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Meeting the Needs of Patients and Practitioners

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Preface

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Telemedicine in Collaborative Diagnosis and Care of Congenital Heart Malformations

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A. Taddei, A. Gori, E. Rocca, T. Carducci, G. Piccini, G. Augiero, A. Ciregia, M. Cossu, R. Conte, G. Ricci, G. Rocchi, N. Assanta, P. Festa, B. Murzi, and L. Ciucci

16.1 Introduction

Congenital heart malformations represent the foremost birth defect in developed countries (incidence of 0,8 per 1,000 cases per year). Echocardiography is applied for diagnosis and management of these malformations while community hospitals often lack access to pediatric cardiology consultants or sonographers and frequently infants or newborns are transported to a specialized pediatric center. Given the wide-bandwidth networks, interconnecting main health institutions today, it is conceivable to set up low-cost telemedicine services, from tertiary to secondary health-care centers, providing collaborative diagnosis, care or intervention planning, and follow-up of heart malformations, early in the fetus, in the newborn, or in the child and up to the adult patient.

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The "Gabriele Monasterio" Tuscany Foundation (FTGM) (http://www.ftgm.it) (a public healthcare research institution, jointly set up by the National Research Council and Tuscany Region and specialized in cardiovascular diseases) developed a number of projects aimed at health cooperation by telemedicine technology in diagnosis and care of heart malformations involving the pediatric division (Cardiology and Cardiac Surgery) and medical informatics at the Heart Hospital in Massa. Since 2008 the FTGM Heart Hospital, supported by the association "Un Cuore un Mondo" and the Tuscany Region, experienced tele-echocardiography with selected pediatric and gynecology centers in the Balkan countries, from Croatia to Bosnia-Herzegovina, Albania, and Romania [6–8].

Since 2013, jointly with CNR Institute of Clinical Physiology (CNR-IFC), FTGM has been involved in the European IPA Program with the project *AdriHealthMob* (http://adrihealthmob.eu), aimed at developing a cross border model of sustainable and efficient transport services for the health and care sector, in order to improve the mobility of passengers (residents/tourists/users/patients) and to improve accessibility to health and care services [7].

The main objectives include the creation of an area within the Adriatic region of cross border health and care made of connected and interrelated best practices and excellences; the promotion of the ICTs and the enhancement of their potential in terms of eHealth and eCare, as opportunity to reduce (and even "delete") geographical distances, allowing a complete "accessibility"; and the promotion of protocols and memorandum of understanding within the Adriatic area, leading to concrete case of Adriatic cross border health and Adriatic Health and Care Insurance Card.

Fifteen partners of eight countries (Albania, Bosnia-Herzegovina, Croatia, Greece, Italy, Montenegro, Serbia, and Slovenia) were involved. *AdriHealthMob* platform for eHealth and eCare was designed for providing service through distance support for the rationalization of mobility flows up to the elimination of useless transfers for health and care. It deals with telecommunication and distance control among health and care institutions; videoconference facilities for face-to-face contact between users and experts; second opinion and clinical support; and telemedicine to connect hinterland/rural areas with doctors, nurses, and specialists, avoiding mobility and travels.

Among the pilot actions of *AdriHealthMob* project, the empowerment and extension of telemedicine services in collaborative diagnosis and care of cardiac malformations, previously experimented by the FTGM Heart Hospital in Balkan countries, is under development.

Recently (since 2015) a telemedicine network was planned in our region (*"Arriviamo al cuore di tutti" – Telemedicine network for early diagnosis and care of congenital heart disease*) interconnecting neonatology, gynecology, and pediatric centers with the FTGM Heart Hospital, with the financial support of Tuscany clubs of Lions International Association (http://lions108la.it) and of Lions Clubs International Foundation (http://www.lcif.org) as well as with the promotion of healthcare regional authorities.

16.2 Methods

Pediatric tele-echocardiography has been used over many years in various countries, since the first live transmission of neonatal echocardiograms in 1996. Recently, Sable et al. (Children's National Heart Institute, USA) evaluated the impact of telemedicine on delivery of pediatric cardiac care in community hospitals. Telemedicine has the potential to increase efficiency and quality of care, improve echo quality, prevent unnecessary transport of babies without critical heart disease, enhance sonographer skill level, yield financial savings, decrease length of hospitalization, and raise patient and physician satisfaction. There has been a steady increase in the numbers of institutions performing tele-echocardiography [4, 5].

While echography equipment allows recognizing cardiac abnormalities, in neonate or even in fetus, often sonographers are not skilled and live guidance during patient examination is demanded to reach an expert-enlightened joint diagnosis. Thus the synchronous approach is preferred for tele-echocardiography.

Real-time tele-echocardiography was implemented, as in other experiences, by use of videoconferencing technology for streaming echocardiograms over network connections and allowing the specialist at tertiary pediatric center (HUB) to guide the remote ultrasound operator. Basically two CODECs are inter-networked (H323 IP, upload >512 Kbps), the first one in the echography room at remote center and the other one at the HUB (FTGM Heart Hospital in Massa), receiving live echocardiograms for second-opinion evaluation (Fig. 16.1). The video signal is online acquired from echocardiography equipment and transmitted to the specialist workstation. Dual video capability is useful for allowing specialist to interact, during echo examination, with the operator or to interview patient's relatives. Protection measures are applied to information transactions by CODEC data encryption or by use of encrypted network connections (VPN).

Medical-grade connections of telemedicine workstation in the echography room are assured. Even if lossy compression is applied for streaming (e.g., H264), high diagnostic accuracy is usually achieved in clinical practice, as reported in a number of experiences [4, 5, 9].

That approach was applied since 2008 for implementing a cross border network with Balkan countries for real-time pediatric/fetal tele-echocardiography (as described in the following paragraph), while further developments in the other projects provided additional facilities aimed at patient data exchange, image recording, second-opinion reporting, and service management. In order to overcome possible drawbacks in synchronous transmission of echo images, mainly due to lossy efficient compression (H264) and performance instability of public network connectivity, store-and-forward facility (recording high-resolution images on echo-equipment in DICOM standard and transmitting them to the specialist center) was introduced. Revision of evaluations of cardiac malformations by DICOM images, preserving diagnostic information according to telemedicine regulations, was thus allowed achieving definitive second-opinion reporting [3, 7].

An information system (eHealth portal), securely accessible over public network, allows to share patient clinical data for thorough second-opinion evaluation

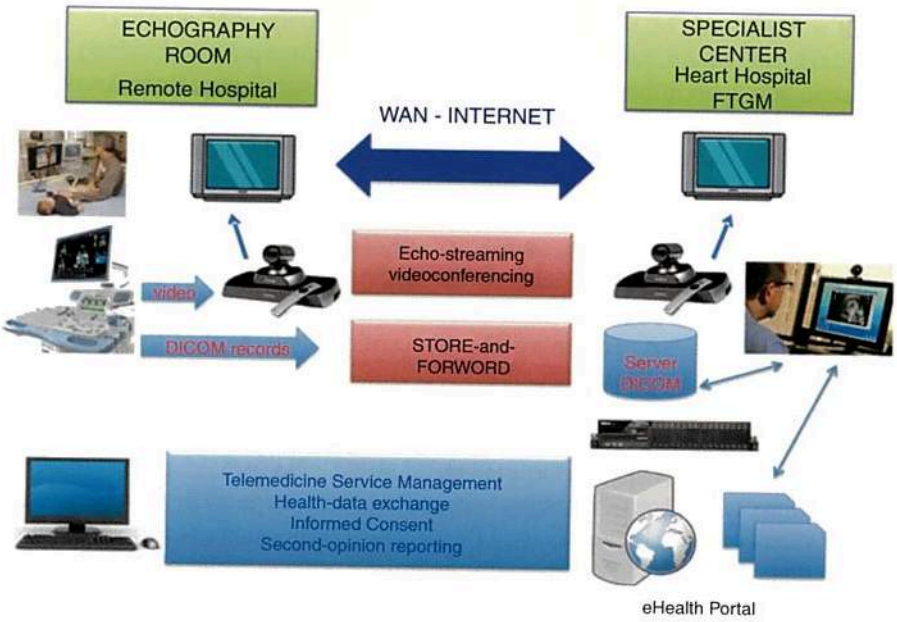

Fig. 16.1 Tele-echocardiography system for collaborative diagnosis of cardiac malformations: videoconferencing is applied during examination for guiding the operator and later DICOM images are transferred for revision and second-opinion reporting. The eHealth portal provides facilities for secure data exchange and documentation of telemedicine service

as well as reporting. Formatted reports with digital signature will be provided. Generally, the physician, who examines the patient, is charged of writing the echocardiography report taking into consideration the second-opinion evaluation of the specialist. Actually according to the protocol of the Tuscan project, the report should be unique, just signed by the two physicians, cooperating by telemedicine.

Finally, tele-echocardiography is a two-step process (as represented in Fig. 16.1):

- Firstly, synchronous tele-echocardiography is achieved by streaming echo low-resolution (compressed) images during videoconference, so allowing remote guide for proper exploration of cardiac anatomy.
- Secondly, at the end of the examination, high-resolution DICOM images are transferred to the specialist center, directly from the echography equipment or from the hospital imaging system (PACS), for allowing revision/confirmation of diagnostic evaluations and second-opinion reporting.

Within the AdriHealthMob project, a central eHealth and eCare web portal will be provided, while in the Tuscan Lions/LCIF project (Arriviamo al Cuore di Tutti), the FTGM information system facilities have been made available by proper adaptation for creating a medical outpatient record for both data sharing and diagnostic reporting.

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Particular attention was dedicated to learning for allowing fruitful at-distance collaboration in pediatric or fetal echocardiography. Initial learning of medical staff is planned by stages at the Heart Hospital while videoconferencing facilities are conveniently used during the project. Technical guides for telemedicine use and troubleshooting were initially provided by FTGM technicians, which have been continued cooperating to assistance at remote centers throughout the activity.

In AdriHealthMob, CNR-IFC was charged of providing the remote learning platform (RLP) for professionals. In accordance with the other partners of the project, CNR-IFC, in collaboration with the FTGM Heart Hospital, will provide a basic echocardiography course on congenital heart disease. RLP is composed of two main components:

- The e-learning application: containing all data needed to acquire knowledge in a specific domain (based on open-source Moodle software for remote learning) (www.moodle.org)
- The e-training application: implementing the programs to improve own knowledge and skill in a specific pathology, by means of evaluations on real clinical studies (web-based tool developed by CNR-IFC in order to improve participants' skills in image interpretation)

16.3 The Balkan Network

Since 2008 the Pediatric Cardiology and Cardiac Surgery teams of the Heart Hospital of FTGM in Massa, supported by Medical Informatics researchers and jointly with the volunteers of "Un Cuore un Mondo" Association, were involved in the International Health-Care Cooperation program of Tuscany Region. The goal was to set up a cooperative network with the clinical centers in Balkan Countries for supporting the diagnosis and care of congenital heart malformations [6, 8].

Tele-echocardiography was first implemented at Pediatric Clinical Centres of Banja Luka (BIH) and Rijeka (KR), at the Gynaecology Hospital in Tirana (AL). Later other centers in Bosnia-Herzegovina (Gynecology Hospital/Sarajevo and Pediatric Hospitals/Tuzla and Mostar) as well as in Romania (Bucharest) were involved. A telemedicine network connecting the remote clinical sites in the Balkan Area with the cardiac department of the Heart Hospital in Massa/Italy (the reference center) was set up over the Internet (Fig. 16.2).

Videoconferencing equipment (Aethra Vega ×3/×5) was applied, for implementing real-time tele-echocardiography. Standard audio/video interaction was provided between the clinicians in Massa and the sonographers/physicians at the remote Balkan sites. Echocardiograms were performed under the remote guide of pediatric cardiologists from Massa. The video analogue output of the echocardiography equipment was connected with the CODEC (Fig. 16.1) for image acquisition/digitization and efficient data compression allowing transmission in real time by standard H.323 protocol on IP network. Upload data transfer rate, greater than 512 Kbps, was provided to ensure quality and low latency of transmitted echocardiographic images.

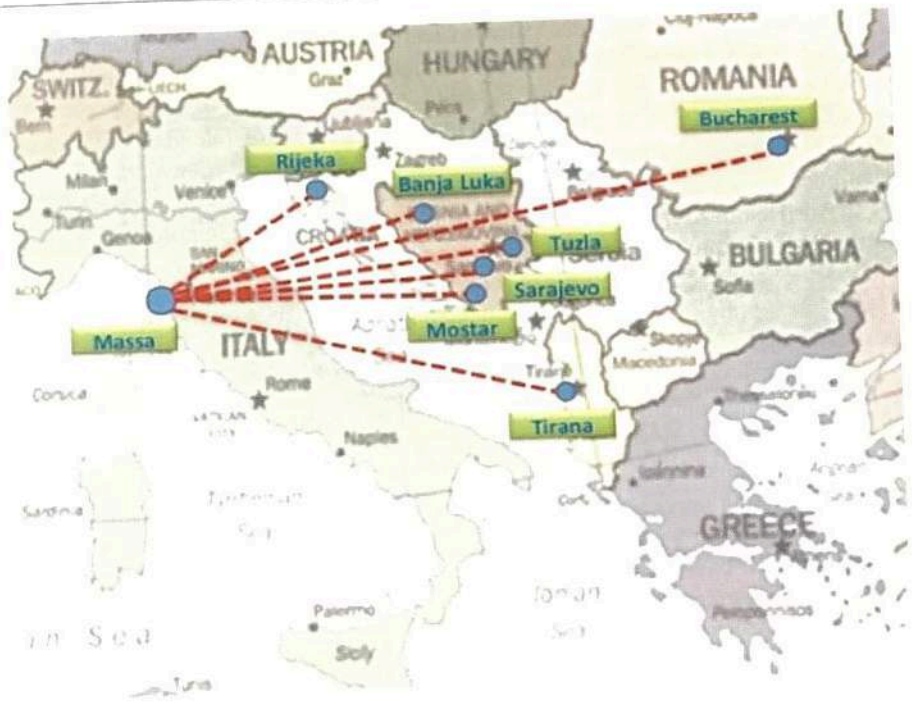

Fig. 16.2 The Balkan tele-echocardiography network

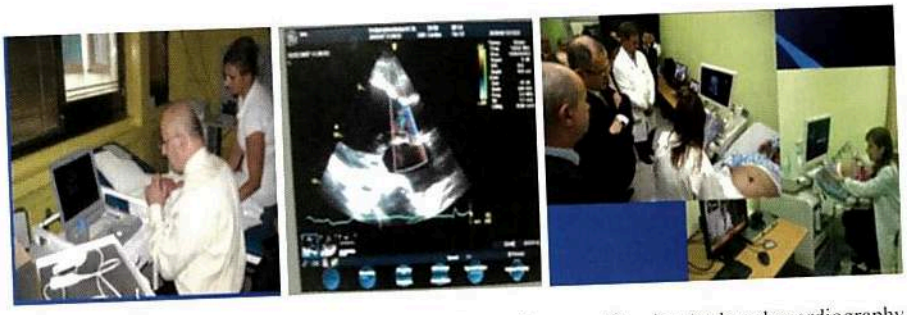

Fig. 16.3 Pediatric (from Banja Luka) and fetal (from Tirana and Sarajevo) tele-echocardiography (*left* to *right*)

At the Heart Hospital in Massa, the echocardiographic images were decompressed and displayed for teleconsulting.

Real-time tele-echocardiography was implemented at both pediatric and gynecology (Fig. 16.3) centers. Real-time teleconsultation helped to plan timely care or intervention in case of critical or complex conditions, even transferring pregnant women before delivery in case of fetal abnormalities. Standard cryptography

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was applied for data protection. At times, limitations of public network bandwidth (the Internet), or instability of it, affected quality of diagnostic images and the degradation was high enough to render detection of cardiac abnormalities difficult. In these situations store-and-forward solution was applied as alternative, transferring imaging records (possibly in DICOM format) thus preserving diagnostic information.

Patients with suspected heart malformations were evaluated on-demand by tele-echocardiography from pediatric cardiologists at the HUB in Massa assessing the abnormal or critical cases. In the last years, 82 patients (29 neonates, 30 infants, and 23 children) were transferred from Albania, Bosnia-Herzegovina, and Croatia for cardiac surgery. Each patient or fetus was first examined by tele-echocardiography in most of the cases. While a part of them were evaluated not complex, minor, or normal, the others were transported to Massa for cardiac surgery intervention or care. Even pregnant women, in case of critical fetal abnormalities, were transferred before delivery to the birth center in Massa to allow prompt intervention on newborns for limiting risks. Follow-up of patients, going back to home, was facilitated by the use of the network.

Videoconference meetings and workshops were organized for discussion of clinical cases and for training healthcare personnel. Nevertheless, adequate exploitation of the network requires refining the cooperation agreements with the hospitals, which were not really active, thus promoting wide cooperation in health care in the Balkan area.

16.4 AdriHealthMob

The EC IPA *AdriHealthMob* (*AHM*) project (Adriatic model of sustainable mobility in health and care sector) (http://adrihealthmob.eu) foresees the participation of 15 partners from the 8 countries that constitute the macro-Adriatic region. By the involvement of institutions, universities and research organizations, public and private stakeholders in the health sector, and ICT companies, a partnership was established aimed at developing guidelines, through research and pilot actions, for a sustainable transport strategy to ensure the citizens an easy access to health services. FTGM Heart Hospital jointly with CNR-IFC is contributing to activity work-packages, particularly involved in the extension and empowerment of previous telemedicine experiences in cardiac malformations.

FTGM and CNR-IFC research teams are involved in developing a pilot service in collaborative diagnosis and care of heart malformations through the *AHM* ICT network.

As described in the methods, the remote learning platform, designed by CNR-IFC, will be experimented, uploading significant cases of heart malformations, cared in FTGM Heart Hospital [1].

Next, after initial training on site, the enrolled centers (up to nine from the different participating countries) in the Adriatic area will be provided with RLP for

acquiring or extending knowledge for ultrasound examination of cardiac malformations.

The tele-echocardiography network will consist of the enrolled centers, all networked across the *AHM* portal platform with the hub centers (FTGM/Massa and others). Each center is equipped with a workstation acquiring echo images from echography equipment (Fig. 16.1) and streaming them to a specialist center for second-opinion evaluation. The eHealth and eCare *AHM* web portal, implemented by the ICT partner company, will provide services for requesting consultations, patient data sharing, and second-opinion reporting. DICOM images will be stored into a server for documentation and revision. Recently, technical solutions for providing both second-opinion evaluation and real-time echo streaming have been designed and proposed to the AHM project partnership.

The pilot action will start after workstations for tele-echocardiography have been installed and tested. The results of 1-year experimentation will be analyzed and reported.

16.5 "Arriviamo al Cuore di Tutti": LIONS/LCIF Telemedicine Network for Early Diagnosis and Care of Congenital Heart Disease

In Tuscany (region in central Italy with three million inhabitants, comprising a couple of major islands), some thousands of patients each year (including pregnant women) are traveling for diagnosis and care of cardiac malformations to specialized centers (FTGM Heart Hospital in Massa and Meyer Hospital in Florence). This project (Fig. 16.4), developed by FTGM with the financial support of Lions Clubs of District 108La Tuscany (http://lions108la.it/) and of the Lions Clubs International Foundation (http://www.lcif.org/) and with the promotion of Health-Care System of Tuscany Region, is implementing tele-echocardiography network interconnecting at least one at each of its ten provinces, with priority for remote locations, not easy for traveling (Fig. 16.5).

Pilot action started at the Hospital of Elba Island: tele-echocardiography was tested successfully connecting the cardiology lab with the pediatric department of Heart Hospital in Massa through a secure network (VPN) (Fig. 16.6).

Echocardiograms, under the guide of the specialist, are streamed for detection and evaluation of cardiac malformations. A portable telemedicine cart has been assembled to facilitate use within the hospital. First, the telemedicine service has been started at Elba hospital (Fig. 16.6). Later, at the hospitals in Lucca, Empoli, Pontremoli, Bibbiena and Arezzo (Fig. 16.7), telemedicine workstations have been installed, while others will be set up within the next year throughout the region (beginning from Prato, Pistoia and Versilia). The Meyer Hospital in Firenze will be involved as second HUB of the network. According to current development plans up to 15 pediatric/neonatology sites will be connected in order to cover the full region. Official agreements have

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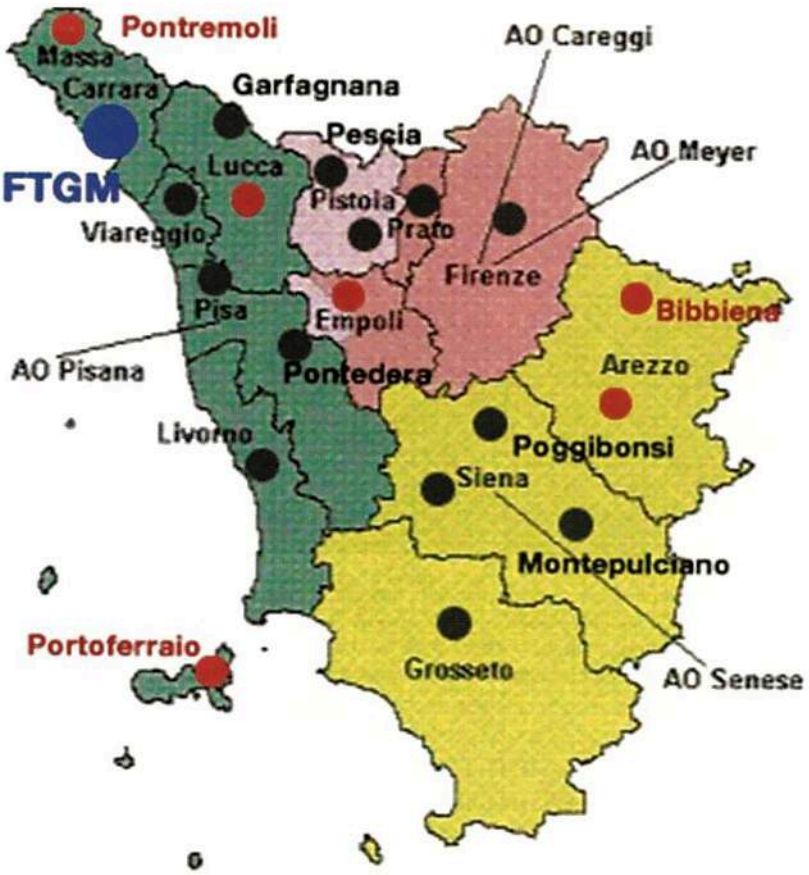

Fig. 16.5 The telemedicine network, developed by LIONS/LCIF "Arriviamo al Cuore di Tutti" project, will interconnect all main pediatric/neonatology centers around Tuscany with the HUB consulting center (FTGM and later Meyer Hospital)

Fig. 16.6 The telemedicine cart applied for teleconsultation from Heart Hospital in Massa during echocardiography examination on neonate at the Hospital of Elba Island in Tuscany

Fig. 16.7 The telemedicine cart (on the *left*) was set up in neonathology at Arezzo Hospital including the following: videoconference equipment is connected with digital video output of echocardiography instrumentation (on the *right*); two monitors are provided: one for videoconferencing and the other for medical reporting. All inputs are medically insulated

been signed by FTGM with Health-Care Institutions to deliver telemedicine services. According to the functional layout of Fig. 16.1, the "live" tele-echocardiography session is followed by the transmission of DICOM records to FTGM server for revision, while a medical record system (running on FTGM server) is securely provided for

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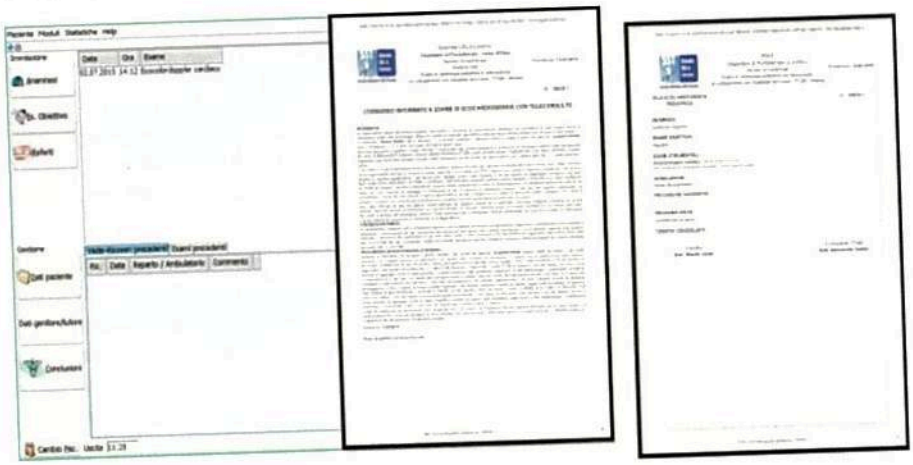

Fig. 16.8 Medical record system for documentation of examinations is provided (by remote VPN access to FTGM clinical information server). From *left* to *right*: the graphical user interface including commands for patient data entry (anamnesis, physical examination, test reports, relatives or tutors, conclusions) and printing visit report with diagnostic evaluation as well as informed consent according to legal constraints

documenting clinical conditions and for preparing a report, agreed by both the physician, caring for the patient, and the specialist colleague. Information document and informed consent are also provided to respect legal constraints (Fig. 16.8).

Conclusion

Tele-echocardiography allows collaborative medical decision making in diagnosis and care of complex and critical heart defects. It plays an important role in the early diagnosis, follow-up, or exclusion of cardiovascular abnormalities, planning patient mobility to tertiary specialist center when really necessary. Quality and continuity of care are provided with overall cost reduction avoiding unnecessary patient transfers, examinations, or hospitalizations. Continuous medical training at secondary centers is also achieved.

The main benefits of telemedicine network are:

- Shortening the time to diagnosis limiting risks for patient
- Preventing unnecessary patient transports and avoiding discomforts for families
- Promoting a real pediatric network, empowering the medical skill out of specialized centers
- Extending specialized remote consultation for follow-up of patients undergoing high-specialty interventions
- Reducing costs for both families and the public health systems

Videoconferencing technology, by wide-bandwidth networking, is promoting diffusion of low-cost telemedicine networks in the study of various medical pathologies, just providing specialized medical care virtually anywhere.

The added value of the cross border cooperation in the *AdriHealthMob* project relies in the implementation of interoperable network for health and care services. Cross border cooperation will allow to improve transport routes for health and care as well as to promote the development and networking of health and care resource in the Adriatic area. The most recent developments on eHealth and the newest mHealth (MobileHealth), together with the directive on cross border health in Europe, confirm how innovations in health and care can influence the transport and mobility schemes as well as the quality of services provided. In the framework of health and care (as well as for transports), services fall within the scope of several legal instruments and legislative framework, asking for agreement, protocols, and procedure; with a view to implement an integrated transport, health and care system, the cross border cooperation will contribute to:

- Clarify areas of legal uncertainty.
- Improve interoperability between systems.
- Increase awareness and skills of target groups.
- Promote initiatives of health (digital and road) routes.
- Ensure legal advice for start-up eHealth business

Expected results are:

- Improvement of accessibility and mobility in health and care sector by simultaneous operational actions on innovation and ICT introduction on one side and on Adriatic regional planning on the other
- Full knowledge of mobility and transport schemes for health and care; introduction of systems for permanent and systematic collection and analysis of data and statistics
- ICT-driven models for the optimization and rationalization of cross border mobility for health and care
- Driving implementation of electronic patient summary, ICT Resource Centre, and platform for eHealth and eCare
- Networking capacity to implement services of telemedicine (tele-assistance/diagnosis/consultation) leading to Adriatic cross border health care
- Strategy for sustainable transport for health and care, based on joint, integrated planning in the Adriatic area

Permanent tool for policy and decision makers, the Adriatic Health and Care Mobility Association (AHCMA), to plan health and care, to network providers, and to identify integrated funding schemes

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