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# A Clinical Quality Management Support System

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**Abstract.** In the CONQUEST Quality Management System, assessment and improvement of the quality of treatment process and outcome is done by introducing a Clinical Quality Management Support System. Initially the treatment of breast cancer was chosen to illustrate the potential benefits of introducing quality management in the treatment process. The main objective of the CONQUEST Quality Management System is to provide a flexible framework for supplying quality management of the treatment process and enable comparison of clinical results, despite differences in the local best clinical practice guidelines used in the participating treatment centres.

## 1. Project Presentation

The work presented in this paper is a result of the CONQUEST project, which is a project funded by the European Commission via the 4th Framework Program, Health Telematics sector. CONQUEST is motivated by studies [1] of cancer treatment, which have shown that although there seems to be consensus on the treatment for a given diagnosis and stage of disease, the treatment outcomes differ significantly between cancer treatment centres in Europe. To assess the reasons for these important differences in treatment outcome, cancer specialists within Europe are now focusing on the assessment of the quality of the treatment process.

The main objective of the CONQUEST project is to support quality management of the treatment process through improved documentation of the process and through support for the daily clinical routines. Local guidelines will be implemented in the system, and deviations from these guidelines will result in a red flag procedure (the system will warn the clinician and ask to document the deviation). Imaging tools will be provided to support the quality assurance process.

Despite differences in the local best clinical practice guidelines used in the participating treatment centres, a clinical database based on the definition of a minimal dataset, will be set up. This will ensure an acceptable degree of comparability between the participating centres. Telematics will be used for comparison of aggregated data and dissemination of knowledge about local guidelines, definitions etc.

## 2. The Course of Treatment

In order to provide such a clinical quality management support system, it is necessary to decide on a framework for describing the course of treatment and illustrate how this framework will be implemented in the CONQUEST quality management system. An

example of a course of treatment is illustrated below in figure 1. This particular course of treatment is for a patient with a small resectable breast cancer. After introductory examinations performed in the diagnostic work-up, a preoperative prescription for a treatment plan is specified. This plan describes the next sequence of events in the course of treatment. The sequence starts with a surgery procedure and a pathological examination of the suspect specimen. After surgery, the preoperative prescription is evaluated against the results of the pathological examination of the resected specimen. Based on this more precise information, a postoperative prescription is made for the subsequent therapy.

Whenever a clinician examines the patient, makes decisions or performs a step within the course of treatment, medical knowledge is used, as illustrated below in figure 1. Parts of the medical knowledge can be described rather formally as best clinical practice guidelines [5,6] of a local treatment strategy .

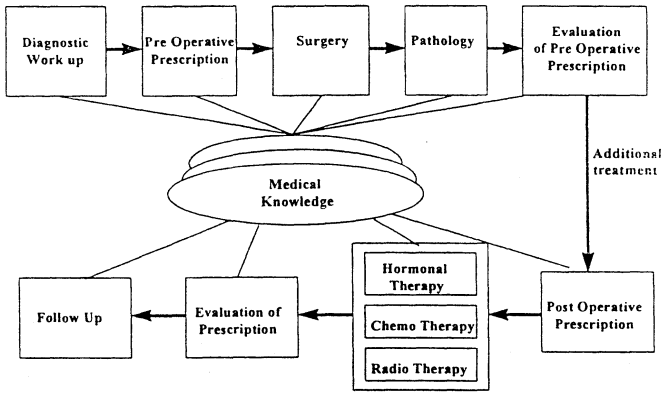


**Figure 1: Course of Treatment**

## 3. The Quality Management System

In order to introduce quality management in a formalised manner it is necessary to rely on a number of concepts: quality plan, quality criteria, quality indicators, quality surveillance, concurrent audit and retrospective audit.

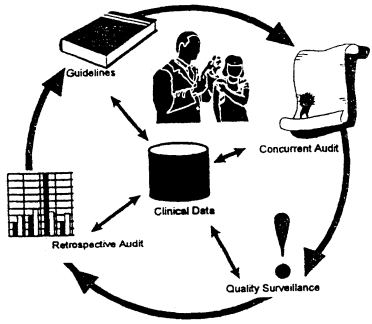


**Figure 2: Quality Management**

A *quality plan* reflects the local treatment strategy. This plan contains the quality criteria, the best clinical practice guidelines and the quality indicators for the individual departments. A *quality criterion* is the overall goal for quality, and *quality indicators* are the means to measure the obtained degree of quality. The *quality surveillance* of the

treatment process is surveillance of the collection of clinical data with respect to best clinical practice guidelines. Quality surveillance will ensure that the treating clinician is reminded of how the treatment should ideally be performed, and an explanation will be requested, if a treatment decision deviates from the guideline in use. If for example the local best clinical guideline for prescription of adjuvant therapy is based on the Nottingham prognostic index (NPI) [7], the implementation of a quality management system will ensure that the necessary data for calculating the NPI is present. The NPI is calculated by adding tumour size (0.2 multiplied by tumour size in cm) to differentiation grade and axillary nodal involvement. On the basis of the NPI and the receptor content of the tumour, a decision on adjuvant treatment is made, e.g., an intermediate NPI with a highly receptor positive tumour in a post-menopausal patient will lead to the prescription of Tamoxifen. If the clinician chooses to prescribe a different adjuvant therapy than the one recommended by the best clinical practice guideline, he is obliged to document the reason for this deviation.

*Concurrent audit* is assessment of decisions made earlier in the course of treatment or audit of clinical data during the treatment process. If for example a breast conserving operation is prescribed initially, but for some reason is changed to mastectomy, then why did this happen ? Was it because the patient changed her mind and insisted on having a mastectomy, although her first decision had been to follow the recommendation of the treating physician? Or was it because the quality of the diagnostic data was poor? The reason will be identified through concurrent audit. Assessment of best clinical practice guidelines and clinical data after the course of treatment is *retrospective audit.* This means audit of clinical data addressing the quality plan specified by the local treatment centre after a treatment process has been completed. If a quality indicator related to the rate of suspect malignant tentative diagnosis, which turns out to be benign, is getting unacceptable, it would be worthwhile to assess the clinical findings and mammograms (report and images) which lead to the suspicion of a malignant lesion (which turned out to be benign at the time of surgery). Knowledge gained in this way will through retrospective audit lead to quality improvement [2] of the process: the preoperative prescription will be more correct, e.g., excisional biopsy instead of mastectomy and axillary clearance avoiding unnecessary anxious patients and inadequately planned operation rooms.

## 4. CoMoQ - the Conceptual Model

The Conceptual Model in Quality Management - CoMoQ - provides an overview of the information flow of the Quality Management system in CONQUEST - from setting up a quality plan for the CONQUEST Quality Management System through quality surveillance and concurrent audit to retrospective audit. The idea illustrated in figure 3 is that the existing medical knowledge - as described in the best clinical practice guidelines and treatment strategies at the hospitals - is implemented in a set of protocols. The term protocol is used as a more formal description of a best clinical practice guideline. The protocols are divided into two categories. One concerning diagnostic work-ups, and one concerning events in the treatment process. By selecting a diagnostic work-up protocol, it is guaranteed that essential examinations are carried out, which ensures that all necessary diagnostic clinical information is present prior to prescription of a certain treatment. Prescription of a specific treatment also involves protocols. Through prescription of a certain treatment, a specific protocol is chosen. If the treating physician deviates from the current treatment protocol, he will be notified and asked to document the reasons for the deviation.

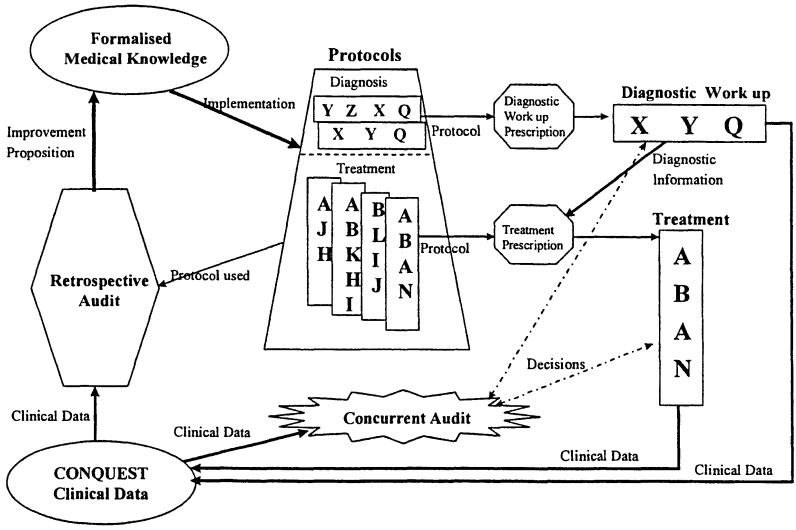


**Figure 3: CoMoQ© The CONQUEST Consortium**

Throughout the diagnostic work-up and the treatment process, clinical data is being collected. The CONQUEST clinical data has a unique character, since all items are linked (via protocol identification) to the context in which they have been collected. The clinical data makes it possible to evaluate the soundness of the diagnostic information used for prescription of a certain treatment. The clinical data will also be used for concurrent audit. If the patient's condition has changed in a way which should affect the future treatment, or if deviations have been made to the protocol during treatment, this will also be documented. The latter kind of documentation provides an excellent opportunity for retrospective audit of the treatment process. As a result of the above process, the protocols are evaluated and the formalised medical knowledge to some extent improved. These improvements will be implemented in the diagnostic work-up protocols and the treatment protocols, and the quality management process continues.

An important side effect of the described model is the fact that patients already undergoing treatment will also be able to benefit from new results within the cancer research area, which is not the case today. Therefore, it is important to be able to change the protocols throughout the treatment process. However, just as the decision as to which protocol to use is the exclusive responsibility of the treating physician, the medical professionals are exclusively to decide when and how to change the current treatment of the patient.

## 5. The System

The overall philosophy behind the CONQUEST Quality Management System is that the clinical workstation should appear as an indispensable daily tool for the clinicians, where collection of clinical data more or less will be conceived as a side effect.

The CONQUEST Quality Management System will be able to support the clinicians by providing the necessary information at the right time - and to some extent - validation of the decisions made by using protocols. CONQUEST provides a flexible framework for comparing the clinical results, although different local protocols have been used in the different treatment centres.

The CONQUEST Quality Management System will present the relevant protocols to the examining and treating specialists. It will guide the specialists through the protocol on each patient encounter, assisting in ensuring that the protocol is followed. Where the treating professional deviates from the protocol, the deviations will be recorded and explanations required. Data recorded during this process will provide the necessary information for use in subsequent quality audits. A standard format for all data related to this aspect is developed, and strong user involvement throughout the development process has ensured that the systems make the entry and re-use of data more efficient for health care professionals without causing extra burdens in their daily work.

To support the quality management activities, the whole treatment process will be documented on-line in a formalised way, and deviations from the best clinical practice guidelines will immediately be detected in the CONQUEST Quality Management System. Instant formal documentation of deviations will be requested by the system. This information will provide clinicians and researchers with more knowledge of the treatment process, especially in relation to assessment of the quality [3,4].

The CONQUEST Quality Management System will be set up in a client server environment, using tools meant for development of electronic patient records, equipped with a leading edge user interface. This ensures that the system has the potential of being an integral part of the overall electronic health care record. The system will provide possibilities for integration with all relevant systems in the clinic. Additionally, the system will be developed in a generic way, allowing it to be applied to other medical fields.

## 6. Conclusion

The main emphasis of the CONQUEST project is to provide a flexible generic quality management system which enables support for improvement of the quality of, to begin with, breast cancer treatment in Europe and support for development and implementation of best clinical practice guidelines. CONQUEST is also adding more value to the traditional way of organising clinical databases by linking all data items to knowledge about which context (protocol) they appeared in originally.

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