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Quality Assurance and Quality Assessment of Health Care Telematic Technologies

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1. Introduction

It is generally accepted, that any technology intended to be used in health care should be able to demonstrate its own efficacy and compliance to general practices, principles of law and ethics, adhere to standards and establish its contribution to the domain it addresses. Technology Assessment will be based on evidence from the implementation of this technology, to provide answers to questions relating to the degree of achievement of these goals. Quality Assurance, on the other hand, is a preventive mechanism. When systematically applied throughout the process of production, of any new health care technology, can provide confidence that the emerging products, techniques or services will effectively address the actual user needs which inspired the particular research and development initiative.

Health telematics has focused largely on the development of advanced tools, catering to specific needs in healthcare, that can disseminate or access information originating at various sites, process it and use in many ways, to support decision making, planning and forecasting.

The accelerated production and placing in the market of these new technologies, however, introduces new concerns about the integrity and quality of information as well as security and confidentiality of sensitive data, while the evaluation and assessment of this technology applications in themselves, remains to a large extend an open issue.

The work presented here concerns the elaboration of a comprehensive Quality Assurance system for research and development projects, aiming to produce new, or expand existing health care telematics technologies. The system, as such, has already been installed in two current HCT projects[1], under the 4th framework program, while an initial validation phase of this system has already been completed.

2. The Quality Initiative

Quality Management of a project shall focus on the general objective of contributing to quality improvement in health care in a clear, well specified fashion. It shall therefore address effectively all aspects involved in the work - that is, both the process and the products - and shall cover all activities and deliverables to be produced. In this context, any research and development project addressing the general health care domain, can be regarded as comprising

[1] BEAM II. Biomedical Equipment Assessment and Management
AMBULANCE. Mobile Unit for Health Care Provision via Telematics Support

the general framework and infrastructure for the design and development of the products and/or services to emerge. The development team and infrastructure may come from a single organization or a consortium of organizations and may be of a national or international character. The ISO 9000 series of quality standards describe the basic principles for quality system development and quality management. Specific guidance on those elements and practices for which the implementation is important to and has an impact on the practice of project management are given in the ISO/DIS 10006 standard.

In summary, Quality and its pursuit is regarded as important for any project. The requirement for Quality is absolute; as such, it shall be addressed by the project management and shall be understood and observed by all parties involved in the development process. The criteria by which quality is to be pursued and the means of such pursuit are flexible and shall be developed within the project. These shall normally occur as a result of consensus amongst project partners.

3. Quality Development

The development of health care technology typically involves the deployment of appropriate tools and methods to collect and analyze requirements and convert them into technical specifications and design, which will then go into prototype development. The emerging technology will undergo thorough testing at the development site and will be followed by verification with the involvement of a small number of users, under controlled conditions, before entering its validation phase. Validation for medical devices or drugs involves clinical investigation of the technology and the process should adhere to the applicable standards.

Building quality into the products is a process that runs in parallel lines with these activities and follows similar phases of development. Quality development is performed in a series of consecutive activities, which can be formulated in the following steps.

3.1 Quality Requirement Definition

The overall as well as the specific goals to be pursued within the project should be clearly stated and directly linked to the anticipated contribution to the health care sector or medical domain concerned. At the same time, the framework of use of this technology and the target audience of the system or services to be produced should be specified. A hierarchical task analysis for the system can prove quite useful in directly associating each one of its subsystems to their intended use. This type of analysis also links development - as this is seen from the developers view point - to the end product - as this is seen from the end users visual angle. This activity thus serves in establishing the context of use, within which all quality related aspects will be addressed.

Health care technologies are subject to a number of technical or application standards. Telematics on the other hand must adhere to communication and data exchange standards while horizontal standards apply to issues such as data security and confidentiality, validation of information etc. Finally, domain specific standards may apply to the certain types of project deliverables. All applicable standards shall form the basis for the elaboration of quality criteria. Where such standards do not exist, criteria shall be elaborated based on existing experience,

they will however need to be certified as credible in the user population. Therefore, all types of intermediate or end project outcomes must be designed and developed such that they fulfill stated or implied user needs. Technical, regulatory, legal and ethical aspects of the deliverables shall be treated in adherence to existing standards.

Quality characteristics for the application must me identified and clearly relate to desirable outcomes or features that are expected of the application under development. All quality characteristics that have been identified as relevant need to be carefully considered. However, some are more critical than others; their degree of criticality realties to the particular features that will guarantee a successful exploitation by the user community. This action will promote a good understanding of the realistically weighted requirements for quality and will also provide a basis for decisions as to the distribution of available resources to the partial tasks.

Furthermore, this type of prioritization will provide an essential selection criterion when determining the scope and depth of the evaluation.

3.2 Establishment of a Quality Measuring System

Quality characteristics comprise a set of monitored variables to be assessed during evaluation. Such characteristics are linked to a number of technical or administrative parameters that are present during development. The latter thus constitute controlled parameters that should be monitored and checked during development for compliance to set values and ranges. Therefore all quality related entities must be converted to a set of easily identifiable and measurable parameters, i.e., a set of quality indicators. Such indicators should be clearly defined and mapped to the quality requirements. They should also be measurable in a straight forward fashion and assigned a range of expected values as well as a ranking system to assess performance.

3.3. Procedures and the monitoring process

Within any project it is necessary to formulate those mechanisms that will allow for continuous monitoring, during the process and recording of compliance and deviation. Such process shall allow for effective and efficient communication between parties involved and shall also incorporate corrective mechanisms. An internal audit, in the form of a review procedure for all project deliverables, whether documents or demonstrators, maybe carried out systematically with the involvement of internal referees; often external referees may be sought in order to bring in an additional element of objectivity and expertise.

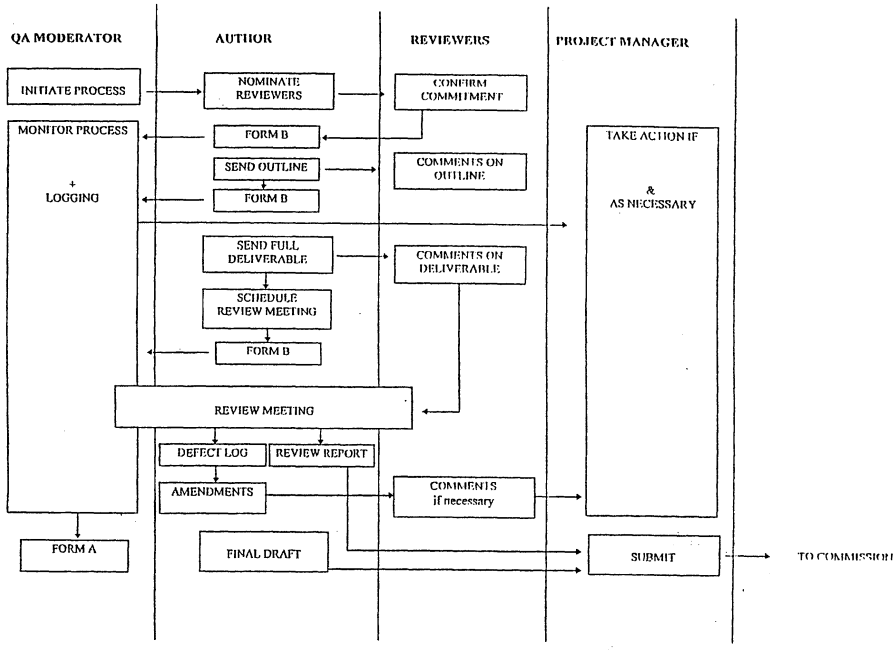

Figure 1. Quality Control mechanism for deliverables across four lines of communication

3.4. Evaluation Plans

The depth and the extent of the evaluation depends on the goals set and the available resources. It is therefore necessary to define the granularity of the evaluation , i.e., the level and the detail at which the system will be evaluated. An additional filtering process can be based on the prioritization performed earlier. Furthermore, the scope of the evaluation will be delimited by any pertinent ethical issues, relating to experimentation with the new application. The scope of the evaluation is therefore defined in terms of the depth and the parameters or variables that will be assessed. For each parameter, whether monitored or controlled, it is necessary to establish the measuring methodology and type of assessment. Explicit descriptions of the evaluation procedures and data collection tools in support of these procedures must be prepared prior to launching the evaluation experiment. These elements will comprise the evaluation plan.

3.3. Feed-back and Continuous Improvement

The establishment of the systematic procedure described in the previous phases for quality definition and evaluation planning, is bound to lead to the collection of evaluation data that can be easily interpretable and directly related to those attributes that are of particular importance for the application. Feed-back routes are thus built straight into the system. The assessment

results of any monitored variable will in this way lead directly to those technical areas that need to be reconsidered and improved.

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