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Quality of Healthcare related Software Applications - setting up an accreditation system in Hungary

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1. Abstract

Meeting expectations of high quality health care, the safe and secure operation of medical information systems is a "must". However for healthcare software nationwide quality control systems are not widely used. A quality control project of health care applications in Hungary has been launched in 1996 by the Hungarian Society of Healthcare Informatics (MEIT) and Medico-Biological Section of Johann Neumann Society of Computing (NJSZT) by establishing a joint Healthcare Informatics Applications Accreditation Board (Board ESAB). The Board developed an evaluation methodology and a legal procedure to test health care software application modules. The evaluation method is based on international standards as ISO-9126 and on emerging European standards of CEN/TC 251. First rounds of accreditation already proved that there is a need among providers and users for the accreditation process. The authors hope that establishing an accreditation system will lead to a more balanced health care software market where users have an opportunity to inform themselves by the opinion of independent experts on the product they intend to purchase.

2. Background and introduction

There is a worldwide need for higher quality healthcare. Meeting expectations of high quality, the safe and secure operation of *medical information systems* is a "must". In other areas as e.g. in case of *medications* and *medical devices* quality control of products is accepted and well established. An example is the activities of the well known Food and Drug Administration in the United States. However for healthcare software applications such nationwide controlling systems are not widely used.

To serve the above mentioned safety, security and effectivity goals quality of health care applications should be measured and monitored. A software quality testing project of health care applications in Hungary has been launched in 1996 by the Hungarian Society of Healthcare Informatics (MEIT) and Medico-Biological Section of Johann Neumann Society of Computing (NJSZT).

3. Methods and Materials

MEIT and NJSZT established a joint *Healthcare Informatics Applications Accreditation Board (*Board ESAB*)*. The Board developed an evaluation methodology and a legal procedure to test health care software application modules. The evaluation method is based on international standards like ISO-9126 [1,2] and emerging European standards of CEN/TC 251 [3,4]. The evaluation itself is done by experts, individually selected by the board, based on their professional background in medical informatics and general computing sciences. The Board controls the activity of assessor experts via a set of contracts.

The activity of the Board ESAB is supported by the Hungarian College of Informatics (the relevant professional advisory body for the Ministry of Welfare) and National Healthcare Administration Fund.

The computing infrastructure of setting up an administration of accreditation process and a database of accredited software products has been provided by a grant of the Soros Foundation - *Development of quality in healthcare : Quality testing and registration of healthcare software applications* (062/0099; 1996) .

The method for evaluation classifies the products by *type of the application* (nursing system, management information system, decision- support application, interfaces for medical devices etc.), in case of patient care system by the *type of care* (inpatient, outpatient, home care etc.), by *product complexity* (institution-wide system, departmental system, task-specific application etc.) and by *user profile* (medical, paramedical staff, management-administrative personnel)

The evaluation system is built around the ISO/IEC 9216 general software quality standard as the six top level assessment domains. Special medical requirements are reflected in the seventh top level domain and in some subordinate levels of the six general informatics domains:

1. *functionality* (specification, maturity, security, networking capability, utilities, distributor's post-purchase services)
2. *reliability* (fault tolerance-stability, error-exception handling, data rollback)
3. *usability* (documentation, learnability, user interface, ease of accomplishing everyday tasks)
4. *efficiency* (resource- and time-effectiveness, operational speed)
5. *maintainability* (programmatical up-to-dateness, changeability, upgradability)
6. *portability* (installation, standard-conformance, consistency, personal configurability, compatibility)
7. *medical aspects* (data content, services, general aspects: conceptuality, consistency with medical terminology, coding systems)

The general informatics assessor evaluates the product in quality indexes 1-6. The medical expert evaluates the product using measurement 7. In special cases concentrated evaluation takes part by the medical informatics evaluator using all seven criteria. The criteria system focuses on user needs: the medical informatics assessor implicitly applies a user perspective during evaluation. The developer-programmer view is reflected in the general informatics expert report. Both the general informatics and medical informatics evaluators pick some aspects of the managerial perspective although the accreditation system is not studying cost-effectiveness (implementation and maintenance costs are institution-dependent). For the extremely complex demands of users in healthcare, the numerical representation of product quality occurs in a seven-dimensional array for each measurement separately. To visualize this many-faceted requirements structure the *"Accreditation Certificate"* features a radar diagram (Figure 1). With this enumeration system the user's product choice is supported by his own favorite standards.

The evaluator makes a recommendation on accreditation rating (five-item scale) for each evaluation criterion domain based on the scoring system detailed above. The final quality scores for a multi-module product result from weighted averaging - the weights are declared by ESAB before product assessment and reflect the relative importance of modules from a health care user's perspective. The evaluated product acquires "unsatisfactory" complex accreditation rating independently from score results if it has not fulfilled the official medical data set requirements or obtained an "unsatisfactory" rating in the 7. medico-professional criterion. If a product acquires in one or more general informatics criterion "unsatisfactory" rating the rejection of accreditation may be considered but is not compulsory.

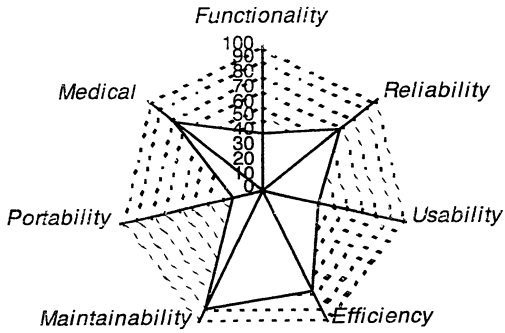

Figure 1. Visual representation of software quality

During the whole accreditation process the company or individual asking for evaluation and the assessor experts do not meet. A fee is paid for the accreditation to the ESAB. Each participant communicates with the ESAB representatives only and - as mentioned already - obligations and rights (i.e. copyright issues) are handled by contracts among the mentioned partners. The result of accreditations might be appealed at the College of Medical Informatics.

4. Current state of the project

The Board ESAB is in function since February 1996. It consists of five-five members delegated by the two medico-informatics scientific societies MEIT and NJSZT, a chairman and a co-chairman. We have approved a paper describing a general set of criteria (discussed above) . Supplements dealing with the special conditions of family practice and hospital information systems are being circulated among experts for consultation and planned for rollout by this summer. A collection of frequently asked questions and answers (FAQ) is under way. Contract templates for software companies and assessors have been completed and approved.

About fifteen expert assessors of various interdisciplinary fields (medical informatics-medicine, biometry, pharmacy, general computing sciences: software development) have been registered and participated in the evaluations.

Data of the evaluated softwares, assessors and full texts of expert reports are stored in a database developed in Microsoft Access. This database is the on-line form of the Accreditaion Registry open for the public. A restricted data set of this database is published on the World Wide Web and traditional paper media (periodicals), too.

The Web site of the ESAB contains all public accreditation-related documents and application templates in Hungarian language
(URL: http://www.pro-patiente.hu/md/soc/meit/esab/index.html)

By now (March 1997) two family practice information systems and a medical telematics system have been approved . A biostatistical package failed the evaluation - the process has therefore not resulted in a successful accreditation. Several software development companies have shown their interest in the accreditation programme and have been put on our waiting list .

5. Results and discussion

The result of the preparatory work of one and half year resulted in a system of health care software accreditation with the following features:

- main tasks:
  - supporting and protecting users in the selection and maintenance of an appropriate healthcare informatics solution for their needs
  - supporting developers in finding the most adequte development directions in harmony with national health strategy aims and needs

- accreditation results
  - products obtain accreditation and are awarded with the title *"Audited and Recommended Healthcare Informatics Application"*
  - (if asked for) are registered in the *"Healthcare Informatics Applications Accreditation Registry"*
  - expert reports presented in the process of accreditation and the *"Accreditation Certificate"* form a professional documentation for the database of accredited products

First rounds of accreditation have already proved that there is a need among providers and users for the accreditation process. The product registry and the assessors' expert reports are on-line and available for local browsing in the Secretariat.

The authors hope that establishing an accreditation system will lead to a more balanced healthcare software market where users have an opportunity to inform themselves by the opinion of independent experts on the product they intend to buy. By developing the open and public evaluation criteria further on, with an open eye on European and world standards we hope that the niveau of health care software products sold in Hungary will approach the European level.

6. References

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