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INNOVATIVE ICT SOLUTIONS IN TELEMEDICINE TO SUPPORT CLINICAL PRACTICE AND RESEARCH IN HOSPITALS

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Index/Summary

Introduction	5
Chapter 1 Telemedicine	7
1.1 A definition	7
1.1.1 Telemedicine services	7
1.1.2 Delivery mechanisms	8
1.1.3 Health information technology	9
1.2 Relevant telemedicine services	10
1.2.1 Tele-monitoring	10
1.2.2 Tele-radiology	11
1.3 Telemedicine: actual and future challenges	12
1.3.1 Effectiveness of telemedicine services	12
1.3.2 Regulations and legal clearance	13
1.3.3 Technical issues	13
1.4 Research projects in telemedicine	14
Chapter 2 Tele-radiology	15
2.1 State of the art and questions in tele-radiology	15
2.1.1 The all-inclusive approach in tele-radiology	16
2.2 International projects in mobile tele-radiology	17
2.2.1 EU projects	18
2.2.2 A Canadian tele-radiology project	20
Chapter 3 ICT systems and solutions in telemedicine for the hospitals	21
3.1 Web sites and portals for telemedicine	22
3.2 Internet and intranet telemedicine services	23
3.3 IT Security and technical infrastructure	24
3.3.1 The information security plan	24
3.3.2 Information risk analysis	26
3.3.3 Conclusion	28
3.4 Tele-radiology at home	28
3.5 From home to mobile?	30
3.6 Innovative technologies and systems for mobile tele-radiology	31
3.6.1 Tablets for tele-radiology	31
3.7 Adopt – Anti Doping Teleconsulting	33
3.8 Tele-presence and tele-monitoring	33
3.8.1 HUB-SPOKE model for ultrasound tele-consult	33
3.8.2 Innovative devices for tele-monitoring	35
Chapter 4 Innovative methods and solutions for telemedicine oriented web-portals	37
4.1 A hospital web-portal for telemedicine	37
4.1.1 Web-portal characteristics and requirements	37
4.1.2 Methods, developments and results	38
4.2 The web “social turning point”	41
4.2.1 The techniques	42
4.2.2 The services	43
4.3 Conclusions	49
Chapter 5 Innovative methods and applications in designing intranet services	50
5.1 Intranet services and solutions for corporate organization and business	51
5.1.1 Methods and materials	52
5.1.2 Development and implementation	53
5.1.3 Results and discussion	56
5.1.4 Conclusion and actual developments	57

5.2 Intranet solutions for management evaluation	57
5.2.1 Purpose	57
5.2.2 Methods	59
5.2.3 Results	61
5.2.4 Discussion	68
5.2.5 Conclusion	69
5.3 Intranet solutions for clinical care	69
5.3.1 Objective	69
5.3.2 Methods	70
5.3.3 Results	72
5.3.4 Discussion	73
5.3.5 Conclusion	73
Chapter 6 Mobile tele-radiology: a present approach for the future.....	75
6.1 Mobile tele-radiology – a clinical approach	75
6.1.1 Materials and methods	76
6.1.2 Results	78
6.1.3 Discussion	78
6.2 Mobile tele-radiology – an engineering approach	79
6.2.1 The evaluation of electronic display devices	79
6.2.2 IT security issues	81
6.3 The assessment of a measurement protocol for mobile tele-radiology	83
6.3.1 Objective	83
6.3.2 Materials and methods	84
6.3.3 Results	85
6.3.4 Discussion	87
6.3.5 Future developments of the study	88
6.4 Conclusion	89
Conclusions and final considerations	91
Acknowledgements	93
References	93
Appendix A	100
Appendix B	117

Introduction

The scope of this study was to examine ICT telemedicine innovations and potentialities in web-portals, intranet services and tele-radiology topics respectively, in order to design, develop and, possibly, realize apposite telemedicine systems and solutions for healthcare and in particular for the hospitals. ICT techniques and technologies are nowadays applied in every area of our common living from work places to our homes, our free-time, schools, universities and so on. Technology is full pervasive our lives, spaces and times. Technology has a cost, even in terms of maintenance; to maintain the drive for producing and marketing new technologies, the elder lower their prices allowing also the realization of low cost infrastructures even in less industrialized countries. Technology has a wide range of products and services covering and supporting industry, education, business and healthcare. The healthcare services offered by hospitals are heavily supported by technologies and, behind them, by a wide research both in ICT and biomedical sciences. Thanks to these advances telemedicine is not more considered a chimera or only speculation, but is now becoming a fundamental part of services offered by hospitals and healthcare structures. The healthcare management, the doctors and the common people are now experimenting how telemedicine is an added value to all the services offered in terms of the quality of care, the patient follow up, the early diagnose and treatment of pathologies and diseases.

Biomedical engineers are the first actors and interfaces that a healthcare staff may consult in order to study, develop and implement telemedicine services. But to propose, study and realize telemedicine systems is important an all-inclusive vision approach. In fact telemedicine needs in fact a multidisciplinary approach forcing medical staff to welcome the technology change meaning a radical shift of their typical activities in taking care of patients. On the other side the technicians (i.e. bioengineering researchers and technical staff) couldn't even design a telemedicine solution without the continuous support (and often compromise) of the actual users, i.e. medical or clinician staff.

Beyond these “border problems”, emerging in all situations where people with different competencies and cultural background try to cooperate, in my research study an attempt is presented of an all-inclusive approach to telemedicine problems and challenges in particular studying, developing and proposing ICT methods and technologies in the above mentioned three areas of interest:

- innovative healthcare and telemedicine-ready hospital website or portal design and development;
- analysis and study of models for the realization of intranet healthcare services to enhance both quality of care and the management of healthcare personnel evaluation;
- tele-radiology and some of its actual new perspectives as the study and the evaluation of the “mobile” tele-radiology approach using commercial tablets (and what it could mean).

Chapter 1 and 2 deals with a general discussion on telemedicine and tele-radiology, presenting some definitions and the context of the topics of the next chapters. In chapter 3 there is a list of telemedicine studies and projects proposed for hospitals with a presentation of the state of the art of

some technologies and solutions proposed. I participated to all the discussed projects proposing ICT innovative methods and solutions. Chapters 4, 5 and 6 are the core of the thesis presenting objectives, problems, methodologies and innovations proposed as well as results obtained in telemedicine oriented web-portals, hospital-intranet applications and services, mobile tele-radiology issues respectively. Conclusions and final considerations chapter closes this work with some final reflections about the obtained results and telemedicine.

Chapter 1

Telemedicine

“Telemedicine is the use of telecommunication and information technologies in order to provide clinical health care at a distance. It helps eliminate distance barriers and can improve access to medical services that would often not be consistently available in distant rural communities. It is also used to save lives in critical care and emergency situations”. This is a definition of telemedicine as found on ATA (American Telemedicine Association) web site [W1]. Telemedicine is essentially a product of 20th century information and communication technologies (ICT) which permit communications between patient and medical staff with both convenience and fidelity, as well as the transmission of medical, imaging and health informatics data from one site to another. Early forms of telemedicine achieved with telephone (i.e. the tele-auscultation of the heartbeat) and radio have been supplemented with videotelephony, advanced diagnostic methods supported by distributed client/server applications, and additionally with tele-medical devices to support in-home care. Other expressions similar to telemedicine are the terms "tele-health" and "e-health", which are frequently used to denote broader definitions of remote healthcare not always involving active clinical treatments.

1.1 A definition

“Telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve patients' health status” (ATA). “Tele-health” is often used to comprehend a broader definition of remote healthcare that does not always implicate clinical services. Videoconferencing, transmission of still images, e-health including patient portals, remote monitoring of vital signs, continuing medical education and nursing call centers are all considered part of telemedicine and tele-health (e-health).

Products and services related to telemedicine are often part of a larger investment by health care institutions and companies in either information technology or the delivery of clinical care. Even in the reimbursement fee structure, there is usually no distinction made between services provided on site and those provided through telemedicine and, mostly in USA, often no separate coding required for billing of remote services.

Telemedicine includes different types of programs and services provided for the patient. Each component involves different providers and consumers.

1.1.1 Telemedicine Services

- Specialist referral services typically involves a specialist assisting a general practitioner in rendering a diagnosis. This may involve a patient "seeing" a specialist over a live, remote

consult or the transmission of diagnostic images and/or video along with patient data to a specialist for viewing later (see chapter 3). Recent surveys have shown a rapid increase in the number of specialty and subspecialty areas that have successfully used telemedicine. Radiology continues to make the greatest use of telemedicine with thousands of images "read" by remote providers each year. Other major specialty areas include: dermatology, ophthalmology, mental health, cardiology and pathology. According to reports and studies, almost 50 different medical subspecialties have successfully used telemedicine.

- Patient consultations using telecommunications to provide medical data, which may include audio, still or live images, between a patient and a health professional for use in rendering a diagnosis and treatment plan. This might originate from a remote clinic to a physician's office using a direct transmission link or may include communicating over the Web (see chapter 4).
- Remote patient monitoring uses devices to remotely collect and send data to a monitoring station for interpretation. Such "home tele-health" applications might include a specific vital sign, such as blood glucose or heart ECG, remote toco-cardio-fetal signals (see chapter 3) or a variety of indicators for homebound patients. Such services can be used to supplement the use of visiting nurses.
- Medical education provides continuing medical education credits for health professionals and special medical education seminars for targeted groups in remote locations.
- Consumer medical and health information includes the use of the Internet for consumers to obtain specialized health information and on-line discussion groups to provide peer-to-peer support.

1.1.2 Delivery Instruments

- Networked programs (at regional or wide-area level) link tertiary care hospitals and clinics with outlying clinics and community health centers in rural or suburban areas. The links may use dedicated high-speed lines or the Internet for telecommunication links between sites. For example the number of existing telemedicine networks in the United States is placed at roughly 200 (ATA). These programs involve close to 2,000 medical institutions throughout the country. Of these programs, it is estimated that about half (100) are actively providing patient care services on a daily basis. The others are only occasionally used for patient care and are primarily for administrative or educational use.
- Point-to-point connections using private networks or VPNs are used by hospitals and clinics that deliver services directly or contract out specialty services to independent medical service providers at ambulatory care sites (cf. chapter 3). Radiology, mental health and even intensive care services are being provided under contract using telemedicine to deliver the services.

- Primary or specialty care to the home connections involves connecting primary care providers, specialists and home health nurses with patients over single line phone-video systems for interactive clinical consultations.
- Home to monitoring center links are used for cardiac, pulmonary or fetal monitoring, home care and related services that provide care to patients in the home. Often normal phone lines are used to communicate directly between the patient and the center although some systems use the Internet.
- Web-based e-health patient service sites provide direct consumer outreach and services over the Internet. Under telemedicine, these include those sites that provide direct patient care.

1.1.3 Health information technology

Health information technology (HIT) provides the umbrella framework to describe the comprehensive management of health information across computerized systems and its secure exchange between consumers, providers, government and quality entities, and insurers. Health information technology is in general increasingly viewed as the most promising tool for improving the overall quality, safety and efficiency of the health delivery system. Broad and consistent utilization of HIT will:

- Improve health care quality;
- Prevent medical errors;
- Reduce health care costs;
- Increase administrative efficiencies;
- Decrease paperwork;
- Expand access to affordable care.

Interoperable or integrated HIT will improve individual patient care, but it will also bring many public health benefits including:

- Early detection of infectious disease outbreaks around the country;
- Improved tracking of chronic disease management; and
- Evaluation of health care based on value enabled by the collection of de-identified price and quality information that can be compared.

1.2 Relevant telemedicine services

As reported in official EU documents [B4],[B5] “telemedicine is the provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients”.

Telemedicine encompasses a wide variety of services. Those most often mentioned in peer-reviews and in scientific literature are tele-radiology, tele-pathology, tele-dermatology, tele-consultation, tele-monitoring, tele-surgery and tele-ophthalmology. Other potential services include call-centres/online-information centres for patients, remote consultation/ e-visits or videoconferences between health professionals. Health information portals, electronic health record systems, electronic transmission of prescriptions or referrals (e-prescription, e-referrals) are regarded as telemedicine services but in particular as e-health services.

In the following sections, tele-monitoring and tele-radiology services are outlined in more detail as together they cover most of the challenges that are relevant to the implementation of telemedicine services in general.

1.2.1 Tele-monitoring

Tele-monitoring is a telemedicine service aimed at monitoring the health status of patients at a distance. Data can be collected either automatically through personal health monitoring devices or through active patient collaboration (e.g. by entering weight or daily blood sugar level measurements into a web-based tool). Data, once processed and shared with relevant health professionals, may be used to optimize the patient's monitoring and treatment protocols.

Tele monitoring is particularly useful in the case of individuals with chronic illnesses (such as diabetes or chronic heart failure). Many of these patients - who are often elderly people - need regular monitoring because of the prolonged duration of their disease, the nature of their health condition and the drugs that they are using.

Tele-monitoring supports patients and health professionals. Its use can allow symptoms and abnormal health parameters to be detected earlier than during a routine or emergency consultation, and corrective measures thus to be taken before more serious complications appear. It may also result in less frequent visits to healthcare facilities, thereby increasing the quality of life for patients and diminishing welfare spending.

1.2.2 Tele-radiology

Tele-radiology is a telemedicine service which involves the electronic transmission of radiographic images (x-rays, CT, MR, PET/CT, SPECT/CT, MG, US...) from one geographical location to another for the purposes of interpretation and consultation. For this process to be implemented, three essential components are required:

- an image sending station,
- a transmission network,
- a receiving-image review station.

Tele-radiology has developed alongside the gradual shift in medical imaging from film-based to digital-based technologies. Well structured professional organizations and early establishment of standards have supported this development.

The most typical implementation are two computers connected via the Internet. The computer at the receiving end will need to have a high-quality display screen that has been tested and cleared for clinical purposes. Sometimes the receiving computer will have a printer so that images can be printed for convenience. The tele-radiology process begins at the image sending station. The radiographic image and a modem or other connection are required for this first step. The image is scanned and then sent via the network connection to the receiving computer.

Today's high-speed broadband based Internet enables the use of new technologies for tele-radiology: the image reviewer can now have access to distant servers in order to view an exam. Therefore, they do not need particular workstations to view the images: a standard Personal Computer, a Digital Subscriber Line (DSL) connection or an UMTS (Universal Mobile Telecommunication System) network are enough to reach a remote central server. No particular software is necessary on the PC and the images can be reached from wherever in the world. Tele-radiology is the most popular use for telemedicine and accounts for at least 50% of all telemedicine usage.

Tele-radiology can help healthcare facilities to deal with with peak workloads, ensure round-the-clock services, reduce waiting lists for specific examinations and, above all, cut costs. Tele-radiology has some specific features:

- It is currently the telemedicine service in the most advanced stage of deployment.
- It is usually (but not always) carried out as an outsourced service, on a commercial contract basis.
- The service can be offered in a national or cross-border mode involving other EU countries or third countries.
- It involves massively engineers and technologies.

The most important challenge for tele-radiology is to ensure that it develops in a manner that benefits patient care and ensures overall patient safety, and does not in any way reduce the quality of radiology services provided to the citizen. Therefore, urgent action needs to be taken to obtain legal clarity, including assurance of high quality in patient care.

1.3 Telemedicine: actual and future challenges

1.3.1 Effectiveness of telemedicine services

There is limited evidence of the effectiveness and cost-effectiveness of telemedicine services on a large scale. Awareness, confidence and acceptance by health authorities, professionals and patients still need to be strengthened.

Various studies have demonstrated benefits of telemedicine on a small scale for patients and healthcare systems. Commonly accepted methodologies for assessing effectiveness, such as those used to assess pharmaceutical products, must be further developed. Health technology assessment approach may result in a more systematic model concerning altogether effectiveness, costs and ICT technologies even if it can be difficult to put a precise monetary value on the factors that are contributing to gains in effectiveness and cost savings: fewer adverse health events; fewer prescriptions; more time spent at work or better quality of life of patients. Savings on health costs may occur in a sector other than the sector where the investments have been made. For instance, investment in tele-monitoring for chronic heart failure patients in the primary care sector may result in savings in hospitals through fewer or shorter hospital stays.

The benefits of action, as well as the full consequences of inaction, can sometimes only be observed over long periods of time and in a broad context. To obtain sustained, large-scale telemedicine programs, it will be essential for the cost of these services to be reimbursed, as shown recent US studies and publications. However, the readiness of health authorities' to reimburse certain types of these services will very much depend on the outcomes of effectiveness and cost-effectiveness studies.

Biomedical industry players do not have the financial capacity to engage alone in large-scale telemedicine trials as do pharmaceutical companies. Stronger intervention by the public sector, fully respecting the National or Community law on state aid and public procurement, seems to be necessary. Public-private partnerships can also be an instrument for the deployment of large-scale telemedicine projects.

Healthcare systems focus on meeting the needs of patients. Achieving telemedicine's potential, therefore, depends on patients being convinced of its ability to satisfy their healthcare needs. Acceptance by patients depends crucially on acceptance by the health professionals treating them, given the high degree of trust the former place in the latter. An important factor for ensuring the confidence and acceptance of health professionals is enhanced dissemination of the evidence base regarding the effectiveness of telemedicine services, their safety features and user-friendliness.

The wider deployment of telemedicine raises new ethical concerns, in particular because of the way in which the patient-doctor relationship is affected.

Privacy and security related aspects are also major components of building trust and confidence in telemedicine systems. The respect of rights and fundamental freedoms, like the fundamental rights to private life and to the protection of personal data, must be guaranteed during the collection and processing of personal data, in particular when relating to health. As any other transmission of personal health-related data, telemedicine can pose a risk to data protection right (in the sense that disclosure of a medical condition or diagnosis could adversely affect an individual's personal and professional life). Data privacy aspects should be systematically assessed whenever telemedicine services are provided.

1.3.2 Regulation and legal clearance

Although telemedicine may be an interesting option for many healthcare facilities, the lack of legal clarity is an obstacle to its wider use. The paramount objective in providing legal clarity in this area is to guarantee that telemedicine develops in such a manner that it benefits patient care while ensuring privacy and the highest standards of patient safety. The lack of legal clarity – in particular with regard to licensing, accreditation and registration of telemedicine services and professionals, liability, reimbursement, jurisdiction – is a major challenge for telemedicine and, in particular, for tele-radiology. Cross border provision of telemedicine services also require legal clarification with regard to privacy.

Only a few States in Europe have clear legal frameworks enabling telemedicine. In some Member States, for a medical act to be legally recognized as such, the physical presence of the patient and the health professional in the same place, is required; this is a clear obstacle to the use of telemedicine. Moreover, there are often limitations in law or administrative practice on reimbursement of telemedicine services.

1.3.3 Technical issues

Although some telemedicine services have existed for a long time and most of the ICT has been in place for a while, there are still areas where technical issues need to be addressed. Broadband access and the ability of providers to enable full connectivity is a prerequisite for the deployment of telemedicine. With broadband for all, telemedicine can eventually become a public good, accessible to all. Connectivity with all geographical areas in the EU, including rural and ultra-peripheral regions, is a precondition for telemedicine deployment and for universal access of all individuals to healthcare. The EU's cohesion policy supports both the broadband accessibility and the development of content, services and applications for citizens.

Interoperability and standardization in telemedicine are crucial to allow widespread use of the technologies, to enable them to benefit from the single market and to contribute to its completion. Use of existing standards and adoption of new standards and standardized approaches to achieve

interoperability should be supported by standards development organizations, with the active participation of industry in a necessary coordinated action.

Trust and confidence in new and innovative technologies and ICT-based services within the health sector need to be built through rigorous testing, agreed standards and a widely accepted certification process. To avoid market fragmentation, concerted action is needed at EU and international level to agree on a common set of specifications for these telemedicine systems and services. Such concerted actions could bring together the necessary expertise and knowledge to ensure that good quality and safe and secure telemedicine services, which are not covered by existing legislation, are available throughout the EU and member states.

1.4 Research projects in telemedicine

The next two chapters will show a general presentation of the state of the art of some national and international telemedicine research projects.

In chapter 2 some international projects - in particular in tele-radiology - realized by international teams and stakeholders are presented.

In chapter 3 some proposed telemedicine projects in which I was directly involved are reported and discussed. These projects were proposed with my participation and collaboration using ICT innovative systems for telemedicine in order to design, develop and, possibly, realize – with an all inclusive approach as described above - appropriate solutions for healthcare and in particular for the hospitals. Chapter's 3 projects may be considered the fertile and multidisciplinary scenario in which the detailed researches and results I gained and discuss in chapters 4, 5 and 6 of the present thesis have been generated and grown.

Chapter 2

Tele-radiology

Tele-radiology may be defined as the “electronic transmission of radiological images between two geographical different places with the aim to diagnose or for a consult”. At the beginning of 80’s the first tele-radiology commercial system was assembled with a camera (a video-grabber) capable to select, to digitalize and to transmit printed images [AA1]. During the 80’s the first industrial not standardized PACS (Picture Archiving and Communication Systems) systems were shipped to the market suffering lots of technical limitations (especially regarding the transmission of the images via the “networks”) and the lack of an industrial common standard [AA3].

2.1 State of the art and questions in tele-radiology

During the last decade many technical lacks disappeared thanks to an increased digitalization of radiological practices and the low network and communication costs. At that point the focus was on the quality systems for medical images, the availability of fastest networks and the utilization of better compression image algorithms. Nowadays, after the consolidation of technical standards and frameworks such as HL7 (Health Level 7), DICOM (Digital Imaging and Communications in Medicine), IHE (Integrating the Healthcare Enterprise), the problems regard the clinical governance (see chapter 1), normative (medical-legal) aspects and quality features.

Tele-radiology has several applications: it could be used to gain a second-opinion on a diagnose in cases of emergency [AA4], personnel availability or expertise consultation. But it is also of value for humanitarian operations, educational purposes or in case of geographical limitations or barriers [AA28]. In some cases as for the IRCCS “Burlo Garofolo” it was adopted in emergency, avoiding the physical presence of the available medical doctor in hospital, allowing the consult, the diagnose and the report right from the remote doctor’s house [AA31]. Other applications in study allow to connect different hospitals belonging to the same region, nation or even different countries (with different time-zones) or continents. The realization of regional PACS spread the diffusion of these kinds of services enabling effective infrastructures in terms of networks, storage and organization (cf. the Friuli Venezia-Giulia (FVG) Regional PACS project on the Italian National Observatory for the e-care projects [W6]).

Tele-radiology as telemedicine in Europe suffers of the different National Healthcare systems of the UE Countries in order to have a continental uniformity and diffusion. As shown in Chapter 1 EU Commission is making cultural and financial efforts to fill the gap [W3],[W5]. In USA there are already institutions like ATA [W1] active and operative from a longer time than the 2008 documents of UE regarding telemedicine in general. In these contest the USA situation is more homogeneous than in UE and research and experimentation of tele-radiological techniques and systems is more advanced and structured than, for example, in Italy, or between Italy and other EU countries. Both Regional or National agencies and private corporations investments are quite low in EU compared to USA, even if the EU Commission is now encouraging researchers, universities,

hospitals and industries to cooperate creating “networks” among different countries as is now highlighted in 7th European Framework (cf. [W8]) .

National and international boundaries are not the only problems regarding tele-radiology (and telemedicine in general). There are a couple of technical difficulties that must be faced to allow the circulation of images, reports, diagnoses or even consultations. By the way most of the actual PACS, RIS and HIS are compliance with a large part of international standards and regulations like DICOM, HL7 and IHE. But for telemedicine isn't enough. For telemedicine such systems must be integrated together and communicate maintaining the availability, the security (privacy) and the integrity of data and information. And this is not a quite simple task even in a Regional implementation among different hospitals or healthcare structures with the same IT provider (such in FVG Region).

In particular for tele-radiology there may be problems about the integration of clinical data concerning patients, image quality assurance during transmission, the countries' in force regulations and provisions regarding data patients, until the mechanisms of refund for the national healthcare structures to be chosen and adopted for a tele-medical service.

At last tele-radiology is not necessarily and immediately associated to lower costs. Efficient and affordable services have a high cost due to technical and organizational aspects. World trend is for e-health or tele-health but this will involve in heavy expenditure for automation and communication together with hi-tech devices and specialized personnel.

2.1.1 The all-inclusive approach in tele-radiology

An all-inclusive approach for tele-radiology presumes some points coherent to the clinical-governance assumptions [B7]:

- Care and responsibility towards the patients
- A healthcare executive model that encourages planning and communication strategies
- Risk and security management
- Staff management and performance measurement
- Education, research and professional advances
- Information management control strategies

About quality and security assurance in data and images transmission there are standardized technical rules published by the NEMA/COCIR/JIRA Security and Privacy Committee. In details there are various policies regarding: information security, network security, data security with their own practical and operational guide-lines. CIA triad (confidentiality, integrity and availability) should be respected implementing controls and systems: confidentiality using VPN networks and encrypted communications; integrity using the DICOM standard; authentication using strong and

individual username and password. Even very early implementations of research tele-radiology systems must obey to these conditions when working and moving personal data across the internet.

To encourage e-health services and initiatives EU emanated, starting from 2008, a series of Community Directives and guidelines: e-Commerce Directive, Transparency Directive, Personal Data Protection Directive, e-Privacy Directive, Recognition of Personal Qualification Directive. All the member countries might transform these Directives in National Laws within a defined range of time [W5]. To understand the importance of these Directives, for example, it is interesting to notice that in the Personal Data Protection Directive is clearly requested that data transfer should be supported by a stable and possibly consolidated (if not redundant) IT infrastructure. The referenced hospital and the tele-radiology service provider have the direct responsibility to guarantee data confidentiality and security both sides of transmission.

The same products and applications need to respect CE standards as the MD directives both for software and devices.

Following the above clinical governance criteria patient data transmission should occur via VPN connections and, possibly, HL7 messages. The “need to know” rule has to be applied for patient data access, consultation and storage. The European Society of Radiology (ESR) [W10], responding at the Communication of the EU Commission on “Telemedicine for the benefits of patients, healthcare systems and society” [B4] published a “White Paper” about tele-radiology where are described the forensic aspects of Tele-radiology.

In this document ESR specified that tele-radiology isn’t only an image tele-reporting, but instead is a real medical discipline consisting of different phases:

- assessment of an exam request
- selection of the proper images
- exam performance optimization
- image and clinical information integration in the (tele)report

ESR assures that tele-radiology success will depend by the quality of care offered to the patient in respect of “traditional” procedures.

Last but not least the Continuing Medical Education program interesting national and international radiologists (as all medical doctors and personnel) should continue, allowing for healthcare stakeholders accreditation and certification credits.

2.2 International projects in mobile tele-radiology

The international arena is moving its first steps into the world of mobile tele-radiology, i.e. the ability to receive on a smartphone or tablet radiological images for reporting or making a second opinion.

2.2.1 EU projects

In the European framework were carried out two interesting projects during the last years: MOMEDA (Mobile Medical Data) And PROMODAS (Professional Mobile Data System).

MOMEDA

Inside the hospital of Oulu, Finland, it has been installed a server MOMEDA on the intranet. In the event of a consultation the server receives DICOM image and sends them, along with patient information that is retrieved in the EPR (Electronic Patient Record), through GSM, to the mobile device. The device is equipped with an installed software similar to that used in the hospital base station with the same functionality but with smaller size. Any additional information requested are extracted from the EPR using a web browser [AA7],[AA13].

Results:

With MOMEDAS GSM terminals the picture quality was good for the diagnosis in 38% of cases and for prior consultation in the remaining 62%. The transmission time ranged between 15-20 minutes and, in particular, 20-30 minutes to read the exams for the radiology and less than 10 minutes for neurology. The reading of the MRI was over 35 minutes. The quality of diagnosis was still considered good for emergencies and then this system was adopted by the hospital of Oulu for consultation with regard to the limitations of radiology.

PROMODAS

This project can be defined as the evolution of mobile technologies seen in MOMEDA, because it uses more affordable and advanced mobile technologies such as VPN (Virtual Private Network) encryption and faster mobile networks.

The feasibility of both projects has been tested in two different evaluations by CT and MRI images sent on mobile systems. For the MOMEDA project have been used a total of 115 images while for PROMODAS 150. For each test there were created detailed reports and then compared with those drawn on a fixed MD workstation in the same hospital; in addition it has been estimated, for an overall assessment, the time required for transmission and review of images on the mobile terminal.

Results:

With the use of PROMODAS GPRS terminals transmission time is decreased to be between 5-10 minutes depending on traffic of the line. The application for viewing images remained similar but thanks to the superior performance of the new terminal the time of visualization and diagnosis was reduced to a range of 5 - 10 minutes. For diagnosis, 40% of cases was good while for consult the remaining 60%.

MTM/CHILI [AA3],[AA6]

Another European project has been named MTM (Multimedia Terminal Mobile) and is CHILI Digital Radiology software-based providing an infrastructure for tele-radiology and PACS architecture. A dedicated version of the CHILI software has been designed for a selected PDA (Personal Digital Assistant). The aim of the project MTM is the use of UMTS for wireless / mobile communication.

The purpose of the project was to develop a system for mobile tele-radiology independent from the physical station and the network wiring computers need. The software for remote mobile tele-radiology uses PDAs or pen-based computers or web-pads for wireless access to archived medical images in PACS or directly in DICOM-compatible workstation.

By means of questionnaires distributed to radiologists the basic requirements needed were the following:

- the minimum size of the images must be 256x256; in fact users have indicated a range between 256x256 and 512x512;
- displays necessitate of a lot of gray levels; the screen size is great and a large display is preferred even at the cost of a higher weight;
- any loss of quality due to compression is still tolerated even if it has visible effects;
- communication must be as fast as possible;
- a pen is preferable for the input, while the keyboard is better for long text entries;
- for developing open-source is preferred because users have indicated a willingness to develop their own applications that work normally on PCs.

The PDA hardware uses a UMTS module for wireless transmission of data. The high-speed communication is within the range of 150 kb/s and 2 Mb/s. Microphone, camera and speakers would be incorporated. IRDA interface allows the exchange of data with the PC.

The device RAM should be between 16-64 MB. The software can be downloaded and stored in a flash memory. The display can be a SVGA color LCD touch screen with a resolution of 240x320 pixels. The basic functions of the Internet should be reading and writing e-mails and browsing through a web browser. The operating system chosen was Linux. The mobile system has been used for the research study was the iPAQ Pocket PC H3600 chosen to be as the "heart" of the MTM hardware.

For the first prototype it was necessary a configuration work and the browser came out only with the next version of the device.

System functioning

A CHILI server sends DICOM images which were then displayed on the Pocket PC. The functionality of the software for viewing images are: the interactive change of the level/window controls, zoom, measure of the lengths, the ROI, the navigation in the image data sets.

The results obtained were poor and insufficient performance of the iPAQ, which makes it difficult to use; size and weight of the device were judged acceptable while quality was considered good enough for the designated scenario. The battery with a continuous use lasts 3 or 4 hours. These results have given a good drive to the improvement of these technologies.

2.2.2 A Canadian tele-radiology project

Another international project among the others comes from Canada and just in the 2011 was published a final study on the use of smartphones such as iPhone and Android for mobile tele-radiology [AA4]. The tele-radiology system developed is based on a client-server architecture that allows quick access to the interactive visualization of 2D and 3D images on new generation smartphones (iPhone and Android version 2.1 or newer) without the patient's data are saved on the mobile device.

The images are not transferred directly to the device but an image rendering is made on the server and then sent to the smartphone. The objective was to study the ability to have a certain accuracy and a sufficiently low time for the interpretation of the images to diagnose a possible acute stroke.

The radiographs were read by two neuro-radiologists: one specialist visualizes the images both on fixed workstations in controlled lighting conditions inside the hospital, and on the mobile device with normal bright office or with neon lights; the other specialist instead only on the smartphone. The connection to the server is done via secure https mode browser, while the connection is via standard Wi-Fi 802.11g, since at the time of the study the 3G mode was too inefficient. The interpretations made on mobile devices were then compared with those of the base station, the slightest difference considered to be error; the interpretation time was recorded for both locations (fixed and mobile) directly from the neuro-radiologists using a watch with stopwatch. The time for the interpretation of the images on the mobile device includes the application start, the start of the connection to the server, the selection of the study to interpret and the reading of the image. With regard to the fixed workstation the calculated time includes the selection of the study and interpretation of the image.

Results

The interpretations are not very different from the two stations. The sensitivity, specificity and accuracy in the recognition of various diseases are very high, always above 90% with the parameter of the extent of measure acceptance between 0.6 and 1.0. There is no statistically significant difference ($P < 0.5$) in the time of interpretation between the base station and mobile device.

The conclusions of this study should be generalized in the clinical utility and acceptance of these tools, especially for their use in diagnosis of cases given the limited number of cases studied (120 and 70) and the number of neuro-radiologists involved (2).

Chapter 3

ICT systems and solutions in telemedicine for the hospitals

The major role of a biomedical engineer in a hospital must concern at least the knowledge of the continuous achievements regarding the technology and the capability to propose and support research topics and possibly to gain funds [A12]. The particular configuration of some hospitals such the IRCCS, which is a scientific institute carrying out biomedical research and clinical activities of national interest, encourages biomedical (and clinical) engineers to realize and participate in both clinical and research activities. IRCCSs represent scientific centers in which biomedical engineers can support all clinical research and researchers, and propose some specific research projects with national or international relevance. Some of these projects may lead to some advances and innovative products in main topics such as telemedicine, IT security, signal and data analysis, web-based software development and implementation, IT infrastructure enhancements, clinical engineering and health technology assessment.

In this chapter the telemedicine projects in which I was directly involved are discussed. Here the ICT innovative systems and methods studied and proposed for telemedicine are presented in order to design, develop and, possibly, realize relevant solutions for the hospitals. According to national and international scientific literature, some of these projects may be considered as the actual state of the art of telemedicine in tele-radiology, internet hospital web-portals and intranet services. They also, as will be discussed in next chapters, may represent the proposed solutions to some of the telemedicine challenges both in clinical and technical issues thanks to the use of information and communication technologies.

In the next three chapters there will be presented the studies conducted in some of these scientific and technical topics regarding telemedicine, reporting the most significant and interesting results and achievements both in terms of scientific research and – eventually - innovative products or services.

The support to all of these projects and to the correlated research programs has been guaranteed by a continuous develop of competencies and by learning the methods and the tools needed to accomplish the different requirements. The focus has been targeted especially on:

- low cost but effective tools such as open-source technologies and systems;
- in-house development of competencies and skills;
- scientific and partnership collaborations with academic, local and even commercial partners interested in promoting and supporting the healthcare processes.

Finally the design and implementation of solutions and services have been focused, starting from the scientific literature and achievements, on the real needs of the “customers” (medical doctors,

researchers, audience-patients, hospital executives), keeping in mind the importance of the continuous innovation process regarding the healthcare.

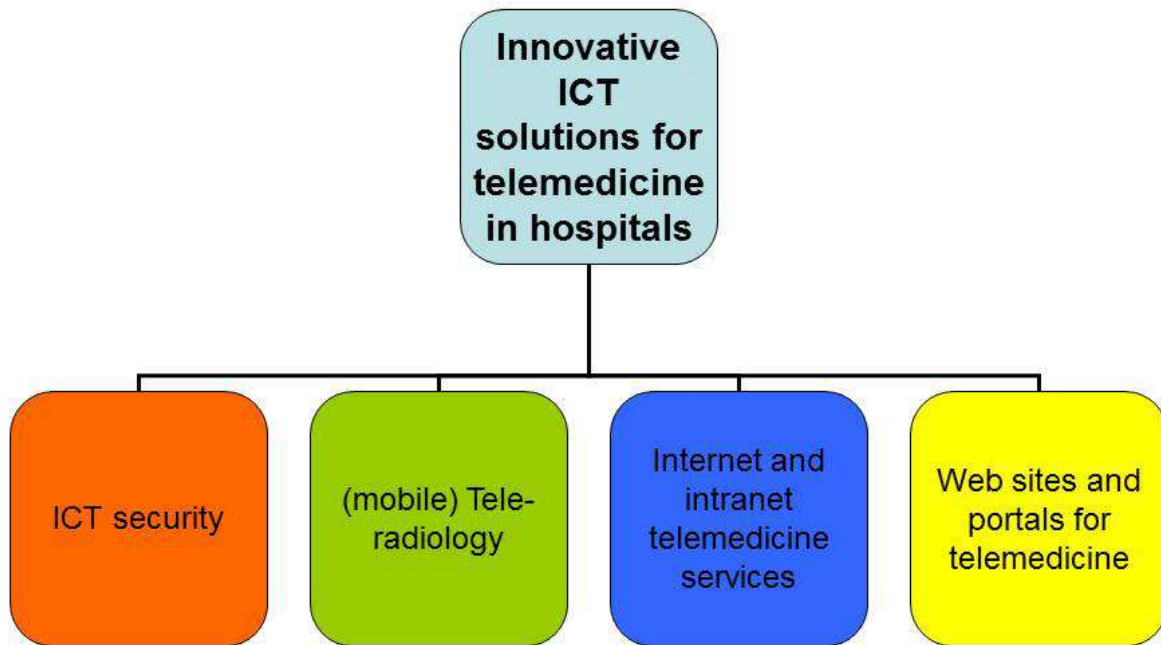


figure 1 – the topics of this thesis

3.1 Web sites and portals for telemedicine

As shown in chapter 1 EU Community does not consider web-portals as a telemedicine topics, but the Commission document consider this as a necessary reduction of the adopted definition. All across Europe and USA patients and medical professionals demand for tele-healthcare (e-health) services as shown in the first two chapter of this thesis. There are EU initiatives and Community programs to promote and invest in the realization of e-health services to spread telemedicine procedures, competences and solutions as to reach the most part of citizens.

Web-portals and sites are considered some of primary drives to offer telemedicine solutions starting from the computerization of some common services as external patient reservation of a visit, or the consult of a laboratory report or a radiological exam. Scientific research in such topics regard especially the creation of service portals for the third world collaborations or co-operations programs, or the creation of international networks for the transmission of data and information in order to enhance the quality of care. In the same way regional or local scientific programs started to

study the realization of services in order to match and maintain the quality of care standards and to enlarge the audience capable to use them.

In particular, as it will be described in chapter 4, starting from a previously internally-developed web site and assessing the needs in particular of the Medical and Scientific Directions, it was proposed the re-definition of an IRCCS web site [A1]. The IRCCS “Burlo Garofolo” is a maternal and child health hospital which supports ICT development since 1998, when it became one of the first Italian hospitals with an internally-developed web site.

To accomplish some innovative telemedicine suggestions regarding both patients and professionals it was proposed to provide the web site with all the modern technologies and advances to allow the external patient reservation, the creation of web forms for the researchers involved in international or multicentric studies, the implementation of telemedicine services for regional ultrasound tele-consultation, the construction of a content management system [A6]. Afterwards, inspired by the same objectives, the portal was enriched and further developed according to the web 2.0 and of the social networking [A4],[A8],[AC1].

3.2 Internet and intranet telemedicine services

Moved by the same telemedicine principles and supported by the web site development, some specific applications and computer based programs have been realized in order to satisfy specific needs. In particular a system for the evaluation of healthcare executives and researchers [A10],[A11] and a web-based TPN (Total Parenteral Nutrition) prescription [A9] have been studied and then implemented, respectively, to improve the management awareness and skills and to guarantee the correct prescription preparation to reduce typical errors occurring in common paper-based prescriptions.

The genesis of these type of services was different but aimed at the same scope: the study of a novel model capable to enhance some clinical and evaluation procedures or processes, keeping in mind the so called “social turning point” and the healthcare certification process (ISO or Joint Commission International standards). The solutions adopted or implemented were designed with this new “interactive” or “peer” model in mind. People can change and modify the way they access the web services choosing what they want or need and discarding what is unimportant. In the same way, as will be shown in chapter 5, medical doctor and pharmacist may interact about a TPN prescription from different wards without moving paper and themselves; evaluator and evaluated professional may interact about the negotiable part of an evaluation sheet, obliging them only to a face-to-face confront for the final score and giving to the evaluated professional great possibilities to promote himself compiling the different sheets of the digital evaluation program.

Last but not least all these “social” and interactive services are realized in an intranet corporative web portal [A3], designed and developed to accomplish the management and communication of corporate documentation according to ISO 9001:2000 certification process.

3.3 IT security and technical infrastructure

IT security topics [B12] are complementary to all telemedicine services. As underlined in the EU Commission Document [B4] and according to the *D.Lgs. 196/03* privacy and security are fundamental to assure a correct design and realization of telemedicine services and solutions. The communication of data and images through the internet needs to know the solutions and the advances to face security and privacy issues, allowing to telemedicine services an affordable infrastructure.

In particular the information “movement” from hospitals to territory following the patients that need telemedicine treatments, force the hospital IT to develop and maintain a network infrastructure affordable and secure both for data integrity and availability. Most of these services need to be fully designed and realized from zero through an experimental time or period, in collaboration with the hospital, the ICT service provider, the clinicians and the patients. To design and realize cheap and affordable telemedicine research projects it is necessary to know national and international standards (like ISO 27001), laws and directives regarding both technical, organizational and risk management aspects.

The next three chapter telemedicine solutions, in different but connected ICT issues, have in common the basic realization of a single technical and organizational infrastructure, done by mean of an IT risk evaluation/assessment process based on the ISO 27001 standard [A7],[A13], and in particular on the writing and editing of the Hospital Corporate Security Plan Document. The ISO 27001 states the requirements of an information security management system (ISMS), and according to this normative a technological and an organizational infrastructure has been created to satisfy the requested requirements. In particular and in terms of study and development a network management system has been implemented to manage all the critical systems and services running on hospital telemedicine servers and network systems (LAN switches and routers). In addition an hospital internal IT regulation cyclically revised has been written according to the Plan-Do-Check-Act model and the ISO 9001:2000 requirements.

In the next sub-sections of this paragraph a brief description of the studied and then proposed IT security solutions is reported according to the national, international and scientific literature and congresses [A7].

3.3.1 The information security plan

Among the standardized approaches for the creation of an IT security model, the ISO 27001:2005 is considered the most suitable for already ISO certified organizations. IRCCSs from 2003 were obliged to certify themselves ISO 9001:2000 so, in order to introduce an IT security model in a hospital like an IRCCS, the ISO 27001 was primarily considered. To realize an IT security model each organization has to develop an Information Security Management System (ISMS) that describes how the organization faces and solves the needs for protection. An ISMS (the so called Security Plan Document for the N°196/2003 Italian Legislation) identifies and organizes the security tasks of the company and is an official registration of the current protection practices. It

represents a description of the current situation and also a development project to improve and consolidate IT security. The plan informs employees, and possibly the control authorities, of any measures that are taken to maintain security at the levels specified by International Standards and current Regulation. There are seven steps that a good security plan must take into account [A7]:

- Defining the objectives to be achieved
- Giving the “snapshot” of the current state
- Suggesting the solutions to be adopted
- Recommending appropriate controls
- Liability
- Training
- Paying close and continuous attention

The methodological approach in creating an ISMS may be structured in: drafting security policies; asset identification; risk analysis; evaluation and treatment of risks; review and reassessment of risks; PDCA model; use of procedures and tools such as internal audits, non-conformity, corrective and preventive actions; monitoring, with continuous improvement.

In particular the PDCA model of an ISMS (Information Security Management System) may be described as:

1. Plan: assessment of information security risks and selection of appropriate controls;
2. Do: implementation of chosen controls (hardware and software);
3. Check: detection and assessment of the ISMS' actual performances (effectiveness and efficiency);
4. Act: implementation of those changes necessary to bring the system into the desired state (maintenance and improvement of the ISMS).

As all processes-like approaches PDCA is a cyclical process that must include updates, changes, additions of new projects and continue auditing (new vulnerabilities, new techniques, new best practices, changes in assets, platforms, configurations, etc..).

The general purpose of the Security Plan for a healthcare organization such as an hospital, is the protection of information relevant to clinical, administrative and research activities. Moreover the plan has been prepared to monitor and enhance the security of the technological resources owned and the telemedicine services the hospital offers. Finally, the plan should help the organization to prevent problems, reduce their impact and to restore in an effective and efficient way what it was, in case, compromised.

3.3.2 Information risk analysis

Risk analysis [B13] is the key component in the determination of those controls necessary to build an effective security system. The usual approach is to identify potential impacts deriving from the unavailability, loss of integrity, malicious intrusions and the economic damage resulting from such threats.

This analysis must be performed on the internal and on the surrounding environment, trying to make a picture of security. From a detailed level of this analysis we can then take all those actions to protect, leading to a process of continuous improvement and hardening.

It has been said that a risk is a potential problem that could affect a system in its resources (natural, economic, human), so the ICT risk analysis, and specifically that related to IT security, may adopt well established methodologies applied in other fields such as system engineering or clinical engineering.

The risk analysis qualitative model adopted for the hospital was the following:

- identification of resources (to be protected or not);
- determining vulnerability (of the discovered resources);
- estimation of the probability that an event occurs & estimation of the probability that the event is exploited;
- calculation of the loss associated (risk impact);
- identification of controls to be acquired and their cost (risk control);
- estimation of the savings due to the adopted controls;

Based on these steps it was chosen to do a risk analysis that:

- involves people, resources (hardware, software, systems, etc), data, information, but also structures, facilities, procedures, training, etc;
- requires an assessment of vulnerability at multiple levels (for example, simply listing all those relating to a possible block of the system);
- includes estimates of possible leaks and their exploitation by the attackers;
- stresses in determining the probable loss due to an exploit or a system crash;
- helps, through technical objective, the choice of remedies to reduce or cancel the effect of a threat (damage);
- offers tools for estimating the effectiveness of the actions that have been made;

This method shows as the design of an IT Security plan in healthcare is not different from what has already been done successfully elsewhere.

The following is a list [A5] of the general adopted controls with the detail of the requirements that each control should front and manage. The listed vulnerabilities all regard telemedicine services, and need to be considered in developing such projects from the earlier state.

Vulnerability	Requirements to be met	Measures: controls / procedures
Logical	<ol style="list-style-type: none"> 1. Need for policies 2. Implementation of security procedures 3. Use of monitoring software and systems 4. Logs and reports 5. Backup systems 	<p>Hospital IT Regulation</p> <p>Groundwork NMS</p> <p>Desktop Management</p> <p>Network and server hardening (eg. domain)</p> <p>Network management tools (free-radius, 802.1x)</p>
Infrastructural	<ol style="list-style-type: none"> 1. Heterogeneous computers fleet management 2. more user activity control 3. more user program installation control 4. Roles separation 5. Data and backup separation 	<p>Desktop management</p> <p>Hospital IT regulation</p> <p>New network architecture (2009)</p> <p>Technological updating</p> <p>VLAN implementation (2009)</p> <p>Firewall</p> <p>Free-radius and 802.1x</p>
Concerning Services	<ol style="list-style-type: none"> 1. Disaster Recovery plan 2. More efficient troubleshooting 3. More network services and application control 4. More email security 5. Inefficiency detection 	<p>Hospital IT regulation</p> <p>Groundwork NMS</p> <p>Moving mail server from external to internal management</p> <p>Certified email (2009)</p>
Organizational	<ol style="list-style-type: none"> 1. Security budget and resources 2. Compliance with standards 3. Compliance with actual Regulation 	<p>Hospital IT regulation</p> <p>Certification</p> <p>Awareness</p> <p>Training</p> <p>IT Security plan</p>

table1 – analysis of vulnerabilities and the adopted controls/procedures to face them

3.3.3 Conclusion

This section showed how a modern hospital must develop and maintain an high level of awareness concerning the IT security problems and challenges, especially regarding the management of complex systems such telemedicine ones.

IT security is a technological and organizational problem and regards at the same time awareness and training of the whole corporative employees and managers.

Hospitals manage patient data and information to guarantee the higher quality of care. Medical personnel must operate using more and more sophisticated clinical information systems capable and suitable to assure effectiveness and efficiency of the healthcare processes. It is also necessary to preserve and to protect clinical data and information in order to assure the requirements stated above. To accomplish these objectives IT security assessment of data, information and systems involved in the complex care giving process is essential and may not be avoided or even deferred.

The pressing need for the creation of an IT security plan or of an ISMS taking in account especially the necessities of the healthcare processes and practices is moving even the ISO to propose the next (but still not defined) ISO 27799:2008 regarding Health Informatics and the ISM in health using ISO/IEC 27002.

In advance to the next proposals of the ISO, in this brief description is showed how to put in practice in an operative way the actual IT security knowledge, policies and standards to create a hospital IT security plan and a related management system to assess actual and next healthcare information security challenges.

3.4 Tele-radiology at home

Tele-radiology projects in collaboration with the IRCCS “Burlo Garofolo” maternal and child health hospital started in 2007. From 2004 the IRCCS’s radiological ward adopted a PACS, moving from a manual and “on paper” medical report to a digital one. After the subsequent consolidation of the PACS and the integration with the Regional RIS already used for scheduling reservations and appointments, emerged the need to allow radiologists to compose medical reports outside of the hospital directly from their houses [A2],[AA31]. This decision was taken for at least two reasons: the radiologist staff availability during nights and week-ends especially in cases of pediatric emergency; the difficulties caused by the reduced personnel in turn during the recent couple of years.

One of the requirements of the project was to achieve at home the same standard levels as at the hospital. To accomplish this requirement it was decided to present a research project joint with information and communication industrial partners (Ebit-Esaote S.P.A.; Insiel S.P.A.) and IRCCS’s Clinical Engineering and Information System unity to study and realize an infrastructure capable to guarantee an equivalent level as the “gold standard” assured by the CE medical device PACS equipped with the CE medical workstations used in hospital. As shown in figure 2 it was planned to

equip medical doctors' houses with MD workstations and monitors, the PACS review application with the already integrated RIS program, and the use of the digital sign to allow diagnose and the complete report of the emergency cases submitted.

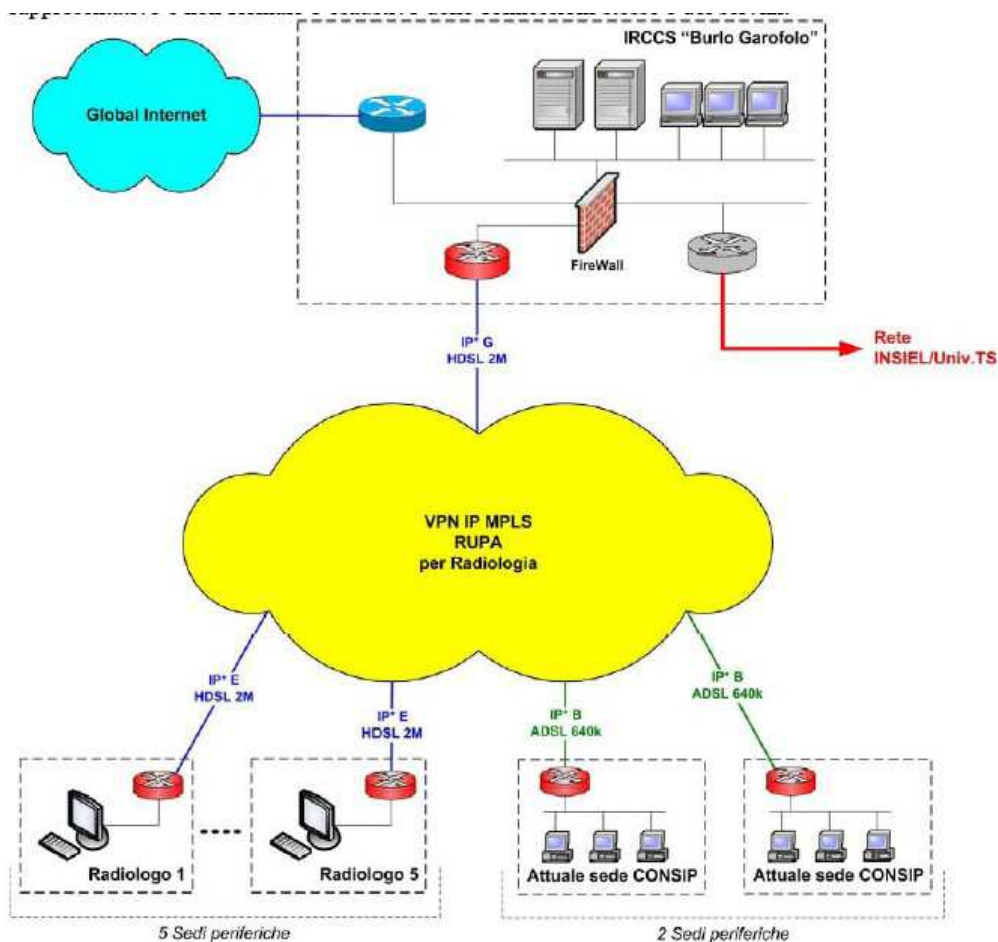


figure 2 – home tele-radiology infrastructure

Network architecture using MPLS VPN encrypted connections was configured as the workstations were on the hospital LAN with all the benefits and protection of the LAN personal computers (patch management, firewall, corporate antivirus, authenticated domain access) allowing, for example, also the printing of the digitally signed reports directly on the radiological ward printer.

For the research project's draft it has been followed scrupulously the SIRM document about Tele-radiology (2004) and the ACR docs [B6],[B8] concerning tele-radiology and the emergency management. The project has been completed and concluded in 2006 and is now operative and still working giving to the radiologists, with no costs and eventually little building adjustments, great advantages during availability periods with no drawbacks for the clinical quality of care.



figure 3 – actual implemented home tele-radiology workstation

3.5 From home to mobile?

In 2009 the tele-radiology collaboration with IRCCS “Burlo Garofolo” moved towards the possibility to research and develop methods and applications for tele-reporting and tele-consultation using tablets, smartphones and netbooks. The Italian Public “*Ricerca Corrente*” “*Teleconsulenza TC and RM mobile mediante l’utilizzo di netbook e telefono cellulare con tecnologia avanzata e connessione internet sicura*” project was proposed in collaboration with the IRCCS “Burlo Garofolo” Clinical Engineering and Information System unities, the Department of Electronics, Informatics and Communications of the University of Trieste, the MEDIKO s.r.l., Esaote S.P.A. and Aycan s.r.l. companies and the IST, Institute of Technologies of Bolzano, Italy.

The objective [AA27],[AA30] was to study the feasibility of tele-consult and possibly tele-report RM and TC images directly on smartphones, examining limitations and providing technical guarantees and medical approval. Keywords of this project were the use of low-medium cost commercial technologies and infrastructures, and mobility.

Last generation smartphones (and then tablets) and netbooks provided with usb pen drive or dedicated circuitry for UMTS wide band communications were all devices disposable for an experimentation, both technical and clinical. The research project started and some adopted methods and results are part of the present study and will be presented in chapter 6. It is worthy to be noted that a mini-PACS was implemented to support the transmission and the communication of the small-matrix RM and CT images, together with the use of dedicated encrypted VPNs (and VPN clients for the smartphones) created to reach a DMZ with an external access to the GARR (the Italian Network for the Scientific Research) network. To assess the clinical performance quality it was chosen to compare the image visualization and the final clinical report on these portable devices with the same images and reports shown on PACS workstations in radiological ward assumed as the “gold standard”. Small matrix (512x512) images were chosen for the display resolution compatibility with smartphones and tablets, in order to reduce artifacts, loss of quality and distortions.

During the first steps of the project besides the mini-PACS derived from the commercial PACS already in production for the radiology ward, it was used and configured the open-source version of

Osirix on the different clients tested. In this way all the RM and TC worklists could be transmitted from the mini-PACS right to the tablet or smartphone client in a DICOM format, allowing the radiologist to fully change, adjust or change parameters such as the windows level (WL) or the window width (WW) to obtain better visual conditions and responses. To guarantee the results obtained for the diagnose and tele-report of the submitted image sets, it was chosen to send to the mobile devices casual and made anonymous previously reported –by the same medical doctor and using the PACS “gold standard”- RM or TC studies.

3.6 Innovative technologies and systems for mobile tele-radiology

Anticipating what will be discussed in chapter 6 about the proposed methods and the obtained results regarding mobile tele-radiology, some research project on mobile tele-radiology have being presented using the same telemedicine framework and infrastructure shown in this chapter for other research projects.

3.6.1 Tablets for tele-radiology

In particular talking about the proposed “*Visualizzazione in real-time di immagini radiologiche su dispositiva tablet per consulenza specialistica ortopedica e neonatologica*” the use of tablet as innovative and emerging technologies for medical applications will be discussed now.

The objective of the project is giving to the senior medical doctors of a Neonatal and/or Orthopedic ward the possibility to visualize on iPad and/or Android tablets in real-time the images generated in the radiology ward PACS 24/7. Each Android or iPad tablet is actually equipped with a DICOM ready app capable to receive and visualize the appropriate and selected images sets as in hospital, via a wireless network or through a secure UMTS/3G broadband connection via secure web applications and protocols. Both the orthopedic and neonatal ward would benefit from the use of these systems and devices in terms of the medical doctors availability, patient quality of care, problematic or emergency taking care timings and regional or wide area visibility as a “HUB” and provider of high level tele-consult or 2nd opinion services.



figure 4 – iPad and Samsung Galaxy tablets

Two different typologies of tablets will be used covering the market offer (and even if with different –sometimes evident- technical specs – cf. chapter 6) :

- Apple iPad (1 and 2) with 10” display capable to communicate with a PACS system through a modified version of Osirix Pro program. This modified version developed by Aycan s.r.l. receives the exams directly in Osirix from the PACS and allows the transfer to the tablet simply via a drag-and-drop operation on screen, choosing both the exams and the device which to send data. Osirix Pro is certified as a medical device software and also the iPad application is labeled Medical Device Class I and responds also to the Apple document “iPad in Business – Security Overview” for security topics.
- Android tablets possibly equipped with 7” and 10” displays are used because of the broad market diffusion. In collaboration with IST of Bolzano and MEDIKO s.r.l. an app called DicomDroid (now available on Android market) has been specifically developed and tested with the IRCCS “Burlo Garofolo” Information System and Radiology ward in order to transmit and visualize PACS images directly on Android mobile devices. Using the same Osirix Pro system as for iPad application, each Android tablet or smartphone has a configured VPN capable to connect to the Osirix Pro server and negotiate the secure transmission of selected patient data and images. The mobile interface download the different modalities worklists and the operator may select the exams and visualize DICOM format images on the tablet or smartphone.

The choice to support both systems is motivated by at least three arguments:

- The important market share of both solutions: developing or publishing apps for Android and Apple it is possible to cover almost all the market. Now, during these last days, has been released an app also for Windows Phone platform.
- The different technological solutions proposed for tablet hardware and in particular displays could be analyzed and studied showing differences and possible advantages of a platform (or hardware implementation and solution) in respect of the other. A comparison among different tablets, vendors, display and ergonomic specs based on selected quality protocols, in particular regarding the fruition in a clinical and diagnostic contest and the correct

visualization of medical images could be a welcome proposal in order to identify limits and possibilities for these promising technologies (see chapter 6);

- Apple platform is a (very) “closed” system while Android platform is an “open” one. This can do the difference for a young developer or a small company (or even a research study) in order to design, realize and implement their own solutions.

From the clinical side of the research project there will be considered some markers to evaluate the quality and the effective utility of using tablets for neonatal and orthopedic studies: a temporal marker for the response time since the exam has sent to the senior medical doctor’s tablet; a device marker for the comparison of the usability, ease of use, quality of perceived images related to the different used tablets for the tele-consult of each exam received.

3.7 A.Dop.T. – Anti Doping Teleconsulting

In Appendix B there can be found the executive summary of a tele-consulting project proposed and selected for the Regional FVG “Start Cup” Finals 2009. The innovative project is based on a pharmaceutical database interactive service designed to be queried by cellular phone or smartphone via short message system with the aim to provide to athletes and subjects involved in sports (coaches, physicians, trainers) a new information reference tool, fast, easy to access in order to check whenever they want if a medication is forbidden or not. A.Dop.T. project was presented as a business plan for the creation of a “Spin-Off” or an IT/healthcare small firm.

3.8 Tele-presence and tele-monitoring

3.8.1 HUB-SPOKE model for ultrasound tele-consult

During 2010 another draft of a telemedicine project has been presented in collaboration with CRS4 research Center in Cagliari, Italy and IRCCS “Burlo Garofolo” hospital. The project called “*Teleconsulenza ecografica ostetrica di III livello mediante l’uso di tecnologie COTS (Commercial Off The Shelf)*” was proposed to give a decision support in treating patients to a I-II level obstetrical center without moving the patient. The aim of the study was to demonstrate the feasibility of a low cost “live” connection for an obstetrical tele-consult on ultrasound diagnostic examinations between two healthcare structures or wards. The first structure acts as a HUB, the excellence center, while the other serves as SPOKE. There could be a single HUB capable of communicates and have relations with different SPOKES, and this is a valid model in cases of a regional or national excellence center capable to deliver high level specialist clinical services. Based on this model the project attempted to accomplish at least two more objectives:

- an educational value represented by the know-how transfer via an A/V connection between a skilled senior operator and a junior or less skilled one;

- a clinical value in cases of emergency using a “live” tele-consult audio/video session in which the senior professional can guide the junior one to accomplish the exam in the best way helping the colleague to move and position the probe as correct as possible.

Following analogous cases found and documented in literature, the system should use a secure connection for the transmission of two video streaming: the first streaming is the output of the ultrasound system due to the probe position (the same viewed by the ultrasonographer on the ultrasound display); the second streaming comes from an ip (or wireless) HD video camera positioned in such a way to show “live” the entire area of the exam and specifically the patient zone. The two streams are transmitted in real time and through a specific encoder and a dedicated secure network are showed together on a web browser. Some of the evaluation parameters of the feasibility of the project have been identified in:

- the homogeneity, frame rate and quality of the transmitted images and videos;
- the quality and the security of the connection between the healthcare structures involved (some tests have been realized in the same hospital between different wards but on the same LAN – see figure 5 below)
- the availability and time response of the III level hospital medical staff for the tele-consult request (especially in emergency or during the night or the week-ends)
- the need to repeat the entire exam in the III level healthcare hospital because of to the difficulty to recognize or to diagnose correctly on the images or videos received from the remote center
- patient satisfaction (apart of privacy awareness and consensus authorizations obligatory for each tele-exam taken)
- creating a technology infrastructure that connects two pilot centers spokes in FVG Region (AO Pordenone, Monfalcone ASS2 Hospital / Hospital of Gorizia) for tele-ultrasound consultation with specialist remote central hub.

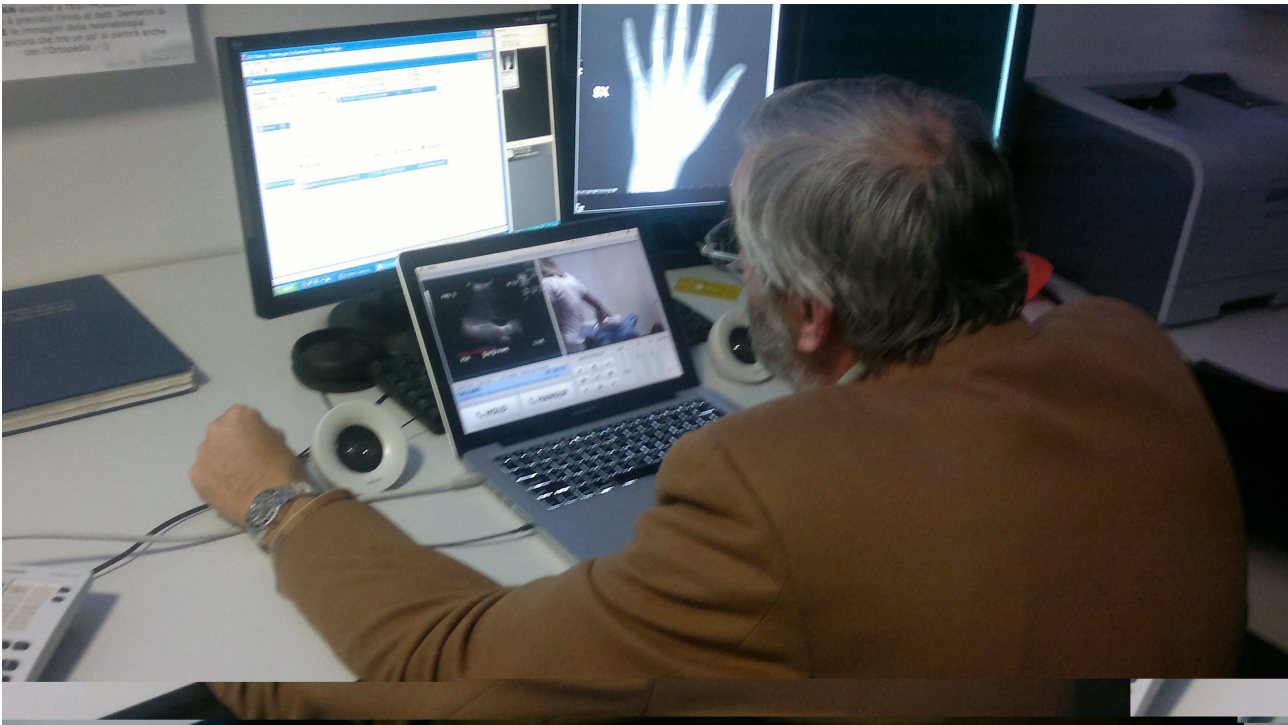


figure 5 – a “live” ultrasound tele-consult

3.8.2 Innovative devices for tele-monitoring

The second project regarding the tele-monitoring of possible at risk pregnancy women is based on a modified HUB/SPOKE model trying to reduce the hospitalization of these women taking care of them thanks to a remote connection and transmission of tocographic traces and clinical data. The IRCCS “Burlo Garofolo” obstetrical department deals with a considerable amount of women coming from outside the metropolitan territory, especially from Friuli Venezia-Giulia Region so far. In a at risk pregnancy could be dangerous (apart the costs for the patients) to move the women until the birth but only in emergency.

Clinically, the activation of such a project is aimed to increase both the appropriateness and effectiveness of treatments provided to the women, pushing up the quality of system performance. The structured information sharing, with a view on the regional registry office and consequently an easy and quick access to patient information, is the operational tool that allows to pursue two objectives.

Technological objectives:

- implement a register of patients involved in the basic project integrated with the existing regional registry
- create a technological infrastructure for tele-home monitoring by means of 20 tablet-pcs connected in real-time with portable and easy-to-use toco and fetal-ECGs, equipped with video conferencing and messaging features, and finally designed to be used by pregnant women at average risk pregnancy belonging to the province of Trieste

Organizational and socio-sanitary objectives:

- An organizational / community health goal is to reduce physical access to the IRCCS “Burlo Garofolo” of women with pregnancies at medium risk requesting a specialist ultrasound consult and thereby reduce premature / unnecessary hospitalization.
- The proposed solution is the creation of a telemedicine platform that will be implemented on a server system to be installed at the IRCCS “Burlo Garofolo” in collaboration with the Information System service.
- Any opportunity to lean to the regional registry system would allow a very flexible system right now, favoring the treatment of patients and pregnant women without limitations related to the location of the various hospitals, districts, houses. The system itself must also insist on the Hermes regional healthcare network to ensure an effective and secure exchange of data and information between the HUB and SPOKE connected to the same network. The data must travel up channels of communications protected by encryption and authentication systems. The web pages should be secured using https, ssl, accessible via tokens or smart cards valid through certificates.

Chapter 4

Innovative methods and solutions for telemedicine oriented web portals

4.1 A hospital web portal for telemedicine

The studies conducted in order to realize some telemedicine services and solutions through the use of ICT technologies in a hospital, lead to a series of steps aimed to the re-design and development of a new web site. The impact of ICT in all healthcare structures was more evident in dealing with web portals and intranet services simply because they are services people initiated to use more and more. As for home or remote banking or internet e-commerce and transactions even the hospital may offer services to their clients – the patients or other professionals – allowing them to visualize information about their healthcare or giving opportunities of on-line visit booking or downloading clinical documentation.

For their primary role in treating patients and clinical diseases hospitals are the most suitable structures which may gain advantage in an computerization process. Worldwide research studies demonstrate the importance of relevant clinical data communication and transmission between patients and the hospitals, and the possibility to make use of advanced health telematics services.

Starting from this wide context it was proposed to “upgrade” a hospital web site in order to offer services to the users, the medical doctors involved in telemedicine and the researchers (medical doctors, biologists, psychologists, epidemiologists) both from university and hospital units [A1],[A6].

ICT technologies allow the use of development platforms (LAMP) and programming languages (PHP) enabling the creation of contents suitable both for the common people and the professionals, or the portal’s administrators. These technologies are open-source and in order to reduce development and maintaining costs the portal was developed by a hospital internal team of professionals and is housed in a dedicated hospital-based server. All the services described below were realized using the LAMP open-source technology, programming the CMS and the interface between forms and database using the PHP language.

4.1.1 Web-portal characteristics and requirements

Keeping in mind an open user oriented design, the requirements of a modern hospital web portal have been summarized in:

- an easy to use and clear home page allowing to reach all the services for the users (i.e. appointments for specialty and private medical visits can be scheduled by compiling an on-line form).

- an account controlled access to a “professional” virtual area page for the clinical professionals and the researchers (i.e. housing data gathering services for research projects or studies).
- the availability of telemedicine services (i.e. services accessible using a required account by which medical doctors could ask a consult related to obstetric ultrasound images).
- the presence of a CMS to create and manage the contents inside the pages of the hospital web site.

4.1.2 Methods, development and results

In order to accomplish these objectives the LAMP open source technology and the use of a new sophisticated hospital-hosted server were chosen. An internal technical group dedicated to the design, the implementation and the updating of the platform was formed.

The operating system used was Linux Debian 4.0 Stable, which was developed and maintained by the open source community and by a pool of Debian developers. The OS license is the GPL-GNU. Apache 2.0 was the web server used for the portal; it was developed and sponsored by Apache Software Foundation both as source code and binary code. The database server was MySQL 5.1 developed by MySQL AB, and PHP 4.4 was used as the server side scripting language.

The first step of the technical group was to replace the old static web site with a new one using the MySQL database and the PHP engine to visualize the web pages. At this step the contents of the old web site were merely duplicated.

At the same time it was developed a new interface (the CMS) to update the web pages, instead of using the old-site Dreamweaver or only HTML interface to modify the pages, and to upload the contents.

Support for the clinical research

The portal houses three databases for scientific data gathering related to three research projects: a) a cohort study; b) the IGARIS study concerning children with gastro-esophageal reflux and early milk allergy; c) a study regarding atypical uterine polyps in women.

i) Cohort study

In 2007 the IRCCS “Burlo Garofolo”, with the co-operation of the University of Udine, started a cohort study to follow a population of mothers and children from the first months of the pregnancy, sampling biological, health and social information. The longitudinal study is composed by five different research projects: PHIME, VIVE, PAPP, OXI, *Alimentazione*. To avoid medical doctors and information physical movement it was proposed to computerize the studies creating the different databases and web-forms. The solution proposed solved IT and personal data security issues too.

According to the needs described above, it was studied with medical doctors and developed a database and then a related PHP form to allow the data entry of clinical and biological information. Every research group involved in the projects is allowed to edit or to view the database fields via the form, and the access to the web pages is protected by https protocol. The actual web form is shown in figure 6.

The screenshot displays a web browser window with the title 'IRCCS Burlo Garofolo - DB registro VR'. The address bar shows the URL 'https://www.burlo.trieste.it/registro_vr?LOC=RIC&DEL=1'. The browser interface includes a search bar, navigation buttons, and a toolbar. The main content area features a header with the 'BURLO' logo and navigation tabs: 'Inserisci scheda', 'Lista schede', and 'Esporta'. A user greeting 'Buongiorno dottor Liza Vecchi' is visible in the top right. Below the header, the page is titled 'Scheda registro' and contains a form for data entry. The form is organized into two columns. The left column lists various fields for data entry, such as 'Progressivo', 'Cod.fisc', 'Cod.papp', 'Cod.oxi', 'Cod.phime', 'Nome', 'Cognome', 'Via', 'Città', 'CAP', 'Tel.1', 'Tel.2', 'Tel.3', 'EG reclutamento', 'Data reclutamento', 'Data presunta parto', 'Data controllo 12 settimana', 'Data controllo 16 settimana', 'Data controllo 20 settimana', 'Data controllo 30 settimana', and 'Arruolamento pap', 'Arruolamento oxi', 'Arruolamento phime', and 'Arruolamento viva'. The right column contains corresponding input fields, including text boxes, date pickers (format: gg/mm/aaaa), and radio button groups for 'si' and 'no' options. The browser's taskbar at the bottom shows the Start button, several open applications, and the system clock displaying 15:56.

figure 6 – cohort study web form

ii) *IGARIS project*

The IGARIS (Iatrogenic Ghost Allergy and Reflux Infant Syndrome) project, addressed to the Friuli Venezia-Giulia pediatricians, analyzes the possibility of causing/sustaining food aversion by means of repeated medical interventions, especially imposing unjustified restricted diets and/or “over-diagnosing” gastro-esophageal reflux. To record the IGARIS patients coming from the Friuli Venezia-Giulia region, and in the near future from other Italian pediatric structures, a database and a related web form have been designed and implemented to monitor the clinical behavior of the involved pediatricians towards the problems of the affected babies. Two masks have been implemented for reporting the gastro-esophageal and the milk intolerance disorders.

To access the forms it is necessary to be a pediatrician and to request the credentials from the hospital Information System Unit.

iii) *Multi-center study of atypical uterine polyps in women*

This study started in 2008 and regards the conservative medical treatment of atypical uterine polyps in women monitored during five years, and eventually surgically operated.

A database has been developed to archive the patients’ clinical data and to follow the patients from different and previously authorized Italian health centers.

Ultrasound web tele-consult

In 2006 the creation of a Virtual Regional Department provided with telemedicine services such as radiological tele-consult and transmission of cardiologic diagrams, was proposed to respond to the needs of exchanging information and data patients through a unique and secure (using https protocols). In order to accomplish this aim and to expedite and secure the sending of ultrasound images and interpretation from the ultrasonographers to other specialists, it was realized a tele-consult system reachable through the hospital web portal.

Using this system the obstetrical ultrasonographers from Regional Hospitals and Health-Districts are provided with telemedicine services accessible using a required account by which they could ask IRCCS's specialists for a consult related to ultrasound images of foetal malformations.

Together with image acquisition the applicants fill in a web-form especially designed to support the diagnosis of a large variety of prenatal diseases regarding the digestive system, the central nervous system and the kidneys. To improve the communication of relevant clinical information the specialists can start a thread, in which they communicate as in a private forum or in a blog (see figure 7).

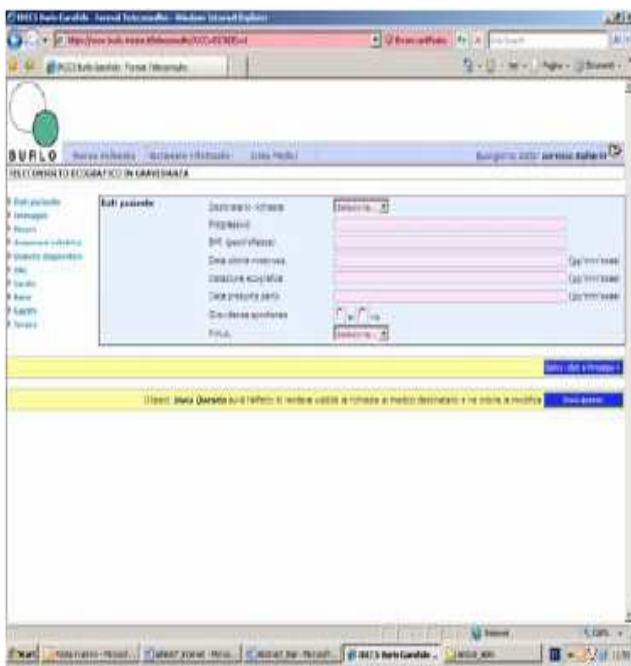


figure 7 - ultrasound tele-consult web-form

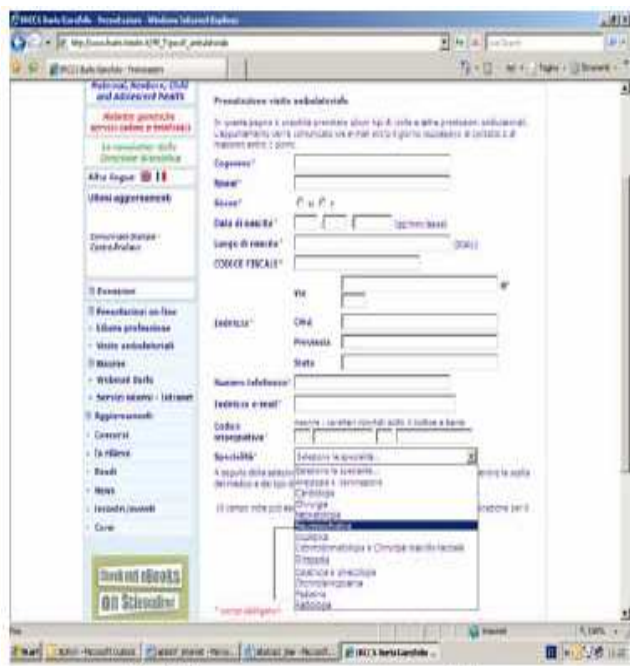


figure 8 – outpatient appointment web-form

Public health services for the users

This was one of the most advanced features of the site giving the possibility to make some specialist and outpatient appointments using a PHP form (figure 8). This feature was very appreciated by the patients/clients (especially younger ones), and was decided to maintain and to improve it during the development of the actual web portal as demonstrates several EU [AC7] and US studies and publications.

The reservation of specialist and private medical visits or outpatient appointments in collaboration with the hospital Unique Center for Reservation (CUP) was made possible by compiling an on-line server-side form. The system was conceived to accept an appointment made by an user without creating credentials but only giving a valid e-mail address. Selecting the visit then the system automatically generate and send a message to the hospital appointment office, that will confirm the request of the sender by e-mail.

In figure 9 below there are some details regarding the quantification of the appointments registered from the first introduction of the system until the passage to the newest one.



figure 9 – total appointment requests visualized per year

CMS and administrator's control panel

At the same time of the development of the public web portal and the services described above, a CMS was created for the management of the web pages and of the contents giving to the web site administrators – not necessarily technicians – the control all over the portal. The CMS, programmed in PHP, has been organized to replicate the web portal menus to facilitate the update process and administration. Through the interface is possible to add or modify some menus of the first level (the horizontal bar) and of the second level (the vertical subjects). There is a third level (like all common CMS) to edit the various pages of the portal, and it is possible to edit all the lateral menus.

Adding more control of the functionality of all the databases and web pages by easily modifying the source code is even possible; through the CMS it is possible to add and control other “satellite” sites residing in other directories (i.e. the English web site or other permanent or momentary initiatives such congresses, courses, schools, etc...).

4.2 The web “social turning point”

During 2008 almost everything changed in the concept, realization and perceiving of the web technologies and services. It was the dawn of “social networks”. A social network service focuses

on building online communities of people who share interests and/or activities, or who are interested in exploring the interests and activities of others. Most social network services are web based and provide a variety of ways for users to interact, such as e-mail and instant messaging services. Social networking has encouraged new ways to communicate and share information. Social networking websites are being used regularly by millions of people. While it could be said that email and websites have most of the essential elements of social network services, proprietary encapsulated services gained popularity in the first decade of the 21st century [AC1].

People started not only to interact with machines and with each other using and sharing already engineered social arenas and games, but to realize and propose their own contents and share them, in theory, with everyone at any geographical distance [AC3].

This is what is called here the “social turning point”: I share my videos, thoughts, personal information, games, contents with everyone at any time, and the web may become a showcase of what I have, what I do/know and even what I am.

From this point of view a hospital web site may become a space where I can not only find services or documentation but a virtual plaza where to exchange information, insert my opinions, comments, ask to the physicians [AC3],[AC6] – the same medical doctors that visit me or my parents -, maintaining and retrieving my data or the setting of a mine personal page or blog. This is a real revolution in approaching to services even if they are provided by public structures and hospitals.

So in re-thinking the characteristic of a hospital web portal in order to provide services in telemedicine and for the people, the web portal must be re-engineered, renewed and updated according to the most recent ICT technologies and social networking “advances”. Some solutions were studied and then proposed to solve the previous requirements according to specific needs and worldwide transition. The result was that all the previous web services regarding the audience, the researchers (biologists, psychologists, epidemiologists) and the medical doctors have to be re-designed, including a new and more flexible CMS for administrators. In the same way it was proposed that the hospital satellite sites have to be integrated in the portal using the same platform. Most important of all it was realized an “open” architecture allowing different and external users to update and modify eventual their own contents. In studying, proposing and developing these services and to enhance communication and integration between users and healthcare structures, concepts such WEB 2.0 and social networking have been emphasized [A4],[A8].

The re-design and the consequent development of a new IRCCS’s web portal is essentially due to:

- the advent of new programming techniques
- the opportunity given by the “social” use of the web through a series of “services”

4.2.1 The techniques

The evolution of the web technologies and the increasing functions of the web browsers promoted the creation and the growth of new standards, based on new programming languages, the development of existing technologies and the aggregation of techniques and languages already in

use. Thus, new techniques and libraries are available to the team of IT professionals, continuing to offer all the proposed and well-established services, taking advantage of the opportunities of data visualization and presentation offered by WEB 2.0.

In particular with regard to the technologies the portal database server is MySQL 5.0, and PHP 5 is used as the server side scripting language. Designed on this architecture the portal for data output and for user-database interaction utilizes a XHTML interface based on AJAX (Asynchronous JavaScript and XML), which allows a background data transmission between the web browser (user side) and the server. AJAX technology creates an abstraction layer between web-browser and web-server as shown in figure 10.

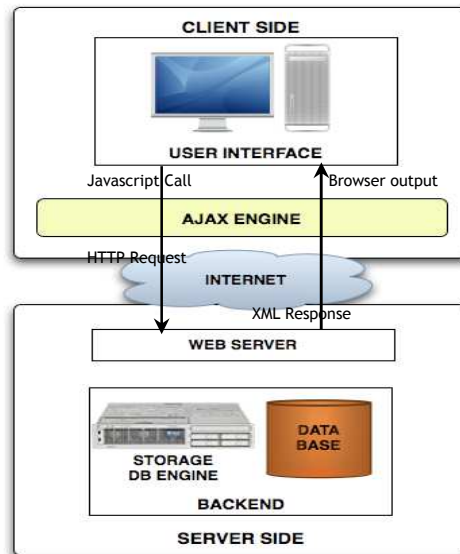


figure 10 – AJAX abstraction layer representation

This layer intercepts the HTTP requests from the browser sending them to the server in a transparent way for the user.

Actual web portals are developed utilizing a whole modern graphical layout and are managed by means of a CMS. The CMS back-end interface gives to the administrators the control of the public contents using a three-level menu architecture, and of the other web-based services regarding on-line appointments for specialist and private medical visits, multi-center studies and telemedicine systems.

4.2.2 The services

The aim of a web portal “social” re-design was to create a network of services not only between the Hospital and the patients as before, but also between the patients themselves, or medical professionals and nonmedical users. In general it is an attempt “to link” and to involve people outside the Hospital.

This healthcare social networking approach will give to the medical professionals the opportunity to share competencies and knowledge with other professionals or with the audience, thus realizing and

implementing some innovative healthcare services already at study or in development in other Countries.

Some of these services are:

- the on-line specialist and outpatient appointment service with a new backend system and interface for the personnel of the hospital appointment office
- the creation of an access reserved patient personal page to maintain and to visualize a whole view of the requested appointments or, in the future, the results of some clinical investigations (such as clinical laboratory examinations) or to evaluate or complain about hospital services or structures;

Optional future services will include exposition of medical doctors personal files to show curriculum (now mandatory for Public Administration management and Medical Doctors – *Operazione Trasparenza*), specializations, offered medical services (with updated prices) and eventually a personal blog.

Other services, developed using more conventional technologies, include the support of scientific databases and studies, the creation of a number of web interfaces to populate some databases for scientific research, and the creation of access controlled forms regarding some clinical research studies to monitor the clinical behavior of the involved pediatricians towards the problems of infants affected by diseases.

Services for the users and the public

As discussed in previous section 4.1, the IRCCS's web portal had been realized to offer services both to scientific and medical professionals, and to the public users. The new portal (concept) aims to maintain the same healthcare services as before, and serves as a platform to support and develop new advanced and innovative services. In particular these new services aim to approach patients and healthcare institutions such as hospitals, giving to the citizens the possibility to register themselves in order to manage, for example, their medical appointments, medical visits, requests and so on.

The user personal page, that was possible to create on the portal, could give to patients a secure and easy access from everywhere (also from foreign countries) to view their own medical data, simplifying other medical visits, consultations, or further accesses to other medical structures both hospitals or health districts.

From the administrators' point of view the platform can unlock the different services in respect to four categories of users, easily allowing further services as soon as they are working and usable.

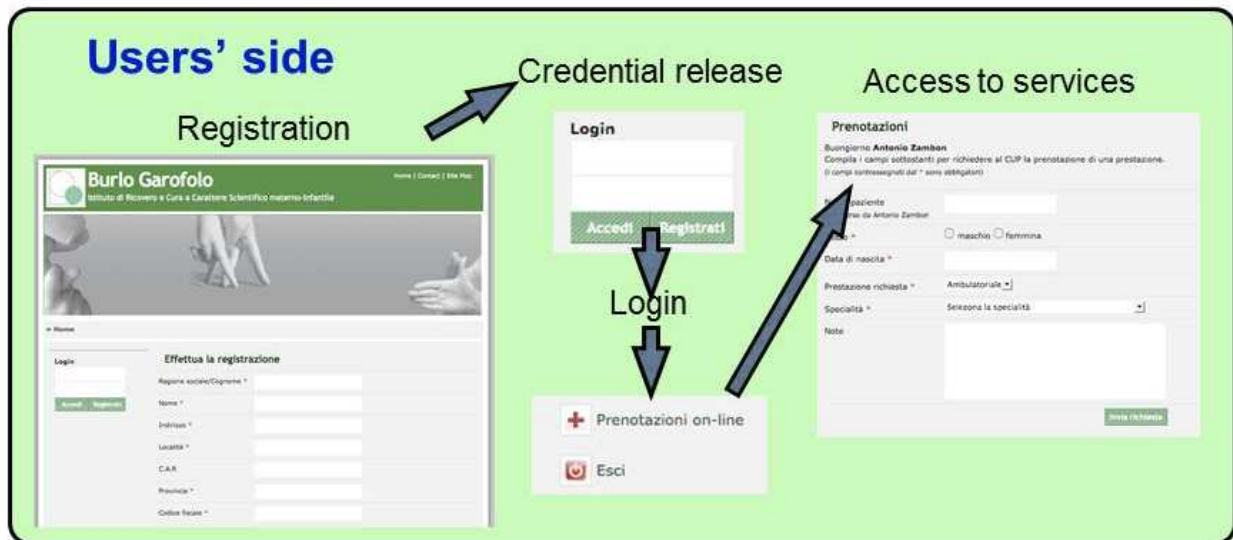


figure 11 – user access to the services

Services for clinical research and diagnosis

The platform continues to support the research activity related to some scientific and clinical projects. Groups of researchers use the web portal to fill electronic forms regarding pediatric and obstetrical studies, extracting and analyzing data for the corresponding researches. As for the audience all the researchers need to identify themselves and can access previously authorized data. As soon as new services will start the administrators will give them visibility to authorized people from the CMS at the backend of the portal (intranet).

Currently some of the services inherited from the previous platform are:

- the tele-consult system capable of receiving ultrasound images and questions from outside obstetrical ultrasonographers (see figure below);
- the web and database support to the cohort study started in 2007 to follow a population of mothers and children from the first months of pregnancy collecting biological samples, health and social information;
- the support to the IGARIS project (see previous section)
- the home page news regarding the institutional activities of the Hospital both in scientific and in clinical fields;
- the renewed support for the multi-center study of atypical uterine polyps in women which regards the medical treatment of atypical uterine polyps in women monitored during five years, and eventually surgically operated. A new database was developed to archive the patients' clinical data and to follow the patients from different authorized Italian health centers.

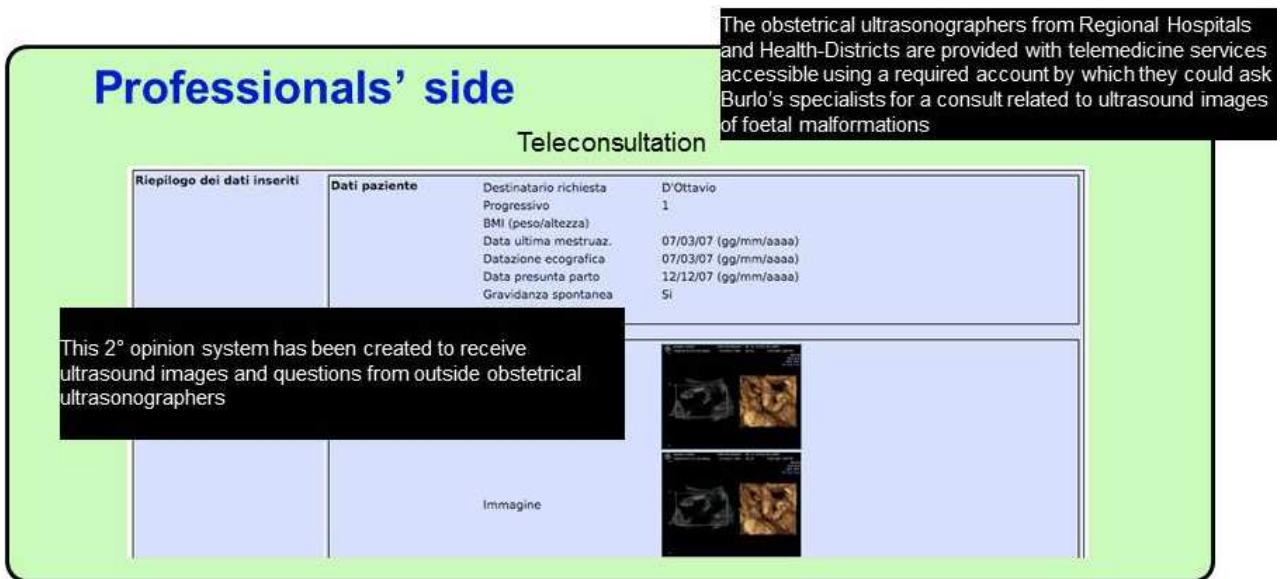


figure 12 – renewed tele-consult web-form

Services for the hospital appointment office

As discussed before the previous on-line reservation system available on the home-page used a form to be filled with data inherent to the requested clinical visit (figure 13). Submitting the request generated a web server call and through a simple mail server the system sent a message to the hospital appointment office, that manually would confirm the request of the sender by e-mail.

The new system allows the Hospital appointment office personnel to receive and dispatch the reservation requests directly on the platform without opening the mail client and sending an e-mail (figure 14). As soon as the personnel check the availability of a medical visit to give the answer to the request, the system will send an e-mail to the patient to confirm the appointment. The trace of all the dispatched (or not) requests will be kept on the server, simplifying procedures concerning the office storage and logistics.

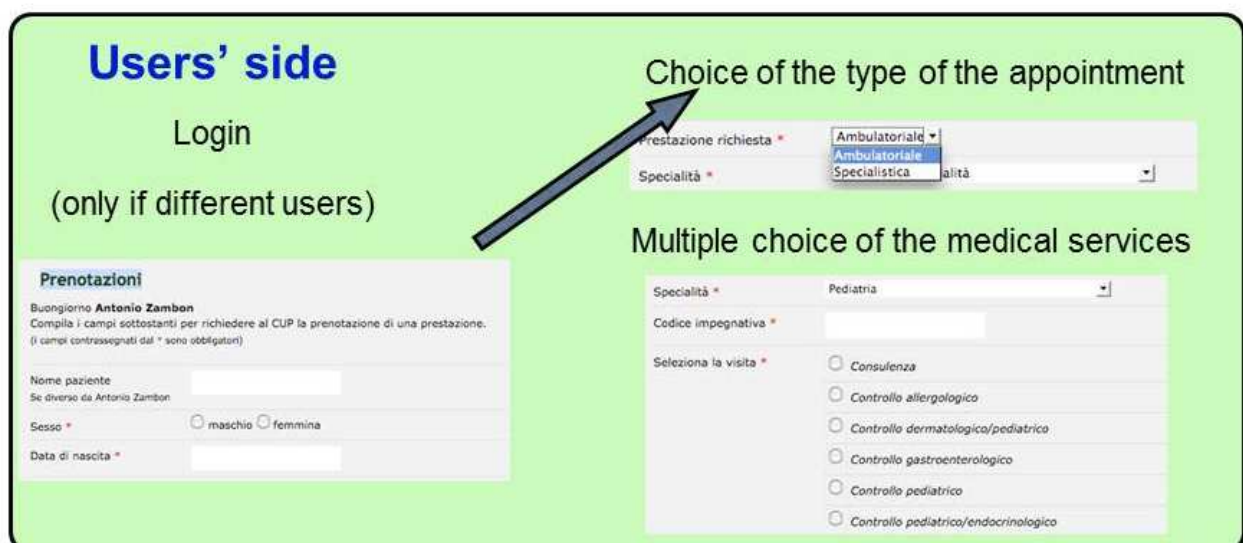


figure 13 – user's appointment web-form

Hospital's side

Request receipt ➔ Request notification

Users receive an automatic e-mail as confirm of clinical reservation; or they may visualize in their own personal area the same information

figure 14 – hospital appointment office web-form for users' request notification

Services for the administrators

The new CMS offers all the functions of a modern file and content management system. Through a common interface it is possible to change the layout model and the visualization options. The CMS has a structure that allows navigation among the different sites (the principal and the satellites) and among the site's menus, each organized in a three-layer model as shown in figure 15

Administrators' side

The CMS interface

figure 15 – the cms interface

The menus' contents can be customized allowing the administrators to create the structure to match the Hospital organization chart or the satellite sites organization. The interface allows to upload files and create contents and dynamic web pages through a complete and easy-to-use editor. From

the CMS it is possible to move to the public area of the sites staying logged and so visualizing the contents or the services the authorization level grants.

From this backend it is possible to reach other areas related to the users accounts and privileges, a Hospital scientific publication database (organized per year – see figure 16), and the other satellite site CMSs. Inside each of these CMSs it is possible, according to the appropriate credentials, to modify the specific contents and pages.



figure 16 – the scientific publications web-form

The last feature of the CMS still in development is a dynamic advanced editor programmed in PHP that, starting from defined database tables and relations, will allow users to define web based forms and pages only dragging and dropping items. This editor will give to some skilled users the possibility to create a personalized interface connected to a database without knowing particular programming or database languages.

Other features

The easy CMS interface was designed to allow the creation of satellite sites in order to extend the possibilities of creating a single hospital web platform even for institutional blog, intranet services and/or other open-source based projects and computer programs. In Chapter 5 there will be presented open-source solutions developed for these intranet and clinical services.

The CMS design of Hospital satellite web sites instead pertain to specific scientific or educational areas that are concerned with the Hospital primary activities but may be thought of as independent functions. In order to enhance the visibility of these activities and to grant an easy and well known access to the same personnel in charge of the hospital portal, all these sites were integrated in the same platform, without turning to outsourcing resources.

These sites are parallel web portals reachable from the hospital's home page, and even if they are organized with the same structure (the three-layer model), they have different contents and offer

different services and information. This is a brief list of the working satellite sites adopting the same CMS as described above:

- the *CIB* (Bioethical Independent Committee) web site. This site is provided with a restricted and secure access and holds information concerning the procedures and regulations for experimental clinical research.
- the English version of the hospital's web portal. It is not a mere translation of the Italian version of the portal, but is an independent site especially committed for the international contents and activities of the scientific professionals of the Hospital.
- the European School for Maternal, Newborn, Child and Adolescent Health web site. This site was created to support the activities of the school, which is in particular dedicated to the formation of Eastern Europe countries healthcare professionals.

Other developing satellite sites will host the volunteer associations and the hospital's epidemiologists informative pages.

4.3 Conclusions

The ICT and in particular the Web 2.0 technologies will offer in coming years more and more opportunities for the worldwide diffusion of telemedicine. The paradigm is changed: the world shifted from an "old" mainframe model then to a client-server model and now to a peer to peer model, and this happened even in healthcare services determining more interaction among users, professionals, developers and administrators: people now expect for services in which they are involved [AC1].

Modern healthcare structures may benefit from these achievements in order to improve quality and the continuity of care. According to this "social" point of view patients-users, medical doctors and IT professionals should cooperate to ensure the creation of useful healthcare tools, considering a correct assessment of the technology including costs and investments.

Only together healthcare and IT may converge towards a sustainable and open model of development that will assure the correct and continuous support of the technology even in critical demanding health applications and systems, such as the complex telemedicine scenario. From this point of view a Hospital web portal of services developed with open-source tools and shared knowledge will assure a technological and economic benefit not only for the management but especially for patients demanding effective, stable and comfortable healthcare services.

Chapter 5

Innovative methods and applications in designing intranet services

As will be showed in the paragraphs of this chapter, the study and the proposal of the realization of intranet services and applications has been faced with the objective to resolve respectively organizational, management and clinical needs in a hospital. The solutions proposed and the results obtained are quite different considering the different fields of application, but there are some common principles regarding the approach and the method (and consequently the chosen technologies) that may unify what seems a not homogeneous whole.

- The all-comprehensive approach adopted considering issues as security or quality of care or international certification standardization
- Quality of care also means the proposal of solutions that are not directly connected with the medical practice or diagnose, but give to the professionals in particular tools to better execute their activities
- Technology is not a secondary or only consequent issue. The chosen instruments should be based on the same platform and might allow to develop systems that are easy-to-use, effective, scalable, customizable (possibly by the users themselves).
- Telemedicine is a concept that may be adopted to propose and solve problems with a different point of view, allowing computerization of even “simple” and not deep researched practices – such as for TPN, see section 5.3.

Some of the results obtained are:

- The proposal of the realization of an open-source web platform capable to host different systems and solutions
- A different way to reach, organize and manage corporate information and data: in a hospital this means clinical data, but also employees data and business documentation (protocols and procedures)
- Specific results for each study which is described below
- A more conscious use of technical resources and awareness about the role covered in a complex organization

5.1 Intranet services and solutions for corporate organization and business [A3]

The study for the realization of an intranet portal where to store and to make reachable all the information and the hospital's knowledge was proposed for at least five reasons:

- the ISO 9001:2000 certification process adopted for all the wards of the hospital (in particular the laboratories and the cross services such as Radiology and Cardiology)
- guarantee high level of healthcare services, and take proper medical treatments
- the consequent need to share documents, communications and explicit corporate knowledge in order to achieve as more employees as possible
- the need to formally describe and store the corporate procedures, protocols, general documents (vacations, illness, employee behavior, etc...) internal or specific rules and regulations
- the effort of the hospital leadership focused to obtain compliance to international and national regulations and to improve the quality of Hospital medical and clinical services.

According to mandatory Italian Law (*D.L.vo 288/2003*) IRCCSs must comply with ISO 9001:2000 standards for Health Processes. To comply with ISO the hospital starts the re-organization of the clinical research and medical practice according to the international healthcare standards. The standard is a model and a method. Its adoption implies the opportunity to monitor the performances and the quality of the offered services (defining protocols, procedures, preventive and corrective actions, etc...).

This chapter describes the proposal for the design and the development of an intranet portal of the hospital, built in accordance with regulations and especially in accord to the Total Quality Management approach [AC14] to enhance the internal communication among the hospital units and wards, guarantee high level of healthcare services, and take proper medical treatments. An intranet portal has been recognized by the Hospital Strategic Direction and the Quality Assurance Office as an innovative tool to be designed, developed and maintained. The portal may improve the distribution of internal documentation, especially guide lines, procedures and protocols.

The availability of such a portal may represent a platform used as a common dashboard where it is possible to retrieve the documentation in force, which is the electronic expression of the corporate knowledge. The subsequent exploitation of this knowledge may allow to evaluate globally the production of procedures, guide lines and protocols by the different wards, avoiding redundancies and enabling work sharing, improving integration and harmonization of the corporate processes.

The portal may encourage communication through the use of an internal blog in which users with accounts may transmit in real time necessary information to get the expected results in a more effective and efficient manner.

5.1.1 Methods and materials

One of the first steps of the study was the analysis of the Total Quality Management (TQM) model (function vs. processes and continuous enhancement) proposed by ISO 9001:2000 and its possible engineering and implementation on an intranet web site (figure 17). The TQM approach for healthcare aims to guarantee high level of healthcare services, and to take proper medical treatments through:

- corporate documentation management and distribution;
- not conformities and corrective actions;
- audit (internal and external);
- continuous improvement

According to ISO 9001:2000 the explicit and formal expression of the TQM approach is the Quality Management System (QMS) formally composed of the quality management manual (at a corporate level), the total quality procedures, the processes manuals (laboratory, pharmaceuticals), and the operative procedures, guide lines, protocols, instructions, services guides, etc created by the hospital wards, structures or departments.

The question is if certain QMS issues for a hospital - those described in figure - may be modeled and implemented via an intranet web portal.

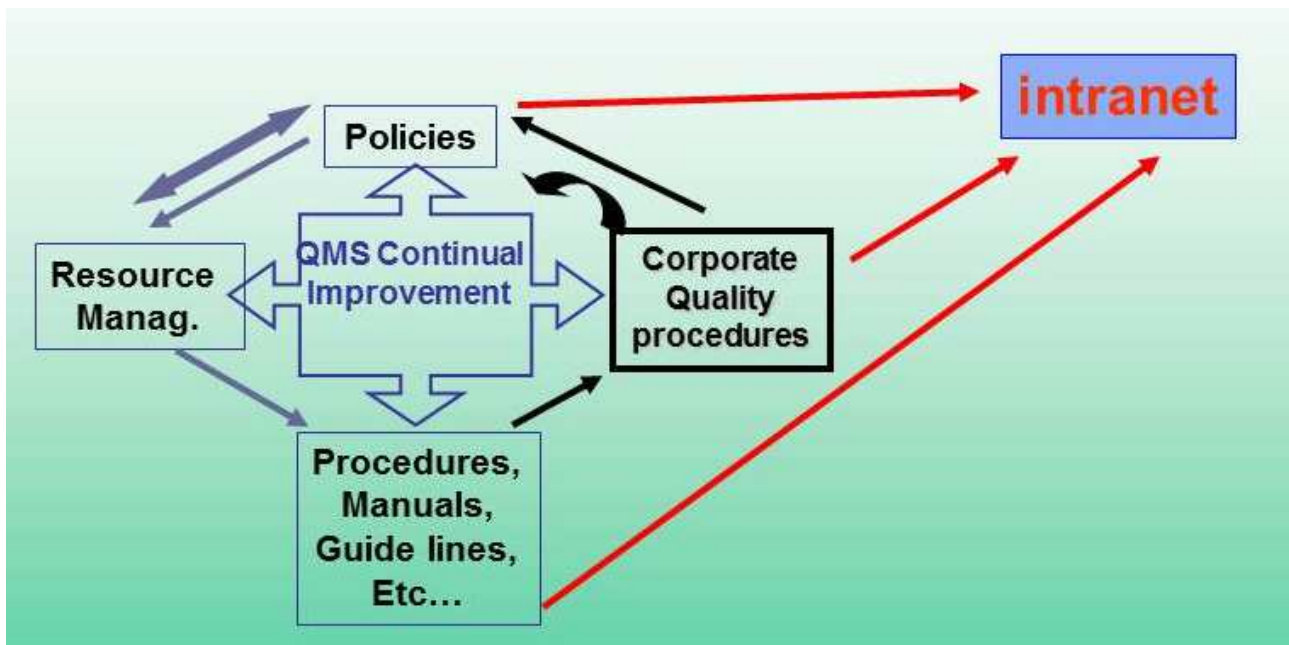


figure 17 – QMS continual improvement process and its possible intranet mapping

Another step was to find the information technologies allowing the creation of such a portal. Not following the same approach used for the design and realization of the hospital internet web-site, it was chosen to adopt an open-source CMS, avoiding the need of programming capabilities and benefiting of the CMS user-oriented layout. After a survey and some tests it was chosen the popular free open-source CMS, “Joomla!” (stable version 1.0.12 – in 2008). Joomla! is a CMS widely

available by the community and developed to offer a large number of modules and features. It is possible to customize the web pages, their contents and the tools for navigation, visualization and use of the web sites in which is implemented.

The platform is based on LAMP technology and may be hosted in a hospital dedicated server. The used operating system was Linux Debian 4.0 Stable; Apache 2.0 was the web server used for the portal. The database server was MySQL 5.1 developed by MySQL AB, and as server side scripting language was used PHP 4.4. Joomla! offers a friendly user interface and a simple configuration control panel to update the contents and the corporate documentation. The control panel can be easily understood, and its use can be taught to the internal personnel in the wards or in the administrative offices.

5.1.2 Development and implementation

In order to accomplish the proposed objectives, the typical structure of Joomla! has been applied to map both the functional organization of the clinical departments and the major quality items (the “processes”) as considered in the above Quality Program Document.

As shown in figure 18 the main menu of the proposed intranet home page was structured into three macro “areas”, the first two designed according to the content structure of Joomla! itself, which is based on the division in sections, categories and articles.

The first “area” is constituted by common interest corporate subjects as:

1. On-line and pdf downloadable address book
2. Guidelines and rules regarding the day hospital activity
3. pharmaceutical vade-mecum
4. hospital forms catalogue
5. stationery catalogue
6. quality programme
7. budget programme



figure 18 – the intranet three macro areas

These subjects reflect the needs both to communicate and to validate general procedures, guide lines and protocols at the corporate level, avoiding redundancies and promoting work sharing to improve the corporate processes and their integration.

The second “area” lists the Hospital Departments and offices reflecting the organization chart, and is composed of:

1. Strategic Office
2. Scientific Office
3. Sanitary Office
4. Administrative Office
5. Paediatrics Department
6. Obstetrical and Gynaecological Department
7. Surgery Department
8. Laboratory and molecular medicine Department

The structures listed above are organized following a general scheme built on the Joomla! “sections -> categories -> articles -> elements” scheme. In this proposed model the sections are the Departments or the Offices (or the processes in the first area); the categories are the functional structures composing the single Department or Office (or sub-processes in the first area); the articles are organized for every structure following the scheme shown in figure 18; the articles are further organized in a table of “elements” (figure 19). The elements are the single procedures, guide lines, etc, all downloadable and generally visible by hospital employees. The articles of each area listed below are further organized in a table in with every element (a specific protocol or guide line or procedure) is identified. This feature was chosen to be adopted to overcome the three layer

limitations of Joomla! The table format was chosen and internally standardized for every article published on the intranet web site.

Table 1

Articles	Date of upload	Author	Contacts
Guidelines	dd/mm/yyyy	admin	n
Projects and programs			
Reports			
Lists			
Plans			
Objectives			
Procedures			
User manuals			
Rules			
Newsletters			

figure 18 – articles’ organization schema

TIPO	COD	rev	data	sostituisce	sostituita da	status	TITOLO + eventuale ESPLICATIVA	Dip/Dir	Strutti/Serv
LEG	LEG 01	0	08/01/2008	\	\	VIG	LEGENDA	DSN	DSN
PRO	PRO Q DRQ	0	10/10/2005	\	PRO DSN 07	OBS	PROCEDURA DI PROGETTAZIONE E DISTRIBUZIONE DEGLI SCHEMI E MATRICI DELLA DOCUMENTAZIONE CLINICA	DSN	DSN
PRO	PRO-G-LAB 03	0	30/05/2006	\	\	VIG	PROCEDURE ESAMI URGENTI (vedi nella sezione "Protocolli" il relativo allegato)	DSN	LAB
PRO	PRO-G-LAB 03 AGGIORNAMENTO	0	30/05/2006	\	\	VIG	PROCEDURA ESAMI URGENTI-AGGIORNAMENTO	DSN	LAB

figure 19 – the elements organized in tables inside each article page

In the third “area” of the menu the links to a variety of services related to the intranet are found (see next sections in this chapter), using it as a unified and common platform.

Accesses and permissions

The access to the front-end of the platform is free although limited to the internal machines located in hospital private subnets. Thus the access is ip-filtered. The back-end of the platform is accessed only by the administrators who control and manage the entire system and by a restricted user of the Technical Office that has been trained to update the list of the technical interventions performed.

Other instruments for communication

An internal blog was proposed to allow better interaction among the hospital’s personnel regarding the corporate objectives and the discussion around five topics:

1. job organization
2. instrumentation and informatics
3. legal features
4. guide lines (add, modify, update, etc...)
5. chain of responsibilities

The blog's home page may be reachable from the intranet portal; to add or update some of the contents concerning the topics listed above, a list of users with different privileges has been prepared, according to the possibilities offered by the platform. Rules have been stipulated for access and for etiquette to continue using the system. The Blog is fully moderated by an internal consultant who acts as a filter for the contents to be published.

5.1.3 Results and discussion

The system was implemented and started in early 2008 still continuing to represent the hospital portal to deliver information and communications. The portal is used to publish and store all the corporate documentation, from the General Manager orders until the procedure, guide-lines and documents of each hospital ward or office. The portal offers as many services as the Hospital wards or structures require to archive, publish and visualize their documentation.

This allows the single department or ward to **be involved** into their own documentation, creating manager users with restrictive access policies than administrators.

From the beginning of the realization of the platform it was necessary to unify, organize and make available the entire Hospital paper documentation in electronic format. This documentation can now be consulted and downloaded in the first area section named "hospital forms catalogue".

Joomla!'s built-in address book module was immediately suitable for the on-line address book allowing an easy search of internal personnel (telephone number, e-mail address, location) and structures

The hospital Quality Assurance Office and the Information System Office **collaborated** to establish the portal, **to improve** and **update** the distribution of internal documentation, especially guide lines, procedures and protocols.

The availability of such a portal represents a platform used as a common dashboard where it is possible to **retrieve the documentation** in force, which is the electronic expression of the corporate knowledge.

The subsequent **exploitation of this knowledge** allows to evaluate globally the production of procedures, guide lines and protocols by the different wards (PDCA), avoiding redundancies and enabling work sharing, improving integration and harmonization of the corporate processes.

The portal **encourages communication** also through the use of an internal blog in which users with accounts may transmit in real time necessary information to get the expected results in a more effective and efficient manner.

After the introduction of the platform in 2008 a **more appropriate** use of the hospital correct forms and a **more punctual diffusion** of information (such as the new Corporate Act or the new information Policies) has been quantified (instead of e-mail...) reporting the visited pages and the documents downloaded.

The possibility of a **continuous update** of the contents and of the documentation complies with the ISO 9001:2000 standards for Health Processes, allowing to know the review number, the author and the date of the document.

Finally, implementing the intranet has achieved a first step to **diffuse explicitly corporate knowledge (both administrative and medical) that was previously hidden or implicit**. This is a process that should be continued, converting more and more of the medical and administrative information into shared knowledge, and even including in this path the peculiar scientific and research aspects of a hospital such as an IRCCS.

5.1.4 Conclusion and actual developments

Apart from the obtained results, remain at least two critical situations: the first regards the extension of the information tools which may introduce more complexity to the system and to the regular and consolidated procedures. The second class of problems is related to the first and regards the formation and the training of the personnel in using the information tools correctly and effectively. This represents a challenge at the organizational level especially because it involves the employment of internal technical competencies and human resources.

Beyond the continuous update of both the corporate documentation and the CMS managed by an internal team composed by IT and healthcare specialists, the near future is characterized by implementing an effective knowledge management system (KMS) by which the ISO 9001:2000 certified wards may control their quality documentation and review/update this documentation systematically and safely.

In recent months such a system has been studied and proposed also to renew the intranet platform: the test of some commercial and open-source products has begun.

5.2 Intranet solutions for the management evaluation [A10],[A11]

5.2.1 Purpose

In some hospitals like the IRCCSs which are research-based hospitals, the coexistence of research activity and the offered healthcare services leads to complex requirements and solutions in different areas. In these institutes healthcare clinicians and researchers overlap, and clinical assistance and research activity are performed very often by the same professional. Both for legal commitments

and to assure the continuous improvement process and quality of care (as discussed in the above section), these professionals must be monitored and evaluated [AB1]. The periodic evaluation of healthcare business managers according to the Italian law which regulates executive healthcare contracts, is mandatory. Even if this evaluation is not binding for the researchers it is an important process in order to motivate and improve individual skills [AB3] and possibly encourage a sense of responsibility to safeguard patient health.

For this reason a model [A10] has been proposed for the periodic evaluation of both activities (clinical and scientific) to enhance and motivate the professionals involved. This kind of model was refined following quality systems as JCI (Joint Commission International) and ISO (International Organization for Standardization), developing the Plan-Do-Check-Act model (Deming cycle) to encourage a continuous professional and cultural growth.

For clinical activity this evaluation should:

- increase the sense of duty towards the patients,
- increase awareness of one's own professional growth and aspirations
- enhance the awareness of the healthcare executive regarding the institute's strategies.

For research activity the evaluation should:

- keep track of the researcher's efforts and involvement,
- measure the scientific productivity in terms of publications, papers, talks, international workgroups, etc,
- calculate an objective index of the effectiveness of the scientific contribution.

To satisfy these requirements the model has been proposed modulating specific literature achievements and the hospital Direction needs especially in terms of the documents to be sent to the Italian Public Health National Department. In particular this evaluation system has been constructed according to the Total Quality Model approach for the healthcare discussed in the above section.

After the construction of the model it has proposed to develop and implement and test two computer programs based on the same open-source platform.

The expected advantages using the models as computer programs/web applications are: immediate availability of tools and information, unavoidable confront between managers and the evaluator (the "social turning point" discussed in chapter 4); an easy consulting and data updating, an easy security and control implementation; and finally great portability of the computerized evaluation tool due to its easy application in other contexts different from public and private healthcare.

5.2.2 Methods

Clinicians' evaluation model

The model referring to the clinicians is divided in two main sections [A10]: the first part is “not negotiable”, while the second is “negotiable” with the CEO and regards quantitative aspects. Both the “negotiable” and the “not negotiable” sections are divided in different sub-sections. Sub-sections are composed of fields, and each field is associated with a score, while a coefficient is associated with every subsection that is fixed in the “not negotiable” part and variable in the “negotiable” part.

The main model sheet is the evaluation report. The evaluation report sheet is divided into two parts, in which the whole evaluation is reported attributing a variable mark from 0 to 3. Its first part is composed of links (see figure H) to user documents which are: the “job description” link which describes the work carried out by the manager (editable by the evaluator and read only by the manager); the “manager target” link (editable by the evaluator and read only by the manager), and the “job assignment” link which describes job motivations, structures, targets, and score/result indicator.

In the first part, the chief executive officer (CEO) scores: 1. behavioral characteristics, 2. multidisciplinary collaboration and involvement, 3. organizational skills, 4. professional quality and training, 5. relationships with the patients. The scores for these fields are decided by the CEO.

The first part is “not negotiable”, while the second is “negotiable” with the manager as regards to quantitative aspects.

The “not negotiable” section is divided in five sub-sections: 1.Characteristic behaviors, 2.Collaboration and interdisciplinary participation, 3.Organizational ability, 4.Quality and vocational training, 5.Relationship with the patients.

In the second part the CEO evaluates: 1. quantitative job dimension, 2.technology innovation, 3. scientific and educational activities. The value scores of these fields are decided by the CEO together with the professional under evaluation. A previously established correction coefficient can be used for all the scores.

The “negotiable” section is divided in three sub-sections: 1.Work quantitative dimension, 2.Technological innovation, 3. Scientific and teaching activities.

In the last part of the evaluation report sheet there is a summary table concerning the performances achieved; the average score of the fields in a subsection, multiplied by a subsection correction coefficient, summed together gives the final vote.

In order to have a positive evaluation, the final score must be greater or equal to the threshold value.

There must be a tabulated appointment calendar which facilitates to plan a series of meetings for future improvements. In addition to the evaluation report sheet there is a training sheet which controls individual abilities.

Users of the “clinicians” evaluation model are divided into four categories:

- the evaluator (typically the CEO) evaluates all managers and inserts almost all documents;
- the evaluated manager who can insert his own documents and consult only his own evaluation reports;
- the administrative staff which introduces only documents regarding the hospital and cannot visualize manager/evaluator reports;
- the administrator that can operate directly on the software for technical problems and issues (only for the computer based program developed).

In figure 20 is shown a graphical schema representation of this clinician model:

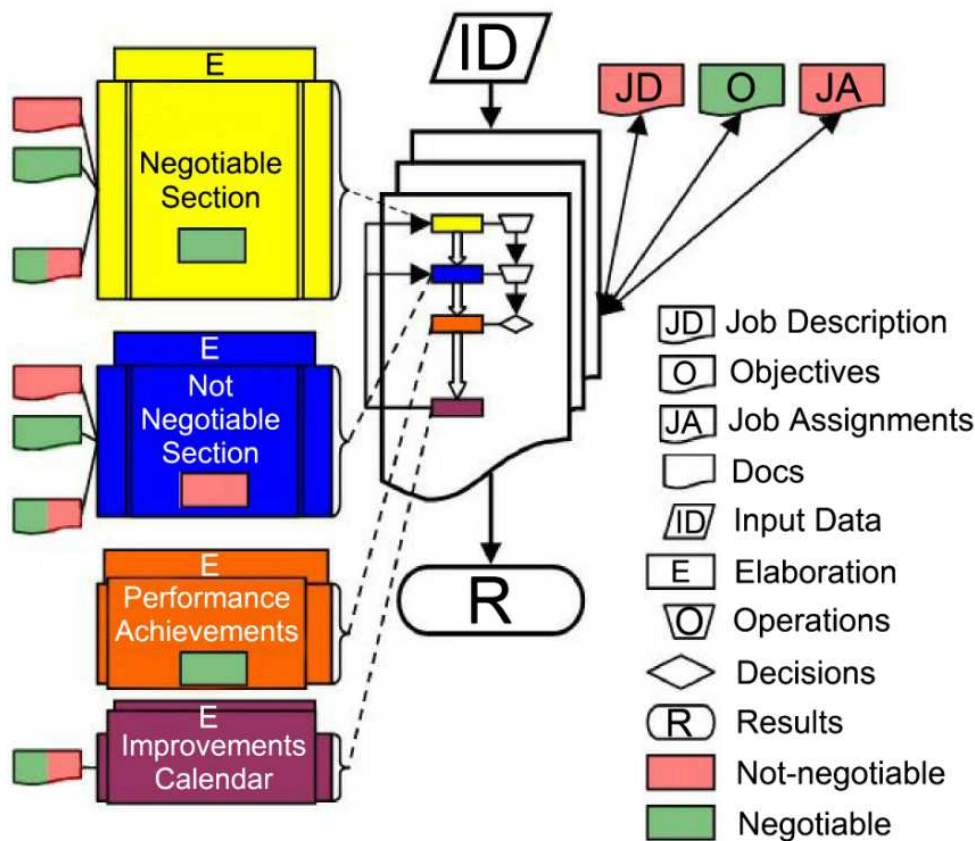


figure 20 – clinician evaluation model schema

Researchers' evaluation model

The model created for the evaluation of the researchers [A11] was divided into different parts:

- the first reports identifying data of the researcher (i.e. age, role, ward or department, etc...);
- the second collects information and activities such as publications,
- the third part meetings and congresses,

- the fourth one lists proposal submissions to National Ministry of Health, European Commission Framework program, etc. For each part there are the scores to evaluate the effectiveness of the researcher's scientific activity per year.

In the researchers' model, it is possible to access to four different sheets: the personal data sheet, the publications sheet, the research projects sheet, and the other events sheet. Moreover, it is possible to get and consult a summary sheet.

In the personal data sheet all the information is reported including name, position, CV, age, structure, department, organized by year, and h-index too. In the publications sheet the produced publications are listed.

All the details about the publications must be collected in different fields, divided by title, journal, year of publication, impact factor IF attributed to the journal. In particular in Italy IF is distinguished in three types: “*grezzo*” (the usual index to evaluate the quality of scientific journals), “*normalizzato*” (Normalized Impact factor – NIF) which is a method to evaluate the quality of journals and research work in different disciplines allowing a direct comparison among different scientific disciplines journals; and finally “*normalizzato corretto*” for which there are some exceptions in the evaluation of IF, e.g. when the product is a letter to the editor. Different authors must be listed in separated cells (name, surname, structure, position in the list of authors). IF score has to be calculated for each author, ward and department of the hospital. Duplicates in calculating IF must be avoided for a correct value calculation in a specific year [AB7].

In the research project sheet there are the proposal submissions reported to the national Ministry of Health programs, European Commission Framework, Interregional projects. The sheet must specify for each project the title, the topic, the budget required, the budget assigned, the role in the proposal as coordinator or partner. In this part all the research projects developed and held by every single researcher are reported.

The other events sheet reports the list of the congresses and meetings to which the researcher has attended actively in oral sessions, as chairman, etc.

5.2.3 Results

To implement the two theoretical evaluation models described above, two web-based software programs were developed using the same LAMP (Linux, Apache, MySQL, PHP) system platform. For data storage a “MySQL” database was used, not only because it is an open-source software but also because it satisfied the project objectives. The graphics interface was developed using both HTML and PHP languages. The programs implement the whole evaluation path (providing user authentication giving different authorization profiles) in respect to individual roles.

Clinician's evaluation program

For the evaluation of the clinician activities, the four different types of user (evaluator, manager, staff and administrator) can authenticate themselves on the login page to enter into their personal home pages as shown in figure 21.

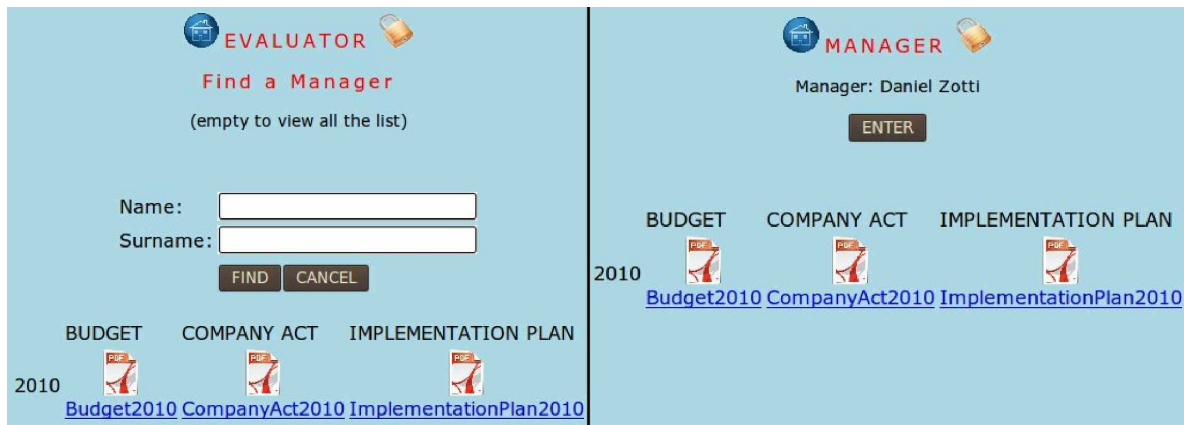


figure 21 - Manager and Evaluator home with documents regarding Hospital activity

For example, the evaluator home page presents a manager research form and the corporate documents. Logged in as Evaluator, for every evaluated Manager the program presents a personal data web-form, an evaluation report web-form which helps to determine the manager final score, and a training web-form which follows the manager activities in parallel with the evaluation report.

The main web-form implemented is the evaluation report (see figure 22). The evaluation report form is divided into two parts, in which the whole evaluation is reported attributing a variable mark from 0 to 3. Its first part is composed of links to the user documents as requested by the model with the requested evaluator and manager permissions.

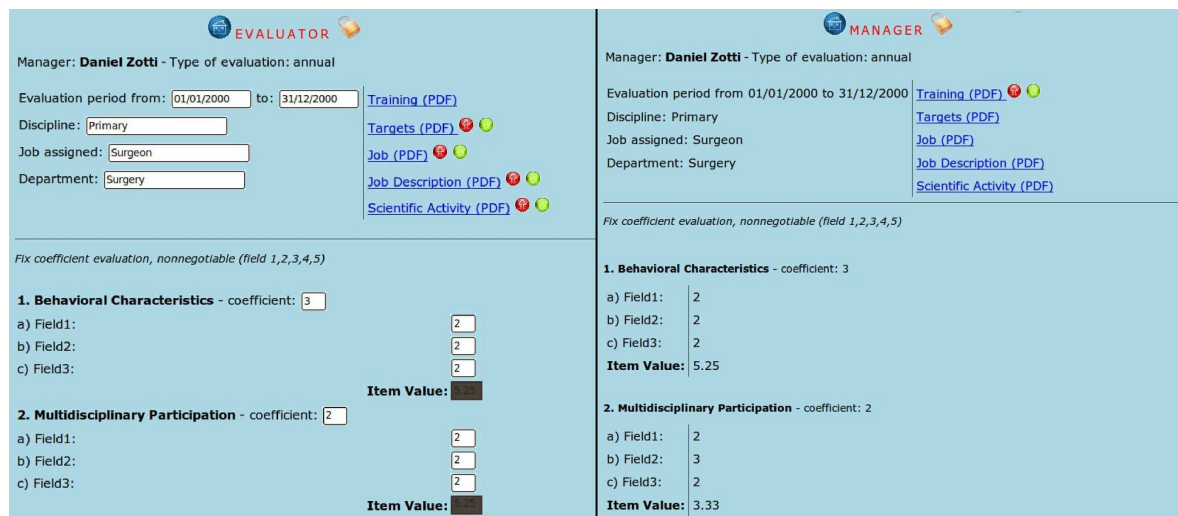


figure 22 - Evaluation report page visualized by the Evaluator and Manager

Then there is the first part with the fields and the scores (behavioral characteristics, multidisciplinary collaboration and involvement, organizational skills, professional quality and training, relationships with the patients) decided by the CEO. This “negotiable” section is divided in three sub-sections: 1. Work quantitative dimension, 2. Technological innovation, 3. Scientific and teaching activities.

In the second “not negotiable” part the CEO evaluates on screen the scores together with the professional under evaluation. The program allows to set a correction coefficient for all the scores.

In the last part of the evaluation report web-form there is a summary table concerning the performances achieved; the average score of the fields in the subsections, multiplied by a subsection correction coefficient, summed together gives automatically the final vote. The program implements a tabulated appointment calendar too, which facilitates to plan, for each manager evaluated, a series of meetings for future improvements.

In addition to the evaluation report web-form there is a training web-form as requested by the model which controls individual abilities, as reported in figures 23 and 24. It is the most complex sheet to be implemented for at least two reasons: the reading/writing permissions on this report are flexible (i.e. both manager and evaluator can read/write on it, in different positions), and the second reason is that it is composed of many fields with different roles facilitating the addition of all types of manager tasks.

EVALUATOR

Manager: **Daniel Zotti** - Type of evaluation: annual

Evaluation period from: to:

Discipline:

Job assigned:

Department:

[Training \(PDF\)](#)

[Targets \(PDF\)](#) ⬇ ⬆

[Job \(PDF\)](#) ⬇ ⬆

[Job Description \(PDF\)](#) ⬇ ⬆

[Scientific Activity \(PDF\)](#) ⬇ ⬆

Fix coefficient evaluation, nonnegotiable (field 1,2,3,4,5)

1. Behavioral Characteristics - coefficient:

a) Field1:

b) Field2:

c) Field3:

Item Value:

2. Multidisciplinary Participation - coefficient:

a) Field1:

b) Field2:

c) Field3:

Item Value:

figure 23 - Training report web-form visualized by the Evaluator



Manager: **Daniel Zotti** - Type of evaluation: annual

Evaluation period from 01/01/2000 to 31/12/2000

Discipline: Primary

Job assigned: Surgeon

Department: Surgery

[Training \(PDF\)](#) 

[Targets \(PDF\)](#)

[Job \(PDF\)](#)

[Job Description \(PDF\)](#)

[Scientific Activity \(PDF\)](#)

Fix coefficient evaluation, nonnegotiable (field 1,2,3,4,5)

1. Behavioral Characteristics - coefficient: 3

a) Field1:	2
b) Field2:	2
c) Field3:	2
Item Value:	5.25

2. Multidisciplinary Participation - coefficient: 2

a) Field1:	2
b) Field2:	3
c) Field3:	2
Item Value:	3.33

figure 24 - Training report web-form visualized by the Manager

Researchers' evaluation program



In the researchers' web based program, from the home page it is possible to access four different web-forms as shown in figure 25: the personal data web-form, the publications web-form, the research projects web-form, and the other events web-form. Moreover, it is possible to get and consult a summary web-form. The program allows to edit the information creating a database of researchers whose information can be recovered any time it is necessary to insert the name of the person, e.g. insert as author.

 RESEARCHERS DB 

<h2 style="text-align: center; color: red; margin: 0;">RESEARCHER</h2> <p>Name: <input type="text" value="Daniel"/></p> <p>Surname: <input type="text" value="Zotti"/></p> <p style="text-align: center;"><input type="button" value="SEARCH"/> <input type="button" value="CANCEL"/></p>	<h2 style="text-align: center; color: red; margin: 0;">PUBLICATION</h2> <p>Title: <input type="text"/></p> <p>Type: <input style="border: 1px solid black; background-color: #333; color: white; padding: 2px 5px; font-size: small; font-weight: normal; text-decoration: none; width: 100px; height: 20px; vertical-align: middle;" type="button" value="ALL"/> ▾</p> <p>Year: <input type="text"/></p> <p style="text-align: center;"><input type="button" value="SEARCH"/> <input type="button" value="CANCEL"/></p>
<h2 style="text-align: center; color: red; margin: 0;">RESEARCH PROJECT</h2> <p>Title: <input type="text"/></p> <p>Number: <input type="text"/></p> <p>Type: <input style="border: 1px solid black; background-color: #333; color: white; padding: 2px 5px; font-size: small; font-weight: normal; text-decoration: none; width: 100px; height: 20px; vertical-align: middle;" type="button" value="ALL"/> ▾</p> <p>Line: <input style="border: 1px solid black; background-color: #333; color: white; padding: 2px 5px; font-size: small; font-weight: normal; text-decoration: none; width: 100px; height: 20px; vertical-align: middle;" type="button" value="ALL"/> ▾</p> <p>Year: <input type="text"/></p> <p style="text-align: center;"><input type="button" value="SEARCH"/> <input type="button" value="CANCEL"/></p>	<h2 style="text-align: center; color: red; margin: 0;">OTHER EVENTS</h2> <p>Title: <input type="text"/></p> <p>From: <input type="text"/></p> <p>To: <input type="text"/></p> <p>Base: <input type="text"/></p> <p>Type: <input style="border: 1px solid black; background-color: #333; color: white; padding: 2px 5px; font-size: small; font-weight: normal; text-decoration: none; width: 100px; height: 20px; vertical-align: middle;" type="button" value="ALL"/> ▾</p> <p style="text-align: center;"><input type="button" value="SEARCH"/> <input type="button" value="CANCEL"/></p>
































figure 25 - The researchers' "home page"

In the personal data web-form (see figure 26 below) all the information is reported including name, position, CV, age, structure, department, organized by year, and h-index too. In this form all the data can be searched for each sheet or a new profile can be inserted and called up or new information regarding the publications or the projects in which the researcher is involved.



 RESEARCHERS DB 

Personal data

Daniel Zotti (16/04/1987)

<p>Name: <input type="text" value="Daniel"/></p> <p>Surname: <input type="text" value="Zotti"/></p> <p>Date of birth: <input type="text" value="16/04/1987"/></p> <p>Address: <input type="text" value="Via Gatteri, 48"/></p> <p>City: <input type="text" value="trieste"/></p> <p>Telephone: <input type="text" value="040367304"/></p> <p>e-mail: <input type="text" value="zotti@burlo.trieste.it"/></p> <p>notes: <input type="text" value="campo note"/></p>	<h4 style="margin: 0;">Attachments</h4> <div style="border: 1px solid #ccc; padding: 5px; background-color: #e6e6fa;"> <table style="width: 100%; text-align: center;"> <tr> <td> Curriculum.pdf </td> <td> car29.exe </td> <td> car30.exe </td> </tr> <tr> <td> delay_flow.gif </td> <td> freccia_dx.png </td> <td></td> </tr> </table> <p style="text-align: center; margin-top: 5px;"> New Upload</p> </div>	 Curriculum.pdf 	 car29.exe 	 car30.exe 	 delay_flow.gif 	 freccia_dx.png 	
 Curriculum.pdf 	 car29.exe 	 car30.exe 					
 delay_flow.gif 	 freccia_dx.png 						

Annual details

Year	Role	Structure	Notes
2010	programmatore	servizio informativo	
2011	programmatore	servizio informativo	note 

[\[add field\]](#)

X

✓

figure 26 - Researcher's personal data web-form

In the publications web-form the produced publications are listed. All the details about the publications are collected in different fields as shown in figure 27, divided by title, journal, year of publication, impact factor IF attributed to the journal, with IF differences and particularities described in previous paragraph. The authors of each publication are listed in separated cells (name, surname, structure, position in the list of authors). An algorithm was developed to calculate automatically the IF for the researcher in a specific year, both the IF gained/reached by all the researchers working in a specific structure in that year.

RESEARCHERS DB

PUBLICATION details

Complications associated with total laparoscopic hysterectomy(TLH)

Publication type:

Title:

Journal:

Volume(installment):pages:

Publisher:

Year:

Project number:


Line:

Type:


Impact Factor:

Notes:

Attachments



pubb.exe



publication.pdf

New Upload

PUBLICATION AUTHORS

Name	Surname	Date of birth	Type	Pos
Daniel	Zotti	16/04/1987	<input type="text" value="2"/>	<input type="text" value=""/>
Mario	Rossi		external	5

[\[add_external_author\]](#)
[\[add_Burlo_author\]](#)




 Back
 DELETE
 EDIT

figure 27 – Publication web-form

For this aim it was decided to insert a field to indicate the position of the authors among the list of authors in order to establish, using another algorithm, the percentage attributed to the author for the publication. In figure 28 a new publication can be added listing apart the authors that can be already found in the database or can be added as external (other institutions) or as internal authors.

RESEARCHERS DB

New PUBLICATION

Publication type:

Title:

Journal:

Volume(installment):pages: e.g. 46(10):21-23

Publisher:

Year:

Project Number:

Line:

Type:

Impact Factor:

Notes:

AUTHORS

Name	Surname	Date of birth	Type	Pos
<input type="text" value="Mario"/>	<input type="text" value="Rossi"/>		esterno	<input type="text" value="5"/> ✘
Daniel	Zotti	16/04/1987	<input type="text"/>	<input type="text" value="2"/> ✘

[\[add external author\]](#)
[\[add Burlo author\]](#)



 CREATE PUBLICATION

figure 28 – New publication web-form

In the research project web-form the proposal submissions are reported to the national Ministry of Health programs, European Commission Framework, Interregional projects. The implemented fields specify the title, the topic, the budget required, the budget assigned, etc... as specified before. In this part all the research projects developed and held by every single researcher are reported. In the web-form there are cells where the number of each research project associated with the main area of study (obstetrics, neuroscience, etc) is edited according to the progressive number of all the IRCCS's projects. It is also possible to associate the publications that are a "product" of the efforts and studies referring to the project.

In the program there is also a "other events" web-form which reports the list of the congresses and meetings to which the researcher attended actively in oral sessions, as chairman, etc.

Furthermore in a summary (query) web-form there are tools to recover useful information regarding authors, publications, IF, to contribute to the evaluation of every researcher.

The program is implemented and updated continuously by the personnel of IRCCS's Scientific Directorate to know in any moment the level and the quality of scientific activity of the Institution.

IT Security issues

Every software which treats personal data has to be protected. In this case the DB was locked by a password and was implemented an authentication and authorization model. An initial login form based on the DB permits entering the corresponding username and password (encrypted) in order to have access to the programs.

Besides the username and password, the reference table contains name, surname and user date of birth (to avoid ambiguity). For the evaluation field “type” is added which represents the role of the user running the program; thus each user visualizes only his personal pages designed dynamically based on the type of authentication respect to the DB. These types are: the “evaluator” that has a main page which permits him to see, create and modify reports of all managers; the “manager” who can visualize only his own page but cannot modify what the evaluator has written about him; the “staff” which is limited to entering only hospital documents and cannot visualize or modify any report sheet; the “administrator” that has the permission to operate on the entire program in case of problems and can perform changes if necessary. Further developing methods are used for the program IT security, such as the use of the POST method in input forms instead of the GET method which shows form data on the URL.

5.2.4 Discussion

There are many advantages using this web application: first of all the model is realized and implemented for the first time and both for clinicians and researchers in a valuable platform designed around a strong database and a widely used and known technologies. Some advantages for both programs are an immediate availability of tools and information, an easy consulting and data updating, saving time, avoiding errors and duplicates, obtaining major information control and coherence, forcing the operators to respect a single procedure of data entry.

Electronic evaluation	Manual evaluation
Saving time in data entry and retrieval	Wasting time in data entry and retrieval
Avoiding duplicates and redundancies	Presence of duplicates and redundancy
Major control in data entry and visualization	Less data control and coherence
Automatic calculations of evaluation indices	Manual calculation and evaluation of indices
Multiple data access	Single data access
Major data security	Less data security
Fast data availability and summary	Slow and complicated data availability

table 2 - Electronic vs. manual evaluation

In particular for researchers’ evaluation the previous approach was based on a series of Excel data sheets, calculating all IF scores manually for each researcher and structure or department, generating errors and duplicates (for instance in IF calculation). Instead with the program is now possible to organize and correlate the information concerning the researchers and all their activities using a single platform and an easy-to-use interface capable even of complicated automatic calculations.

5.2.5 Conclusion

The programs replicate the evaluation processes creating different profiles of authentication and authorization which can then give to the evaluator the possibility to make lists of the professionals to evaluate, to upload documents regarding their activities and goals, to receive individual documents in automatically-generated folders, to obtain year-by-year individual scores and profiles.

The programs help to control and check all the activities performed by the managers and researchers in a more efficient and intelligent way establishing a skilled and easy-to-use monitoring instrument. The use of a web interface equipped with adequate security levels permits simplified management for all users, and can be easily reached everywhere at every moment.

In addition, the program itself encourages the dialogue and the exchange of ideas between the evaluator and the professional (both clinician or researcher) allowing to schedule meetings in order to discuss factors of observation/evaluation and to improve the manager/researcher activities.

The program is open designed and not proprietary avoiding difficulties in exportation and portability on different platforms (i.e. the use of a single application such as Excel); the graphics interface is user-friendly and at a high level of automation, hence it can even be used by users with less informatics skills.

The advantages of using web-based open-source software include easy data consultation and update, the implementation of IT security issues, the easy portability and scalability of the system itself.

Finally the software are easy to configure and are very scalable, and thus can even be used in other business or research (other IRCCS?) organizations.

5.3 Intranet solutions for clinical care [A9]

After the discussion of intranet services regarding document management and personnel evaluation, this chapter ends with the presentation of a solution designed and implemented for clinical practice. In respect of the other solutions proposed, this time - in the evaluated hospital - there was a well established and consolidated model using paper requests among the pharmacy and the requesting wards. So the process was to change (process mapping) the technology and measure the results, instead of the creation of a theoretical model and then its implementation. Anyway the intranet telemedicine services have been enriched with the creation of a platform for the total parenteral nutrition prescription.

5.3.1 Objective

Total Parenteral Nutrition (TPN) is defined as feeding a new born baby or a child by infusing nutrients intravenously, bypassing the usual process of eating and digestion. TPN has extended the

life of children born with nonexistent or severely deformed digestive organs and is a vital support for young patients. In the studied IRCCS (Scientific Institute carrying out biomedical research and clinical activities of relevant national interest) the formulation of TPN is one of the main activities of the hospital pharmacists both for hospitalized and home patients. There are two kinds of TPN [AC10]: short-term TPN may be used when a patient's digestive system is temporarily nonfunctional because of an interruption in its continuity; long-term TPN is used to treat patients with an impairment or a lack in nutrient absorption. The pediatricians must rigorously schedule and continuously monitor the nutritional needs of the patient. To accomplish this process they prescribe TPN by completing a paper-based form which is then sent to the pharmacy. Clinical pharmacists evaluate the patient's individual data and decide which TPN formula to prepare and use.

In this chapter is described the introduction and the use of an electronic web-based form in order to enhance the TPN prescription processes assuring a series of advantages in terms of IT security, affordability and risks evaluation [AC11] in comparison with the paper-based TPN prescription process [AC12].

5.3.2 Methods

To enhance the TPN prescription process a web-based system has been designed, developed and implemented to replicate the original paper based forms according to a “process mapping” approach. The software, developed in PHP programming language and based on open-source tools and services, is embedded in the hospital intranet and has been constructed according to the requirements of the pharmacists and the needs of the doctors. Figure 29 summarizes the architecture, showing the virtual database and application server, a few connected web browser clients and the intranet network layer below.

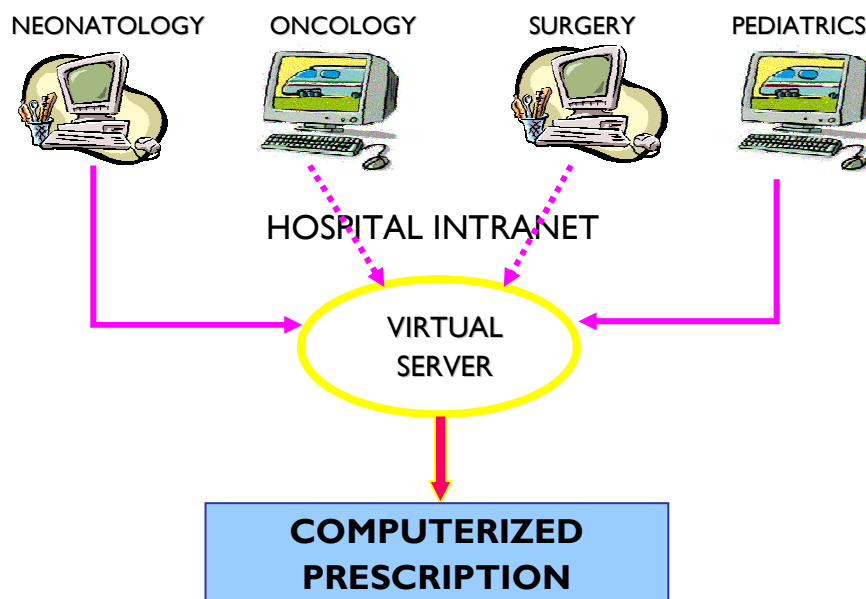


figure 29 – TPN computerized architecture

The system is based on a LAMP (Linux Apache MySQL PHP) open-source platform and functions on a internal virtual server; it consists of a database loaded with prescription data and information from the authorized wards, and of an on-line form in which data is added through a common web browser or even a smartphone connected to the hospital network via wi-fi.

In such a way doctors can prescribe TPN from any pc connected to the hospital intranet network, using a secure and personal authentication method in order to guarantee their correct identity. The pharmacists open a secured web page where, through a continuous polling of the requests' status, the complete list of the treated patients appears with, in particular, an alert active on the last requests inserted. Until the request has been processed and completed the alert remains. Figure P shows the different steps of the TPN prescription process different steps starting from the doctor's direct request through the original (translated from paper) web-form reported, as example in figure 30, until the final step where pharmacy receives the request and prepare the TPN formula [AC13].

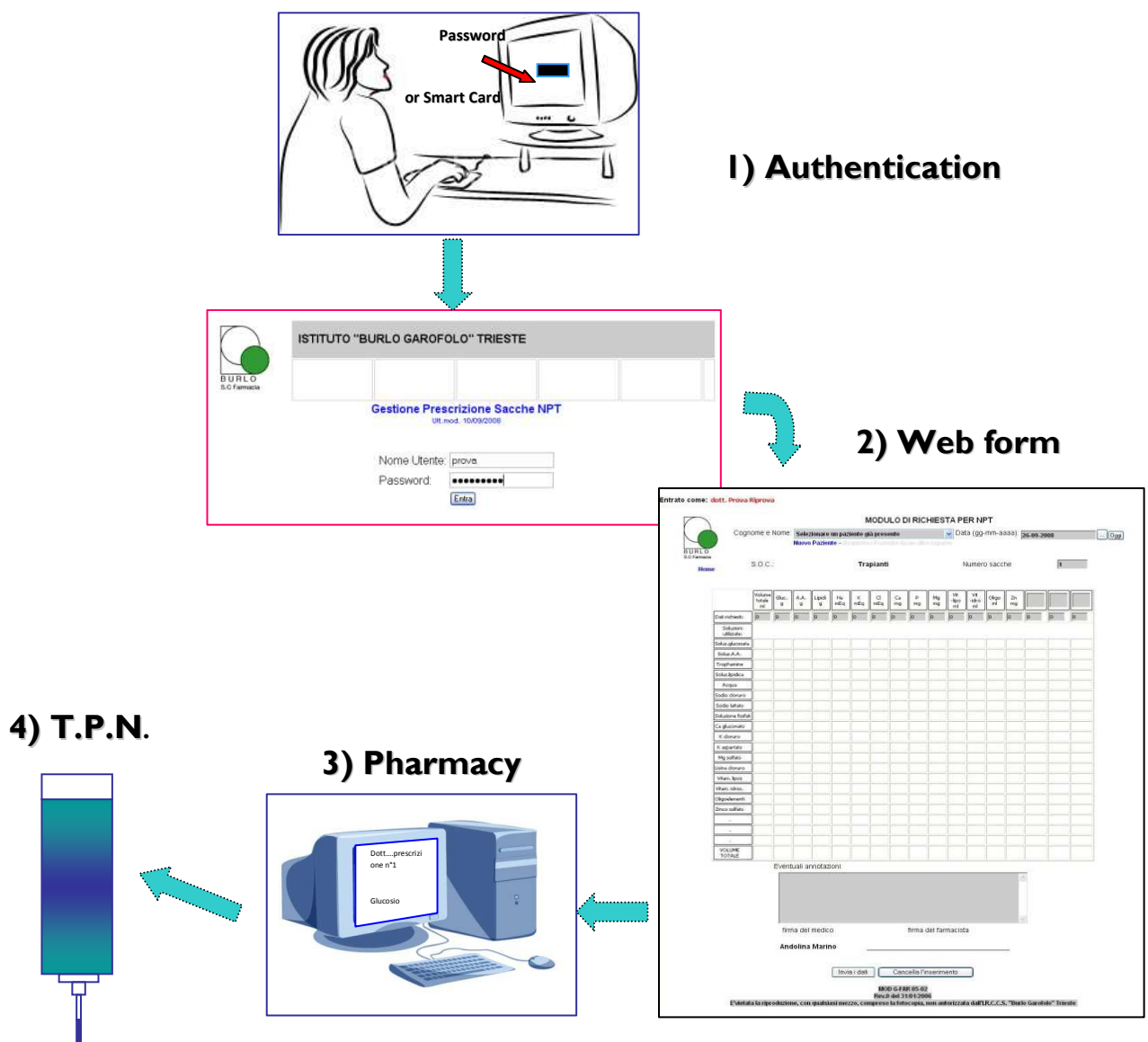


figure 30 - TPN prescription process. 1) Login and access; 2) Computerized TPN sheet as visualized by the doctors; 3)The pharmacists receive the prescription and 4) prepare the TPN

5.3.3 Results

The two figures below show, respectively, the mean of the computerized TPN prescriptions obtained per year from 2008 (figure 31) and an error comparison between the paper-based and computer-based requesting forms (figure 32). The system started up during 2008, is actually in use and now almost all the IRCCS hospital wards have been activated, distributing access credentials in particular to the neonatologists and pediatricians involved [A9].

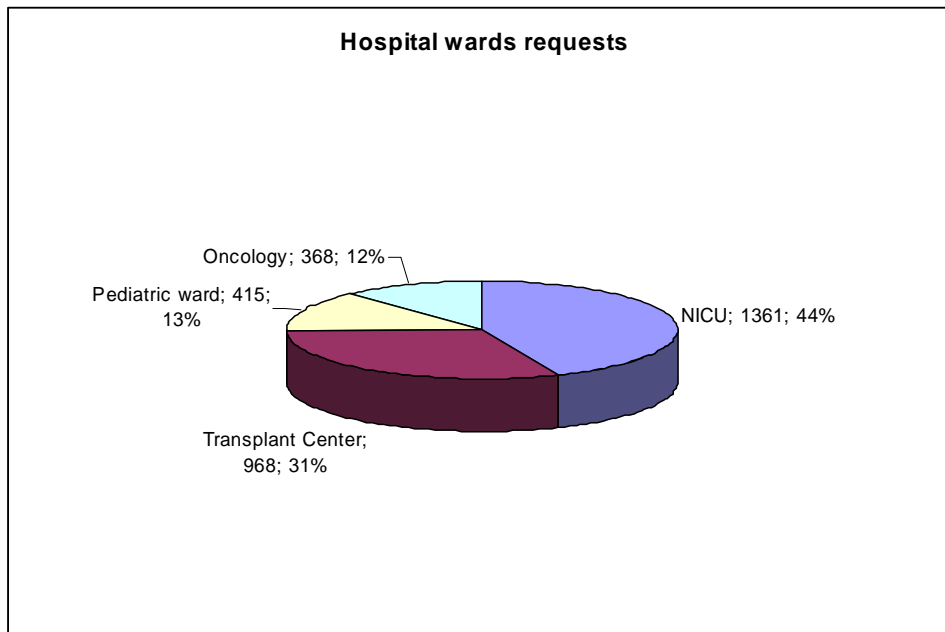


figure 31 - total distribution of TPN mean requests per year from 2008

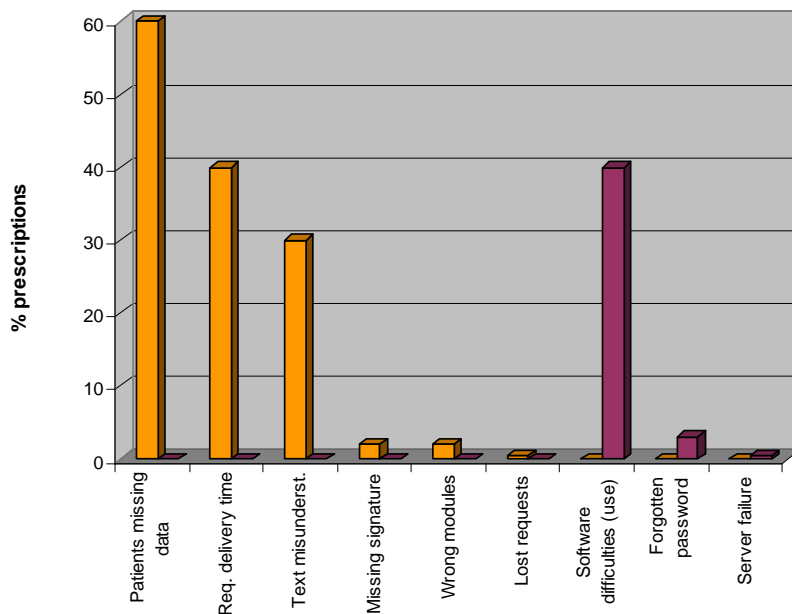


figure 32 - paper-based versus computer-based error frequencies

Figure 32 summarizes the problems deriving from the use of the paper-based and computer-based TPN prescription [AC12]. In the paper-based format problems occur due to: missing patient data; delays in the delivery of the request; reading and copying misunderstandings. Electronic-based forms have reduced the incidence of these errors, but there are still some drawbacks and difficulties regarding the software use because of the necessary training in managing it.

5.3.4 Discussion

Computer-based prescription assures the correct completion of the form, reducing common writing and reading errors, improving the correct text comprehension. In addition there is no risk in losing the form as is the case with the paper forms. The requests are immediately available to the pharmacists as soon as the doctors compile and send the data.

Other observed advantages in using the computerized prescription may be summarized as follows:

- to guarantee the correct prescription preparation, administration and tracking through the use of common .pdf file formats directly on the pharmacists' personal computers;
- to reduce medico-legal and clinical risks through the use of a password to authenticate both the doctors and the pharmacists;
- to obtain a medical prescription correctly and rapidly;
- to assure the not-ambiguous identification of the patients eventually coded anonymously (to extract data for clinical studies and research);
- to plan in advance the daily work-lists for pharmacy personnel involved in TPN request preparation.
- the availability of affordable IT instruments gives the perception of the advantages that such systems have in improving clinical practice and quality of care.

5.3.5 Conclusion

The introduction of this system provided advantages to improve the security of the pediatric healthcare process as mentioned above. The system was devised with the goal to avoid common reading errors, to improve the correct text comprehension, to ensure prescription preparation, administration and tracking. The obtained results demonstrates the accomplishment of the declared objectives. According to a process of total quality control, the system reduces clinical risks regarding issues such as the correct and rapid availability of medical prescriptions and the incorrect identification of the patients.

In comparison with paper-based TPN prescriptions, electronic-based forms have reduced the incidence of errors, the possible lack of patient data and reading misunderstandings.

In addition the system is ready to support a series of improvements such as the compatibility with hospital information system architecture, the integration of the system with the hospital electronic medical records, the possible integration with digital sign processes and legal conservation of electronic parenteral requests. TPN requests are in fact official medico-legal documents.

Regarding future developments implementing a TPN system working on a smartphone or an I-phone has been proposed, developing an application ready to manage the prescription process.

Chapter 6

Mobile tele-radiology: a present approach for the future [A14],[A15]

As discussed in Chapter 3 (mobile) tele-radiology may be used in an emergency when the specialist or senior staff are not available, and a quick consultation is necessary. Recently smartphones and tablets with high quality display have been marketed. The mobile tele-radiology study started in 2011 aimed to determine if these devices can be used for radiologic review, diagnosis and consultation without diagnostic information loss. The study was faced both from a clinical [A14],[A15] and an engineering [A17] points of view and is reported in the next sections (6.1 and 6.2). In section 6.3 there is the presentation of the tablet/smartphone evaluation protocol, suggested in order to obtain a more objective evaluation of the devices' displays under test [A16].

Apart the considerations and the results obtained in this study, it is worthy of note that some of these mobile devices and their apps intended for medical diagnostics are reaching the compliance with international regulations and standards. U.S. Food and Drug Administration (FDA) [W7], for example, cleared in February 2011 “a mobile radiology application (Mobile MIM, manufactured by Cleveland-based MIM Software Inc.) that allow physicians to view medical images on the iPhone and iPad manufactured by Apple Inc”. The FDA news release continues specifying that “the application is the first cleared by the FDA for viewing images and making medical diagnoses based on computed tomography (CT), magnetic resonance imaging (MRI), and nuclear medicine technology, such as positron emission tomography (PET). It is not intended to replace full workstations and is indicated for use only when there is no access to a workstation”. About the certification regarding the compliance to regulations and standards, similar evaluations start to be done for other marketable products as the Aycan Mobile App used in this study. The collaboration with Aycan Digitalsysteme GmbH started in early 2011 when Aycan Mobile App was still in beta release. This App is labeled with a CE-Mark as a Medical Device Class I in Europe and provides also a visualization correction Function (VCF) according to the DICOM GSDF curve, which is similar to a DICOM Preset medical grade display. Finally the same iPad touchscreen reaches during 2011 regulations of DIN V 6868-57:2001-02 (Consistency and uniformity testing for medical displays).

6.1 Mobile tele-radiology – a clinical approach

In the clinical part of the study there were evaluated almost 100 exams [A14]. CT and MRi images were chosen because of their low matrix, usually less than smartphones and tablets display resolution. CT and MRI examinations were randomly chosen among exams performed in the IRCCS's Pediatric Radiology ward in the last two years. Anonymous exams were sent to smartphones and tablets using a VPN encrypted connection and analyzed (interpreted) by two senior radiologists. Apple (iPhone 3 and 4 and iPad 1 and 2) and Android (Nexus One smartphone and Asus Transformer tablet) devices were used for our study. Results were collected in a database

and compared with gold standard results. The gold standard is the PACS system used in the Pediatric Radiology ward. No significant loss of information was detected. Small inter- and intra-operator differences were shown and were due more to individual variability than to device inadequacy. CT abdominal examination were the most demanding reports because of the high number of slices. MRI exams, on the contrary, were the easiest to report, having a low number of scans and lower resolution. Preliminary results confirm that there is no significant loss of diagnostic information in CT and MRI exams reported using smartphones.

6.1.1 Materials and methods

Recently smartphones with high quality display have been marketed, and at the same time fast internet connections are easily available. To evaluate if these devices can be used for mobile and remote radiologic consultation without diagnostic information loss, the two most widely spread systems were chosen: Apple IOS and Android OS based devices.

Dealing with the technical specs the iPad's 9.7" LED-backlit display supports pixel density greater than standard PACS monitors, with resolution (1024x768) sufficient for 2 frames of 512 x 512 CT or US images and 8 frames of 256 x 256 images plus function keys. Display luminance is 300 cd/m², on par with 24" PACS monitors. The A4 System-on-a-Chip combines CPU, GPU, and hardware controllers, with CPU performance significantly faster than most netbooks. The GPU provides graphics acceleration sufficient to deliver 720p video with parallelization of CPU and GPU tasks. Data connectivity is via 802.11n Wi-Fi, capable of 300 Mbps throughput plus 3G capability (real world max throughput of 1.7 Mbps), in addition to Bluetooth 2.1. There are 16-GB, 32-GB, or 64-GB flash memory storage options. From 2010 iOS4 the operating system supports multitasking (for applications like DICOM viewer, EMR, and speech recognition [SR]).

On the other side Android devices may reveal very different specs according to the manufacturer: in general there were used devices with Android OS 2.3 or greater.

Two DICOM viewers were used: OsiriX v.2 for the Apple iPhone (version 3 and 4), Aycan Mobile App. for the iPads and DicomDroid beta v. 0.9 for Android devices. All the viewers are image processing software dedicated to DICOM images. They are fully compliant with the DICOM standard for image communication and image file formats. They are able to receive images transferred by DICOM communication protocol from any PACS or imaging modality including the open-source DCM4CHEE server. They query and retrieve studies from/to a PACS server or a PACS workstation. The iPhone 4 is equipped with a retina display screen, with a resolution of 960 x 640 pixels. Nexus One, for example, has an AMOLED screen with a resolution of 600 x 480 pixels. Both smartphones have a 3.7 inch screen. The Asus eee-PAD Transformer uses an IPS display technology as the iPad 1 and 2.

Anonymous exams stored in an ad-hoc mini-PACS were sent to smartphones using an encrypted connection based on a point to point VPN realized on a common mobile network or directly using the Aycan Mobile App.; the exams were interpreted by two senior radiologists (80% and 20%). In the study there have been evaluated 93 exams.

CT and MRI images were chosen because of their low matrix, usually less than the smartphone or tablet display matrix. CT and MRI examinations were randomly chosen among exams performed in the Pediatric Radiological ward in the last two years. In particular there were 24 CT and 69 MRI exams. CT abdominal examination was the most difficult to interpret because of the high number of scans (slices). MRI exams, on the contrary, were the easiest to report, having a low number of slices and low matrix.

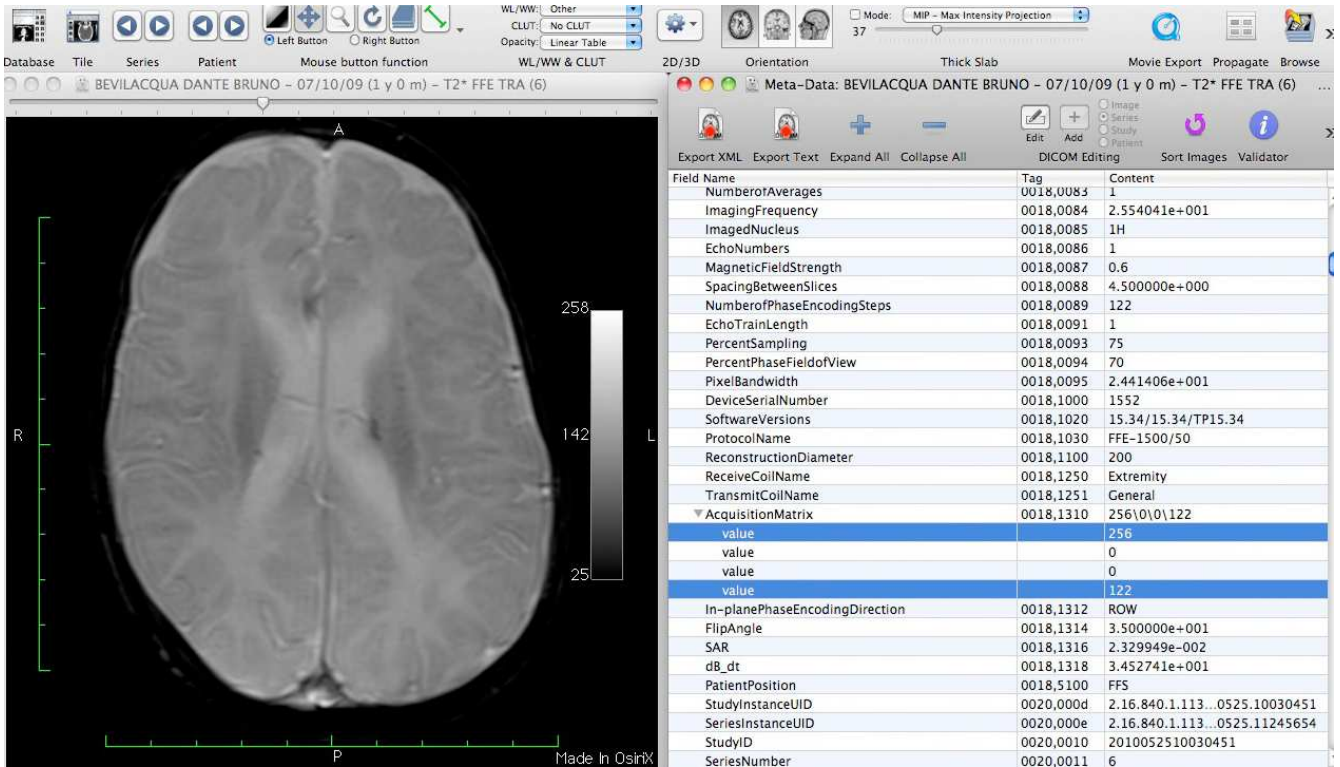


figure 33 – 256x122 MR image

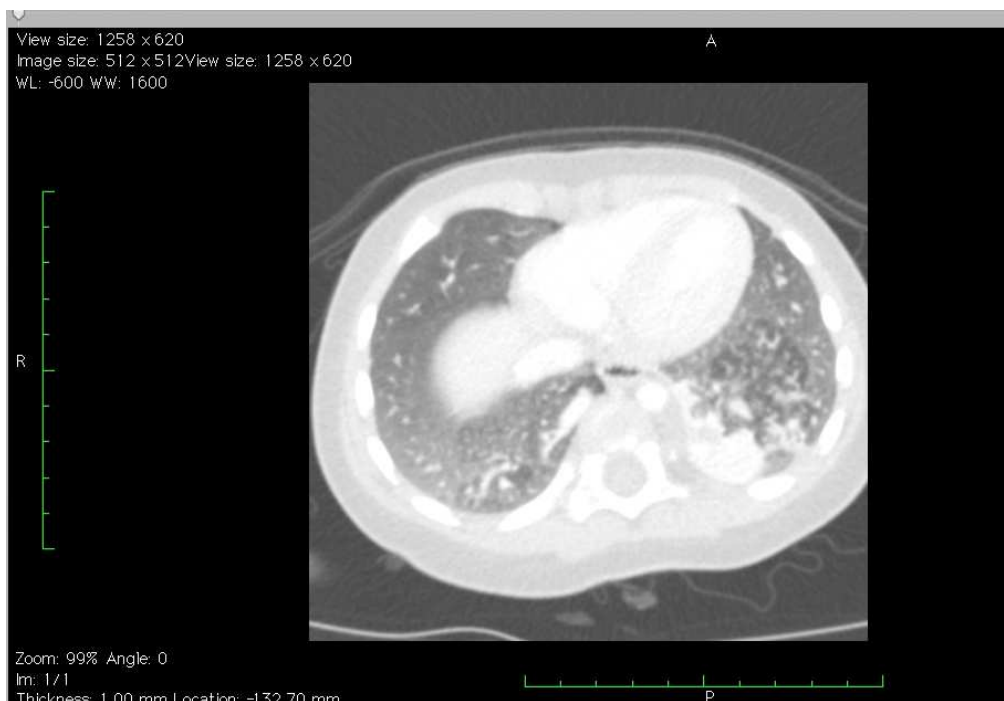


figure 34 – 512x512 MR Image

The large number of findings in an entire exam did not easily allow for objective analysis. Thus, only one slice for each exam was chosen by the PACS radiologist to be submitted to the smartphone radiologist for evaluation. Results were collected in a database built using Filemaker Bento and compared with gold standard results. The Gold standard is the PACS system used in pediatric radiology ward, an Esaote Aet DICOMed Review, v.4.1.

6.1.2 Results

There have been evaluated 93 exams. No significant loss of information was detected. Insignificant inter- and intra-operator differences were found to be due more to individual variability than to device inadequacy. All missing findings were detected without any difficulty on a second check.

Almost as a paradox missing findings concerned more the image interpretation on the PACS workstation rather than on the mobile devices. The reason of this anomalous result may be the fact that working on a small new workstation focuses all the physician attention, more than working routinely on an everyday used workstation. Missing findings were only minor ones, while the report was essentially the same.

Total no. exams	Matching	Partial matching	Non matching
24 CT	22	2	-
69 MRI	68	1	-
93 CT+MRI	90	3	-

figure 35 - results

6.1.3 Discussion

This part of the study evaluated the use of smartphones and tablets for radiologic review, diagnosis and consultation. The obtained results confirm that there is no significant loss of diagnostic information in CT and MRI exams reported using mobile devices in accordance with other literature studies and projects (see Chapter 3). Radiologists have, however, reported a subjective sensation of fatigue after long sessions essentially in using smartphones; this fact confirms that the systems are suitable for consultation, not for primary interpretation or report.

iPADs' and tablets' applications could instead include primary interpretation, radiographic viewing, speech recognition (SR), resident education, and patient/clinician interaction [AA30]. Advanced visualization applications are under development; some obstacles may remain in 510(k) FDA

approval or CE Mark certification for all the applications and all the devices [AA29]. Further, the tablet's displays require closer positioning, with potential vision, technical and ergonomic challenges as showed in next section. The iPad and Android tablets more than the smartphones, can provide a portable means for house staff to view radiographic images/reports. The use of a microphone and a speaker opens the door for SR applications. For resident education, the tablets can deliver electronic books, web content, and synchronous and individualized viewing for interactive case-based learning. The device offers opportunities for clinician/patient interactions and numerous EMR applications (e.g., a dashboard integrating a range of patient data/images with the tablets' intuitive interface).

6.2 Mobile tele-radiology – an engineering approach

From an engineering point of view the mobile tele-radiology challenge may be faced considering the international standards for the evaluation of medical electronic display devices and the evaluation of IT security issues in transmission, communication and media access accountability, availability and data integrity.

6.2.1 The evaluation of electronic display devices

International standards and regulations propose a series of technical controls in order to assess the industry or marketable compliance of display devices [B2]. Here is proposed a brief list of some of these standards that may be adopted for the evaluation of the tablet displays for review, visualization, diagnosis and possibly report of medical images.

The AAPM TG-18 report

The intent of the AAPM TG18 “Assessment of display performance for medical imaging systems” report [B2] is to provide standard guidelines to practicing medical physicists, engineers, researchers, and radiologists for the performance evaluation of electronic display devices intended for medical use. The scope of the TG-18 report is limited to display devices that are used to display monochromatic medical images. Cathode-ray tubes (CRTs) and even more liquid crystal displays (LCDs) are currently the dominant display technologies in medical imaging. Even if there are still many cathode-ray tubes (CRTs) displays used in medical imaging as described in the report, for the scope of this research, tests are referred to tablet's LCD panels. Many of the tests and concepts in the report could be adapted to other display technologies that might find their place in medical imaging now and in the future. The report describes the actual primary display technologies; gives some engineering specs for display devices; and suggest an assessment of display performance through a series of tests intended for quality of control and technology acceptance, regarding geometric distortions, display reflection, luminance response, luminance spatial and angular dependencies, display resolution, display noise, veiling glare, display chromaticity and

miscellaneous general tests. As shown in Appendix A the proposed assessment protocol for the evaluation of tablet display characteristics is essentially based on the AAPM TG18 tests.

NEMA-DICOM Standard (PS 3)

In 1984, the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) formed a committee that produced and currently maintains the Digital Imaging and Communications in Medicine (DICOM) standard. For the scopes of this study on the quality of the tablets' displays it is important to consider a document the NEMA-DICOM committee produced and called "Part 14: Grayscale Standard Display Function" (PS 3.14 – 2006) [B3]. The document specified a standardized display function known as the Grayscale Standard Display Function (GSDF) for grayscale images. The intent of the standard was to allow images transferred using the DICOM standard to be displayed on any DICOM-compatible display device with a consistent grayscale appearance. While other parts of the DICOM Standard specify how digital image data can be moved from system to system, it does not specify how the pixel values should be interpreted or displayed. PS 3.14 specifies a function that relates pixel values to displayed luminance levels. The consistent appearance of images was approached through perceptual linearization, where equal changes in digital values cause equal changes in perceived brightness/luminance. The relationship that PS 3.14 defines between digital image values and displayed luminance (the GSDF) is based upon measurements and models of human perception (Barten model) over a wide range of luminance, not upon the characteristics of any one image presentation device or of any one imaging modality. It is also not dependent upon user preferences.

ISO 13406

Flat panel display devices were addressed by ISO 13406-2:2001, Ergonomic Requirements for Work with Visual Displays Based on Flat Panels. Part 2: Ergonomic Requirements for Flat Panel Displays (ISO 2001). The key display issues covered by this standard were display luminance, contrast, reflection, color, luminance uniformity, color uniformity, font analysis, pixel defaults, and flicker. Under ISO 9241, ergonomic requirements for display devices were specified under parts 3, 7, and 8.

VESA Flat Panel Display Measurements Standard

In May 1998, the Video Electronics Standards Association (VESA) released Version 1.0 of the Flat Panel Display Measurements standard (FPDM) (VESA 1998). The purpose of this document was to specify reproducible, unambiguous, and meaningful electronic display metrology. The FPDM standard was strictly not a compliance standard, but rather a manual of procedures by which a display's conformance to a compliance standard could be verified. It was intended to extend the standard so that it could be used for all display types. However, the standard focused on emissive or transmissive color displays that are used in the workplace, in laptop computers, or equivalent. Particular attention was paid to the measurements that would characterize the performance of flat-

panel displays. The measurements were divided into the following categories: center measurements of full screen; detail, resolution, and artifacts; box-pattern measurements; temporal performance; uniformity; viewing-angle performance; reflection; electrical performance; and mechanical and physical characteristics.

SID (The Society for Information Display)

Through its journal, publications, symposiums and proceedings SID publishes original and objective reports and works dealing with the business and the technology (theory and practice) of information displays. Issues include manufacturing technologies and the underlying chemistry, physics, physiology, psychology and human factors; measurement techniques and all aspects of the interaction between equipment and its users.

6.2.2 IT security issues

The overall security topics regarding the use of tablets and related apps in telemedicine solutions or projects and in particular in tele-radiology may be summarized as [B12]:

- Device Control and Protection
- Data Protection
- Secure Network Communication
- Secure Platform Foundation

For example the apps for iOS are reviewed by Apple before they are released for customers. This is a benefit for the integrity and security of the software and the iPad. Currently there are no known viruses and other compromising software published for iOS.

Confidentiality topics

Confidentiality assures that no unauthorized users have access to the information. There are two possible sources identified which might cause a risk regarding confidentiality:

- Access to the information during the information is transmitted to the device.
- Access to the information while the information is on the device.

This is addressed by the following topics:

- Use of encrypted transmission channel; data is encrypted during transmission.
- Data is stored encrypted on the device.
- Application and data access is secured by password.

- It is recommended to send only anonymized data to the mobile devices. Anonymization of the 'patient name' can be used by default or switched on/off for each individual transfer.
- It is recommended to make use of remote deletion services for the mobile device from the manufacturer of the device.
- It is recommended to secure access to the mobile device by password.
- If a user logs into the application which keeps data for another target user at this time, the data for the other user is deleted during the login process.

The encryption is implemented in a way which doesn't even allow the device respectively the operating system manufacturer to get access to the data.

Integrity topics

Integrity assures that the information is correct - that is, it has not been improperly modified.

The data is encrypted during transmission (over an encrypted channel) and during storage on the device. From that point where the data left the source node until the data is displayed on the screen there is no possibility to alter the information at the data sets because modification would imply correct decryption and correct encryption after modification, which is not possible with reasonable effort.

The data transfer mechanism assures that incomplete or modified transmissions can be detected and that the user is notified. Regarding the software distribution process it can be assumed that only the developer or the manufacturer is able to replace the application itself by another version. Software modifications on the device are not envisioned. Therefore unwanted software changes can be seen as precluded.

Availability topics

Availability suggests that the information will be available when needed. It is in the nature of a mobile device that it has to handle the uncertainty of the transmission channel especially if the area of mobility is not limited to a certain area where somehow controlled transmission channel conditions can be expected like at a hospital building or campus.

Topics regarding availability in use of mobile devices in telemedicine are:

- Eventual device usage in time critical scenarios.
- The problem to ensure to have a reliable transmission channel when needed (access to WiFi hotspots or 3G/EDGE/... network access – depending on the technique and on the position of the user).
- Correct operation of the update/upgrade functionality from any previous apps' version will be checked during the verification process.

Accountability topics

Accountability is the application of identification and authentication to assure that the prescribed access process is being done by an authorized user.

- Every person who wants to use the system must have a valid user account. For each user account a unique user name has to be selected. It is recommended not to share user accounts but to have a dedicated account for each person that would like to use the system.
- People who would like to exchange messages respectively images have to authorize each other before one is able to send data to the other.
- Each message or sent image set from a fixed station to the mobile app/user has one unambiguous user as the target of the message/image set.
- Access to data of a certain user is only possible after successful login

6.3 The assessment of a measurement protocol for mobile tele-radiology

As shown in chapter 3 (sections 3.4, 3.5 and 3.6) and in sections 6.1 and 6.2 tele-radiology is an articulate and complex section of telemedicine regarding the use of radiological high technological devices and PACS systems to provide appropriate tele-diagnosis and tele-consulting. Mobile tele-radiology in particular is a very recent discipline whose potentials and feasibility have been explored during the last years in US and European wireless hospital wards using MD certified tablets and medical records, to visualize and report patient clinical images and data. Some recent studies (Chapter 3) are now proposing and demonstrating the use of commercial tablets such as iPad and Android tablets in hospitals, evaluating compliant technical specs and clinical benefits or drawbacks deriving from their clinical use. Tablets seem very attractive both for medical staff and for technicians, especially because the leading and emerging displays technologies (OLED, IPS, AMOLED, RETINA Display, ecc...) and the ease of use.

6.3.1 Objective

The specific aim of this study focuses about the clinical and technical international standards and regulations concerning mobile radiological tele-consultation and/or tele-reporting platform, in order to identify the criteria, to propose a possible evaluation measurement protocol for mobile devices' displays and establish how tablets and smartphones are suitable for radiological diagnosis and medical image reporting [A16],[A17].

However, the use of mobile devices also for tele-consultation presents some restrictions and drawbacks concerning the reliability and the security of the networks, the proper set of DICOM

images transmitted, the use of software and hardware certified as Medical Device (MD), and at last the technical specs and performances of mobile devices' displays. After the evaluation of the proper display technical specs for mobile tele-radiology, in this study it has been proposed a TG18 and DICOM compliant measurement protocol for mobile devices' displays similar to the calibration and evaluation protocol used for medical imaging systems. The protocol evaluates when mobile systems based on tablets and/or smartphones could be used for tele-consulting and possibly tele-reporting in different environmental conditions.

6.3.2 Materials and methods

The proposed measurement protocol has been applied to get display's performances of a couple of tablets both Android and Apple. The devices are equipped with DICOM compliant apps and have been chosen among different vendors in order to take into account different display technologies. The two Android and Apple mobile architectures and systems used are similar and provide a transparent way to share DICOM images in local and also to distant networks. The DICOM images are stacked into cases (at the workstation OsiriX PRO software inside the hospital/imaging center) and sent to iPADs via the aycan mobile app integrated in OsiriX PRO and via a VPN to the DicomDroid application on Android tablets. In figure 36 there is a representation of the workflow to send image sets to the remote aycan mobile app via a 3G/WiFi connection and a Notification Server. This server doesn't store any patient data and is only used for establishing the proper connection between sender and receiver.

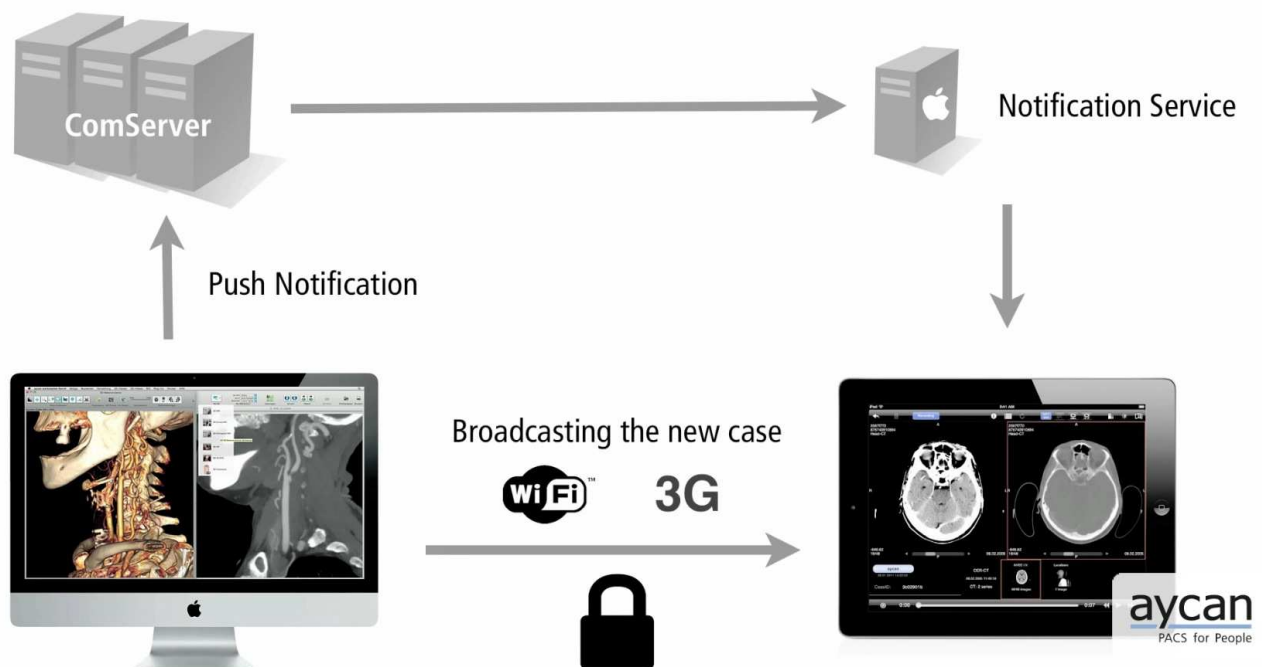


figure 36 – aycan mobile workflow (thanks to Aycan GmbH)

For Android tablets the network connections are assured via a VPN established directly on the OsiriX PRO workstation. The existence of a new case is signaled to the iPad user through the Apple Push Notification service, while for DicomDroid is acquired as for a PACS node. After login to the aycan mobile App some meta data and thumbnails of the case are retrieved by the iPad and

the same is for DicomDroid. For the iPad application if both devices (aycan mobile and aycan workstation OsiriX PRO) are logged in at the same network, they will establish a secure, encrypted channel and send the images directly to the iPad. If they are in different networks without routing, they will establish a secure, encrypted ad-hoc SSL tunnel between the devices and send the images to the iPad. Used AES encryption has the advantage to eliminate the need for time-consuming VPN connections (as requested for DicomDroid application).

AAPM report of TG18 “Assessment of display performance for medical imaging systems” has been used and in particular TG18-LN, TG18-QC, TG18-CQ, TG18-UNL, TG18-CX, TG18-AFC, TG18-GV, TG18-AD tests (see Appendix A). Some of the measures regarding the luminance and illuminance tests have been performed with the Scanditronix LX Plus photometer with the same ambient illuminance and physical conditions.

6.3.3 Results

In a preliminary set of measures almost all the tested displays show that, in an environment with repeatable and controlled illuminance and display luminance conditions, they may obtain satisfying responses according to the measurement protocol proposed. In particular, regarding the TG18-LN luminance tests, the best responses (within the $\pm 10\%$ limits for MD Displays) have been obtained in images sets with low contrast range; and in general a better perceptual linearity (figure 37) has been obtained in respect to a typical secondary radiological monitor. Figure 38 shows a comparison between an iPad not-calibrated luminance response versus a secondary class radiological monitor with evidence of the Grayscale Display Function (GSDF) and the $\pm 10\%$ limits for dL/L.

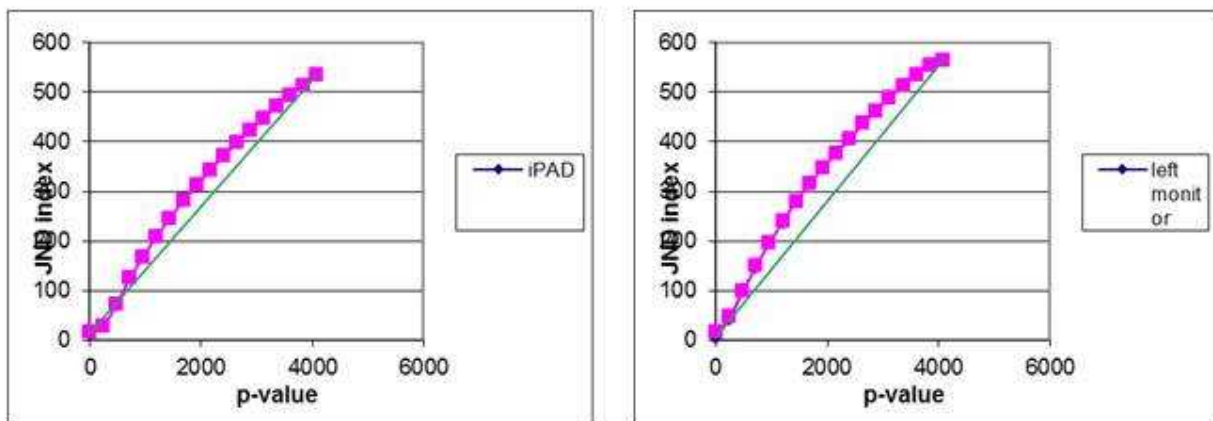


figure 37 – perceptual linearity calculated for the iPad (left) and a secondary display device (right)

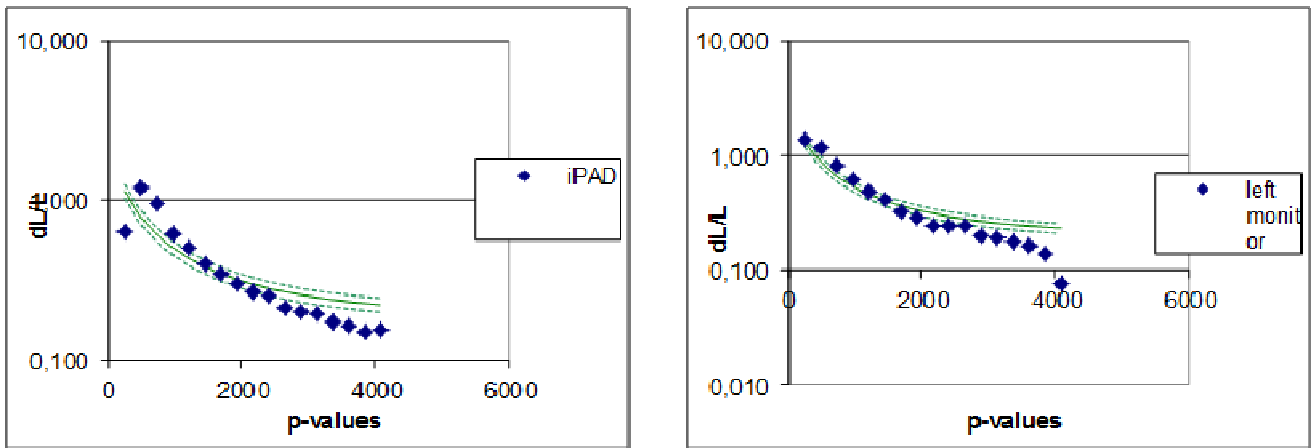


figure 38 - iPad not-calibrated luminance response versus a secondary class radiological monitor luminance response

In the table below are reported the tests and the results of the measurement protocol (cf. Appendix A) for two tablets, respectively an Apple iPad 1 and an Asus eeePad Transformer Android tablet. Not all the tests are reported. The measures were taken in a Magnetic Resonance room built for the diagnosis, interpretation and report of clinical images.

Excepting the luminance response (that was worse for the Asus tablet and is not reported here) the two tablets, built with the same declared display technology (the IPS – In Plane Switching - active matrix LCD flat panel technology), showed a good protocol evaluation regarding especially geometric distortions, spatial resolution and luminance uniformity; display noise and visual angles reported values comparable to secondary class display devices. Both the tablets suffered for diffuse and specular ambient reflection artifacts.

Measured characteristic	Test	iPAD	Asus Transformer
L(min)	TG18-LN	0,13 cd/m ² ;	0,11 cd/m ²
L(max)		153,9 cd/m ²	180 cd/m ²
Luminance response	TG18-LN	(figure 37)	-
Geometric distortions	TG18-QC	(<2%)	(<2%)
Luminance uniformity	TG18-UNL	0,10% (<30%)	0,25% (<30%)
Spatial resolution	TG18-CX	3 (<4)	3 (<4)
Display Noise	TG18-AFC	only details of two quadrants on four are visible	only details of two quadrants on four are visible
Veiling glare (and Glare Ratio)	TG18-GV		

		3 details are clearly visible	3 details are clearly visible
Diffuse ambient reflection	TG18-AD	Better if activated the visual correction function (vcf) L(min)>4*L(amb)	Worse with L(amb) L(min)>4*L(amb)
Specular ambient reflection	-	L(min)>4*L(amb) but there are reflected artifacts on the screen	L(min)>4*L(amb) but there are reflected artifacts on the screen
Ambient luminance (L(amb))	-	0,02 cd/m2	0,02 cd/m2
Ambient illuminance	-	6,2 lux	6,2 lux
Visual angle	TG18-CT TG18-LN	Almost 130° LR'=103,9 (>70)	Almost 130° LR'=75,88 (>70)

table 3 – the protocol test results

6.3.4 Discussion

Medical images produced by the same signal may have completely different visual appearance, information, and characteristics on different display devices. In medical imaging, it is important that there be a visual consistency in how a given digital image appears. A digital image which has good diagnostic value when viewed on one device could look very different and have greatly reduced diagnostic value when viewed on another device. GSDF was developed to provide an objective, quantitative mechanism for mapping digital image values into a given range of luminance. An application which knows this relationship between digital values and display luminance can produce better visual consistency in how that image appears on diverse display devices.

The relationship that DICOM PS-3.14 defines between digital image values and displayed luminance is based upon measurements and models of human perception over a wide range of luminance, not upon the characteristics of any one image presentation device or of any one imaging modality.

Operatively there are two requirements for obtaining equivalent image appearance on different display devices, as requested by the TG18 report and the DICOM PS 3.14. The first requirement is that the devices be calibrated using the same luminance response standard. The DICOM Grayscale Display Function (GSDF) is the model selected for the standardized luminance response. The second requirement is that the devices have the same luminance ratio, $LR=L'(\max)/L'(\min)$ (see Appendix 1). When viewing an image, the human visual system adapts to contrast within a limited

range of luminance. After adaptation to the overall brightness of an image, the visual system has reduced contrast in brighter and darker regions. An image viewed on a device with a large luminance ratio will have poor contrast in bright and dark regions when compared with the same image display on a device with a small luminance ratio (e.g., a secondary class display with LR = 100). Thus, equivalent appearance requires that images be displayed on GSDF-calibrated devices with the same luminance ratio.

It is notable that equivalent appearance can be achieved with devices having different $L'(\max)$. While visual perception has poor sensitivity in dark regions, the GSDF increases the contrast between display controller input states, p-values, at low luminance levels. The value of a bright display device is that $L'(\min)$ is large for the same luminance ratio, and therefore higher values of $L(\text{amb})$ can be tolerated. Bright displays can thus be used in clinical locations where it is impractical to reduce ambient light levels.

The obtained results show the iPad measured characteristic curve with a shape, a slope and a degree of scatter not so far from the ideal GSDF. For low contrast images and studies the luminance obtained values respect the $\pm 10\%$ limits imposed for the primary class medical devices displays. The curve obtained in the above figure 37 shows that iPad measured values regarding perceptual linearity which assesses a good or bad correspondence between the luminance values (in terms of Just Noticeable Differences) and the grayscale values (p-values), is more linear for the tablet than that measured for a secondary class display device. From a clinical point of view, according to the standard, this is a good result because a good perceptual linearity means a better image interpretation reducing and avoiding misinterpretation and diagnosis errors.

6.3.5 Future developments of the study

Mobile devices measurement protocol must be evaluated in different conditions in respect of the controlled illuminance and physical conditions of a MRI or TAC hospital dedicated room. This is a critical task and the compliance with the protocol settings and requirements will be more difficult and problematic (if not impossible) to be achieved and respected. In these conditions the physicians must be warned in using the device especially for a diagnosis or a tele-consult. Automatic warning systems must be implemented in programs dedicated to mobile tele-radiology almost immediately in order to inform physicians of the risks may occur in the visualization and interpretation of the medical images.

A touchscreen is **always affected by fingerprints** while usage. Users should always check the display before and while usage and clean the display when necessary or use special “pens” in order to reduce and avoid perceived image artifacts.

The commercial tablets haven't the hardware and/or the software to be calibrated according to the DICOM GSDF, but there is a way for the tablets to approximate the GSDF as illustrated in Annex C of the DICOM PS-3.14 document. In particular a statistical analysis of the measured characteristic function according to the DICOM PS-3.14 will be performed. The analysis will regard both the shape of the TG18 luminance curve and the scattering of the measured luminance values obtained on all the tested tablets compared with literature models. The analysis will show the

conformance or not with the desired DICOM GSDF (Grayscale Standard Display Function). This desirable conformance will state an important step for the affordable use of tablets as devices for tele-diagnosis and especially tele-report of selected radiological images (such as MR, CT or PET images), despite of actual commercial tablets are not certified as MD in particular for their display lacks. The TG18 compliance and a consequent certification of some devices and apps in repeatable and controlled environmental conditions may allow mobile tele-reporting.

It is still in development an algorithm capable to return a score from the measured and qualitative values and results obtained from the application of the protocol. The algorithm's output will be encoded in a classification similar to the risk's tables used in risk management procedures.

6.4 Conclusion

Almost all the actual tablets displays suffer the limit of a native resolution of 1024x768 in respect of the TG18 1024x1280 recommended specification. The proposed protocol has been revised to evaluate the tablets performances in different ambient conditions, with the aim to define their limitations and possibilities of use for clinical investigations.

Due to the characteristics of the display technology, the diagnostic use is limited to low resolution medical studies like MRI, CT, US, NM and PET. Local regulations about display technology should be followed also. These apps for transferring and displaying DICOM images, may be used in many medical facilities for different use cases.

Finally information security regarding confidentiality, integrity, availability and accountability (aycan mobile app uses an automatic 256-bit AES encryption, password protection, and the ability to anonymize patient names on image files), as requested in section 6.2, is ensured on a solid level and complies the current state of the technology, following the Italian data protection and security law (*D.Lgs. 196/03*) which might considered one of the toughest laws about this topic worldwide.

It is in development an Android app compatible with DicomDroid capable to auto-regulate the brightness (and then the luminance) of the display according to the ambient illumination, and, consequently, to warn the physician in regard of the tablet's use for image visualization and diagnose. An algorithm will try to reconstruct a characteristic curve as much as possible "near" to the GSDF starting from the environmental illuminance and performing an interpolation of the display luminance values between the maximum ($L'(max)$) and minimum ($L'(min)$) calculated (or permitted by the device).

The mobile tele-radiology softwares have to allow the physician to measure distance on the image and image intensity values and display measurement lines, annotations and regions of interest. The tests for an evaluation have to measure luminance, image quality (resolution), noise, etc... in accordance with international standards and guidelines, reviewing results from demonstration studies with qualified radiologists under different lighting conditions. The aim is everyone agrees that the devices may be considered "sufficient" for diagnostic image interpretation under the recommended lighting conditions and in respect of some standard requirements (i.e. obtaining a valid score using an assessment measurement protocol).

The display performance of mobile devices can experience significant variations in luminance levels even between mobile devices of the same model. The mobile applications must include sufficient labeling and safety features to mitigate the risk of poor image display due to improper screen luminance or lighting conditions.

The device should include interactive (regarding contrast? luminance?) or automatic tests in order to reduce the interferences the lighting conditions have with the physician's ability to discern subtle differences in the image contrast or luminance.

Conclusions and final considerations

Nowadays telemedicine begins to be considered more and more as a service; this means the realization of infrastructures (from the single device to the remote server or user) that allows users not to mind about the network failure or the application or data corruption. In perspective all telemedicine services should converge to a plug-and-start approach, with people and medical professionals not concerned about anything of push a button. This is what it was called in this thesis an all-inclusive approach to telemedicine.

The principal objective of this work was to study, select and develop methods to enhance the clinical practice and the biomedical research in a modern Italian hospital by using telemedicine support. To accomplish this goal it was analyzed the state of the art of the technologies and of the telemedicine research (chapter 2 and 3) in order to choose systems and applications as to enhance for example the clinical practice. Beyond this, a study of IT infrastructure and security issues was indispensable if not almost mandatory.

The occurred choices were realized together with the participation of medical doctors and, in some cases, other researchers. The whole research study involved these professionals starting from the initial brainstorming to the effective realization of studies, models, applications and programs. The creation of a multidisciplinary group with different professionals allows to realize a research or a study or even a product for the market (or even a spin-off).

The results obtained in the three principal topics of this thesis concerned the realization of innovative solutions for telemedicine oriented web-portals, the proposal of new methods and model for hospital intranet services, and the evaluation of ICT technologies in tele-radiology. The approach was multidisciplinary considering infrastructure and security arguments too.

For the first topic the results may be summarized in the development of a more interactive and “social” hospital web-portal offering original solutions and services to all the categories of users (audience, professionals, researchers), allowing them – through the use of advanced tools - to configure and select their own pages and interests. The originality of this approach consists in a good cost/effective result in the respect of the last and worldwide accepted Internet regulations and policies too.

A similar approach regarded the intranet services and the design of web interfaces for the clinical practice and the executive evaluation. These kind of innovative systems regard a limited and selected number of more skilled users, typically belonging to a corporation or to specific offices. As above the approach is important: interactive services, innovative tools and affordable instruments are the keywords of the systems designed or proposed to solve specific problems or needs.

Another original research topic concerned the protocol for the assessment of medical images on commercial displays, interesting the stakeholders and the groups involved in medical images treatment, visualization and communication. The potentialities of the mobile tablet devices improve day after day. New devices are marketed every week and the innovation is round the corner. The potentialities must encounter the medical diagnostics world and meet the standards and the regulations the international community established. It will be difficult for a commercial tablet to

obtain the medical device CE mark not only for commercial reasons, but the technical limits may be reached and even surpassed adopting objective measures and evaluations. This study demonstrates that commercial tablet may be used in clinical practice for the correct visualization and diagnose of medical images. The measures of some display characteristics may be considered acceptable for mobile interpretation (even report?) of medical images, but if and only if the ambient lighting conditions are under objective control and integrated automated systems in tablets warns physicians about bad or borderline technical and ambient restrictions or bonds.

All these topics are a real challenge for ICT in telemedicine because if it is true that the objectives of similar studies are often of medical relevance, the methods and the results have significant technical preambles and consequences. Studies in telemedicine allows not only the re-mapping of processes and clinical protocols but also the creation of innovative services or applications, allowing a re-engineering of consolidated procedures. The re-engineering perspective allows users to re-think what they are doing in terms of new technologies and enhancements of previous obsolete procedures. Re-think a hospital web portal using technologies capable to push new services to the audience or to the professionals (chapter 4); or allowing the fruition of innovative services of tele-consultation by means of blogs or private intranet dashboards (chapter 5) are both examples on how the re-think and the innovation together with the disposable technologies may bring a wave of change even in consolidated practices.

Another interesting aspect of this work on telemedicine was the multidisciplinary approach even in the specific technical and research approach. The study and the realization of telemedicine innovative systems may be conducted gaining an overall view of many aspects regarding, for example, information and data security, affordable networks and communications, the respect of national or international technical standards and so on. Such problems are very sensitive especially in a hospital. So it is indispensable to think and design a whole hospital infrastructure considering matters as information security, privacy, prevention of data lost, affordable networks, redundancy of servers and systems. Privacy and security are technical, normative and organizational features that must be taken into account, not only as border conditions but in the core definitions of telemedicine studies and research projects.

Innovation is not something like a spot but is a continuous process of growth and knowledge. Innovation in telemedicine is something that must take in consideration more and more of the aspects and competencies described and presented in this work. Innovation in telemedicine in a hospital is a real challenge because it not concerns only the “to know” aspect but the “to know how to do” aspect. That is, as told me long time ago a professor I consider one of my masters, what define at all an engineer.

“All life is problem solving” – Karl Popper

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----- **Web-sites** – Telemedicine and ICT

[W1] www.americantelemed.org (American Telemedicine Association web site)

[W2] www.aitim.it (Italian Association of Telemedicine and Medical Informatics web site)

[W3] http://ec.europa.eu/information_society/activities/health/policy/telemedicine/index_en.htm
(EU program and communication in telemedicine)

[W4] <http://www.salute.gov.it/eHealth/paginaInternaEHealth.jsp?id=2515&lingua=italiano&menu=telemedicina> (Italian telemedicine projects)

[W5] http://ec.europa.eu/information_society/activities/health/policy/ehealth_governance_initiative/index_en.htm (EU e-health Governance Initiatives)

[W6] <http://www.onecare.cup2000.it/> (web site of the Italian National Observatory for the e-care projects)

[W7] <http://www.fda.gov/> (US Food and Drug Administration web site)

[W8] www.cordis.eu (European web-portal for research and development)

[W9] www.ihe-italy.org (Integrating the Healthcare Enterprise web-portal)

[W10] www.myesr.org (European Society of Radiology web site)

Appendix A

A TG18 Compliant Measurement Protocol for Mobile Teleradiology

List of chosen tests

Measured characteristic	Test	Type	N° of images
L(min), L(max), Luminance ratio	TG18-LN	quantitative	2
Luminance response	TG18-LN	quantitative	18
Geometric distortions	TG18-QC	quantitative	1
Luminance uniformity	TG18-UNL	quantitative	2
Display Spatial and uniformity resolution	TG18-CX	qualitative	1
	TG18-QC	quantitative	1
Display Noise	TG18-AFC	qualitative	1
Veiling glare (and Glare Ratio)	TG18-GV	qualitative	2
	TG18-GQ, TG18-GQB, TG18-GQN	quantitative (proposed)	3
Diffuse ambient reflection	TG18-AD	qualitative	1
Specular ambient reflection	-	-	-
Ambient luminance (L(amb))	-	-	-
Ambient illuminance	-	-	-
Visual angle	TG18-CT	qualitative	1
	TG18-LN	quantitative (proposed)	1
Display Chromaticity	TG18-UNL80	quantitative	1

(proposed)			
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General Notes: measures must be taken with tablet displays turned on from at least 10 minutes. AAPM TG-18 tests are performed in the same radiological room with the same ambient conditions (T, luminance and illuminance), with the tablets placed in the same positions of the medical device displays.

All the tests are previously loaded on tablet' software or apps suitable or studied to receive and visualize DICOM images. The tests are performed with the native resolution of the tablets, eventually scaled and considering the proper bit-depth (8 or 12 bits).

The test's values or thresholds have been gathered from AAPM TG18 report.

Monitor calibration

(L(min), L(max), Luminance Ratio, Luminance Response)

Reference

AAPM Report of Task Group 18: "Assessment of display performance for Medical Imaging Systems"

Recommended Values and thresholds

Primary medical display:

$L(\max) > 171 \text{ cd/m}^2$

$L(\min)$: $L(\max)/L(\min)$ (luminance ratio) ≥ 250

dL/L within the DICOM GSDF standard: $\pm 10\%$

Secondary medical display:

$L'(\max) \geq 100 \text{ cd/m}^2$

$L'(\min)$: $L'(\max)/L'(\min)$ (luminance ratio) ≥ 100

dL'/L' within the DICOM GSDF standard: $\pm 20\%$

Expected response

The slope of the measured response should agree with the slope of the standard response.

The tolerances must be respected

Instrumentation

Photometer. The photometer is used with a ring (or a capsule) capable to reduce the influence of ambient light and is put in contact with the display.



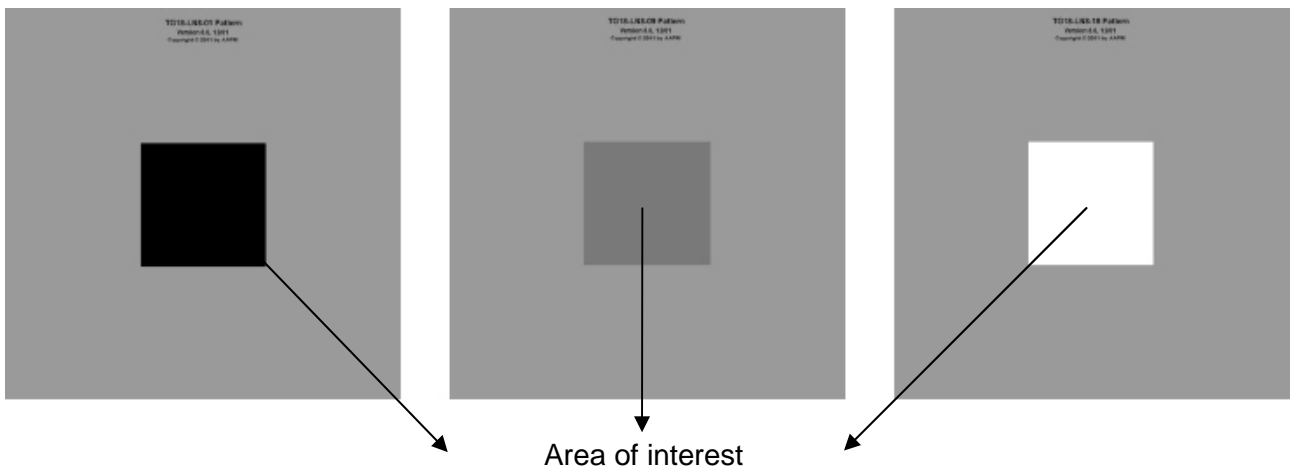
The measurements

tests: TG18-LN

file TG18-LN-1k-01.dcm,, TG18-LN-1k-18.dcm

Through the software or app mounted on the tablet select on the screen the test pattern AAPM TG18-LN12-01, in 1X1 modality (test pattern is inside the TG18-LN-1k-01.dcm file), make the measure and read the luminance value obtained measuring the central region of the pattern.

Repeat the measures for all the patterns (AAPM TG18-LN12-02,, AAPM TG18-LN12-18).



Measurement evaluation

$L(\min)$, $L(\max)$ e $L(p)$ are measured luminance values with $L(\text{amb})$ equal to zero. If $L(\text{amb}) > 0$

$$L'(\min) = L(\min) + L(\text{amb})$$

$$L'(\max) = L(\max) + L(\text{amb})$$

$$L'(p) = L(p) + L(\text{amb})$$

$L'(\max)/L'(\min)$ is defined as luminance ratio, while $L'(\max)/L'(\min)$ is defined contrast ratio when $L(\text{amb})$ is unimportant.

Geometric distortions

Reference

AAPM Report of Task Group 18: "Assessment of display performance for Medical Imaging Systems"

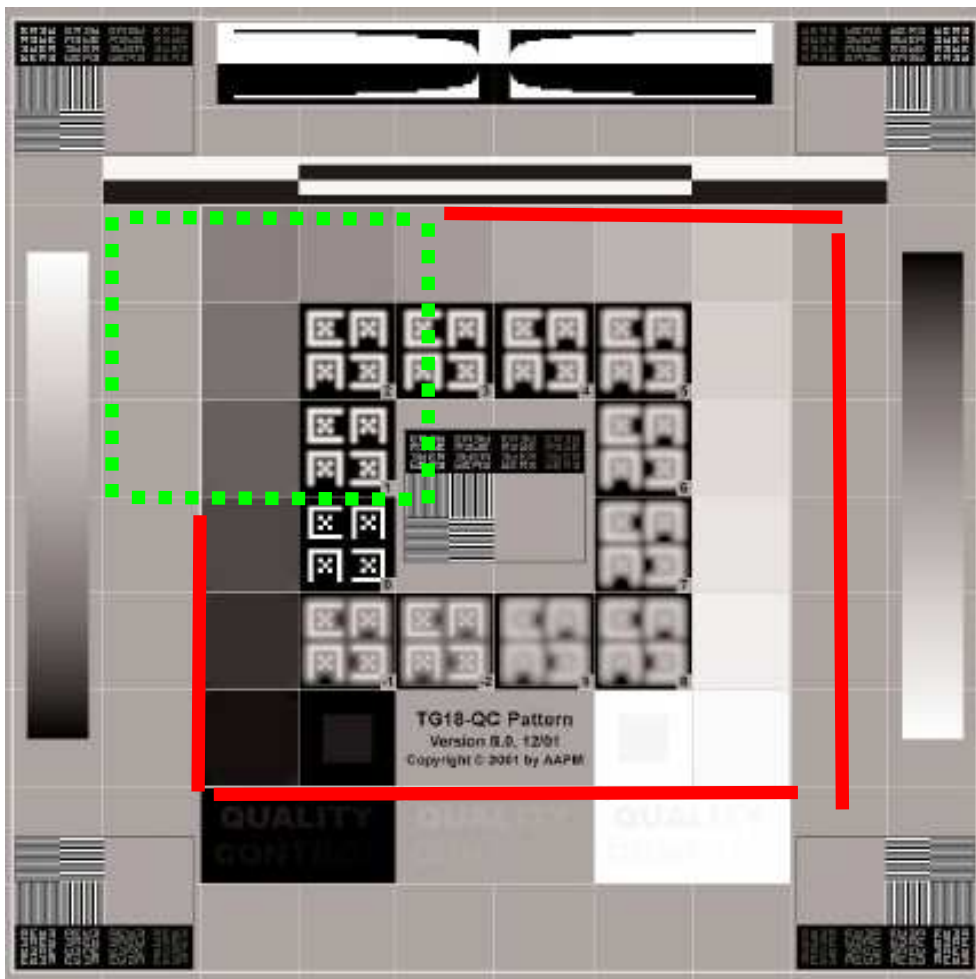
Recommended values and thresholds

The maximum spatial deviations between orthogonal measurements should not exceed 2% (5% for secondary class devices) within either direction and between directions, within each quadrant and within the whole quadrant.

Instrumentation

Test pattern AAPM TG18-QC

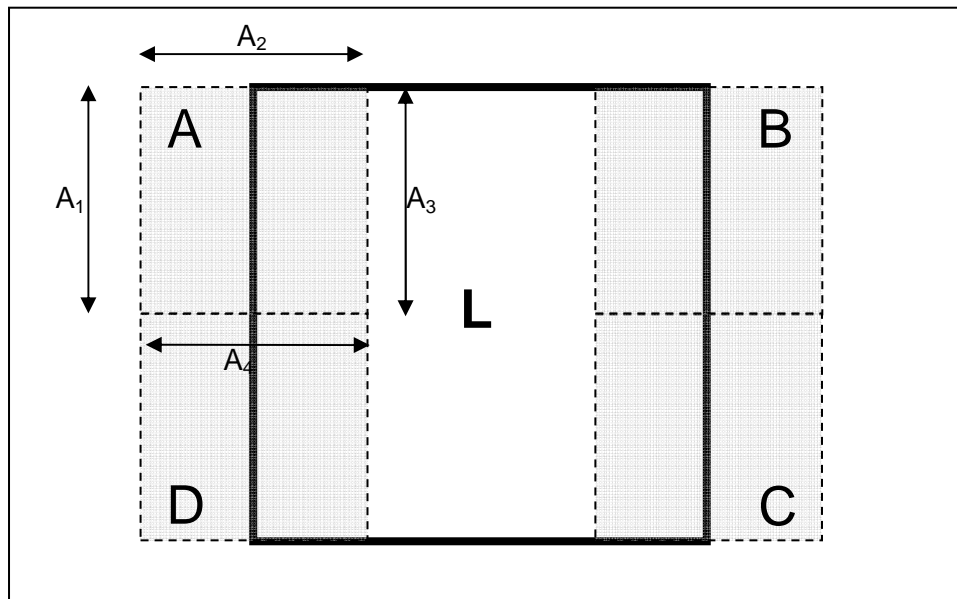
A flexible plastic ruler



Procedure of measurement

test: TG18-QC

Visualize the test pattern in 1X1 modality.



Quantitative evaluation

Maximize the pattern to fill the entire display area. Measure the length of the four sides of each quadrant traced in dashed line (A1, A2, A3, A4; B1, B2, B3, B4; C1, C2, C3, C4; D1, D2, D3, D4) and of the square traced in bold continuous line (L1, L2, L3, L4).

Qualitative (visual) evaluation

Maximize the pattern to fill the entire usable area display and examine it from a viewing distance of 30 cm.

Expected response

Quantitative evaluation

Maximum spatial deviations between orthogonal measurements should not exceed 2% (or 5% for secondary display devices) within either direction and between directions, within each quadrant and within the whole pattern.

Qualitative (visual) evaluation

The pattern should appear straight without significant geometric distortions and should appear square.

Luminance uniformity

Reference

AAPM Report of Task Group 18: "Assessment of display performance for Medical Imaging Systems"

Recommended values or thresholds

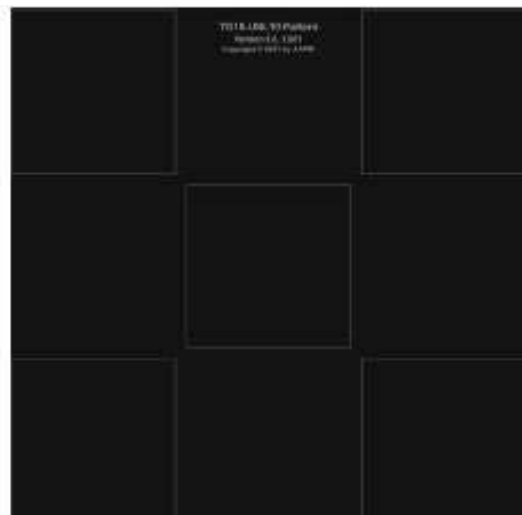
$$200 * (L_{\max} - L_{\min}) / (L_{\max} + L_{\min}) < 30\%$$

Instrumentation

Test pattern AAPM TG18-UNL10

Test pattern AAPM TG18-UNL80

Photometer



Measurements

test: TG18-UNL

file TG18-UNL-1k-01.dcm and TG18-UNL-1k-02.dcm

Visualize the test patterns in 1x1 modality. Using the TG18-UNL10 and TG18-UNL80 test patterns (respectively shown in figure), luminance is measured at five locations over the faceplate of the display device (center and four corners) using the calibrated luminance meter equipped with a cone or baffle close to the display.

Measurement evaluation

According to GSDF the maximum luminance deviation for each display pattern (the four quadrants) calculated as the percent difference between the maximum and minimum luminance values relative to their average value ($200 * (L(\max) - L(\min)) / (L(\max) + L(\min))$) must be less than 30%.

Spatial resolution

Reference

AAPM Report of Task Group 18: "Assessment of display performance for Medical Imaging Systems"

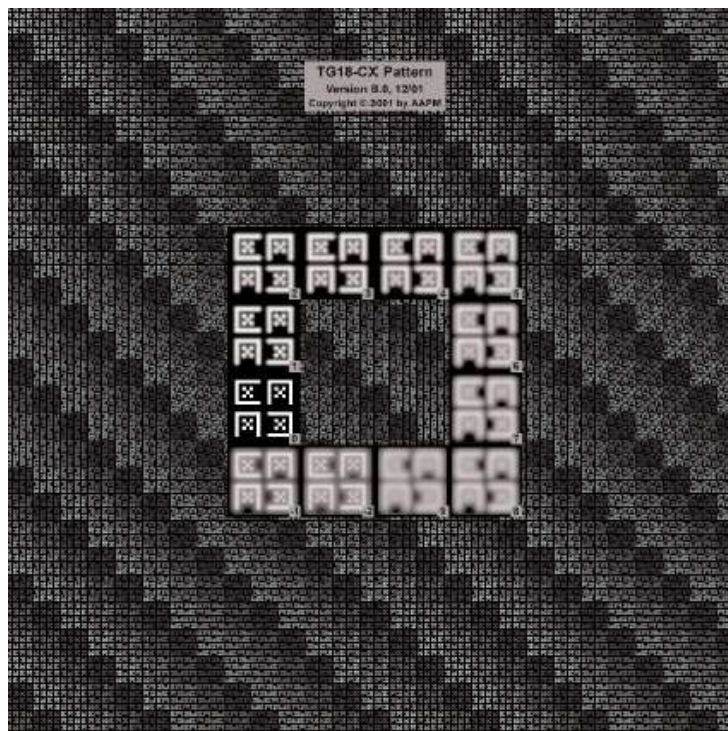
Recommended values and thresholds

The Cx elements should be scored between 0 and 4 (0 and 6 for secondary devices) at all locations

Instrumentation

Test pattern TG18-CX

(Telescopic photometer)



Procedure of measurement

test: TG18-CX

file TG18-CX-1k-01.dcm

Qualitative (visual) evaluation

Visualize the image in 1:1 modality (one display pixel per image pixel). Using the scores in the middle of the test image assign a score to the detail visibility at different grayscale levels.

Quantitative evaluation (luminance method)

Using the telescopic luminance meter focusing on the entire central patch with the 100% modulation horizontal line-pair pattern, measure the average luminance of the patch. Repeat the measurement on the adjacent vertical line-pair patch, and calculate the percent difference between the two luminance values relative to the maximum measured luminance value. Eventually repeat the procedure for all four corners.

Expected response

Qualitative (visual) response

The score assigned must be less or equal than 4 for primary medical displays (6 for secondary displays).

Quantitative response

The percent luminance difference at the center should be less than 30% for primary class display systems (50% for secondary devices).

Display noise

Reference

AAPM Report of Task Group 18: "Assessment of display performance for Medical Imaging Systems"

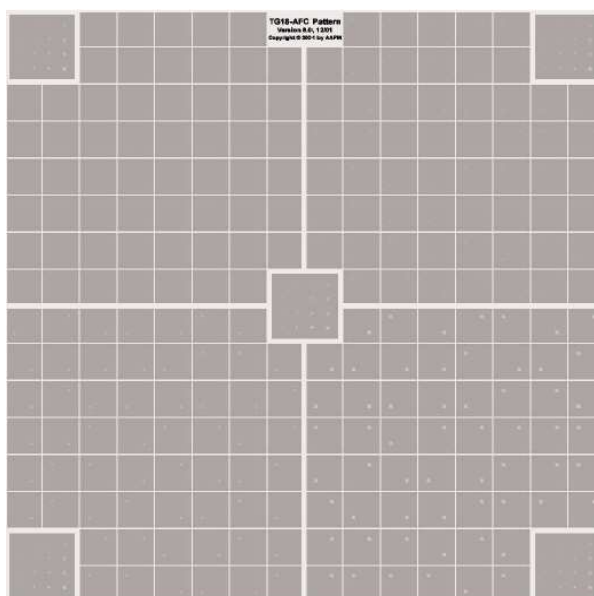
Recommended values and thresholds

Primary devices: all the targets should be visible in almost three (on four) quadrants

Secondary devices: all the targets should be visible in almost two (on four) quadrants

Instrumentation

Test pattern AAPM TG18-AFC



Procedure of measurement

Test: TG18-AFC
file TG18-AFC-1k-01.dcm

Evaluate the visibility of the small details for each quadrant viewing the test pattern from a distance of at least 30 cm.

Expected results

Respect the indicated tolerances for both primary and secondary devices.

Veiling glare

Reference

AAPM Report of Task Group 18: "Assessment of display performance for Medical Imaging Systems"

Recommended values and thresholds

More than 3 visible details in the central zone (qualitative measure)

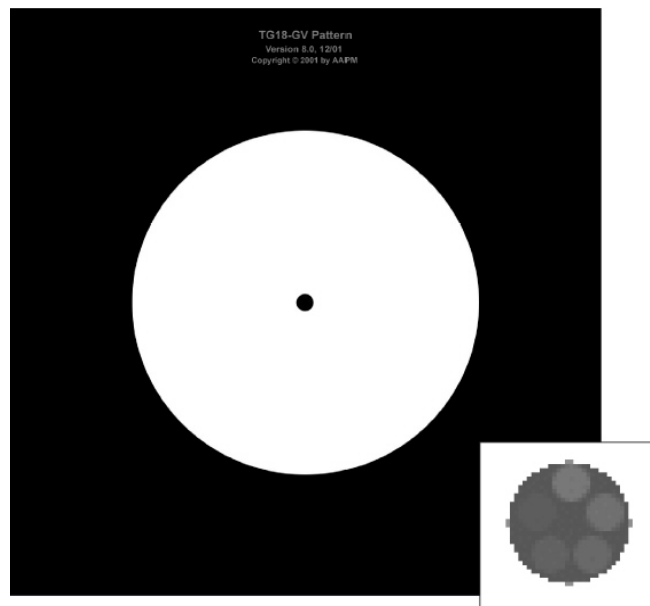
Glare Ratio $GR \geq 400$ for primary class devices

Instrumentation

Test pattern AAPM TG18-GV e TG18-GVN

Test patterns TG18-GQ, TG18-GQB and TG18-GQN

A (high collimated) luminance meter



Measurement procedure

test: TG18-GV, TG18-GVN, TG18-GQ, TG18-GQB and TG18-GQN

file TG18-GV-1k-01.dcm e TG18-GV-1k-02.dcm

Qualitative (visual) evaluation

Visualize the test pattern TG18-GVN in 1x1 modality and then count the visible details in the central zone of the pattern. Then visualize the TG18-GV pattern setting the bright zone diameter on almost 20 cm (100% bright surround) in order to cover the bright zone and count the details in the inner central circle.

Quantitative evaluation

Calculate the Glare Ratio using the TG18-GQ luminance value of the center of the central dark region L , the TG18-GQB luminance value calculated in the center of the white region L_b and the background luminance value in the center of the TG18-GQN pattern L_n :

$$GR = (L_b - L_n) / (L - L_n)$$

Expected results

Qualitative (visual) results

No significant reduction in the contrast of the target objects should be observed between the two patterns, one with and one without the bright field. In particular for primary devices almost three details in the central zone should be visible.

Quantitative results

GR \geq 400

Diffuse ambient reflection

Reference

AAPM Report of Task Group 18: "Assessment of display performance for Medical Imaging Systems"

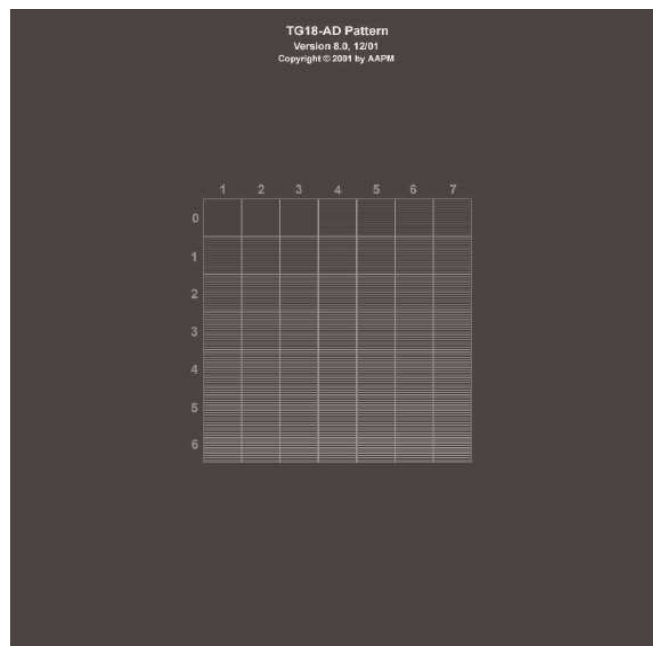
Recommended values and thresholds

The minimal visible detail in the test pattern should be the same in total dark as in usual operative conditions

$L(\min) \geq 1.5 L(\text{amb})$ (ideally $\geq 4 L(\text{amb})$) – the measured values should be useful to regulate the ambient illuminance

Strumentazione

Test pattern AAPM TG18-AD



Measurement

test: TG18-AD

file TG18-AD-1k-01.dcm

Visualize the test in 1x1 modality both in standard (operative) ambient light conditions and in total dark conditions.

Measure evaluation

Minimum viewed details should be visible both in total dark and usual operational conditions.

Specular ambient reflection

Reference

AAPM Report of Task Group 18: "Assessment of display performance for Medical Imaging Systems"

Recommended values and thresholds

There must be no reflected images on the display

$L(\min) \geq 1.5 L(\text{amb})$ (ideally $\geq 4 L(\text{amb})$) – the measured values should be useful to regulate the ambient illuminance

Instrumentation

Not requested

Procedure of evaluation

Turn-off the tablet display and verify the presence of reflected artifacts or images on the screen.

Expected result

No reflected images should be appear on the display.

L(amb) calculation

Reference

AAPM Report of Task Group 18: "Assessment of display performance for Medical Imaging Systems"

Recommended values and thresholds

Primary class devices: $L_{\text{amb}} \leq 0.25 L_{\text{min}}$

Secondary class devices: $L_{\text{amb}} < L_{\text{min}}$

Instrumentation

Telescopic luminance meter.

Procedure of evaluation

The luminance meter (as shown in figure) is used with the collimator cone inserted and the display zone in which to evaluate the measure is selected pointing the device at almost 50 cm. of distance using the viewfinder.

Viewfinder



Measurement procedure

Turn-off the display. Point the luminance meter towards the center of the display from a distance of almost 50 cm. Read the luminance value measured.

Expected response

Match the obtained result with the indicated tolerances.

Ambient illuminance

Reference

AAPM Report of Task Group 18: "Assessment of display performance for Medical Imaging Systems"

Recommended values and thresholds

Operating theatre:	300 – 400 lux
Emergency medicine:	150 – 300 lux

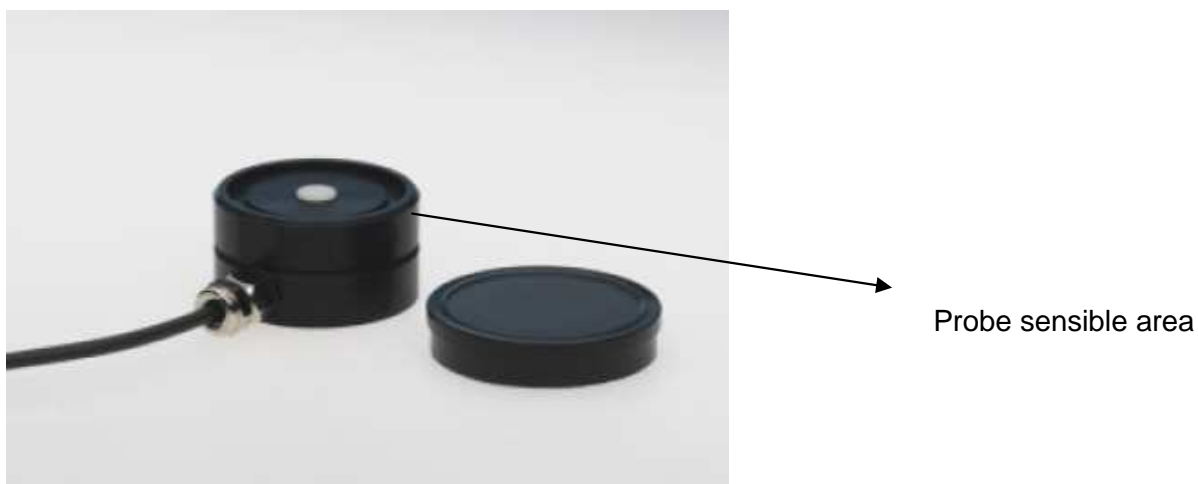
Typical hospital visualization workstations:	200 – 250 lux
TC, MR PACS workstations:	15 – 60 lux
Typical diagnostic PACS workstations:	2 – 10 lux

Instrumentation

Photometer

Procedure of measurement

Turn-off the display and place the photometer probe in the middle of the display. Then read the obtained measured value (in lux).



Measure evaluation

Match the measured value with the reference value.

Visual angle

<p>Reference</p> <p>AAPM Report of Task Group 18: “Assessment of display performance for Medical Imaging Systems”</p> <p>Recommended values and thresholds</p> <p>The angular response should not reduce the luminance ratio by more than 30%</p>

Instrumentation

Test pattern TG18-CT

Test pattern TG18-LN

Luminance meter

(figure)

Procedure of measurement

test: TG18-CT; TG18-LN

file TG18-CT-1k-01.dcm; TG18-LN-1k-01.dcm, TG18-LN-1k-18.dcm

Qualitative (visual) evaluation

The pattern should first be viewed on-axis to determine the visibility of all half-moon targets. Change the viewing angle until the on-axis contrast thresholds are rendered invisible.

Quantitative evaluation (luminance method)

At different viewing angles determine the angular luminance variations of the display at the 1 and 18 luminance levels using a conoscopic device and TG18-LN-1k-01 and TG18-LN-1k-18 test patterns.

Expected response

Qualitative (visual) response

The viewing angle cone within which the TG18-CT test targets remain visible is the cone within which the device may be used clinically.

Quantitative response

The angular response of the display should not reduce the luminance ratio by more than 30%. An acceptable viewing angle cone can be defined within which luminance ratio ($L'(\max)/L'(\min)$) is greater than 175 for primary class display devices and 70 for secondary displays.

Appendix B

A.Dop.T project – executive summary and finance highlights

Executive summary

This project is based on a pharmaceutical database interactive service designed to be queried by cellular phone or smartphone via short message system.

The aim is to provide a new information reference tool, fast, easy to access by everyone and everywhere, addressed in particular to athletes and subjects involved in sports (coaches, physicians, trainers) in order to check whenever they want if a medication is forbidden or not. In other words, if it is doping or not.

Nowadays, more and more Governments (193) agree to the Declaration of Copenhagen against doping in sports, and in the last five years many anti-doping programmes of almost every Sport Federations (598 in the world) are growing in particular focusing on out of competition un-announced tests.

These tests are lately getting more and more importance by athlete's health viewpoint, because they are the only tests that can verify cycle of assumption of illicit drugs.

But very often athletes ignore, either superficiality or because anti-doping matter is developing continuously, that forbidden drugs are divided into categories: in-competition, out-of-competition, allowed only with a TUE (Therapeutic Use Exemption), allowed only in certain Sports.

This regulation induces athlete to have many fears about medicines or to change a therapy during a competition or a training without knowing if that medication was forbidden or not.

It is also important to remark that according to recent studies of Italian Pharmacist Association, 15 teenager out of 100 use to take medicines without any medical consultations.

Today such a tele-service is not available neither yet planned in Italy and around the world.

For example, in Italy, where there is one of the most advanced law about anti- doping, every medicines have impressed on the packaging a logo that indicates if they are forbidden in sports. But now, this is not enough.

It's a given there are a lot of drugs forbidden in sports but many of them are forbidden, only, for instance, in competition.

So, this project could be very useful to all the athletes (as well as to the coach and his medical staff) that can verify immediately if what they are assuming is doping or not, or, in other words, if that medication can lead to serious consequences or not.

And what is the best and easiest way to do it once the doubt comes out? What's better than a simple sms!

It is really user friendly, and at the same time, today everybody know how to send a sms, and it is of great attractiveness in particular among young people cellphone addicted as athletes.

The project's title is:

A.Dop.T. - AntiDoping Teleconsulting

It encapsulates a message, the slogan of the project:

AdopT it!

Means: take it! Make one of your sport tool and use it whenever and wherever you want!

Even the logo we designed it is well studied for this tele-service. It is not a case that our logo reminds WADA's logo (World AntiDoping Agency).



Before projecting this application, we studied on the market other examples of database consultation for athletes. What we found are many different antidoping consultation services: on the web, by telephone calls and by emails. But each of them have some important weaknesses.

AdopT is the only one who is based on a sms consultation and it is available 24H everywhere, any time, doesn't need any internet connection or PC or advanced technology and keep your privacy safe!

This service could be the missing link in the anti-doping information chain towards the athlete so that no more excuses can be accepted because of athlete's ignorance on misuse of drugs.

What we consider crucial in this project is the marketing campaign. It is fundamental to have a strong marketing campaign in order to reach every Sport Federation and athlete, and to be endorsed by an important event or sponsor (Anti-doping Agency, CONI, Olympic Committees) involved in sport so that users can trust in it.

Finanche – highlights

Fixed assets. No fixed asset is required to be purchased as the service is supplied by calls to the server; the server is owned by the provider: the NewCo should rent the server of the provider.

Running expense. They are very limited; for the most they refer to provider fee, advertisement and company administrative and compliance services.

Cash. A minimum capital stock of Euro 20K is enough cash size for meeting initial cash needs. Non loan is planned. Yearly profits are planned to be retained for financing further service offers and geographical expansion.

Performance. The investment of Euro 20K is expected be multiply by 8 times in 5 financial years at 10%-NPV-rate.