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Høstgaard, Anna Marie Balling; Bertelsen, Pernille; Petersen, Lone Stub; Nøhr, Christian

*Published in:*
Scandinavian Conference on Health Informatics 2013

*Publication date:*
2013

*Document Version*
Early version, also known as pre-print

*Link to publication from Aalborg University*

*Citation for published version (APA):*

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Constructive Technology Assessment for HIT development: Learning, feedback and user involvement

Anna Marie Høstgaard⁷, Pernille Bertelsen⁷, Lone Stub Petersen⁷, Christian Nøhr⁸

⁷Department of Planning, Danish Center of Health Informatics, Aalborg University, Denmark

Abstract
Experience and time has shown a need for new evaluation methods for evaluating Health Information Technology (HIT), as summative evaluation methods fail to accommodate the rapid and constant changes in HIT over time and to involve end-users, which has been recognized as an important success factor in HIT development. A new evaluation methodology, including an analytical framework, has been developed specifically for HIT development: Constructive Technology Assessment (CTA) for HIT. It offers solutions to both the problems associated with summative technology evaluation and a way to involve end-users. The CTA methodology is based on a Socio-technical understanding of technological development as an open ended, emergent process. The CTA was used during the EHR development process in the Region of North Jutland where it proved successful in providing learning and feedback between all relevant groups during all the phases in the process. Therefore a number of problems were prevented to occur later on. Thus, the CTA method and its framework are useful for evaluators and project-management in order to facilitate and support successful HIT development.

Keywords: Constructive Technology Evaluation, Evaluation, Health IT, User involvement, Systems development

Background
Traditionally, summative evaluation methods have been the preferred methods for assessing health technology during the past decades, and still is[1,2]. However, in the case of assessing health information technologies (HIT), summative evaluation methods, as the often-used traditional Health Technology Assessment (HTA) method, pose more challenges [3]. HTA is meant to provide decision support for management for choosing between comparable fully developed technologies based on an evaluation of organizational, social, economic and ethical aspects [4,5]. One major challenge for using HTA for the evaluation of HIT is that many HIT systems are being tailor made for specific purposes. This means that the development process extends over a longer period of time, which again means that the technology might have changed more times before the evaluation is completed. Also, because traditional HTA is conducted when the technology is fully developed, major changes can only be made with great difficulty and at great expenses. This often results in only minor changes being implemented [6]. Last but not least, traditional HTA fails to accommodate the vast complexity of the health care sector: the departments and the wards have their own work practices, the clinical specialties have different needs, contemporary healthcare comprises different professional groups, and the end-users have different individual work practices.

Therefore, the rapid and constant changes in HIT over time pose specific needs for the evaluation methods used in HIT evaluation [7-9].

Already in the 1980s, researchers within the early science-technology-society (STS) movements in the Netherlands, Scandinavia, the UK and USA respectively, set a new research agenda aiming at challenging the limitations to summative technology evaluation methods. The outcome was the development of a formative technology evaluation methodology: Constructive Technology Assessment (CTA) [6,9,10]. With CTA the focus shifted from only assessing the various impacts of fully developed technologies to also paying attention to the technological process as a learning and feedback process, when new technologies are developed and implemented [6].

During the late 1980s researchers at Aalborg University further developed the CTA for the evaluation of HIT specifically [6,11]. The objective was to deliver a constructive evaluation of both intended and unintended consequences of HIT implementation. Besides, it was to involve the end-users at an early stage in the process, as they were seen as the most important knowledge capacity with respect to the work practices into which the technology should be integrated [12]. However, the CTA methodology did not gain ground in HIT development at that time. According to Müller this was due to management’s and staffs view on researchers as foreign intruders and of past experiences on technology evaluations without any significant effect on technological development [10,12].

During the past decades, experiences have shown the need for new methods to improve HIT development [13-15]. At the same time, the importance of end-user involvement in HIT has been increasingly recognised [16-18]. Thus in the newly published eHealth Task Force Report: “Redesigning Health in Europe in 2020” by the European Union, end-user involvement is mentioned as a key recommendation [19].

Within systems development methodologies agile development methods have been shown to be a successful approach with a focus on iterative processes and user involvement. These methods emphasize the need to integrate product developer perspectives with management, user and evaluation perspectives. This has not only to do with changing processes but also changing the way management, end-users, and evaluators view the HIT development process [20].

Based on these insights, we argue that time is now mature for reintroducing CTA in HIT evaluations, as the CTA methodology offers solutions to both the problems associated with summative technology evaluation (e.g. traditional HTA) and a way to involve the end-users throughout the technological life
The concept: “development” is being used both to designate the entire HIT development process and the third phase in the development process. The meaning will appear from the written context.

Methods

Theoretical approach

The CTA for HIT methodology is based on Socio-technical theory with a focus on user participation. Socio-technical theory is characterized by a view on technological innovation as an adaptation process, during which both the technology and the user's work practice are changed through mutual and lasting impacts. However, if social balance in the work is to be attained when implementing new technology, both social and technological needs must be met [21]. In Scandinavia, a broad concept of technology was introduced in Socio-technical theory in the 1980ies, focusing on the micro-level and the user as opposed to the macro-level and the technology. According to this, technology embraces: technique, knowledge, organization and product. These four constituents are inseparable components of any technology. However, active users within each of these, is a prerequisite for a technology being considered as such [6,22]. HIT-research in DaCHI is based on this concept and on a strong focus on the user perspective. The CTA for HIT methodology and its associated analytical framework is developed from previous research in DaCHI, hence the focus on user participation [23,24].

Design and data-collection methods

The “CTA for HIT” methodology was applied in a case study aiming at assessing the EHR system: Clinical Suite, in the Region of North Jutland (RNJ) in Denmark (the RNJ case). Evaluators from DaCHI conducted the evaluation from phase 1 to 4 (see below). The evaluation took place at different locations at four hospitals in the region 2006 – 2010. Data were collected by questionnaires, interviews (personal and focus-group), observations and insight into documents [25-27]. The final evaluation (phase 5) remains to be done once the implementation process is completed.

Analytical framework

Based on our studies within the healthcare sector, we have developed the following analytical framework for CTA for HIT development1 divided into five phases:

1. Research and planning phase
2. Design phase
3. Development phase
4. Implementation and diffusion phase
5. Summative evaluation and reporting phase

It is important to notice that in practice, the phases are not distinct, but overlap.

Results and Discussion

In this section, the “evaluator” is referred to in each phase. The evaluator is the person responsible for the evaluation (summative as well as formative) during the HIT development process. He/she can be hired from outside as a consultant or be part of the development team or the project management. This depends on the system being assessed, the method of systems development used and on the decisions taken by the executive board. The main responsibility of the evaluator, besides conducting the outcome evaluation at the end of the implementation phase, is to facilitate learning and feedback between the different groups involved during the entire process.

Based on our experiences, more preconditions have to be met to conduct CTA for HIT. Firstly: Throughout the process, good practice for evaluation studies has to be followed carefully [7,28]. Secondly: both the contracting authorities and management at all levels have to support it and have to have a full understanding of its implications with respect to both advantages and disadvantage. Thirdly: the evaluator has to be involved during the entire process, in contrast to in e.g. HTA, where the evaluator is first involved at the end of the implementation phase. This has to be fully understood and agreed upon by both the contracting authorities and management at all levels.

This section is structured in the following way: for each of the phases in the analytical framework provided with the CTA, general recommendations for using the framework is first presented. Then the evaluator’s role in the respective phases is described, followed by a description on how the framework was used during the RNJ case study. Finally, the results of using the method in the RNJ case are discussed.

1. Research and planning phase - Identifying and assembling the relevant actor groups

The identification of the relevant groups of actors to be involved in the different HIT development phases can be conducted by using e.g. partner analysis [29,30]. Obvious groups in HIT development are: groups of professionals at ward level (the end-users), the executive board, the management, vendors and it-professionals. The evaluator’s role is to ensure that when steering committees and HIT-working groups are assembled, all identified relevant actor groups are represented – and that focus is on the end-users. Besides, it is to ensure that the representatives from each user-group are appointed by members of the respective groups themselves - and not handpicked by management. Experience show that this is important with respect to achieving ownership to the decisions taken during the process [17,31]. At regional and hospital level the most natural way to find representatives is asking the respective professional associations representing the different groups to identify their own representatives. At ward level a useful method is the “Participatory method” [32]. However, in the RNJ case, the outlined approach was not followed.

In the RNJ case, the members of the project management group were handpicked by the executive board. This resulted in protests from the end-users at ward level, which led to a decision in the executive board to expand the group. However, this was done half way through the design phase, resulting in

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1 The concept: "development" is being used both to designate the entire HIT development process and the third phase in the development process. The meaning will appear from the written context.
the newcomers not having the necessary knowledge to make informed decisions. As a consequence not feeling any ownership to the decisions made through this phase [26].

2. The design phase – needs and problem analysis

During the design phase, needs- and problem analyses have to be implemented in order to clarify, which needs and functions the new technology must fulfill. In 2005 the EU announced a new way to implement tender processes aimed at particularly complex contracts, where the provider (the HIT project management) is not able to define technical, legal or financial matters related to the project: The Competitive Dialogue Process (CDP) [33] (fig. 1). The field of application of the CDP applies to the development of most new HIT systems, when no off-the-shelf items meet the provider’s needs and requirements. This way of conducting a HIT development process is fully in line with the CTA for HIT methodology. During this phase, the evaluator’s role is to facilitate learning between all groups involved. This must be done in close collaboration with the project management.

In the RNJ case, the CDP comprised (fig. 1): a) The prequalification phase: the provider (the project management) developed a tender notice inviting vendors to apply for the development of a new EHR system for RNJ. Among all the applying vendors, the provider - based on criteria’s decided on beforehand - choose four vendors for further dialogue. b) The dialogue phase: Based on experiences and knowledge from both existing technologies and work practices in RNJ and other regions, the provider devised a document describing provisional requirement specifications. This document constituted the basis for the initial dialogue between the provider and the four respective vendors – one at a time. c) The quotation phase: At some time during the process, the vendors were all asked to present provisional solutions/quotations for the new EHR. These were based on the knowledge of the provider’s needs gained during the initial dialogue. These provisional solutions/quotations then constituted the basis for further dialogue. During this dialogue with one vendor at a time, the provider gained further knowledge and insight into the possibilities for new technical solutions and work practices. The dialogue process continued until the provider had the gained enough knowledge to work out the final requirement specifications. d) The decision phase: Based on the final requirement specifications, the vendors forwarded their final quotation, and - based on certain criteria’s – one vendor (CSC) was chosen to develop the EHR for RNJ (Clinical Suite).

The greatest advantage of the competitive dialogue is that it allows the single members of the project management to gain a deeper insight into – for most members in the RNJ case - unknown technological areas by means of dialogue with the different vendors. This allows them greater influence on decision-making. The disadvantage is that it requires many resources (time- and personnel wise) to organize the process and to hold dialogue meetings with each vendor at a time. However, the provider in the RNJ case had a very positive attitude to the CDP and recommended the EU to allow the use of the CDP in a broader context and not only for complex projects [33].

3. The development phase – user involvement and agile development

During this phase, the project management in close collaboration with the end-users and the vendor/it professionals, outline possible technical configurations thought into different clinical contexts. A useful method for this process is the “User Innovation Management” (UIM) method, where the focus is on involving the end-users in designing the functionalities of the new technology [34]. The outcome of this process is the development of a prototype of the HIT system. This might first be tested in a usability laboratory or in clinical set-ups in order to assess e.g. user-friendliness and the consequences on clinical word practices. Jacob Nielsen has developed ten heuristics to follow for usability studies [35]. When the laboratory testing is completed, the next step is to test the prototype in real clinical settings. Experience shows that no matter how realistic a usability study has been performed, unforeseen disruptions and communication challenges can be hard to imitate [36]. The role of the evaluator in this phase is to ensure that the end-users are involved throughout the phase, and that they are working closely together with the vendor/it-professionals.

In the RNJ case the project management group (which included end-users) and the vendor conducted this phase together in close collaboration. Initially, they designed parts of the EHR (e.g. the user-interface) using different games and mock-ups, and as a result the involved actors developed a strong sense of ownership to the different decisions and solutions. Based on the result of this process, the vendor developed a pre-prototype of the EHR, which were pre-pilot tested at one ward. This test went on for several months, during which the pre-prototype was redesigned more times based on feedback from the end-users. During this phase, the evaluators from DaCHI facilitated feedback between the different groups. Besides, a number of meetings were held, and more reports were delivered to the project management, thereby proving them the necessary information’s for changing direction during the process, if necessary [27].

4. The implementation and diffusion phase – pilot testing and redesign

During this phase, prototypes of the new HIT system are implemented at selected wards for pilot testing. At this point of time, working-groups at ward level is set up to give feedback on the system’s functionalities and user friendliness. The evaluator’s role in this phase is to: a) make sure that all relevant groups are represented in the new groups. It is especially important to ensure that the vendor/it-professionals are an integrated part of the groups set up during this phase, as they must work closely together with the end-user in order to ensure that the new system meets the requirements, e.g. on clinical benefits. b) to provide feedback from observations and interviews at ward level between groups to share experiences and knowledge, and to management for learning and management reasons.

Figure 1- shows the different phases in the Competitive Dialogue Process method, which was used in the Region of North Jutland [33]
During the pilot testing of the EHR in the RNJ case, which took place at four hospital wards, the evaluators from DaCHI gave feedback to the project management on a number of occasions. A few examples are given in the following: a) At the Gynaecological ward, we found that the project management had forgotten to include the midwives, when the working group at ward level was set up. The most important work document for the midwives is the so-called “Partogram” which is a graphical record of key data recorded during labour. Because of the midwives not being part of the working group from the start, this record was initially not part of the EHR, which meant that the EHR did not provide any clinical benefits for this professional group. Because of our feedback to the project management, the midwives were included in the working group, and the EHR was expanded to include the Partogram.

b) At the Emergency ward we encountered complains of a too long startup time of the new EHR system in the different emergency rooms, resulting in the system not being used. It turned out that a certain procedure beforehand handled by the night duty staff, here re-starting all the computers during night shifts, had been closed down by mistake when reorganizing work procedures. This meant that when the staff entered the emergency room with patients in the morning, they had to wait for the computers to start up in order to enter the EHR. This was very time consuming and meant that they did not use the system. When this was reported to the project management, the previously used work procedure was reintroduced. A pocket size EHR system guide was available for all staff. However, only a few found them useful. At one pilot ward, staff members had encountered a number of errors in the guide and therefore, they had lost faith in using the guide to solve problems. On all these occasions, and all others encountered, we provided feedback to all relevant actors, thereby preventing a number of problems to occur later on in the process.

During this phase we had regularly meetings with the project management, on which we provided feedback on our observations. Our final recommendations based on observations and interviews with the end-users, were to await full implementation/diffusion until more of the functionalities were able to meet the end-users needs. The Region of North Jutland did adjust these functionalities and did wait another year before starting the implementation of the system to all hospital wards in the region, thereby presumably preventing a number of problems later on in the process [25].

5. Summative evaluation and reporting phase – reflections on outcome and process:
The outcome evaluation in CTA for HIT is different from traditional outcome evaluations with outcomes decided on very early in the process and rigidly assessed up upon at the end of the process. In CTA for HIT the formulation of outcomes is early in the process and rigidly assessed up upon at the end of the process. The CTA method is useful for evaluating different phases in the process. Thereby a number of problems were prevented. Thus, the CTA method is useful for evaluators and project-management in order to facilitate and support successful HIT development.

The CTA for HIT was used during the EHR development process in the Region of North Jutland. Despite the fact that not all recommendations in the CTA analytical framework were followed, the method proved successful in providing learning and feedback between all involved groups during the different phases in the process. Thereby a number of problems were prevented. Thus, the CTA method is useful for evaluators and project-management in order to facilitate and support successful HIT development.

Acknowledgments

We want to thank the Region of North Jutland and all actors involved in the EHR development process in RNJ.

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Address for correspondence
Anna Marie Høstgaard annamarie@plan.aau.dk