Assessing an Electronic Health Record (EHR): How Do Basic Assumptions in Traditional Health Technology Assessment (HTA), and Empirical Features Fit?

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***Abstract*—The use of health technology assessment (HTA) in the field of information and communication technologies (ICT) is receiving increasing attention. However, assessments this far are limited. In HTA, randomized controlled trials (RCTs) are the gold standard approach, building on a coherent set of basic philosophical assumptions. Scholars have raised questions concerning the assumptions and their fit with e-health, and thus questioned the ability of HTAs to produce useful assessments. The failure of assumptions to reflect empirical features of e-health is one explanation. This paper discusses this tension. Based upon the conference paper "Assessing Electronic Health Records: Are Basic Assumptions in Health Technology Assessment Useful?," presented at The Eight International Conference on eHealth, Telemedicine, and Social Medicine eTELEMED 2016, April 24–28, 2016, in Venice, Italy, we have elaborated the empirical substantiation and present an extended version. Using a sociotechnical perspective, we studied a large-scale electronic health record program in northern Norway. Drawing on data over a 5-year period, we discuss how the program's plans, organization, and activities correspond to RCT assumptions. We found that the RCT assumptions of a stable world, fixed interventions, and controlled implementation processes differ substantially from the real-life processes. Thus, RCT approaches that build on such assumptions fail to address important features of the program and fail to produce knowledge that fully demonstrates (the causes of) empirical benefits or pitfalls. As a result, we suggest embedding a world in flux in the assumptions of HTA where social, technical, and clinical entities continuously shape each other in dynamic processes. This may increase the relevance of HTA in ICT implementation projects.**

Keywords-health technology assessment (HTA); approaches and methods in randomized controlled trials (RCT); empirical features of electronic health records; assumptions in constructive assessments.

I. INTRODUCTION

A. Background

This paper is an extended version of a paper presented at the Eighth International Conference on eHealth, Telemedicine, and Social Medicine, eTELEMED 2016, April 24–28, 2016, in Venice, Italy [1]. The six-page conference paper allowed limited space for empirical documentation and data from participation in an implementation process of the electronic health record program (FIKS). In this extended paper, the empirical documentation is presented to substantiate the argument in the conference paper, for novel and more relevant assumptions to guide assessment approaches within the health technology assessment (HTA) tradition. In addition, the account in the conference paper of the steps within the HTA communities was very broad. Therefore, in this extended paper, we also describe and discuss in detail the policy and scientific steps within segments of this community. The paper provides an account of processes initiated by the International Health Technology Assessment network (HTAi) to meet challenges concerning assessment.

By expanding the authorship and time period of the data material to include the year of 2011, the extended paper also incorporates novel detailed empirical content to strengthen the argument of the conference paper. This paper also refers to previously published results that provide new perspectives on the empirical development of information and communication technology (ICT) in health care.

The new material is in line with the original topic but substantiates and expands the argument. The conclusion is

updated to capture the new content by suggesting steps for updating the theoretical assumptions behind HTA approaches.

This paper is, similarly to the original, positioned within a sociotechnical perspective and seeks to produce insights into the compatibility between the assumptions behind HTA approaches to assessments and the practices that are assessed. The main idea is that there has to be coherence to produce relevant knowledge.

The need for assessments of ICT programs has been strongly expressed. For instance, the Parliament in the United Kingdom (UK) stated 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" [2].

Health technology assessments are designed for, and expected to, produce knowledge to help decide about and procure technology and services that are accurate and cost-effective and have the expected value and quality [3]. The Norwegian health authorities and international scientific networks for conducting HTAs have called for steps to strengthen its use in ICT. In 2016, the Regional Health Authority, North Norway (NNHA) funded a three-year project for developing and adapting HTA approaches and tools: HTA for ICT [4]. The project builds on the "One Patient–One Record" white paper presented to the Norwegian Parliament [5]. This extended paper is part of the HTA for the ICT project.

The need to adapt and develop assessments for e-health has also been expressed in several scientific publications; some are referred to in Section C. A common concern is that established assessments have weaknesses in that they produce less relevant and timely knowledge. In this paper, weaknesses connected to basic theoretical and philosophical assumptions in HTA are addressed, more specifically, those expressed in the gold standard approach of randomized controlled trials (RCTs) and related to the development of electronic health records (EHRs) in northern Norway.

The research question is how assumptions of RCT are amenable to empirical features of the Common Implementation of Clinical Systems (the Norwegian acronym is FIKS), a large-scale program for developing and implementing a new EHR [6][7]. The paper also briefly comments on RCT approaches and methods, because they rely on the same set of basic assumptions. FIKS started in 2012 and was scheduled to last through 2016. It lies within the jurisdiction of the NNHA in North Norway. The goal is to establish a common electronic patient record for all hospitals in the northern region of Norway. No pre-implementation or baseline evaluation was carried out.

The first objective of the investigation is to contribute to a knowledge base for dealing with challenges experienced when conducting traditional HTAs for ICT. The second objective is to briefly present and substantiate alternative assumptions and assessment designs. The alternative assumptions are presented as logical consequences of the study's empirical findings. They are discussed as capable of strengthening HTA use in ICT for the benefit of patients, health professionals, policy makers, leaders, and industry.

In Sections B and C, HTAs, represented by RCT assumptions and weaknesses, are presented. In Section II, an account of FIKS is given, followed by the methods and materials. The results and discussion in Section III are divided into three sub-sections; each addresses different assumptions in RCT: a singular reality (context), a clear definition of the intervention, and a controlled implementation process. Approaches and methods that accommodate different assumptions (a reality in flux and interventions and implementation as ongoing socio-, technical, and medical achievements) are discussed in Section IV. In conclusion, the paper argues that exploring such assumptions could be a path for developing more relevant HTA approaches for assessing e-health.

B. Health Technology Assessment and RCT

HTA is a research field defined and explained as follows: "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" [8].

The purpose of HTA is to establish a decision basis for procuring the right health technologies [9]. 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" [8].

Health technologies comprise "Diagnostic and treatment methods, medical equipment, pharmaceuticals, rehabilitation and prevention methods, but also organisational and support systems used to deliver healthcare" [10]. The inclusion of the EHR as a health technology refers to the description above. The EHR comprises technology but also involves organizational structures, routines, and coordination components. In addition, the EHR includes vulnerable information, ethical considerations, social interactions, relationships, and competencies among users (e.g., doctors, nurses, and

patients) which are necessary to deliver health care. In that respect, the EHR can be subsumed under the concept of a health technology, albeit a complex one.

In HTA, different products have been developed to support knowledge-based decisions in health care, such as systematic reviews, meta-analyses, economic modeling, and case or experimental assessments of new medical methods. These tools draw on basic philosophical assumptions and form a coherent approach. The gold standard tool for assessments is RCTs. An RCT is a type of scientific (often medical) experiment, where the people studied are randomly allocated to a treatment or intervention under study. RCTs are often used to test the efficacy or effectiveness of various types of medical interventions, such as drugs, or devices, such as pacemakers. The clinical quality of medications, for example, is also tested via RCTs. The interventions tested for different outcomes are assumed to be clearly defined and demarcated and capable of providing evidence for adverse effects, such as drug reactions.

C. Assumptions and Weaknesses

Accurate assumptions to guide approaches are imperative to produce useful knowledge for different stakeholder groups. The assumption underlying an RCT is that there is a singular reality amenable to objective scientific measurement to provide universal evidence for the outcome of the specified interventions. Human bodies, for instance, are assumed to mainly react similarly to a drug, so that general conclusions can be drawn about its effects. A stable situation is assumed and set up for the experiment, so that causal variables and links can be identified to generalize and repeat the outcome. One challenge for applying RCTs for ICT and e-health programs is that the empirical situation, reality, in general is more messy and in flux [11].

An example is the assessment of electronic health records in the NHS IT program in the United Kingdom. Greenhalgh and colleagues addressed this challenge, and 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 allocating the resources to pursue them [12]. The authors suggested that interpreting practice in context, therefore, could be an alternative to producing evidence for universal truths in controlled experiments as recommended in RCTs.

A second assumption underlying RCTs is 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 conduct 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 far outpaces the field's capacity to demonstrate the conceptual or empirical benefits [13].

A different challenge is the pressure to roll out new ICT services before pilots are fully evaluated. Implementation, thus, is 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 an obstacle in such processes. The alternative is proposals to address closer person-to-person interaction between users and designers to understand how collegiate and interpersonal elements of care delivery can be better embodied in assessments and therefore brought to consciousness to influence development [14]. In design, the emerging openEHR standard represents a step in this direction as clinical personnel can define for themselves how the content of an EHR should look, that is, the type and degree of various structured elements in order to lay the foundation for interoperability, decision support, and clinical research [6]. OpenEHR is promoted through the international openEHR foundation (a not-for-profit company), and the openEHR standard represents the specification of an EHR system: the management, storage, and retrieval of health data [15].

The three challenges described, and the assumptions behind them of a singular and stable reality, a fixed intervention, and a linear process of implementation, are interconnected. These assumptions and subsequent approaches could fail as guiding principles for addressing all the important aspects that affect knowledge about the value of ICT. Evidence of positive or negative effects based on erroneous assumptions might support overly optimistic and overly pessimistic expectations for future development.

In HTA assessments, different models are, however, defined for the assessment of innovations and form part of the initiatives taken for novel approaches. The Core model distinguishes two models: the diffusion model and the translation model which are relevant to the discussion in the paper. These will be described and discussed in Section III D.

In the remainder 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 or context, 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 that can improve 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 at EUR 90 million, and the vendor (DIPS) is the largest EHR vendor in Norway [7]. The aim is to introduce a single electronic patient record at the 11 northern Norwegian

hospitals, including radiology, lab, pathology, and electronic requisition of laboratory services for general practices in the region [16].

An important goal for the Regional Health Authority, North Norway was to acquire a process- and decision-supportive EHR. Thus, the bid for tender asked for an EHR with high interoperability and configurability that would enable users to tailor the software to their needs. DIPS was commissioned to develop the new EHR infrastructure based on the openEHR architecture [16]. Due to the high configurability associated with an openEHR-based EHR, it was expected that openEHR would have the potential to support collaboration and workflow of flexible patient pathway processes across department and institutional boundaries.

B. Methods and Materials

The paper is based upon 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 5 years, from 2011 to February 2016. Data were collected via observations, interviews, participation in meetings and conversations, and access to documents and presentations. The authors collected data, as did PhD students who conducted participatory projects of aspects of the development process. References [6][21][23] and [25] are papers for which PhD students are the first author. The authors and the students are members of the research group of Telemedicine and e-health at UIT - The Arctic University of Norway. Different aspects of the processes have been extensively discussed in the research group, as well as at the Norwegian Centre for e-health Research (NSE). Numerous professionals were involved in these discussions, whom we thank.

In addition, papers and reports from two large-scale evaluation and assessment projects in the UK connected to the NHS ICT program were studied: “The UK Summary Care Record Programme” [12] and “Healthcare Electronic Records in Organisations” [18]. Many scientific papers were recommended in publications from the two programs that focus on assessment traditions. The papers are discussed in the background and discussion sections.

The different data sources are combined through a triangulation process. Triangulation is a social science technique that facilitates validation of data through cross-verification from two or more sources [19]. In particular, triangulation 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 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 [20].

III. RESULTS AND DISCUSSION

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

In this section, the context of FIKS is substantiated, and the program itself can be understood in terms of complexity, multiplicity, and dynamism. Making a clear distinction between the context and the program is not straightforward. Stable variables depicting the reality, or context, are, however, also distinguished and discussed. These are the terms in RCTs for distinguishing external and internal causal variables and links in order to be able to repeat outcomes in controlled ways.

The context of FIKS is many mutually dependent actors, representing numerous interests trying to accomplish a unified vision. This was apparent in the formative stages of the project where several development tracks were established, and more than 150 users were invited to associated regional workshops to identify what needed to be developed. The workshops became an arena for the users from the different hospitals to understand how the practices differed. Accordingly, the users had to negotiate and compromise in order to agree upon standards and trajectories across organizational boundaries. To illustrate, in the first workshops, much time was spent discussing the different needs of small and large hospitals related to the role of coordinator in the operating rooms. In the smaller local hospitals with two rooms, this role had a very different meaning for users than it had for users from a university hospital with 16 operating rooms. This difference had clear implications for designing the new surgical planning module where clinicians from the smaller hospitals generally preferred simplicity in use instead of the more complex functionality that typically was needed at a university hospital.

Another illustration is how differently the vendor’s developers and users understood surgery planning. While the vendor planned to develop a functionality in a business-like manner where activities could close at different steps of the surgical planning process to exploit the surgical resources better (personnel and operating rooms), the users argued that planning surgery was a continuous process that did not stop until just a few days before the surgery. Thus, the regional workshops had to take into account different contexts of patient care and treatments in the hospitals.

In this project, the vendor and the hospitals were committed to developing an EHR with highly structured content. Unfortunately, they had different understandings of how this should be achieved. Many users believed that they would get a structured record as part of the delivery of the new EHR. However, DIPS had in accordance with the openEHR architecture made it technically possible for the users to easily do this themselves. Accordingly, in the first pilots, the users missed the structured content. As a result, a national organization had to be established to standardize the EHR.

In addition, the different hospitals where the implementation occurred represent different socio-political and institutional contexts. The context, therefore, is complex, interconnected, and politicized, as health political decisions affect resources necessary to add affordances of, and accommodation of the record. For example, in one aspect it was quite easy to agree to centralize the IT portfolio in a regional version from the previous 11 hospitals. However, an emerging crucial question was who should run and control the daily operation (the regional ICT governance) and who should decide the functionality and use patterns. The university hospital took for granted that it should have this responsibility, but some of the smaller hospitals found this unacceptable. As a solution, in 2014 the University Hospital of North Norway (UNN) suggested a fragmented governance model in which each health trust, meaning each of the eleven hospitals in the region, should be responsible for regulating areas of the ICT portfolio on behalf of the others, meaning that one health trust would govern the EHR: One would regulate the laboratories, another radiology, and so on [21].

In addition, the historical process accounts for the dynamic and interwoven characteristic of the context and intervention. In 2011, contracts for the program had been signed, showing the different industrial actors involved. The web page presented some of the milestones: In 2011, Helse Nord Regional Trust signed a contract with Sectra, Tieto, and DIPS. In 2013, Helse Nord Trust signed a contract with CompuGroup Medical Norge (CGM), and Infodoc. In addition, the pathology systems in two major hospitals merged. In 2015, Helse Nord Trust signed a contract with Hove Medical Systems [7]. 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. Instead, the multiple and mutually dependent actors and interests depict a reality 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 FIKS web page and Facebook page, the goal is described as the 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, not to a defined and fixed intervention as assumed in RCTs. The notion rather refers to assumptions of a creative process as in "Design Thinking". One of the first features of the intervention was described in 2013: "Moving the databases of the hospitals in health region 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" [7].

New components were added to the service. Events were planned as an ongoing deployment process, and the program was described in terms of technical and operational events: the connection of the Narvik medical center to the Health Nords regional solution for electronic requisitioning of laboratory services (11/25/2015), the connection of the Leirfjord medical office to the Health Nord regional solution for electronic requisitioning of laboratory services (11/25/2015), the connection of the Nordreisa medical office to the Health Nords regional solution for electronic requisitioning of laboratory services (11/24/2015), the connection of Træna medical office to the Health Nords regional solution for electronic requisitioning of laboratory services 11/24/2015), and the connection of the Skjervøy medical office to the Health Nords regional solution for electronic requisitioning of laboratory services [22].

By distinguishing events this way, the foundation is laid for RCTs of each part of the process, but the resources needed for this endeavor would be vast. There are also connections between the parts, and therefore, it is difficult to single out clearly demarcated interventions. For example, the different hospitals had older versions of DIPS (DIPS classic) in play, as well as existing systems for other areas, such as the laboratory and radiology. The implementation of the new portfolio cannot be achieved without taking into account foreseen and unforeseen constraints (and opportunities) in the existing systems.

Based on this, the senior management found it was enormously risky to replace the existing portfolio in one stroke and decided to pursue a stepwise strategy in which different modules of the existing portfolio were replaced at a time [23]. This made it essential that the new system had to be compatible (data integration) with the old system since they were supposed to work together over several years. Since this also was a development project, it was easy for the users to give feedback to the vendor on what worked and what did not and how newer versions of the software should be tailored to the users' need. In this way, the implementation was far from clear-cut but had to be adapted based on existing practice, functionality in existing technology, and users' feedback.

Moreover, to make the software flexible to allow future configurations, the EHR was developed in accordance with the openEHR approach, which encourages users to make changes to the software themselves. In this way, the EHR will never be a finished product but will continue to grow and transform after it has been put into daily operation.

Another process that affected the implementation of the new EHR was another large-scale project that started in 2014. The goal of the project is to implement an electronic medication management (EMMS) system in the health region [24]. The EMMS and the new EHR are supposed to be closely integrated, meaning that many adaptions have to be made in both systems on what to integrate, when to integrate, and how to integrate them. Since the EHR and the EMMS are crucial systems for clinicians, and have much

overlapping functionality, it is not obvious in both projects how to establish the integration.

Currently, there is an ongoing discussion about which one of the two systems that should archive the master data (true version) of overlapping and integrated data. One example is information that a patient is allergic to certain medications or food, which is crucial information for the EMMS and the EHR.

When it comes to the affordances of FIKS, the web page states that the next-generation patient record is under development and is being tested in the region. Some milestones on the path to one common medical record were listed in 2016: There is one common medical record at the hospitals in Hammerfest and Kirkenes, the UNN employs regional radiology solutions, including a common radiology archive, and the hospitals in Helgeland, Mo I Rana, Mosjøen, and Sandnessjøen employ one common medical record (DIPS) [7].

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

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

The notion "roll out new ICT services before pilots are fully evaluated" involves the assumption that implementation is a linear, top-down, and controlled process of a ready-made intervention. In addition, it involves an assumption that implementation 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), a laboratory information system, radiology systems (Sectra, RIS, and PACS), joint pathology system in Tromsø and Bodø, and electronic requisition of laboratory services [22].

In 2011, DIPS decided to use the openEHR framework to develop its next-generation EHR for the hospital market [5]. 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 (EHR Development), Theater nurse meeting, Planning and booking DIPS Arena; 11.26.2015, Workshop (EHR Development), Theater nurse meeting, meeting with clinicians; 11/26/2015, Workshop (EHR Development), Decisions in psychiatry, new module in DIPS Arena; and 11/12/2015: Operation Planning (EHR Development) and meeting with clinicians at University Hospital of North Norway [7]. This process adds to the previously documented process of negotiating contracts with producers and vendors.

FIKS also designates and educates super-users and states that employees' competencies 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" [7].

The description of the implementation shows a multitude of inter-related operational, interactional, and relational processes. Thus far, the roll-out process has been far from linear, pre-defined, and controlled. It has, instead, been characterized by continuous interaction, discussions, and tensions between different users and between users and developers. In turn, this has transformed how the vendor collects requirements for functionality, how new functionality should be tested, and how and whom to include in the various steps of the design and implementation process.

For example, at the beginning of the project, the vendor invited users to define their requirements through user stories that were small descriptions (three to four lines) of work situations. The developers then used these stories as a basis when developing the new functionality. However, this appeared to be very problematic because due to the heterogeneous user group, it was difficult for the vendor to find coherence in the many (and diverging) user stories [25]. As an alternative, the vendor had to change the method for communicating with users.

The users now had to define steps of, for instance, surgery planning in a several-page document, and the process revealed that the steps were performed by different professionals: sub-specialized physicians, nurses, and secretaries. This diversity implied that the developers had to broaden their perspective to look beyond the physician's role. Even so, it became increasingly clear that the developers needed more contextual data, and therefore, they decided to spend more time in the hospital departments in order to identify what was needed of the new EHR in specific work situations [25].

The first pilot of a smaller segment of the new EHR conducted in a smaller hospital in southern Norway also revealed that there was a clear gap between the functionality offered in the system and what was needed in clinical practice. This gap underscored that users had to be even more involved in experimentation and testing of new functionality before it was put into action.

A crucial project management issue was that after four years of development, the UNN stated that it had spent too much user resources on the project and therefore wanted more in return from the vendor. It was difficult to come to an agreement on this, and a hospital in western Norway replaced the university hospital as the key collaborating partner in the development of the new EHR.

A linear, pre-defined, and controlled roll-out process is not present, as assumed in order for an ICT to be performed

and produce generalizable knowledge about the effects of an implemented intervention.

D. Summary and Discussion

Among the challenges in applying a HTA framework for the study of effects of an electronic patient record is that HTA tools form a coherent approach and draw on common basic assumptions. As shown in the accounts of FIKS, the assumptions differ from the empirical features. The basic assumptions of a stable reality where generalizable effects of a pre-defined intervention can be transferred to other settings via an operational and linear implementation process, fail to address the empirical features described. This issue has been discussed in different HTA bodies, related to innovation research. As mentioned in the introduction, two different models or approaches are described in the core model. The first of these is the linear diffusion model, which perceives new technology as an external stable entity that is brought to a (health care) system and induces change [26].

A competing paradigm, the translation model is also embedded in the core model. Within this model, technology is perceived to undergo changes as it interacts with the environment in which it is used. Hence, the final impact will not depend on the original technology only [26]. In the case of FIKS, both the technology, the health-care setting or environment, and the implementation process seem to be in a state of mutual translation. The findings, therefore, encourage openness to even more complexity than the two different models denote, in assumptions governing assessments. The empirical features of the applications and services connected to the record, are highly diverse and constantly in flux within the shifting social and organizational contexts.

Challenges were connected to the discrepancies between the RCT assumptions and the 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 on other assumptions are briefly addressed.

IV. COMPLEMENTARY ASSUMPTIONS: THE CONSTRUCTIVIST UMBRELLA

Challenges concerning the validity of evidence in the face of the involvement of different stakeholders have been articulated within the HTA tradition, which is looking to overcome such challenges. One HTA tool is consensus conferences with different stakeholders [26]. Such conferences have been investigated, and the following assertion strengthens the argument of a shifting social reality and the need to consider social relations as drivers for 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" [27]. This is a long quotation, which we have chosen to cite because it illustrates the fact that HTA institutions are highly up to date on the complexity of evidence production. The importance of addressing social and political interests and processes are clearly recommended in order to understand the way evidence can be produced and affect the results of ICT use in health services.

In contrast to assumptions in RCTs about a stable and objective reality, a fixed intervention, and a linear and controlled implementation process, constructivist traditions assume that flux occurs. This comprise that reality is under development, the interventions are subject to change, and implementation is partly unpredictable and depends on, for instance, resource allocation. Implementation is considered an ongoing process where certain types of support or lack of support strongly influence the outcome. Therefore, it is not considered possible to generalize evidence-based outcomes to repeat good results in new or future settings. Within such traditions, a formative idea exists. It implies to feed assessment results, which are produced along with the development processes, back into a pragmatic and political process of deciding priorities and allocating resources to pursue them.

In this perspective, validation is 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 [28].

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

In a paper building on discussions in the annual meeting in 2016 within HTAi, the topic of changing HTA paradigms was addressed [29]. The new HTA paradigm is characterized by a more agile and adaptive HTA process across the life cycle of technologies, reacting quickly to new and real life data when they become available or when changes in the technology life cycle emerge; assessment methods and language that go beyond incremental cost-effectiveness ratios, incorporating meaningful results for clinicians and patients; where information on what the health system and patients need from innovation, and what the health system may need to do to get value from it, is

discussed through the lens of health services delivery and product lifecycle; through multi-lateral stakeholder dialog and collaboration that addresses health needs and product conceptualization; through development, evaluation, introduction, and appropriate use in a changing landscape as other developments come on stream.

As the last point in this discussion, we focus on research networks and institutions where assessments and evaluations have been carried out, explored, and substantiated over more than three decades. We briefly introduce several papers and highlight basic assumptions. The point is to highlight shared basic assumptions to comment on a discussion of the need to unite networks to develop more operational approaches to assessments of e-health, as well as to unite forces.

What seems to characterize some of the research networks, is that papers have been produced periodically. Constructive technology assessment (CTA) was introduced in the 1990s [30]. It shifts the focus away from assessing impacts of new technologies to broadening design. This approach in general, assumes that design and assessments are co-producers of innovations, a dynamic and processual view of the context, intervention, and implementation processes [31]. Numerous papers were published around the start of the 1990s. Around 2005, a new wave of papers were published on the subject; see, for instance, Genus, who discusses assumptions of stakeholders and democratic processes as foci important for assessing added value [32]. Since 2013, papers and books have addressed pragmatic evaluations, and different institutions seem to share basic assumptions of dynamics and the use of real life data. Monitoring data is, for instance, a fast-growing option for knowledge production that invites collaboration between different assessment networks and units [33]. This point has been promoted by the Organization for Economic Cooperation and Development (OECD). Scholars have also recently argued for the need to unify the efforts of different evaluation and assessment networks; see, for instance, [34].

What is suggested for a new paradigm in HTA seems to reflect a combination of two broad traditions, the positivist as in RCTs and the constructivist as briefly outlined. To bridge the gaps between the assumptions of the two traditions, the positivist and the constructivist, should be important to produce valuable e-health assessments. This point was also noted by Ammenwerth et al. [35]. 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.

The different networks and institutions briefly introduced in this section are the Science and Technology Studies network (STS) and the Medical Informatics network. Another research environment to consider is various social science networks, which have a long tradition for theoretically advanced assessment approaches. In this short introduction, we mention the book by Guba and Lincoln called “Fourth Generation Evaluation” [36]. The book was followed by a number of discussions on “naturalistic inquiry”. Fourth Generation Evaluation moves beyond science to include the myriad human, political, social, cultural, and contextual elements that are involved in processes of change. Based upon relativism, a unity between knower and known, and a subjective epistemology, the authors show how the concept fourth generation evaluation unites the evaluator and the stakeholders in interaction to co-create the product of the evaluation.

All these networks are highly present communities in assessments of e-health and telemedicine. Their work should be considered, as well as initiatives within the OECD domain. We also introduced the MethoTelemed Team [20]. As a follow-up of the work in [20], this team is currently embarking on a review to assess telemedicine and e-health assessments, the methodologies used, as well as the review author’s conclusions. This work should provide additional clues about how different traditions have developed concerning assumptions and approaches. This work could strengthen the knowledge base for discussing joint forces.

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? Who does it work for? 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? Who owns the definition of success?

This paper focused on the fluctuating character of reality, interventions and implementation processes alon with the development of FIKS. Nevertheless, the three elements have some stable features. In process approaches, investigations are directed toward the conditions included in the development processes, to feed the 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, and patients) and the organizational, economic, political, and ideological settings in which these practices are embedded. This approach is formative. The intervention also contributes to shaping these settings as the approach pre-supposes that all entities are in a process of mutual shaping. Influence and success are empirical questions, in turn, potentially enacting different answers in each situation assessed. Obtaining the power to control conditions will be the crucial task for the future results of innovations. Power may be based on participatory or top-down models. Process investigations may produce knowledge to understand how successes are defined, produced and maintained.

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 even if the HTA communities have not been extensively attentive to e-health. E-health communities have also not been attentive or interested in HTA. Steps to unite different research networks and institutions that make profound efforts to address the vast task of assessing ICTs in health care are also timely. Approaches that take into consideration dynamics and complexities in contexts, interventions, and processes of implementation are discussed in all communities. Knowledge about the 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. We suggest further exploration of assumptions that encourage participatory and process assessment approaches. Such assumptions will strengthen the knowledge base for future procurements, as human interactions play important roles in the development. We also recommend controlled studies of stable components of e-health.

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