Executive Summary

Electronic health records (EHRs), or digital copies of patient medical records, have gained momentum due to their ease of use and aid in enhancing medical care. However, security concerns on the regulation of EHRs pose a threat to patient safety and privacy. To better support EHRs in their mission to provide access to health information while maintaining secure standards, federal legislation on EHR information sharing, clarification on privacy standards, and physician training are all necessary.

Background Information:

Electronic health records (EHRs) began to gain traction in the late 1900s as a "communication tool that supports clinical decision making, coordination of services, evaluation of the quality and efficacy of care, research, legal protection, education, and accreditation and regulatory processes" (Harman et al., 2012). They were created with the intention of establishing streamlined processes to support these efforts, and were additionally intended to mitigate the drawbacks associated with maintaining paper records. Despite initial pushback due to issues such as misspellings, security issues, cost, and undertaking the task of learning a completely new system, they became popular following establishments of standards for electronic health records, such as the HL7 EHR-S, and as a result of publications from the Institute of Medicine that supported the use of EHRs through enumerating associated benefits (Harman et al., 2012).

There is a large quantity of stakeholders involved in updating, maintaining, and utilizing electronic health records. Just to list the large stakeholders, service providers, insurance companies, health care providers, physicians, and patients all interface in some capacity with electronic health records. Each stakeholder plays a unique role in how they interact with electronic health records. Service providers develop, maintain, and distribute the service of EHRs and are in charge of adding updates to the softwares and handling technical issues. Insurance companies use EHRs to evaluate new customers and determine which medical procedures of existing customers to cover. Health care providers use electronic health records to connect patients to specialists and other physicians. Physicians use EHRs in an extremely direct way - they often update the record and use it to order prescriptions or medications, and can use the record to determine the need for additional medical procedures, tests, or scans. Patients use EHRs primarily to access their records and also are the recipient of the care facilitated by the other stakeholders as a result of EHR usage (Harman et al., 2012). Each stakeholder contributes differently to the efficacy of EHRs.

Amongst these stakeholders there is a large number of "big players" that dominate the market share of some of these stakeholders. Particularly, there are many service providers of

EHRs nationally and worldwide, however, a few big ones, namely Epic, Cerner, and Allscripts dominate the market share of electronic health records (Landi, 2020).

Interoperability is a concept about the sharing of electronic health records across other systems. As per the 21st Century Cures Act, interoperability is defined as "(A) enabl[ing] the secure exchange of electronic information from other health IT without special effort on the part of the user; (B) allows for access, exchange, and use of all electronically accessible health information for authorized use; and (C) does not lead to information blocking" (TigerConnect, 2022). Electronic health records are under interoperability standards. The most widely recognized set of standards for EHR interoperability are the Fast Healthcare Interoperability Resources (FHIR) (TigerConnect, 2022). Interoperability was unfortunately not one of the main priorities of EHRs when they first began to emerge, and as a result, many stakeholders that would benefit from interoperability are finding this as a primary issue that is challenging to resolve retrospectively.

Implementation and Issues

Although EHR adoption has followed an increasing trajectory of usage due to government and market-based incentives, its implementation is not effectively reaching all of its goals. According to a paper by the American Medical Association, some of the primary challenges associated with electronic health record usage include "issues with care coordination due to lack of interoperability," "increased cognitive workload for physicians," "insufficient support for incorporating end-user input into product design" (American Medical Association, 2014). The challenges compound upon each other to place a high burden on health care.

The issue of care coordination because of insufficient interoperability is challenging due to both technical reasons and cultural reasons. Out of the hundreds of EHR products, each product has distinct "clinical terminologies, technical specifications, and functional capabilities" (Reisman, 2017). These technical distinctions make EHRs difficult to standardize. However, the arguably larger issue is that effective interoperability would require a cultural shift in the realm of healthcare. Greater interoperability would necessitate more collaboration amongst the stakeholders, including the patients, which is difficult to do when the focus of some stakeholders conflict with each other, such as the tension between prioritizing profit and receiving the effective, affordable health care. Along with this, the United States healthcare system is known for having "a culture defined by silos, fragmented processes, and disparate stakeholders, and where data [is] more of a commodity and competitive advantage than a basis for coordinated care" (Reisman, 2017). Surveys results indicate that across EHR systems and hospitals, there is a prevalent problem of selective information sharing, or information blocking, and also health systems "routinely coerce providers to adopt and use certain EHR technology rather than simply make it possible to collaborate across these technologies" (Reisman, 2017). Other respondents also reported EHR service providers charging anywhere up to \$50,000 to connect their services to the services of another EHR service provider (Reisman, 2017). This hinders the ability for

multiple stakeholders, including physicians and other healthcare providers to provide appropriate medical care to patients; these challenges result in poor incentivization for physicians and healthcare providers to take the best action for patients. This violates the primary goal of electronic health records as a communication tool.

Unfortunately, this is not the only issue of EHR adoption that has compromised patient care. When physicians meaningfully utilize electronic health records, it often comes with an additional amount of burden in learning how to use the system, which can, in the long run, reduce efficiency and lead to professional burnout. According to a recent study, "physicians spend approximately 33% of their work hours performing direct clinical work and 49% completing clerical tasks and interfacing with the EHR. For every hour of clinical work, physicians spent two hours on clerical or EHR-related tasks" (Sinsky et al. 2016). Further analysis within this study indicated that this was a result of the federal government incentivizing meaningful use and the design of EHRs to focus on reporting requirements, but this neglected the needs of physicians and patients as well in their integral process in the effective use of EHRs (Reisman, 2017). Additionally, many current EHR systems "focus primarily on data collection rather than synthesis of data at the patient levels...typically neither context nor patient specific" (American Medical Association, 2014). This is another way that poor EHR implementation can backfire on the goals of EHRs, and can actually hinder quality patient care and motivation for physicians. This, paired with the lack of space for users of EHRs to provide constructive feedback that can be implemented in the system, makes it incredibly challenging to improve the systems, which simply leads to greater frustration and compromised healthcare.

At the onset, policies encouraged competition between EHR providers, incentivizing new service providers to develop different systems (Adler-Milstein, 2017). Initially, this process helped refine EHR interfaces and improve the underlying mechanics, enhancing user experience and security. Yet, without established limitations, hundreds of EHR services have entered the market. Despite a few EHR vendors dominating this sector, each EHR system is often customized to an individual health care provider's needs and workflow (Reisman, 2017). With so much variety, it is nearly impossible to issue a single set of standards to unify EHR platforms and simplify information sharing. Indeed, current legislation has succeeded innserving to optimize EHR capabilities. Now, though, new goals have arisen, and the expansive diversity within these technologies acts as a barrier to increased interoperability.

Recommendation

To address interoperability issues, the federal government should play a larger role in regulating information sharing and preventing information blocking. Their focus should reaffirm the prioritization of physicians and patients along with the priorities of service providers and insurance companies. Therefore, we recommend that the federal government impose a federal floor for electronic health records usage specifically with encouraging affordable collaboration and the sharing of data across EHR systems to encourage physicians and healthcare providers to

make the best choices for the patient, rather than the best choices *under a constrained system* for the patient. This will encourage doctors to leverage electronic health records in order to actually make the best decision for the patient. The role of EHR service providers in this process would not only be to facilitate this exchange of data, but to also create features such that a referring physician is able to track the patient's progress while they are receiving care elsewhere, so that in situations where the patient returns, all parties are consistently up-to-date with the most accurate information. This would require greater standardization across EHR service providers through collaboration to ensure that updates are consistently made across different platforms.

Another important part of this process that would be necessary to facilitate the flow of highly secure data across EHR platforms or hospital systems would be the need for the federal government to establish baseline guidelines on cybersecurity recommendations to prevent breaches or interceptions of data in the sharing pipeline of protected health information. Unfortunately, with greater sharing of data, there is greater scope for there to be a vulnerability that can be exposed, and ensuring a baseline level of security measures in this pipeline is a crucial step. Currently, HIPAA's privacy rule does establish a federal floor on identifiable PHI. Yet, it crucially fails to completely safeguard PHI protections by falling to some of the same pitfalls that plague PHI under HIPAA. This new federal floor for EHR cybersecurity will include necessary provisions to encourage collaboration in the healthcare sector without introducing additional privacy risks. Currently, HIPAA's privacy rule does not include enough information to protect electronic health information. On paper, legislation such as the 21st Century Cures Act, HITECH, and HIPAA outline guidelines for protecting PHI, but there is a difference between what is legislation and what happens in practice. To work around some of these issues, the "gag rule" must be eliminated.

The gag rule refers to the practice of individuals not being able to share information about EHR systems due to restrictions by service providers (i.e. EPIC). Service providers argue that the confidentiality of their systems is to maintain security and prevent other companies from reverse-engineering the code (Goldberg, 2019). A negative aspect of having the gag rule is that it prevents the training of physicians from system errors in service providers. Loosening the gag rule that service providers have would benefit information sharing as well. Currently, companies like EPIC state that they do not prohibit any critical information, but it does prioritize safeguarding information (Goldberg, 2019). More information is needed to better understand this and can be found through investigations from HHS.

Another step towards bettering EHR systems and reducing the cognitive workload on physicians is standardizing the style of EHRs so that they provide context-sensitive and concise areas to input data, and also allowing them to be customizable such that it is most beneficial for the users. This flexibility will not only be able to accommodate physicians and other users, but will also allow for flexibility in terms of what data needs to be stored for a specific case and specific patient. It is unreasonable to expect that EHR service providers will be able to accurately predict the specific data-storage needs of all physicians, and thus, it is unreasonable to expect that a one-size-fits-all method of EHR format will be effective for all physicians and all patients (American Medical Association, 2014). This addresses the current issue in EHR systems of record complexity resulting in cognitive overload and burnout, and will give patients back more of the time they need with physicians to receive appropriate care.

In addition to standardization of EHR styles, it is crucial to officially regulate physician training with these systems. Rather than learning on the job, legislation should ensure that physicians come prepared to use EHR systems effectively and securely. Though EHRs successfully eliminate different medical errors—such as non-compatible prescriptions, overlooking patient history, and general miscommunications—they have introduced new types of errors based on structural misuse and typos (Menachemi & Collum, 2011). Often, these new mistakes are based on a lack of training with EHR systems (Campbell et al., 2006). Hence, new policy should mandate that prior to gaining complete autonomy on EHR systems, physicians must receive certifications for general EHR best practice, including cybersecurity protocols to minimize the risk of data breaches. Additionally, as technology continues to rapidly evolve, continued learning including relevant case studies and safety modules can ensure physicians and health care providers remain updated on the best EHR practices. In conjunction, these provisions can help reduce unnecessary privacy risks and minimize human error that are prevalent in EHR systems.

Limitations

While setting a federal floor on actions that have to be taken by stakeholders in the EHR landscape would be beneficial for ease of data sharing and overall health care delivery, there are some limitations to this set of recommendations. Additional legislation to expand privacy regulations may be redundant, especially with HIPAA and HITECH Act. However, violations of patient information privacy and security occur regardless, so clarifying the guidelines on how EHR information is regulated would benefit the exact protections that are enforced under federal guidelines while raising awareness on the electronic health record aspect of patient information.

A further limitation is the feasibility of providing continuous regulation of EHRs services, especially given the limitations of HHS to manage the current HIPAA compliance. A solution to this issue is to explicitly give regulatory authority to the HHS Office of the National Coordinator for Health Information Technology (ONC) (CMS, 2020). This role was alluded to in the Final Rule; however, clear delineation of the roles and responsibilities of the ONC would provide the office with more resources and authority over EHR regulation. Despite the limitations, the benefits of improved quality, efficiency, and convenience of care outweigh the drawbacks of this recommendation.

Conclusion

By introducing further government regulation over EHR information sharing, clarifying privacy standards, and mandating physician training, US healthcare can again emphasize patient treatment. These recommendations will incentivize the major stakeholders to not only maintain

their bottom line profit but to ensure quality healthcare delivery as well. However, these new policies will not deter the innovations that incentivized the development of technological advancements like EHR systems. Instead, these changes will help promote quality physician-patient interactions along with the continuation of new technologies that streamline patient treatment.

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