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Requirements and Design for Smart Healthcare Applications

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Abstract

When developing a "smart healthcare" application that takes the participants beyond their experience of the conventional analogue of that application, a challenge is to gather the requirements for the application and to map those requirements onto a successful design. Some requirements will come from the conventional way of delivering the healthcare service. Some will come from the domains of the technologies that have been used to create the smart healthcare application. Some requirements, however, particularly for point-of-care applications, will emerge from the interplay of the actual clinical situation and the novelty of the smart healthcare application. This paper draws on a case study of the development and clinical trial of a point-of-care telehealth application at a tertiary level of healthcare to illustrate the process of requirements elucidation and the mapping of those requirements onto the design of the telehealth system. The telehealth application supports outpatient consultations for post-operative paediatric surgery patients. The consultations involve multiple participants, each with different requirements for the application. They engage in a complex dialogue supported by many shared sets of patient data. They bring differing points of view to the consultation and have differing criteria for a successful outcome.

The case study highlights that, at this complex level of healthcare, important requirements for the ongoing success of a smart healthcare application may be uncovered during early clinical trials. While these early clinical trials need to focus on clinical outcomes, they also need to not be bound by rigid trial protocols. Unforeseen events and behaviour may occur during the trials. These should be accommodated, in the interests of the patient, and properly recorded, so that they can contribute to a wider understanding of what is needed for the healthcare application to be successful.

Keywords: Telehealth Requirements; Telehealth Design; Human-Centred Evaluation; Early Clinical Trials

1 Introduction

The telehealth case study referred to in this paper is an example of applying information and communication technologies (ICT) to a complex healthcare situation, so that the participants in that healthcare situation are able to interact and communicate, discuss the patient's condition, make reasoned judgements based on shared access to patient data and reach an agreed conclusion on advancing the patient's healthcare trajectory [1] towards full recovery. The "smartness" of this type of healthcare application lies in the ability of the application to provide close-to-seamless communication and data links between the participants, so that the participants can focus on the healthcare situation at hand and have all the information that they need readily available. Important requirements for such a telehealth system will relate to the information and communication needs of the participants.

The telehealth system constructed for the case study was designed to support outpatient consultations for paediatric patients who were recovering from surgery. The project to build and conduct a trial of this system was initiated by surgeons from the Royal Children's Hospital (RCH), Melbourne, Australia. This tertiary-level hospital provides specialist children's health services for a catchment of more than six million people, covering a large part of south-eastern Australia. Recovery and rehabilitation from paediatric surgery can take years and many of the surgeons' patients and their families were regularly making long journeys to attend outpatient clinics at

the hospital, creating a significant burden of travel. The surgeons envisaged a telehealth solution for many of these consultations, perhaps linking RCH to a regional hospital near the patient's home.

Clinical requirements were gathered from the analogous face-to-face outpatient consultations that the surgeons conducted at RCH. The project team observed four clinics (half-day sets of consultations) at RCH and during an off-site visit by the surgeons to the Royal Hobart Hospital in Tasmania. These observations showed what happened during the consultations. They also showed the level of involvement of the patients and their families in the rehabilitation progress and their level of active participation in the consultations.

Technical and social requirements were drawn from the technology fields that would support the telehealth system, from the research fields of Human-Computer Interaction and Computer Supported Co-operative Work, and from prior work in telehealth. Design decisions were reached from these requirements and working prototypes were progressively constructed and evaluated with laboratory-based human factors studies.

The laboratory-based studies were limited in what they could achieve. Individual components could be tested for correct technical performance and the communication systems could be exercised at an abstract level to test the ways in which they supported dialogue between the two nodes of the telehealth system, interactive shared access to data, collaborative behaviour amongst the participants and joint decision making. Testing the complexity of actual consultations, however, required real patient cases conducted in the hospital context.

The following sections briefly describe the telehealth study. They set the context for a detailed account of the requirements gathering and design decisions during the construction of the telehealth system. A description of the clinical trial and its results highlights the requirements that had not emerged during the development process but became known only as a result of conducting the clinical trial. Conclusions are drawn about the nature of these early clinical trials and the way data gathered at these trials can be used.

Aspects of this telehealth study have been published separately: a clinical evaluation [2], a system for remote guidance [3], a human factors study [4], a case-study in a comparison of broadband telehealth [5], a study of training and process change for clinical staff [6] and as the author's doctoral thesis [7].

1.1 The Telehealth Case Study

The aim of this case study was to investigate whether the telehealth outpatient surgical consultations could be conducted in an acceptable manner, where the judgement of "acceptable" would come from multiple points of view. The clinical cases all involved long-term rehabilitation of the patients. From the surgeon's point of view, "acceptable" meant being able to move each patient one step further towards recovery by adequately assessing the patient's condition and by proposing a continuing plan of treatment or management.

From the patient's and family's point of view, their own situation was the one that mattered. For them, "acceptable" meant being able to express their concerns and have those concerns addressed, being confident that the surgeon had adequately examined their child and being confident in the proposed treatment or management plan for their child.

From the point of view of the clinician who would assist the patients, "acceptable" meant being able to manage the communications between the surgeons and the patients and families, and being able to conduct the hands-on examination of the patient on behalf of the surgeon.

The telehealth study required the construction of a telehealth system. Work on this construction (requirements, design, building and laboratory testing) commenced in 2006 and was completed in August 2007. An important part of this work involved mapping the requirements into design features then reviewing the implemented designs against the original requirements.

The study included a four-week clinical trial located within RCH, with two meeting rooms serving as the "surgeon's room" and the "patient's room". The trial had a weekly pattern of three clinics (general orthopaedics, limb reconstruction and maxillo-facial) with between 2-6 patients per clinic. The surgeons paired with more junior clinical staff to conduct these clinics, the surgeon located in the surgeon's room and the clinical partner located with the patient and family in the patient's room. With minor variations to allow for prior commitments outside the hospital, the surgeon-assistant pairs gained repeated experience of conducting their particular clinic over the four weeks, seeing a total of 44 patients.

This four-week trial was both a case study and a clinical trial. Robson used the term "case study" to mean "... a strategy for doing research which involves an empirical investigation of a particular contemporary phenomenon within its real life context using multiple sources of evidence" [8]. The

sources of evidence included clinical judgements on the part of the surgeons, personal judgements on the part of the patients and families, and situational judgements on the part of the assistants. They included observations of what the participants said and did during the consultations and exit interviews with the participants conducted immediately after the consultations. It was a clinical trial because the concepts of acceptability required the full clinical situation – actual patients, surgeons and assistants and the clinical information systems of the hospital – representing Robson's "real-life context".

1.2 The Telehealth System

The telehealth system was designed for whole-of-room use and comprised two rooms, the surgeon's room and the patient's room. The telehealth link between the two rooms consisted of:

- Three bi-directional video and audio links, one giving a wide-angle overview of each room and the other two providing close-up videoconference-like links between the surgeon and two different locations in the patient's room.
- A number of special-purpose video cameras which could be used to show objects of interest to participants in the other room, for example, to provide a close-up view of the patient.
- Four tablet displays with electronic pens (two per room) on which any available image or video stream could be shown, shared and annotated, for example, digital X-Ray images from the hospital's Picture Archiving and Capture System (PACS).

Figure 1 shows the surgeon's room. The surgeon sits inside a curved desk with easy access to the two video-conference-like systems and easy access to specialist display facilities: document camera, 3D image and video display and a secure computer for accessing the hospital's PACS system.

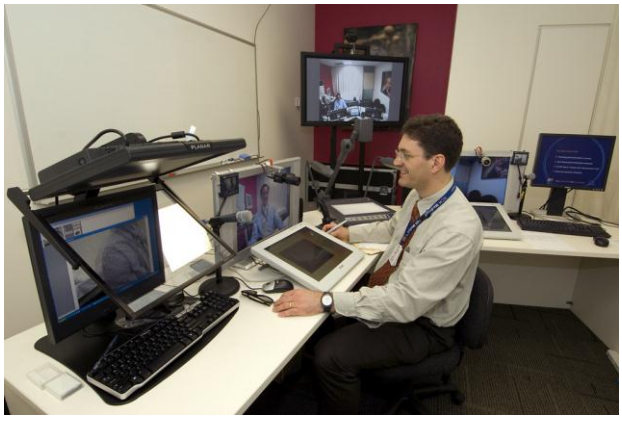

Figure 1: Surgeon's room. An overview of the patient's room can be seen in the plasma display by the far wall. (Photo courtesy Royal Children's Hospital)

Figure 2 shows the patient's room. The participants sit on the outside of a matching curved desk. The patient and family would be on the left side of this picture where they sit to talk to the surgeon and observe the consultation. The assistant would be on the right side of the picture, where he or she would examine the patient on behalf of the surgeon:

Figure 2: Patient's room showing three members of the research team. An overview of the surgeon's room can be seen in the plasma display by the wall.

1.3 The Clinical Trial

The clinical trial involved patients whose situation matched the intended purpose of the telehealth system, namely that they were attending a review consultation where no intervention was planned and where no major decisions about treatment were anticipated. The patients invited to take part in the trial had a medical history that indicated normal progress for their situation. Only patients with an appointment already scheduled for September 2007 were invited to take part, so that there was minimal disturbance to their consultation regime.

The trial protocol called for a telehealth phase to the consultation, followed immediately by a face-to-face phase. At the end of the consultation, the surgeon and assistant each completed a short questionnaire about the acceptability of the consultation. The patient and family completed an exit interview, which addressed several aspects of their response to the telehealth experience. At the end of the clinic the surgeon and assistant, each completed an exit interview. Both phases of the consultation were video-recorded.

The face-to-face phase ensured that there was an opportunity for the participants to address any issues that might not have been adequately supported by the telehealth system. The ordering of the phases placed emphasis on the telehealth phase. Given the nature of these consultations, with their discovery components (examination of the patient, review of

that day's radiology data) and the agreed outcome (the plan for managing the patient's condition), there would have been no logic in reversing the order of the phases. If the face-to-face phase had been completed first, then the telehealth phase would have been reduced to role-playing, and, in cases where there was bad news or confronting clinical observations, there could have been distress for the patients and families.

At this level of healthcare, each case is potentially quite different from the rest, even within the same group of consultations. Therefore, there was no fixed protocol for conducting the consultations. Instead, it was left to the surgeon to lead the consultation in whichever direction the surgeon saw as being in the best interests of the patient, in the same way that normal face-to-face consultations were conducted. This was in contrast to some approaches for clinical trials that require a rigid protocol for the clinicians to follow. Nelson and Palsbo, for example, discuss their perceived difficulties in conducting telehealth trials with a clinically trained person as the "presenter" (corresponding to our assistant) located with the patient. Their presenters tended to step outside the scope of the trial to do things that they felt were necessary for the wellbeing of the patient. As a result, Nelson and Palsbo felt that it might be better for their experiment not to have a clinically trained person with the patient. They observed that the presenters "needed to be socialized to the rationale for strong research design in order to encourage strict adherence to the protocol" [9].

2 Requirements and Design

This section presents the requirements that were gathered from interviews with the clinicians and from observation of face-to-face consultations at the hospital. It also presents requirements that were derived from the computer science field of telecollaboration, both from published literature and from the research team's prior experience.

2.1 Clinical Requirements

Clinical requirements for the telehealth system were gathered by interviewing the surgeons and by observing normal face-to-face outpatient consultations in the areas of surgical specialty that were to be covered in the planned clinical trial. They were:

- The consultations often occupied the whole of the consulting room especially when the surgeons were encouraging young patients to move about in order to demonstrate mobility of limbs and joints.
- Access to radiology data (such as X-Rays) was important for explaining the current state of the patient's condition, both to the patient and to the family. The team observed that this was often difficult to achieve in the normal consulting rooms. Wall-mounted flat-panel screens were difficult to point at or gesture over and the surgeon's own computer screen was generally not visible to the patient and parents.
- The level of personal communication between the surgeon and the patient and family was often intense. There were times where the surgeon needed to hear the patient's frustrations and difficulties and times when the surgeon needed to deliver unwelcomed news about future treatment plans.
- The surgeon often needed to annotate sketches of joints and limbs to illustrate their explanation of the patient's condition.
- Physical examination of the patient formed an important part of the consultation.
- There was a wide variety in the situations of the patients, even within the one block of supposedly similar cases.
- The patients and their families (usually their parents) were generally very familiar with the structure of these outpatient consultations, having already attended many of them during the course of the patient's treatment. The parents were very familiar with the progress of their own child, having been responsible for managing the steady recovery from surgery during the preceding months.
- The patients, especially those from outside Melbourne, were often accompanied by parents, siblings and other relatives.

These clinical requirements led to the following design features:

- The patient's room was chosen large enough that it could be divided into two regions. One region held enough seating for the accompanying family so that they could see and hear what was happening but did not obstruct activities of the assistant or the patient. The other region held an examination couch, a chair for seated patients, an overhead steerable camera and other special-purpose examination cameras.
- The desks in both rooms were curved to emphasise the spatial partition in the patient's room and to facilitate the surgeon's view into both partitions.
- Close-up video systems, similar to video-conferencing systems, with high-quality video streams were installed. One supported direct dis-

cussion between the surgeon and patient/family. The other gave the surgeon a view of the examination area and supported dialogue between surgeon and assistant during the examination of the patient.

- Four tablet displays, with electronic pens, were installed: one for the family, one for the assistant (on an adjustable arm) and two for the surgeon (one at each of the close-up video systems). These displays were configured so that they all displayed the same data, thereby making sure that all parties could see the same thing simultaneously. The electronic pens were configured to support freehand pointing and drawing gestures over the displayed image or video data.

2.2 Requirements Drawn from the Telecollaborative Technology Field

In the field of computer science, there is a long history of work connecting spaces in different physical locations by networks of video, audio and data. This particular configuration is known as a media space, a term coined in 1988 by Robert Stultz (cited by Mackay [10]). Several groups of researchers reported on long-term use of a media space (connecting office spaces of colleagues located in different buildings or different cities) [11-13]. Researchers conducted experiments in which participants were placed in a media space (typically two rooms connected by video, audio and control links) and asked to complete sets of experimental tasks that required involvement of participants in both rooms for their completion [14-17]. Other researchers discussed public availability of artefacts and actions within shared spaces [18], the distinction between "place" and "space" (the physical setup and spatial metaphors versus cultural understandings about behavior and action) [19] and issues of privacy in a media space [20-21]. In reporting on these facets of media space research, these papers raised issues that their authors expected to be of concern for future developers of telecollaborative applications.

Researchers in the emerging field of broadband telehealth have published their experiences in using high-quality video and audio communications technologies in the health sector. There is a decade of experience in the use of the Digital Video Transport System (DVTS), an open-source software system for encoding/decoding video signals at near-broadcast quality. Shimizu, in a review paper, reported on 100 examples of demonstration use of this technology in healthcare [22], highlighting the value that such high-quality video and audio gives to telehealth applications.

Requirements that emerged from the literature and from this team's experience of using media space technology include:

- The importance of high-quality low-latency video to support dialogue between the two rooms
- The need for multiple video cameras to cover the activities that span the patient's room
- The need for the surgeon to have a coherent mental model of the multiple video streams coming from the patient's room (Luff and co-authors call this problem "fractured ecologies")

These led to the following design decisions:

- A high-quality video encoder/decoder system was used. Initially the project had access to gigabit/second research bandwidth and used DVTS but for the clinical trial this was replaced by a security video system that used about five megabits/second/video-stream to meet bandwidth limitations of the hospital's intranet.
- Video coverage of the remote room was delivered by three video streams. Two formed the close-up video-conferencing systems and the third (displayed on a raised flat-panel display) used a wide-angle camera to span the whole room (see Figures 1 and 2). The video cameras were fixed in position, direction and field-of-view so that they formed stable reference points for people using the system.
- The curved desk arrangement supported the mental model that linked the three video displays with the actual remote room. When the surgeons panned from left to right across the three displays, they saw a sequence of left-hand region, room overview and right-hand region of the patient's room. Similarly, anyone in the patient's room could see whether the surgeon was looking at them because they could see either the surgeon's face or the side of the surgeon's head (as can be seen in Figure 2). This unusual arrangement of furniture was proposed by Matthew Hutchins and developed by him and Jocelyn Smith, two of the author's former colleagues.
- In each room the furniture was oriented so that the room overview camera pointed at the door leading into the room. This meant that all participants were aware of anyone entering or leaving the room.
- Small fold-back display screens were attached to the display screens for the close-up video systems. This let the participants know when they were on-camera so that they could properly position themselves to be seen by the remote participants.

2.3 Testing the Mapping of Requirements into Design

The clinical and technology requirements led to design decisions that could be tested in an analytic manner [23], walking through the consultation scenarios. This was done during the development of the system, once at a meeting of surgeons at the hospital and three times in the laboratory with clinical specialists leading the walkthrough [7]. The requirements relating to the effectiveness of the communications and shared data links between the two rooms of the telehealth system, however, needed to be tested in a more active way so two human factors experiments were conducted in the laboratory [4, 7, 24].

It was not appropriate to recruit actual patients for these human factors experiments because the experiments dealt with components of the telehealth system rather than with the system as a whole. It would have been impractical to explain the relevance of the experiments to patients and their families whose focus was the immediate wellbeing of their children. In addition, it would have been inappropriate to disrupt the lives of families already stressed by their children's healthcare situation. Equally, it was not appropriate to recruit clinicians to take part in these experiments. At this level of healthcare, clinicians have a heavy workload and it would not have been a good use of their time to have them take part in component experiments. Instead, the human factors experiments used abstractions of tasks that had been observed in normal consultations and generic adult participants. The results of the experiments concerned the way the system components supported awareness between the two rooms of the telehealth system and collaborative behaviour of the participants, rather than completion of the experimental tasks.

3 Observations from the Clinical Trial

3.1 Training and Process Change

The telehealth system was installed at RCH in the week prior to the trial and training sessions were held for the clinicians using the installed system. During these sessions it was found that the surgeons and their assistants quickly grasped the functionality of the system but spent considerable time establishing how they would need to adapt their normal clinical practice to the telehealth mode of seeing their patients [6]. They focused on how the surgeon would direct the assistant to examine the patient and how the assistant would present the examination and its findings to the surgeon. In some cases, specific adjustments to the telehealth system were required, including provision of an additional special-purpose video camera to enable a low-level horizontal view of small children walking and standing.

It was observed that even though different surgeons worked on similar cases, they often had different preferences and requirements for the way information was presented to them. For example, when the assistant tested for angles of movement of the patients' joints some surgeons were content to be told the assistant's estimates of the angles reached. Other surgeons preferred a square-on video view of the position of the joint at its extremity of movement and a software protractor to measure the angle themselves.

3.2 Telehealth Outpatient Consultations

Even though the surgeons and assistants were shown how to use the telehealth system prior to the trial, as the trial progressed they all commented on the progress they were making in learning to use the system in a fluent and natural manner. The surgeons became more comfortable talking to the patients, directing the assistants and interpreting the assistants' findings about the patient. They became more comfortable with the concept of not being able to put their own hands directly on the patient. For their part, the assistants reported increasing skill in examining the patient so that the surgeon could see and follow their examination, using the various video cameras of the telehealth system. Self-reporting on this learning phase continued into the third week of the trial.

As the telehealth system was intended for use between RCH and a regional hospital, it was thought that the person taking the role of assistant at the regional hospital would be a generally trained clinician. Because the staff taking the role of assistant during the trial had special skills in the area of the consultations, the surgeons could direct the examination of the patient and request specific results using high-level clinical language. They concluded that the original concept, of using a generally-trained clinician as assistant, would not have succeeded because it would have been too laborious to micro-direct the examination of the patient and because they would not have known how to correctly interpret the assistant's findings.

Although the surgeons and their assistants knew

each other (they worked in the same department in the hospital), their previous working relationships had involved supervision and review. For example, the surgical registrars who took the role of assistants might, in their normal clinical work, see outpatients by themselves and then have the specialists come in to review their findings about the patient. Here, the surgeons and assistants had to work together to conduct the consultation, so they needed to establish a new form of their working relationship.

This trial was conducted in a near-to-realistic situation and, although the researchers and clinicians saw it as a trial of a new way of delivering outpatient consultations, the patients and their families saw it as a continuing part of their overall treatment. They did not really distinguish between the telehealth phase and the subsequent face-to-face phase of the consultation and, when asked specific questions about the acceptability of their experience, sometimes answered with their overall hospital experience in mind. This led to some apparent contradictions in answers to the exit interview questions. Of the 43 patients and families who completed the exit interviews, 35 replied "Yes" to the hypothetical question as to whether they would have used this system had it been available closer to their home rather than travelling to the hospital. However, 13 patients and families reported that the subsequent face-to-face phase of their consultation was indeed necessary.

This contradiction is resolved by referring to the interview responses where the patients and families discussed their points of view in detail. It is clear that they answered the second question with a wider context than that of the trial in mind. Some had travelled long distances for this consultation and it would have been unthinkable on this occasion not to have seen the surgeon in person. Others were referring to their presence in the hospital and to appointments with other specialists scheduled on the same day for their convenience. Still others had a personal preference for the surgeon to make actual contact with their child.

For clinical situations of this complexity, there are likely to be aspects of the telehealth equivalent that are not in the scope of early trials. This trial was conducted entirely within RCH, so there were no provisions for simulating the logistics of a remote hospital such as separate scheduling of clinical staff, synchronizing of medical records or transfer of X-Ray images. The clinicians took additional steps on behalf of the patient in an ad hoc manner. For example, in one case the assistant happened to be a physiotherapist who took advantage of the face-to-face phase to refresh the patient's knowledge of his stretching exercises and to reinforce the importance of doing these exercises regularly.

3.3 Requirements that Emerged from the Clinical Trial

Two different forms of requirement emerged during the training sessions that were conducted for the clinicians at the hospital prior to the trial:

- Fine-tuning of the telehealth system in situ
- Awareness on the part of the clinicians about how they would need to modify their clinical practice in order to be able to conduct their outpatient consultations in a telehealth mode

Both of these requirements related to the clinicians' experience of the system in the context of the hospital. Intended pairs of clinicians (surgeon and assistant) needed to be present together to establish how they would either adapt the telehealth system to their practice or adapt their practice to the needs of the telehealth consultations.

The requirements that emerged during the clinical trial relate to intentions for longer term trials or deployment of this style of telehealth:

- Provision for a learning phase when a new surgeon or assistant is assigned to use the telehealth system. It was not sufficient for the surgeons to be trained in the use of the system; they needed time to become fluent in communicating with the patient, family and other clinicians and in using the interactive shared data facilities. In the context of a formal evaluation, the data gathered during this learning phase should be quarantined from the evaluation process.
- Using generally trained clinicians in an actual remote hospital would not be acceptable because they would lack specific skills for examining patients for these surgical specialties and it would be impractical and unreliable for the surgeon to micro-direct the patient examinations. An appropriate solution would be to identify candidate assistants at each remote hospital and to train them in the particular tasks required.
- Even with an appropriately trained assistant at the remote hospital, for the efficient conduct of these consultations it would be necessary that the assistant and the corresponding surgeon develop an appropriate working relationship. The assistant would then be able to properly interpret the surgeon's directions and the surgeon would have confidence in interpreting the assistant's examination outcomes.

- When gathering exit interview data, the researchers need to have the patients' and families' whole-of-consultation point of view in mind, including awareness of the interactions that the patients might have had with clinical and hospital staff on the day of their consultation. The particular consultation under study, at this level of healthcare, is often linked to other consultations scheduled on the same day; for example, the maxillo-facial patients may also see the orthodontist, the speech therapist and the radiography staff. The patients may not necessarily respond to the exit interview with just the telehealth consultation in mind.

4 Discussion

Novel healthcare applications, such as the telehealth case study used in this paper, will have requirements for design, requirements for evaluation and requirements for long-term use. Requirements can be sourced from knowledge of the conventional method of handling the healthcare situation and from the field of expertise in the technologies used to create the novel applications. How well these requirements map into design features may be tested by analytic methods or by human factors experiments in the laboratory, as illustrated in the telehealth case study.

For complex, interactive point-of-care applications, however, it may not be possible to test the overall system without the context of an actual clinical trial, as the telehealth case study also illustrated. In this case study the complexity arose both from the advanced level of healthcare and from the involvement of multiple participants, each with their own point of view and criteria for success. It would not have been sufficient for the surgeons alone to have role-played a consultation and then pass judgement on the telehealth system, because it was regarded as important to assess the judgements of all the participants, especially the patients and their families.

In the telehealth case study there were requirements that did not emerge until the clinical trial. Setting the system up in the hospital gave the surgeons and assistants their first operational understanding of the system. Their response, which was to explore adapting their clinical practice to the system and adapting the system to their clinical practice, required the presence and connectedness of the system to the wider hospital context. During the trial, the surgeons and assistants became aware of issues that would form the requirements for any long-term deployment of this style of telehealth. These issues included the learning curve for the surgeons, the importance of training any candidates for the role of remote assistant and the need to establish a particular form of professional working relationship between the surgeon-assistant pairs prior to conducting consultations with the system.

The exploratory nature of the clinical trial of the telehealth system led to a trial protocol that was driven by the surgeon's and assistant's perceptions of the needs of the patient and family. This matched the nature of the clinical process at this tertiary level of healthcare, where there is a variation in the needs of patients who are in apparently similar situations. Events that occurred which might have disrupted a more rigid trial protocol were flagged as out-of-scope and recorded for later study.

The patients and families approached the consultations in a manner that was consistent with the realistic nature of the clinical trial, which was itself designed to fit with their normal experience of the hospital during their consultations. Perhaps as a result, they responded to the exit interview questions with their whole-of-hospital experience in mind, rather than having a focus on the smaller events of the outpatient consultation. The exit questionnaire contained items of fact, items of opinion and hypothetical questions; in many cases, their view of the wider hospital context led patients and families to give apparently contradictory answers.

5 Conclusion

A point-of-care telehealth application for a complex area of healthcare has been used to highlight sources of requirements for smart healthcare applications. Requirements may come from analysis and observation of the conventional method for delivering the particular form of healthcare and they may come from study of the technologies used to create the smart healthcare application. Analytic evaluation and laboratory studies may be used to test the mapping from these requirements into the design features of the application. Where the application involves complex, real-time interaction between clinicians, patients and data, however, there may be requirements that emerge only during actual clinical trials, where the full context of the clinical situation is present. Requirements that may emerge during early clinical trials can relate to the use of the system and to the ways in which the system might be evaluated.

Implications for researchers developing future smart healthcare applications are twofold. Firstly, the researchers should remain open to the possibility that early clinical trials will uncover requirements that

relate both to the dynamics of the application and to the structure of the trials. Secondly, they should maintain a flexible evaluation approach so that both quantitative and qualitative data can be collected and, in particular, they should be alert to the possibility that out-of-scope or out-of-protocol events may indicate the need for further refinement of both the application and the evaluation.

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