



TELPASS Project:

B2B Teleconsultation for Pediatric Hospices

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Abstract— In this work the TELPASS project is presented. The project aims at establishing a telemedicine service in the form of teleconsultation between two institutions located in different Italian regions: Local Health Unit of Potenza (ASP) and the Pediatric Hospital Santobono Pausilipon of Naples (Santobono). The teleconsultation service enables the clinicians working at ASP to exploit the expertise and the clinical skills of the multidisciplinary team of Santobono for training and during the clinical assistance the patients assisted at ASP Pediatric Hospice.

In particular, the work introduces the designed and the implementation of the first activity of a wider collaboration project, composed of three main tasks. This activity consists in the setting up and configuration of a cloud based system for sharing clinical documentation for second-opinion consultation. Particularly, the technical implementation and the actions performed to guarantee the compliance with General Data Protection Regulation are described.

Keyword: Telemedicine; Teleconsulation; Cross-region health data exchange; Pediatric Hospice.

I. INTRODUCTION

The Italian ministry of health is motivating the regional health policy makers to build new organizational models of connected care by means of telemedicine services [1]. In fact, telemedicine can help to face the increasing of elderly and chronic disease with its potentialities in terms of continuity of care and efficiency are widely recognized [2].

Today in Italy there are patchworked telemedicine initiatives. The most consolidate ones are: telemonitoring of home care chronic patients [3], teleconsultation service between specialized doctors and territory [4], dermatological and cardiological teleassistance [5], regional telemedicine service for remote medical consultancy between different hospitals [6], telemedicine for continuity of care [7] and stroke management [8] in rural areas.

From these experiences emerged that the use of telemedicine and teleconsultation services can offer significant benefits to patients in hospice care.

A pediatric hospice is an inpatient facility in which incurable children and their family can find relief from physical and psychological suffering. However, hospice does not treats only cases of terminal patients, but treats also ill children who leave the acute phase for entering in the chronic phase of the

disease. In Italy, currently, there are 6 pediatric hospices. Two of them are located in the South of Italy: the newly open pediatric hospice of Lauria, managed by Potenza Healthcare Unit - Azienda Sanitaria Potenza (ASP) in Basilicata Region, and 8-years Santobono Pediatric Hospices, managed by Pediatric Hospital Santobono Pausilipon (Santobono) in Naples, Campania Region.

Given the solid experience of Santobono in the treatment of palliative pediatric patients, the TELPASS project has the aim to build an innovative service to support clinicians working at Lauria hospice with the expertise and the clinical skills of the multidisciplinary team of Santobono.

It is to underline that Italian health system is based basic level of assistance defined by National Ministry of health which are implemented by the 21 regional based health systems. Therefore, the cooperation in patient assistance between health units from different regions (here Basilicata and Campania) requires particular attention starting from the poor interoperability between health information systems.

TELPASS project started in January 2019 [9] with the formalization of the collaboration between ASP and Santobono in the framework of a Master Agreement about the management of pediatric palliative care.

In the following, the TELPASS project is presented with a particular focus on the first activity performed, which is dedicated to business-to-business (B2B) teleconsultation for second-opinion. Specifically, the technical implementation and activities pursued for the GDPR compliance are described, and the project perspectives are presented in the Conclusion Section.

II. THE TELPASS PROJECT

TELPASS project aims to connect two pediatric hospices that are placed in two different Italian regions.

Specifically, Lauria Hospice was activated in 2019 and it is managed by Potenza Healthcare Unit, ASP, located in Basilicata Region. ASP covers the entire province of Potenza (more than 100 cities) offering services to a total population of more than 350.000 inhabitants. ASP includes 4 hospitals and almost 70 clinics for day-services.

Santobono Pausilipon Hospice is managed by Santobono Pediatric Hospital of Naples. The hospital is one of the main hubs of the National Health Service in the South of Italy. It offers specialized and high quality care for pediatric and neonatal patients.

As mentioned, the TELPASS project has been conceived in the framework of the partnership between these two health institutions, with the perspective to improve the quality of pediatric palliative care, realizing a new organizational model that promotes the sharing of skills, knowledge and professional and resources (Figure 1).

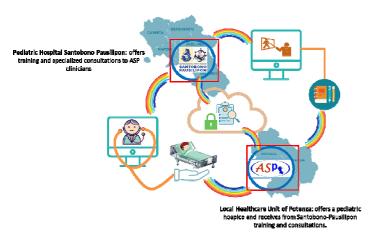


Figure 1 - Graphical representation of TELPASS project

In order to construct the integrated and collaborative model, three main activities have been planned, constituting TELPASS project work packages. Each activity in the list includes a specific enabling technology.

WP1: B2B teleconsultation: sharing clinical documentation for second-opinion,

WP2: Distance learning by means of web-conference,

WP3: Real time medical tele-examination.

In this work, the activities performed in WP1 are presented, detailing the tasks that have been carried out to perform its implementation, such as:

- A. B2B teleconsultation implementation,
- B. Regulation (EU) 2016/679 (GDPR) compliance.

A. B2B teleconsultation implementation

1) Technical implementation

Sharing clinical documentation for second-opinion consultation provides a set of solutions designed to enable remote collaboration of groups of professionals operating between ASP and Santobono.

In order to be able to provide a second opinion, it was necessary to identify a effective and secure means for sharing clinical information. This information must also be accessible in mobility and protected as sensitive data. For these purposes, a cloud solution has been identified.

Following a careful evaluation of different cloud solutions (e.g., Boxcryptor, Tresorit), it was decided to use DropBox with a cloud space dedicated to the service, including specific security measures. Indeed Dropbox has implemented several

protection measures to preserve data from sniffing by adopting Secure Sockets Layer (SSL) / Transport Layer Security (TLS) technology, which allows data protection during the transit between Dropbox and the servers. Furthermore, the data is expected to pass over a protected "tunnel" in which the data is encrypted with the 128-bit Advanced Encryption Standard (AES) algorithm. User-uploaded files are stored on Dropbox storage servers in discrete file blocks. Each block is encrypted with 256-bit Advanced Encryption Standard (AES).

In addition to Dropbox security measures, specific procedures have been defined to guarantee data security: the shared documents (e.g. clinical reports, second opinion requests) are anonymized: patient identifiers and medical records' sensitive data obscuration are used. Moreover, files and folders are encrypted with passwords; the ever-changing alphanumeric passwords are generated with rules known only to the involved clinicians. Specifically, two ciphers are provided: (i) for the document (i.e. Word "Password Encryption" option) and (ii) for the folder containing documents and shared in the dedicated DropBox space (i.e. 7zip password option).

2) Organizational requirements

As regards to technical implementation, Figure 2 shows the cloud scheme designed and implemented for allowing ASP clinicians to request a second-opinion consultation to Santobono clinicians.

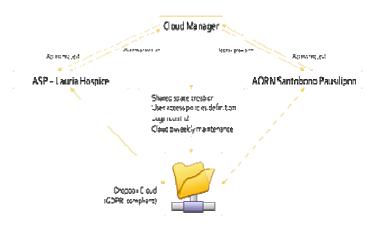


Figure 2 - TELPASS cloud scheme

At the top of the scheme there is the cloud manager; it manages accesses to the cloud. Specifically, the cloud manager is responsible for: (i) the creation of the shared space, (ii) the definition of user access policies, (iii) the control of the login and (iv) bi-weekly maintenance of the cloud.

When an ASP clinician has a second-opinion request there are some steps to fulfill; these are described in the following:

 Editing specific documents for second-opinion, in particular: a) a *Clinical report* in which the clinician summarizes patient clinical conditions, b) a pre-defined *Form* that details the clinical question subject of the second opinion request. The clinician can also

- attach medical records that may be useful to enrich the clinical picture, obscuring any sensitive data.
- ii. Moving all documents in a folder that has an encrypted name;
- iii. Protecting with an encrypted password the created folder (obviously rules for generating the alphanumeric passwords are known only to authorized users);
- iv. Accessing to the cloud with personal credentials and uploading the encrypted folder;
- v. Notifying Santobono clinician about the new secondopinion request (by phone and/or email);
- vi. Updating the log-in register (that is shared among all the team) about the fulfilled access and uploading.

It is important to highlight that all the files only contain a pseudonym of the patient and any sensitive data in the medical records are removed.

From the other hand, Santobono clinician to provide the second-opinion has to perform the procedure summarized in the following steps:

- Accessing to the cloud with personal credentials to download encrypted folder containing the secondopinion request;
- ii. Carrying out the second-opinion within 72 h from the notification;
- iii. Uploading the *Form* updated with the second-opinion consultation;
- iv. Updating the log-in register;
- v. Deleting the downloaded folder.

Finally, to guarantee that all the procedures are performed in accordance with cloud manager instructions, a user guide has been prepared to detail instructions for each clinician according to the specific role.

B. Regulation (EU) 2016/679 (GDPR) Compliance

Since TELPASS expects an exchange of health data, several measures were put in place according to Regulation (EU) 2016/679 (GDPR) specifications. This aspect is of primary importance if we consider that the Italian health systems is composed of different regional health systems and therefore each region applies different informative health models [10].

In compliance with GDPR, two documents have been arranged:

- The Informed Consent with which parents or legal representatives, read the informative, authorize the treatment of patients' personal data for the purposes and with modalities specified,
- The External Data Processor Nomination with which ASP (i.e. the controller) appoints Santobono as external data processor.

In order to ensure data security and be compliant with the GDPR other key features have been considered:

- Personal login credentials,
- Limitation of the number of accesses,
- · Pseudonymisation,

- · Encryption of names and passwords,
- Login and tasks register.

The cloud space dedicated to the service includes specific security features, such as: personal access credentials, limitation of the number of accesses, pseudonymisation, encryption of names (of patients and folders) and passwords, keeping a log of accesses and operations performed in the cloud. As said, Dropbox provides security measures during data transmission and storage by adopting Secure Sockets Layer (SSL) / Transport Layer Security (TLS) technology.

Any shared document (clinical reports, diagnostic reports, questions) is anonymized and protected with an alphanumeric password. The passwords are always different and generated with a variable rule from time to time, made known only to team members. Specifically, there are two ciphers: one for individual documents and another for containing folders that are loaded in the cloud.

III. CONCLUSION AND FUTURE WORK

The actual challenge of health systems is the effective management of prevalent and complex diseases with ICT support. New ICT solutions introduce the need for new organizational models able to guide decision makers towards an appropriate use of resources, decreasing the hospitalization and the transfers outside regions.

Telemedicine is one of these emergent ICT tools for medical diagnosis and patient care. From its beginnings, telemedicine has been used in a variety of health care fields with significant advantages [11]. One of the first applications regards the remote monitoring of chronic patients assisted at home. In fact, the improvement of quality and safety for home care patients has always been a priority, for the growing portion of elderly and chronic diseases deriving from the evolution of the demographic dynamics [12-1315].

Although, pediatric palliative care can also benefit from the development of specific telemedicine tools that may improve the collaboration between healthcare professionals working in dedicated health facilities.

In this work the TELPASS project is presented. The project aims at establishing telemedicine and B2B teleconsultation services between two pediatric hospices located in different Italian regions.

TELPASS telemedicine and teleconsulting solutions ensure the connection of two health facilities and professionals, promoting an integrated approach of collaboration; improving the effectiveness, efficiency and appropriateness of the pediatric palliative care in the South of Italy.

In particular, for the design of a secure B2B teleconsultation solution, in line with the privacy-by-design GDPR requirement, a detailed analysis was necessary. In fact, during the designing of health data exchange solution, many legal and ethical issues arise, that need to be identified and addressed in order to ensure the correct management of sensitive data [16-17-18].

A consistent activity of B2B teleconsultation implementation regards the GDPR compliance and privacy

preservation. The technical measures implemented for the data transmission (e.g., SSL/TLS protocols) are in line with the requirements suggested by the Italian Institute for Privacy and Data Enhancement defined in [19].

Currently, the B2B teleconsultation service has passed the functional test phase, the clinicians of both health institutions were trained to its usage and it is ready to be used. Moreover, in order to make the technological solution effectively adopted, the principle actors of each step of the procedure were identified and empowered and an operating manual was prepared with detailed instructions on the operations to be performed.

The service will be fully activated in November 2019, when the first admissions to Lauria pediatric hospice are planned.

Future works will regard the central phase of evaluation of quality service by means of specific indicators [20-21] and the design and implementation of the other TELPASS work pages for which the suitable technological equipment is under examination.

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