

Assessing Electronic Health Records: Are Basic Assumptions in “Health Technology Assessment” Useful?

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Abstract—The use of Health Technology Assessment (HTA) in the field of information and communication technologies (ICT) is limited. The Norwegian health authorities and international networks call for steps to strengthen its use to support the development of good e-health services. Randomized controlled trials (RCT) are the gold standard approach in case studies in HTA and scholars have raised questions concerning their relevance in e-health assessments. Failure of basic philosophical assumptions inherent in RCT to reflect empirical features of e-health is one explanation. In a sociotechnical perspective, this paper explores empirical features of “Common Implementation of Clinical Systems” (FIKS), a large-scale electronic health record program in North Norway. Drawing on documents, information and presentations over a 4 year period, it discusses how empirical features correspond to assumptions of RCT. Also considering scientific literature from assessments of electronic records, complimentary assumptions are presented. The objective is to contribute to a knowledge base for improving HTA of ICT. Results show that RCT assumptions of a stable world, fixed interventions and controlled implementation processes differed from empirical processes. Hence, RCT approaches fail to address important features of the program and produce knowledge that fully demonstrate (causes of) empirical benefits or pitfalls. The paper briefly considers complementary assessment perspectives. Embedding assumptions of a world in flux where social, technical and clinical entities influence each other in dynamic processes should increase the relevance of HTA of ICT, and affect real time developments. Further exploration of assumptions that encourage participatory and process assessment approaches is timely.

Keywords- *Health Technology Assessment (HTA); challenging assumptions, approaches and methods; programs of electronic health records; assumptions in constructive assessments*

I. INTRODUCTION

A. Background

The paper is positioned within a sociotechnical perspective and seeks to produce insights into the coherence between assumptions in health technology assessment (HTA) and the

practices that are assessed. The need for assessments of information and communication technology (ICT) programs have been strongly expressed for instance by The parliament in United Kingdom (UK) in a summary of the National Health Service (NHS) information technology (IT) program. “The original objective was to ensure every NHS patient had an individual electronic care record which could be rapidly transmitted between different parts of the NHS, in order to make accurate patient records available to NHS staff at all times. This intention has proved beyond the capacity of the department to deliver and the department is no longer delivering a universal system. Implementation of alternative up-to-date IT systems has fallen significantly behind schedule and costs have escalated” [1].

Health Technology Assessment is expected to produce knowledge to help decide on and procure technology and services that are accurate, cost effective and with expected value and quality [2]. For those purposes, the Norwegian health authorities and international scientific networks for the conduct of HTA call for steps to strengthen its use in the field of ICT. As part of this, the Northern Norwegian Health Authorities (NNHA) in 2016 funded a three-year project for developing and adapting HTA approaches and tools. The project builds upon the White paper to the Storting: one patient – one record [3]. This paper is part of the project.

The need for adapting and developing assessments for the field of e-health is expressed in several scientific publications, some of them referred to in section C below. A common idea is that established assessments have weaknesses in that they produce less relevant and timely knowledge. In this paper, weaknesses connected to basic philosophical assumptions in HTA are addressed. More specifically, those expressed in the gold standard approach of Randomised Controlled Trials (RCT) and related to development of electronic health records (EHR) in North Norway.

The research question is how assumptions of RCT are amenable to empirical features of “Common Implementation of Clinical Systems” (in Norwegian an acronym, FIKS), a

large-scale program for developing and implementing a new EHR [4, 5]. The paper also briefly comments on approaches and methods of RCT, relying on equal assumptions. FIKS started in 2012 and is scheduled to last through 2016. It lies within the jurisdiction of the NNHA in North Norway. One common electronic patient record for all hospitals in the northern region of Norway is a goal. No pre-implementation evaluation has been carried out.

The objective of the paper is to contribute to a knowledge base for addressing weaknesses of HTA of ICT and to briefly point to alternative assumptions which might strengthen its use for the benefit of patients, health professionals, policy makers, leaders and industry.

In sections B and C to follow, HTA, its assumptions and weaknesses are presented. In section II an account of FIKS is given, followed by methods and materials of the investigation. The results and discussion section is divided in three sections each addressing different assumptions in RCT: a singular reality (context), a clear definition of the intervention and a controlled implementation process. Section IV points to approaches and methods accommodating different assumptions: a reality in flux, and interventions and implementation as ongoing socio/technical/medical achievements. In conclusion, the paper argues that exploring such assumptions should strengthen the relevance of HTA methodology for e-health.

B. Health Technology Assessment (HTA) and RCT

HTA is a research field defined as “the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods [6].”

The purpose of HTA is to establish a decision basis for the procurement of the right health technologies [7]. The European network for HTA, EUnetHTA justifies the research field as follows: “Health care decision making requires the right evidence at the right time. Every day there are new health technologies available that can improve patient outcomes and refine health system efficiency. HTA is a tool to review technologies and provide evidence of the value these technologies can deliver to patients and their families, health system stakeholders, and to society more broadly [6].”

Health technologies comprise “Diagnostic and treatment methods, medical equipment, pharmaceuticals, rehabilitation and prevention methods, but also organisational and support systems used to deliver healthcare” [8]. The electronic patient record is a type of system that not only comprises of technology, but also involves vulnerable information, social interactions, relationships, and competencies among users (e.g. doctors, nurses, patients) as well as organizational structures, routines and coordination components.

In HTA, different products have been developed to support knowledge-based decisions in health care, such as systematic reviews, meta-analyses, modelling and assessments of new medical methods. All tools draw on basic philosophical assumptions and form a coherent approach. The gold standard tool in case assessments are Randomised Controlled Trials (RCT). RCT is a type of scientific (often medical) experiment, where the people being studied are randomly allocated to one or other of the different treatments or interventions under study. RCTs are often used to test the efficacy or effectiveness of various types of medical interventions. The interventions are assumed to be clearly defined and demarcated and may provide evidence for adverse effects, such as drug reactions.

C. Assumptions and Weaknesses

Accurate assumptions to guide approaches is imperative for the production of useful knowledge to the confidence of different stakeholder groups.

A basic assumption underlying an RCT is that of a singular reality amenable to objective scientific measurement to provide universal evidence for outcome of specified interventions. A relatively stable situation and causal variables and linkages has to be identified in order to be able to generalize and repeat outcome. One challenge for applying RCT for ICT and e-health programs is that empirical situations in general are more messy and in flux [9].

In their assessment of electronic health records in the National Health Services (NHS) IT program in United Kingdom, Greenhalgh and colleagues addressed this challenge. They asserted that e-health initiatives occur in complex and fast moving socio-political arenas. Evidence is produced by, and fed back into a political process of deciding priorities and allocate resources to pursue them [10]. Interpreting practice in context can therefore be an alternative to the production of evidence for universal truths in controlled experiments as recommended in RCT.

A second assumption underlying RCT is that of a clear demarcation and definition of the intervention, including a fixed start and endpoint. In ICT programs, this can be difficult to achieve given the fast-paced technological development and the seemingly endless range of possibilities for novel service delivery platforms. It normally takes years to accomplish an RCT and this is described as the most formidable challenge threatening to upset the very promise of potential solutions: The rate of emerging technologies and services is far outpacing the field’s capacity to demonstrate the conceptual or empirical benefits [11].

A third challenge described is pressure to roll out new ICT services before pilots are fully evaluated. Implementation is hence assumed to be a linear operation where readymade technological applications are “rolled out” to an organization and can be objectively assessed. Human interaction might be considered as an obstacle. The alternative is proposals to address person-to-person models to understand how collegiate and interpersonal elements of care delivery can be

better embodied in assessments and as such brought to consciousness for influencing development [12]. In design, the influential openEHR standard represents a model driven approach allowing clinical personnel to be involved in development processes [4]. OpenEHR is a virtual community working on interoperability and computability. Its main focus is electronic patient records (EHRs) and systems [13]. Other innovation and design philosophies/practices such as “Design thinking” involve future thinking and creativity as main assumptions behind innovation [14].

The three challenges and assumptions behind them are interconnected. It seems that basic assumptions and subsequent approaches of RCTs could fail as guiding principles for addressing all important aspects that affect the relevance of ICT. Evidence for positive or negative effects based upon erroneous assumptions might support both over optimistic and over pessimist expectations for future development.

In the rest of the paper, steps to address these challenges connected to the FIKS program are discussed. The research question is specified and discussed in three parts: How are assumptions about the reality, the intervention, the process of implementation and subsequent approaches and methods of RCT, amenable to empirical features of FIKS? Based upon scientific literature, complementary assumptions capable of improving HTA for ICT are presented.

II. THE FIKS PROGRAM, METHODS AND MATERIALS

A. FIKS

FIKS is a large-scale program for developing and implementing a new electronic health record system, running from 2012 through 2016. The costs are estimated to EUR 90 million and the vendor (DIPS) is the largest EHR vendor in Norway [4]. The aim is to introduce a single electronic patient record at the eleven North Norwegian hospitals, including radiology, lab, pathology and electronic requisition of laboratory services for general practices in the region [15]. An official information sheet of FIKS is published in English [5]. Additional description of the program and implementation is provided in the results and discussion sections.

B. Methods and Materials

The paper is based upon a mixed data material consisting of documents, web sites, information from advisors and presentations of the FIKS program to different actors in the hospitals in North Norway over a period of 4 years, from 2012 to February 2016. In addition, document studies of papers and reports from two large scale evaluation and assessment projects in UK connected to the National Health Services (NHS) ICT program were studied: “The UK Summary Care Record Programme” [10] and “Healthcare Electronic Records in Organisations” [16]. A number of scientific papers were recommended in publications from the two programs with a focus on assessment traditions. These are reflected both in the background and discussion sections.

Triangulation is a social science technique that facilitates validation of data through cross verification from two or more sources [17]. In particular, it refers to the application and combination of several research methods in the study of the same phenomenon. Such techniques were applied to combine information from the multiple sources refined into useable assemblages. These culminated to form recognizable examples for the discussion of assumptions and approaches. The discussion sections also draw on arguments developed with the support of the MethoTelemed team, whose contribution is acknowledged [18].

III. RESULTS AND DISCUSSION

A. Assumption one: A Singular Reality Amenable to Scientific Measurement and Control

This section will substantiate that the context of FIKS and the program itself can be understood in terms of complexity, multiplicity and dynamism. To single out a clear distinction between the context and the program is also not a straightforward task. Relatively stable variables depicting the reality, or context, will, however also be distinguished and commented. This is one premise in RCT for defining external and internal causal variables and linkages in order to be able to repeat outcome in controlled ways.

The context of FIKS is a number of mutually dependent actors, representing a myriad of interests trying to accomplish a unified vision. This is documented in the web page informing that the FIKS project implements the new systems in close cooperation with health authorities, Health Nord ICT (An organization established by the Regional Health Authorities designated to implement ICT services) and the various system suppliers.

In addition, the different hospitals where the implementation occurs, represent different socio-political and institutional contexts. The context is therefore complex, interconnected and politicized, as health political decisions affect resources necessary to add affordances of, and accommodation of the record. Concerning affordances, the web page of FIKS informs that the next generation patient record is under development and is tested in the region. Some upcoming milestones in 2016 on the path to one common medical record are listed:

- One common medical record at the hospitals in Hammerfest and Kirkenes cities
- University Hospital North Norway employs regional radiology solutions including one common radiology archive
- The hospitals in Helgeland, Mo I Rana, Mosjøen and Sandnessjøen employ one common medical record (DIPS) [5]

This information tells us that both the contexts and the intervention consist of multiple, developing and mutually dependent components.

Also the historical process accounts for a dynamic and inter-woven character of the context and intervention.

Already in 2011, necessary contracts for the program were signed, showing the different industrial actors involved. These are some of the milestones presented on the web page:

2011

- Helse Nord Regional Trust signed a contract with Sectra
- Helse Nord Regional Trust signed a contract with Tieto
- Helse Nord Regional Trust signed a contract with DIPS

2013

- Helse Nord Trust signed a contract with CompuGroup Medical Norge (CGM)
- Helse Nord Trust signed a contract with Infodoc
- Merging of pathology systems in two major hospitals

2015

- Helse Nord Trust signed a contract with Hove Medical Systems [5]

The assumptions for the conduct of an RCT, a controlled, measurable and relatively stable reality, are not reflected in the empirical features of the context/intervention. Rather, the multiple and mutually dependent actors and interests, depict a reality and situation under development and flux, depending on negotiations, shifting political conditions and resources.

B. Assumption Two: A Clear Demarcation and Definition of the Intervention

On the web page as well as the Facebook page, the goal of FIKS is described as an ambition that the people of the north will have their clinical history assembled in one patient record and that the practice of sending records between hospitals will end. An ambition refers to a work process, and not to a defined and fixed intervention as assumed in RCT. The notion rather refers to assumptions of a creative process like in “Design Thinking”. One of the first features of the intervention was described in 2013: “Moving the databases of the hospitals in Helse Nord to one central common database, is an important condition for the implementation of common patient administration and treatment systems and one common electronic record for the individual hospitals in North Norway.”[5]

New ingredients were added to the service. Events were planned as an ongoing deployment process and the program was described in terms of technical/operational events:

- Connection of Narvik medical center against Health Nords regional solution for electronic requisitioning of Laboratory Services 11/25/2015
- Connection of Leirfjord medical office against Health Nord regional solution for electronic requisitioning of Laboratory services 11/25/2015
- Connection of Nordreisa medical office against Health Nords regional solution for electronic requisitioning of Laboratory Services 11/24/2015

- Connection of Træna medical office against Health Nords regional solution for electronic requisitioning of Laboratory Services 11/24/2015
- Connection of Skjervøy medical office against Health Nords regional solution for electronic requisitioning of Laboratory services[19]

By distinguishing events this way, the grounds are laid out for RCT of each part of the process, but the resources needed for accomplishing such an endeavor would be vast. There are also interconnections between the parts and therefore difficult to single out as clearly demarcated interventions.

C. Assumption Three: Implementation as a Linear and Controlled Operation

The described pressure to roll out new ICT services before pilots are fully evaluated involves an assumption that implementation is a linear, top down and controlled process that can be distinguished from context and socio-political or human processes. The description of the implementation of FIKS, however, clearly points to an ongoing and changing process where different components should be aligned. This is how it is expressed on Facebook: The FIKS program in Helse Nord consists of six projects intended to develop and implement joint electronic record systems at the hospitals in Northern Norway:

- One joint electronic record (DIPS)
- New features of the electronic record (DIPS Arena)
- Laboratory Information System
- Radiology Systems (“Sectra”, “RIS” and “PACS”)
- Joint pathology system in Tromsø and Bodø
- Electronic requisitioning of laboratory services[19]

In 2011 DIPS decided to use the OpenEHR framework for developing its next generation EHR for the hospital market [4]. This involves negotiations on development directions. The role of interaction between different participants in the process is a collegial and interpersonal process, enacted as different meetings for dialogue and negotiations:

- 11.26.2015: Workshop (EPR Development): Theater nurse meeting - Planning and booking DIPS Arena
- 11.26.2015: Workshop (EPR Development): Theater nurse meeting - meeting with clinicians
- 11/26/2015: Workshop (EPR Development): Decisions in psychiatry - new module in DIPS Arena
- 11/12/2015: Operation Planning (EPR Development): Meeting with clinicians at University Hospital of North Norway [5]

This process adds to the formerly documented process of negotiating contracts with producers and vendors.

FIKS also designates and educates super users, and state that the competencies of employees are crucial for the

development of good record systems: “Close to 190 super users at Nordlandssykehuset are ready to be educated on use and routines of the new electronic record and become leading DIPS experts [5].

The description of the process of implementation shows a multitude of inter-related operational, interactional and relational processes. A linear, pre-defined and controlled “roll-out” process is not present, as assumed for RCT.

D. Summary and discussion

Among challenges in applying a HTA assessment framework for the study of an electronic patient record, is that HTA tools form a coherent approach and draw on common basic assumptions, which differ from empirical features. The basic assumptions of a stable reality amenable to objective measurement, a defined intervention and an operational and linear implementation process fails to address the empirical features described. This issue has been discussed in HTA, related to innovation research. Two different models or approaches are described in the core model (reference 20, page 15). “The linear diffusion model perceives new technology as an external stable entity that is brought to a (health care) system and induces change. A competing paradigm, the translation model, presumes that technology undergoes change in the environment it is brought into. Hence the final impact will not depend on the original technology only” [20]. In the case of FIKS, both the technology, the health care setting and the implementation process seem to be in a state of mutual translation. The empirical features of the applications and services connected with the record are highly diverse and constantly in flux within shifting social and organisational contexts.

Challenges were connected to discrepancies between assumptions and features of the context or “reality” within which the electronic record is embedded, the intervention itself and the implementation process. In the next section, approaches that build upon other assumptions are addressed.

IV. COMPLIMENTARY ASSUMPTIONS - THE CONSTRUCTIVIST UMBRELLA

Challenges concerning the validity of evidence in the face of involvement of different stakeholders have been articulated within the HTA tradition, which is looking to overcome such challenges. One of the tools of HTA in that respect is consensus conferences with different stakeholders [21]. Such conferences have been subject to investigations and the following assertion strengthen the argument of a shifting social reality and the need to consider social relations as drivers for both intended and unintended outcome:

“Consensus development programs are not immune to the economic, political, and social forces that often serve as barriers or threats to evidence-based processes. Organizations that sponsor consensus development conferences may do so because they have certain expectations for the findings of these processes, and may find themselves at odds with evidence-based findings. Other

stakeholders, including from industry, biomedical research institutions, health professions, patient groups, and politicians seeking to align themselves with certain groups, may seek to pressure consensus development panelists or even denounce a panel’s findings in order to render desired results, the evidence notwithstanding.” (Goodman 2004:49) [22]

The citation points to the importance of addressing social/political interests and processes to understand the way evidence can be produced and affect results of ICT use in health services.

In contrast to assumptions in RCT about a relatively stable and objective reality, a fixed intervention and a linear and controlled implementation process, constructivist traditions assume flux. This implies a reality or context under development, interventions which are also subject to change, and implementation as partly unpredictable and depending on for instance resource allocation. Implementation is considered an on-going process where support or lack of support strongly influence the outcome. Therefore, it is not considered possible to generalise evidence based outcome in order to repeat good results in new or future settings. Assessment results are aiming to be fed back into a pragmatic and political process of deciding priorities and allocate resources to pursue them.

In this perspective, validation is considered to be obtained through negotiations between the context, the researchers, the intervention and other stakeholders. Context is considered by involving different stakeholders’ interests and validity is addressed by asking what the study is valid for (Aguinaldo 2004:127) [23].

Such assumptions and resulting approaches may have particular strengths where the goal is to develop good e-health services, to the confidence of users, professionals, policy makers and payers, and as a lead market in Europe. Thus, obtaining balance between different validity claims is a vast challenge.

This paper has focused on the fluctuating character of reality, interventions and implementation. Nevertheless, there are also stable features of the three elements. To bridge the gaps between assumptions of the two traditions, the positivist (as in HTA) and the constructivist should be important for assessments of e-health. This point is also noted by Ammenwerth [24]. One goal should be to open the borders between traditions and identify how evaluators may draw on the benefits the different ones have to offer.

Answers to the question “Does it work?” to produce evidence for universal truths, need to be supplemented by a whole range of answers to questions that reflect the complexity of most e-health interventions. “How does it work?” “What components are vital to success, and which are redundant?” “Why does it work in this context (and equally important not work)?” “Is this an appropriate and acceptable way of tackling the problem?” “How is quality produced and defined within certain innovation processes? Moreover, “who owns the definition of success?”

In process approaches, investigations are directed towards the conditions that are included in development processes, with a purpose to feed results back into the process for dialogue and improvements. The “intervention” is shaped and adjusted in and through practices of professional-social interaction between participants (doctors, nurses, patients) and the organisational, economic, political and ideological settings these practices are embedded in. The intervention also contribute to shape these settings as the approach presupposes that all entities are in mutual shaping. Controlling conditions will be the crucial task for future results of innovations. Process investigations may produce knowledge to this end.

V. CONCLUSION AND FURTHER WORK

The paper has substantiated empirical features of a reality in flux, an intervention under development and implementation processes as ongoing negotiations for the FIKS program. HTA assumptions of a stable reality, a fixed intervention and a controlled implementation process were not present. Steps to strengthen HTA use for ICT are timely. Knowledge about conditions for large processes with escalating costs is important as conditions built into the programs vastly influence the effects that emerge and manifest. Embedding assumptions of a world in flux where social, technical and clinical entities influence each other in dynamic processes should increase the relevance of HTA of ICT, and affect real time developments. Further exploration of assumptions that encourage participatory and process assessment approaches is timely.

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