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Adapting the STARE-HI Guidelines for the Evaluation of Home Care Telehealth Applications: An Interpretive Approach

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ABSTRACT

An important issue in the advancement and deployment of home care telematic services is their assessment, especially with the goal of improving such services and making them easier to integrate into the social and clinical setting. The meaning that researchers apply to assistive environments and telehealth in general, (i.e. a medical innovation or a drug that can be prescribed to patients or an information system primarily serving information transmission and processing needs), is critical to the method they select for evaluation. In our opinion home telehealth has characteristics of an assistive environment and is best evaluated using an interpretive approach. In this paper we propose an adapted framework for evaluating home telehealth interventions and describe how the Statement on the Reporting of Evaluation Studies in Health Informatics (STARE-HI) guidelines can be adapted to home care telematics.

INTRODUCTION

Home care telehealth is one of the fastest growing healthcare delivery sectors in the developed world. Its importance is being reinforced as the healthcare delivery paradigm shifts from doctor and hospital-centred care towards a new model where citizens become responsible for the personalised management of their healthcare, delivered whenever possible in their own homes. An important issue in the advancement and deployment of home care telehealth services is its assessment. Information from properly conducted evaluations is vital to improving such services and making them easier to integrate into social and clinical settings. However, assessment is not straightforward as to a large extent it is dependent on how telehealth is perceived since this influences the evaluation method.

From a review of the literature we identified three main perceptions of home telehealth. The most dominant perception is that it is analogous to a treatment that can be prescribed to patients. Patients may adhere to this 'prescription' and use the

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technology in their homes with an expected positive benefit on their health condition. In this context the most suitable method to evaluate home telehealth is through randomised control trials (RCT) which effectively eliminate spurious causality and bias. Indeed most critical reviews in the literature exclude studies that do not use RCTs[1].

Others, however, believe that the analogy of home telehealth as a prescribed treatment has a number of flaws and consequently RCTs are not appropriate to evaluate home telehealth applications. Their reasoning is that in the case of a prescribed treatment such as a drug, patients have two options: to adhere to the prescription regime or not to comply with it. However, in the case of home telehealth, patients interact with the ICT system and in doing so they '*enact structures which shape their emerged and situated use of it*'[2]. Each patient will draw on their skills, power, knowledge, assumptions, and expectations about the technology when using it at home and therefore enact a distinctive 'technology-in-practice'. RCTs focus only on certain predefined outcomes and do not take into account any influence that could be attributed to interaction of patients with the ICT system. If this interaction significantly influence outcomes, then RCTs are not the most appropriate method to evaluate home telehealth. The view of these researchers is that home telehealth should be considered as fitting in with the structuration theory model[2] and is best evaluated using interpretive techniques.

Another common view is that telehealth should be considered as a technical/managerial innovation that will reduce the cost of healthcare delivery, and increase the productivity of clinicians and the satisfaction of patients (or customers). Based on this view evaluation is performed to assess cost effectiveness and productivity, and is usually done on a short term basis rather than assessing the long-term value of telemedicine[3].

Several researchers have taken the view that home telehealth should be considered as an information system that is embedded in a clinical/social context. All three components of telehealth – technology, people and context – should be included in the evaluation and the interplay between them should be examined in depth. Pragmatic approaches that consider the organisational context have been proposed and qualitative evaluation using semi-structured interviews have been carried out[4–6]. However, most of this work has not employed any theoretical framework to guide research and draw conclusions[7]. Researchers have generally not presented detailed descriptions of their method of gathering data and this leads to doubts about the credibility of their work and results.

The present paper has largely been stimulated by the need for evaluating a novel telehealth service for the monitoring of home peritoneal dialysis[8,9]. Based on our knowledge and understanding, we believe that home telehealth interventions more than any other health information system application, require a holistic, interpretive approach in their evaluation. We believe that this should encompass an overall assessment of the telehealth service with the emphasis on an information system

embedded in a clinical and a social context, rather than merely being considered as a technical innovation or a drug. This paper presents an adapted framework for evaluating home telehealth interventions based on an interpretive evaluation approach. It is based on the Statement on the Reporting of Evaluation Studies in Health Informatics (STARE-HI) guidelines[10,11] and shows how these can be adapted to home care telehealth using home peritoneal dialysis as an example.

INTERPRETATIVE EVALUATION AND THE STARE-HI GUIDELINES

In 2004 during a special workshop on health informatics evaluation, concern was raised that without proper guidelines for the design, planning, execution, and reporting of evaluation studies in Health Informatics, it would be difficult to build up a proper evidence base that can be used to make informed decisions regarding IT interventions in healthcare. As a consequence the Statement on the Reporting of Evaluation Studies in Health Informatics (STARE-HI) guidelines were developed and published[10,11]. The STARE-HI guidelines include a comprehensive list of principles relevant for properly describing Health Informatics evaluations and recommends a structured list of items that should be included in Health Informatics evaluation reports. The items cover all key aspects of a paper including: Introduction, Study context, Methods, Results and Discussion. These primary categories include more detailed items and the Methods section for example has the following seven subsections.

Methods

- Study design
- Theoretical background
- Participants
- Study flow
- Outcome measures or evaluation criteria
- Methods for data acquisition and measurement
- Methods for data analysis

These individual subsections will now be considered with respect to home telehealth.

Study Design

Statement: This describes the overall study design and the motivation for choosing it.

If we consider the interpretive approach on home telehealth evaluation this involves basing the study mainly on qualitative research. In qualitative research the aim is to get an in-depth understanding of stakeholders' actions and the reasons underlying these actions, i.e. why stakeholders perform certain actions. Small groups are subjected to in-depth investigation to determine the meanings that stakeholders attach to home telehealth systems and the interpretation of these meanings. The

research questions can be adapted to accommodate unexpected issues. One problem with qualitative research is that the people conducting the research are generally not considered to be neutral or objective; for example questions can be phrased in a way that creates bias. As a consequence caution needs to be exercised when interpreting the results of qualitative studies.

Theoretical Background of the Study

Statement: Where appropriate, state the theories – with sufficient references– on which the study is based, which guided the selection of the measurement instruments used and which form the basis for interpretation of the results (e.g. the user acceptance model that guided a quantitative survey or the organizational theories that guided a qualitative study).

Evaluation activity that is based on interpretive methods aims "*at producing an understanding on the context of the information system, and the process whereby the information system influences and is influenced by its context*"[12]. Two theoretical frameworks can be selected to guide the research:

(a) The content, context and process framework[13] serves to present the evaluation activity that was conducted. According to this framework, content describes what is to be evaluated, process refers on how the content is evaluated and context includes the social, political and economic environment.

(b) The 'structure, process and outcome' framework[14]. This evaluation framework particularly fits in with our view that the evaluation should be an attempt to understand the context, and the interplay between technology-people-context and as a "*continuous learning process rather than a search for judgment*"[15].

This evaluation framework views telehealth effects from the three different angles, i.e. Structure, Process and Outcome at three different levels – Systems, Human and Organisational (Table 1)[15].

At the level of systems functions the evaluation of structure involves the assessment of the technical details of the telemedicine application, the examination of the process focuses on the information processing and that of the outcome on whether the system as a technological innovation has relevant, applicable and reliable results. For the human perspective level, all stakeholders and participants in the telemedicine application are included and their acceptability determined. Actors may vary from owners, providers, and consumers of the system. In each case, the changes in their work conditions, or their behaviour should be assessed in the structure layer, their view on the changes in the mode of operation and healthcare experience is to be addressed in the process layer while systems effectiveness through the eyes of the different actors is judged in the outcome layer. The aim is to view the system applying different lenses according to the actors' role in it. Finally, at the organisational context level which in the case of telemedicine is the healthcare system in the layer of structure, attention is drawn to sustainability

Table 1. *The Structure, Process and Outcome Framework applied to Home Telehealth*

	Home telehealth functions	Human perspectives			Renal disease clinic context/ Patients' home context
		Physicians - Medical personnel	Patients	Administrators	
Structure	Are the hardware and software technical requirements met? Does the system work? Does it present technical problems?	What are the changes to physicians' and medical personnel's working conditions and practices? Do they need to obtain new skills, and abilities?	Are patients required to obtain new skills, and abilities?	Is the system cost-effective?	Could this home telehealth system be sustained and supported within the renal disease clinic context? Could it be accepted within the home context?
Process	Is telehealth service operation correct & valid? (collection & transfer of biometric data, communication between different units, presentation of telemetry data)	How are physicians' and medical personnel's mode of operation changed? Are these changes seen as desirable to them?	How are renal patients' behaviour altered? What are the changes in their everyday practices at home? What is the effect on their families?	Does it imply changes to administrator's working practices?	Could such a system be institutionalised?
Outcome	Are the functions of the telehealth application usable and reliable?	Was their effectiveness within the health-care system affected?	Does the use of the system result in changes in the perceived quality of care/life?	Does the system improve specific clinical parameters?	Could such a system improve the health status and quality of life for renal patients?

assessment of systems, while impact on the delivered quality of health provision and on the health status of the patients is examined in the process and outcome layers respectively.

In our work, we have adopted this model to evaluate home telehealth services[9]. In our adaptation, we have further analysed the framework in order to account for the special requirements of the home care environment and its actors. Emphasis is given to the human perspective, as in home telehealth applications the patient is in their own home without ready, direct access to healthcare personnel and/or technical support. Table 1 shows the basic issues that have to be addressed for each evaluation angle at every level. It should be noted that depending on the goal of the evaluation, not all of the cells in the proposed framework may be relevant. In our case the proposed framework was developed and implemented for the evaluation of PERKA a novel telehealth service that supports peritoneal dialysis at home[8]. The aim was to understand how various users involved in the service interact with it in the

particular setting of a pilot implementation. The process of evaluation was viewed as a learning process used as an input for the advancement of the service and to study the interaction of the service with its human and organisational environment.

Participants

Statement: Describe the methods of selection of participating users, patients, units, hospitals, etc., including – if applicable –inclusion and exclusion criteria for each type of participant in a study.

Interpretive evaluation examines and reports on all groups of stakeholders: patients, physicians, nursing staff, technicians, administrators, etc. The focus is placed on their interaction with one another and their interaction with the technology. A challenging activity in home telehealth service development is the involvement of patients in the design of the system and the evaluation of their interaction with the system. The level of users' participation during the development of an information system is seen as a determinant of users' commitment to the project and therefore to their perceived understanding of the usefulness of it and their satisfaction with it[16–18]. The view of patients being expressed by clinicians is not enough to get a clear specification of their requirements and trigger their active participation and engagement in the later stages of service deployment. In the case of home telehealth although patients are the key stakeholders they often cannot easily participate in the development process for two basic reasons. One is that their health condition usually doesn't allow them to participate in long meetings between system developers and users, and the other is that getting involved in the development process requires them to have significant knowledge and understanding of information technology terminology. Most patients do not have this and acquiring it may cause them confusion and stress. As a consequence involving patients in the life cycle model at the stages of requirements specification can be considered as posing an unrealistic demand.

To overcome this drawback that patients as users have, we have opted for the use of prototyping in order to evaluate patients' contribution during design[19]. Once a first service prototype reaches maturity, it is used in a controlled environment by a number of representative patients. The key issue here is the proper selection of the controlled environment. In our case, we have chosen the one-day or out-patient clinic, where the renal patient on peritoneal dialysis and their relatives often spend several hours, in order to re-adjust treatment and to obtain personal re-training on peritoneal dialysis. Introducing the service during such sessions within the hospital/clinic helps patients easily grasp the concept of the service, and do this without any technology related anxiety that may arise when they are alone at home. During such pilot uses/demonstration of service prototypes, patients have the opportunity to express requirements in terms of tangible features rather than abstract concepts. Additionally, their needs are captured while at the same time they acquire confidence on the usage in the prospective service.

Study Flow

Statement: Give sufficient details on date of beginning and end of the overall study and any study periods; give clear description and date of intervention.

Evaluation is considered as an activity during all stages from design and development (as described above) to implementation and deployment of the technology. It is seen by interpretive researchers as a life long learning process that can contribute to the understanding of any deficits early enough to make improvements.

Outcome Measures

Statement: Clearly state outcome measures or other evaluation variables of interest that were used in the study.

The key themes under research are presented in the adapted framework in Table 1 together with a detailed description.

Methods for Data Acquisition and Measurement

Statement: This section should provide sufficient detail such that others are able to duplicate the study or to use some of the methods for other studies.

Qualitative researchers may use different approaches in collecting data, such as the grounded theory practice, narratology, storytelling, classical ethnography, shadowing, etc. The techniques employed are observation of the different stakeholders groups, unstructured and semi-structured interviews, documentation review and the interaction of researchers with the technology used.

Interviews can be conducted using the following model. At least one meeting is arranged with patients preferably on the day that the intervention is introduced to them. Issues on this first meeting could be the identification of their technological competence, their introduction to the new system and to its usefulness. After a week of usage a telephone interview can be conducted on issues such as ease of use, user satisfaction, how the system fits in with the users' needs, changes in their practices and ways of communication with technicians, or clinicians, their expectations, etc. It is suggested that telephone interviews are arranged once a month. These may be substituted with home visits, depending on the patient's health condition and preferences. In a similar manner, medical personnel and administrators' interviews can be conducted, and questionnaires used to identify any problems.

An interpretive evaluation approach should encompass the following aspects:

- The researcher should be present on site to get a proper understanding of and grasp the context of stakeholders' acts and to properly interpret the meaning which they give to their interactions
- The researcher can be biased and thus any competing interests and/or personal predispositions should be taken into account and reported

Data collection involves the following issues that have to be accounted for and discussed:

- Semi-structured interviews conducted with key stakeholders

- Interviewees' views being expressed freely guided by the researchers' themes
- Researchers' themes being based on the literature review and on the adapted evaluation framework proposed

Methods for Data Analysis

Statements: This section describes the methods used for data analysis. The selection of those methods depends on data acquisition methods and study questions. When several methods are used, combine the description of data acquisition and data analysis for each method.

Analysis of empirical data can be done so as to reveal the relations between actual subjective events and the interpretation of reality as observed in the field. Some indicative steps to follow are identification of themes based on the research question, classification of the information gathered from the interviews based on these themes, identification of the importance and value of each theme, the relationship between them, and the reasons that causes them. Each event should be analysed and its connection with the research question should be examined in order to construct a logical chain of causes and effects.

DISCUSSION

Investigators of home telehealth applications generally agree that the evaluation process is much more complicated than for other telemedicine applications[4]. This is in a large part related to the perception of what kind of intervention home telehealth should be considered as. Some take the view that home telehealth is analogous to a drug or treatment being prescribed and should be evaluated through randomised controlled trials. Others including ourselves are of the opinion that home telehealth has a number of characteristics which makes it unsuitable to be evaluated through RCTs and that it is more appropriate to evaluate it using interpretive techniques.

With interpretive techniques it is important to obtain the views of all major stakeholders and this presents a number of problems for evaluating home telecare applications. Stakeholders are diverse coming from different parts of the healthcare system with different value systems, different perceptions of risk and different expectations of home telehealth applications. In particular costs and benefits expectations may be significantly different between the various groups of stakeholders.

Another problem is that home telehealth applications are rarely designed with the participation of the most important group of stakeholders, i.e. the patients, frequently because their medical condition does not allow them to readily participate. As a consequence whole systems may be developed without patients being asked about their needs and preferences. They may then be subsequently expected to use a system that does not fit in with their abilities or meet their specific needs.

Another important consideration is that in home telehealth interventions, the surrounding context varies as patients are alone in their homes and have to cope with new information technology. Analysing their behaviour, reactions and resistance to home telehealth should be a major part of any evaluation activity since patients are the most important stakeholders. More emphasis on patients' views during evaluation could provide valuable answers to a number of questions that are important to development, training and implementation as well as the outcome of home telehealth. Some examples of these are:

- How are patients selected to use the proposed home telehealth application for pilot/prototype evaluation within a controlled environment?
- Should home telehealth be considered as 'mandatory' or 'voluntary' usage? Can patients be offered the opportunity to choose?
- Should patients be included during the planning stage?
- What should we know about each prospective patient user before introducing them to home telehealth?
- In general, telehealth aims to broaden the provision of healthcare services irrespective of distance to the healthcare centre, thus removing distance and place barriers. However, is it possible that home telehealth may be in fact be creating a new distinction between patients by excluding from advanced care patients who are unable to use information technology?

Evaluation of pilot projects can produce valuable insights on some of the above issues. It can be the starting point of discussions on issues of approaching, training, involving patients and getting their commitment on home telehealth applications. Studying the influence of patients' cognition, personality, ideologies, knowledge, and social situation on home telehealth usage could offer answers to both development and implementation issues. Evaluation should aim to identify which factors are important in affecting patients' acceptance of home telehealth. Is it their technological ability, their confidence or anxiety about inability to use and control technology or is it their fear of not following their physicians' recommendation.

Home telehealth interventions more than any other health information systems application require a holistic, interpretive approach in their evaluation, emphasising the overall assessment of the telehealth service, and seen as an information system embedded in a clinical and a social context, rather than seen merely as a technical innovation or a drug. To conduct such evaluation a formal framework should be described and adopted. Such an example has been presented in this paper, where the general "structure-process-outcome" health informatics evaluation framework has been adapted for the special case of home telehealth. Special issues pertaining to evaluation of home telehealth interventions include patients' participation in the design phase as well as taking into account varying context and related ethical issues. This interpretive approach for telehealth evaluation also imposes certain requirements for the reporting of the study and its results. Following the STARE-HI

guidelines, one should especially take into account certain recommendations when reporting on the evaluation method.

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