches.
Goal: find the system's breaking point.	1200 searches

Table 7: **Survey - GPs' priorities**

Information sharing (reports, records, images, etc.)	93,2 %
E-prescription de-materialisation (complete application)	88,1 %
Interaction with pharmacies of the territory (sharing of the pharmaceutical dossier)	87,8 %
Tele-consulting/tele-cooperation tools (with other GPs or health care specialists)	87,2 %
Sharing a subset of clinical records (with clinical diary) with patients	86,7 %
Tele-health/tele-visit tools (for patient monitoring/visiting)	84,2 %

Table 8: **Survey: GPs' barriers**

Reduced availability of economic resources	54,1 %
Lack of knowledge about digital system potentials	48,3 %
Difficulties on understanding potentials and evaluating investments	33,8 %
Perception of cybersecurity and privacy issues	27,2 %
Absence of on-the-shelf solutions and immaturity of actual systems	21,7 %
Difficulties using available ICT solutions and perception of usefulness	20,3 %

Table 9: **Comparison of data quality retrieved from audit procedures on two different GPs with respect to the average of the AFT.**

Quality Audit Metric List for 3 GPs			
Metric description	GP1	GP2	AFT
Incidence of diabetes (% of the total population)	3,2 %	6.2 %	6.4 %
Number of prescriptions per month related to the diabetic ICD9	4.6 #	8.1 #	8.2 #
Average time (days) between blood-sugar measurements	38 d	17 d	18 d
Average age of diabetic patients (years)	72 y	67 y	64 y
Number of clinical diary records per diabetic patient	49 #	93 #	88 #
Males diabetic patients (%)	78%	81%	82 %
Average number of vital-signs values per month	9 #	16 #	18 #
Number of concomitant diseases per diabetic patient	2,2 #	1,6 #	1,5 #

Summary Points

Please include a list of Summary Points, stating 2-4 bullet points describing what was already known and 2-4 bullet points describing what this study has added.

ALREADY KNOWN

- Need for an EHR
- Acceptance and data quality have essential roles in care quality improvement
- Shared Decision Support Systems in medicine and in primary care

ADDED BY THIS STUDY

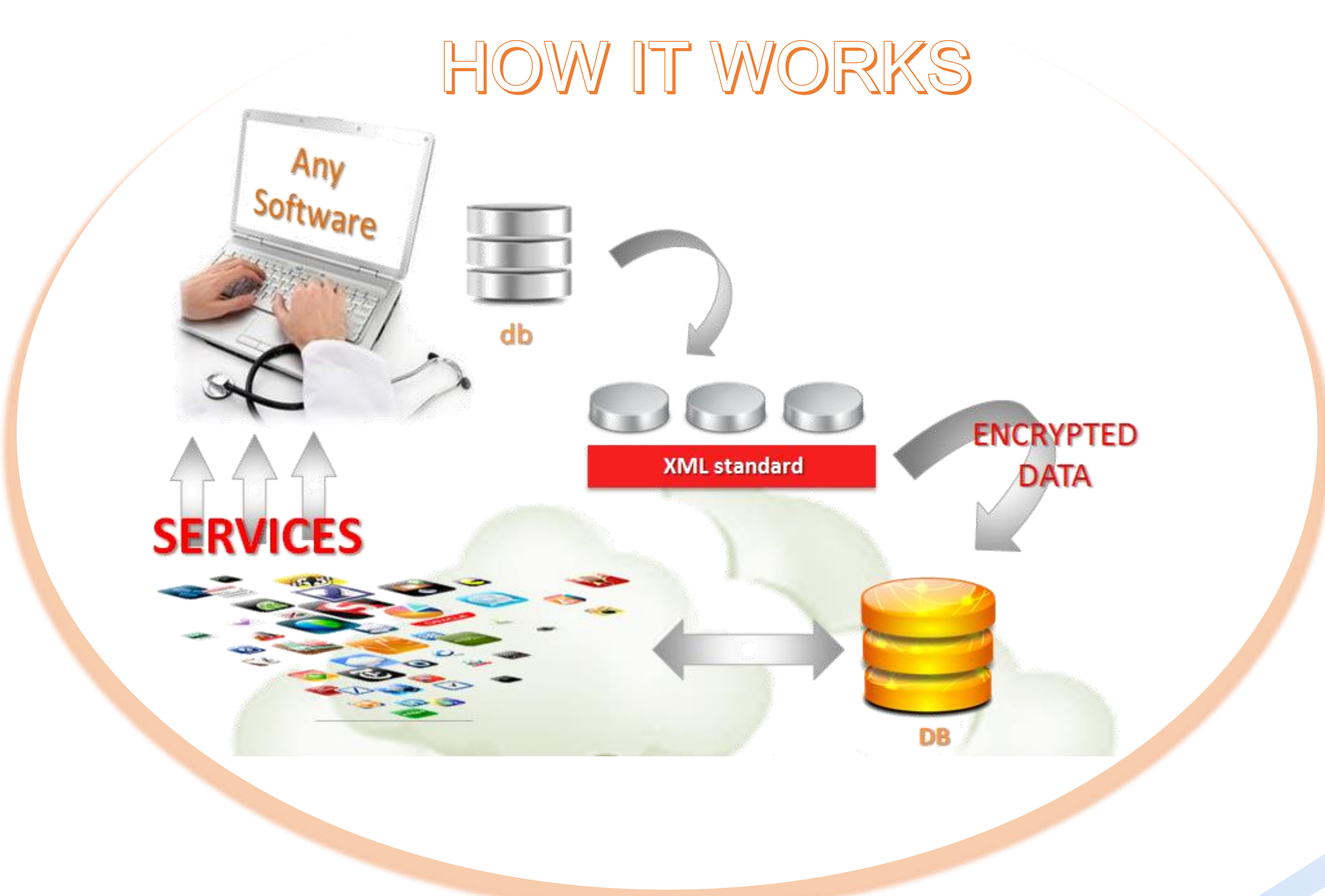
- Novel Data sharing work flow and data quality assessment on GPs heterogeneous systems.
- Fully interoperable healthcare system with public data standard connecting patients, GPs, healthcare organizations, and healthcare professionals.
- Application of this scenario at a national level with scalability demonstration.
- Results showing improvement of HER efficiency, acceptability, data quality and a reduction of social costs.

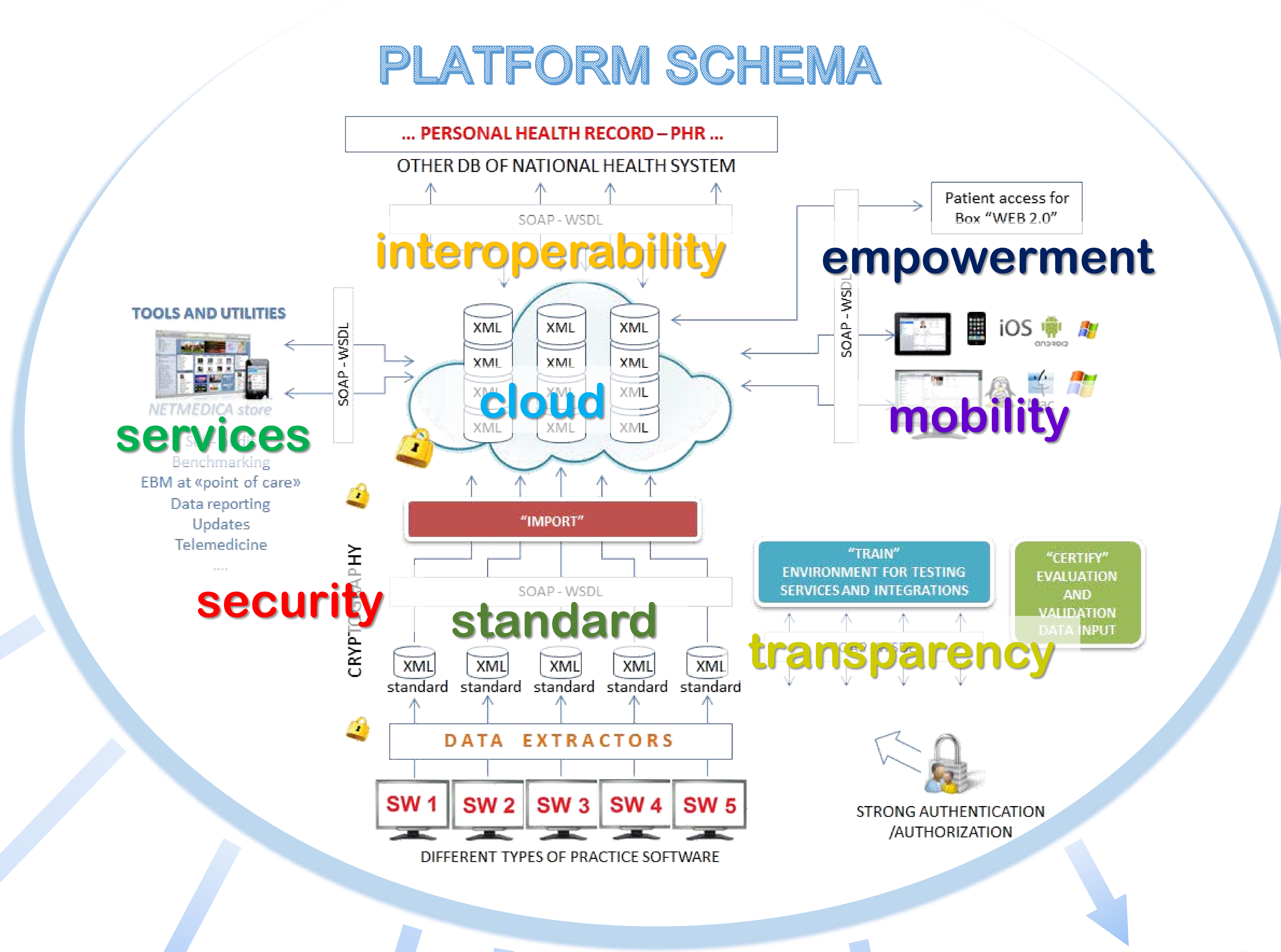
SCENARIO

Several types (>20) of practice software
No data standardization
Imminent reorganization of primary care
ICT & GPs: bureaucracy driven

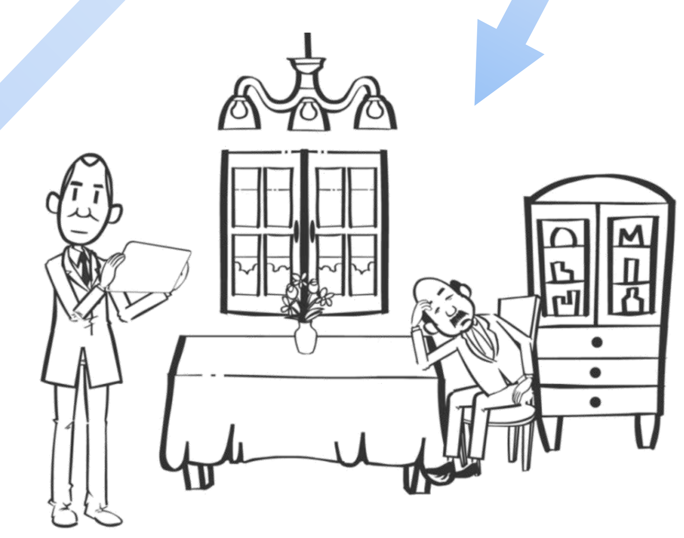
AIMS

Share clinical data between GPs involved in care process
Provide professional services to GPs
Promote patient empowerment
Realize doctor-friendly computing processes





SOLVES THE PROBLEM CONCERNING THE DIFFERENCES IN TYPES OF OUTPATIENT SOFTWARE



ALLOWS THE GP TO BE KEPT INFORMED, BY CONSULTING DATA EVEN ON THE MOVE

ALLOWING THE CREATION OF PROFESSIONAL GROUP FOR SHARING DATA (*by mutual invitation*)

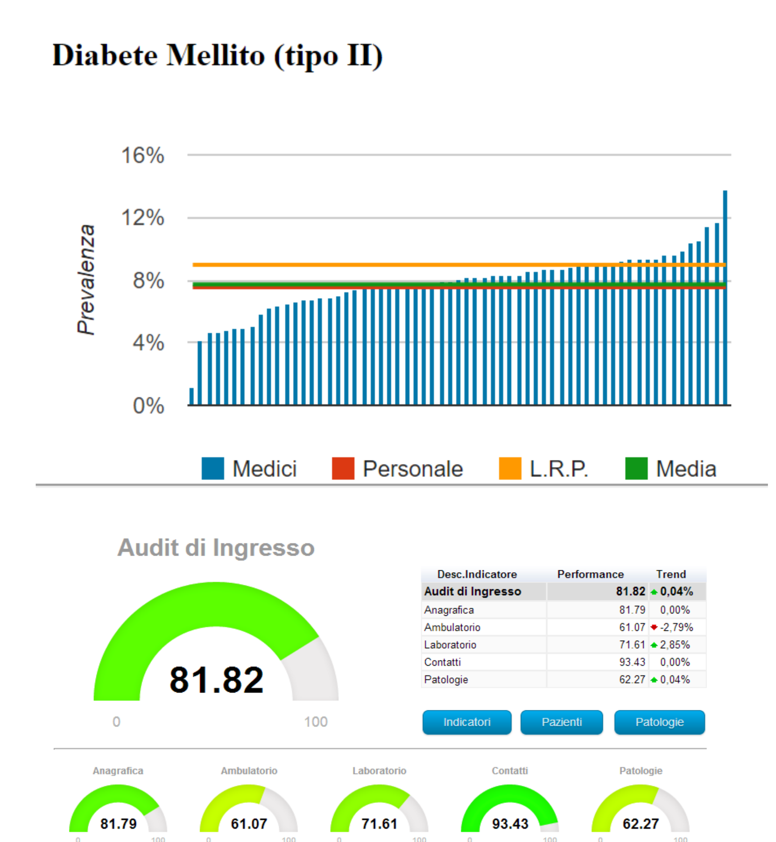
ALLOWS DATA SHARING WITH OUT-OF-HOURS SERVICES

ALLOWS A SPECIALIST TO RECEIVE A PATIENT'S CLINICAL HISTORY

FACILITATES THE REPORTING OF DATA

FACILITATES TELEMEDICINE INITIATIVES

PROMOTES PATIENT EMPOWERMENT



PROMOTES PROFESSIONAL PERFORMANCE IMPROVEMENT (*Audit – Benchmarking*)

Highlights

- Fully interoperable healthcare system connecting patients, GPs, healthcare organizations, and healthcare professionals.
- Data sharing work flow and data quality assessment on heterogeneous systems.
- Application of this scenario at a national level.
- Improvement of HER efficiency, acceptability, data quality and a reduction of social costs.