THE SET UP OF A QUALITY CONTROL PROCESS IN TELEMEDICINE

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Abstract: The described methodology was experienced by the Authors inside the e-R.ME.TE project (Regions for Telematic Medicine). The project originates from a team work of several research institutions, regional governments institutionally deputed to Health management in Italy and specialized hospital centres already committed in telemedicine trials.
The Ministry of Health partially funded this project, oriented to promote the "certification", the diffusion and the use of telemedicine systems developed at regional level.

Introduction

Telemedicine applications are heterogeneous systems created through the integration of parts that involve more disciplines: namely, biomedical engineering, clinical engineering, health physics and telematics. Up today, such systems are often created through prototypal and pilot experiences based, sometimes, even on discontinuous financings during the production. Moreover, disregarding the specifically used biomedical devices, further technological/organization issues are involved in a telemedicine application; in fact, we deal with a telemedicine "process". Then the whole telemedicine process must respect a pre-defined threshold of quality to be effectively exploited inside the health service (namely the National Health System, NHS), supplying the necessary "continuity of care", rightly expected by the citizens. The process that transforms a telemedicine prototype in a system qualified enough to be inserted in the Public Healthcare System is obviously complex and needs a gradual approach.

The inhomogeneous diffusion of telemedicine systems and the lack of a global development strategy are problems that can be solved with a bottom-up approach, building upon the existent previous activities of local institutions, and a scalable methodology for telemedicine diffusion. This was the methodological approach pursued in the e-RMETE project (Regions for Telematic Medicine) purposely designed in order to promote the standardization, the diffusion and the exploitation of valid telemedicine systems developed at regional level. The Italian Ministry of Health contributed by partially funding the project (article 12/bis, Law 229/99) [1], managed by the Region of Toscana; the beginning date, the project duration, the public funding obtained and the total sustained expenditure are shown in Table 1

Table 1: The e-R.ME.TE project

THE E-RMETE PROJECT	
Beginning date	March 2002
Project duration	24 months
Public funding	2.152.218 €
Total expenditure	9.166.593 €

e-RMETE was organized in Operating Units, involving five research Institutions: the Institute of Clinical Physiology of the National Research Council (IFC-CNR), the Italian Institute of Health (ISS), the Center for Scientific and Technological Research (ITC-irst), the Center of Excellence For Research, Innovation, Education and industrial Labs partnership (CEFRIEL) and the Euro Mediterranean Scientific Biomedical Institute (ISBEM) and seven Italian regions (Toscana, Lombardia, Puglia, Valle d'Aosta, Lazio, Basilicata and Trentino) . A summary of the different roles inside the e-rmete consortium and the corresponding Operating Units is shown in Table 2.
The applications up to day available in the e-RMETE Catalogue (http://ermete.ifc.cnr.it) are the following:
- CAROLIN (Cooperative Application for Remote On-Line INteractive diagnosis): multimedia application (developed by Cefriel for the Region of Lombardia) for videoconferencing and cardiology teleconsulting [3,4] among the hospitals of the telemedicine network called CARDNET.
- GIR (Gestione Infermieristica di Reparto that literally means "ward nursing management"): application, developed by IFC-CNR of Pisa, for computer management of hospital nursing activities [5].
- ONCOTEL (Oncological Teleconsulting): the application, developed by ITC-irst of Trento, concerns a

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virtual cooperative system for inter-hospital and hospital-territorial teleconsulting as support to a tool, integrated into the healthcare system, for the management of the oncological patient [7].

- STeMiSy (Static TeleMicroscopy System): the application, developed by ITC-irst of Trento, concurs in the execution of the frozen section examination in the surgeries of the hospitals lacking a service of local Pathology Department; the system is based on the usage of a robotic microscope, that can be online operated by a remote pathologist [6].

Material and methods

The activity, oriented to the mentioned "quality" assurance of the whole telemedicine process, started by selecting the Authors in the e-RMETE Consortium as the task force with the necessary skills concerning the various types of experience and knowledge to adopt a multifunctional and versatile approach to as the basis for telemedicine qualification process (health Physics, Clinical Engineering, Biomedical Instrumentation, Telemedicine Models, Data transmission, Quality and safety, etc.).
The first activity concerned the analysis of standards and rules in Information technology, in communication systems and in biomedical instrumentation, that constitute the technical reference matters of Telemedicine. A lot of technical norms both resulted by the de facto standards and/or in force regulations were collected.

Table 2: The operative units in the e-RMETE Projects

ROLE	OPERATING UNIT
Financial management	Toscana
Scientific management	IFC-CNR
Technical committee	ISS
	IFC-CNR
	ITC-irst
	CEFRIEL
	ISBEM
System producers	Lombardia
	IFC-CNR
	ITC-irst
Potential users	Toscana
	Puglia (ISBEM)
	Valle d'Aosta
	Basilicata
	Lazio
	Trentino

Taking in account this reference data base of existing technical regulations, we conceived a practical approach for setting up the evaluation methodology for quality assurance evaluation of the telemedicine process. We referred to the available telemedicine products, already operating in specific departments in health care, that were available to be transferred to other potential users by some Partners of the e-RMETE Consortium; a pragmatic analysis of each selected system has been continuously performed by using the achievements in progress in a in procedure refining, focused to improve both the telemedicine process under test and the own qualifying methodology. This approach, although not constituting an exhaustive design methodology, represents an effective mean for a quick development of a possible consolidated architecture of quality assurance analysis process.
We considered four available telemedicine products, well known and tested in clinic and health care: a teleconsulting software for second opinion in oncology, a telepathology apparatus, a tele-consulting and analysis system in echo-cardiology and a nurse activity management for cardio-pulmonary department.
The generic telemedicine process was divided in two stages:

1) Classification of the telemedicine system and preliminary rough evaluation
2) Assessment of the telemedicine products/processes

Classification of the telemedicine system and preliminary rough evaluation

It was defined a surveying instrument, that we called General Questionnaire (GQ), in order to allow a structured collection of the information and in order to carry out a first evaluation based on the earlier state of the telemedicine systems analysed . The GQ was available also as a Form, to be filled also via Web, equipped by POP-up and cascade menus with mandatory fields and windows to be selected/filled by alphanumeric strings and/or images and/or documents (using standard format document as .doc, PDF, jpg, etc.). For what concerns the Structure, the Questionnaire was branched in six sections

1 General information and Self Classification
2 Topology and Organisation of the system
3 Census of the biomedical and non biomedical instrumentation used in the telemedicine application
4 Used telematic networking
5 System documentation features
6 Office for Technology Assessment

Question 1.1 concerns some information about the system, such as the identity of the producer and the responsible, a short description and the destination of the use; moreover, it presented POP-up and cascade

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menu corresponding to a scoring system that provide the user to roughly self-classify the telemedicine process.
Question 1.2 asked information about the topology of the whole system, the type of architecture (client-server, peer to peer, etc), the policy adopted for the security of the used computer, and of the software packages installed.
Question 1.3 refers to detailed information about the biomedical instruments concerning the telemedicine process (e.g. microscopes for tele-pathology) and the I/O peripherals connected to the nodes of the system.
Question 1.4 asked information about the network requirements of the system (e.g. use of 4 ISDN channels, ADSL, leased data line, satellite channels, etc.) and about the possibility for the telemedicine process to use alternative communication channels.
Question 1.5 1 (1.5) concerns information about the available user documentation , the installation documentation, the availability and features (e.g. its format as XML, PDF or other format, as well as the access to the demo program as Internet download, etc.).

Question 1.6 of the questionnaire is based on a study which was carried out by the Office for Technology Assessment of the Congress of the United State nine years ago, just before closing its doors on September 1995; thi should be considered another investigation approach of the telemedicine applications. This work identified the necessity to focus on the following 8 aspects in a telemedicine application

The reference issues of this information are reported in the following:

§ 6.1 electronic patient records
§ 6.2 structured data entry
§ 6.3 advanced human-computer interface technologies
§ 6.4 portable computers
§ 6.5 automated capture of data from diagnostic and monitoring equipment
§ 6.6 relational databases with online query (keyword search and retrieval)
§ 6.7 knowledge-based computing
§ 6.8 computer networks

Together with the filled sections of the questionnaire, the considered producers of telemedicine system were requested to supply all the documentation well organised in handbooks both for the system set up and its use (in standard formats as XML or PDF). Both the documentation supplied and the general questionnaires compiled by the producers were analysed by the e-RMETE validation team. The analysis pursued an iterative process, devoted to a better set up of the questionnaire from the Authors point of view, and, from the producer's point of view, to obtain the possible maximum system performance (and than evaluation score) after reviewing the system problems, well putted in evidence by a detail analysis, performed by the questionnaire. In this way a self-classification of the telemedicine process was obtained for any considered system. The questionnaire demonstrated to be a powerful tool for an effective preliminary analysis.
The approach based on two different points of view was very useful, in particular the use of the OTA model [2]; in fact, even if in some cases the double approach caused a redundancy of data, it contributed in enlarging the investigation range of the normalization process, providing information, for example, about common and uncommon fields used by the different telemedicine systems in the patient records.
According to the results of the preliminary evaluation phase, the necessary re-engineering processes of the applications had to be carried out; the purpose of these processes was to make the applications effectively "exportable" elsewhere with minor adjustment due to the resulted modular architecture. The reengineering processes were referred to existing established standards in healthcare delivery (such as healthcare protocols: e.g. HL7, DICOM, etc.), ICT best practice guidelines and regulations concerning the availability, the privacy, the security and the continuity of the informative service.
Each re-engineering process was performed by the producers in order to satisfy not only common transferability requirements, but also the different needs of the users interested to the transfers.

Assessment of the telemedicine products/processes

In order to facilitate the final assessment of the applications, at the end of a careful gathering and analysis of the information related to the technical, legal and regulatory aspects of telemedicine, an assessment checklist was developed; this checklist contained the requirements that each telemedicine system should satisfy and was meant to be eventually used also as a reference tool for every organization that needs to implement telemedicine applications.
Substantially, the checklist was a numbered list of selected requirements regarding issues that are central to the practice of telemedicine. Thus, it could be considered a good starting place for telemedicine systems suppliers and for a quality control or certification body operating in the field of telemedicine.

The checklist contained three main sections:
- Operational requirements of the system
- Requirements addressed to the design and development processes of the producers
- Requirements concerning economical and social evaluations

The first section faced issues regarding patient security, patient privacy and confidentiality, data integrity and transmission security.
It contained requirements regarding the maintenance of patient privacy and confidentiality in the transmission and in the storage of electronic health records.

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Other requirements of the first section was meant to check what clinical tools and technologies and standards were used for the implementation of the telemedicine system, others to assess the quality of the software used, others to evaluate the efficacy of different telemedicine applications (for diagnosis, therapy or distance learning) and the ethical and legal aspects associated to the usage.
The second section was meant to check quality criteria (such as ISO 9000/Vision 2000 standards) and best practice rules. The requirements of this section regarded the organizational aspects of the manufacturing process and were essentially addressed to companies and/or organizations that design and build their own products. The organisational aspects involved also the standard policies adopted for the documentation (for instance in naming and archiving documents), for the design and development of products and for the customer satisfaction (e.g. the declared policies for the technical assistance).
The third section was an additional section that checked if some economical and/or social indicators were adopted by the producers in order to make comparisons with the similar traditional health care processes. These indicators were considered because of their importance in making cost-benefit analysis, in estimating the price of services for health care reimbursement, in testing customer satisfaction (both patients and health professionals) and improvements in life quality.
The checklist was rendered to every supplier of telemedicine systems for the eRMETE catalogue and various work groups were constituted to estimate the applicability and the validity of the checklist. Such work groups were formed by members belonging to three OU: ISS, IFC-CNR and the producer.
Each producer proposed modifications and suggestions to the checklist. This process of review with the producers allowed a tuning of the checklist so as to make it adapt to multiple telemedicine systems, optimizing the process of assessment.

Results

At the end of the tuning process of the checklist, the workgroups finally decided to adopt two different checklists: one dedicated to telemedicine products (e.g. workstations for teleconsulting from point to point) and one dedicated to telemedicine processes (e.g. web archives for the exchange of clinical information).
The checklist was presented to each producer for the compilation and when it was compiled and sent back, the team started to analyze it. At the end of the examination, a score indicating the quality level of the product/process was calculated: if the score was greater than the minimum standard threshold fixed by the consortium, a quality level was assigned to the product/process, otherwise a report was emitted. The report contained useful recommendations for the producer about the improvements needed by the product/process; at the end of the necessary reengineering cycles, the assessment of the modified product/process restarted in order to verify the overtaking of the minimum standard threshold.
The score indicating the quality level of each product/process was based on a weighted calculation of the percentages of requirements satisfied. According to this weighing system, the evaluation criterion consisted in calculating, for each requirement level (A, B and C), the ratio between the number of requirements satisfied and the number of requirements presented. Then, these three ratios were compared with some minimum thresholds in order to assign to the product/process one of the five quality levels, ranging from the lowest one, the Standard quality level Q1(S), to the highest one, the Excellent quality level Q5(E).
In order to obtain the "standard quality level", the conformance to those requirements guaranteeing patients and data security was required. To obtain the higher quality levels, the systems had to satisfy also other requirements concerning the design, the development and the organization of the product/process.
The five quality levels and their minimum thresholds are reported in Table 3.

Table 3: Computation of the quality level.

Quality Level	Criteria (levels and percentages of requirements satisfied)
Q1 (S)	**Standard quality level** Level A requirements = 100 %
Q2	**Intermediate I** Level A requirements = 100 % Level B requirements ≥ 50 %
Q3	**Intermediate II** Level A requirements = 100 % Level B requirements ≥ 75 % Level C requirements ≥ 25 %
Q4	**Intermediate III** Level A requirements = 100 % Level B requirements = 100 % Level C requirements ≥ 50 %
Q5 (E)	**Excellent quality level** Level A requirements = 100 % Level B requirements = 100 % Level C requirements = 100 %

For what concerns the first results of the checklists compiled by the producers, they showed that no applications, both products and services, had critical non-compliances with basic requirements (level A), regarding information integrity and security, either in handling, archiving and transmitting clinical data.

Discussion

The proposed quality control program mainly concerns a technical assessment of the telemedicine systems, with a special focus on security and privacy issues. Besides these technical aspects, a deeper quality assessment

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process should require also the evaluation of additional aspects (medical, economic, organizational, quality of life, etc) that should always be carefully considered in designing, implementing and clinically exploiting a telemedicine system.
Specific initiatives should be activated for reporting the progresses in the diffusion of the catalogued products, in order to maintain it appealing for new producers and new users. In particular, a specific section of the web portal will be updated with the publication of the declarations of interest received and the deployment processes activated, underlining the results and the critical issues.
Foreseeing the possibility of a renewal for the project, the Region of Toscana has proposed to take on the activation of a quality control service in collaboration with IFC-CNR and ISS that will allow the continuity of the interaction between the old e-RMETE Operating Units involved in the validation and new producers interested in inserting their applications in the Catalogue.
Soon, the e-RMETE team will also start a specific search on the possibility of transforming e-RMETE in an effective Consortium based on the open source model. This Consortium might connect the demand and the offer of telemedicine systems on the European territory through a series of certified processes.

Conclusions

Today we can find plenty of telemedicine systems across most of the Italian regions, and all of them are honourable applications, indeed. In theory, all these telemedicine systems should be "ready-to-export" to the National Health Service but, in reality, they differ very much in structure one from one another. This reality is a crucial passage, because in health care field we find a lot of little applications, maybe well-established on their own, but draining highly-prized human, organizational, technological and financial resources from the Health System as a whole. Thus, what is truly needed is a global and standardized service logic supporting closely a health production cycle in terms of disposal and quality of services and financial assessment. From this point of view, both the quality process and the Catalogue provided by e-RMETE are practical results that could be adopted by the National Health Service in

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References

[1] ALMANSI G, BEDINI R, BENASSI A, et al.: eRMETE: Telemedicine for Regions. Proc. of Telemedicine in Care Delivery, Pisa, Italy, 2002: 341-344

[2] OFFICE OF TECHNOLOGY ASSESSMENT – OTA. Bringing Health Care Online: The Role of Information Technologies. OTA-ITC-624, September 1995

[3] FRUMENTO E, RINCÓN D, VIÑAS MA.: Description of a Teleconsultation Platform and its Interaction with Access Networks. Proc. of the 5th Open European Summer School 'Access to Internet in the Next Century' - EUNICE99, Barcelona, Spain, 1999: 145-150

[4] FRUMENTO E, BIANCHIN E, GUERRIERO L.; Echo-cardiography on the Web: design and set-up of a virtual community of experts. Proc. of the 2003 ACM symposium on Applied computing, Melbourne, Florida, USA, 2003: 240-245

[5] FRANCHI D, CINI D, BELARDINELLI A, et al.: A Web Based Nursing Management of a Cardiology Department. Proc. of The 30th Annual Conference on Computers In Cardiology, Thessaloniki, Greece, 2003: 413-416

[6] LARCHER B, GRAIFF A, FORTI S, et al.: An evaluation of the use of and user satisfaction with a teleconsultation system in oncology practice. Journal of Telemedicine and Telecare 2002, **8** (suppl. 2): 28-30

[7] DEMICHELIS F, BARBARESCHI M, DALLA PALMA P, FORTI S, and GRAIFF A.: Information Technology in Pathology: from Telemicroscopy application up to date. Proc. of Symposium 'Telemedicine in Care Delivery', Pisa, Italy, 2002: 139-140

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