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The DIABCARD Feasibility Study

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Abstract DIABCARD, a project sponsored by the European Union, has developed the core of a Chip Card Based Medical Information System for chronic diseases in ambulatory and hospital care. Specific functions deduced from the requirement analysis were implemented into a prototype. A pilot of this system was run for 3 months. This paper shows the approach of the project and the results of its first field test.

1. Introduction

The need to improve medical documentation is evident. This is due to an increasing average life-span, to an increased mobility of the patients and to multi-morbidity requiring treatment by different specialists. While it is widely agreed that everybody involved in the process of care should have controlled access to comprehensive and accurate information about the patient's diagnosis and problems including current therapy, the structure of health care is moving towards shared care. On top of that improving medical documentation is thought to be one way of limiting the constantly rising costs in healthcare.

The medical paper record often held in different places makes efficient patient management difficult. It has been estimated that physicians spend around 38% and nurses 50% of their time on paperwork (including deciphering each other's handwriting, looking for records, etc.) [1]. When compared to paper records, electronic medical records are more easily accessible for health care providers, they contain less mistakes, they provide better privacy protection and they are more suitable to support medical research.

DIABCARD is based on the idea of a portable electronic medical record. That way information on the patient can be shared between the different health care professionals and the different institutions.

2. The Patient Data Card

The smart card seems an ideal carrier for an electronic medical record. It is small, easy-to-handle and patient based. Chips with 32 Kbytes EEPROM will be available in the near future and thus smart cards will be able to store besides the patient's actual state-of-health-data, his/her medical history and even biosignals and images [2].

The patient carries the card and is thus actively involved in the health care process. The introduction of the patient data card does not require any vital modification of existing structures and practices.

3. Diabetes

Diabetes is one of the major chronic diseases in Western societies. It threatens at least 10 million European citizens [3]. Regularly, it causes acidosis, nephropathy up to acute renal failure, vascular diseases and neuropathy. Diabetic retinopathy is one of the major causes of blindness in the European population. The severity and onset of complications could be considerably reduced if the patient's health status was to be monitored regularly, as could be shown in a long term trial with approximately 1400 insulin-dependent Diabetes mellitus patients [4].

In 1992 in Europe, 7% of the total health care expenditure was devoted to Diabetes management (on 5-7% of the European population), while in the Unites States this percentage was rising to 14.6% (people with Diabetes constituting 4.5% of the US population). This shows that significant savings to the health care system can only be realised if even a fraction of these costs can be saved through prevention or effective management of the disease [5].

The "St. Vincent Declaration"[1] puts its main emphasis on monitoring the Diabetic's state-of-health and describes goals and targets for prevention, identification and treatment of diabetes to be performed on a local, national and European level [3]. Quality assurance in Diabetes is a major part of the St. Vincent Declaration. Quality indicators were for this purpose designed and constitute the DiabCare dataset, laid down in the Basic Information Sheet (BIS). Via the BIS data for quality assurance is collected on an annual basis using paper forms. Data derived from an electronic medical documentation means improved quality and cost effectiveness.

4. The DIABCARD Chip Card Based Medical Information System (CCMIS)

The project team has developed a health smart card for Diabetic patients. The card has to be seen as part of a chip card based medical information system (CCMIS).

4.1 Design Considerations

The long term objectives of the project are to improve the quality of Diabetes care and to reduce costs in healthcare. When designing the CCMIS the project team therefore concentrated on the demands on a medical record (up-to-date, comprehensive, fast retrieval, access control, data integrity, confidentiality) and at the structuring and the standardisation of documentation on the one hand and on good management of Diabetes mellitus on the other hand. Prime goals therefore are improving the communication between and in-between primary and secondary healthcare, enforcing preventive methods and better emergency treatment at the same time involving the patient.

4.2 System Architecture

The basic communication model consists of different types of workstations for the different environments. Communication channel is the card. The architecture can be implemented into existing information systems and into different networking environments. It can be adapted to technological advancements of the chip card. Its specification is not limited to Diabetes and adaptable to general health care data and other chronic diseases. The

[1] An intitiative to improve the life and health of Diabetic people started under the aegis of WHO Regional Offices of Europe and the International Diabetes Federation in 1989

DIABCARD architecture is covered by standards and pre-standards defined within ISO and ETSI. High security standards are part of the design [6]. DIABCARD could also connect to existing computer-based approaches which assist in the treatment of long-term management of Diabetic patients and which include a number of knowledge-based systems [7,8].

5. Pilot Scheme

In 1995 the project concentrated on the development of a first prototype and its evaluation. An overall assessment in a long-term pilot must, of course, be one of the major goals of any project. At this stage, however, it was most important to find out whether the right concept had been chosen, as well as to test the functionality of a basic DIABCARD system and to assess the acceptance of the users, i.e. patients and physicians. Therefore, the functionality was only partly integrated into the prototype.

6. Prototype

The prototype itself consists of a computer-based medical record (CPR) system and the DIABCARD smart card enhancements. The software is an easy-to-use, easy-to-learn tool designed by Boehringer Mannheim. It is based on the Diabcare®-system, which was designed as a tool for quality assurance in Diabetes care. The requirement analysis showed that the medical content, management, report and card functions had to supplement the Diabcare®-system. This meant that e.g. an additional database was added and a consultancy paradigm included.

The system contained different categories of data, i.e. administrative data and medical data (the data of the BIS; pregnancy data; nephrology data; endocrinology data; ophthalmology data) and emergency data. The last visit is completely stored on the card: updated record items are being overwritten, old data items - not updated during the visit - are kept on the card.

7. The Pilot Organisation

Hospital organisation is based on a network of different speciality departments. This network constitutes a federation of autonomous units - each one with its own work organisation. Shared care requires the management of the information to and from other units. In the 'Hospital de la Santa Creu i Sant Pau' the hospital units are in no way electronically connected to each other.

The pilot development took place in 1994 and 1995. The first implementation was run for 1 month. The redesigned and revised implementation constituted the 3-months pilot phase. 3 departments (Endocrinology, Obstetrics and Nephrology) were involved.

108 Diabetic patients were asked to participate in the test, only 5 refused. The patients were randomised into a trial group using DIABCARD and into a control group. All the trial group's patient's records were put onto the central data base on the server in the endocrinology department, respectively on the smart card. Cards were personalised and handed to the patients by the treating physician. A copy of the Diabcare®-system was installed in the Nephrology and Obstetrics departments having their own database. The data transfer and the synchronisation of the 3 data bases was handled using the chip card. The trial patients held no - additional - paper record during the time of the pilot. For the control group the physicians used the "old" system including paper records.

8. The Evaluation

The pilot was designed to assess the concept of DIABCARD; the functionality of a basic DIABCARD system; and to give indications concerning the acceptance of the users. Specific indicators had been set up for each of these objectives taking into consideration the specific conditions of the pilot site.

After each patient visit the physician had to assess the system's performance. He answered a questionnaire in terms of availability of the clinical data; the system's effectiveness as a communication tool; the system's effectiveness as a tool for quality assessment and on difficulties regarding technical issues. Additionally, reports on system errors were automatically generated.

The patients filled in questionnaires on consultation satisfaction at the start and at the end of the pilot.

9. Results

One indicator for the *system's effectiveness as a communication tool* was the availability of Clinical Data and additional questions that had to be posed to colleagues. The physicians felt that the data on the card was not comprehensive enough. In 15,5% of the cases (compared to 8.3% of the control group) the physician had to contact a colleague or the laboratory to solve important questions.

The results of the pilot indicate that DIABCARD is able to fulfil the criteria designed in DiabCare for *quality assessment*. BIS data could be generated. The quality of this approach will be tested in the next stage.

When assessing the *functionality and efficiency* of the system, one has to keep in mind, that the Diabcare®-system replaced the paper record totally. For legal and medical reasons (e.g. treatment in other departments) paper records were generalised and added to the original patient record. The pilot clearly demonstrated that there was more time needed for the electronic system - resulting in a prolonged consultation period. Especially, database access and printing took very long.

The use of the system did not affect the *patients' attitude* towards the doctor's consultation. The trial group was satisfied with the consultation process and felt "that the physician spent more time on the consultation", while at the same time thinking that "the DIABCARD did not increase the duration of their visit". It was also felt that the card did not alter the relationship with the doctor. The majority of patients (95%) considered it useful to have the card with them all the time.

10. Discussion

DIABCARD has designed a smart card system for people suffering from chronic diseases using Diabetes as an example. This first trial had its recognised success, but also showed its limitations. The results of the pilot indicate that a smart card in the case of the patient with chronic diseases - where care is provided by different people and/or several institutions and where frequent updating is necessary - is feasible.

The physicians did not feel quite comfortable with the system. One has, however, to keep in mind, that before the test only hand-written records had been used. This means that the physicians involved did not just have to get used to the DIABCARD system, but to the use of computers altogether. As mentioned above only part of the functionality had at this stage been implemented, and that meant incomplete documentation and extra time for the

physician to complete the patient's record or to ask for extra information from the referring physician. Additionally, the prolonged consultation time and technical problems lowered the acceptance of the system by the physicians.

Neither all the technical problems nor the other problems could be solved in the course of the 3 months trial. The performance of the system will, of course, be improved for the next phase. There is also the factor of getting used to a system as could be clearly seen: while 70.8% of the physicians felt uncomfortable with the CPR system in the first half of the pilot, the dissatisfaction went down to 51.5% after half-time.

It has to be emphasised again that the evaluation concerned the overall system and not the smart card and that the main problems mentioned above concerned the CPR system functionality.

11. Conclusion

The first pilot has shown that it is vital to test a system - even if incomplete - at an early stage. It could be demonstrated that the project is on the right track; that a portable medical record for Diabetes care is feasible and that the DIABCARD offers an alternative to the paper record. The results also clearly indicate that patients want to be involved in the healthcare process. On top of that, the trial demonstrated that short-term trials are important but that many criteria can only be assessed in long-term studies.

References

[1] Dick R. S., Steen E.B. (eds.): The computer-based patient record. National Academy Press, Wash. DC. (1991).

[2] Intercai Telematics Consultants (eds.): Chipcards - Applications and Opportunities. Telematics Research Centre, Enschede, (1993).

[3] Krans H. M. J., Porta M., Keen H. (Eds.): Diabetes Care and Research in Europe; the St. Vincent Declaration action programme. Implementation Programme. (WHO, Regional Office for Europe, Kopenhagen (1992).

[4] The Diabetes Control and Complications Trial Research Group: The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus, The New England Journal of Medicine 329 (1993) 977-986.

[5] R. Bellazzi, C. Cobelli, E. Gomez, M. Stefanelli: The T-IDDM project: Telematic management of Insulin Dependent Diabetes Mellitus. Proceedings of the Health Telematics 1995, Naples (1995) 271-276.

[6] Engelbrecht R., Hildebrand C., Jung E. et al., DIABCARD 1 Final Report, available at medis-Institut, Munich (1994).

[7] Piwernetz K., Massi-Benedetti M., Bauersachs R., Sönksen P.H. (Eds.): Whither computers in diabetes care? Diab. Nutr. Metab. 4 (Suppl. 1), 1991: 1-214.

[8] Carson E.R., Carey S., Harvey F.E., Sönksen P.H., Till S., Williams C.D.: Information Technology and Computer-based decision support in diabetic management. Comp. Meth. Prog. Biomed. 32 (1990) 179-188.