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PROJECT STATUS REPORT II
Project documentation & Technological solution

March 2005

General summary of period 16/01/2005 – 20/03/2005

1. Project solution was focused mainly on model implementation of dose intensity and health technology assessment principles in Masaryk Memorial Cancer Institute (MCI) (as model case)
2. Project team successfully finalized audit of data sources in MCI and proposed corresponding adjustment for actual situation (i.e. namely parametric update of hospital information system)
3. Key topic of the summarized period was documentation and plans of software to be developed in the project. Project must search for sufficiently wide variety of solutions as the equipment of target clients in very heterogeneous. Software developers reached consensus on three modes (regimes) of software tools that should cover all aspects or situations:
    a. Direct implementation in routine processing of data in health care facilities (model sub-project in MCI)
    b. On-line version for tests and ad hoc studies
    c. Minimum system proper for situations with very limited data input
4. All three modes of software tools were carefully designed and necessary components were defined. It means:
    a. Way of communication with data sources
    b. Analytic tools associated with dose-intensity (DI) monitoring
    c. Implementation of DI principles into common standards of health technology assessment

Project reached the point, where the development of proposed software tools can start. It means software development in model hospital (MCI) and development of local tools as well.

Model implementation in Masaryk Memorial Cancer Institute

The key aim of this project topic is (A) to demonstrate real evaluation of DI inside hospital and (B) to create model implementation that can be offered in the form of guidelines. Basic principles applied in this study are described in **enclosure 1 of this report.**

Following list summarizes reached outputs:

- **Audit of data sources in MCI.** Successfully finished. A total number of 11 modules was defined from the viewpoint of content and functionality. Especially careful attention was devoted to modules working with data on clinical records.

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- **Proposal of electronic documentation of patients.** Final proposal was successfully prepared in a way compatible with the structure of databases in hospital. List of proposed parameters were reviewed and nowadays it is prepared for implementation. A final set of endpoints, including dose intensity monitoring was prepared.
- **Minimal set of parameters.** The whole developmental process is carried out with respect to the situation in the other health care facilities with probably very limited support from information systems. For these circumstances, a special minimized set of parameters was proposed that can be used in any hospital of Czech Republic. This approach is based on reports for health insurance companies where we can get time-related items describing all therapeutic steps and aggregated data on pharmacotherapy.
- **Technological solution.** A pilot model based on aggregated data warehouse and subsequent client-oriented automated analytical tools was proposed.

Software development

Three different modes for SW development in project DIOS were proposed. These modes imply different types of data entries and different regimes of work as well. The proposal is motivated by heterogeneous reality of Czech health care system and its data sources, so we searched for robust tools that are able to cover a wide variety of circumstances. Technological aspects for the solution are described in **enclosure 2** and final proposal of regimes is listed in **enclosure 3** of this report.

Proposed SW types are as follows:

- **REGIME A.** On-line solution working with central database out of health care facilities. This system is based on central (on-line accessible) database, built on ORACLE technology, directly connected with analytical tools. Central database should include both basic clinical records and therapeutic plans. Each user can obtain locally installed analytical software with straightforward access to the database. The system will be developed for the following reasons:
  - as test version for pilot validation of electronic records out for routine clinical practice
  - as a platform widely accessible for all potential participants from Czech Republic
  - as ideal tool for realization of case studies, i.e. multi-centric projects focused on dose intensity monitoring in relation to clinical assessment

- **REGIME B.** Local implementation of parametric structure and standards into databases directly in health care facility. This regime will be realized through model implementation in Masaryk Memorial Cancer Institute and subsequently a methodical guidelines will be prepared and published. Analytical tools will be installed in the hospital in direct connection with its data sources. The implementation requires fully functional parametric electronic records, processed in clinical practice (see also enclosure 3).

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- **REGIME C.** Local minimal solution, developed for the situation with lack of valid and parametric clinical data. This approach calculates with very limited set of accessible data that can be obtained from internal data sources. Second assumption is to ensure universal and standardized solution, acceptable for most of the health care facilities in Czech Republic.
    - SW will be prepared for local installation, with standardized interface for exports from reporting system for health insurance companies (the only fully standardized platform with therapeutic records in Czech Republic)
    - Based on these minimized entries, therapeutic strategy and steps can be viewed retrospectively in time-related schedule, and aggregated according to other clinical criteria.
    - These automatically accessible data can be supplied with very small set of parameters describing therapeutic plans and dosage regimes for final dose-intensity evaluation.

Model case studies

Model case studies are prepared in accordance with project aims and plan. Based on circumstances, we decided to speed up the pilot phases and to design case study for Masaryk Memorial Cancer Institute simultaneously with software development. It means that pilot data gathering should start in April – May 2005 (instead of autumn months). The study will begin with breast carcinoma as the best test model. By the end of May it should be advertised in a nationwide communication and introduced in national conferences. Recruitment from further participants can be initiated from June 2005. The study will be based on SW regime A (see above stated description and enclosure 3 as well).

Publication plan

Four abstracts for conference lectures and posters have been issued (see enclosure 4):

Conference BOD 2005, Brno, May 2005

- **Dose intensity principle as a part of health technology assessment standards in oncology (Project DIOS).** Dušek L., Koptíková J., Coufal O., Klimeš D., Brabec P., Vydlák J.
- **Parametric patient's documentation in oncologz / standardize and accessible software solution.** Dušek L., Klimeš D., Coufal O., Novák J., Beneš M., Koptíková J., Brabec P., Brož M., Šlampa P., Bartonková H., Andres P., Vyzula R., Žaloudík J.