# **Evaluating a Proof-of-Concept Approach of the German Health Telematics Infrastructure in the Context of Discharge Management**

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## Abstract

Although national eHealth strategies have existed now for more than a decade in many countries, they have been implemented with varying success. In Germany, the eHealth strategy so far has resulted in a roll out of electronic health cards for all citizens in the statutory health insurance, but in no clinically meaningful IT-applications. The aim of this study was to test the technical and organisation feasibility, usability, and utility of an eDischarge application embedded into a laboratory Health Telematics Infrastructure (TI). The tests embraced the exchange of eDischarge summaries based on the multiprofessional HL7 eNursing Summary standard between a municipal hospital and a nursing home. All in all, 36 transmissions of electronic discharge documents took place. They demonstrated the technical-organisation feasibility and resulted in moderate usability ratings. A comparison between eDischarge and paper-based summaries hinted at higher ratings of utility and information completeness for eDischarges. Despite problems with handling the electronic health card, the proof-of-concept for the first clinically meaningful ITapplication in the German Health TI could be regarded as successful.

#### Keywords:

eHealth Strategy; Health Telematics; Electronic Health Card; Nursing; Patient Discharge.

# Introduction

National eHealth and Health Telematics strategies came into existence more than a decade ago [1] and have been implemented with varying success [2, 3]. In Germany, the Health Telematics Infrastructure (TI) based on an electronic health card for the patient and an electronic health professional card, was announced in 2004 but was delayed several times due to politically motivated criticism of the physician associations and other stakeholders [4]. Consequently, systems based on other technologies, and pursuing other approaches, were developed [5, 6]. In the meantime, the development of the Health Telematics Infrastructure (TI) had been carried on, the use of the electronic health card all over Germany is mandatory from January 2015 on [7], and basic IT-applications such as the online management of patient demographics are ready for piloting in several federal states. So far the electronic health card contains administrative data only. The clinical eHealth-applications that had a true chance to run on the

Health TI were rather unclear at the onset of the project, so was a realistic timetable of the availability of the TI.

Against this background, it seemed desirable to develop and test applications with a high potential impact on patient care that make use of TI elements such as the electronic health card as a gatekeeper to the patient data. Among these applications, the electronic health record possesses paramount importance for supporting all health care processes as well as for supporting the discharge process. Discharge management is particularly crucial in patients with chronic conditions and is reported to be problematic in many countries [8]. However, when organised properly, discharge management can help significantly. This, for example, could be demonstrated in geriatric patients [9], just to mention one group of patients that benefit from these measures. Elderly patients often require medical and nursing information to be transmitted at discharge to the institution providing follow-up care in order to maintain the continuity of care [10].

We, therefore, aimed at developing a prototype for an eDischarge application based on an EHR that was embedded into a laboratory Health TI and served as a proof-of-concept for the TI. The eDischarge application should transport administrative, nursing, social and medical data between health care organisations. In this study, we particularly wanted to evaluate its technical-organisational feasibility, usability, information completeness and utility.

#### **Materials and Methods**

#### Discharge application embedded into Health TI

The eDischarge application was built on the ground of the German national HL7 CDA based standard of the eNursing Summary [11]. It included data about the patient and the health care professionals involved in the structured CDA header, and nursing, social and medical data in the body. In detail, the body contained the nursing process, social information, references to legal documents, home care status and medical information, mainly medical diagnoses and medication (extracted with authorisation from the medical summary). The eDischarge solution was a Web application that was connected to a central electronic health record (EHR), in which the eNursing Summary documents were stored. The eDischarge solution also included a certified card reader for the electronic health card (eHC). Patient's demographics were

read via the eHC and nursing, social and medical information of the patient were entered manually via the eDischarge client. Authentication via the health professional card was simulated by a software-key. Patient data could only be accessed when this key was invoked and the eHC was inserted (authorisation and authentication principle of the Health TI). As the current version of the eHC card that had been rolled out to the citizens did not have a pin-code on it, a second card carrying this information was used in the tests.

Certified card readers for the eHCs, software-key, electronic health record kernel and server and secure client-server communication constituted the laboratory Health Telematics Infrastructure, which had been developed by Fraunhofer Fokus in a previous project and was extended in this project to demonstrate the feasibility of implementing the Health TI specifications. The eDischarge application and the laboratory Health TI formed the proof-of-concept to be evaluated. The EHR server was located at the University Hospital Göttingen to comply with the privacy and data security regulations.

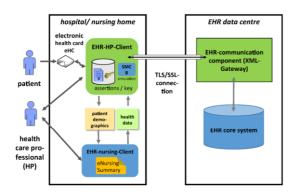


Figure 1 – Laboratory Health Telematics Infrastructure (TI)

#### **Evaluation phases**

The eDischarge application and its communication with the EHR server were evaluated during four phases, in which we aimed at measuring different targets (Table 1). The applications tested comprehended the creation and update of the eNursing summary and its storage into and retrieval from the central EHR server. Thus "sending" and "receiving" a discharge document were technically identical to storing and retrieving it centrally.

Table 1 - Evaluation Phases and their duration

No.	Primary aim	Duration
Ia	technical feasibility	(14/01 - 03/08/2014)
Ib	technical-organisational feasibility	(04/08 - 31/08/2014)
II	usability	(01/09 - 28/09/2014)
III	usability and utility	(29/09 – 31/03/2015)

In phase Ia, we wanted to know what types of problems occurred once the application was transferred from the technical laboratory of the developers to the *field laboratory* of the evaluators. The system was operated by two nurses of the evaluation team. In phase Ib, the evaluation took place at two clinical sites with two chief users (nurses) testing the system in a realistic environment (office at clinical site) with 20 realistic but fictitious discharge documents. Phases Ia and Ib covered the issues of a formative evaluation where the system still was technically adapted in accordance with the evaluation results. During all the phases, the users recorded the type, location and severity of the problems in standardised and structured log books. In addition, usability was assessed in phases II and III by the IsoMetrics questionnaire [12]. During these two phases, nurses, who were on duty, operated the system in the same realistic environment as in phase Ib. In phase II, data of six past discharges (real documents with modified identification data) were sent. Finally in phase III, 13 ongoing discharges were included in the study. Phase III was particularly designed to measure information completeness and utility of the eDischarge application in comparison to a paperbased discharge. To this end, discharge patients were randomly allocated to the eDischarge group or the paper discharge group. In phase III, we were also interested whether there were specific problems using the electronic health card and obtaining the declaration of consent.

#### **Evaluation setting**

We chose two evaluation sites in Osnabrück that were used to cooperating and communicating with each other; a municipal hospital with 717 beds (Klinikum Osnabrück) and a health system with nine nursing homes and three ambulant nursing services (Diakoniewerk Osnabrück). The testing was based on bi-directional communication, thus we looked at the discharge from the hospital to the nursing home and also from the nursing home to the hospital. To this end, we involved the Department of Neurology at Klinikum Osnabrück and Küpper-Menke-Stift (137 residents) as one of the nursing homes within the Diakonie. Two chief users from Klinikum Osnabrück and Diakonie accompanied the study in phases Ib to III.

During two information meetings, representatives from the two evaluation sites were informed about the study, its aims, the procedure and the technology involved. There were four user trainings that took place on the  $21^{st}$  and  $25^{th}$  of July 2014 in Küpper-Menke-Stift and the  $22^{nd}$  and  $24^{th}$  of July 2014 in Klinikum Osnabrück. In case of problems, the two chief users supported the users when operating the system. All users belonged to the group of nurses. The patients involved in phase III testing had to give their informed consent to take part in the study and also to allow the organisations to transfer their discharge data to the other organisation. The study design obtained approval from the ethics committee of Klinikum Osnabrück.

#### Pretest eNursing Summary as the eDischarge data set

In order to make sure that the HL7 eNursing Summary standard was suitable for the eDischarge application, we tested it against commonly used discharge forms. We were particularly interested in whether there were any data in the forms that were not covered by the HL7 standard and vice versa. We drew a regionally clustered random sample of 375 institutions throughout Germany (hospitals, ambulatory nursing services and nursing homes), which covered all three types equally. They were asked to send us their discharge forms. We received a set of 69 forms, which was enriched by forms retrieved from the Internet. Finally, a set of 114 different forms was obtained and independently analysed by two nurses regarding the match of potential data entries.

#### Results

### Pretest results

The analysis of the 114 forms showed that all nursing, social and medical information found in the forms could be matched with fields in the HL7 standard. Only very specific information that was found in individual forms that concerned organisational issues and specific information on hygiene and physiotherapy could not be represented in the standard. In contrast, none of the forms contained all information items of the HL7 standard. Most of the forms were problem-oriented (77%). However, even if the problem could be entered, only in 23% the reason could be inserted. Only in 45% the interventions, and in 44% the means that were associated with a problem could be given. We concluded that the HL7 eNursing Summary was a valid and suitable standard for the eDischarge application, which contained more information to be carried than the paper forms.

#### Technical-organisational feasibility

The evaluation results are presented in the following in accordance with the respective research questions and topics.

In phase Ia, a series of many problems occurred. Examples are: installation of the clients in the hospital and the nursing home, the compatibility of the card reader, moving the server to the University Medical Centre Göttingen, terminology used in the application, workflow and pdf presentation. These problems could be solved during a continuous formative evaluation with several feedback loops that took eight months all in all (Table 1). The actual evaluation started in Phase Ib. In the following the results, which were obtained from analysing the logbooks in terms of the number and severity of problems, are presented. The logbooks allowed entries describing the following steps of operating the application: starting the program, reading patient demographics, creating a new summary (inserting, buffering, resuming, changing and deleting), transforming into pdf, printing, storing in EHR (sending), opening/browsing EHR and retrieving/viewing eDischarge summary (receiving). Problems and their severity could be documented for each of these steps.

The percentage of problems per discharge session (Figure 2) decreased from phases Ib to II and rose again when operating the system during real discharges (phase III).

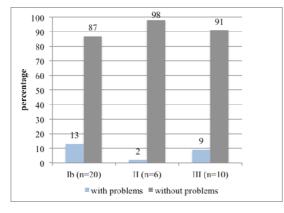


Figure 2 – Mean percentage of problems in phases Ib – III

Out of the 26 individual problems in phase Ib, 46% were rated as "1" and 46% as "3". On a severity scale from 1-3, "1" was denoted as "a problem that could be solved during the session" and "3" as "several problems that could not be solved during the session". Four percent of the problems in Ib were rated as "2" and 4% as "4". In phase II there was only one problem that was judged "1" and in phase III 25% of the 12 problems received the lowest severity level "1" and 75% level "3".

#### Usability

Usability data from phases II and III were pooled due to the small number of different nurses who actually used the system. Selected results for suitability of the task (median 4), error tolerance (median 3.25) and suitability for learning (median 3) of the IsoMetrics questionnaire [12] are shown in Figure 3. The scale ranged from 1 (strongly disagree) to 5 (strongly agree).

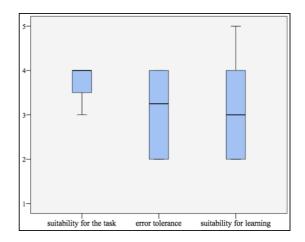
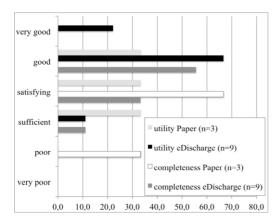


Figure 3 – Usability profile in phases II and III (n = 6 nurses)

#### eDischarge vs. paper discharge: utility and completeness

Fourteen patients met the criteria for inclusion in phase III. In one case, no consent for the participation could be obtained. In the other case, the electronic discharge summary could not be opened by the recipient due to a severe error (type 3). Thus, nine electronic and three paper discharges were rated with on the utility and completeness by the recipient on a sixpoint Likert scale (1 being very good and 6 very poor) in phase III.

Electronic discharges were rated better than paper discharges both with regard to utility and completeness (Figure 4). This judgement corresponded with the sum of entries of 18.4 ( $\pm 2.5$ ) for eDischarge summaries and 10.7 ( $\pm 6.7$ ) for paper summaries. Table 2 shows the average number of entries per category.



*Figure 4 – Ratings of utility and completeness by recipients* 

Category	eDischarge	Paper discharge
	n=9	n=3
sender	1	0.3
recipient	1	1
patient demographics	4.4	2.7
nursing problem/intervention	4.3	2.7
assessments	1.0	0
social/administrative information	4.3	2.0
living environment	1.6	0.7
comments	0.8	1.3

Table 2 - Average number of entries

The number of entries in eDischarge summaries exceeded the number in paper discharges in all categories with the only exception of "comments" and information about the "recipient". There were no assessments mentioned in the paper-based discharge form because the nurses decided not to include it in the summary.

There were a couple of problems associated with the handling of the electronic health card; in one case, the card was not available, and in the other case, the patient belonged to the group of privately insured persons who are not obliged by law to obtain an electronic health card. There was a general problem of getting the informed consent for sending the data electronically to the other institution. All the patients involved could not decide for themselves and thus the consent from a relative or the guardian had to be given. This procedure turned out to be complicated.

### Discussion

This study is the first to investigate the feasibility and usefulness of the German Health Telematics Infrastructure in a clinically meaningful scenario. In addition, it is the first to evaluate the TI using a German national HL7 based standard, the eNursing Summary CDA. It is noteworthy, that the scenario tested mainly embraced nursing discharge management, which is a scenario that has been severely neglected by German TI executives before [13] and that still is not covered properly by the law [14].

There was a rather long period that was dedicated to formative evaluation in phase Ia with many feedback loops and meetings between the developers and the evaluation team. This long time proved to be absolutely necessary for having a system that worked in an acceptably stable manner and was adjusted to the workflows both at the hospital and the nursing home. The evaluation would not have been possible if the system had been taken out of the technical laboratory into the field without modifications. This particularly held true because the application still was in a proof-of-concept state. A dedicated phase of intertwined less formal evaluation and technical adaptations therefore seems advisable for applications in early stages to be evaluated successfully later.

The results of the formal evaluations in the following phases show that the software application stabilised with regard to the number and the severity of problems from phase Ib to II reaching almost no problems at all. However, the number and severity rose again in phase III, which was probably caused by the new users operating the system. They had received a training session but still may have felt unsure about how to use the system correctly.

The most important finding with regard to the usability was the good and quite unanimous rating for the suitability for the task. Analysing the usability also showed a median of 3.25 for error tolerance, which is slightly above the value in the middle of the codomain and corresponds with the number of errors particularly in phase III. Also, the suitability for learning was rated only moderately with a high variability showing that there is still enough room for improvements.

What counts at the bottom line is what the receivers say. Their judgement about the utility and the completeness gives an account of what the system can achieve. In both cases, the eDischarge approach yielded better ratings than the paper discharge. This was not surprising. It was very likely caused by the different types of forms used for eDischarge and for discharge as usual, i.e., a two-page paper form designed by Klinikum Osnabrück and a one-page summary used by Küpper-Menke-Stift. Whereas the eNursing Summary allowed the user to insert many different types of information and as often as necessary, the paper form was restricted to the maximum of two pages and so was the amount of information.

All of these results have to be treated with caution due to the small number of discharges in phase III. More data will have to be collected.

There are several limitations due to the laboratory Health TI into which the eDischarge application was embedded. They include first and foremost the complicated workaround because of the missing pin codes on the current version of the electronic health card and the non-usage of health professional cards for nurses. Their implementation is planned but has not yet materialised.

Adoption of IT standards such as the HL7 CDA based eNursing Summary and the eMedical Summary are rather slow in Germany due to unclear regulations. This was the reason why we could not test the standard in a fully fledged manner, i.e., connecting systems from different vendors.

Problems with handling the eHC that had been anticipated generally in the context of the Health TI actually occurred in

our small sample and therefore seem to be quite likely. Card based access control is a safe and elegant way but can cause a considerable delay in the process once they are not available. In this test environment, we could overcome the missing eHC via the manual input of patient data and via the second card with the pin code that was produced for each patient in this test. In the real world scenario, a missing card would have prevented the health care professional from reading the data not only on the card but also in the EHR. Thus, patients controlling their own health data is a highly desirable goal but it can turn out to be a big barrier when the card and the patient have to be at the same place at the same time. It is therefore advisable to rethink the use of eHCs in a discharge scenario.

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Obtaining informed consent for elderly people who need assistance due to physical or mental disorders was not easy, but is feasible. Regulations for allowing health data to be transmitted electronically between health organisations in Germany, therefore, must be changed. A more generic solution seems appropriate, i.e., a citizen giving an informed consent that applies to many cases of when the data need to be transferred.

Meanwhile, the German government announced an eHealth act to give a fresh impetus to the Health TI and its applications [15]. The act addresses various clinically meaningful scenarios, in particular the electronic discharge summary, the medication plan and the emergency data set. This underpins the importance of this study, which provides useful insight into the mechanism of one of the high priority scenarios. However, it needs to be said that the eHealth act in its current version refers to nurses only as potential future users, despite its focus on the demographic change.

In summary, this study could demonstrate the technicalorganisational feasibility of Health TI supported discharges. The usability of the web-based eDischarge application definitely needs to be improved for daily routine usage and to be integrated into the real Health TI. The study also highlights the importance of electronic data and electronic data transmission in terms of completeness of the information and demonstrates the utility of eDischarges. It thus makes the case for eDischarges in general and in nursing particularly. eNursing summaries and their standardisation and implementation must become a high priority goal in eHealth, and this not only in Germany [16].

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