
APPLYING AN INTEGRATED APPROACH TO THE DESIGN, IMPLEMENTATION AND EVALUATION OF A TELEMEDICINE SYSTEM

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Abstract

Telemedicine evaluations are usually decoupled from other aspects of design and implementation, and therefore not considered until late in the project cycle. In addition to this, evaluations are often performed by outside bodies without an interest in the outcome, a practice intended to strengthen the independence and objectivity of the findings. In this paper, we describe an alternative approach in which the design, implementation and evaluation of a telemedicine system were considered to be complementary stages of the project occurring in parallel and where members of the project team were involved in all three. We demonstrate the advantages of this approach through the ECHONET project - a trial of an experimental system implemented in the context of Intensive Care across two hospitals in Tasmania, Australia.

This paper describes benefits associated with this integrated approach. Innovative aspects of the approach include the number of pre-implementation activities such as stakeholder interviews, design workshops and a baseline study, which enabled the project to adapt to the complex needs of its health context.

The integration of the design, implementation and evaluation activities enabled the project to adapt to changing needs as the project evolved, and ensured that it was evaluated against appropriate criteria.

Keywords: telehealth; telemedicine; evaluation; evaluation model; participatory design; action research; intensive care.

Introduction

The motivation for telemedicine evaluation is often to establish a case for continuation, expansion or further adoption of the elements of a particular system. This case can exist across a number of disparate domains including clinical, economic or social and organizational, which can require different methods for determining the overall benefits.

One characteristic of telemedicine evaluations is that they are often decoupled from other aspects of design and implementation, and therefore not considered until late in the project cycle. Indeed, evaluation is often performed by outside bodies without an interest in the outcome, a practice intended to strengthen the independence and objectivity of the findings.

In this paper, we describe an alternative approach in which the design, implementation and evaluation, were considered to be complementary stages of the project occurring in parallel, and where members of the project team were involved in all three. We demonstrate the advantages of this approach in a trial of an experimental system, ECHONET (EchoCardiographic Healthcare Online Networking Expertise in Tasmania) implemented in the context of Intensive Care across two hospitals in Tasmania, Australia. The process model that was adopted emerged from a combination of earlier studies in complex broad band telehealth undertaken by our research group,^{1,2} and from the information systems literature.

To illustrate our process model this paper is divided into five sections. The rest of Section 1 explains some of the challenges associated with design, implementation and evaluation of telemedicine

systems; Section 2 describes ECHONET, the telemedicine case study on which this research is based; Section 3 outlines the process model used in the ECHONET project; Section 4 describes some of the outcomes in the ECHONET project as a result of the approach taken and finally Section 5 discusses the implications of our research.

The objective of this study was to acquire an understanding of the role of a telecommunications operator in the value chain, the partnerships that need to be set up, the types of technological and organizational solutions to be rolled out and the models that would achieve lasting operational viability.

Design challenges

The evaluation literature differentiates between formative and summative evaluation. Formative evaluation provides information and assistance to those making change, while summative evaluation supports decision makers in deciding on the future of that change.³ While formative evaluation is sometimes considered in projects like ECHONET, the technology design is usually a separate process. However, trends in telemedicine evolution are creating strong pressures on the design of the technology, especially as experienced by the user. Two strong trends in healthcare are an evolution into more patient-centric models of health care and the increasing use of telemedicine in critical care and other complex point-of-care applications.⁴ Patient-centred models of health care are more likely to involve the patient as a participant in telemedicine enabled interactions, especially when healthcare is delivered directly into the home.⁵ This will require a stronger emphasis on usability than systems used exclusively by professionals.

Telemedicine is expanding into complex point-of-care applications such as critical care, facilitated by the availability of advanced networks. Design challenges include ease of use to facilitate a high degree of patient focus, and strong activity focus in order to support work practices and team interactions in a complex environment.^{1,2} Applications in emergency⁶ and intensive care units (ICU) are becoming relatively common.⁷ Such applications can be facilitated through

iterative design processes,¹ although opportunities to modify commercially-available equipment are usually not available. Further design challenges include the need to combine the contradictory constraints of multi-purpose technology (to avoid multiple pieces of equipment for multiple purposes) with activity-focussed design.

The separation of the design, implementation and evaluation activities has become the norm both for practical purposes (the use of commercial equipment which has been developed for generic purposes) and for objectivity in the evaluation process. The benefits of approaching these activities as complementary to each other have not so yet properly explored.

Implementation challenges

With few exceptions, the implementation of hospital-based telemedicine systems does not pay adequate attention to understanding the organizational context and environment in which the system will be used.^{8,9} Decisions to implement telemedicine systems are typically made by hospital administrators, without adequate consideration and involvement of the clinicians who will use it.¹⁰ Whether the technology is off the shelf technology or designed specifically for purpose, there is a need to understand the context and environment in which a new system will be used in order to enable appropriate implementation strategies to be applied.

Evaluation challenges

Evaluation based on theoretical models is not widely practised. Although integrated evaluation models have been suggested since 1999,¹¹ there has been little convergence on agreed models in the intervening years. In a 2007 survey of 1,615 papers on telemedicine studies, only 5% of these were based on a theory or paradigmatic approach, and 11% provided explicit hypotheses or research questions.¹² A 2009 study of 526 telemedicine studies and 104 reviews found a lack of consistency of evaluation criteria across a wide range of clinical applications, with cost-benefit being rarely considered.¹³ A 2012 “review of reviews” of telemedicine study methodologies called for larger controlled trials to test well-formed hypotheses, but also for “Assessments that formatively engage with stakeholders including patients, in natural

settings".¹⁴ Notable among recent proposed systematic evaluation models is the MAST (Model for Assessment of Telemedicine Applications) developed within the European Union.¹⁵ This identifies seven domains (health problem, safety, patient perspective, economic aspects, organizational, socio-cultural, and ethical and legal) and three steps in an evaluation (preceding considerations, multidisciplinary assessment, and assessment of transferability).

As telemedicine moves from an era of small pilots to system-wide implementations, and into more complex applications, the need for a better and more universal framework for evaluation is becoming a necessity.

Case Study: The ECHONET Project

Prior to the ECHONET project, our group was involved in design, implementation and evaluation of a number of broadband telemedicine pilots.² This experience pointed to the need for a more integrated approach, with a stronger emphasis on the pre-implementation phases. More complex systems (such as critical care telemedicine) require more complex metrics for their evaluation, and it might not be clear even at the implementation phase what those metrics are.

The ECHONET project was the last of the sequence of systems, and the only one in which all aspects of our approach could be applied. It served as both a test-bed for refining the model and a case study that supports the benefits of an integrated approach. To set the context of our research, the ECHONET project will be described in the next section.

Background

Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO) is a large, multidisciplinary research organisation with a unique range of skills. In the context of telemedicine, a single team can participate in all aspects of a telemedicine project, including specification, technical design, engineering, clinical implementation and post-trial evaluation.

The principal aim of the ECHONET system was to support the Intensive Care Unit of the North West Regional Hospital (NWRH) located in Burnie, North Western Tasmania. This ICU had basic intensivist

coverage, but relies on other hospitals (notably Royal Hobart Hospital) for support in other specialist services, particularly bedside echocardiography.

In this project, three mobile multi-channel broadband telemedicine units connect, over a broadband network, the ICU of NWRH with separate nodes in two departments (Cardiology and ICU) of Royal Hobart Hospital (RHH), a major tertiary referral hospital. The aim was not to provide a fully outsourced intensivist service, the model for many recent eICU implementations,¹⁶ but to provide support for the small, isolated specialist staff at NWRH.

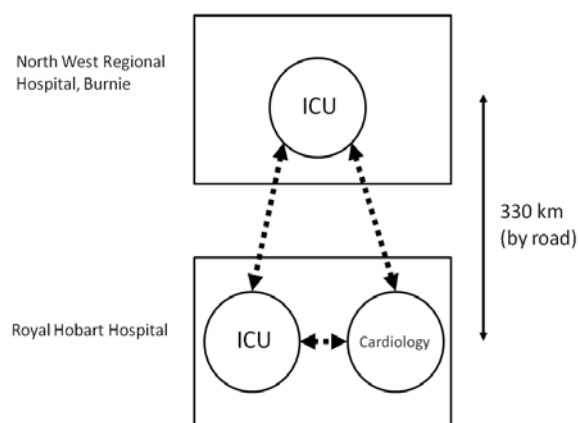


Figure 1. The ECHONET system.

The project originated from a community focus group, (that included several clinicians), set up in North Western Tasmania to advise a team of technology developers how applications on an advanced network might benefit their regional community. A compelling case emerged for developing technology which would permit a cardiologist based in Hobart to participate in an echocardiographic examination of a patient located in the Intensive Care Unit of North West Regional Hospital, Burnie, approximately 4 hours drive from Hobart (figure 1). The expectation was that the success criteria of the exercise would be based around better targeting of transfers of patients from NWRH to Hobart, with subsequent reduction in cost associated with transferring ICU patients. The ECHONET project

provided an opportunity to refine and test an integrated approach to evaluation.

Applying an Integrated Approach

A combination of an action research philosophy and learnings from the team's previous experience with telemedicine systems influenced the approach taken by the ECHONET project team. As such, it was agreed from the beginning that an integrated design, implementation and evaluation approach would be adopted. Underpinning the practice of action research is an intention of the researcher to effect positive change on the situation within which the research is taking place while simultaneously conducting research, and a collaborative approach between the researcher and subject in reaching this objective and developing understanding.¹⁷ In keeping with this, the same small team took responsibility for the design, pre-trial studies, training, trial and evaluation. A detailed explanation of the relationship between the action research philosophy and the ECHONET project is beyond the scope of this paper but is described in some detail elsewhere.¹⁸

Activities were carried out in the ECHONET project that informed the design of the system, the implementation strategy adopted and the criteria assessed in the evaluation. These activities consisted of stakeholder interviews, a baseline study, several design workshops and activities relating directly to the clinical trial of ECHONET including interviews, questionnaires and log books.

Stakeholder interviews

Traditional telemedicine evaluations set out to verify a hypothesis, usually formulated as the equivalence of telemedicine and face-to-face consultations, or a measurable improvement in patient outcomes after the introduction of a telemedicine service. By doing this, they miss out on potentially capturing evidence of other value that a telemedicine system may add to a clinical environment. They do not recognise the complexity of determining a project's success as there are many criteria that may be used to assess success. Stakeholder interviews are a method of capturing the agendas of all those who may influence the success or failure of the system and the many different ways that success can be defined.

In the ECHONET project, the stakeholder interviews helped to establish the success criteria by which the system was assessed in the evaluation phase. It also served to inform the design workshops by establishing potential applications which lay outside the design brief.

Design workshops and formative assessment

The scope of the design workshops is strongly dependent on the extent to which the technical design can be modified for the application domain. In our case study (see below), the research team designed and constructed the hardware and designed the graphical user interface (GUI). Previous studies have established the vital importance of user-centred design in eHealth systems.^{1,19} Several design workshops were carried out with mock-ups of the GUI and as early prototypes became available. Data gathering took the form of interviews with clinicians, observations and questionnaires.

We acknowledge that most implementations will have less flexibility to design telemedicine hardware. However, the wide range of systems now available, increasing ability to tailor such systems for specific applications and the need to work with users for process change management, mandate that design workshops be conducted, even with reduced influence on the technology.

Clinical trial design

The three preceding phases inform both the system design and the criteria by which a system may be assessed in the clinical trial and broader evaluation. Protocols for conducting clinical trials are well established,²⁰ and the focus of this work is on the pre-implementation phases, rather than the clinical trial itself. Ideally, such trials are conducted on a Randomised Control Trial (RCT) basis which is preferably a double-blind study. We maintain that such studies may not elicit the true value of a telemedicine system. In keeping with the blurring of distinction between experimenters and subjects, our framework includes the possibility of following up the stakeholder interviews with a set of mid-trial interviews to monitor progress and possibly modify the system or trial conditions if this optimizes the system's demonstrated efficacy.

Demonstrating the integrated nature of design, implementation and evaluation

While the stakeholder interviews, baseline study, design workshops and clinical trial were each targeted at addressing the design, implementation or evaluation of ECHONET, each of the activities carried out influenced all three. How each of the activities contributed to the design, implementation and eval-

uation of ECHONET is captured in table 1.

A significant activity missing from table 1 and the project itself was a comprehensive needs assessment. The unique, community and politically driven origin of the project did not support us conducting a formal needs assessment for reasons that are beyond the scope of this paper. Although this was partially overcome by the processes that followed, it should be noted up front

Table 1. The contribution of activities to design, implementation and evaluation.

Activity	Design	Implementation	Evaluation
Stakeholder Interviews	Design suggestions for application discussed	Key factors to consider in implementation discussed Reservations influencing project viability and implementation process raised	Success criteria identified and used to shape evaluation
Design Workshop 1	Design tested in NWRH Mersey clinical environment Necessary design modifications identified	Further people to involve in implementation process identified	Factors to consider in evaluation raised – e.g. data available
Baseline Study	Further design suggestions discussed	Scope of the project expanded to accommodate baseline findings Baseline used to form clinical protocols	Baseline of current work practice established
Design Workshop 2	Design tested in RHH clinical environment Position of network plugs determined	Key RHH staff introduced to ECHONET system and involved in project	Scenario's of use discussed and capture of these uses in evaluation discussed
Design Workshop 3	Interface requirements determined	Clinicians actively engaged in design process to facilitate ownership and uptake of system Clinical protocols further refined	Clinician engagement facilitating potential participation in future evaluation activities
Staff Training	Design recommendations made by staff	Clinical and technical staff trained to use ECHONET system	Evaluation of training sessions conducted to establish adequacy of training
Clinical Trial	Design recommendations made by staff	ECHONET system used in hospital environment	Outcome evaluation performed

that where possible, a needs assessment should be incorporated into an integrated approach.

Project Outcomes

The ECHONET project took place over a period of two and a half years of which there was a 9 month clinical trial. The system continued to remain in use

Therefore it was imperative that the design be flexible enough to be easily appropriated for both anticipated and unanticipated uses.

A multi-purpose system and node design was adopted, with three nodes located in the NWRH ICU, the RHH ICU and the Cardiology Department at RHH. Two or three-way connections were possible with the system.

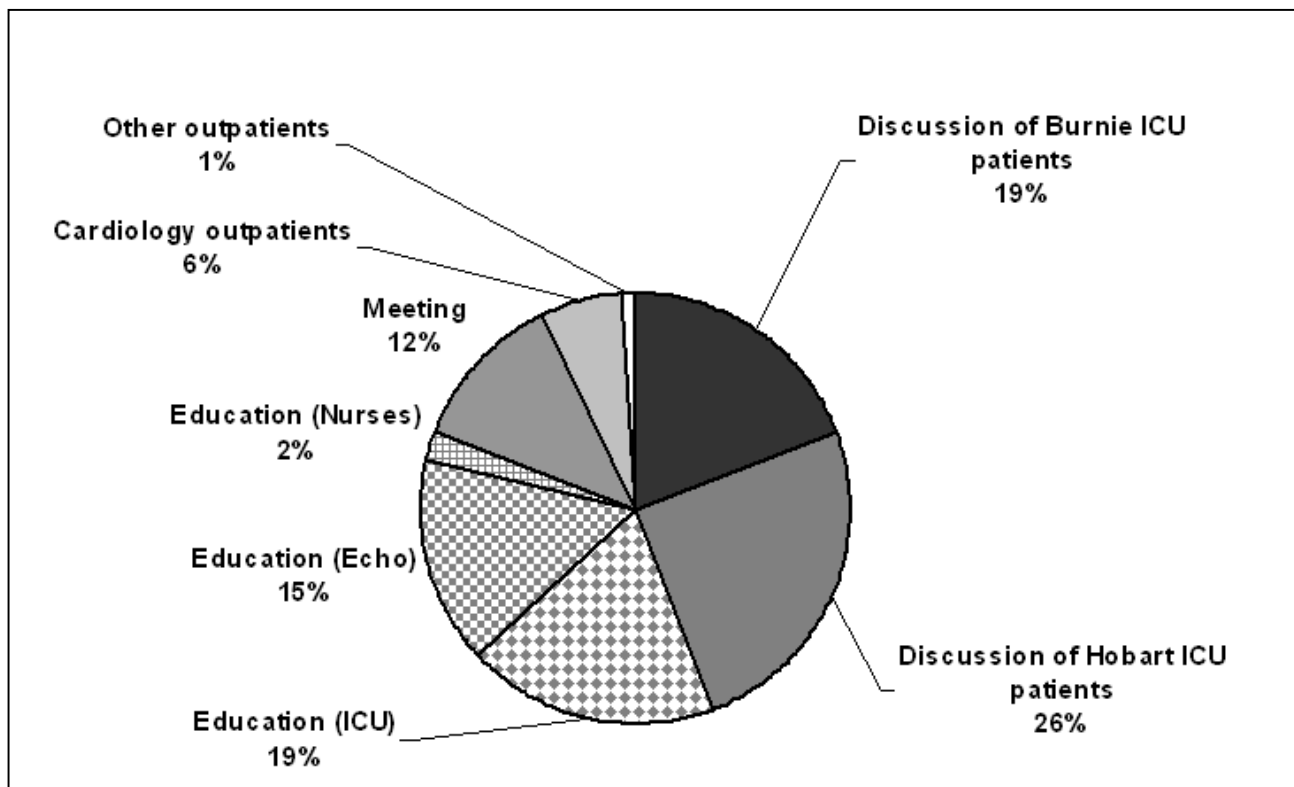


Figure 2. Distribution of ECHONET activities as a percentage of all activities.

following the clinical trial. The range of activations recorded during the trial is shown in figure 2.

How the integrated approach contributed to the technology design, implementation strategy, evaluation design and project outcomes is described under their respective headings below.

Technology design

A combination of the stakeholder interviews and design workshops supported the likelihood of the system being used well outside its design brief.

Each node consisted of a trolley equipped with two monitors and a locally-controlled camera. The camera could be configured for videoconferencing, documenting or viewing ICU bed instruments. A second video channel provided simultaneous viewing of an external input, which could be an instrument (such as ultrasound scanner) or computer (for teaching presentations).

The system was designed for possibly unscheduled use by inexperienced users. It was therefore decided to use the simplest GUI consistent with anticipated usage

patterns. Several proposals were work-shopped with potential users who were also able to use mock-ups to design their own GUIs. While not all of these ideas could be implemented in the final system, these workshops provided valuable insight into the requirements. The final interaction design had user-friendly features such as the ability to connect with a single mouse click, selected from a menu which is automatically generated when the system starts. A broadband connection provided near broadcast quality video with excellent reproduction of the rapidly-moving structures observed in echocardiography.

Implementation strategy

The original aim of the ECHONET project was to enable cardiologists to interpret echocardiography images acquired in a small regional hospital in Tasmania in real-time, which also inspired the name ECHONET. Following the baseline study, the project team realised that due to the limited number of echocardiographic scans performed in North West Regional hospital, the telemedicine system would be unlikely to be used very much. The baseline study revealed however that clinical staff in the North West Regional hospital were very interested in the staff development and education activities in the larger Royal Hobart hospital, and in the possibilities of having bed-side case discussions of interesting or challenging patients. As reflected in figure 2, the majority of uses of the ECHONET system were bedside case discussions and education sessions which may not have occurred if the project team hadn't identified the potential early in the project and supported its use that way.

Evaluation design

Instruments deployed during the trial included weekly interviews with all users, log books, and a series of mid-trial interviews to monitor the trial for possible modifications, and to refine the end-of-trial processes. The need to accommodate a range of possible uses was borne out when the users began a series of consultations with cardiac outpatients living in the Burnie area who normally travelled to Hobart for follow-up consultations; using ECHONET they were able to have their consultation with their Hobart-based cardiologist without the need for travel.

While improved clinical outcomes are usually regarded as the primary benefit of telemedicine systems, in this case clinically driven activations of the system proved to be a relatively minor application, and the trial yielded too few such activations to achieve statistical significance. Nevertheless, a protocol using each patient as their own control and an expert panel was devised, and can be applied when more patients have had their management affected by an ECHONET consultation.

The integrated approach directly influenced the success criteria assessed in the evaluation which had been derived from the stakeholder interviews conducted at the beginning of the project. These success criteria were divided into four broad categories, which formed the four broad categories of evaluation and are presented in table 2. Examples of measurable success criteria are shown in italics following the criterion listing. In this study it was not possible to quantify all of these criteria.

Project outcomes

The most significant outcomes centred around improved collegiate relationships and educational opportunities among the users. Participants, in both the interviews and questionnaires, were very positive about the usability and usefulness of ECHONET, with some reservations about size and portability. Some of the key project outcomes are described.

Strengthening collaboration and relationships

Participants identified the facilitation of professional relationships amongst clinicians as one of the greatest benefits of using ECHONET. While the benefits of the collaboration supported by ECHONET for clinicians in the more remote hospital site at NWRH were more obvious and expected, clinicians in Hobart also recognised that they had benefited from the collaborations made possible by the new technology.

Education

One of the earliest and most frequent uses of ECHONET was for educational purposes. Education represents a good area in which to start using new telemedicine systems as sessions can be scheduled to allow familiarisation with the system in a relatively low pressure situation facilitating routine use.²¹ The

Table 2. ECHONET success criteria.

Evaluation domain	Usability and technical	Social/organisational	Clinical	Cost/benefit
Success criteria <i>Evaluation measure</i>	Technology works without too many problems <i>E.g. fault log</i>	Clinicians see value	Save unnecessary transfers <i>E.g. number of highly expensive transfers of ICU patients Burnie to Hobart</i>	
	In routine use <i>E.g. number of activations, esp. post-trial</i>	Improved clinical satisfaction/ satisfaction from clinicians	Improved patient management	Continuing use following trial/ clinical sustainable <i>E.g. number of activations, esp. post-trial</i>
	Successful, acceptable image transfer	Raising knowledge and skills/ clinician development <i>E.g. benchmarking ICU procedures at NWRH</i>	Improved patient outcome	Sustainable within hospital resources <i>E.g. ongoing costs – telecoms, maintenance</i>
	Clinicians find it easy to use <i>E.g. number of users</i>	Share expertise <i>E.g. number of bedside consults and number of participants</i>	Improved support for family and carers <i>E.g. reduced travel for family and outpatients</i>	Cost neutral/ return from investment <i>E.g. cost/benefit analysis based on other criteria outcomes</i>
		Clinically safe <i>E.g. no adverse outcomes</i>	Timely diagnosis <i>E.g. comparison with previous comms. procedures</i>	
		Improved contact between clinicians in NWRH and RHH <i>E.g. number of sessions; Increased popularity of postings to NWRH</i>		
		Accepted as part of normal workflow <i>E.g. post-trial activations</i>		
		Strengthen ICUs <i>E.g. long term benchmarking</i>		
		Clinician perceived better quality of care		

potential for ECHONET to be used for this purpose emerged early and strongly during the baseline study and this potential was confirmed and further explored during the clinical trial by clinicians at both hospitals.

Quality of care

Clinical and cost-benefit outcomes are difficult to assess in intensive care; for example a recent detailed study of the impact of the use of the eICU system failed to detect any measurable changes in outcome after introduction of the system.²² Our patient sample size was too small and diverse to draw any quantifiable conclusions. Based on the questionnaires and interviews however, all clinical users felt that there was benefit to patients (and in some cases, their families), when the system was used, especially in terms of eliminating the need for travel or the possibility of transfer to a tertiary referral hospital.

Evaluation Process Model

The ECHONET project enabled the application of an integrated approach to the design, implementation of a telemedicine system. The activities conducted and their relationship to each other is captured in figure 3.

In the ECHONET project there was a strong relationship between pre-trial activities and outcome measures. In particular, the success criteria were established through activities conducted at the same time as the design of the system.

The figure should not be taken as a prescriptive model, but as a guide. The mid-trial instruments (in the ECHONET case, questionnaires) and more particularly, the post-trial clinical analysis, will be highly dependent on the clinical scenario that is the subject of the trial.

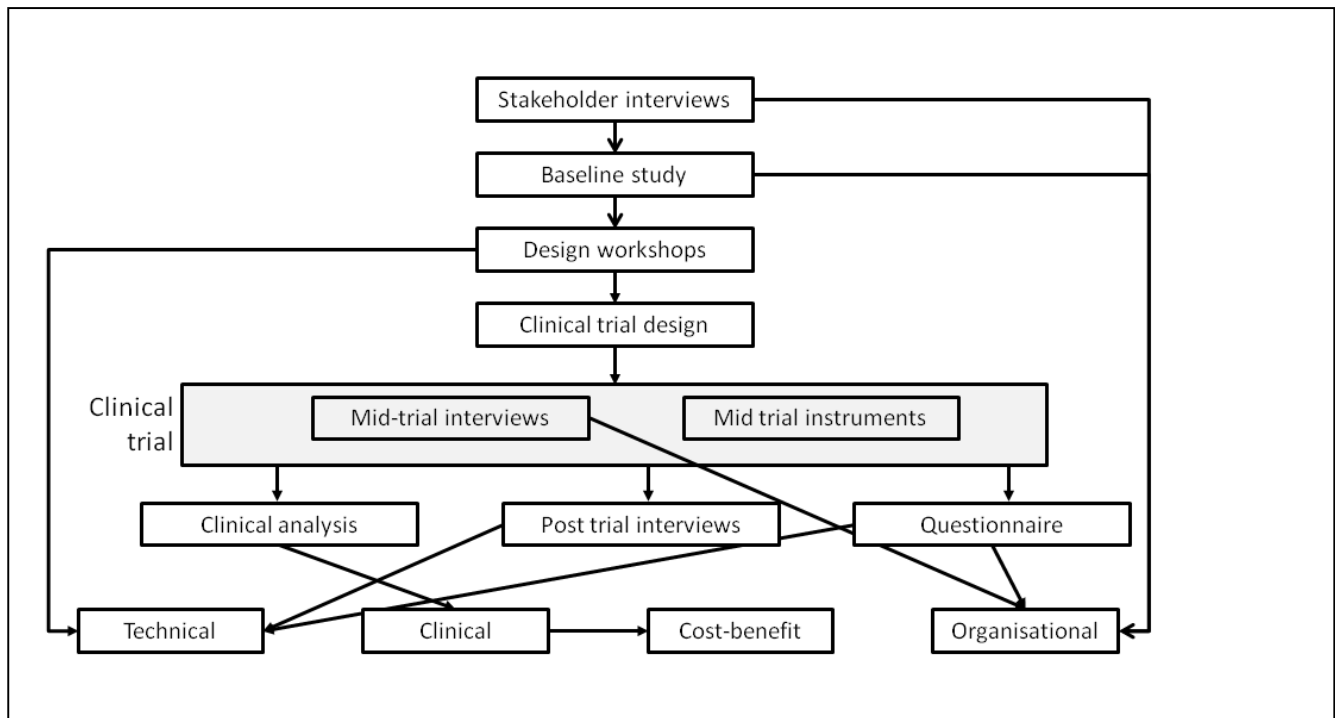


Figure 3. Design, implementation and evaluation activities conducted in ECHONET

Limitations

We acknowledge that there are limitations of this study as a full demonstration of the model. While we have demonstrated improved clinical processes, quantifiable benefits may require further analysis, which was not possible in this study, mainly due to limitations of time and budget. Also, these were not a priority for the key stakeholders. In particular, cost/benefit is often the most significant success measure for systems such as this. While economic analysis is beyond the scope of this model, there is an economic outcome (and possibly other quantifiable benefits) associated with most of the outcome measures shown in figure 3. Only when the benefits and outcomes are clearly identified can a cost-benefit analysis be carried out.

The lack of a thorough clinical needs assessment at the outset of the project is also a limitation identified in the model. As mentioned in Section 3, although this was partially overcome by other processes, a needs assessment should be incorporated into an integrated.

Discussion

Through the ECHONET case study, we have demonstrated the application of an integrated approach to the design, implementation and evaluation of a novel telemedicine system. Our case study has established the feasibility and advantages of such an approach in a practical setting, despite some of the limitations of the trial such as the lack of a formal needs assessment or rigorous clinical and cost-benefit analyses, all of which could easily be incorporated into larger scale trials. In particular we have demonstrated some of the advantages of applying an integrated, human-centred approach, which involves the researchers as active participants rather than as objective observers, as well as involving the users as designers. These advantages include identification of success criteria outside the design brief and the ability to interactively modify the aims of the implementation based on findings during the project.

Importantly, this work has described and demonstrated an approach rather than a generalizable framework for telemedicine evaluation, and re-opened the debate on how to assess and implement telemedicine applications. Future work could include the adoption

of this approach to other clinical domains and technical environments (e.g. off the shelf technology), which could in turn contribute to the refining and development of this approach into a more formal framework that can be adopted for implementing telemedicine systems. Like the systems it aims to optimize, the approach itself should evolve and be adapted according to the context in which it is applied.

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