The Influence of Researchers, Clinicians, and Legislation on one another, and the Effects on Electronic Health Records

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction: The Key to Improving EHRs

Governmental legislation requires that hospitals adopt electronic health records (EHRs), yet the dynamic between clinicians, researchers, and legislators in developing EHRs remains unexplored. Effective EHRs help detect fraudulent billing practices, improve the shareability of patient files, and promote data analysis. However, engineers and scientists are not heedless of the flaws and negative consequences of EHRs. Poorly designed EHR user-interfaces pose a risk to clinician health and quality of patient care. Convoluted and inefficient EHRs increase susceptibility to physician burnout, reduced face-to-face patient time, and increased work-load (Arndt et al., 2017). Furthermore, misdiagnoses due to glitches in EHRs may threaten patient safety. Scientists, engineers, and doctors constantly work towards eliminating such limitations. The key to creating well designed and effectively integrated EHRs lies in identifying the balance between the actors behind the scenes of EHR development, as well as identifying the positive and negative consequences of EHRs in medical practices.

Conclusions drawn from an analysis of EHRs through the lens of Sheila Jasanoff's theory of coproduction provide physicians with suggestions for more efficiently implementing changes to EHRs and better promoting EHR research to ultimately guide the improvement of future EHR iterations. The theory of co-production reveals the interconnection and professional dynamic between EHRs, doctors, patients, hospitals, legislation, and medical technology; all of which influence one another and the success of EHRs in hospital systems. The theory of co-production also provides a framework for an anthropological analysis of EHRs. The following STS research question is proposed: **How do health system actors influence one another in the development of electronic health records since their introduction in the 1960s?** The STS research question

analyzes the nuances of designing health care records and the associated implications on EHRs, as well as health care systems and practices.

Research Question and Methods: Dissecting EHRs

Analyzing health care systems and practices with respect to the introduction and growth of EHRs highlights the social implications of EHRs on patient-care. The STS research question—**How do health system actors influence one another in the development of electronic health records since their introduction in the 1960s?**—unravels interconnectedness between clinicians, researchers, and legislators that dictates the design of EHRs. Documentary analysis and historical case studies guide the results and analysis presented in this investigation. The data assembled for the documentary analysis and historical case studies includes scientific and peer-reviewed articles pertaining to current and previous electronic medical technology; secondary sources of paper health records, organized chronologically; and comments from medical professionals regarding their experiences with electronic medical technology, respectively. The New England Journal of Medicine, British Medical Journal, AnthroSource, JSTOR, and PubMed present literary sources for the documentary analysis and historical case studies. Key words include evolution of EHRs, history of EHRs, and EHR legislation. Paper versions of patient health records, prominent before the 1960s, serve as a basis of comparison for the current user-interface of EHRs. Clinicians interact differently with electronic interfaces than they do with hand-written, paper documents. Documentary analysis and historical case studies establish a cohesive set of results that effectively unravel relationship between the actors that influence the evolution of EHRs since their introduction in the 1960s.

Intended Purpose of EHRs

While hospital culture and hospital hierarchies mirror those of the nineteenth century, the exponential growth of technology introduces medical devices, techniques, and data platforms that are startlingly different from the early stages of medicine (*The Law of Accelerating Returns | Kurzweil*, n.d.; Thimbleby, 2013). Even seemingly simple technologies may cause ripples in the social network of health care systems. Take the transition from paper to electronic prescriptions, for example. Patient's now leave doctor's appointments empty handed without physical prescriptions that once reminded them to pick up drugs from the pharmacy (Thimbleby, 2013). EHRs are not exempt from the cosmic effects of technology on health care systems.

EHRs extend beyond the basic medical encounters between doctors and physicians. They pervade and transform all realms of clinical care in both positive and negative ways. One negative effect of EHRs is that they transform patients into digital entities that doctors no longer see as individual persons (Hunt et al., 2017). Additionally, unintended glitches in EHR platforms also tarnish and disrupt the integrity of medical systems. For example, Annette Monacelli fell victim to a glitch in the EHR software, eClinicalWorks; her doctor ordered a critical brain scan necessary for ruling out the possibility of an aneurysm and made note of the request in her EHR, but the order never reached the lab (*eClinicalWorks Responds To $155 Million Settlement That Rocked The Healthcare IT Industry*, n.d.). Physicians support EHRs in concept—the ability to work remotely, reduce paperwork, and enhance patient privacy (*What are the advantages of electronic health records? | HealthIT.gov*, n.d.). However, many physicians dislike EHRs in practice. The current state of EHR technology is time-consuming, non-intuitive, and interferes with face-to-face patient care (Chen et al., 2013).

Whether the pros outweigh the cons, or vice versa, remains a topic of debate. This investigation presents a thorough analysis that clearly defines the relationship between the actors that influence the development of EHRs. EHR developers can thus consider the relationships isolated in this investigation to effectively implement change, and ultimately improve the balance between new technologies and effective patient care.

STS Framework: Theory of Co-production in the Context of Medical Systems

Physicians, patients, legislators, and technology constantly interact with one another, making hospital systems very complex and dynamic. Defining the relationships between the actors in hospital systems from an STS perspective helps pinpoint the means necessary for revising or improving EHRs. Sheila Jasanoff's **theory of co-production** helps form such relationships.

Jasanoff, Pfsorzheimer Professor of Science and Technology Studies at the Harvard Kennedy School, defines co-production as "the simultaneous process through which modern societies form their epistemic and normative understandings of the world" (*Jasanoff—Co-production.pdf*, n.d.). The theory of co-production unravels the influence of stakeholders (medical professionals, patients, and researchers), physical artifacts (paper medical records and computers), and non-physical artifacts (government legislation and software) on one another. The influence of these actors traces the relationship between electronics and health care systems, as well as the ways in which they shape EHR systems.

While Jasanoff argues that thinking of the natural and social orders that are produced together provides explanatory power, critics argue that the theory of co-production fails to encompass the coproduction of scientific knowledge and social order (Swedlow, 2012). However, applying the natural and social orders explored through the theory of co-production to

scientific knowledge still provides valuable feedback. The theory of co-production encourages an anthropological analysis of EHR system technologies. Humans exist at the heart of healthcare systems because society established and maintains the medical industry. Anthropological analyses are thus essential for diligently and meticulously researching the effects of EHRs on healthcare systems.

Results and Discussion: The Role of Various Actors in EHR Development

Medical workers and government officials share the same goal: protect the public and support the greater good. The commonly established goals between these actors set the objectives, standards, and framework that ultimately affect EHR systems. Researchers and doctors must comply to the law, while the lawmakers must consider the importance of supporting medical research. Exploring the co-production of the scientific community and legislation paves the way for understanding the factors contributing to EHRs and the steps necessary for improving future EHR systems (Figure 1). The actors behind EHRs continuously review the side-effects of EHRs to prevent adverse effects. Identified positive and negative qualities then feed back into the system outlined in Figure 1, and the cycle begins again.

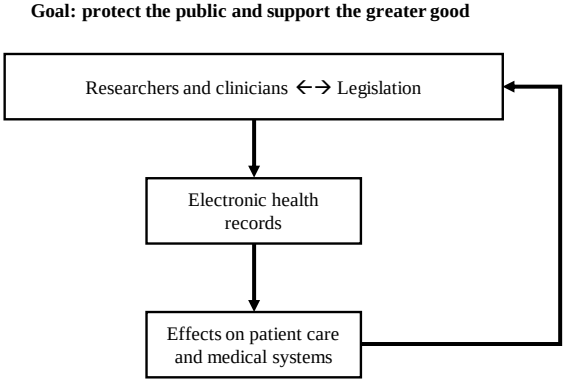

Figure 1 Co-Production of Researchers and Clinicians, and Legislation in Influencing Electronic Health Records (Ghajar-Rahimi, 2019)

Although the effects of EHRs on hospital systems remain subjective, the relationships defined below will help resolve the discrepancies between EHRs in theory and EHRs in action.

Role of Researchers and Clinicians

Tracing the origin of the structure of modern medical records highlights the role of the stakeholders, researchers and clinicians, in developing EHRs. While EHRs, a non-physical artifact, are rapidly replacing paper medical records, a physical artifact, the purpose of medical records has remained the same.

In 1968 Lawrence Weed, MD, created the Problem-Oriented Medical Record (POMR) with the intention of providing structure to the multiplicity of problems that clinicians face on a daily basis (Jacobs, 2009). POMRs supplement medical analysis and help doctors make more informed decisions. Although Dr. Lawrence initially created POMR with paper medical records, the five components of POMR have influenced the organization of past and present EHRs (Schultz, 1986):

I. Database: thorough patient information
II. Complete problems list: list of problems
III. Initial planning: diagnostic, therapeutic, or patient education
IV. Daily progress notes: commentary on patient's status
V. Discharge summary

Even when existing outside the realm of electronics and technology, clinicians serve a crucial role in the development of medical products by setting precedence with their own practices or supporting medical technology. As EHRs continue to advance, more and more clinicians recognize that the capabilities and applications of EHRs exceed those of paper medical records and that the future of medicine lies in technology. In an interview conducted by Dr. Lee

Jacobs in 2009, Dr. Lawrence stated that he "realized that medicine must transition from an era where knowledge and information processing capacity resides inside a physician's head to a new day where information technology would provide knowledge and the processing capacity to apply it to detailed patient data" (Jacobs, 2009). Dr. Lawerence's statement reflects the role of clinicians in recognizing clinical needs and in acting as motivators for technological innovation. Although clinicians and researchers are the leading forces in advocating for medical advancement, they rely on funding, public support, and governmental support to put their research plans into action; whether that be marketing a new technology or changing the structure of an entire hospital system. Therefore, the ability of a researcher or clinician to apply his/her feedback relies on gaining either financial and/or social support. Clinicians and researchers, and external parties must effectively share their knowledge with one another to ensure that medical devices, including EHRs, are effective and worthwhile for the patients.

This significance of clinician feedback in medical design also exists in small scale projects. The biomedical engineering capstone project, *The Development of Infectious Diseases Data Analysis Program (IDDAP)*, creates a proof-of-concept for user-friendly patient data analysis programs that may be integrated into future iterations of EHRs (Ghajar-Rahimi, Hughes, Mahoney, 2020). Before submitting a project proposal, the capstone group met with Dr. Joshua Eby in the Department of Infectious Diseases at the University of Virginia to better understand the clinical need of data analysis programs. The capstone project proposal was then formed around the feedback Dr. Eby provided during the interviews. Dr. Eby's feedback directly shaped the format of IDDAP.

Doctors can also influence the laws and legislation which affect both them and EHR systems as a whole, and consequently patients in EHR systems. International review boards

(IRBs) serve as a good example in which the scientific community influences policy and decisions that affect medical research. IRBs are constituted groups formally designated to safeguard patients and participants in behavioral and biomedical research in the United States (US), as well as more than 80 other countries (Grady, 2015). IRB committees include at least one individual experienced and trained in scientific areas; for example, a clinician or medical researcher (*Institutional Review Board | Human Research Protection Office*, n.d.). In accordance with FDA regulations, IRBs govern the right to approve, modify, or disapprove research (Commissioner, 2019). US research institutions must comply with IRB regulations in order to receive US government funding; this also applies to non-US research that the US government funds (Grady, 2015). The individuals with scientific backgrounds on IRB committees contribute to the IRBs decision making process, therefore either enabling or preventing research projects. The effect of researchers and clinicians on legislation and decision-making processes goes both ways.

Role of the Legislation

The US government provides funding for both national and international medical research projects. Therefore, the US government requires that the funded institutes researchers comply to a set of ethical and medical standards.

EHRs inherently rely on patient information, and thus, pose ethical concerns with patient privacy and the bioethics principle of nonmaleficence. The principle of nonmaleficence is rooted in the Hippocratic maxim and requires that persons in clinical medicine and scientific research do not intentionally harm or injure patients (*Principles of Bioethics | UW Department of Bioethics & Humanities*, n.d.). When personally identifiable health information is released to unauthorized individuals, the patients may become embarrassed, discriminated against, or

subjected to social stigmas. Maintaining privacy and protecting sensitive patient information in EHR systems encourages more effective communication between physicians, researchers, and patients; a symbiotic relationship. Furthermore, individuals are more likely to participate in research when their privacy is protected and are more likely to provide accurate and complete data or information (Nass et al., 2009). The thoroughness and accuracy of data dictates the reliability of results drawn from medical research studies. The more trust worthy a medical study is, the better the outcome will be for a patient when results from the study are applied in practice. Subsequently, data collected and analyzed using secure methods are less vulnerable to ethically controversial issues than data collected in a non-protected manner. The Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH) act are two prominent contributors to enforcing and protecting patient autonomy, consent, and privacy. The regulations outlined in HIPAA and the HITECH act set expectations that clinicians and researchers, including those developing EHRs, must abide to.

HIPAA, established by the federal government in 1996, institutes a minimum set of guidelines for increasing the security of patient data and personal health information (*HIPAA and Health Information Technology*, 2017). Specifically, the HIPAA Security Rule provides a set of national security standards for the "protection of all electronic protected health information that [covers] entities and their business associates create, conceive, maintain or transmit" (*HIPAA and Health Information Technology*, 2017). Researchers and institutes must put administrative, physical, and technical safeguards in place to shield patient information in EHR systems. Subsets of the Security Rule require that covered entities calculate the cost of security measures, conduct risk analysis, limit physical access to facility and control areas, and provide appropriate authorization and supervision of individuals working with the EHR system (Rights (OCR),

2009). These legislative requirements set the bounds for program functions that clinicians and researchers can implement when designing EHRs. These requirements also set a standard of expectations that the EHRs must satisfy prior to commercialization. Henceforth, an inseparable relationship forms between legislators, clinicians, and researchers in creating EHRs.

Believing that EHRs increase the quality and efficiency of patient care, the US government created the HITECH act in 2009 to increase the adoption of EHRs. Governmental encouragement of the meaningful use of EHRs in hospital systems pushes hospitals to change their current practices, creating a relationship in which the government and clinicians must work together. The HITECH act promotes the development of EHRs. More specifically, the title IV of the HITECH act provides incentive payments for institutions and practices that EHRs. This increases the demand for further improving EHRs, and consequently drives the research industries that design and implement EHRs. EHRs then continue to adapt and change, as do the patients. The strength and structure of EHRs, influenced by the actors involved with developing EHRs, directly influences the quality of patient care.

Discussion: The Vacillation between Scientist, Clinician, and Legislator Decisions

As stated in the theory of co-production, "the ways in which we know and represent the world are inseparable from the ways in which we choose to live it" (*Jasanoff—Co-production.pdf*, n.d.). People and institutions produce scientific knowledge and technology. Simultaneously, scientific knowledge and technology affect the actions of people and institutions. The actors and technology feed off of one another in a dynamic state. The vacillation between the scientific community, clinicians like Dr. Lawrence; and legislation, such as the HITECH act, never ceases. Clinicians and researchers comply to US regulations, while also partaking in the decision-making process of the regulations themselves. Ultimately the co-

production of researchers and clinicians alongside legislation instigates the properties of EHRs that pose downstream effects on patients. The truth behind the effect of EHRs on hospital systems lies in the co-production of the scientific community and medical legislation. Unlocking the co-production of these two entities creates a method for effectively implementing revisions to EHRs by working alongside the scientific community and lawmakers that influence EHRs.

When used properly, EHRs provide three overarching benefits: better informed clinicians and researchers, improved relationships, and improved workflow. User-friendly and advanced EHRs include tools for medical professionals to visualize data values overtime and to quickly conduct data calculations (body mass index, Framingham calculators, etc.) (Manca, 2015). Effective EHRs also include alert and reminder features for providers, as well as improved access to laboratory data (Manca, 2015). Observing long-term trends in patient symptoms and responses to medication amongst other things, is crucial to treating chronic diseases which are characterized by persistent, long-term issues. These diseases include diabetes, arthritis, and any unknown disease or symptom that lasts for more than three months. The introduction of EHRs has helped clinicians better observe the long-term trends in patient data that are necessary to treat chronic illnesses. EHRs, unlike paper medical records, includes information from all physicians involved with a given patient and all involved physicians can independently access the patient's data (*What are the differences between electronic medical records, electronic health records, and personal health records? | HealthIT.gov*, n.d.). Consequently, EHRs improve cross-disciplinary collaboration amongst all entities involved in patient treatment. For example, in 2009, a longitudinal survey of 86 primary care clinicians measured changes in primary care clinician attitudes towards EHRs over the course of a year following implementation (El-Kareh et al., 2009). The study concluded that although clinicians may initially perceive issues with a

new EHR, they become "more receptive to [the EHR] within 1 year of implementation"(El-Kareh et al., 2009). The existence of medical notes, chart summaries, prescriptions, electronic medical billing, and scheduling in a single source improves patient-physician relationships. EHRs and electronic medical records give patients access to their own health records. With the ability to track their own health, patients can more readily manage their own care (Manca, 2015). In a National Physician Survey in 2015 across Canada, 65% of doctors said patient care became better or much better after they implemented electronic records and less than 5% reported that electronic records negatively impacted quality of care (Collier, 2015). The storage systems that host EHRs occupy less physical space than paper medical records, while also including more in-depth patient information. EHR storage systems are reservoirs for patient information and allow medical professionals to view a larger number of patients.

Future Studies and Limitations

The scope of this STS study focuses on the co-production of EHRs and legislation within the US, limiting the broad range applicability of the conclusions drawn. Research standards and governmental legislation greatly differ between countries. Therefore, this study is not representative of the effect of EHRs on hospital systems worldwide, but rather a localized study for US medical practices. Additionally, the subjective nature of qualitative research that leaves scholars waffling over the advantages and disadvantages of EHR systems. Studies exist both in favor of and against the implementation of EHRs. Most importantly, the push for world-wide acceptance of EHRs relies on the assumption that hospital systems use EHRs meaningfully and properly. While researchers and lawmakers seek to benefit the greater good, a schism exists between EHRs in theory and in action. One must also note that the complexity of EHRs and hospital systems makes it impossible to embody every actor with a single methodology.

Applying the actor network theory in future STS projects exploring the effects of EHRs on hospital studies will improve the thoroughness of this analysis. Tracing the evolution of health records, starting with the oldest evidence of paper health records and ending with modern technology will shed light on the nuances of recording health information and the day-to-day tasks of clinicians.

Conclusion

Researchers, clinicians, and lawmakers co-produce one another in the process of developing EHRs. These actors form a never-ending cyclic relationship with EHRs, as they assess the implications of their technology on hospital systems. The theory of co-production presents the scientific community and legislation as a fluid unit that vacillate back and forth. The framework described in this STS topic will help clinicians fully unlock the potential of EHRs. Exploring physician, researcher, and lawmaker perceptions of one another, as well as their perceptions of EHRs, lights the way for effectively implementing change. Additional research is required to overcome the subjectivity that limits researchers in concretely deciding whether EHRs uphold the promise of improving healthcare systems.

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