Real-time Telemedicine in Pediatric Cardiology

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***Abstract*—Point-of-care echocardiography is a very common technique in neonatal intensive care units, but it is often hampered by the lack of on-site specialists. The effectiveness of this procedure is directly related to the quality of the collaboration between the specialists involved, which can be influenced by the convenience of training new specialists in remote districts. In this study we report the results of the REMOTE project, which studied the feasibility of a real-time echocardiographic image transmission system that allows direct interaction between the doctors involved; the project adopts an innovative, low-cost, cross-platform and open-source strategy that enables neonatal ultrasound consultative services in remote districts and secondary care centers. We analyze the results from two perspectives: clinical and technological. From the clinical point of view, we report the preliminary results of our experimentation involving 42 patients and two hospitals in Sardinia, Italy: a tertiary hospital, with senior expertise in pediatric cardiology, and a secondary hospital with a neonatal unit. From the technological perspective, we describe the overall system model and the motivation of its design.**

***Index Terms*—Real-time telemedicine; tele-ultrasound; COTS technologies; pediatric cardiology.**

I. Introduction

Congenital heart diseases (CHDs) are the most common congenital disorders [1][2][3] affecting 6 to 13‰ live-born infants [4][5][6][7]. Critical CHDs, defined as those requiring surgery or catheter-based intervention in the first year of life, occur in approximately 25% of those with CHDs [8]. Although many newborns with critical CHDs are symptomatic and identified soon after birth, others are not diagnosed until after discharge from the birth hospitalization [7][9][10]. In infants with a critical cardiac lesion, the risk of morbidity and mortality increases when there is a delay in diagnosis and in timely referral to a tertiary center with expertise in treating these patients. More than 50% of patients with a missed or delayed CHD diagnosis die at home or in the hospital emergency department with a median age of 13.5 days [11]. Point-of-care echocardiography is the most common diagnostic method for the detection of CHDs (nearly 100% of precision in detection) in fetuses or newborns [12][13], but it is hampered by the lack of on-site specialists [14]. In addition, unlike in Anglo-Saxon countries where the sonographer plays a key role in the management of echo-laboratories, in Italy and many other European countries the echocardiographic studies have to be performed by medical doctors (mostly cardiologists) [15][16]. This model can constitute a barrier to the access of specific exams, particularly in sparsely populated areas and in extremely specialized care, such as pediatric cardiology, because of a lack of physician with a precise expertise in the pathology. Through the REMOTE project [17], based on the results of the first prototype [18], we propose a new model to enable access to specialized care, such as pediatric cardiology exams, in underserved areas through the use of real-time telemedicine. The system devised in this project has been clinically tested in the region of Sardinia where there is a mean incidence of CHDs of 20.25‰ (more than twice the incidence in literature) [19] and where the 17.3% (284,000 people) of population is concentrated in two big cities (>100,000 inhabitants) and the remaining 82.7% (1.4 Million people) is dispersed across a great number of small villages (375) in a relatively large territory (24,090 km^2) [20]. The main objectives of the project are to:

Figure 1. Representation of the two video streams (ultrasound and ambient camera)

- enable real-time echocardiographic consultations with direct interaction between clinicians involved;
- reuse any echocardiographic devices available in remote districts;
- restrain the costs of additional material/software required;
- lower the learning curve for the secondary care doctors;
- facilitate teaching sessions via video conferences with many participants.

II. Materials & Methods

The REMOTE system allows a specialist at a tertiary care center to remotely guide the execution of an echocardiographic exam performed by a medical doctor in a geographically remote secondary care center, seeing both the exam scene and the sonographic video stream while directly interacting with the operator in real-time, Figure 1. The system has been developed with a focus on pediatric cardiology. This remote diagnosis tool, which is already in its testing phase, currently connects four Sardinian hospitals to the specialized pediatric cardiology tertiary center in the island. During

 ISBN: 978-1-61208-252-3

the course of an examination, a clinician (usually a cardiologist or a pediatrician without specialized expertise in the pathology) visits the patient and operates the echocardiograph. A specialist at the tertiary center uses the combined view of the echocardiograph screen and a robotized remotely controllable camera to determine the patient clinical conditions, his posture on the bed and the appropriate position of the probe. For some pathologies, like CHDs, the accuracy of the examination is highly dependent on the operator: the results may not be revealing when the exam is performed by an ultrasound technologist (sonographer) or by a generic medical doctor, and consequently exams often have to be repeated by a specialized cardiologist. In the study of Meyer-Wittkopf et al. a complete correlation between sonographers and pediatric cardiologists prenatal cardiac findings was achieved in only 62% of cases and the diagnosis accuracy could be improved by allowing a pediatric cardiologist to work collaboratively with sonographers [21]. The technique described in our work reduces the repetition of exams and helps guarantee the correctness of its execution and the subsequent diagnosis.

A. Approach

The main advantages of the system are:

- Real-time transmission. Carrying out the remote consultation through the transmission of audio / video streams in real-time enables the physician to start counseling at the same time of the examination rather than after viewing the whole documentation sent by the remote center (store-and-forward protocol).
- Reduction of both patient and physician transfers. Due to the particular geographic conformation of the region, moving a specialists to the remote center or the patient to the referral center means a significant increase of time before the diagnosis. With this system, local physician can benefit of great specialized services without transferring the patient.
- Scheduling of consultation. Thanks to computerized booking and scheduling procedures, the system can optimize the communication between the local centers scattered in the territory and the referral center.
- Emergency management. An accurate, priority-aware management procedure significantly reduces the time to diagnosis for urgent cases.
- Clinical record and remote reporting. Clinical records and reports are accessible using a web browser, letting all the operative units get immediate access to the patient data.

Each feature has been added to solve medical needs: the following sections highlight the main issues faced during the development of the teleconsultation system and how they were approached.

- **Issue:** operator dependent exam.
  Approach: direct interaction between the operator and the specialist (real-time voice and video chats) enables correct exam execution. Due to the complex nature of the examination and even more to the difficulties in diagnosing a CHD in children, echocardiography in pediatric field is considered a highly operator-dependent practice [22]. This reason invalidates the use of the traditional procedure of second opinion. Thus, our system deals with this issue by providing the specialist with video feed of the examination thanks to a robotized camera with a variable magnification, in addition to the bidirectional real-time voice channel between the operator and the specialist. Driven by the specialist, it makes possible to assess patient conditions and to focus on the precise positioning of the probe, the correctness of the projections performed by the operator and also on the proper use of the ultrasound device itself.
- **Issue:** high incidence of congenital heart diseases combined with lack of specialists in secondary healthcare structures.
  Approach: virtual presence of specialists through telemedicine applications. The system can be activated at a relatively low cost in any remote center [14][23][24][25] equipped with broadband connection: specialists can be concentrated in tertiary hospitals and the logistics and shifts can be optimized at a single point. The physician who requires the teleconsultation and executes the echography does not need to have specific expertise in the field of pediatric cardiology, but he must have proper skills on the use of an echograph. As argued in Widmer et al. [26], it is crucial to improve remote operator skills and reduce the learning curve; in this scenario the system assumes a significant educational value for the echograph operator.
- **Issue:** ultrasound devices heterogeneity and age.
  Approach: any kind of device with a video output can be digitalized and used. Through the use of different types of encoder and encoding technologies, the system is able to capture and stream the output video of any ultrasound device equipped with a nonproprietary video output, from the analog signal of the most dated devices, to the most recent digital ones.
- **Issue:** low investments in remote districts.
  Approach: Commercial Off-the-Shelf (COTS) low cost devices and open source software. Although further research is needed to assess such a telehealth system from an economic point of view [27], some benefits are expected. First of all, access costs of telemedicine and its compatibility with consumer-type hardware decrease to the minimum the initial investment for linking a new remote unit to the pre-existent infrastructure of the system. In addition, the choice of using COTS hardware minimizes the economic and technological risks arising from the use of proprietary hardware and systems. Last but not least is the adoption of open-source licenses for the whole software, which permits a flexible reuse of the developed platform in scenarios not considered in the initial project.

B. Components

The system is based on three main components, as summarized in Figure 2:

- **The control station (one per tertiary care center):** it is a software system that can be accessed using a common laptop; through it a specialist can manage remote requests prioritization, view patient data and start teleconsultation.
- **The base station (one per secondary care center):** based on a mixture of hardware and software, it digitizes echograph video outputs and shots of the exam scene. It also enables voice chats with the remote medical doctor.
- **The data hub (one for the whole system):** this is a central server that stores medical records and patient data, manages voice chats, video streams, resource allocation and bookings.

1) Control Station:

1. **Specialist Desktop Application:** allows the specialist to view the list of patients waiting for teleconsultation, to select the desired consultation, and to perform it through an audio chat with the echocardiographer, using remote visualization of echo and PTZ (Pan/Tilt/Zoom) camera. The specialist may control pan, tilt and zoom of the camera through the keyboard or the on-screen graphical interface.
2. **Web Application:** used to schedule the availability of specialists, view the clinical records and create or edit consultation reports.

 ISBN: 978-1-61208-252-3

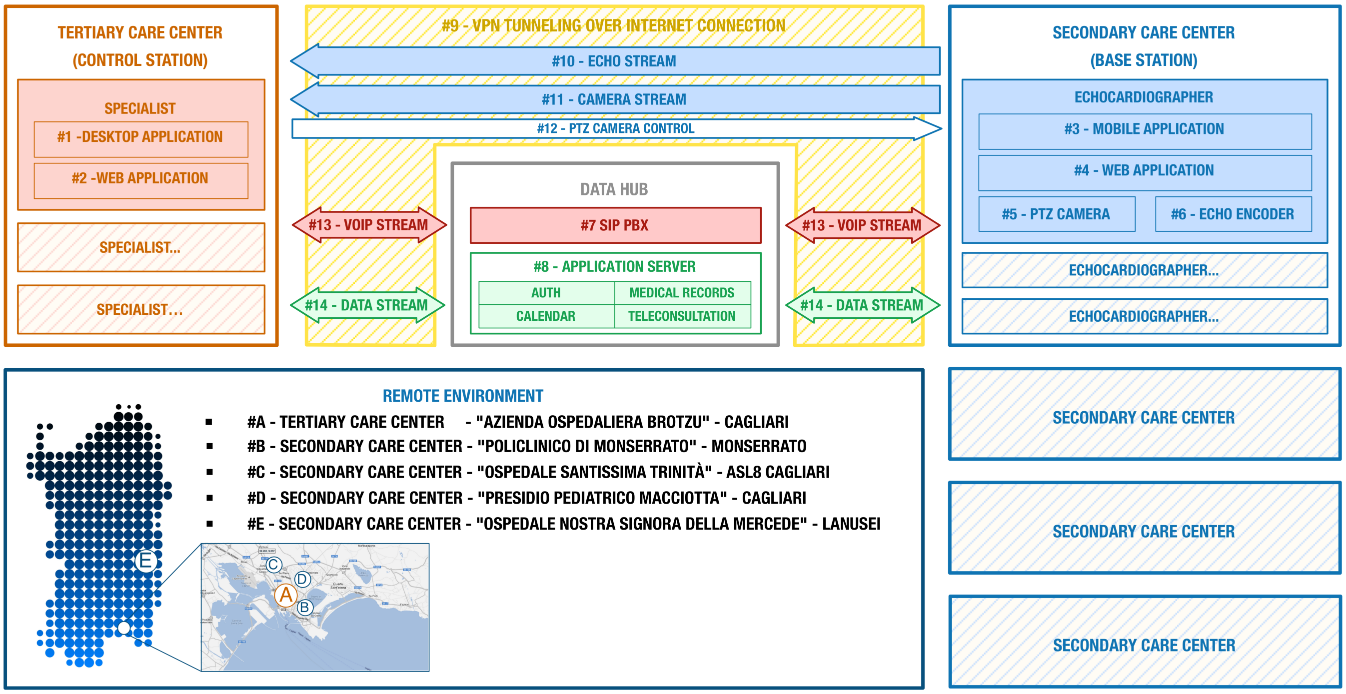

Figure 2. System architecture

2) *Base Station:*

3. **Echocardiographer Mobile Application:** it allows the echocardiographer to create, manage and run teleconsultations. After answering the call of the specialist, no further interaction with the mobile device is required, in order to leave the operators hands free.
4. **Web Application:** it is used by the echocardiographer or other supporting personal to create and manage personal patient data, to schedule consultation, edit and view clinical records.
5. **Network A/V Encoder:** this device enables remote transmission of video and audio streams generated by the Doppler ultrasound device. Through the use of network and streaming protocols that enable low latency real-time transmissions, it allows the specialist to receive in almost real-time the output of the medical device. Due to the number of sonographic device available, we adopted several different types of encoder: for older medical devices that emit analog video we chose a BNC/RCA to RTP/H264/AAC encoder (using various kind of adapters we can link any standard analog connector), while for modern devices that provide a digital video output we used a network frame grabber (VGA/DVI/HDMI compatible).
6. **PTZ Network Camera:** this device provides the streaming video capture of the entire environment of teleconsultation (room, patient, echocardiographer) and allows the specialist to focus on the details of the examination. In addition, it can be used as a backup for the encoder by targeting the Doppler ultrasound monitor. For experimental purposes we selected a PTZ camera with night/day switch (infrared when 0.005 lux or under) that features an optical zoom (18x) and a reversible horizon (ceiling mount).

3) *Data Hub:*

7. **Sip PBX:** this component acts as IP PBX and VOIP gateway and is responsible for connecting and managing audio calls between clinicians.
8. **Application Server:** this is the core of the system and it consists of four logical components responsible for user authentication, scheduling and management of teleconsultations and writing clinical records. The authentication module permits application, device and user authentication via a custom version of standard OAUTH protocol. The planning module allows the tertiary center to report the available time slots of specialists and secondary centers as to schedule patient visits during those time slots. The teleconsultation management module is responsible for managing the entire process for the remote visits, starting with the request of the teleconsultation, through its acceptance by the specialist, ending with the correct routing of audio streams video and voice chat. The clinical records module allows the specialist to analyze patient data and past clinical image records during the teleconsultation, thus providing valuable information to help compile the final medical report. It also allows the secondary care center involved in the visit to manage, export and print the report. Finally, it contains an administrative module for the management of care centers (i.e., register devices, sip info, etc.).

4) *Interconnections:*

9. **VPN Tunneling:** it groups all devices in a single encrypted virtual network, thus ensuring higher security for the transmitted data.
10. **Encoder Stream:** it is an A/V stream carrying both the video and audio channels from the ultrasound device. The stream is transmitted directly from secondary to tertiary care

 ISBN: 978-1-61208-252-3

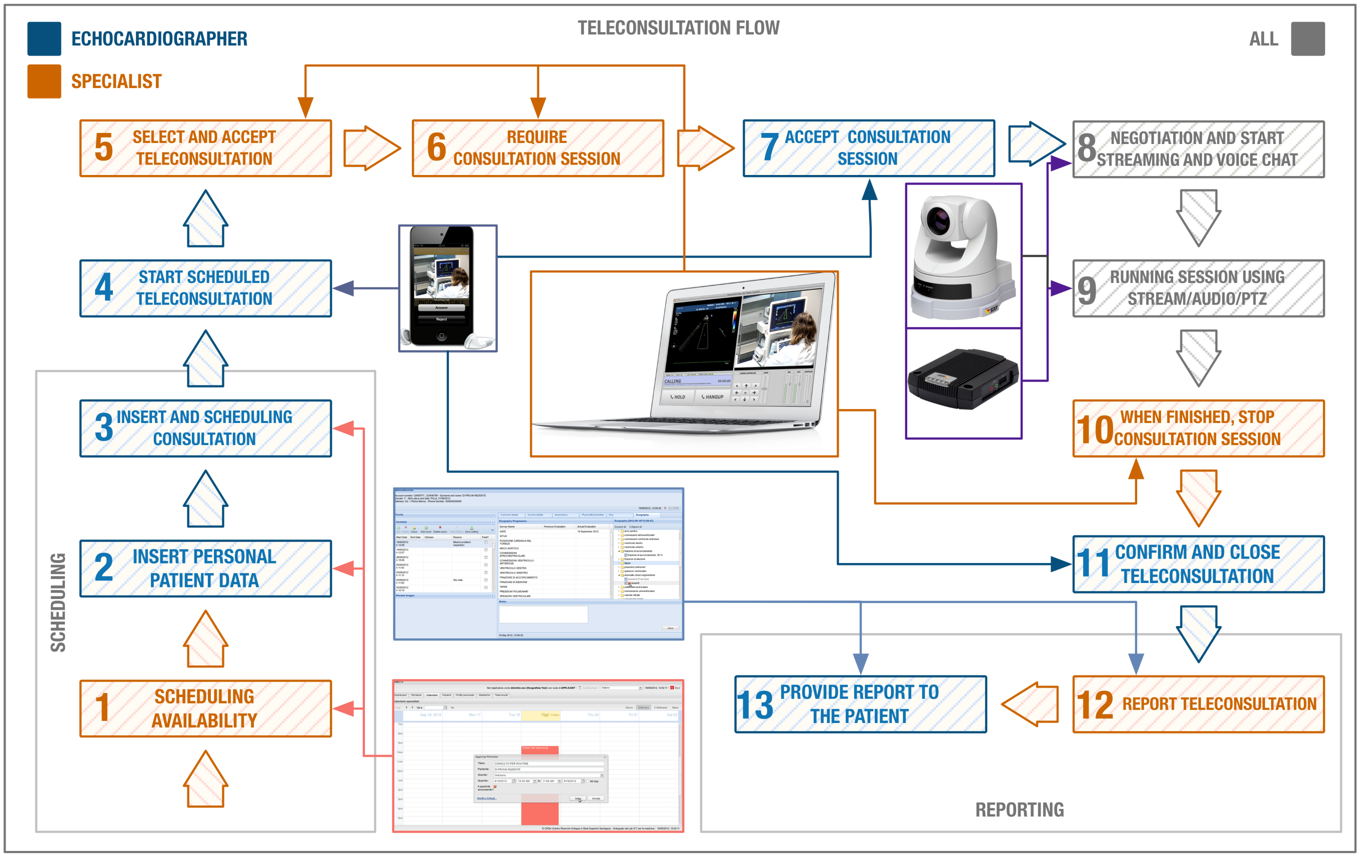

Figure 3. Teleconsultation workflow

center without passing through an intermediate data center.

11. **Camera Stream:** the PTZ Camera video stream, transmitted directly to the tertiary center like the encoder stream.
12. **PTZ Camera Control:** an HTTP channel through which the specialist can control the camera pan/tilt/zoom features.
13. **VOIP Stream:** the audio stream that allows voice communication between sonographer and specialist. It is routed, managed and distributed through the aforementioned Sip PBX.
14. **Data Stream:** an HTTP stream through which all data are exchanged between the data hub components and the other systems.

C. *Workflow*

The main workflow consists of three phases:

- **scheduling:** the exam is requested and scheduled;
- **teleconsultation:** the examination is performed;
- **reporting:** the medical report is prepared and given to the patient after the consultation.

Figure 3 shows each step in the process. To better understand the diagram, it is helpful to clarify the meaning of Teleconsultation and Teleconsultation Session. The former is the digital representation of the visit provided to the patient. The latter is the single voice chat session between the physicians. Each Teleconsultation may have multiple session within it.

1) Scheduling:

1. **Scheduling Availability:** via a web browser, the tertiary unit registers the hourly availability of the specialists for a given time period.
2. **Insert Personal Patient Data:** the secondary unit enters patient data.
3. **Insert and Scheduling Consultation:** the secondary unit inserts and schedules a new teleconsultation according to the availability of specialists specified at the tertiary unit.

2) Teleconsultation:

4. **Start Scheduled Teleconsultation:** at the scheduled time, the echocardiographer logs in via the mobile app, selects the scheduled teleconsultation and waits for the specialist.
5. **Select and Accept Teleconsultation:** at the scheduled time the specialist logs in and accepts the teleconsultation selected by the sonographer before.
6. **Require Consultation Session:** the specialist invites the echocardiographer to start a teleconsultation session.
7. **Accept Consultation Session:** the echocardiographer accepts the session of the specialist.
8. **Negotiation and start Streaming and Voice Chat:** automatically, the system enables the routing of the audio channel between the physicians involved in the consultation, enables the video streams and provides the specialist with the control of the remote camera.
9. **Running consultation using stream/audio/PTZ:** during the teleconsultation session, the specialist can direct and zoom the camera to improve the quality of the consultation. The specialist is able to take snapshots of streams which are automatically added to the patient medical records and associated with the current visit. Both physicians can arbi-

trarily decide to pause the session for a certain time (during the pause the audio and video channels are temporarily suspended).

10. **When finished, stop Consultation Session:** the specialist can arbitrarily terminate the session at any time, after which the specialist can resume the teleconsultation by creating a new session, or choose to permanently close it.
11. **Confirm and Close Teleconsultation:** at this stage, the echocardiographer can confirm the end of the teleconsultation to the system. The system enables the possibility to write the visit report for the specialist.

3) Reporting:

12. **Report Teleconsultation:** the specialist can access the patients medical records via web to edit the visit report.
13. **Provide Report to The Patient:** the secondary unit prints the patients copy of the report.

D. Clinical Trial Protocol

Following an agile software development process, the system was tested repeatedly during its development to quickly gather and incorporate suggestions from clinical use. After the first release and a set of preliminary tests, in order to evaluate its diagnostic effectiveness, the system is under a clinical trial involving 42 cases, approved by the ethics committee of Brotzu Hospital (the tertiary care center) on July 2012. The protocol involves two specialists in pediatric cardiology that perform a series of medical examinations using the traditional and teleconsultation approaches according to an established rotation: each physician performs the same number of examinations directly or by the teleconsultation system, in order to minimize the variance, and each subject undergoes both diagnostic methods. Two categories of patients are admitted: children under 6 years and adults over 18 years of age, to test the system with newborns, young children and adults. In all cases, the patients can participate in the trial only after giving their informed consent (personally or through their parents), by which they declare to accept the aims and the conditions of the study. As the procedure states, one of the two specialists performs the assessment of the patient traditionally (direct consultation) by running the echocardiography directly, while the other one guides a third operator a physician trained in the use of the ultrasound machine but without a specialized expertise in a teleconsultation. During the examination the physician executes four projection planes (subcostal, parasternal, suprasternal and apical), as indicated by the protocol, and transfers his findings to a structured report by filling out the dedicated form in the software. The result is a tree-structured document, which is specially designed to make the two reports comparable and suitable for the subsequent statistical analysis.

III. RESULTS

The system has been tested according to the protocol described in Section II, which defines a precise examination sequence and the use of a structured report to better compare the tests performed by two different physicians, with and without the teleconsultation application. The clinical results were very good: considering all the 42 cases, an analysis from the main diagnosis point of view showed a 97.6% agreement rate between the two techniques. Likening the structured report single sections some differences appeared: the detailed results for this point-to-point comparison will be presented in a paper by the clinicians involved in the experimentation. Anyway, these differences are not related to critical aspects of the examination (in fact the global diagnosis is not affected by these punctual disagreements) nor attributable to the use of the teleconsultation system. According to the clinicians, the model created for the report covers all the fields necessary to describe the patients' clinical conditions: the design of this model was fundamental to enable the quantitative comparison of the reports and can be a good starting point to perform statistical and epidemiological studies, since it can lead to a computable formalism easily used for clinical research. Regarding the ability of the participants to collaborate through the system, the feedback was quite positive. The participants considered the system to be a good tool, enhancing cooperation between clinicians with different levels of experience. In preliminary tests the system has been effective for both operators with no experience in pediatric echocardiography and operators who were working for the first time with the model of ultrasound machine used during the examination. Over the course of the study, we also determined that there is a need to establish a very precise procedure for teleconsultation, which must be set and followed accurately step by step to obtain a correct diagnosis. The link created by the teleconsultation application is good, but it can be really effective only if all the components involved (human, technological and about the process) act together. It would be insufficient to use the system only to transmit images and instructions; the specialist connected needs detailed feedback from the operator performing the examination and directly seeing the patient. The more details are coded within this feedback (e.g., checklists), the more effective the collaboration. The training potential of the system has also been evaluated. The system was considered very useful to train specialists through both in-class demonstrations and while training on-the-job. In fact, because of the collaborative design of the system young specialists can be easily supported in their case evaluations. It has also been highlighted that the system alone, as is, cannot be an effective training instrument unless the student has already undergone in-depth clinical training to learn the main projections used in echocardiography and the many important aspects connected to the manual operations necessary to obtain these projections (e.g., where pressure has to be applied, etc.). The technological design of the system was conceived to achieve a real-time transmission system with a latency lower than one second. The adoption of an A/V trasmissions, with priority on constant frames per second, has made possible to keep the streams in sync even in condition of high network traffic. Part of the clinical trials were been performed between the more distant tertiary and secondary centers involved in the project (approximately 120 km) through an xDSL business connection, without any perceivable signal degradation or increased latencies. The maximum bandwidth allocation during a teleconsultation remains within 2.5 Mbit/s (TABLE I).

Furthermore, the system remains operational even in case of a reduction of the available bandwidth by switching to the still-image recording feature. This mode of operation provides static full-resolution images instead of moving video that is usable during the visit and during the reporting. Moreover, the adoption of a mobile device with earphones and directional microphone has subjectively improved the usability of the system for the ultrasound operator. Concerning the quality of the VoIP transmission, the use of the TCP protocol (instead of UDP) with subsequent adoption of a TURN proxy improved the reliability of the audio channel between the sonographer and the specialist and helped simplify network configuration for each operating unit. All the software can be reused and extended with a relatively modest investment on a large number of software platforms, thanks to the detailed analysis performed to select the appropriate software libraries for developing the system and the preliminary tests conducted during the development phase (TABLE II).

 ISBN: 978-1-61208-252-3

TABLE I
MAX BANDWIDTH USAGE FOR SINGLE CONSULTATION

DIRECTION	**INBOUND**	**OUTBOUND**
TERTIARY CENTER	500 kb/s	2.5 Mb/s
SECONDARY CENTER	2.5 Mb/s	500 kb/s
DATA CENTER	500 kb/s	500 kb/s

TABLE II
SOFTWARE LIBRARIES COMPATIBILITY

	OSX	**Windows**	**Linux**	**Android**	**IOS**
Language	python	python	python	java	objc
Auth	oauth	oauth	oauth	oauth	oauth
API	qt	qt	qt	native	native
Gui	qt	qt	qt	native	native
Voip	pjsip	pjsip	pjsip	pjsip	pjsip
AV	gstreamer	gstreamer	gstreamer	native	native

IV. DISCUSSION

The adoption of telemedicine solutions is spreading out but in most cases the projects, even if good from a technological and clinical point of view, remain local and short-lived [27]. In order to learn from the errors of the past, we made interoperability (technological, semantic and process interoperability, as outlined in [28]) and long-term usability of all components a priority for our project, even when this approach was more difficult than creating a customized solution. The main challenges emerged with the following issues:

- Connecting different clinical institutions also meant connecting different wards inside the institution itself, which often do not really communicate. In this case, it is crucial to follow a general approach that does not focus on any single aspect (clinical, technical, organizational, administrative, etc.) of the integration.
- The importance of clinical training before the use of the system is often underestimated. Interoperability must be also semantic and the creation of a common model greatly facilitates this communication.
- The system has to be designed to easily integrate with previous existent systems, and its results have to be integrated in the hospital system and in the patient electronic health records in order to enable its use in real clinical activity.
- Roles and accountability must be defined in detail so that it is clear who is responsible for every single step of the process, who has to pay and how much. A clear business model is essential for the completion of the pilot project and also for the system to have a chance to continue its existence in the future.

V. CONCLUSION AND FUTURE WORK

The system described in this paper addresses to diagnostic contexts in which the lack of specialists is critical because the ability of the operator performing the examination is essential to obtain a correct diagnosis. To give a solution to the principal aspects related to these situations, we realized a real-time telemedicine system with open technologies and low-cost consumer components. The main components are a real-time teleconsultation application, a precise workflow and a EHR application to support the remote interaction between clinicians, also thanks to a structured diagnostic report. The system was clinically tested via a comparison to direct examination and the results showed a 97.6% agreement rate between the two techniques. The case study was pediatric tele-echocardiography, a test that is strongly operator-dependent where it is crucial that the person performing the examination has a specific expertise in the pathology, but the same approach can be applied in diagnostic areas with similar peculiarity.

ACKNOWLEDGMENT

This work was partially funded by the Regione Sardegna (grant L.7 N.2039/270). We wish to thank the IT staff of all the hospitals involved, in particular, *Carlo Corona* and *Emiliano Deplano*, for the network infrastructure implementation; the medical staff involved, *Alessandra Atzei*, *Carlo Balloi*, *Laura Sau* and *Monica Urru*, for the clinical trial support;*Cecilia Mascia* and *Alessandro Piroddi* for technical support.

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