



Norwegian Centre for  
E-health Research

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## Changing Health Technology Assessment Paradigms – Rethinking Basic Assumptions for e-HTA?

Anne Granstrøm Ekeland

PhD

[Anne.Granstrom.Ekeland@ehealthresearch.no](mailto:Anne.Granstrom.Ekeland@ehealthresearch.no)

[www.ehealthresearch.no](http://www.ehealthresearch.no)





# CHANGING HEALTH TECHNOLOGY ASSESSMENT PARADIGMS?

- Don Husereau , Chris Henshall, **Laura Sampietro-Colom**, SarahThomas
- International Journal of Technology Assessment in Health Care, 32:4 (2016), c  
Cambridge University Press 2016. doi:10.1017/S0266462316000386 Policies



# Claudia Stein

## *Opening Ceremony*



### The European health reports

- WHO Flagship corporate publication every 3 years;
- Reporting on implementation of Health 2020 for health & well-being;
- **2018 report will report on progress with new concepts, including community resilience.**
- Paradigm shift from purely quantitative to inclusion of qualitative evidence to report progress;
- 'New evidence for the 21<sup>st</sup> century' – a mixed methods approach.



HEALTH EVIDENCE NETWORK SYNTHESIS REPORT 49  
Cultural contexts of health: the use of narrative research in the health sector

Highly commended  
BMA Book Awards  
2017

 World Health Organization  
Regional Office for Europe

rsary Year

@EPHConferenc





# Agenda

1. Health Technologies in HTA
2. Electronic Health Records as Health Technologies?
3. Gold standards i HTA
4. Basic Assumptions in HTA
5. Assessment of a large scale EHR-program in Norway: FIKS
6. Examples of empirical features of FIKS related to assumptions in HTA
7. Rethinking assumptions and some future trajectories for e-HTA



# References

- Ekeland, A. G. and G. Ellingsen, *Assessing an Electronic Health Record (EHR): How Do Basic Assumptions in Traditional Health Technology Assessment (HTA), and Empirical Features Fit?* International Journal on Advances in Life Sciences, vol 9 no 1&2, 2017,

[http://www.iariajournals.org/life\\_sciences/lifsci\\_v9\\_n12\\_2017\\_paged.pdf](http://www.iariajournals.org/life_sciences/lifsci_v9_n12_2017_paged.pdf)

- Ossebaard, H.C., van Duivenboden, J. and Krijgsman, J.: *Evaluatie van eHealth-technologie in de context van beleid (Evaluation of eHealth technology in a policy context)* DOI: 10.13140/RG.2.2.17002.31688

[https://www.researchgate.net/publication/317544956\\_Evaluatie\\_van\\_eHealth-technologie\\_in\\_de\\_context\\_van\\_beleid\\_Evaluation\\_of\\_eHealth-technology\\_in\\_a\\_policy\\_context](https://www.researchgate.net/publication/317544956_Evaluatie_van_eHealth-technologie_in_de_context_van_beleid_Evaluation_of_eHealth-technology_in_a_policy_context) ISBN 978-90-820304-8-8



# Health Technologies in HTA

- Health technologies comprise “Diagnostic and treatment methods, medical equipment, pharmaceuticals, rehabilitation and prevention methods, but also **organizational and support systems used to deliver healthcare**”. Eunethta, HTA Common Questions. [Online]. Available from: <http://www.eunethta.eu/about-us/faq#t287n73>  
2016.03.14



# Electronic Health Records as Health Technologies?

- The EHR comprises technology, but also involves organizational structures, routines, communication and decision support components
- In that respect, the EHR can be embodied under the concept of a health technology, albeit a complex one:
- The EHR stores, organizes and communicates vulnerable information with ethical and legal implications, facilitates social interaction and relationships, and both demands and support competencies among users (e.g., doctors, nurses, and patients) which are necessary to deliver quality health care
- It therefore affects domains that are considered crucial for HTA



# HTA and gold standards

- Different products have been developed to support knowledge-based decisions in health care, such as systematic reviews, meta-analyses, economic modelling, and case- or experimental assessments of new medical methods and devices
- These tools draw on basic philosophical assumptions and form a coherent approach
- In HTA, randomized controlled trials (RCTs) are the gold standard approach, building on a coherent set of basic philosophical assumptions
- Knowledge summaries of RCTs are considered to provide the best evidence for effects





# What are the basic philosophical assumptions underlying RCT?

- I now take a closer look at the basic assumptions in RCT compared to empirical features of the EHR program FIKS
- Why was it difficult to use RCT to assess the EHR program?
- One explanation (but not the only one) is connected to basic assumptions



# Basic Assumption One

- There is a **singular reality or object of study** amenable to objective scientific measurement to provide universal evidence for the outcome of a specified intervention: The EHR then had to be assessed in a clearly defined setting
- Human bodies, for instance, are assumed to be relatively unified and mainly react similarly to a drug, so that general conclusions can be drawn about its effects
- A stable context is assumed and set up for the experiment, so that causal variables and links can be identified to generalize and repeat the outcome



## Basic Assumption Two

- A second assumption underlying RCTs is a **clear demarcation and definition of the intervention to be assessed**, including a fixed start and endpoint



# Basic Assumption Three

- In innovation processes, a **linear and controlled process of implementation is assumed**
- Accordingly, readymade technological applications are expected to be rolled out to an organization and their effects to be objectively assessed and transferred to similar other settings



# The FIKS program

- FIKS is a large-scale program for developing and implementing a new electronic health record system, running from 2012 through 2016. The costs were estimated at EUR 90 million, and the vendor (DIPS) is the largest EHR vendor in Norway .
- The aim was 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



# Assumption One: A Unified Reality Amenable to Scientific Measurement and Control

- The organization where FIKS should be implemented consisted of different departments, partly depending on each other, representing numerous interests trying to accomplish a unified vision
- The assumptions for the conduct of an RCT; a relatively unified reality where measurements could be undertaken, were not reflected in the empirical features of the organizations and their socio-economic contexts
- Instead, the multiple and mutually dependent actors and interests depicted a complex reality, under development and flux, involving negotiations, shifting political conditions and resources
- Obtaining similar outcome of the intervention in different units was not possible



# Assumption Two: A Clear Demarcation and Definition of the Intervention

- In FIKS, the intervention consisted of multiple, developing, and mutually dependent components and processes
- The content was partly defined through participatory processes with different user groups
- Accordingly, the users had to negotiate and compromise in order to agree upon standards within the intervention across organizational boundaries



# Assumption Three: Implementation as a Linear and Controlled Operation

- In 2011, the vendor decided to use the openEHR framework to develop its next-generation EHR for the hospital market. This involves negotiations on development directions. Interaction between different participants in the process is a collegial and interpersonal process, expected to affect the features through dialogue and negotiations.
- This is the opposite of a top down and streamlined roll out process





# Dynamics between object of study, intervention and implementation processes

- 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 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
- Accordingly: the intervention was developing and adapted to certain organizational user groups, the other ones had to adapt to the intervention
- Accordingly: the implementation process did not run smoothly, some were happy, other ones were not



# Summary

- Among the challenges in applying a traditional 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
- In the case of FIKS, both the technology, the health-care organization and the implementation process seemed to be in a state of mutual translation and adaption – inter-dependencies
- The basic assumptions of a coherent study object (reality) where generalizable effects of a pre-defined intervention can be produced and transferred to other settings via an operational and linear implementation process, failed to address the empirical features



# Alternative models in HTA

- In HTA bodies, two different models or approaches are described in the core model, related to innovation research
- **The linear diffusion model**, which perceives new technology as an external stable entity that is brought to a (health care) system and induces change
- **The translation 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



# An alternative: Constructivist models

- Constructivist traditions assume that flux occurs:
- Reality is considered to be under development
- The interventions are subject to change, and
- Implementation is partly unpredictable and depends on, for instance, resource allocation.
- **The “final” impact will not involve either the original technology, the original organization or the originally planned implementation process**



# Challenges and solutions

Stable and objective evidence, predictability and transferability of e-health is difficult to obtain because:

1. Socio-political contexts differ, and negotiations and interdependencies may produce different results in different contexts
2. In future “deployments” of the technology investigated, the technology will seldom be similar because of the rapid pace of development



# Conclusion

- Conclusion: HTA must (in addition to investigations of effects) also:
- Dynamically assess the inter-dependencies between object of study, intervention and processes of implementation and account for differences as well as conformities in different contexts
- Assess how actors creatively use e-health in different contexts



# The main message of this presentation

- Contexts, objects of study, interventions and implementation processes are differentiated, inter-dependent and dynamic
- In order to assess e-health and m-health, such assumptions should guide approaches within HTA to help produce more relevant knowledge to the benefit of both policy makers, professionals and patients
- A systematic approach that comprises posing the right questions, cooperating strategically and using multiple sources can reduce uncertainty, facilitate decision-making and support right innovations in health
- Mixed methods and evidence in context should be further explored



Thanks for your attention

[anne.granstrom.ekeland@ehealthresearch.no](mailto:anne.granstrom.ekeland@ehealthresearch.no)