Understanding the Current Landscape of Direct-to-Consumer Health Literacy Interventions

By Michael Truong, BSA, and Susan H. Fenton, PhD, RHIA, FAHIMA, FAMIA

Executive Summary

Background Information

Health information can be collected through platforms outside of traditional healthcare settings. Examples of these platforms include personal health records, web portals, and mobile health applications. On the personal level, health literacy is the degree to which individuals can find, understand, and use information and services to inform health-related decisions and actions for themselves and others. Individuals with lowhealth literacy will have difficulty understanding and utilizing these platforms or services to their fullest potential in self-management and improving health outcomes.

Purpose

The purpose of this literature review is to identify gaps in the current landscape of direct-to-consumer health literacy interventions. The findings will be used to inform future interventions.

Findings

- Individuals with lower incomes and educational attainment are the least likely group to seek out assistance with health literacy.
- Consumers with chronic diseases are common users ofelectronic healthcare services.
- Direct-to-consumer health literacy interventions are shifting toward mobile health applications.
- Direct-to-consumer health literacy interventions are transitioning to a community-based participatory research approach.
- There is a lack of follow-up in direct-to-consumer health literacy interventions to assess retention of electronic health tools or clinically significant change in health outcomes.

Introduction

Consumers can generate health data and obtain health information across multiple, digital platforms beyond the traditional healthcare settings.[1]These platforms fall under the umbrella of eHealth, which can be defined as "cost-effective and secure use of information and communication technologies (ICT) in support of health and health-related fields".[2]Examples of ICT outside of the traditional healthcare setting include untethered personal health records (PHR), web portals, and mobile health (mHealth) tools. In recent times, mobile technology is commonly used in eHealth due to its ease of access for consumers in terms of portability and usability.[3] mHealth can now be considered a subset of eHealth, which involves tools such as applications found on smartphones, tablets, and computers.[4]

Health literacy can be described as “the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others”.[5] Low levels of health literacy have been linked to poor health outcomes, so it is important that individuals have sufficient health literacy when using eHealth.[6]

A well-known health literacy intervention is the teach-back method. Healthcare professionals use this method to ensure patients understand their treatment plan and/or diagnosis.[7]Other health literacy interventions come in the form of eHealth through direct-to-consumer models.[8] However, there is limited knowledge about eHealth and its impact on health literacy levels in various populations.[9] Thus, understanding the current landscape of direct-to-consumer health literacy interventions will allow for future development of interventions for users with varying degreesof health literacy.

A literature review was conducted to understand the current landscape of studies on direct-to-consumer health literacy interventions. The literature review will attempt to answer several research questions about health literacy:

- What factors drive consumers to determine they need assistance with their health literacy?
- Where do consumers turn to find help with health literacy?
- What health literacy resources exist outside of the provider settings? If they exist, how do they operate to meet consumers’ needs?
- What gaps in direct-to-consumer health literacy are unanswered?

Methods

In this study, a search strategy was created to search for relevant articles. The search period lasted from September 2, 2021, to September 15, 2021. From the research questions, key concepts identified as relevant for the literature review analysis included mobile technology, personal health information, health literacy, self-efficacy, and personal health records. These key terms were used to construct search terms to find relevant publications. The search terms were finalized based on input from a medical librarian at the Texas Medical Center Library. PubMed was chosen as the sole database, as it contains millions of full-text articles from life sciences and biomedical science journals. Duplicate publications were removed using Zotero’s duplication finder. During the full-text review and analysis process, additional relevant articles were identified through forward snowballing.

Only articles within the last 10 years were included in the study’s evaluation process. After the duplicate articles were removed, the titles and abstracts were screened based on an inclusion/exclusion criterion for relevance. Articles were deemed relevant if they tracked health literacy scores or health-related scores/parameters or self-efficacy, the basis of the study revolved around personal health management or self-management or self-efficacy in relation to health promotion and health education concepts or health literacy, and the interaction was performed outside of the traditional healthcare setting such as interactions with one’s healthcare provider. This same screening criteria was utilized during the full-text review. Many articles were excluded because usability principles in mobile application design were the primary objective of the study. Other studies were excluded if they included interaction with doctors as part of the intervention or tethered personal health records and patient portals were used in the study, as these tools are connected to a medical organization's electronic health record (EHR) system. The only exception to this rule is when a study involves the use of an untethered PHR where an individual has the choice to integrate their personal health record into a medical organization's EHR system.

Full-text articles were reviewed in an ascending chronological order with column topics using the Matrix Method,which involved the construction of a matrix with column topics such as: title, purpose, variable(s), methodological design, number of subjects, sampling design, results, and significance of the article in relation to the objective of the literature review.[10]**Figure 1**depicts the flow of the documents throughout the review in a PRISMA Flow diagram.[11]

Results

A total of 712 articles were identified from the initial search strategy. Eighteen of these articles were duplicates. Zotero was used to remove the duplicate articles, and 19 additional articles were found through forward snowballing. A total of 713 records were screened using the inclusion/exclusion criteria. After screening the title/abstracts, 104 articles were determined to meet the criteria for full-text assessment. A total of 74 full-text articles were excluded after the full-text assessment, leaving 30 articles included in the final review. **Table 1** summarizes the type of research approach and study design for the 30 studies.[12–41]

Twenty-two of these studies were quantitative studies, five studies were qualitative studies, and three studies were mixed-methods studies. From the 24 quantitative studies, eight of the studies were cross-sectional studies;10 studies were randomized controlled trials; two studies were a pre-test, post-test study; one study was a longitudinal study; and one study was a non-randomized controlled trial. From the five qualitative studies, four of the studies were thematic analysis through oral communication (focus groups and interviews), and one study was a content analysis. From the three mixed-methods studies, one study was a prospective study, one study was a feasibility study, and one was an exploratory sequential mixed-methods study design. The 30 studies were analyzed for broad areas or themes. Eight themes were identified, and the themes are presented in the following subsections titled accordingly to the research questions.

What Factors Drive Consumers to Determine They Need Assistance With Their Health Literacy?

Theme 1: Individuals with low incomes and educational attainment are the least likely group to seek out assistance with health literacy.

Two cross-sectional studies examined the association between demographic and/or socioeconomic factors with the usage of eHealth or health-related seeking behavior on the Internet.[20,25,30] One study found older males (>65 years old) with a low socioeconomic (defined by education and income) status were the least likely group be associated with eHealth activities such as tracking personal health information online, looking for health information online, or utilizing an online social support group compared to counterpart groups such as women, 18-34 year old adults, and high SES adults.[20] Another cross-sectional study reported individuals with low SES were least likely to engage in using the internet to search for health information.[25] In the same study, the researchers reported individuals who did use personal health information management tools were more likely to engage in eHealth activities. Lastly, another cross-sectional study found individuals who were young, college-educated, or have high family incomes use personal health management (PHM) tools (text messaging services, scheduling appointments online, and refilling prescriptions online) more than their counterpart groups.[34]

Other studies targeted specific populations researchers thought to be considered low SES status such as disadvantaged mothers and pregnant women, rural communities, undernourished communities, and underserved communities.[17,26,29] For example, researchers created a mHealth intervention targeting Type 2 diabetic individuals in rural communities using a pre-test, post-test study design.[26] The two-week mHealth intervention consisted of diabetes self-management videos accompanied with quizzes, reminders, and a diabetes dictionary. Results from this study were improvements in scores for Rapid Estimate of Adult Literacy in Medicine (REALM), which measures health literacy; Diabetes Knowledge Test, which measures diabetes knowledge; and Diabetes Self-Efficacy Scale, which measures diabetes self-efficacy. The researchers noted these changes were clinically significant.

Theme 2: Consumers with chronic diseases are common users of electronic healthcare services.

A key finding was individuals who are frequent users of healthcare or are managinga chronic condition are common users of electronic healthcare services. One cross-sectional study measured hypertension prevalence and its association with personal health information management. The researchers found adults who reported a hypertension diagnosis were more likely to conduct health-related searches than adults who did not have a hypertension diagnosis.[25] Another cross-sectional study found the proportion of individuals who reported either a single chronic condition or multiple chronic conditions used PHM tools (text messaging services, scheduling appointments online, and refilling prescriptions online) significantly more than individuals with no chronic conditions.[34] Among those with multiple chronic conditions, those who reported "Good/Excellent" health status were more likely to use PHM tools than those who reported "Fair/Poor" health status. This observation was seen in the aforementioned cross-sectional study as well.[25]

Although some studies did target the general population, many studies looked at populations with chronic diseases. Examples of these chronic diseases are hypertension, diabetes, pediatric cancer, HIV/AIDS, and breast cancer.[13,16,19,22,24,26,32,33,37,40] For one of these studies, the researchers conducted a randomized controlled trial mHealth intervention for persons living with HIV (PLWH).[37] The intervention group received a customized PHR for PLWH and received educational sessions on HIV literacy and eHealth competency skills. Researchers reported the intervention group showed significantly greater improvements in Patient Activation Measure (PAM), which measures patient activation, and eHEALS,which measures eHealth literacy, than the control group.

Theme 3: Major barriers to eHealth for current and potential consumers are concerns about privacy.

Nine studies reported consumer's concern about privacy related to sharing health information data through eHealth.[13,21,23,24,28,28–31,36]Consumers were generally fearful about their privacy. Key findings concluded that consumers are concerned their confidentiality could be breached or that sensitive personal health information was not safe from hackers. One study examined potential barriers to implementation of a personal health information management system, and the researchers found individuals who reported discomfort about the use of technology or the security of online health information were less likely to believe PHM systems would help achieve one's health goals compared to individuals who are comfortable with using technology or the security of online health information.[30] Assurances about online data being secure would be beneficial and needed before engaging with an eHealth tool. However, some studies did find individuals were willing to use an eHealth tool despite their concerns about security and privacy.[24,28] In one study, Type 2 diabetic individuals were given a PHR for three to six months.[24] The researchers interviewed the individuals about their usage at follow-up visits. Very few participants expressed privacy, which was surprising to the researchers in which they argued the participants accepted potential positive gains regarding PHR usage despite security and privacy risks. Another study in postpartum women and their opinion about PHR usage through a mobile device identified a minority (20 percent of the total participants) group of women who were concerned about privacy and security.[28] However, 93.8 percent of individuals who reported privacy concerns were still interested in using a PHR. The researchers did not offer an argument for this observation, but they noted the high interest suggests PHRs are an underutilized tool.

Where Do Consumers Turn to Find Help With Health Literacy?

Theme 4: Consumers utilize the internet and provider interactions rather than eHealth tools to search for health-related information.

A few studies looked at consumer engagement with digital health technology in health-related information searches.[18,29,31] Key findings were that consumers prefer using the internet (e.g. Google, YouTube, and Facebook) or found helpful information in patient forums or online support groups. In one study with disadvantaged mothers and pregnant women, participants valued face-to-face contact more than the use of patient portals or text messaging systems.[29] Another study found college aged individuals using a personally controlled health management system identified the poll and forum as the most engaging and useful feature of the system.[18] Old consumers who did engage in health-seeking behavior on the internet reported they had trouble identifying credible and trustworthy sources.[31]

What Health Literacy Resources Exist Outside of the Provider Settings? If They Exist, How Do They Operate to Meet Consumers' Needs?

Theme 5: Direct-to-consumer health literacy interventions are shifting toward mHealth applications.

AppendixAsummarizes the study and results of the direct-to-consumer health literacy interventions.[12,15–19,22,24,26,27,32,33,35,35,37–41] Unless stated otherwise, the subjects were based in the United States.In recent times, the technology medium has shifted from web portals and computer-based resources (eHealth) to smartphones (mHealth). Some of these tools involved instructor-based methodology (e.g., virtual advisor, researcher-led educational sessions, and expert support) while other tools were used as a stand-alone resource, which included educational modules and/or videos accompanying the modules.[12,15–19,22,24,26,27,32,33,35,35,37–41]

Theme 6: Direct-to-consumer health literacy interventions are transitioning to a community-based participatory research approach.

Previous research did not mention the involvement of participants during the eHealth development process.[12,15–19,22,24,26,27,32,33,35,39,40]Over time, the researchers deliberately involved the target audience in developing the technology through a study methodology known as community-based participatory research (CBPR).[17,37,38,41]One direct-to-consumer health literacy intervention targeting insurance health literacy in ethnic minority groups developed a partnership with organizations involved in Affordable Care Act outreach.[38] The partnership worked together to develop a website and video series designed to improve health insurance literacy. Contents of the website were developing using findings from focus groups with participants. The researchers reported intervention participants had animproved knowledge of health insurance eligibility, higher self-efficacy, and intention to seek help with insurance navigation compared to the control group. Another health literacy intervention using a CBPR methodology was the previously mentioned HIV+ PHR study in Theme 2.[37] Stakeholders and people living with HIV (PLWH) had an active role in the development of the study. The educational sessions about HIV knowledge and eHealth competency were developed using findings from one-on-one interviews with PLWH. The difference in Patient Activation Measure and eHEALS was statistically significant between the intervention and control group.

What Gaps in Direct-to-Consumer Health Literacy Are Unanswered?

Theme 7: No standard measurement for health literacy combining general functional literacy skills and eHealth literacy skills was across all studies.

From the studies included in this review, various instruments were used to measure and test changes in health literacy. Examples of these instruments include the eHealth Literacy Scale (eHEALS), Rapid Estimate of Adult Literacy in Medicine (REALM), and the Newest Vital Sign instruments.[13,14,22,26,29]However, no standardized assessment was used across all interventions. Many of the direct-to-consumer health literacy interventions utilized a knowledge or literacy test pertinent to the study's research topic such as the Literacy Assessment for Diabetes, Diabetic Knowledge Assessment, Diabetes Knowledge Test, an Arabic translation of the Diabetes Knowledge Test, an adapted version of the Health Insurance Literacy Measure, a nutrition literacy test for mothers, or interpreting health data in various presentation formats.[19,26,32,38,39,41]

Theme 8: There is a lack of follow-up in direct-to-consumer health literacy interventions to assess eHealthtool retention or clinically significant change in health outcomes.

Although a majority of the direct-to-consumer health literacy interventions reported statistically significant differences in levels of health literacy (as measured by a scale or knowledge assessment test) between intervention and control groups, littletono follow-up was done to evaluate whether the intervention led to significant changes in health outcomes. Only one longitudinal study followed the usage of personal health records (PHRs) over five years.[33] The researchers found long-term users were diabetics who measured their blood glucose levels. Also, studies have indicated changes in health literacy did not lead to changes in clinical outcomes. For example, the direct-to-consumer health literacy involving HIV+ patients indicated the intervention group showed statistically significant change in e-health literacy and patient activation.[37] However, the researchers point out no statistically significant differences in medication adherence or health status levels were found between the control and intervention group. Another study identified levels of internal health orientation and having trust in digital information were more significant predictors in the usage of digital health than health literacy.[29] This observation was consistent with another study that found certain coping mechanisms and adjustment toward a disease correlated with an internal motivation to use a PHR.[27] The researchers identified approach-oriented coping style individuals were more likely to use the PHR heavily in tracking symptoms versus avoidance-oriented individuals.

Discussion

An analysis of the studies in the review led to the identification of eight themes that could be utilized in the development of future direct-to-consumer health literacy interventions.

The review identified two major groups where health literacy interventions can have a noticeable impact in health literacy skills and health outcomes: low SES individuals and individuals with chronic diseases. The *American Journal of Managed Care* (AJMC) reports both of these groups as vulnerable populations in the United States.[42]According to *AJMC*, these populations experience “greater risk factors [and] worse access to care” compared with the general population. The presence of limited health literacy in vulnerable populations could be an explanatory factor in the development of disease, so future health literacy interventions targeting vulnerable individuals may reduce health disparities.[43]For chronic diseases, six in 10 adults in the United States have at least one chronic disease.[44] Dunn and Conard argue providing only education to individuals with diabetes or cardiovascular disease is not enough in eliciting behavior change because these diseases require a high level of patient involvement.[45] The researchers believe effective self-management skills include knowledge about the disease and medication as well as being able to communicate information effectively to a healthcare team. Furthermore, Dunn and Conard propose a solution in which a progressive model, the Dunn-Conard model, for building functional and critical health literacy skills in chronic disease individuals. They envision the ideal active participant would be involved in shared decision making with the healthcare provider. The usage of the Dunn-Conard model in direct-to-consumer health literacy interventions may not be feasible due to limited provider or expert support. To increase this feasibility, a CBPR methodology could be used to involve expert stakeholders in developing educational content delivered in a stand-alone manner.

Nonetheless, privacy and security concerns exist as a barrier for increasing health literacy through eHealth. In fact, users who expressed being uncomfortable with technology or concerns about the privacy of health information online were more likely to report the usage of personal health information management tools would not have a positive effect on their overall health.[30]Addressing security and privacy concerns through general education about technology and cybersecurity throughout the intervention could be a way to overcome this barrier.

The transition from direct-to-consumer health literacy technological mediums to mHealth such as smartphones, laptops, and tablets was not surprising. According to Lin and Lou, the transition from eHealth to mHealth is due to the removal of barriers related to accessibility of technological equipment and integrated communication channels.[46] Developing direct-to-consumer health literacy interventions through mobile health technology may be appropriate for low SES populations because the current technology landscape in the United States indicates there is an increase in smartphone ownership among lower-income Americans.[47]Current research indicates mHealth are difficult for current consumers to utilize to its fullest potential because consumers have trouble interpreting the health information and applying it toward improving health outcomes.[48]

Tailored health communication promotes change in health behavior due to an increased level of perceived personal relevance, so specific populations should be identified before developing mHealth.[49] Incorporating community-based participatory research (CBPR) methodologies in the development of direct-to-consumer health literacy interventions can lead to the promising development of a robust tool for patient engagement. An advantage of CBPR is that individuals will feel empowered and engaged with the intervention.[50] Cultural humility is demonstrated between the researchers and participants, as collaboration provides a way to address cultural differences between individuals. Trust is developed between the members of the partnership, and the project becomes credible as it aligns with the community in shared social and health goals.

Other technical suggestions in the design of mHealth include the presentation of educational material and health-related information being at an eighth-grade level or below since the average resident in United States reads at an eighth grade level.[51]In the development of mHealth applications, design and usability considerations must be taken into account because the majority of users may stop using the applications due to loss of interest, burdens in data entry, and hidden costs.[52]One way to evaluate the usability of the application is to utilize a usability questionnaire. One questionnaire has been developed for mobile health applications known as the mHealth App Usability Questionnaire (MUAQ). The questionnaire has demonstrated reliability and validity which makes it a valuable scale for mHealth usability inquiry.[53]

Current research indicates the lack of a standardized instrument in measuring health literacy across all interventions, but reliable and valid scales do exist, which can be used as screening measures for low health literacy levels.[54]These screening tools can identify low functional skills relevant to health literacy such as the Short Assessment of Health Literacy and the Rapid Estimate of Adult Literacy in Medicine.[55] E-health literacy can be screened using the eHEALS scale, which has been shown to be a reliable and consistent measurement tool.[56]The usage of these tools can identify specific skills that are assessed in future direct-to-consumer health literacy interventions. Furthermore, specific knowledge assessments can be used in-conjunction with these screening tools to determine statistically significant changes in health knowledge between the intervention and control groups.

It is important to acknowledge health literacy does not always correlate with self-efficacy and health outcomes.[37,57] In other words, a high health literate individual may not have the best health status or believe they can change their health status compared to individuals with lower health literacy. This observation suggests the plausible interaction between social determinants of health, self-efficacy, and health literacy in affecting one's health outcome.[43]Current research has shown critical health literacy, which involves higher level thinking, is an important skill, leading to higher levels in self-reported involvement of medical decision-making.[58]Other research has indicated individuals with higher levels of internal health locus of control are willing to utilize health applications to monitor or change their behavior than groups with lower levels of an internal health locus of control.[59]Future direct-to-consumer health literacy intervention should address levels of self-efficacy and work toward improving the individual's self-efficacy and internal health locus of control.

The literature review has limitations. First, the study may not have captured all relevant articles to direct-to-consumer health literacy interventions in the PubMed database. A reasoning for this event may be due to the search terms. Terminology regarding direct-to-consumer health literacy interventions may be difficult to identify in a database context, so a wide range of terms need to be used in the future. Also, other peer-reviewed journals in different databases may have relevant articles not found in the PubMed database. Future research should include more databases and develop a robust search strategy to ensure more studies regarding direct-to-consumer health literacy interventions are identified.

Conclusion

eHealth and mHealth technology are promising mediums for direct-to-consumer health literacy interventions with mHealth becoming more relevant due to the high prevalence of smartphone users in the United States population. The literature review identified several themes that could be utilized in the future development of direct-to-consumer health literacy interventions. Barriers deterring future users of these tools include privacy and security concerns, as well as the design and usability of potential mHealth. Potential target audiences have been identified such as low socioeconomic status groups, but interventions in health literacy may not be enough to induce clinically significant behavior change. Direct-to-consumer health literacy interventions should address an individual's self-efficacy and internal health locus of control throughout the usage of the tool.

Notes

1. Pagliari, C. Digital health and primary care: Past, pandemic and prospects. *J. Glob. Health*11, 01005.
2. WHO EMRO | eHealth | Health topics. http://www.emro.who.int/health-topics/ehealth/.
3. Marcolino, M. S. *et al.* The Impact of mHealth Interventions: Systematic Review of Systematic Reviews. *JMIR MHealth UHealth*6, e23 (2018).
4. CDC. Health Literacy Research and Best Practices. *Centers for Disease Control and Prevention* https://www.cdc.gov/healthliteracy/researchevaluate/eHealth.html (2021).
5. CDC. What is health literacy? Take action. Find out. *Centers for Disease Control and Prevention* https://www.cdc.gov/healthliteracy/learn/index.html (2021).
6. McDonald, M. & Shenkman, L. Health Literacy and Health Outcomes of Adults in the United States: Implications for Providers. *Internet J. Allied Health Sci. Pract.* (2018) doi:10.46743/1540-580X/2018.1689.

7. Yen, P. H. & Leasure, A. R. Use and Effectiveness of the Teach-Back Method in Patient Education and Health Outcomes. *Fed. Pract.*36, 284–289 (2019).
8. Watkins, I. & Xie, B. eHealth Literacy Interventions for Older Adults: A Systematic Review of the Literature. *J. Med. Internet Res.*16, e225 (2014).
9. Manganello, J. *et al.* The Relationship of Health Literacy With Use of Digital Technology for Health Information: Implications for Public Health Practice. *J. Public Health Manag. Pract.*23, 380–387 (2017).
10. Garrard, J. Part II: The Matrix Method. in *Health sciences literature review made easy: the matrix method* 95–176 (Jones & Bartlett Learning, 2017).
11. Page, M. J. *et al.* The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*372, n71 (2021).
12. Austvoll-Dahlgren, A., Bjørndal, A., Odgaard-Jensen, J. & Helseth, S. Evaluation of a web portal for improving public access to evidence-based health information and health literacy skills: a pragmatic trial. *PloS One*7, e37715 (2012).
13. Logue, M. D. & Effken, J. A. An exploratory study of the personal health records adoption model in the older adult with chronic illness. *Inform. Prim. Care*20, 151–169 (2012).
14. Noblin, A. M., Wan, T. T. H. & Fottler, M. The impact of health literacy on a patient's decision to adopt a personal health record. *Perspect. Health Inf. Manag.*9, 1–13 (2012).
15. Xie, B. Improving older adults' e-health literacy through computer training using NIH online resources. *Libr. Inf. Sci. Res.*34, 63–71 (2012).
16. Bolin, J. N., Ory, M. G., Wilson, A. D. & Salge, L. Diabetes Education Kiosks in a Latino Community. *Diabetes Educ.*39, 204–212 (2013).
17. King, A. C., Bickmore, T. W., Campero, M. I., Pruitt, L. A. & Yin, J. L. Employing virtual advisors in preventive care for underserved communities: results from the COMPASS study. *J. Health Commun.*18, 1449–1464 (2013).
18. Lau, A. Y. *et al.* Social and self-reflective use of a Web-based personally controlled health management system. *J. Med. Internet Res.*15, e211 (2013).
19. Moussa, M., Sherrod, D. & Choi, J. An e-health intervention for increasing diabetes knowledge in African Americans. *Int. J. Nurs. Pract.*19 Suppl 3, 36–43 (2013).
20. Kontos, E., Blake, K. D., Chou, W.-Y. S. & Prestin, A. Predictors of eHealth usage: insights on the digital divide from the Health Information National Trends Survey 2012. *J. Med. Internet Res.*16, e172 (2014).
21. Quinlivan, J. A., Lyons, S. & Petersen, R. W. Attitudes of pregnant women towards personally controlled electronic, hospital-held, and patient-held medical record systems: a survey study. *Telemed. J. E-Health Off. J. Am. Telemed. Assoc.*20, 810–815 (2014).
22. Ruiz, J. G. *et al.* Computer-based programmed instruction did not improve the knowledge retention of medication instructions of individuals with type 2 diabetes mellitus. *Diabetes Educ.*40, 77–88 (2014).
23. Cochran, G. L. *et al.* Consumer Opinions of Health Information Exchange, e-Prescribing, and Personal Health Records. *Perspect. Health Inf. Manag.*12, 1e (2015).
24. Fuji, K. T., Abbott, A. A. & Galt, K. A. A qualitative study of how patients with type 2 diabetes use an electronic stand-alone personal health record. *Telemed. J. E-Health Off. J. Am. Telemed. Assoc.*21, 296–300 (2015).
25. Sandefer, R. H., Westra, B. L., Khairat, S. S., Pieczkiewicz, D. S. & Speedie, S. M. Determinants of Consumer eHealth Information Seeking Behavior. *AMIA Annu. Symp. Proc. AMIA Symp.*2015, 1121–1129 (2015).

26. Wood, F. G., Alley, E., Baer, S. & Johnson, R. Interactive Multimedia Tailored to Improve Diabetes Self-Management. *Nurs. Clin. North Am.*50, 565–576 (2015).
27. Schneider, H., Hill, S. & Blandford, A. Patients Know Best: Qualitative Study on How Families Use Patient-Controlled Personal Health Records. *J. Med. Internet Res.*18, e43 (2016).
28. Fernandez, N., Copenhaver, D. J., Vawdrey, D. K., Kotchoubey, H. & Stockwell, M. S. Smartphone Use Among Postpartum Women and Implications for Personal Health Record Utilization. *Clin. Pediatr. (Phila.)*56, 376–381 (2017).
29. Guendelman, S., Broderick, A., Mlo, H., Gemmill, A. & Lindeman, D. Listening to Communities: Mixed-Method Study of the Engagement of Disadvantaged Mothers and Pregnant Women With Digital Health Technologies. *J. Med. Internet Res.*19, e240 (2017).
30. Neyens, D. M. & Childers, A. K. Determining Barriers and Facilitators Associated With Willingness to Use a Personal Health Information Management System to Support Worksite Wellness Programs. *Am. J. Health Promot. AJHP*31, 310–317 (2017).
31. Ware, P. *et al.* Using eHealth Technologies: Interests, Preferences, and Concerns of Older Adults. *Interact. J. Med. Res.*6, e3 (2017).
32. Alanzi, T., Bah, S., Alzahrani, S., Alshammari, S. & Almunsef, F. Evaluation of a mobile social networking application for improving diabetes Type 2 knowledge: an intervention study using WhatsApp. *J. Comp. Eff. Res.*7, 891–899 (2018).
33. Park, Y. R. *et al.* Managing Patient-Generated Health Data Through Mobile Personal Health Records: Analysis of Usage Data. *JMIR MHealth UHealth*6, e89 (2018).
34. Sandefer, R. H., Westra, B. L., Khairat, S. S., Pieczkiewicz, D. S. & Speedie, S. M. Assessment of Personal Health Care Management and Chronic Disease Prevalence: Comparative Analysis of Demographic, Socioeconomic, and Health-Related Variables. *J. Med. Internet Res.*20, e276 (2018).
35. Tanaka, K. *et al.* Professional dietary coaching within a group chat using a smartphone application for weight loss: a randomized controlled trial. *J. Multidiscip. Healthc.*11, 339–347 (2018).
36. Walsh, L. *et al.* A content analysis of the consumer-facing online information about My Health Record: Implications for increasing knowledge and awareness to facilitate uptake and use. *Health Inf. Manag. J. Health Inf. Manag. Assoc. Aust.*47, 106–115 (2018).
37. Carroll, J. K. *et al.* 'Get Ready and Empowered About Treatment' (GREAT) Study: a Pragmatic Randomized Controlled Trial of Activation in Persons Living with HIV. *J. Gen. Intern. Med.*34, 1782–1789 (2019).
38. Patel, M. R. *et al.* Insuring Good Health: Outcomes and Acceptability of a Participatory Health Insurance Literacy Intervention in Diverse Urban Communities. *Health Educ. Behav. Off. Publ. Soc. Public Health Educ.*46, 494–505 (2019).
39. Tao, D., Yuan, J. & Qu, X. Effects of presentation formats on consumers' performance and perceptions in the use of personal health records among older and young adults. *Patient Educ. Couns.*102, 578–585 (2019).
40. Kim, H.-J. & Kim, H.-S. Effects of a web-based expert support self-management program (WEST) for women with breast cancer: A randomized controlled trial. *J. Telemed. Telecare*26, 433–442 (2020).
41. Seyyedi, N. *et al.* Smartphone-Based Maternal Education for the Complementary Feeding of Undernourished Children Under 3 Years of Age in Food-Secure Communities: Randomised Controlled Trial in Urmia, Iran. *Nutrients*12, 587 (2020).

42. 5 Vulnerable Populations in Healthcare. *AJMC* https://www.ajmc.com/view/5-vulnerable-populations-in-healthcare.
43. Schillinger, D. The Intersections Between Social Determinants of Health, Health Literacy, and Health Disparities. *Stud. Health Technol. Inform.*269, 22–41 (2020).
44. Chronic Diseases in America | CDC. https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm (2021).
45. Dunn, P. & Conard, S. Chronic Care Model in research and in practice. *Int. J. Cardiol.*258, 295–296 (2018).
46. Lin, Y.-H. & Lou, M.-F. Effects of mHealth-based interventions on health literacy and related factors: A systematic review. *J. Nurs. Manag.*29, 385–394 (2021).
47. Record shares of Americans have smartphones, home broadband. *Pew Research Center* https://www.pewresearch.org/fact-tank/2017/01/12/evolution-of-technology/.
48. Kreps, G. L. The relevance of health literacy to mHealth. *Inf. Serv. Use*37, 123–130 (2017).
49. Bol, N., Smit, E. S. & Lustria, M. L. A. Tailored health communication: Opportunities and challenges in the digital era. *Digit. Health*6, 2055207620958913 (2020).
50. Holkup, P. A., Tripp-Reimer, T., Salois, E. M. & Weinert, C. Community-based Participatory Research. *ANS Adv. Nurs. Sci.*27, 162–175 (2004).
51. Stossel, L. M., Segar, N., Gliatto, P., Fallar, R. & Karani, R. Readability of Patient Education Materials Available at the Point of Care. *J. Gen. Intern. Med.*27, 1165–1170 (2012).
52. Krebs, P. & Duncan, D. T. Health App Use Among US Mobile Phone Owners: A National Survey. *JMIR MHealth UHealth*3, e4924 (2015).
53. Zhou, L., Bao, J., Setiawan, I. M. A., Saptono, A. & Parmanto, B. The mHealth App Usability Questionnaire (MAUQ): Development and Validation Study. *JMIR MHealth UHealth*7, e11500 (2019).
54. Huhta, A.-M., Hirvonen, N. & Huotari, M.-L. Health Literacy in Web-Based Health Information Environments: Systematic Review of Concepts, Definitions, and Operationalization for Measurement. *J. Med. Internet Res.*20, e10273 (2018).
55. Health Literacy Measurement Tools (Revised) | Agency for Healthcare Research and Quality. https://www.ahrq.gov/health-literacy/research/tools/index.html.
56. Nguyen, J. *et al.* Construct Validity of the eHealth Literacy Scale (eHEALS) Among Two Adult Populations: A Rasch Analysis. *JMIR Public Health Surveill.*2, e24 (2016).
57. Medina, L. A. C. *et al.* Correlation Between Functional Health Literacy and Self-efficacy in People with Type 2 Diabetes Mellitus: Cross-sectional Study. *Clin. Nurs. Res.* 10547738211006840 (2021) doi:10.1177/10547738211006841.
58. Brabers, A. E. M., Rademakers, J. J. D. J. M., Groenewegen, P. P., van Dijk, L. & de Jong, J. D. What role does health literacy play in patients' involvement in medical decision-making? *PLoS ONE*12, e0173316 (2017).
59. Bennett, B. L., Goldstein, C. M., Gathright, E. C., Hughes, J. W. & Latner, J. D. Internal health locus of control predicts willingness to track health behaviors online and with smartphone applications. *Psychol. Health Med.*22, 1224–1229 (2017).

Author Biographies

Michael Truong (mikeydtruong@gmail.com) is a graduate student in the School of Biomedical Informatics at the University of Texas Health Science at Houston.

Susan H. Fenton(susan.h.fenton@uth.tmc.edu) is an associate professor and associate dean of academic and curricular affairs at The University of Texas Health Science Center at Houston School of Biomedical Informatics.

Sponsored by the AHIMA Foundation with support from Anisa Tootla and Megan McVane, LCSW.

Rural Access and Usage of Patient Portals: A 2019 Health Information National Trends Survey Analysis

By Grishma P. Bhavsar, PhD, MPH; Ashley S. Robertson, PhD, JD; and Dalton Pena, MSHA

Abstract

To examine differences in rural and urban respondents' use of and access to patient portals in the United States, this study used the 2019 National Cancer Institute's Health Information National Trends Survey (HINTS) 5, Cycle 3.A cross-sectional secondary data analysis utilizing jackknife weighting procedures was used to generalize the findings to be nationally representative.Despite similar rates of providers maintaining an electronic medical record system, adjusted analyses found that rural respondents had lower odds of being offered access to a patient portal by their healthcare provider (OR: 0.60; 95 percent CI: 0.39-0.91) and accessing their patient portals in the last 12 months (OR: 0.62; 95 percent CI: 0.43-0.91) when compared to their urban counterparts.Additional research is needed to determine effective strategies for overcoming geographic and structural barriers to adoption of this technology by rural residents.

Keywords: rural, patient portal, disparity, technology

Introduction

Healthcare continues to experience a need to meet the ambitious systematic approach of the Institute for Healthcare Improvement's (IHI) Triple Aim initiative: to improve the health of populations, reduce per capita cost of healthcare, and improve the patient experience.[1] In an effort to meet the needs of improving the patient experience, collaboration between healthcare organizations, physicians, and the engagement of patients is fundamental.[2] While initiatives foster collaboration at professional levels, patient engagement tends to be a more challenging aspect of individualized, family, and population healthcare. The use of electronic medical records (EMR), personal communication technologies, and patient portals provide a means to increase patient engagement and thus improve quality care and patient satisfaction.

Patients are showing an increased need to access their health information since the "Big Push" for EMR systems in 2009.[3] A patient portal, the primary method of accessing one's own health information, is "a secure online website that gives patients convenient, 24-hour access to personal health information from anywhere with an internet connection."[4] Patient portal use is primarily used to securely message physicians, schedule appointments, request prescription refills, and review lab results and educational materials.[5,6] The benefits of patient portal use have shown to increase patient satisfaction,[7,8] disease awareness,[9] communication with providers,[10] and support medication management and adherence.[11-14]Studies on the association of patient portal use and improved patient outcomes, however, have mixed results.[15-18]

Despite these benefits and an increase in the use of other technologies in healthcare, access and use of patient portals remains low in the United States, increasing from 25.6 percent in 2014 to 31.4 percent in 2018.[19-21] Barriers to patient portal adoption include lack of provider and patient buy-in, lack of awareness of portal functions, and negative patient experiences using portals.[22]Additional reasons for not using patient portals include patients' desire to speak directly to healthcare providers and privacy and security concerns.[23,24]

The lack of patient portal use is particularly concerning for residents of rural communities, who generally experience reduced access to healthcare at all levels, as well as a greater travel burden to access care.[25] This population stands to benefit considerably from increased utilization of patient portals, as they provide a salient means of direct engagement between patients and providers. Despite recent studies finding healthcare providers in rural areas maintaining EMRs at similar rates to urban areas, rural patients are less likely to access online medical records, email providers, and manage personal health information online.[26,27] This study examines disparities in both:being offered access to and utilization of patient portals, as well as patient-reported explanation of utilization or non-utilization, by rurality.

Methods

Data for this analysis was drawn from the National Cancer Institute's 2019 Health Information National Trends Survey (HINTS) 5, Cycle 3. The annual survey provides a nationally representative sample of civilian, non-institutionalized adults aged 18 and older and monitors changes in health communication, with a specific interest in use of cancer-related information. Data collection for this particular cycle of the survey took place from January through May 2019 via a mailed questionnaires and web pilot and collected a total of 5,438 responses. Specific details on the sampling and data collected protocols can be found in the dataset's methodology report.[21] Respondents that reported their provider did not maintain an electronic medical record were excluded from the analysis (*n*=1,053).

This analysis examined two dependent variables: whether the respondent was offered access to the patient portal ("Have you ever been offered online access to your medical records by your healthcare provider?" dichotomized as yes versus no/don't know) and whether the respondent accessed the patient portal within the last 12 months ("How many times did you access your online medical record in the last 12 months?" dichotomized as yes [1 or more times] versus no [0 times]). The term "online medical record" in the survey was appropriately interpreted as a patient portal in this analysis. Using the United States Department of Agriculture's (USDA) 2013 Rural-Urban Continuum Codes, respondents were categorized as urban (1-3) and rural (4-9) as the independent variable. The control variables included gender (male, female), age (18-34, 35-49, 50-64, 65-74, 75-plus years), race and/or ethnicity (non-Hispanic white, non-Hispanic Black, Hispanic, non-Hispanic Asian, non-Hispanic other), education (less than high school, high school graduate, some college, college graduate or more), health insurance (yes/no), regular healthcare provider (yes/no), and use of internet (yes/no).

Using SAS 9.4, this cross-sectional analysis utilized jackknife weighting procedures for complex survey design to generalize the findings to be nationally representative. Additional information about the weighting procedures can be found in the HINTS methodology report.[28] Descriptive statistics were performed to describe the sample characteristics. In bivariate analysis, chi-square tests at the 95 percent confidence level (α=0.05) were conducted to examine rural or urban differences in being offered access to a patient portal and accessing the patient portal. An adjusted logistic regression was performed to examine potential predictors of the dependent variables, controlling for respondent demographics.

Results

There were no differences in providers maintaining electronic medical records (79.1 percent urban versus 76.5 percent rural; *p*= 0.4607; analysis not shown). The remaining analyses included only the providers that were maintaining an electronic medical record (*n*=4,293). Of the 4,293 respondents, 3,826 (89.1 percent) were urban residents and 467 (10.8 percent) were rural residents. Respondents were predominately female, non-Hispanic (NH) white, 50-64 years old with some college education, health insurance, a regular healthcare provider, and access to internet (**Table 1**).

Chi-squared tests found significant differences in race and/or ethnicity and education by rurality. A larger percentage of rural respondents were NH white (84.5 percent versus 63.2 percent), while a smaller percentage were Hispanic (7.4 percentversus 16.4 percent) when compared to urban respondents. Fewer rural respondents were college graduates (21.4 percentversus 33.2 percent; *p*=0.0017). In bivariate analysis, there were significant differences in whether providers offered access to and whether the respondent accessed a patient portal (**Table 2**). Rural respondents were less likely to report being offered access to a patient portal (56.9 percentversus 66.9 percent; *p*=0.0397) and less likely to access a patient portal (35.9 percentversus 48.4 percent; *p*=0.0046).

No differences in primary use of patient portals or reasons for not accessing patient portals were found among rural respondents when compared to their urban counterparts (**Table 3**). The majority of patient portal users found it easy to understand (90.6 percent) and useful (86.7 percent). The primary use of patient portals was to view test results (86.6 percent), securely message a healthcare provider and staff (52.7 percent), and request a refill of medication (46.7 percent). The primary reasons for not accessing a patient portal were that respondents preferred to speak to a healthcare provider directly (73 percent) and they did not perceive a need to use the patient portal (59.1 percent). Again, no differences in reasons for lack of accessing a patient portal were found between rural and urban respondents.

Adjusted logistic regression (**Table 4**) estimated differences in accessing a patient portal in the last 12 months (Model 1) and being offered access to the patient portal by a healthcare provider (Model 2). In Model 1, identifying as female (OR: 1.52, 95 percent CI: 1.18-1.97) and having an education of high school graduate or greater was associated with greater odds of having accessed a patient portal in the last 12 months. While living in a rural area (OR: 0.62; 95 percent CI: 0.43-0.91), identifying as NH Black (OR: 0.56; 95 percent CI: 0.36-0.89), not having a regular healthcare provider (OR: 0.49; 95 percent CI: 0.35-0.70), and having no internet use (OR: 0.28; 95 percent CI: 0.15-0.51) were associated with lower odds of having accessed a patient portal in the last 12 months.

Model 2, which demonstrates the odds of being offered access to a patient portal by a healthcare provider, shows that living in a rural area (OR: 0.60; 95 percent CI: 0.39-0.91), identifying as Hispanic (OR: 66; 95 percent CI: 0.48-0.90) or NH Asian (OR: 0.46; 95 percent CI: 0.27-0.77), not having a regular healthcare provider (OR: 0.40; 95 percent CI: 0.29-0.56), and not having internet use (OR: 0.30; 95 percent CI: 0.20-0.45) were associated with lower odds of having been offered access to a patient portal.

Discussion

Coinciding with other recent studies, this study found no differences in providers maintaining electronic medical records whether in rural or urban areas.[29,30]Despite providers using electronic medical records at similar rates, the findings from both models in this study indicate rural residents have lower odds of being offered access to a patient portal and are subsequently less likely to actually access a patient portal. Adjusted models are consistent with rural, racial, and education disparities found in the literature on access of and being offered access to patient portals.[31-40] Additionally, these findings confirm previous studies on reasons patient portals were utilized[41]and further confirm that there are no rural or urban differences in reasons for not wanting to access a patient portal.

This analysis demonstrates that despite continued attempts to focus on patient engagement, low patient portal use continues. Without providers encouraging and supporting use of patient portals, low adoption rates are likely to persist and potential benefits and improvements to the patient experience will go unrecognized.[42,43] Previous studies have found that provider encouragement to use patient portals increases the odds of a patient using the portal by almost 10 times.[44]Helping patients understand the benefits of accessing their patient portal is critical to ensuring this technology is used to improve health outcomes for all.However, provider encouragement is only a piece of the puzzle to increasing patient portal use. Other studies have pointed to effective strategies that can be implemented at an organizational level, such as: providing ongoing technical assistance or continuing to monitor usage and satisfaction.

Limitations

Several limitations should be considered when evaluating the results of this research. The first is that the HINTS survey response rate was approximately 30 percent, leading to the potential that the findings of this study are not representative of the study population as a whole due to nonresponse bias. The survey is also limited to those living the United States and, therefore, cannot be generalized to other countries. In addition, as this study analyzes cross-sectional data, we cannot infer a causal relationship between rurality and odds of use of and access to patient portals. Further, given the limitations of the survey data, we were unable to control for a number of provider-level factors that could help to elucidate likelihood of patient exposure to patient portals or effectiveness of portals at the provider level. While additional data on patient preferences could be used to explain some of the reasons for the limited access of patient portals by rural populations and assist vendors in designing more useful patient portals, this analysis was limited to the data available in the HINTS survey. Finally, as HINTS data is self-reported, there is a strong potential for inaccurate recollection of past offers of access to such portals. Given the relative lack of assignment of social desirability value of actually accessing patient portals, there is little concern as to potential for social bias.

Conclusion

Patient portals hold the potential of further engaging patients in their care by connecting them to their own health information. However, our results indicate that there remain significant differences in the access and usage of patient portals by rural populations. Continued support in the form of financial incentives and legislative provisions must focus on addressing geographic and structural barriers faced by rural communities in adopting and embracing technology, such as patient portals. In the meantime, it is imperative to recognize that the digital divide continues to exist and increasing the availability of the internet and using provider encouragement as a tool to promote the use of patient portals continue to be necessary. Additional research must be conducted to determine effective strategies to overcome barriers to patient portal adoption among rural populations and determine specific features within patient portals that lead to consistent improvements in care processes and health outcomes.

Notes

1.Institute for Healthcare Improvement. "The IHI Triple Aim Initiative." IHI.org; 2020. Available at: http://www.ihi.org/engage/initiatives/TripleAim/
2. Whittington JW, Nolan, K, Lewis, N, Torres, T. "Pursuing the Triple Aim: The First 7 Years." *The Milbank Quarterly* 93, no. 2 (2015): 263-300. doi: 10.1111/1468-0009.12122
3. Heath S. "Top Challenges Impacting Patient Access to Healthcare." Patient Engagement HIT. 2018. Available at: https://patientengagementhit.com/news/top-challenges-impacting-patient-access-to-healthcare
4. HealthIT.gov. "What is a patient portal?." 2017. Available at: https://www.healthit.gov/faq/what-patient-portal
5. Ibid.
6. Patel V, Barker, W, Siminerio, E. "Trends in Consumer Access and Use of Electronic Health Information." 2015. Available at https://dashboard.healthit.gov/evaluations/data-briefs/trends-consumer-access-use-electronic-health-information.php
7. Kruse S, Bolton, K, Freriks, G. "The Effect of Patient Portals on Quality Outcomes and Its Implications to Meaningful Use: A Systematic Review." *Journal of Medical Internet Research* 17, no. 2 (2015): e44. doi: 10.1111/1468-0009.12122
8. Wade-Vuturo A, Mayberry, L, Osborn, C. "Secure Messaging and Diabetes Management: Experiences and Perspectives of Patient Portal Users." *Journal of the American Medical Informatics Association* 20, no. 3 (2013): 519-525. doi: 10.1136/amiajnl-2012-001253
9. Kruse S, Bolton, K, Freriks, G. 2015.
10. Devkota B, Salas J, Sayavong S, Scherrer JF. "Use of an Online Patient Portal and Glucose Control in Primary Care Patients with Diabetes." *Population Health Management* 19, no. 2 (2016): 125-131. doi: 10.1089/pop.2015.0034
11. Kruse S, Bolton, K, Freriks, G. 2015.
12. Osborn CY, Mayberry LS, Wallston KA, Johnson KB, Elasy TA. "Understanding Patient Portal Use: Implications for Medication Management." *Journal of Medical Internet Research* 15, no.7 (2013): e133. doi: 10.2196/jmir.2589
13. Sarkar U, Lyles, C, Parker, M, Allen J, Nguyen R, Moffet HH, Schillinger, D, Karter, AJ. "Use of the Refill Function through an Online Patient Portal is Associated with Improved Adherence to Statins in an Integrated Health System." *Medical Care* 52, no. 3 (2014): 194-201. doi: 10.1097/MLR.0000000000000069

14. Lyles CR, Sarkar U, Schillinger D, Ralston JD, Allen JY, Nguyen R, Karter, AJ. "Refilling medications through an online patient portal: consistent improvements in adherence across racial/ethnic groups." *Journal of the American Medical Informatics Association* 23, no. e1 (2016): e28-e33. doi: 10.1093/jamia/ocv126
15. Kruse S, Bolton, K, Freriks, G. 2015.
16. Wade-Vuturo A, Mayberry, L, Osborn, C. 2013.
17. Lau M, Campbell H, Tang T, Thompson DJ, Elliott T. "Impact of Patient Use of an Online Patient Portal on Diabetes Outcomes." *Canadian Journal of Diabetes* 38, no. 1 (2014): 17-21. doi: 10.1016/j.jcjd.2013.10.005
18. Dumitrascu AG, Burton MC, Dawson NL, Thomas CS, Nordan LM, Greig HE, Aljabri, DI, Naessens, JM. "Patient portal use and hospital outcomes." J*ournal of the American Medical Informatics Association* 25, no.4 (2018): 447-53. doi: 10.1093/jamia/ocx149
19. Patel V, Barker, W, Siminerio, E. 2015.
20. Hong A, Jiang, S, Liu, P. "Use of Patient Portals of Electronic Health Records Remains Low From 2014 to 2018: Results From a National Survey and Policy Implications." *American Journal of Health Promotion* 34, no.6 (2020): 677-680. doi: 10.1177/0890117119900591
21. Fraccaro P, Vigo M, Balatsoukas P, Buchan IE, Peek N, van der Veer SN. "Patient Portal Adoption Rates: A Systematic Literature Review and Meta-Analysis." *Studies in Health Technology and Informatics* no. 245 (2017): 79-83.
22. Amante DJ. "A Systematic Review of Electronic Portal Usage Among Patients with Diabetes." *Diabetes Technology & Therapeutics* 16, no.11 (2014): 784-793. doi: 10.1089/dia.2014.0078
23. Patel V, Barker, W, Siminerio, E. 2015.
24. Anthony DL, Campos-Castillo C, Lim PS. "Who Isn't Using Patient Portals And Why? Evidence And Implications From A National Sample Of US Adults." *Health Affairs* 37, no. 12 (2018): 1948-1954. doi: 10.1377/hlthaff.2018.05117
25. Bolin JN, Bellamy GR, Ferdinand AO, Vuong AM, Kash, BA, Schulze A, Helduser, JW. "Rural Healthy People 2020: new decade, same challenges." *Journal of Rural Health* 31, no.3 (2015): 326-33. doi: 10.1111/jrh.12116
26. Greenberg AJ, Haney D, Blake KD, Moser RP, Hesse BW. "Differences in Access to and Use of Electronic Personal Health Information Between Rural and Urban Residents in the United States." *Journal of Rural Health* 34, no. Suppl 1 (2018): s30-s38. doi: 10.1111/jrh.12228
27. Krakow M, Hesse, B, Oh, A, Patel, V, Vanderpool, R, Jacobsen, P. "Addressing Rural Geographic Disparities Through Health IT: Initial Findings From the Health Information National Trends Survey." *Medical Care* 57, no. Suppl 2 (2019): S127-S132. doi: 10.1097/MLR.0000000000001028
28. Health Information National Trends Survey 5 (HINTS 5) Cycle 3 Methodology Report. Bethesda, MD: National Cancer institute Health Information National Trends Survey. 2019. Available at: https://hints.cancer.gov/data/methodology-reports.aspx
29. Krakow M, Hesse, B, Oh, A, et al. 2019.
30. Health Information National Trends Survey 5 (HINTS 5) Cycle 3 Methodology Report. 2019.
31. Osborn CY, Mayberry LS, Wallston KA, et al. 2013.
32. Sarkar U, Lyles, C, Parker, M, et al. 2014.
33. Hong A, Jiang, S, Liu, P. 2020.
34. Anthony DL, Campos-Castillo C, Lim PS. 2018.

35. Greenberg AJ, Haney D, Blake KD, et al. 2018.
36. Krakow M, Hesse, B, Oh, A, et al. 2019.
37. Ancker JS, Barron, Y, Rockoff, ML, Hauser, D, Pichardo, M., Szerencsy, A, Calman, N. "Use of an Electronic Patient Portal Among Disadvantaged Populations." *Journal of General Internal Medicine* 26, no. 10 (2011): 1117-1123. doi: 10.1007/s11606-011-1749-y
38. Jhamb M, Cavanaugh KL, Bian A, Chen G, Ikizler TA, Unruh ML, Abdel-Kader K. "Disparities in Electronic Health Record Patient Portal Use in Nephrology Clinics."*Clinical Journal of the American Society of Nephrology* 10 (2015): 2013-2022. doi: 10.2215/CJN.01640215
39. Goel MS, Brown TL, Williams A, Hasnain-Wynia R, Thompson JA, Baker DW. "Disparities in Enrollment and Use of an Electronic Patient Portal." *Journal of General Internal Medicine* 26, no. 10 (2011): 1112-1116. doi: 10.1007/s11606-011-1728-3
40. Peacock S, Reddy A, Leveille SG, Walker J, Payne TH, Oster NV, Elmore JG. "Patient Portals and Personal Health Information Online: Perception, Access, and Use by US Adults." *Journal of the American Medical Informatics Association* 24, no. e1 (2017): e173-e177. doi: 10.1093/jamia/ocw095
41. Greenberg AJ, Haney D, Blake KD, et al. 2018.
42. Patel V, Barker, W, Siminerio, E. 2015.
43. Krakow M, Hesse, B, Oh, A, et al. 2019.
44. Amante DJ. 2014.

Author Biographies

Grishma P. Bhavsar (grishma.bhavsar@csun.edu) is an associate professor in the Department of Health Sciences at California State University Northridge.

Dalton Pena (depena@uab.edu) is a PhD student in administration-health services at the University of Alabama, Birmingham.

Ashley S. Robertson (ashsrobe@iu.edu) is an assistant professor of health services management at Indiana University Purdue University Indianapolis/Indiana University Fort Wayne.

Perceptions and Concerns of SUD Treatment OrganizationsRegarding the CARES Act's Alterations to Patient Confidentiality Regulations

By Julia Ivanova, MA; Michael Saks, PhD; George Karway, MS; Anita Murcko, MD; Candy Espino, MBA; Chase Millea, JD; Melissa Soliz, JD; and Adela Grando

Abstract

Objectives: Learn how substance use disorder (SUD) treatment organizations view and respond to changes in confidentiality and disclosure law following adoption of CARES ActSec. 3221 and prior to promulgation of revised implementing regulations.

Methods: Online survey followed by informal interviews. Representatives of SUD organizations reported their degree of awareness of Sec. 3221 provisions and their organizations' views on amendments to disclosure practices;current and future changes of organizational policies; difficulties anticipated in implementing new rules; and preferences for resources.

Results: Forty informant surveys on 30 organizations completed. Participants (62.5 percent) indicated being somewhat knowledgeable about Sec. 3221. Evenly divided positive and concerned views on Sec. 3221 reflect tension between preserving confidentiality of patient records and improving coordination of care. Most (76.7 percent) reportedorganizational discussions on Sec. 3221. Some (30 percent) identified changes to make in near future.Over a third expected few or no barriers to implementing changes to privacy and disclosure practices, while most (64.7 percent)expected hindrances including complexity and tensions in the law, staff education, cost, technological adjustments, and changes in the ways SUD organizations interact with external organizations and individuals. To overcome barriers noted, participants expressed desire (66.7 percent) for teaching tools such as webinars and templates to follow.

Conclusions:SUD treatment organizations began thinking of and planning for proposed changes well before expected implementation ofSec. 3221. Their concerns reflected practicalities of implementation, determining content of law, and wondering about the extent to which it solves problems (improving coordination of care among various providers) or endangered other goals (protecting confidentiality of SUD patient records).

Keywords: Part 2, CARES Act Sec. 3221, substance use disorder treatment organizations, confidentiality, coordination of care

Introduction

In March 2020, Section 3221 of the Coronavirus Aid, Relief, and Economic Security Act (hereinafter referred to as Sec. 3221) became law, calling for substantial changes in long-standing privacy and confidentialityregulations (42 U.S.C. § 290dd-2), which had protected the personal health information of patients withsubstance use disorder (SUD) who are treated by federallyassisted SUD treatment organization providers. This change creates a set of challenges to patients and providers in that it shifts the working presumption of the law from restricting disclosure of SUD patient records to encouragingHealth Insurance Portability and AccountabilityAct (HIPAA)-like disclosure.

Existing law, including its implementing regulations (42 C.F.R. Part 2) (collectively, “Part 2”),had restricted whetherand what identifiable health information of such patients may be disclosed without the patient’sprior written consent. Part 2’s central purpose was to encouragepatients to seek and remain in treatment by ensuring the confidentiality of their SUD information.[1-4] That contrasts with HIPAA, which permits treating providers and other regulated entities to shareidentifiable information for treatment, payment, and healthcare operations (TPO) without a patient’s additionalauthorization or consent.

Sec. 3221 changes Part 2 most notably by streamlining disclosure requirements to alignmore closely with HIPAA by expressly permitting use of one-partyconsent to authorizeall subsequent disclosures,[5] as well as re-disclosures, of Part 2-protected SUD information for atleast HIPAA-permitted TPO purposes, unless thepatient revokes consent. In contrast, the prior rule required patient consent for each disclosure of the patient’s Part 2 data (including for TPO).[6]

Ease-of-disclosure versus privacy-of-records is a controversial issue. On one hand are the benefits of improved coordination of care.[7] By authorizing disclosure with a single act of consent, patients can facilitate the integration of their care, enabling their healthcare providers to work together more easily for the patient’s benefit. Illustrating the problem, one study found that use ofelectronic health information exchange (HIE) on discharge from acute care hospitals was 88 percent, while the frequency from psychiatric units was only 56 percent.[8] More expansive consent would also facilitate such activities as quality improvement,claims management, patient safety, training, and strengthening of program integrity.

On the other hand, a high degree of confidentiality is thought to be necessary to help SUD patients feel safe enough to seek treatment. Indeed, that was one of the central motivations for the initial statute, 42 U.S.C. 290dd-2, which led to Part 2.[9]Without such protection, the concern is that fewer patients will obtain treatment and society’s SUD challenges will persist or worsen.

Under Sec. 3221, SUD patientscan give broad and perpetual permissionfor disclosure of their health information without appreciating how extensive that consent might be.[10]If shared with anHIE, disclosure becomes widely available for all permitted uses. At the time of granting consent, typically at the initiation of care, patients are unlikely to anticipate the extent or consequences of future disclosures and uses of their SUD information. Later revocation of consent is legally possible, but then the burden is on patients to initiate the revocation, and carrying out the patients’ changed wishes presents practical difficulties. Once disclosed and re-disclosed, information cannot easily be undisclosed.

Sec. 3221 attempts to mitigate risks associated with relaxed limitations on disclosure through several other vital provisions: 1) tracking of disclosures of Part 2information; 2) continued emphasis that Part 2 information may not be used in criminal, civil, oradministrative proceedings against the person suffering from SUD; 3) breach notification reporting requirements; 4) shifting of enforcement awayfrom the US Department of Justice (DOJ) to HHS with new civil penalties and strengthened criminalpenalties for violation of those protections; and 5) an express prohibition against using Part 2information to discriminate against a person with respect to that person's treatment, employment,worker's compensation, housing, court access, social services, or benefits—known issues forpeople with SUD.[11-13]

The CARES Act, containing Sec. 3221, became law on March 27, 2020. Enabling regulations were to be drafted by the US Department of Health and Human Services (HHS) within one year, but doing so has taken longer. As of this writing (March2022), no proposed amended regulations have been announced.With amendments to the law coming one on top of another, a former director of the Center forSubstance Abuse Treatment atthe Substance Abuse and Mental Health Services Administration (SAMHSA) has characterized the situation as "mass confusion."[14]

What are SUD treatment organizations doing during the interregnum between the passage of the statute and the promulgation of new implementing regulations? This study used the period of delay to explore stakeholders'knowledge, opinions, plans, and actions regarding Sec. 3221's alterations to Part 2.Specifically,[15] 1) awareness of the new statute, 2) views on revisions to disclosure practices, 3) internaldiscussions regarding changes within organizations, 4) anticipated difficulties implementingprovisions of Sec. 3221, and 5) preferences for assistance or resources to facilitate compliance.

Evidence-based data on the perspectives and needs of SUD organizations mightfacilitate the work of those organizations, as well as entities trying to assist theminimplementing the new law. A 2021 scoping literature review of Part 2 recommended further "research on Part 2 and [HIPAA] alignment," as well as on the actual, measured effects of Part 2 on patients, providers, and other stakeholders.[16]Therefore, notonly is there a need for stakeholder engagement in Part 2 modernization but also for research onthe rationale and feasibility of Part 2 alignment with HIPAA.

Methodology

Study Site and Participants

Our study focused onSUDtreatment organizations in Arizona, of which there are 137. In addition to Arizona being where the researchers are located (and therefore have relationships that facilitated carrying out the study), Arizona is a reasonably representative state for this research. The center of Arizona's population is Maricopa County, which contains over 61 percent of the state's population.[17] As of the 2019 census, Arizona has a population of 7,278,717, with a racial makeup of82.8 percent white, 5.3 percent American Indian and Alaska Native, 5.1 percent Black, 3.7 percent Asian, 0.3 percent Native Hawaiian and Other Pacific Islander, and 2.9 percent being two or more races.[18] Hispanics and Latinos of all races make up 31.6 percent of the state's population; non-Hispanic whites make up 54.4 percent. Arizona has the third highest number (and the sixth highest percentage) of Native Americans of any state in the Union.
The Arizona Health Care Cost Containment System (AHCCCS) is Arizona's Medicaid. AHCCCS implemented Complete Care (ACC) in 2018, a system that integrated physical and behavioral health (mental illness and SUDs) services to treat all aspects of members' healthcare needs under a chosen health plan.[19] ACC encourages coordination between providers within the same network to achieve better health outcomes for members. The Arizona Substance Abuse Partnership (ASAP) serves as the single statewide council on substance abuse prevention,

treatment, and recovery efforts. Arizona also has a single state-based HIE, Health Current. Health Current is a public-private partnership that supports the medical record exchange between behavioral and physical care providers.

Following approval from the Arizona State University Internal Review Board (IRB) (Study 11902), researchers began recruitment of persons occupying positions within SUD organizations.Information sought included: (1) their organization's policies concerning confidentiality and sharing of patient records, and (2) planning for possible changes in those policies.

Outreach and recruitment were undertaken via email with the help of the Arizona Council of Human Service Providers (ACHSP) and the Arizona Opioid Treatment Coalition (AOTC), which sent invitations on our behalf to their members. Additional organizations were identified using the most current edition of the SAMHSA directory.[20] Potential participants were provided an overview of the project, its goals, and participant inclusion criteria, and were invited to visit the survey website.

ACHSP, the main source of participants, recruited from a pool of 105 member organizations. Most or all members of ACHSP are also part of the AOTC. The SAMHSA directory listed 137 unique SUD organizations in Arizona, not all of which are treatment providers. We were, therefore, sampling from a population of between 105 and somewhat under 137 organizations. Thirty unique SUD organizations were represented in our collected data. Thus, the response rate for organizations was somewhere between 28.6 percent and (somewhat more than) 21.9 percent.

The main unit of analysis of the study was the organization, and the individuals we surveyed were informants about those organizations. Responding to our invitations, a total of 65 surveys were started and 40 individual surveys were substantially completed and analyzed. All informants were English speakers over the age of 18.

Data Collection

An online survey using Qualtrics was developed that included demographic information, multiple choice questions, and free-response questions. The survey (Appendix 1) took about 10 minutes to complete. At the end of the survey, participants were invited to arrange a time to discuss the issues further with a member of the research team. Nine volunteered to do so.

Data Analysis

The multiple-choice survey data were analyzed using descriptive statistics.For seven ofthe organizations, we had data from more than one informant. Responses from those multiple informants were combined to reflect the actions and views of their organization. Free responses in the survey were analyzed in MAXQDA 2020. (MAXQDA 2020 is an advanced qualitative and mixed methods software package used for comprehensive qualitative data analysis.See https://www.maxqda.com/new-maxqda-2020.)

Responses were organized by participants and coded within each free response question, with researchers checking whether participants from the same organizations provided conflicting information.Thematic analysis was conducted using participants' full question response as the code of analysisby two authors to identify emerging topics and concerns from organizations regardingSec. 3221.[21]Over three iterations, two authors assessed differences in their coding, and discrepancies were resolved by consensus to reach complete agreement.[22,23]Codes were organized by free-response topic.

Results

Respondents

Table 1 lists the job titles of the informants, arranged (and grouped) according to seniority level in their organization as indicated by job title. Table 2 lists their roles in their organization, arranged (and grouped) by how "close" or "far" they seem to be to the problem at issue. When asked about their knowledge of Sec. 3221 and Part 2, participants responded by indicating they were: very knowledgeable (22.5 percent), somewhat knowledgeable (62.5 percent), uncertain,(5 percent), not very knowledgeable (10 percent), or not at all knowledgeable (0 percent). These responses suggested that our respondents were informed about their organizations' reactions to Sec. 3221.

Structured survey response

The collected data reflect actions, plans, and concernsat the level of those organizations–that is, by the collective, internal policy team rather than those of the individual respondents.Regarding discussions of Sec. 3221 at the policymaking level within organizations, 76.7 percent of organizations reported having such discussions, 20 percent had not, and 3.3 percent did not know.

Of the organizations that reported having discussions at the policy level, 25 percenthad already started making changes in line with Sec. 3221, 30 percent had identified changes they intended to make, 25 percentwere waiting for more concrete federal guidance before making their decisions, 20 percentsaid their discussions were only very general, and another 15 percent indicated their discussions were of some other nature.

Free-response themes

Informants provided more detailed comments in response to semi-structured questions in the survey, and a subset of them also participated in subsequent informal conversation with one of the researchers, providing further information.Themes and subthemes of responses to the open-ended questions in the written questionnaire are enumerated in Figure 1. Illustrative verbal responses from both the questionnaire and informal verbal discussion are listed in Table 3, grouped by topic.

Of the few organizational changes already made or being made in relation to Sec. 3221,nearly all focused on disclosure policies and practices (83.3 percent). In addition, one organization addressed re-disclosure policies: “Reviewed and modified language on the redisclosure policy.”

Ofchanges being contemplated by SUD organizations, most responses focused on privacy practices. This subtheme contained a diversity of topics, including consent practices, coordination of data flow, re-disclosure, and program impact.For example, one respondent noted that theorganization was anticipating changes to “Consents and changes with collaboration with PCPs [primary care physicians]and HIE.”

Participants were also asked about any barriers the organization had experiencedthat they anticipated might impede the implementation of new policies and practicesdesigned to respond to Sec. 3221. This question elicited 34 responses, including specific challenges such as educating staff (11.8 percent), adapting information technology (8.8 percent), and cost (2.9 percent). Others were more nuanced, such as complexity and tensions of Sec. 3221 (20.6 percent) and dealing with external agencies (which, at least initially, were not expected to be synchronized with the changes being made by SUD organizations) (14.7 percent). Comments reflecting difficulties interpreting the law included: “Inconsistencies with how the regulations are interpreted and implemented” and“There have been either gray areas, or areas difficult to understand when it comes to what the law states.”But 35.3 percentof respondents indicated they anticipated no barriers or very minor barriers.

Respondents were then asked about assistance and resources they thought would be helpful for overcoming barriers to putting Sec. 3221 policy changes into effect.Organizations expressed a desire to be educated and advised, notably through webinars (66.7 percent) and to be provided with teaching tools (53.3 percent), such as models and guides to use as templates for developing their own forms and policies. For example, one respondent commented that a “Step-by-step guide of the changes and recommendations of correct implementation…would be useful.” Another participant specified some of what might be included in webinars: “Lots of webinars for the provider community so we are on the same page. More clarification around the designated record set and when non-Part 2 agencies have a Part 2 program operating within—unable to segregate the records.”Further, providingSec. 3221education beyond the domain of SUD organizations was thought to be beneficial: “A big reason why HIPAA has been so effective is because it is so widely known by people outside the healthcare space. A public information campaign targeted at these third parties would be beneficial...”

Additional issues arose in the informal interviews with respondents and researchers.Mentioned relatively often were concerns about tensions between Sec. 3221 and Part 2, gray areas in understanding the requirements and applications of these patient privacy laws, the tension between patient privacy rights and the integration of physical and behavioral healthcare, the possibility of patients exercising granular control of disclosure of their records (being able to specify what information could be disclosed to whom), and technological challenges such as interfacing efficiently with HIEs, which is not yet easy to do.

Opinions on Sec. 3221 were nearly evenly divided between positive and negative views, aligning with preferences for greater ease of integrating behavioral and physical care versus protecting the privacy rights of SUD patients as a means of facilitating their willingness to seek and remain in treatment.

Another large theme had to do with interpreting and applying Part 2, suggesting that hardships and gray zones were concerns for organizations. Some viewed Part 2 as adverse to care standards (e.g.,coordination of care) or incongruent with technology, dated, needing granularity, and tending to be unenforced. As one informant stated, "We're kind of small, and we don't really have an IT department. So maybe we haven't set things up quite right with our EHR to be able to do what it's supposed to do…[The HIE is] figuring it out…by the time we get set up with the new electronic health record, hopefully they'll have more of the glitches worked out….You're trying to take the lead from the higher ups and hopefully they'll figure it out before we need it."

Respondents sometimes mentioned the struggle to adhere to Part 2 confidentiality in the face of law enforcement efforts to obtain information about patients. As one commented: "…It's very clear, in fact, the CARESAct just reinforced[Part 2] that [SUD] treatment is not supposed to be used in criminal cases…it's getting treatment instead of incarceration, so they are trying to help coordinate the clients getting what they need. But at the same time they are law enforcement. So is it really coordination of care, and should they really be part of our team meetings and be getting updates regularly, and does the consent really cover that…?"This participant also states that while Sec. 3221 reinforces many aspects of Part 2, it does not add clarity to law enforcement disclosures. Another said, in regard to both Sec. 3221 and Part 2: "[With HIPAA,] people already know that you can't do this … they call you first instead of just dropping a subpoena on you or showing up with a search warrant."

Finally, we coded all of the respondents from the survey based on the groupings in Table 1 and ran a complex coding query (intersections). Because the results are most meaningful when the groups' frequencies are comparable, we focused on the CEO group (top group in the table) versus the other C-suite group (the group immediately below the CEO group). Results of thecoding query yielded no identifiable differences between those twogroups. The themes are addressed similarly by both groups.Further analysis looked for whether subtopics of the themes showed any identifiable differences, but they did not. Still further analysis looked to see whether differences could be detected in comparison with the privacy and/or quality and the licensed counselor groups. Here, too, we found no differences in themes being discussed.

In summary, the diversity of opinions and level of planning by SUD organizations regarding Sec. 3221 suggest the impact will vary among organizations and reflect concern with different barriers and benefits.

Discussion

By the time data collection began, less than six months after passage of Sec. 3221 of the CARES Act and long before implementing regulations will have been promulgated, most SUD treatment organizations were aware of the Act, discussing it at internal policy levels. A third of the organizationswere planning concrete changes,and a fifth had already undertaken changes.The rest were discussing the implications of Sec. 3221 and waiting for more guidance before undertaking more concrete planning.

Informal interviews suggested that organizations were evenly divided on whether they had favorable views versus concerns about Sec. 3221. Representatives of most organizations viewed Sec. 3221'ssupport of patient-directed granular information sharing as positive, though such disclosures are often constrained based on the sophistication of provider segmentation technologies, as well as facility discretion. Because SUD organizations are a key stakeholder in implementation oftechnology to facilitate granular disclosure, those findings should interest theOffice of the National Coordinator for Health Information Technology (ONC), a long-standing supporter of patient-directed granular consent.[24,25]

Implementation barriers identifiedby participants ranged from comprehension challenges to changing consent policies and forms, upgradingelectronic health records, training staff on new processes, and navigating newly complicated relations with external entities. Generally, SUD organizations are anticipating the required changes in the form of SAMHSA regulationsin the future but are seeking details that will empower them to plan and confidently implement changes under the new law.

Organizations overwhelmingly desire specific teaching tools,such as templates and examples, as well as trainings, webinars,and teaching materials detailing Sec. 3221regulatory requirements. Due to comprehension challenges and operational implementation concerns, organizations have expressed the need for expert legal advice regarding interpretations in order to move forward.

Participants indicated thata highprofile, broad community effort to integrate new requirements, in partnership with state Medicaid, would be beneficial to ensure efficient and effective adoption. Participants suggested thateducational outreach for HIPAA business associates and other outside entities, such as law enforcement and contractors, would be particularly helpful.Such a coordinated effort would increase discussion and understanding of patient confidentiality processes and policy across entities working with SUD treatmentorganizations.[26]As some study participants noted, ensuring all stakeholders are "on the same page" is a necessary step in clarifying expected external and internal processes for Sec. 3221.

Harmonizing the confidentiality of SUD treatment records with evolving state regulations wasa concern for studyparticipants. Regarding the state prescription drug monitoring program (PDMP), one participant specifically pointed out: "You know, reporting methadone—it's never been done before, it's like the sacred rule you know if there's any substance abuse information, that's private it's the facts and evidence, it's like a whole other level on top of CFR 42 and you know it's not written in…it's not something we're rushing to do."

Sec. 3221 promises to streamline the consent and disclosure process for SUD treatment records.[27,28]Study participants feel, however, that unwritten community standards will persist and evolve, at times creating community norms that overlay what the law requires. Some organizations mention they do not anticipate modifications to theircurrent privacy and disclosure processes: "Because we are a comprehensive agency, a lot of things are already in place that we don't need to change, and even though it's kind of loosening up in our favor, we aren't necessarily going to change anything. We're just going to rest a little easier, that's probably the best way." Some organizations maintain that keeping current processes, so long as they are more stringent than what the law requires, will be a less costly, less disruptive response that continues a high level of patient confidentiality, regardless of theflexibility provided by Sec. 3221: "We're probably going to continue doing what we do. It's already built into our system, so I don't see that there would be additional cost to bear out from it."

The survey and informal interview results highlight the complicated environment for SUD organizations as they juggle coordination of care, consent, patient rights, and the patchwork of existing laws to which Sec. 3221is being added. Over a third cited the complexity of integrating Part 2 with Sec. 3221, namely the new relationships with external agencies, organizations, and contractors. The informal discussions particularly exposed hardships and ambiguities SUD organizations currently experience with Part 2compliance and Sec. 3221's apparent absence of remedies for known thorny issues. Campbell et al. observed that Sec. 3221 follows the pattern of earlier amendments to Part 2 by not addressing fundamental stakeholder dilemmas such as the tension between confidentiality and integrated care.[29]In fact, the recent scoping review of the Part 2 literature reporteda dearth of research on the impact of Part 2, particularly on patients, providers, and other key stakeholders.[30]The conflict between patient rights, especially confidentiality, and coordination of care is well-documented.[31-35]We are at the beginning of the Part 2 andSec. 3221harmonization journey.

Limitations

While the sample of organizations was small, the method of analysis showed theme saturation was reached. Nearly all participants who failed to complete the survey stoppedas soon as they were asked about their specific role in their organization's Part 2 compliance.Those not directly involved in organizational policymaking regarding legal compliance, including with Sec. 3221, did not complete the survey.Most (85 percent) survey participants considered themselves knowledgeable or somewhat knowledgeable on the topic.Overall, this study's response rate fell within expected parameters.[36]

Conclusion

This study took advantage of a rare opportunity to gain some understanding of how SUD organizations are approaching regulatory changes that will substantially affect their work but for which they do not yet have implementing regulations to guide them. Future studies are needed to analyze how organizations are implementing Sec. 3221 and how the process impacts patients and other stakeholders. Our findings may serve as a point of reference or a comparison for later studies and policymaking, as well as offer some insights for efforts to assist SUD organizations in navigating changed law.

The study reveals a spectrum of reactionsby SUD organizations to the changes that will be wrought by Sec. 3221and identifies a clear need for impact research engaging patients, providers, and other key stakeholders. Though these provisions seek to align standards for confidentiality of SUD treatment with HIPAA and general clinical workflows,[37] Sec. 3221seems to fall short of addressing key needs and concerns of SUD organizations and patients. As of this writing, the SUD community still awaits promulgation of the regulations to implement the Sec. 3221 changes. The new balance between confidentiality and coordination of care for those involved in SUD care is unclear and will inevitably develop over time. Future research would do well to assess the views of and impact on key stakeholders, and, particularly, patients.

Support

This work was supported by the National Institute of Mental Health through *My Data Choices, evaluation of effective consent strategies for patients with behavioral health conditions* (R01 MH108992) grant.

Notes

1. Helms DJ. “A Guide to the New Federal Rules Governing the Confidentiality of Alcohol and Drug Abuse Patient Records.”*Contemp Drug Probs*. 1975;4(3):259–84.

2. McGovern TF. “Vulnerability: Reflection on Its Ethical Implications for the Protection of Participants in SAMHSA Programs.”*Ethics & Behavior*. 1998 Dec 1;8(4):293–304.

3. Rosenthal RN, Welsh JW, Connery HS, Barnett BS, DeVido J, Hill K, et al. “Advocacy and Public Policy Efforts of the American Academy of Addiction Psychiatry.”*Am J Addict*. 2020 Sep;29(5):401–6.

4. Walley AY, Farrar D, Cheng DM, Alford DP, Samet JH. “Are Opioid Dependence and Methadone Maintenance Treatment (MMT) Documented in the Medical Record? A Patient Safety Issue.”*J Gen Intern Med*. 2009 Sep 1;24(9):1007–11.

5. Coronavirus Aid, Relief, and Economic Security (CARES) Act [Internet]. Sect. §3221.116th Congress, Second Session, H.R. 748. Available from: https://www.congress.gov/bill/116th-congress/senatebill/3548/text

6. Walley AY, 2009.

7. Rosenthal RN, 2020.

8. Shields MC, Ritter G, Busch AB. “Electronic Health Information Exchange at Discharge from Inpatient Psychiatric Care in Acute Care Hospitals.”*Health Affairs*. 2020; 39(6): 958-67. Available at doi: 10.1377/hlthaff.2019.00985

9. Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6052, 6053

(Jan. 18, 2017) (codified at 42 C.F.R. pt. 2).

10. “Anonymous, Health Affairs Blog Downplays Importance of Privacy Loss in CARES Act Changes.”*Alcoholism & Drug Abuse Weekly*. 2020 Jun 15; 32(24):1-3.

11. CARES Act, 2020.

12. Dineen KK, Pendo E. “Substance Use Disorder Discrimination and the CARES Act: Using Disability Law to Inform Part 2 Rulemaking.”*Ariz State Law J*. 2020;52(4):1143–66.

13. Dineen KK. “Disability Discrimination Against People With Substance Use Disorders by Postacute Care Nursing Facilities: It is Time to Stop Tolerating Civil Rights Violations.” *Journal of Addiction Medicine*. 2021 Feb;15(1):18–9.

14. Anonymous, 42 CFR Part 2 Final Rule Clears OMB, Setting Stage for Confusion. Alcohol & Druge Abuse Weekly. 2020 Jul 13; 5-6.

15. Karway G, Ivanova J, Bhowmik A, Murcko A, Saks M, McCarty D, et al. “Recommendations to Inform Substance Use Disorder Data Sharing Research: Scoping Review and Thematic Analysis.” *Journal of Addiction Medicine*, July 13, 2021. At https://europepmc.org/article/med/34261889

16. Ibid.

17. Population of Counties in Arizona (2020) [Internet]. [cited 2020 Jun 8]. Available from: https://worldpopulationreview.com/us-counties/az/

18. U.S. Census Bureau QuickFacts: United States [Internet]. 2019. Available from: https://www.census.gov/programs-surveys/acs/news/updates/2019.html

19. AHCCCS Complete Care: The Future of Integrated Healthcare [Internet]. [cited 2022 April 18]. Available from: https://www.azahcccs.gov/AHCCCS/Initiatives/AHCCCSCompleteCare/.

20. Substance Abuse and Mental Health Services Administration, National Directory of Mental Health Treatment Facilities 2020 (n.d.). Available from: https://www.samhsa.gov/node

21. Bernard HR. Research Methods in Anthropology: Qualitative and Quantitative Approaches. Rowman Altamira; 2011. 681 p.

22. Ibid.

23. Braun V, Clarke V. “Using Thematic Analysis in Psychology.”*Qualitative Research in Psychology*. 2006 Jan 1;3(2):77–101.

24. Ivanova J, Grando A, Murcko A, Saks M, Whitfield MJ, Dye C, et al. “Mental Health

Professionals' Perceptions on Patients Control of Data Sharing." *Health Informatics J*. 2020 Jan 8;1460458219893845.

25. Recommendations to the National Coordinator for Health IT | HealthIT.gov [Internet]. [cited 2019 Jun 11]. Available from: https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it

26. Karway G, 2021.

27. Bahorik AL, Satre DD, Kline-Simon AH, Weisner CM, Campbell CI. "Serious Mental Illness and Medical Comorbidities: Findings from an Integrated Health Care System."*Journal of Psychosomatic Research*. 2017 Sep 1;100:35–45.

28. Han B, Compton WM, Blanco C, Colpe LJ. "Prevalence, Treatment, and Unmet Treatment Needs of US Adults With Mental Health and Substance Use Disorders."*Health Affairs*. 2017 Oct 1;36(10):1739–47.

29. Campbell ANC, McCarty D, Rieckmann T, McNeely J, Rotrosen J, Wu L, et al. "Interpretation and Integration of the Federal Substance Use Privacy Protection Rule in Integrated Health Systems: A Qualitative Analysis."*Journal of Substance Abuse Treatment*. 2019 Feb 1;97:41–6.

30. Karway G, 2021.

31. Rosenthal RN, 2020.

32. Han B, 2017.

33. Grando A, Ivanova J, Hiestand M, Soni H, Murcko A, Saks M, et al. "Mental Health Professional Perspectives on Health Data Sharing: Mixed Methods Study."*Health Informatics J*. 2020 Jan 11;1460458219893848.

34. Houser SH, Houser HW, Shewchuk RM. "Assessing the Effects of the HIPAA Privacy Rule on Release of Patient Information by Healthcare Facilities." *Perspectives in Health Information Management*. 2007 Spring; 4. Available at https://perspectives.ahima.org/assessing-the-effects-of-the-hipaa-privacy-rule-on-release-of-patient-information-by-healthcare-facilities/

35. Theodos K, Sittig S. "Health Information Privacy Laws in the Digital Age: HIPAA Doesn't Apply." *Perspectives in Health Information Management*. 2021 Winter; 18. Available at https://perspectives.ahima.org/health-information-privacy-laws-in-the-digital-age-hipaa-doesnt-apply/

36. Baruch Y, Holtom BC. "Survey Response Rate Levels and Trends in Organizational Research." *Human Relations*. 2008 Aug 1;61(8):1139–60.

37. "COVID-19: Substance Use Disorder, Privacy, And The CARES Act," *Health Affairs Blog*

[Internet]. [cited 2021 May 6]. Available from: http://www.healthaffairs.org/do/10.1377/hblog20200605.571907/full/

Author Biographies

Julia Ivanova (julia.ivanova@asu.edu) is a PhD candidate at Arizona State University.

Michael Saks (Michael.Saks@asu.edu) is a regents professor at Arizona State University.

George Karway (George.Karway@asu.edu) is a PhD candidate at Arizona State University.

Anita Murcko (amurcko@asu.edu) is a clinical associate professor at Arizona State University.

Candy Espino (cespino@azcouncil.com) is the president and CEO of the Arizona Council of Human Service Providers.

Chase Millea (chase.millea@gmail.com) is an associate at Snell & Wilmer.

Melissa Soliz (msoliz@cblawyers.com) is a partner at Coppersmith Brockelman.

Adela Grando (agrando@asu.edu) is an associate professor at Arizona State University.

A Local Perspective into Electronic Health Record Design, Integration, and Implementation of Screening and Referral for Social Determinants of Health

By Christopher K. Rogers, PhD, MPH; Manisha Parulekar, MD, FACP, AGSF, CMD;Fareeha Malik, MPH; andCiara A Torres, PhD

Abstract

The use of the electronic health record (EHR) system to identify and address social determinants of health (SDOH) in vulnerable patients is still lacking, and examples for customizing the EHR to meet the workflows of clinical and administrative professionals are missing. We custom designed and built into the Epic EHR a SDOH screening tool integrated with a community resource network management (CRNM) software-as-a-service (SaaS) platform to systematically identify and address SDOH in Medicare and Medicaid beneficiaries across multiple clinical care settings. We further describe our workflow redesign and EHR implementation process to maximize SDOH screening and referral efficiency. The SDOH EHR solution has been operationally used over three years by staff to screen 111,486 Medicare and Medicaid beneficiaries, identify 7,878 SDOH, and refer 6,103 high-risk beneficiaries to community resources.Transforming an EHR into a catalyst software to support SDOH screening and referral in a clinical settingis an interdisciplinary process that benefits from various technical, administrative, and clinical experts that provide subject matter knowledge into all phases of the build.

Keywords: community referral summary, electronic health records, health information technology, social determinants of health, social needs

Introduction

Social determinants of health (SDOH)continue to be both undetected and unaddressed despite research demonstrating that social, economic, and physical environment factors have an estimated relative contribution of 55 percent to health outcomes that include measures of mortality and morbidity.[1,2]Recent healthcare deliverysystem reforms have spurred health policy innovations that have placed increasing emphasis on healthcare systems to respond to SDOH and improve population health through systematic strategies that improve patient access to social resources that may address their unmet social needs.

One such healthcare delivery innovation is the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation's (CMMI) Accountable Health Communities (AHC) Model. The goal of the AHC Model is to assess whether systematically identifying and addressing SDOH in community-dwelling Medicare and Medicaid beneficiaries through building effective social services, medical care, public health, and community-based partnerships can improve health outcomes and lower healthcare costs and utilization.[3] Participating clinical delivery sites use the CMS CMMI's 10-item Health-Related Social Needs (HRSNs)Screening Tool, the AHC screening tool, to identify non-medical needs across five social risk domains: housing instability, food insecurity, transportation problems, utilities, and interpersonal safety.[4]

Furthermore, there has been a rise in recent research underscoring the importance of incorporating SDOH screening and referral in the electronic health record (EHR).[5-7] Few studies, however, have described their design and implementation approach to integrating an EHR with a community resource network management (CRNM) software-as-a-service (SaaS) platform to systematically identify and address SDOH in community-dwelling Medicare and Medicaid beneficiaries across multiple care settings. In addition, an Institute of Medicine committee[8] has highlighted the importance of standardization of data collection on SDOH into patient EHRs as a critical factor that influences treatment care and improves health outcomes.

The purpose of this paper is to describe the design, integration, and implementation of a systematic strategy to identify and screen inpatient, outpatient, and emergency department Medicare and Medicaid beneficiaries for SDOH utilizing EHR decisional support clinical workflows integrated with a CRNM SaaS platform, and upon patient's response, to congruently refer beneficiaries with identified social needs to social service resources in their community. Although this paper is specific to design and integration into Epic EHR (Epic Systems, Verona, Wisconsin), the intent behind the design elements can be generalized to the field and other EHRs.

Methods

Setting

This prospective study is being implemented at Hackensack University Medical Center (HUMC), a suburban research and academic hospital, part of Hackensack Meridian Health Networkand the largest provider of inpatient and outpatient services in New Jersey, which includes the Hackensack University Medical Group Accountable Care Organization (ACO). We utilize an enterprise-wide EHR (Epic Systems) integrated with Healthify (2019), a CRNM SaaS platform, to screen and refer Medicare and Medicaid beneficiaries across inpatient, outpatient, and emergency department settings since the implementation of the AHC Model at HUMC in 2018. The description of the available CRNM platforms on the market has been published elsewhere.[9] Institutional review board approval was obtained before implementation of the AHC Model at HUMC. HUMC is one of 28 organizations participating in the AHC Model.[10]

EHR SDOH Screening and Referral Key Design Elements

In this section, we describe the EHR SDOH screening and referral design,operational elements, and related clinical workflow functions in ambulatory, inpatient, and emergency department settings (**Figure 1**). Our EHR design goal was to build on familiar processes by modeling our approach after existing clinical workflows. For example, some of our clinics had an established falls risk screening workflow similar to what we intended to develop for SDOH screening. Therefore, we built upon the existing workflow in the EHR to support the screening process. It is important to note that the SDOH screening is administered to all Medicare and Medicaid beneficiaries regardless of language, literacy level, or whether the patient has a disability.

Prior to implementation, we undertook several tasks. First, we reviewed the AHC Model data system logic to guide the modification and configuration of the EHR and the CRNM SaaS platform. While the AHC Model data system logic and the design of the CRNM SaaS platform are beyond the scope of this paper, the data system is required to support activities related to systematic SDOH screenings, providing social service referrals to beneficiaries with identified HRSNs, randomizing high-risk navigation-eligible beneficiaries, and conducting community service navigation.

Concurrently we met with stakeholders across all clinical departments conducting SDOH screening and referral to identify workflows that could be integrated into their existing workflows as to ensure that operations run effectively and efficiently as possible. We focused on automation to decrease the human factor in initiating screening, to minimize burden on screening staff, and to align with current workflows, thereby making this a standard of care. Stakeholders included physician-leaders (e.g., department chairs), administrators, nursingleaders, managers and supervisors, and front-line staff (front desk staff, medical assistants, unit clerks, nurses). Workflow topics ranged from but not limited to: job tasks and system requirements, key processes, EHR applications, implementation barriers, quality improvement plan, and resources required. To support pre-implementation workflow meetings, we created flowcharts of key processes, mapped proposed workflows, and drafted standard operating procedures. The EHR Committee comprisedan information technologist, health information management staff, information systems staff, vendors, and trainers, and worked closely with project, clinical, and administrative staff to define workflow requirements, business rules, and other processes. During the implementation phase, customized support and training materials were distributed to clinical departments. Involving people who were affected by the workflow changes strengthened acceptability, effectiveness, and efficiency during testing and rollout. Careful monitoring ensued to track adherence to workflows, end user satisfaction, and EHR design elements. Refinements were made to the workflows and the EHR design throughout testing and implementation to ensure clinical staff needs and internal productivity standards were met.

Ambulatory SDOH Screening

The Epic EHR was configured to allow staff at the clinical delivery sites to conduct the SDOH screening and referral workflow as part of their routine clinical workflow. The EHR was modified in several ways to identify eligible beneficiaries who require SDOH screening. First, we modified EpicCare Ambulatory's Departments Appointments Report (DAR), Multi-Provider Schedule (MPS), and Technologist Work List (TWL) to display an "Offer SDOH screening /Health Related Social Needs(HRSN)" column to staff that indicates by a "Yes" or "No" if the patient meets certain eligibility criteria, namely that the patient is a community-dwelling Medicare and/or Medicaid beneficiary and resides in our catchment area (**Figure 2**). If the "Offer HRSN" indicates a "Yes," staff have been trained to screen the patient for SDOH. Additionally, to ensure all Medicare and Medicaid beneficiaries are screened for SDOH, we incorporated into the EHR an alert when a patient meets the eligibility criteria. During the registration and check-in workflows, we added a warning message to the "Confirmation Messages" box on the Appointment Review/Confirmation screen to remind the frontdesk receptionist to offer the HRSNs screening to the patient (**Figure 3**). Also, when a medical assistant, sleep technologist, or nurse rooms a patient, or a community health worker engages a patient, and the patient's chart is opened, Epic will display a Best Practice Advisory (BPA) to remind these staff to screen the patient for HRSNs (**Figure 3**). Upon identifying an eligible patient, staff administer the

HRSNsscreening tool in one of three ways, or a combination thereof, depending on the method most conducive to the office and patient: 1) self-administered screening where the patient completes the HRSNs screening tool themselves by using a tablet or hardcopy version; 2) proxy-administered screening where the parent, guardian, or caregiver is completing the HRSNs screening tool on behalf of the patient by using a tablet or hardcopy version; or 3) interviewer-administered screening by using a desktop or laptop where the staff member (e.g., medical assistant, sleep technologist, nurse, community health worker, frontdesk receptionist) administers the HRSNs screening tool by reading the questions aloud to the patient or proxy. Based on the user role and/or menu settings,staff can access the HRSNs screening tool on any of the following: DAR, MPS, TWL, registration interactive face sheet, or rooming tab, by clicking the "CMS-HRSN" activity button found in the menu toolbar of each of these activities. The staff member who administers the HRSNs screening tool or an office colleague records the patient's responses in the Epic flowsheet. The Epic flowsheet is reflective of the AHC Screening Tool. Screenings completed using a tablet are automatically stored in the patient's EHR as a flowsheet. If the patient screens positive for a SDOH social risk domain, the patient will receive a tailored CRS with their After Visit Summary (AVS). Providers can run a quick report within the patient's EHR to see which SDOH the patient screened positive for (**Figure 4**).

Emergency Department SDOH Screening

In the emergency department (ED), we identified research assistants and unit clerks as the most appropriate roles to conduct SDOH screening based on pre-implementation meetings with leadership. We modified Epic ASAP's ED Track Board to display an "Offer HRSN" column to staff that indicates by a "Yes" or "No" if the patient meets AHC eligibility criteria (**Figure 2**). Primarily, select research assistants and unit clerks are assigned areas of the ED to screen. Using the ED Track Board as a guide to view patients' requiring screening, if the "Offer HRSN" indicates a "Yes" the staff followed up with eligible patients in the ED to offer the screening. The staff use EHR carts ("workstations on wheels") to administer the HRSNs screening tool by reading the questions aloud to the patient or proxy. Staff document the patient's SDOH screening results in the Epic flowsheet by clicking the "Yes" button found on the ED Track Board of each "Area" tab (**Figure 2**). We added the HRSNs Screening report to the ED Track Board report pane to allow clinicians to see which SDOH the patient screened positive for. If the patient screened positive for a SDOH, the discharge nurse will give the patient a tailored CRS with their AVS.

Inpatient SDOH Screening

In the inpatient setting, we identified case managers and social workers as the most appropriate roles to conduct SDOH screening based on pre-implementation meetings with leadership. We modified EpicCare Inpatient's Clinical Case Management platform to display a BPA (**Figure 3**) upon staff opening the medical record of an eligible patient. This clinical decision support tool provides the staff with an alert to screen eligible patients during the hospital stay. Upon receiving the BPA, the case manager or social worker will navigate to the "Case Mgmt" activity, select the "HRSN Screen" section, then select "New Reading" to open the Epic flowsheet and document the patient's SDOH screening results (**Figure 5**). Clinicians can run a quick report in the patient's EHR to see identified SDOH. Patients screening positive for a SDOH domain will receive a tailored CRS with their discharge instructions.

Other EHR Environments

We also maximized the use of MyChart patient portal to allow patients to complete the SDOH screening prior to their appointment. Within the Medicare and Medicaid beneficiaries' MyChart portal, the SDOH screening is available in the Questionnaires section under the Health tab. Additionally, the SDOH screening is listed as a To Do task to remind the patient to complete the questionnaire. Patients also receive an inbox message within their MyChart portal that alerts them to complete the SDOH screening questions. After completing the SDOH screening questions in MyChart, the patient's responses are filed within their EHR until they present to the clinic for their appointment. If the patient screens positive for a SDOH, the patient will receive a tailored CRS with their AVS.

We added the patient's SDOH screening results to Epic's SnapShot tool so healthcare providers can see a quick overview of the identified health-related social needs. Incorporating the patient's social needs data into the SnapShot allows clinicians to have a comprehensive, yet quick overview of this information in light of other important data for population healthcare planning, such as aproblem list, medications, history, and follow-up on unmet social needs.

Results

Figure 6 provides a schematic of the HUMC Epic and CRNM SaaS platform integration workflow. Shared dictionaries and rules between Epic EHR and the CRNM SaaS platform make it possible for the two software to extract, transform, and load Health Level Seven(HL7)SDOH data to create a logic workflow that is triggered whenever a new HL7 message (e.g., patient screening) is added to the queue of Epic EHR.The resulting integration workflow is as follows: 1) systematic screening for SDOH; 2) capture responses in the EHR as flowsheet values; 3) securely transmit screening (i.e., flowsheet) values from the EHR to the CRNM SaaS platform as HL7 messages; 4) CRNM software's algorithm reviews screening values for the patient's demographics (i.e., age, gender, and ZIP code) and positive SDOH responses; 5) CRNM SaaS platform generates tailored CRS from the CBO repository and in real-time returns the tailored CRS (PDF) to the patient's EHR as HL7 messages; and 6) staff prints the tailored CRS from the EHR and gives it to the patient with their discharge summary or AVS.

All Medicare and Medicaid beneficiaries who screen positive for at least one SDOH receive a tailored CRS upon discharge or checkout. The tailored CRS lists community service providers (CSPs) across community-based organizations in the beneficiary's ZIP code (or nearest ZIP code) that may be able to assist with resolving each one of the SDOHs identified through the screening. The CRS includes the name, contact information (i.e., addresses, phone numbers, website, and email, as applicable), type of SDOH resource (e.g., housing), and hours of operation for each CSP. We also modified Epic's Chart Review tool to store the CRS so healthcare providers can review the CSPs the patient was referred to. Upon the patient being discharged from the ED, inpatient, or ambulatory location, Community health workers conduct outreach to randomized and navigation eligible high-risk patients in order to coordinate and connect them to community resources through community service navigation.

The CRNM SaaS platform has three primary roles: 1) storage of the community resource inventory, 2) real-time generation of the CRS, and 3) ability of CHWs to document and track whether patients have accessed a CSP via the referral platform and, if not, identify additional CSPs that may help with resolving social needs. The community resource inventory includes the information for each CSP in the defined geographical region that provides services and supports that might be able to assist with resolving at least one of the five core social risk domains.

This custom-built SDOH EHR solution has been in operational use for over three years by clinical and administrative staff to screen 111,486 Medicare and Medicaid beneficiaries, identify 7,878 SDOH, and refer 6,103 beneficiaries to community services to address their identified needs.

Discussion

Key elements of our project have been 1) to begin with stakeholder engagement (informatics professionals, health information management professionals, organizational and departmental leadership, clinicians, front-line staff) to understand preferences about social needs screening and referral workflows at the point of care and to gain buy-in; 2) to design the EHR using clinical decision support features to enhance decision-making in the SDOH clinical workflows; and 3) to automate the multiple steps of the SDOH screening and referral workflow to optimize staff engagement and buy-in at all of the clinical delivery sites.

Organizations that collect and store SDOH patient data within their EHR are well suited for population health management because they have the data to evaluate and deploy value-based models that take actionable steps to achieve health equity and reduce health disparities in healthcare. Collating SDOH data with clinical data helps organizations to know where and how to invest resources to keep their populations healthier. By building SDOH data into the patient data capture process, clinicians have a complete picture of their patients' needs. This allows clinicians to co-create a person-centered care plan that tracks individuals along the care continuum, thus improving the likelihood of care plan success.

In addition, collecting and storing SDOH data within the EHR has the advantage of access to an engaged user base with whom the screening and referral design elements can be co-created with. Including care team members in screening and referral workflow design can optimize usability and improve the end user experience. Through this process, clinicians, developers, and other key stakeholders communicate openly and share specific usability and safety challenges associated with EHR technology.

Depending solely on clinical data to advance value-based care often provides a disparate picture of the patient and the determinants of their health. Population health transformation requires healthcare organizations to reach across the care continuum to share and integrate SDOH data and applications to drive awareness into innovative care models that prevents disease, enhances treatment and management care, and improves patient outcomes. Enterprise integration encourages key stakeholders involved in the design and implementation process to consider not just clinical data, but how SDOH data can be collected throughout the healthcare enterprise, including at different points of care within and outside the organization, and all the different data standards that facilitate or impede this process. While national data standards for capturing and integrating SDOH data across care continuums are in early stages, an EHR that offers full integration support coupled with a CRNM SaaS platform using HL7's Fast Healthcare Interoperability Resources (FHIR) standards, ensures the standardization, reuse, and integration of the SDOH data across applications throughout the healthcare enterprise is extremely important to advancing value-based care.

Conclusion

Addressing SDOH is an essential component of person-centered medical care. EHR SDOH screening and referral design and integration is an interdisciplinary process that benefits from various technical, administrative, and clinical experts that provide subject matter knowledge in the planning, analysis, design, development, implementation, integration and testing, and operations and maintenance phases of the project. Including the SDOH screening questions in multiple Epic EHR environments ensures comprehensive screening and referral across multiple care settings. Incorporating electronic clinical notifications such as BPAs into the EHR to alert providers to screen and refer for SDOH has multiple advantages, such as ensuring every patient every time is screened for these vital determinants of health. Additionally, we designed the EHR so that the personalized CRS automatically prints with the patient's AVS or discharge summary at the point of care.This helps overcome literacy barriers to care by ensuring the patient understands how to use the information for the social services resources listed.

Continued monitoring and quality improvement efforts are needed to ensure the EHR design supports the SDOH screening and referral workflow of clinical staff members and providers. For example, the project staff conducted repeated Plan-Do-Study-Act (PDSA) method cycles in a number of provider practices and clinical departments to optimize usability of the SDOH customized build EHR, screening and referral workflows, and training procedures.

Institutional support was crucial for garnering together resources and momentum for SDOH screening and referral. It has become increasingly clear that optimizing and using EHRs as an effective tool to screen and refer for SDOH minimizes burden on screening staff and allows access to large data that are needed to map and improve effective population health.

Support

This project is supported by the Centers for Medicare &Medicaid Services (CMS) of the US Department of Health and Human Services (HHS) as part of a financial assistance award totaling $2,500,000 with 100 percent funded by CMS and HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by CMS or HHS, or the US government.

Acknowledgments

Hackensack University Medical Center clinical and administrative teams involved in planning and implementing the AHC program.
Hackensack University Medical Center EHR applications team.

Conflict of Interest Statement

None declared.

Notes

1. Alley DE, Asomugha CN, Conway PH, Sanghavi DM. *“*Accountable Health Communities--Addressing Social Needs through Medicare and Medicaid.” *N Engl J Med* 2016; 374((1):p. 8-11.

2. Park H, Roubal AM, Jovaag A, Gennuso KP, Catlin BB. “Relative contributions of a set of health factors to selected health outcomes.” *Am J Prev Med* 2015; 49((6)):p. 961-9.

3. Alley DE, et. al, 2016.

4. Centers for Medicare & Medicaid Services. *The Accountable Health Communities Health-Related Social Needs Screening Tool.* 2018. Available at https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.

5. Gottlieb LM, Tirozzi KJ, Manchanda R, et al. “Moving electronic medical records upstream incorporating social determinants of health.” *Am J Prev Med* 2015; 48:p. 215–218.

6. Adler NE, Stead WW. “Patients in context—EHR capture of social and behavioral determinants of health.” *N Engl J Med* 2015;372((8)):p. 698-701.

7. Chen M, Tan X, Padman R. “Social determinants of health in electronic health records and their impact on analysis and risk prediction: A systematic review.” *J Am Med Inform Assoc*2020; 27((11)):p. 1764-1773.

8. Institute of Medicine. *Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2.* Washington, DC: The National Academies Press; 2014. Available at https://doi.org/10.17226/18951.

9. Cartier Y, Fichtenberg C, & Gottlieb L. *Community Resource Referral Platforms: A Guide for Health Care Organizations.* San Francisco, CA: SIREN; 2019. Available at https://sirenetwork.ucsf.edu/tools-resources/resources/community-resource-referral-platforms-guide-health-care-organizations.

10. Centers for Medicare & Medicaid Services (CMS). (2017). *Accountable Health Communities (AHC) Model Assistance and Alignment Tracks Participant Selection.* Available atehttps://www.cms.gov/newsroom/fact-sheets/accountable-health-communities-ahc-model-assistance-and-alignment-tracks-participant-selection.

Author Biographies

Christopher K. Rogers was the project/program manager for the Accountable Health Communities Program at Hackensack University Medical Center.

Manisha Parulekar currently serves as the director in the Division of Geriatrics and the program director for the Accountable Health Communities Program at Hackensack University Medical Center.

Fareeha Malik was the Master of Public Health graduate intern for the Accountable Health Communities Program at Hackensack University Medical Center.

Ciara A. Torres currently serves as the program manager for the Accountable Health Communities Program at Hackensack University Medical Center.

Impact of the COVID-19 Pandemic on HIM Professionals in a Rural State

By Jaime Sand, EdD, RHIA, CCS, CAHIMS

Abstract

The COVID-19 pandemic has greatly disrupted the healthcare industry, impacting health information professionals through facility changes, remote work, shifting priorities, and personal stressors. This study explores the impacts of these disruptions on health information professionals in a rural state. Participants indicated involvement in expanding and new responsibilities related to tracing and data collection, the expansion of telehealth services, and disaster planning. Their work was impacted by facility closures and suspended services, an increase in remote work, increased communications during the pandemic, and the shift to virtual continuing education. As with much of society, many participants also experienced worsening mental well-being, social wellness, and stress related to a variety of factors. Despite the stress and uncertainty, participants also found inspiration in the pandemic, taking time to reprioritize, connect with others, and find strength in human resilience.

Keywords: HIM profession, pandemic, remote work, rural, COVID-19

Introduction

The COVID-19 pandemic has created unprecedented disruptions in multiple industries and throughout society. This includes the healthcare industry and health information management (HIM) professionals. Public health officials rely on data from healthcare organizations for case reporting and to inform best practices in addressing the virus and associated complications. HIM professionals are essential to capturing and reporting this accurate data. Despite the increased demand on the healthcare system, many facilities still had to utilize furloughs and reduce staffing due to budget restraints, quarantine restrictions, and other pandemic factors. Those who were able to work had to do so with considerable new restrictions, and many were sent to work from home. This required changes in workflow and communication strategies, necessitating rapid response by health information managers to update policies and procedures. Telehealth expanded rapidly to address the continued needs of patients, impacting HIM processes and requiring enhanced privacy and security measures. The stress of the pandemic, restrictions, and ongoing changes to work situations and environments has impacted employee mental, physical, and social well-being, with many healthcare professionals experiencing heightened anxiety, frustration, and stress.

Literature Review

Addressing the pandemic has required significant data-driven public health efforts. HIM is essential in acquiring and providing this data. HIM professionals have been involved in manual and electronic case reporting (eCR) to public health agencies, ensuring the health record system capabilities to collect and report accurate data. eCR is the automated generation and transmission of care reports from the electronic health record (EHR) and, if available, can save time and provide more accurate and complete data.[1] This data has also been used for contact tracing, early identification, risk scoring, and enhanced understanding of clinical indicators, risk factors, and biomarkers.[2]Organizations adopted additional tools such as electronic check-in, standard ordering and documentation, secure messaging, and real-time data analytics to help maintain the quality of pre-pandemic care.[3]Studies have been done using longitudinal EHR data to create algorithms and models to analyze prognoses, predict the clinical course, and guide decisions and treatment of COVID-19 illnesses.[4,5] Some facilities have even established COVID-19 data registries based on chart review and data extraction.[6] Such data has been essential to understanding the virus and pandemic, and informing policymakers and the general public on prevention, interventions, and outcomes.[7]

Despite the need for essential data gathered by health information professionals, many suffered furloughs or even loss of employment due to the pandemic. Many facilities were shut down or significantly reduced services provided, eliminating any care not directly related to emergencies and COVID-19.[8]Education services and research efforts were suspended with laboratory closures and the inability to participate in-person. Many facilities were short-staffed due to both budget constraints and loss of employees to illness and quarantine requirements.[9]HIM managers had to manage this negative impact on the budget and staffing while still providing the services needed to treat patients, continue the revenue cycle, and meet the reporting requirements of the pandemic. This may have included involvement in disaster planning efforts, addressing and updating acommunication plan, informational materials, employee sick leave policies and procedures, physical safeguard requirements, education and training efforts, and surge capacity plans.[10]

Many HIM managers had to also manage a larger remote workforce. The HIM discipline is not new to remote work, with many organizations implementing remote coding, clinical documentation improvement, and even release of information prior to the pandemic. However, the pandemic quickly made remote work essential, sending home many employees who had not opted into telecommuting with little notice. This required rapid expansion of policies related to remote work, technical and physical equipment to support secure at-home offices, and expansion of HIM services offered remotely.

In addition to many employees being sent home to work, the pandemic impacted work practices in other ways. According to DeFilippiset al., the number of meetings and emails increased for many employees following lockdown.[11] Meetings and emails generally included more attendees and recipients, highlighting an increase in both frequency and scope of communication. However, on average, meeting length and the total amount of time spent in meetings decreased. In addition, many employees adjusted work schedules and sent more emails outside of standard working hours. This may have been related to the rapidly changing situation and potentially returned to normal levels once organizations had their pandemic plan in place.

Despite the limitations of many facilities during these unprecedented times, the pandemic has broadened the use and availability of telehealth across the country as an alternative to provide safe and effective care.[12]In previous years,telemedicine was met with hurdles and some resistance, but demand for commercial telemedicine services has increased and vendor traffic skyrocketed.[13] Telemedicine can provide less expensive care with improved access, particularly during times of crisis. It offers a way to provide continuity of care for patients while protecting staff and reducing burnout of providers. In 2020, it was supported with expanded flexibility in policies, such as allowing patients to be seen through videoconferencing without a qualifying site visit and allowing prescription of controlled substances through telemedicine without an in-person evaluation.[14]Centers for Medicare & Medicaid Services (CMS) and other payers issued multiple waivers and offered payment parity for Medicare.[15]

In response to this expansion of telehealth services, the Centers for Disease Control and Prevention (CDC)has offered guidance related to best practices in telemedicine during the pandemic.[16] Health information professionals may be involved in developing or implementing many of these recommendations, depending on organizational structure. This guidance includes identification of encounters appropriate for telemedicine and protocols for triaging and assessing patients. These policies, practices, and protocols for using telehealth services must be communicated to providers, including those related to appointment scheduling, documentation and billing, referral processes, urgent care, ancillary services, and follow-up visits, among others. Those involved in telehealth services must continuously monitor federal and state regulations and restrictions, temporary mandates and directives, and expiration dates. It is recommended that at-risk populations are prioritized, with outreach to patients with limited connectivity. The CDC also recommends regular communication with payers to verify coverage of telehealth, telemedicine, or nurse advice line services.[17]Although telemedicine has been relatively successful throughout the pandemic, there are still concerns related to privacy and efficacy considerations. Regulation of commercial teleservices should address licensing and liability, and health information best practices should clarify informed consent and protection of data and confidentiality. Medical practice guidelines should consider ethical issues, professional conduct and relationships, patient autonomy and safety, cultural diversity, and malpractice and liability.[18]

These strained effects were felt more significantly at facilities in rural communities. Many of these facilities have been and remain under-resourced with issues related to infrastructure, lack of equipment, and disparities in workers, training opportunities, and revenue compared to those in urban areas.[19] The pandemic strained already thin margins, increasing the financial and operational burden on rural hospitals that carry significant administrative burden. The trend toward remote work and expanded telehealth services may be more difficult for rural facilities that lack the infrastructure and technology to support these services, including access to high-speed internet.[20]

In addition to hospital and service closures, required changes in HIM workflow processes, and expansion of telehealth and remote work, the pandemic has impacted the HIM workforce in a variety of other ways. In a study by Sethi et al., health professionals indicated an impact on mental, physical, and social well-being.[21] Any type of quarantine can incite mass hysteria and distress, with many feeling a loss of control.[22] As with most of society, there have been feelings of anxiety, frustration, and stress among healthcare employees.[23] This relates to a variety of things, including but not limited to: worrying about the safety and wellness of themselves and their families; separation from loved ones; fear of the virus and potential complications; insufficient supplies of basic essentials; and dealing with furloughs, pay cuts, and layoffs. Those that have to work on-site worry about their vulnerability and exposure, particularly in facilities with limited personal protective equipment (PPE) and infrastructure. They may also have to deal with uncooperative, stigmatized, and panicked patients.[24] Some have found it challenging to stay motivated, exhausted from public indifference, misinformation, and non-compliance. Despite these challenges, some employees have also reported more time for self and family.[25]

This study explores the impact of these rapid and unforeseen changes and actions, addressing the following questions:

- How were HIM professionals in a rural state involved in facility changes related to the pandemic, such as data capture, disaster planning, and the expansion of telehealth services?
- To what extent were HIM professionals in a rural state impacted by facility closures, reduced services, and furloughs?
- How were HIM professionals in a rural state impacted by the expansion of remote work?
- How are HIM professionals in a rural state currently coping with the physical, mental, and social stresses of the pandemic?

Methods

The sample population included health informatics and information management professionals in Idaho. This is considered a relatively rural state, with a population less than 2million, 27 critical access hospitals, and ninerural health clinics.[26] Many facilities have HIM professionals that are members of the state's relevant professional associations, including the Idaho Health Information Management Association (IdHIMA) and the Healthcare Information and Management Systems Society (HIMSS) Idaho Chapter. IdHIMA has over 400 members, and HIMSS Idaho has approximately 250 members. These individuals work in a variety of health informatics and information management areas throughout many types of organizations.

A survey of open and closed questions was created by the researcher based on the findings of the literature review (see**Appendix 1**). Questions were written to gather information on the participant's work setting, work, and personal experiences during the pandemic, such as changes to work duties and impact on wellness. Upon institutional review board(IRB) and association approval, it was distributed by email to members of IdHIMA and HIMSS Idaho. A snowball sampling technique was used, asking recipients to distribute the survey to additional co-workers in the health information and informatics disciplines. These individuals were targeted to provide a broad base of professionals in jobs relevant to health information and informatics to provide insight into the impact of the pandemic.

Descriptive analysis was done using Qualtrics software, summarizing results with percentages and frequency distributions. Chi-square and *t*-test analyses were conducted when appropriate to compare acute care hospital responses with the other patient settings. The questions related to work-related communications, overall rating of organizational response, and the impact of the pandemic on health and wellness of participantswere five-point Likert scale questions and wereanalyzed using dummy codes 1-5 to obtain means and standard deviations where 1:Excellent, 2:Good, 3:Average, 2:Poor, 1:Terrible; 1:Much higher, 2:Slightly higher, 3:About the same, 4:Slightly lower, 5:Much lower; and 1:Much better, 2:Better, 3:Same, 4:Worse, 5:Much worse, respectively. Free-text items, such as responses under the “others” and the three open-ended questions, were reviewed to identify common, recurrent themes.

Results

The survey was completed by 76 individuals from primarily acute care hospitals (54.1 percent), but also critical access hospitals (5.4 percent), physicians’ offices (5.4 percent), insurance companies (4.1 percent), long-term care hospitals (4.1 percent), skilled nursing facilities (2.7 percent), and other types of organizations (24.3 percent) (see **Figure 1**). Other types of organizations included health systems, ambulatory settings, state and federal organizations, software companies and other IT vendors, specialty clinics, academic institutions, and consulting companies.

Responses were obtained from directors and managers, coding specialists, systems analysts, registry specialists, consultants, and educators, as well as a variety of other professionals in compliance, health IT, and administration. Specific health information domains included coding (33.3 percent), information systems (22.7 percent), management (17.3 percent), and the revenue cycle (12 percent), with others in registries and indexes, analytics, and education(see **Figure 2**).

Expanded and New Responsibilities

Tracing and data collection. As outlined in the literature review, the COVID-19 pandemic has necessitated intensive tracing and data collection to track cases and patient outcomes, and organizations have relied on a variety of individuals to assist. Just over a quarter (30.9 percent) of participants indicated they were involved in these efforts in some way (see **Table 1**). There was no significant difference in involvement of these efforts between those in acute care hospitals and other settings, $\chi^2(1, N = 68)=0.18, p=0.6714$. Of those involved, several participated in data collection for clinical indicators and risk factors (38.1 percent) and case reporting, early identification, and registry development and/or data collection (28.6 percent). Just a few were involved in risk scoring, contact tracing, and tool development. Those involved in other activities (38.1 percent) listed duties related to case identification through coding and coding audits, management of the COVID-19 attestation desk, data collection for employees and visitors, inpatient outcomes tracing, and screening. Fortunately, the majority of respondents indicated that the additional case reporting requirements did not increase burden on their department, although 15indicated it did. There was no significant difference in this response between those in acute care hospitals and other settings, $\chi^2(1, N = 38) = 0.85, p=0.3568$. Some of these responses may have come from the 17.2 percent who indicated that their EHR did not already have the capabilities required for eCR. Of those who did utilize eCR, most (61.1 percent) indicated that it helped them improve reporting efforts. There was no significant difference in whether or not the EHR had eCR capabilities between those in acute care hospitals and other settings, $\chi^2(2, N = 62) = 3.06, p=0.2170$. Most participants also felt that the contact tracing and case reporting requirements did not cause privacy and security concerns for their organizations (72.7 percent). Those that indicated concerns addressed them by increasing oversight and limiting access as necessary.

Expansion of telehealth services. Participants were asked if their facility expanded telehealth services during the pandemic, with 84.6 percent indicating they did. Those who indicated that telehealth services were not expanded were from a physical therapy or specialty clinic, or an organization that did not provide direct patient care. Half of the participants of the surveyindicated they were directly involved in tasks related to this expansion (see **Table 2**). There was no significant difference in involvement of these efforts between those in acute care hospitals and other settings, $\chi^2(1, N = 68) = 2.514$, p=0.1128. Participantsassisted with physician and provider training (50 percent), ensuring compliance with privacy practices (44.1 percent), creating and updating policies and procedures for telemedicine (38.2 percent), communicating with payers to verify coverage (17.6 percent), regulation and restriction monitoring (14.7 percent), identifying and prioritizing patients by risk (8.8 percent), and only one was involved in patient outreach. Other duties included tool development for remote patient monitoring, volume monitoring, setting up telehealth billing, monitoring for fraud and abuse, and coding of telehealth visits.

Disaster planning. Participants were also asked about their involvement in assisting their organization with disaster planning efforts related specifically to COVID-19, with 44.1 percent indicating that they did participate in at least one task category (see **Table 3**). There was no significant difference in involvement of these efforts between those in acute care hospitals and other settings, $\chi^2(1, N = 68) = 3.06$, p=0.0800. Participants were involved in committees (56.7 percent), the communications plan (50 percent), education and training (50 percent), recommending and/or implementing physical safeguard requirements and installation (26.7 percent), updating employee sick leave policies and procedures (23.3 percent), and surge capacity planning (20 percent). Overall, the majority of participants indicated confidence in their organization's response to the pandemic ($M = 1.59$, $SD = 0.74$), with 54.3 percent rating their facility as excellent and 34.3 percent as good. There was no significant difference in these ratings between those in acute care hospitals and other settings, $t(68) = 1.59$, $p = 0.12$.Qualitative responses indicated frequent and effective communication, early implementation of policies and procedures, fiscal responsibility, and employee support as reasons for a high rating. The few who responded negatively criticized an overreaction without consideration of consequences or a lack of reaction at all, difficulty in getting employees to return to on-site work, extensive furloughs, and lack of monitoring noncompliance with safety protocols.

Other Work-Related Impacts

Facility closures and suspended services. The pandemic has significantly disrupted facilities, with many having to reduce or eliminate services either temporarily or permanently, and some expanding other types of services. According to respondents, 37.2 percent reported that their facility had to suspend elective surgeries due to COVID-19, and 33.1 percent had to suspend non-urgent surgeries. Outpatient services were suspended slightly less at 17.6 percent, just 2 percent suspended laboratory services, and only a few suspended research activities. Other suspended services included travel, community outreach, in-person meetings and conferences, annual exams, live education lessons, and on-site implementation of system upgrades. A few even indicated that all services were suspended.

Increase in remote work. As mentioned above, the pandemic resulted in significant work disruptions, with furloughs, a dramatic increase in remote work, and an increase in relevant communications. Fortunately, only 10 of the respondents indicated that they were furloughed due to the COVID-19 pandemic. Five respondents were furloughed for one to three months, three for more than three months, and the remaining two for less than a month. The percentage of respondents working remotely was significantly higher. Forty-four percent of respondents began working from home due to the pandemic, and 41.3 percent were already working from home. Of those who were already working remotely, 67.8 percent have done so for three to 10 years, 22.6 percent for more than 10 years, and 9.7 percent for less than three years. The majority of participants (75.8 percent) felt that they were able to effectively achieve their work duties from home. The remaining participants felt they were somewhat effective (19.7 percent) or not effective (4.6 percent). Just 12.2 percent did not work remotely, but several of those participants still managed remote employees.

Increased communications. Participants indicated that work-related communications, including number and length of emails and meetings, increased during the pandemic with 38.8 percent indicating it was much higher and 28.4 percent that it was slightly higher ($M = 1.94$, $SD = 0.87$). Some indicated it was about the same (31.3 percent) and just one participant that it was slightly lower.There was no significant difference in these responses between those in acute care hospitals and other settings, $t(62) = 0.94$, $p = 0.35$.

Virtual continuing education. The pandemic also caused many live events and conferences to be canceled. Most of the participants (76.8 percent) participated in virtual education events to obtain continuing education units.

Impact on Health and Wellness

In addition to disruptions in the workplace, studies have highlighted a variety of other, personal impacts of COVID-19 and quarantine restrictions. Ultimately, these may impact the ability of an employee to meet the demands of their job. Participants were asked about the impact of the pandemic on their anxiety, general mental well-being, physical wellness, social wellness, and stress. The responses averaged between about the same and somewhat worse (see **Table 4**). Social wellness (3.67), stress (3.55), and anxiety (3.48) had the highest averages, but general mental well-being (3.35) and physical wellness (3.24) were not far behind. The standard deviations indicate relatively high variations amongst participants.

Negative feelings were associated with a variety of reasons. Many were concerned about loved ones catching the virus (66.2 percent) and/or being separated from them (58.8 percent), and 26.5 percent indicated the loss of a loved one. Many were also concerned about their own health, potentially catching the virus and suffering complications (57.4 percent). Participants were also concerned for patients who were facing potential death without their own loved ones (42.6 percent), co-workers who were involved in direct patient care (35.3 percent), and disgruntled and noncompliant patients (27.9 percent). Furloughs and pay cuts (30.9 percent) also caused negative feelings, as well as fear of insufficient basic supplies at home (29.4 percent). Many were also concerned about misinformation about the virus and CDC recommendations (58.8 percent) and some worried about limited PPE at work (11.8 percent). Other negatives listed by participantsincluded political unrest, an increase in work hours, school closures, and forced masking and lockdowns. (See **Table 5**.)

Despite the disruption and unease created by the pandemic, participants did denote some positives experienced due to the changes necessitated by COVID-19. Qualitative responses showed that many recognized it as a time to create more balance mentally, physically, and spiritually by taking the opportunity to reprioritize. Many participants mentioned more time with their children and other family members, and some noted more time for home projects, personal hobbies like reading and gardening, and for personal health and fitness.Participants felt that some of this came from the reduced commute time of remote work and reduced work-related travel, which also helped them save money and reduced their carbon footprint.Several participants mentioned that money was also saved by not eating out and reducing shopping. Participants were inspired to reach out to family, friends, and acquaintances that they had not spoken to in a significant amount of time, and were reminded of what to appreciate in life. Some felt recognition for the human ability to adapt, appreciating our strength and resilience. A few participants also mentioned feeling more educated on surface contamination and an appreciation for the heightened cleaning procedures in public spaces.

Discussion

Despite what may have felt as temporary solutions to unprecedented times, many believe the significant changes to the workplace implemented due to the pandemic will continue. According to a survey of industry leaders by Kuofie and Muhammad, the majority definitely or somewhat think that the practices performed during the COVID-19 period will become the new normal, and just over half indicated that the health industry will continue to maintain the same practices beyond the pandemic.[27] In addition to hearing from industry leaders, it is important to consider the impact the pandemic has already had on health information management and what these changes mean for the future.The results of this survey provide insight into that impact on a sample of health information professionals in a rural state, demonstrating similar experiences across settings and domains.

The COVID-19 pandemic has emphasized the need for better informatics infrastructure, interoperability, and ethical guidelines.[28] AHIMA has highlighted critical areas of focus to improve the readiness of disease surveillance systems and system preparedness for global public health events. These include accurate patient identification, protections for consumer privacy, and comprehensive data collection for public health.[29] Without a nationwide patient identification strategy, the data collected and analyzed during public health events such as a pandemic maybe be incomplete or incorrect, which can impact contact tracing and large-scale immunization programs as has been experienced with COVID-19.

As we move forward, we can reflect on the pandemic to learn from the experience and continue to explore ethical, legal, and social issues related to health information technology and disease surveillance.[30] Fortunately, as indicated by survey participants, most facilities felt equipped to address privacy and security concerns related to contact tracing and case reporting by increasing oversight and limiting access. Expansion and new forms of communication and technology in healthcare, including consumer-facing applications and products, highlight the importance of established privacy, confidentiality, and ethical principles beyond HIPAA-covered entities.[31]Consent processes must include protection from potential consequences of technology, and expansion of telehealth services across jurisdictional boundaries requires evaluation of regulations and policies related to areas like licensing, credentialing, and liability. As indicated by the survey, many facilities are expanding these services and relying on HIM professionals to help with training, compliance, and communication.The pandemic may have been the push needed to expand telehealth services permanently, but further consideration of access and quality are needed. Telehealth efforts should include access for all populations, including patients that are cognitively impaired, elderly, disabled, illiterate, or living in areas with little to no internet access.[32] Health information professionals will need to continue to be involved in such efforts, including in areas highlighted in the survey such as training, compliance, and regulation. As the industry stabilizes after the height of the pandemic, telehealth best practices should be continuously evaluated while assessing the impact on the patient record and care outcomes. Additional resources may need to be allocated to telehealth efforts to ensure proper documentation, reimbursement, and compliance.

The pandemic has again brought health disparities to the forefront, reinstating the need for standardized data collection of elements related to the social determinants of health (SDOH) to better allocate resources and prevention efforts.[33] Once comprehensive standardized data collection is established, facilities and public health organizations can analyze the data to gain valuable insights into patients and populations.[34] As indicated by survey responses, tracing and data collection may continue to be tasks performed by health information professionals in various organizations. Facilities may consider cross-training employees or dedicating an individual position to these tasks, depending on the time commitment. It is also recommended that facilities without eCR functions evaluate this need with their EHR vendor, particularly if the task is burdensome. Health information professionals remain the experts in data governance and are essential to improving the data infrastructure at the national and global levels to be better prepared for the next global incident.

The pandemic created significant strain on the healthcare system, causing many facilities to reduce or eliminate services such as elective and non-urgent surgeries. Fortunately, this is not an impact that is anticipated to be long-term for most facilities, although it may have long-term financial impact on those in rural communities. Managing these reduced services and disaster planning efforts were temporary consequences of the pandemic, but both experiences can help better prepare facilities in the future. It is important that health information professionals remain engaged in these planning efforts and that facilities take note of the practices that instilled confidence in their employees. These include, as indicated by survey participants, a solid communication plan, clear policies and procedures, fiscal responsibility and transparency, and strong employee relations.

As organizations evaluate the continuation or expansion of remote work, it is important to consider best practices. This includes policies and procedures related to expectations and requirements. While the pandemic mandated some employees work remotely, in less restrictive times this should be evaluated on an individual basissince, as indicated by the survey, not everyone feels effective at home. Employees and employers should consider the fit of flexible work arrangements with the organization, position, and person as remote work may not be suited to everyone. Particular challenges potential in remote work identified during the pandemic included procrastination, ineffective communication, disruption of the work-life balance, and social isolation.[35] Work and communication expectations should be clarified in policy and monitored regularly. Large virtual meetings or email blasts can be used to share important information to all relevant individuals, ensuring inclusivity in communications. This may include information on new policies or plans, work that has been accomplished, increasing accountability, and/or alignment of priorities. Meeting length should be a consideration, however, as employees may find it challenging to stay engaged in long meetings.[36]Remote employees should be encouraged to create a routine within their working hours, designate a space to work, and avoid excessive multitasking.[37] Virtual and occasional in-office meetings and social events can provide space for connection between remote employees, strengthening the team environment.

As indicated by the results of the survey, employees are feeling burdens of the pandemic beyond the rapid changes in working conditions. Unfortunately, these may continue for a time after the pandemic ends. Disaster models predict continued stress, exhaustion, and burnout. This can increase the risk of depression, anxiety, sleep disturbances, and even substance abuse, particularly for employees who have poor coping strategies such as self-blame or avoidance.[38]As noted in this survey, many HIM employees are already feeling worsened mentalwell-being, social and physical wellness, anxiety, and stress. This can impact employee work, causing reduced productivity or increased absences.[39]While some stressors related to the early days of the pandemic with higher uncertainty and more extreme isolation are becoming less relevant, those related to moral distress, personal safety, economic uncertainty, and a sense of powerlessness still linger.[40]However, organizations can take action to support employees through training and resources.[41]If feasible, organizations should consider offering access to counseling services and training in effective emotional coping methods. This could include webinars on such topics as resilience, stress management, and the work-life balance.[42]Facilities can designate further resources to create a wellness response team, resource hub, and dedicated space for employees who need respite.[43]Mitigating these external pressures and concerns can help improve employee morale and productivity.

Despite the unprecedented stress, health information professionals can also choose to recognize some positives that have emerged from the pandemic, such as more time with family, reduced commute time, a chance to reprioritize life, and appreciation of the resilience of the human spirit. The actions and consequences of the pandemic can fuel the advocacy for improved infrastructure and the heightened need for interoperability. It has brought data to the forefront, including the need for better documentation of the SDOH and accurate patient identification. Facilities and employees are better prepared for emergencies and disasters, remote work, and telehealth. The importance of employee wellness and support has been highlighted, allocating resources in this area. Health information professionals have more access to virtual continuing education credits and training programs, expanding the opportunity for advancement and improvement of new skills. As these improvements are realized, HIM professionals will be ready to step into new roles in data analytics, research and development, compliance, information governance, project management, and process improvement.[44]

These findings are limited to the respondents of a researcher-created survey in a rural state, primarily targeted at members of HIM professional associations. Further studies should expand the population of interest to other HIM professionals and those in more urban areas. The survey was distributed approximately 16months into the pandemic and practices continue to change in response to the variants and other factors. The continued uncertainty may have impacted participant responses, heightening the perception of temporary and fluctuating solutionsthat could feel erratic or unstable. Follow-up studies could further investigate the long-term effects of the pandemic on HIM practice and the health and well-being of healthcare professionals.Post-pandemic, research in this area can focus on the permanent impact and significance on the future of HIM.

Conclusion

The needs and guidelines of the pandemic have impacted many health information professionals, including disruptions in both the workplace and personal lives. This survey provides a snapshot of those impacts on HIM professionals in a rural state where resources and infrastructure can be limited. This included expanding or changing roles in areas such as data collection, case reporting, and most widely, telehealth. HIM managers should consider if and how these demands will continue after the pandemic and how that impacts current job descriptions, workflows, policies and procedures, and needed EHR functions. HIM professionals should continue to be involved in disaster preparedness efforts, reinforcing transparency and inclusion in facility operations, and encouraging frequent communication, early implementation, budgetary responsibility, and employee support.In addition to creating new tasks and priorities, the pandemic clearly impacted ongoing work practices. The long-term impact of the temporary closures and service suspensions on facilities remains to be seen, but health information managers can use the lessons learned during the pandemic to improve transparency and confidence in employees through fair and rational policies and practice. Health information managers can also continue to improve and expand remote work options, a trend that is anticipated to stay at higher levels after the pandemic. The pandemic also pushed many professional associations to expand virtual continuing education opportunities, improving the expansion of this modality in the future.The long-term impact of the pandemic and shutdown on the physical and mental wellness of healthcare professionals and society in general also remains to be seen. As the pandemic transitions to an endemic, hopefully levels of anxiety and stress will reduce to improve overall wellness. HIM professionals should advocate for employee wellness support at facilities, including education and training and other support services. Despite the many disruptions and stressors of the pandemic, experiencing a global life altering event can reignite the passion for our relationships, our profession, and our resilience.

References

Adibe, Bryant, Charles Hebert, Kathryn Perticone, and Sheila M. Dowd. "Creating Wellness in a Pandemic: APractical Framework for Health Systems Responding to COVID-19." *NEJM Catalyst Innovations in Care Delivery* 2, no. 2 (2021).

Alvin, Matthew D., Elizabeth George, Francis Deng, Shantanu Warhadpande, and Susanna I. Lee. "The Impact of COVID-19 on Radiology Trainees." *Radiology* 296, no. 2 (2020): 246-248.

Bassett, Ingrid V., Virginia A. Triant, Bridget A. Bunda, Caitlin A. Selvaggi, Daniel J. Shinnick, Wei He, Frances Lu et al. "Massachusetts General Hospital COVID-19 Registry Reveals Two Distinct Populations of Hospitalized Patients by Race and Ethnicity." *PloS one* 15, no. 12 (2020): e0244270.

Blow, Matthew, David T. Marc, and Shauna Overgaard. “The Public and Pandemics”. *Journal of AHIMA*, (2021).

Centers for Disease Control and Prevention (CDC). “Comprehensive Hospital Preparedness Checklist for Coronavirus Disease 2019 (COVID-19).” *U.S. Department of Health & Human Services*. Last modified March 25, 2020. https://www.cdc.gov/coronavirus/2019-ncov/hcp/hcp-hospital-checklist.html

CDC. “COVID-19 Electronic Case Reporting for Healthcare Providers.”*U.S. Department of Health & Human Services*. Last modified November 19, 2021. https://www.cdc.gov/coronavirus/2019-ncov/hcp/electronic-case-reporting.html

CDC. “Using Telehealth to Expand Access to Essential Health Services During the COVID-19 Pandemic.” *U.S. Department of Health & Human Services*. Last modified June 10, 2020. https://www.cdc.gov/coronavirus/2019-ncov/hcp/telehealth.html

DeFilippis, Evan, Stephen Michael Impink, Madison Singell, Jeffrey T. Polzer, and Raffaella Sadun. *Collaborating During Coronavirus: The Impact of COVID-19 on the Nature of Work*. No. w27612. National Bureau of Economic Research, 2020.

Dubey, Souvik, Payel Biswas, Ritwik Ghosh, Subhankar Chatterjee, Mahua Jana Dubey, Subham Chatterjee, Durjoy Lahiri, and Carl J. Lavie. "Psychosocial Impact of COVID-19." *Diabetes & Metabolic Syndrome: Clinical Research & Reviews* 14, no. 5 (2020): 779-788.

Eramo, Lisa A. “Leading HIM Reimagined by Example.” *AHIMA HIM Body of Knowledge*. (2018).

Gavin, B., J. Hayden, D. Adamis, and Fiona McNicholas. "Caring for the Psychological Well-being of Healthcare Professionals in the COVID-19 Pandemic Crisis." *Irish Medical Journal* 113, no. 4 (2020): 51.

Kaplan, Bonnie. "Revisiting Health Information Technology Ethical, Legal, and Social Issues and Evaluation: Telehealth/telemedicine and COVID-19." *International Journal of Medical Informatics*, (2020): 104239.

Kuofie, Matthew, and Nik Maheran Nik Muhammad. "Leaders Perspective on Post COVID-19 Pandemic Period: Global Business Focus." *International Journal of Health and Economic Development* 7, no. 1 (2021): 13-36.

Lakhani, Hari Vishal, Sneha S. Pillai, Mishghan Zehra, Ishita Sharma, and Komal Sodhi. "Systematic Review of Clinical Insights into Novel Coronavirus (CoVID-19) Pandemic: Persisting Challenges in US Rural Population." *International Journal of Environmental Research and Public Health* 17, no. 12 (2020): 4279.

Latifi, Rifat, and Charles R. Doarn. "Perspective on COVID-19: Finally, Telemedicine at Center Stage." *Telemedicine and e-Health* 26, no. 9 (2020): 1106-1109.

Oetjens, Matthew T., Jonathan Z. Luo, Alexander Chang, Joseph B. Leader, Dustin N. Hartzel, Bryn S. Moore, Natasha T. Strande et al. "Electronic Health Record Analysis Identifies Kidney Disease as the Leading Risk Factor for Hospitalization in Confirmed COVID-19 Patients." *PloS one* 15, no. 11 (2020): e0242182.

Osborne, Thomas F., Zachary P. Veigulis, David M. Arreola, Eliane Röösli, and Catherine M. Curtin. "Automated EHR Score to Predict COVID-19 Outcomes at US Department of Veterans Affairs." *PLoS One* 15, no. 7 (2020): e0236554.

"Idaho State Guide." *Rural Health Information Hub (RHIhub),* 2021. https://www.ruralhealthinfo.org/states/idaho

Segel, Joel E., Hannah I. Ross, Jennifer L. Edwards, Kelly A. Braun, and Lisa A. Davis. "The Unique Challenges Facing Rural Providers in the COVID-19 Pandemic." *Population Health Management* 24, no. 3 (2021): 304-306.

Sethi, Bilal Ahmed, Ahsan Sethi, Sadaf Ali, and Hira Shireen Aamir. "Impact of Coronavirus Disease (COVID-19) Pandemic on Health Professionals." *Pakistan Journal of Medical Sciences* 36, no. COVID19-S4 (2020): S6.

Trougakos, John P., Nitya Chawla, and Julie M. McCarthy. "Working in a Pandemic: Exploring the Impact of COVID-19 Health Anxiety on Work, Family, and Health Outcomes." *Journal of Applied Psychology*, (2020): 1234-1245.

Tsui, Eva L. H., Carrie S. M. Lui, Pauline P. S. Woo, Alan T. L. Cheung, Peggo K. W. Lam, Van T. W. Tang, C. F. Yiu, C. H. Wan, and Libby H. Y. Lee. "Development of a Data-driven COVID-19 Prognostication Tool to Inform Triage and Step-down Care for Hospitalised Patients in Hong Kong: A Population-based Cohort Study." *BMC Medical Informatics and Decision Making* 20, no. 1 (2020): 1-19.

Wang, Bin, Yukun Liu, Jing Qian, and Sharon K. Parker. "Achieving Effective Remote Working During the COVID-19 Pandemic: A Work Design Perspective." *Applied Psychology: An International Review* 0, no. 0 (2020): 1-44.

Wiggs Harris, Wylecia. "Preparing for the Next Pandemic," letter to Senator Lamar Alexander,June 25, 2020.

Notes

1. CDC. "COVID-19 Electronic Case Reporting for Healthcare Providers." U.S. Department of Health & Human Services. (2021): 1.

2. Oetjens, Matthew T., et al. "Electronic Health Record Analysis Identifies Kidney Disease as the Leading Risk Factor for Hospitalization in Confirmed COVID-19 Patients." PloS one 15, no. 11 (2020): 2.

3. Latifi, Rifat, and Charles R. Doarn. "Perspective on COVID-19: Finally, Telemedicine at Center Stage." Telemedicine and e-Health 26, no. 9 (2020): 1107.

4. Osborne, Thomas F., et al. "Automated EHR Score to Predict COVID-19 Outcomes at US Department of Veterans Affairs." PLoS One 15, no. 7 (2020): 1.

5. Tsui, Eva L. H., et al. "Development of a Data-driven COVID-19 Prognostication Tool to Inform Triage and Step-down Care for Hospitalised Patients in Hong Kong: A Population-based Cohort Study." BMC Medical Informatics and Decision Making 20, no. 1 (2020): 1.

6. Bassett, Ingrid V., et al. "Massachusetts General Hospital COVID-19 Registry Reveals Two Distinct Populations of Hospitalized Patients by Race and Ethnicity." PloS one 15, no. 12 (2020): 2.

7. Oetjens et al., 7.

8. Blow, Matthew, et al. "The Public and Pandemics". Journal of AHIMA, (2021): 4.

9. Alvin, Matthew D., et al. "The Impact of COVID-19 on Radiology Trainees." Radiology 296, no. 2 (2020): 246.

10. CDC. "Comprehensive Hospital Preparedness Checklist for Coronavirus Disease 2019 (COVID-19)." U.S. Department of Health & Human Services. (2020): 2-11.

11. DeFilippis, Evan, et al. Collaborating During Coronavirus: The Impact of COVID-19 on the Nature of Work. No. w27612. National Bureau of Economic Research, 2020: 1.

12. Latifi and Doarn, 1108.

13. Kaplan, Bonnie. "Revisiting Health Information Technology Ethical, Legal, and Social Issues and Evaluation: Telehealth/telemedicine and COVID-19." International Journal of Medical Informatics, (2020): 2.

14. Latifi and Doarn, 1107.

15. CDC. "Using Telehealth to Expand Access to Essential Health Services During the COVID-19 Pandemic." U.S. Department of Health & Human Services. (2020): 2.

16. Ibid.

17. Ibid.

18. Kaplan, 13.

19. Lakhani, Hari Vishal, et al. "Systematic Review of Clinical Insights into Novel Coronavirus (CoVID-19) Pandemic: Persisting Challenges in US Rural Population." International Journal of Environmental Research and Public Health 17, no. 12 (2020): 4279.

20. Segel, Joel E., et al. "The Unique Challenges Facing Rural Providers in the COVID-19 Pandemic." Population Health Management 24, no. 3 (2021): 304-306.

21. Sethi, Bilal Ahmed, et al. "Impact of Coronavirus Disease (COVID-19) Pandemic on Health Professionals." Pakistan Journal of Medical Sciences 36, no. COVID19-S4 (2020): S7.

22. Dubey, Souvik, et al. "Psychosocial Impact of COVID-19." Diabetes & Metabolic Syndrome: Clinical Research & Reviews 14, no. 5 (2020): 779.

23. Sethi et al., S10.

24. Dubey et al., 782.

25. Sethi et al., S9

26. "Idaho State Guide." Rural Health Information Hub (RHIhub), 2021.

27. Kuofie, Matthew, and Nik Maheran Nik Muhammad. "Leaders Perspective on Post COVID-19 Pandemic Period: Global Business Focus." International Journal of Health and Economic Development 7, no. 1 (2021): 24-26.

28. Kaplan, 13.

29. Wiggs Harris, Wylecia. "Preparing for the Next Pandemic," letter to Senator Lamar Alexander. (2020): 1.

30. Kaplan, 11.

31. Wiggs Harris, 1.

32. Kaplan, 11.

33. Wiggs Harris, 4.

34. Blow et al., 5.

35. Wang, Bin, et al. "Achieving Effective Remote Working During the COVID-19 Pandemic: A Work Design Perspective." Applied Psychology: An International Review 0, no. 0 (2020): 13.

36. DeFilippis et al., 7.

37. Sethi et al., S10.

38. Adibe, Bryant, et al. "Creating Wellness in a Pandemic: A Practical Framework for Health Systems Responding to COVID-19." NEJM Catalyst Innovations in Care Delivery 2, no. 2 (2021): 2.

39. Gavin, B., et al. "Caring for the Psychological Well-being of Healthcare Professionals in the COVID-19 Pandemic Crisis." Irish Medical Journal 113, no. 4 (2020): 51.

40. Adibe et al., 10.

41. Gavin et al., 51.

42. Trougakos, John P., et al. "Working in a Pandemic: Exploring the Impact of COVID-19 Health Anxiety on Work, Family, and Health Outcomes." Journal of Applied Psychology, (2020): 1241.

43. Adibe et al., 2-6.

44. Eramo, Lisa A. "Leading HIM Reimagined by Example." AHIMA HIM Body of Knowledge. (2018): 2.

Author Biography

Jaime Sand (jaimesand@boisestate.edu) is an associate professor at Boise State University in the Department of Public Health and Population Science.

Human Factors in Electronic Health Records Cybersecurity Breach: An Exploratory Analysis

By Liu Hua Yeo, MS, and James Banfield, PhD

Abstract

The healthcare sector continues to be the industry suffering one of the highest costs of a data security breach. Healthcare lags behind other industries in cybersecurity preparedness despite advances in cybersecurity technologies. Technical safeguards to protect electronic health records must be combined with human behavioral interventions to promote a robust cybersecurity plan. Using data from the United States Department of Health and Human Services, we conducted an exploratory analysis of past data breaches in healthcare organizations from January 2015 to December 2020 to explore the extent to which human elements played a role in data security incidents. We found that a vast majority of health records were compromised due to poor human security. The mean number of records affected by a breach due to unintentional insider threats is more than twice that of breaches caused by malicious intent such as external cyberattacks and theft. Our findings also indicate that, on average, more patient records are compromised from falling for a phishing scam than any other reason. We argue that proper cybersecurity contingency plans in healthcare must include human behavioral interventions that go beyond technical controls.

Keywords: cybersecurity, healthcare breaches, human factors, insider threats

Introduction

The digitization of medical records has changed the landscape of healthcare systems worldwide. With the advent of the information age, paper-based healthcare records were gradually and systematically converted into digitized electronic health records (EHRs). In the last two decades, the push toward resource sharing in technology is revolutionizing the healthcare sector by providing an efficient way of sharing patient records between healthcare professionals. Compared to paper-based records, EHRs require less manpower, time, and physical storage. Caregivers and providers use EHRs to access care-related activities and provide evidence-based decision support and quality care.[1] However, the ease of access to EHRs is accompanied by rising cybersecurity threats and challenges.

In the annual "Cost of Data Breach" report conducted by the Ponemon Institute, the 2020 study noted that each compromised record cost an average of $146 to the healthcare organization (HCO). That figure increases to $150 per compromised record where personal health information (PHI) was involved. According to the report, healthcare continues to be the industry suffering the highest cost of a data breach at $7.13 million when factoring in other costs such as incident response, lost business, and notification costs. Eighty percent of the breached organizations participating in the study reported that PHI was involved. The cost of healthcare breaches is expected to increase during the COVID-19 pandemic, as 76 percent of HCOs in the survey predicted that implementing an incident response strategy will be made much more difficult by the ubiquity of remote work during the pandemic.[2] Most healthcare executives lack overall information security, employee security awareness, and incident response strategies.[3] Breaches related to EHR can significantly affect HCOs, such as the accidental release of PHI to disruptions in clinical care.[4-6] Disruptions and delays in patient care can result in patient death, and the impact on patient safety is likely to be underreported.[7]

Federal compliance laws such as Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act were enacted to require the adoption of electronic medical records and protect privacy and data security of PHI.[8]As required by section 13402 (e) (4) of the HITECH Act, The United States Department of Health and Human Services (HHS) Office for Civil Rights (OCR) must post a list of breaches of unsecured protected health information affecting 500 or more individuals. The HIPAA Security Rule requires healthcare organizations and covered entities protect electronic personal health information from cybersecurity threats.[9] It also imposes administrative, technical, and physical standards for safeguards that organizations must implement. These entities must implement data security safeguards to protect PHI, such as medical records and insurance information. This paper presents an exploratory analysis of past EHR breaches in the United States from 2015to 2020. By exploring the factors that led to violations, executives and decision-makers in HCOs can apply lessons from these breaches in securing their organizations.

Research Question

We investigated the extent to which the lack of proper human security enabled data breaches in HCOs. Our research questions were thus:

1. To what extent did the lack of human security result in data security breaches in healthcare records?
2. On average, how does the lack of human security affect the number of records breached in a cybersecurity incident in healthcare?

We hypothesized that data breaches in healthcare caused by unintentional human factors, such as carelessness, negligence, and falling victim to phishing and ransomware, outnumber those caused by malicious intent. The following sections discuss our observational study results and help research determine solutions for incorporating human security into organizational policies. We argue that any security framework must emphasize securing the human in HCOs.

Classification Method

We conducted an exploratory study on the factors that play a role in EHR-related cybersecurity breaches. HCOs are required by law to notify the OCR after a breach compromising EHRs and PHIs. The OCR publishes details of these reported breaches beginning October 2009 and makes the dataset publicly available.[10] It includes reports from HCOs that have suffered breaches that compromised 500 or more EHRs. Since the law requires HCOs to notify HHS in the event of a violation, we believe that this nationwide sample is sufficiently representative of the population of EHR-related breaches in healthcare, with some limitations. Our analysis used a methodology based on the Joanna Briggs Institute (JBI) approach, which provides an evidence-based process for qualitative research.[11] We modified a similar method by Walker-Roberts et al.[12] in our classification process. **Figure 1** shows a graphical representation of the flow process, which describes how we identified and screened each entry in our dataset for inclusion in the exploratory analysis. Our criteria for inclusions were that entries:

- Included valid and clear descriptions of the breach incident.
- Occurred between January 1, 2015, and December 31, 2020, inclusive
- Constituted a breach as defined under HIPAA. Entries alleging violations by entities not covered under HIPAA, or those determined by OCR to have not violated any HIPAA rules, were excluded.

We limited our analysis of the OCR dataset to the years spanning January 2015 to December 2020; after removing incomplete records and other entries that do not constitute a breach of PHI, the resulting set of data contained 1,485 security incidents. The data was then analyzed to determine the type of the cybersecurity breach. Entries were categorized based on the presence or absence of malicious intent. In 15 cases, we could not establish those criteria based on the incident descriptions provided in the original dataset. These cases were noted with an "Insufficient information" designation. Once the type of breach has been identified, we further classified each entry into the primary source or cause of the breach for analysis. **Table 1** describes in detail our classification methods for each entry.

Results and Discussion

We studied 1,485 breach events occurring between January 2015 and December 2020, affecting 141,252,797 medical records. Of that number, 73.1 percent of all affected records resulted from breaches caused by unintentional factors, while 26.7 percent were caused by malicious factors. **Figure 2** shows the resulting classification of thesources of EHR breaches in HCOs and their frequency of occurrence in the United States from January 2015 to December 2020. We found the most frequent reason for a cyber breach in HCOs is the result of carelessness and negligence (382 incidents), followed by theft (222 incidents), and falling victim to a phishing scam (221 incidents). Similarly, **Table 2** shows the total number of records affected by each breach categories based off our classification method.

Carelessness/Negligence

Existing literature on insider threats generally assumes that individuals who commit cybersecurity transgressions do so due to an ulterior motive that is typically accompanied by malicious intent or the desire to enrich themselves for financial or personal gain.[13] However, our dataset analysis revealed that 382 incidents, or 26 percent of all human factor-based breaches, were due to an insider's carelessness, negligence, or apathy. In each of these cases, no malicious intent was visible in that there was no intent to access patient data, but a data breach occurred. Employees or business associates may partake in risky cybersecurity behaviors due to a highrisk tolerance or the desire to be efficient or helpful.[14] In some cases, employees may inadvertently circumvent established policies because they view those policies as cumbersome or unrelated to patient outcomes.[15] This paper does not intend to define a framework for what constitutes an insider threat but rather to show that carelessness and negligence stemming from risky behaviors, lack of awareness, and apathy are essential domains of human security.

Of the 382 incidents stemming from carelessness or negligence, 212 (55.5 percent) were incidents whereby an employee or business associate erroneously mailed or emailed PHI to the wrong recipients. Some were caused by misalignment in the printing process or information mismatched with patient data. In other cases, PHI may have been mailed to the correct recipients but done so in a manner that unintentionally exposed the PHI in transit.

Misplaced hard drives or documents containing PHI lost in the mail or transit were described in 71 incidents. In most of these cases, the covered entities never recovered the lost records. According to the dataset, some of these losses were attributed to carelessness on behalf of an employee. We note that we did not include cases where external individuals deliberately stole PHI during a burglary; these entries were classified under the "Theft" source of breach category due to the clear presence of malicious intent. These cases are therefore distinguished from incidents where PHI was lost due to negligence or carelessness. In a further 59 incidents, PHI was unintentionally and improperly exposed by individuals who uploaded the data onto publicly accessible websites or databases without taking security steps such as encrypting or sanitizing the data beforehand.

These accidental transgressions led to tangible consequences for both the offending employee(s) and the organization. According to the HHS dataset, consequences included penalties ranging from reprimand and retraining of the individual(s) to the suspension or termination of employment, depending on the severity and impact of the risky behavior. In addition, under HIPAA, organizations face substantial fines for noncompliance with the HIPAA Privacy Rule. In a February 2022 update, the OCR noted that since the compliance date of the Privacy Rule in April 2003, it has imposed civil penalties totaling $131 million to organizations for non-compliance.[16]

Phishing/Ransomware

Falling victim to a phishing scam made up most of the number of EHRs affected in our dataset. There were 221 incidents directly attributed to phishing scams, and 119 reported breaches were related to ransomware. Together, they make up 40.7 percent of all non-malicious events in our chosen time range. Our analysis combined phishing and ransomware incidents because a cybersecurity victim's vector to produce that outcome is similar. Phishing, which is the act of tricking a user into disclosing confidential information[17] through a legitimate-looking email or link, is the vehicle that delivers the ransomware payload.[18]

In a phishing attack, one compromised credential can lead to multiple subsequent attacks, as we saw in Anthem Inc. in 2015,[19] whereby a targeted spear-phishing campaign opened the door to further parts of its network. During the attack, 78,800,000 affected records were attributed to Anthem's breach incident as corroborated by the OCR dataset. Anthem had disclosed that it had suffered a data breach that affected almost 80 million customers.[20,21]Anthem discovered that the attackers had managed to obtain several employees' credentials, possibly through a phishing attack in their investigation. Once the attackers had obtained the credentials, they ran several data queries between December 2014 and January 2015. The database credentials would then be trivial to access using the stolen credentials.[22] Eventually, the attackers could access Anthem's enterprise data warehouse containing personally identifiable information (PII) and stole almost 80 million unique user records.[23]

Although the Anthem incident may seem like a statistical outlier, we argue that, on the contrary, it further underscores the gravity of falling victim to a phishing attack. One phishing incident led to the most significant cybersecurity breach in the healthcare industry. Victims of phishing, ransomware, and other social engineering attacks become a new vector or vehicle to launch more in-depth and large-scale attacks.[24] Once in the system, the attackers ran queries and worked from there to gain higher-level access. The Anthem administrator who found the breach noticed that his password was used to run queries that he did not initiate.[25] The ability for an administrator's password to be used in this manner points to a possible flaw in Anthem's data management policy; actions executed by elevated privilege accounts should always be accompanied by some form of additional verification or authentication beyond a simple password requirement. While it cannot be said definitively that the presence of an additional authentication factor would have prevented the breach, it would have been an extra layer of defense against the attack.

Malicious Insider

Malicious insiders refer to individuals with knowledge or access to internal systems or networks, who then commit cybersecurity crimes with the express intent of enriching themselves for financial, personal, or other gains.[26,27] As we noted earlier in this paper, the allure of economic gains from PHI on the black market may drive individuals to commit cybercrime. However, malicious insiders may have motives other than profit, such as disgruntled employees attempting to exact revenge for a perceived wrong or a sense of entitlement. Cybersecurity controls typically are designed to thwart external attacks, and there are few, if any, technical controls that specifically defend against internal threats.[28] Insiders have a crucial advantage: They are generally knowledgeable about systems and processes in the organization and may have varying administrative access levels that external actors do not.

To illustrate this, we found that in our analysis of the OCR dataset, there were 217 incidents of malicious insiders, affecting a total of 55,199,447 records. In as many as 170 of these cases, employee(s) of the HCO accessed PHI without a legitimate business need.

Other Sources of Breach

Under the "Unintentional" type category, the source of a breach in a total of 32 incidents was something other than the abovementioned categories. Since there were relatively few of these, we combined and classified these entries as "Other" in our analysis. In three incidents, the breaches were caused by employees falling for a social engineering attack. Social engineering, which is an umbrella term that includes phishing and ransomware, describes a process whereby an attacker uses social interaction to deceive and obtain sensitive information from a victim.[29-31] For instance, an attacker may pose as an authorized individual and trick a user into divulging credentials to an internal network. In the OCR dataset, due to the prevalence of healthcare breach incidents caused by falling victim to phishing or ransomware attacks, we distinguished these categories from the more broadly applicable social engineering category. Ten incidents in the "Other" category stemmed from a lack of a business associate agreement between a covered entity and its business associate. Under the HIPAA Rules, a business associate agreement must be executed to ensure that any business entity that establishes a relationship with a covered HCO will commit to safeguarding PHI. Other incidents include breaches due to miscellaneous policy violations (eight occurrences), unintentional physical exposure of PHI (five occurrences), easily guessed passwords (four), and natural disasters (two).

Across all incidents, the OCR dataset shows that from 2015 to 2020, the mean number of records affected by unintentional factors is 123,446, more than twice that of the mean caused by malicious factors. **Figure 3** shows the mean number of records affected when considering the type of breach. A closer look at the subfactors shows that phishing and cyberattacks led to the highest mean number of records affected at 421,038 and 153,644 records. **Figure 4** breaks those categories down further into its subcategories based off our classification method and shows the mean number of records affected by each subcategory.

Conclusion

As healthcare services evolve in technology and coverage, they aim to provide a variety of treatments in order to accommodate diverse patient demographics. This was especially noticeable with the influx of patients impacted by the COVID-19 global pandemic. Due to the volatile and unpredictable nature of the virus, healthcare providers were forced to find alternative means of treatment in order to adequately provide necessary services to their patients. This included an increase of services, which entailed the usage of tools such as technology through cloud-based data inference, surveys, COVID-19 screening symptom checklists, and virtual appointment services. Such alternative means of seeking treatment were designed to minimize risk of exposure to patients, healthcare providers, and workers. With the increase in telehealth services, many healthcare workers began to perform remote work during the pandemic.[32] The Federal Bureau of Investigation (FBI) have reported that cyberattacks have increased almost 400 percent by the first few months of the pandemic.[33] In addition, the rise of telehealth means that many remote employees are now using their personal computers and home networks to perform their jobs. HCOs with essential workers working on-site are also grappling with the necessity of "bring your own device" (BYOD) policies to maintain patient care and outcome pre-pandemic. Working remotely means that HCOs have to deal with significant amounts of data being sent over the network off-premises in remote locations. In addition to expanding the attack surface for cyber criminals to take advantage of,[34,35] these developments and decentralized resources also increase the risk of accidental exposure of PHI as telehealth signals a necessary paradigm shift in providing patient care.

Data breaches in healthcare are incredibly lucrative as pathways to identity theft on the black market. According to Verizon's latest data breach report, published in May 2021, 85 percent of all breaches involved a human element, and during the COVID-19 global pandemic, phishing continued to be one of the most commonly employed methods in a data security incident across all industries. The report also indicated that ransomware has jumped to third place in terms of the most frequently occurring source of breaches. Similarly, the Healthcare Information and Management Systems Society (HIMSS) released a survey report stating that phishing is the most common attack vector in healthcare.[36] This finding is consistent with our discovery with the OCR dataset. We showed that, on average, more EHRs are compromised to a phishing scam (mean of 421,938 records affected) than any other reason. We also noted that in the time range of our analysis, carelessness, negligence, and phishing were the most frequently occurring sources of EHR breaches.

The discourse on data breaches and EHR exposure has changed from "if" to "when" an HCO will experience a data breach. Based on our observational study of the OCR dataset, threats involving human elements continue to be significant risk factors for EHR breaches. An organization's ability to train and impart information awareness to its employees' behaviors is paramount in the fight against cybersecurity attacks on HCOs. A survey conducted in Germany by PricewaterhouseCoopers (PwC) revealed that a staggering 87 percent of participants believe that better education for medical staff is crucial to an HCO's cybersecurity hygiene.[37] Phishing as a security incident is not new, yet the fact that it remains one of the most common occurrences of data breaches suggests that it may not be taken as seriously as it should be. Organizational data security policies may not receive widespread compliance in an HCO because employees may not perceive the risk of poor cybersecurity hygiene. An effective information awareness and training program must do more than simply transfer knowledge about proper behavior in cybersecurity. Incorporating behavioral science into training programs to change deeply rooted online habits is crucial in combating human-influenced breaches such as carelessness and phishing.[38-40] Technical safeguards should not be the only avenue to accomplish this goal; rather, it needs to be bolstered by the cyber vigilance of human elements.[41] There is no one holy grail of countermeasures sufficient to prevent human risks that lead to cyberattacks. Each HCO must conduct its own risk assessment that accounts for resource constraints and the feasibility of such methods.[42]

Our analysis of the data breaches in healthcare as reported to HHS has identified several contributing factors. As we have observed, many of the cases we analyzed involved unintentional insider threats, and these cases lead to significant loss and exposure of EHR. This analysis was informative in specifying directions for future research and areas to focus on in mitigating cyber-attacks.

Notes

1. Kruse CS, Frederick B, Jacobson T, Monticone DK. “Cybersecurity in healthcare: A systematic review of modern threats and trends.” *Technology & Health Care*. 2017;25(1):1-10. doi:10.3233/THC-161263

2. “Cost of a Data Breach Report 2020.” Ponemon Institute LLC; 2020. https://www.capita.com/sites/g/files/nginej291/files/2020-08/Ponemon-Global-Cost-of-Data-Breach-Study-2020.pdf

3. Castelli C, Gabriel B, Yates J, Booth P. “Strengthening digital society against cyber shocks: Key findings from The Global State of Information Security® Survey 2018.” *Cybersecurity and Privacy*. Published online 2017:22.

4. Gordon WJ, Fairhall A, Landman A. “Threats to Information Security - Public Health Implications.” *N Engl J Med*. 2017;377(8):707-709. doi:10.1056/NEJMp1707212

5. Jalali MS, Russell B, Razak S, Gordon WJ. “EARS to cyber incidents in health care.” *J Am Med Inform Assoc*. 2019;26(1):81-90. doi:10.1093/jamia/ocy148

6. Bhuyan SS, Kabir UY, Escareno JM, et al. “Transforming Healthcare Cybersecurity from Reactive to Proactive: Current Status and Future Recommendations.” *Journal of Medical Systems*. 2020;44(5). doi:10.1007/s10916-019-1507-y

7. “2020 HIMSS Cybersecurity Survey.” Healthcare Information and Management Systems Society; 2020. https://www.himss.org/sites/hde/files/media/file/2020/11/16/2020_himss_cybersecurity_survey_final.pdf

8. Koch DD. "Is the HIPAA Security Rule Enough to Protect Electronic Personal Health Information (PHI) in the Cyber Age?" *Journal of Health Care Finance*. 2016;43(3). Accessed March 10, 2021. https://healthfinancejournal.com/index.php/johcf/article/view/67

9. Kosseff J. "Cybersecurity Requirements for Specific Industries." In: *Cybersecurity Law*. 2nd ed. John Wiley & Sons, Ltd; 2020.

10. "Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information." U.S. Department of Health & Human Services - Office for Civil Rights. https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf;jsessionid=48C4A2DEB0F6F4053924B40BF2B12B12

11. Aromataris E, Munn Z, eds. *JBI Manual for Evidence Synthesis*. JBI; 2020. doi:10.46658/JBIMES-20-01

12. Walker-Roberts S, Hammoudeh M, Dehghantanha A. "A Systematic Review of the Availability and Efficacy of Countermeasures to Internal Threats in Healthcare Critical Infrastructure." *IEEE Access*. 2018;6:25167-25177. doi:10.1109/ACCESS.2018.2817560

13. Hadlington L. "The "Human Factor" In Cybersecurity: Exploring the Accidental Insider." In: *Psychological and Behavioral Examinations in Cyber Security*. 1st ed. IGI Global; 2018:46-63.

14. CERT. "Unintentional Insider Threats: A Foundational Study." Software Engineering Institute; 2013.

15. Mansfield-Devine S. "Leaks and ransoms – the key threats to healthcare organisations." *Network Security*. 2017;2017(6):14-19. doi:10.1016/S1353-4858(17)30062-4

16. Office for Civil Rights. Enforcement Highlights. HHS.gov. Published February 28, 2022. Accessed March 16, 2022. https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/enforcement-highlights/index.html

17. Barrett MP. "Framework for Improving Critical Infrastructure Cybersecurity Version 1.1." *NIST Cybersecurity Framework*. Published online April 16, 2018. doi:10.6028/NIST.CSWP.04162018

18. Croke L. "Protecting your organization from e-mail phishing and ransomware attacks." *AORN Journal: The Official Voice of Perioperative Nursing*. 2020;112(4):P10-P12. doi:10.1002/aorn.13229

19. "Anthem breach traced to admin's stolen login." *Healthcare Risk Management; Atlanta*. 2015;37(3). Accessed February 22, 2021. http://search.proquest.com/docview/1987263449/abstract/37CE188769A0479DPQ/1

20. Mathews AW. "Anthem: Hacked Database Included 78.8 Million People." *Wall Street Journal*. https://www.wsj.com/articles/anthem-hacked-database-included-78-8-million-people-1424807364. Published February 24, 2015. Accessed April 19, 2021.

21. Riley C. “Insurance giant Anthem hit by massive data breach.” CNNMoney. Published February 4, 2015. Accessed March 22, 2021. https://money.cnn.com/2015/02/04/technology/anthem-insurance-hack-data-security/index.html

22. “Anthem breach traced to admin’s stolen login.” *Healthcare Risk Management; Atlanta*. 2015;37(3). Accessed February 22, 2021. http://search.proquest.com/docview/1987263449/abstract/37CE188769A0479DPQ/1

23. Miller NA. “Report of the Multistate Targeted Market Conduct and Financial Examination.” Alvarez & Marsal Insurance and Risk Advisory Services, LLC; 2016.

24. Gyunka BA, Christiana AO. “Analysis of Human Factors in Cyber Security: A Case Study of Anonymous Attack on Hbgary.” *Computing & Information Systems*. 2017;21(2):10-18.

25. McGee MK. “A New In-Depth Analysis of Anthem Breach.” Published January 2017. Accessed May 5, 2021. https://www.bankinfosecurity.com/new-in-depth-analysis-anthem-breach-a-9627

26. Greitzer FL. “Insider Threats: It’s the HUMAN, Stupid!” In: *Proceedings of the Northwest Cybersecurity Symposium*. ACM; 2019:1-8. doi:10.1145/3332448.3332458

27. Homoliak I, Toffalini F, Guarnizo J, Elovici Y, Ochoa M. “Insight Into Insiders and IT: A Survey of Insider Threat Taxonomies, Analysis, Modeling, and Countermeasures.” *ACM Comput Surv*. 2019;52(2):30:1-30:40. doi:10.1145/3303771

28. Greitzer FL. 2019.

29. Aldawood H, Skinner G. “Reviewing Cyber Security Social Engineering Training and Awareness Programs—Pitfalls and Ongoing Issues.” *Future Internet*. 2019;11(3):73. doi:10.3390/fi11030073

30. Guitton MJ. “Cybersecurity, social engineering, artificial intelligence, technological addictions: Societal challenges for the coming decade.” *Computers in Human Behavior*. 2020;107:106307. doi:10.1016/j.chb.2020.106307

31. Salahdine F, Kaabouch N. “Social Engineering Attacks: A Survey.” *Future Internet*. 2019;11(4):89. doi:10.3390/fi11040089

32. Kim L. “Cybersecurity and related challenges during the COVID-19 pandemic.” *Nursing*. 2021;51(2):17-20. doi:10.1097/01.NURSE.0000731916.83045.e6

33. Miller M. “FBI sees spike in cyber crime reports during coronavirus pandemic.” TheHill. Published April 16, 2020. Accessed November 13, 2021. https://thehill.com/policy/cybersecurity/493198-fbi-sees-spike-in-cyber-crime-reports-during-coronavirus-pandemic

34. Kim L. “Cybersecurity and related challenges during the COVID-19 pandemic.” *Nursing*. 2021;51(2):17-20. doi:10.1097/01.NURSE.0000731916.83045.e6

35. Internet Crime Complaint Center. *Cyber Actors Take Advantage of COVID-19 Pandemic to Exploit Increased Use of Virtual Environments*. Federal Bureau of Investigation; 2020. doi:10.6028/NIST.SP.800-46r2

36. *2021 HIMSS Cybersecurity Survey*. Healthcare Information and Management Systems Society; 2022. Accessed March 30, 2022. https://www.himss.org/sites/hde/files/media/file/2022/01/28/2021_himss_cybersecurity_survey.pdf

37. von Grätz PG. "The real cybersecurity risk sits between the chair and keyboard." Healthcare IT News. Published October 3, 2019. Accessed April 4, 2021. https://www.healthcareitnews.com/news/europe/risk-between-chair-and-keyboard

38. CERT. *Unintentional Insider Threats: A Foundational Study*. Software Engineering Institute; 2013.

39. Bada M, Sasse AM, Nurse JRC. "Cyber Security Awareness Campaigns: Why do they fail to change behaviour?" *arXiv:190102672 [cs]*. Published online January 9, 2019. Accessed April 28, 2021. http://arxiv.org/abs/1901.02672

40. *Verizon 2021 Data Breach Investigations Report*. Verizon; 2021. https://enterprise.verizon.com/resources/reports/2021/2021-data-breach-investigations-report.pdf

41.Greitzer FL. 2019.

42.CERT. *Unintentional Insider Threats: A Foundational Study*. Software Engineering Institute; 2013.

Author Biographies

Liu Hua Yeo (lyeo@emich.edu) is a PhD candidate in cybersecurity at Eastern Michigan University. His research interests include risk factors in healthcare cybersecurity.

James Banfield (jbanfield@emich.edu) is an associate professor of cybersecurity at the School of Information Security and Applied Computing at Eastern Michigan University.

Economical Utilization of Health Information with Learning Healthcare System Data Commons

By Thomas O'Hara, PhD; Anil Saldanha, MS; Matthew Trunnell, MSc; Robert L. Grossman, PhD; Bala Hota, MD; and Casey Frankenberger, PhD

High-Level Statement

The ability to inventory institutional data assets, design research studies, and to share and analyze data has proven challenging for healthcare systems that are focused on delivery of care. Here, the use of data commons is described as a low-cost and low-staff approach to data utilization to facilitate quality improvement and research in such cases.

Abstract

Finding, accessing, sharing, and analyzing patient data from a clinical setting for collaborative research has continually proven to be a challenge in healthcare organizations.The human and technological architecture required to perform these services exist at the largest academic institutions but are usually under-funded.At smaller, less academically focused healthcare organizations across the United States, where the majority of care is delivered, they are generally absent.Here we propose a solution called the Learning Healthcare System Data Commons where cost is usage-based and the most basic elements are designed to be extensible, allowing it to evolve with the changing landscape of healthcare.Herein we also discuss our reference implementation of this platform tailored specifically for operational sustainability and governance using the data generated in a hospital setting for research, quality, and educational purposes.

Introduction

Information management professionals within healthcare organizations navigate a high degree of complexity for each project and for each data source used for research and quality improvement services.[1]Data and data policy must be governed tightly, consistently, and transparently to meet the expectations of patients and to comply with the high ethical and legal standards in the healthcare industry.[2]Even prior to the pandemic, access and sharing of patient data has been of paramount importance to assess current status of medical knowledge, as well as to accelerate clinical research related to diagnosis, prognosis, and therapeutic intervention in the context of cancer care; complex, or rare disease; and in the face of rapidly changing technologies for telehealth, surveillance, engagement, and intervention.[3,4]

The COVID-19 pandemic has highlighted the need for unified and harmonized data sets. Early in the pandemic, an urgent need to evaluate outcomes related to COVID-19, efficacy of treatments, risks for severe disease, and health equity differences was identified. The diversity of patients' current health and medical history relative to various viral strains presents issues for all medical research institutions both in the capacity to access data in real time and the costs to maintain such flexible, agile analytics environments. The need to search, access, analyze, and share medically related data of patients in a manner that isreliable and secure has required separate teams to architect and manage data flow and to manage data governance. Additionally, interfaces that are accessible to experienced careproviders/researchers are needed to integrate and contextualize results to the larger community.

Here we present the Learning Healthcare System Data Commons (LHSDC), a cloud-based orchestration environment and governance framework that meets the highest standards for security, cost efficiency, and platform extensibility, enabling scalable access to a FAIR[5] computing environment (data are findable, accessible, interoperable, and reusable). This platform is open source, pay-as-you-go, and cost efficient, making it interoperable across an ecosystem of National Institutes of Health (NIH)-supported commons-based data enclaves and supportive of big data initiatives within academic or public-private partnerships. The LHSDC attempts to realize the re-usability and easyupkeep of data-as-a-service made possible with a data commons.[6]

Methods

The Gen3 Platform: A Scalable Open-Source Platform for Data Storage and Governance

The Gen3 platform (https://gen3.org/), an open source data commons framework, is cloud-native and makes central control of data access and data use possible. It generates a FAIR environment.[7] The Gen3 platform is currently used in different ways by different research communities.For example, some Gen3 commons are focused on data types, such as the BloodPAC Data Commons for liquid biopsy data and the National Institute of Biomedical Imaging and Bioengineering Medical Imaging and Data Resource Center (MIDRC)(https://data.midrc.org/), while others are focused on specific diseases, such the Pandemic Response Commons,which is currently focused on COVID-19 (https://pandemicresponsecommons.org/).There are examples of life science industry adoption, as this framework also serves public-private partnerships. The LHSDC differentiates itself from previous work in two important ways: 1) It is the first data commons in general, and Gen3 data commons in particular, designed to facilitate quality improvement and research for a healthcare provider. 2) It is also the first Gen3 implementation on the Microsoft Azure platform and was developed in collaboration with Microsoft.

Data volumes per site can range by orders of magnitude depending on the number of patients seen in practice as well as the nature of the data being investigated.A small practice can see hundreds of patients, but the largest hospital systems have seen millions of patients in aggregate. The overall data storage burden is not determined by patient count alone, but rather what data files are included. Typical data may include image files and genomic data in addition to medical records, and so even individual files can be “large.” This creates specific challenges in how to house the data in a manner that is readily accessible and to “focus” the data to deliver meaning at manageable storage volumes.[8] The Gen3 commons framework linksout to data objects for storing images, genomic data, wearable data, and other large files,in whatever commodity storage is most convenient (e.g., Azure Blob storage, Amazon Web Services (AWS) Simple Storage Service (S3) buckets). A Gen3-hosted Postgres database houses structured data and metadata, which consumes orders of magnitude less storage than the externalized rawdata and makes it findable through a graph data model. Facets of the metadata are exposed for interactive exploration using an Elasticsearch index (pre-populated as configured). All metadata is granularly accessible, monitored, and governed through application programming interface

(API)-based calls in the Jupyter Notebook.The centralization of the infrastructure of these resources means that the whole environment can be managed by a small team or even one individual. Additionally, the analytic team can be greatly streamlined, as they can reuse data sources, methods, and code.

Implementation

Data Assets, and Assets Loaded (Counts of Files by Type)

Rush University, operating as a major medical hospital in a diverse major city, is home to diverse troves of multimodal (i.e., wholly different information categories: medical images, genomic sequences, and clinical records) diagnostic and medical treatment outcomes data assets. Historically, much of this data has been stored in on-premises data centers. More recently, data has been stored in external data centers and in the cloud.

Rush Research Analytics provides access to clinical data records from the electronic health record (EHR). Medical images from CT/PET/MR, etc., are available for research (via a picture archiving and communication system (PACS) serverin midst of migration to Flywheel). Biospecimens at Rush are extensive. For example, in the last two years, tens of thousands of COVID-19 sputum samples and thousands of cancer biopsy specimens have been collected. Together with its next-gen sequencing partner Tempus, Rush owns tens of thousands of diagnostic sequences. Internet of Things (IoT) streaming data is being collected from multiple sensors involved in patient care. Rush collects and analyzes data related to social determinants of health, an active area of ongoing research funded by the Robert Wood Johnson Foundation.

The data assets described above are all related to individual patients, which can be de-identified carefully following contemporary best practices for personal health information definition and removal. Importantly, the assets are stored and managed separately and, thus far, there has been no coordinated effort to bring together a holistic view of care and outcomes with an eye toward better care with efficient use of resources. However, this cohesion is possible at Rush and similar medical centers, facilitated by efforts like theLHSDC.

Deployed Components and Improvements Advanced by this Implementation

The LHSDC is the first deployment of the Gen3 framework in the Microsoft Azure Cloud. Gen3 microservices were forked from open-source versions available from University of Chicago's Center for Translational Data Science (github.com/uc-cdis), and they were modified to include support for Azure-specific resources. This includes support for Azure Active Directory for user authentication and authorization (analogous to AWS Identity and Access Management (IAM)), and also support for Azure Blob storage (analogous to AWS S3). We strengthened the security of communication between services and the backend database by introducing support for secure sockets layer (SSL) with Postgres. These improvements have been merged back into the main/master branches of the open repositories for the Gen3 components (specifically, indexd, sheepdog, tube, and fence).(Visit gen3.org and github codebase (https://github.com/uc-cdis/gen3.org) for detailed information on these microservices and the roles they play in a Gen3 data commons.)

We introduce a novel deployment paradigm that utilizes Terraform (infrastructure as code language and framework by HashiCorp, https://www.terraform.io/) and/or Azure DevOps pipelines to stampout instances of the commons. To orchestrate the configuration of Gen3 components (aka microservices), a high-level-definition (HLD) is supplied (in yaml) that defines which services to deploy, which tagged version to use, and where to find that build. The specific build can be a custom version, as was the case during development of the LHSDC before improvements/updates for Azure listed above were publicly available. These custom images were built by a pipelineafter testing and were stored in Azure Container Registry, where they could be referenced by an HLD configuration. Now that the microservices with the updates are public, the images in a configuration can be references to tagged public builds (quay.io/organization/cdis). Open-source publication of HLD orchestrations and Terraform scripts for Azure deployments, to be made available among Gen3 resources (github.com/cdis), are forthcoming. Our specific realization of the HLD concept for continuous deployments is based on the genera-use freeware offered by Microsoft as "bedrock" (https://github.com/microsoft/bedrock).

Results

Data Governance and Cybersecurity

There are numerous opportunities to perform research and collaborate within or across an organization; however, prior to the data commons implementation, each new project requires its own new data preparations and its own new governance. Data can be pulled from the electronic health record into a clinical data warehouse, processed to remove any identifying information, and potentially combined with other data resources and prepared for research investigation. These activities currently operate on a per-project manner with the data decentralized and put into the hands of investigators at the earliest stage.The current procedures for sharing prepared research data can vary widely from project to project. Access to files for a research team is managed ad-hoc, with users granted credentials to view to files in shared directories (e.g.,Google Drive, Dropbox, Box) or with users sent email attachments. Though these various modes of sharing can be accomplished securely, the lack of centralized and uniform control over the sharing procedure prevents meaningful audits and provides opportunity for access leakage or data leakage. The data can be copied, and the copies and user list is not tracked. This creates a problem for data governance, as usage and compliance are largely self-reported.Because of the transition to cloud computing, all of this can be done in an environment that is accessible to researchers but controlled centrally.With highly centralized data sharing, research analytics can become a self-service enterprise, with authorized scientists logging in to view and work with already available data. The data will have already been approved by institution review board (IRB)/governance entities. The oversight of the resources will be operated by a small team of data software developers whose operational practices are monitored and approved by institutional cybersecurity and treated very much like any other website (albeit one with sensitive data).

Governance pre-approval of data for centralization in a general purpose (or narrow focus) database is a growth and maintenance process, with small but regular updates to be made. This is in contrast to the current state of data request processes, where decentralized data requests are considered in isolation from each other in a case-by-case manner. Even if there exist redundancies or overlap, the cases each require separate and end-to-end judgements without coordination around a unifying dataagenda and without exploiting efficiencies of a once-for-all approach for shared needs. The use of the cloud also enables centrally managed authentication and authorization, which eliminates the need for additional outlets or copies of data. This results in an overall more closed and, therefore, more secure, system. This data flow is depicted in **Figure 1A**, from research concept to centralized sharing.

Data Sharing and Cohort Discovery

Commonly, biomedical research is a multi-institutional enterprise. Data use and data sharing agreements can be slow to take full shape and take time to gain full support and buy-in. Following the establishment of such agreements among parties, there remains the challenge of data harmonization, which can often take time and require debate and eventual endorsement by all. With multimodal aggregated data from multiple sources, and adhering to diverse standards, it can be tedious to arrive at a point where research analytics can finally begin (**Figure 1B**).

With centralized data aggregation and sharing across institutions from the start, as has been the case for recent COVID-19-related databases, it is possible to provide a single shared resource with a single set of standards and interrelationships among data in a data model. The data model can be managed as open-source code and versioned as it evolves. The debate and buy-in over this standard presentation of the data in this data model is integral to its very existence as code in a shared repository (e.g.,github) where users can create branched/forked versions with special features that can evolve on their own or be merged back into the main (or master) branch once consensus is reached and the model is tested by the community of interested and authorized developers.

Streamlined Logistics and Pay-As-You-Go Economics

Currently, research projects can begin with IRB approval of the proposed undertaking. This is followed by a formal data request, which is queued for data extraction (and de-identification).Once the research analytics team is engaged on a request, data is identified and accessed, and an ETL (extract, transfer, load) operation is performed. The resulting records are presented in a usable research database. This process is often iterative; once analysis begins in earnest, non-obvious deficiencies in the original request may be revealed. Scientists connect their database with a provisioned and reserved virtual machine where allowed site licensed software is installed and/or custom code is developed, tested and refined, and executed. Again, this is iterative, and the data request or even the IRB may need updates as the research matures toward conclusions.[9]

The above process takes weeks to months before actual science can begin (**Figure 1B**). The back-and-forth communication between researchers and analytics and the IRB is typically accomplished over email and scheduled meetings, which can be slow. The data extraction results in a static and single-use database that is typically highly specific and not readily re-usable or applicable to other projects. The provisioned virtual machine(s) are reserved and cost money even when idle.

In contrast, with the LHSDC, general purpose (de-identified) multimodal data can be presented in a general purpose data model to a general audience of scientists, exploration can begin right away for those with access. The IRB approval to serve this data to the intended audience can be earned early, once and for all, and approved by any other comprehensive research data governance body. A sufficiently large and general purpose multimodal dataset will not suffer from incompleteness or deficiencies for preliminary exploration. Any need for more specialized, PHI-containing, or otherwise excluded information will reveal itself upon preliminary exploration, and not after rounds of iteration from (request, acquisition, analysis, repeat). The general purpose database can be explored where it sits, in the cloud and utilizing cloud-native processing power with preinstalled software and off-the-shelf analytics (e.g.,JupyterNotebook). This compute resource can be a shared cluster, provisioned when needed with pay-as-you-go billing, with low or no cost when idle, available anytime from any web browser on any platform (**Figure 1C**).

Rush University Reference Implementation

At Rush University, to improve the auditability, sustainability, and efficiency of research informatics, we have developed a reference implementation for data storage and access using Gen3.Our implementation consists of a three-tiered model for data governance and operations: 1) a data governance committee, 2) a research informatics core, 3) a Gen3 learning healthcare system data commons.We have observed an increase in projects that have come to our organization through both academic and commercial channels. A data governance committee was developed to have a diverse and representative team review each project with respect to legal, ethical, and practical aspects and to ensure documentation and consistency of the projects approved, the parameters by which the projects are defined, and, where applicable, the standards to which the project and involved parties will be held.[10,11]Once projects are defined, documented, and ready for operationalization, our internal team, defined as the research informatics core, will either provide access to data sets already contained in the data commons or load data into the data commons and provide access to the newly loaded data. These data can be as diverse as medical history data derived from our electronic health records combined with raw and processed files related to genomics or imaging.Multimodal data has long been a Holy Grail for precision medicine analytics, but the diversity of data elements can present problems for housing data in traditional databases. The Gen3 data commons framework is an ideal intermediary for multimodal data. Essentially, it holds data in a data lake, has a searchable index of metadata for each data point, and holds each data element using interoperable data formats where possible and where there exists some degree of consensus for what the interoperable format can and should be. In the Rush pilot, we have included EHR patient data, genomics files, pathology files, PACS image files, and biorepository data in our initial instantiation (**Figure 2A**). We have plans to incorporate IOT hub reporting and clinical trial management system (CTMS) integration over time and as usage becomes more widespread.

One example of the power of this approach is the development and use of a common data model for clinical data.A common trope is the phrase “if you have seen one instance of Epic, you have seen one instance of Epic," which alludes to the significant customizations for each institution using EHRs.[12]This can be largely resolved by the use of a common data model like OMOP (Observational Medical Outcomes Partnership), PCORI (Patient-Centered Outcomes Research Institute), I2B2 (Informatics for Integrating Biology & the Bedside), and others.[13]We have selected Fast Healthcare Interoperability Resources (FHIR) as the basis for our EHR data due its relatively low level of loss and its ability to be converted to other data models such as OMOP or PCORI with minimal loss of resolution.FHIR presents numerous advantages in that it is a required resource for many hospital organizations and that it can be accessed through a pull mechanism across organizations. In addition to the standard Gen3 components, which include a userinterface or website frontend, a flexible data model (as code) with graphical representation, faceted search cohort discovery (rapid Elasticsearch), a SQL command window, and workspaces that allows for custom analytics using custom code (Python, R, etc.), the LHSDC introduces new features. The workspaces feature has been enhanced by using operating through the Azure Machine Learning Studio to load in data available to the user and perform complex analyses by harnessing an expandable cluster of computers and baked-in resources. This workspace implementation allows for compute resource expenditure on a per-user basis that can be important for controlling and recouping (or directly charging) for operating costs. Data exploration and analysis interfaces are shown in **Figure 2B**.

The LHSDC project has developed a data model that makes use of standard naming from HL7.org to facilitate data sharing outward via the FHIR API. The exploration tabs for faceted search in Gen3 is customizable, and we have designed tabs with features and plots tailored to an idea of usertypes (e.g., researchers interested in genomicsversus those interested in social determinants of health) get separate specific tabs that surface data of expected high relevance. A periodic or event-based automatic data loading feature has been developed which facilitates the incorporation of summarized (or directly streamed) data from IoT devices.

Conclusion

Using the principles of the Learning Healthcare System Data Commons framework to support research in quality improvement, clinical and translational investigation and training and educationally focused activities, here we present an open source technology reference architecture based on the infrastructure-as-a-service cloud computing, which greatly reduces inefficiencies in operational costs and greatly increases findability, accessibility, interoperability, and reusability of data and code. This Learning Healthcare System Commons solved an unmet need, made clear during the COVID-19 pandemic, for rapid, self-service access to health data sets for our researchers, with appropriate governance over use. Rush University Medical Center served as an ideal laboratory for the trial of this platform, as it has multiple types of healthcare data and multiple stakeholders across its academic mission, but also values efficiencies to broaden access to data. **Figure 2C** illustrates the expansion of this model from this reference (pilot) to outside institutions, and integration into existing data ecosystems (i.e., commons of commons).

Organizational digital transformation around research data in healthcare is an inevitability.[14] The data used in clinical decision-making is increasingly heterogeneous, ranging from electronic medical records that can be flat image files; structured and unstructured fields; notes; medical image files, including high resolution flat images of tissue pathology or three dimensional radiological images; biorepository specimens; genomics files at various stages of processing and annotation; and other ancillary data from Internet of Things devices or status updates from clinical trial management systems. Accessing the sheer scale and heterogeneity of data became a clear issue over the past two years, as the COVID-19 pandemic has presented many clinically complex situations where urgency for data-driven insights were clear and the need to aggregate and share data responsibly was paramount. Here we present an open source technology reference Gen3 architecture based on the infrastructure-as-a-service cloud computing to execute a "data first" strategy through a holistic technology-enabled approach to data planning, governance, and usage.

Funding

The Learning Healthcare System Commons was funded through a generous donation from the Searle family and by donated time from the Microsoft Cloud Acceleration Program.

Acknowledgements

The authors would like to extend their appreciation to the Cloud Acceleration Program at Microsoft and to the scientific computing team at BioTeam Inc. for support in further developing and porting the Gen3 platform to the Azure environment and for developing aspects of the Gen3 framework applied to an academic medical center research and learning environment.

Notes

1. Mandl KD, Perakslis ED. "HIPAA and the Leak of 'Deidentified' EHR Data." *The New England Journal of Medicine*, 2021. https://www.nejm.org/doi/full/10.1056/NEJMp2102616

2. DeMets DL, Ellenberg SS. "Data Monitoring Committees — Expect the Unexpected." *The New England Journal of Medicine*, 2016. https://www.nejm.org/doi/full/10.1056/NEJMra1510066

3. Grossman RL. "Data Lakes, Clouds, and Commons: A Review of Platforms for Analyzing and Sharing Genomic Data." *Trends Genet*. 2019 Mar;35(3):223-234. doi: 10.1016/j.tig.2018.12.006. Epub 2019 Jan 25. PMID: 30691868; PMCID: PMC6474403.https://pubmed.ncbi.nlm.nih.gov/30691868/

4. Barnes C, Bajracharya B, et al. "The Biomedical Research Hub: a federated platform for patient research data." *Journal of the American Medical Informatics Association*, Volume 29, Issue 4, April 2022, Pages 619–625, https://doi.org/10.1093/jamia/ocab247

5. Parciak M, Bender T, Sax U, Bauer CR. "Applying FAIRness: Redesigning a Biomedical Informatics Research Data Management Pipeline." *Methods Inf Med*. 2019 Dec;58(6):229-234.

doi: 10.1055/s-0040-1709158. Epub 2020 Apr 29. PMID: 32349157. https://pubmed.ncbi.nlm.nih.gov/32349157/

6. Grossman RL, Heath A, Murphy M, Patterson M, Wells W. “A Case for Data Commons: Toward Data Science as a Service.” *ComputSci Eng*. 2016;18(5):10-20. doi:10.1109/MCSE.2016.92 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5636009/

7. Parciak M, 2020.

8. Shneiderman B, Plaisant C. “Sharpening analytic focus to cope with big data volume and variety.” *IEEE Comput GraphAppl.* 2015 May-Jun;35(3):10-4. doi: 10.1109/MCG.2015.64. PMID: 26010786. https://pubmed.ncbi.nlm.nih.gov/26010786/

9. Obeid JS, Tarczy-Hornoch P, Harris PA, Barnett WK, Anderson NR, Embi PJ, Hogan WR, Bell DS, McIntosh LD, Knosp B, Tachinardi U, Cimino JJ, Wehbe FH. “Sustainability considerations for clinical and translational research informatics infrastructure.” *J ClinTransl Sci.* 2018 Oct;2(5):267-275. doi: 10.1017/cts.2018.332. Epub 2018 Dec 5. PMID: 30828467; PMCID: PMC6390401. https://pubmed.ncbi.nlm.nih.gov/30828467/

10. Weng C, Kahn MG. “Clinical Research Informatics for Big Data and Precision Medicine.” *Yearb Med Inform*. 2016 Nov 10;(1):211-218. doi: 10.15265/IY-2016-019. PMID: 27830253; PMCID: PMC5171548. https://pubmed.ncbi.nlm.nih.gov/27830253/

11. Unertl KM, Schaefbauer CL, Campbell TR, Senteio C, Siek KA, Bakken S, Veinot TC. “Integrating community-based participatory research and informatics approaches to improve the engagement and health of underserved populations.” *J Am Med Inform Assoc*. 2016 Jan;23(1):60-73. doi: 10.1093/jamia/ocv094. Epub 2015 Jul 30. PMID: 26228766; PMCID: PMC4713901. https://pubmed.ncbi.nlm.nih.gov/26228766/

12. Kiourtis A, Mavrogiorgou A, Menychtas A, Maglogiannis I, Kyriazis D. “Structurally Mapping Healthcare Data to HL7 FHIR through Ontology Alignment.” *J Med Syst*. 2019 Feb 5;43(3):62. doi: 10.1007/s10916-019-1183-y. PMID: 30721349. https://pubmed.ncbi.nlm.nih.gov/30721349/

13. Pfaff ER, Champion J, Bradford RL, Clark M, Xu H, Fecho K, Krishnamurthy A, Cox S, Chute CG, Overby Taylor C, Ahalt S. “Fast Healthcare Interoperability Resources (FHIR) as a Meta Model to Integrate Common Data Models: Development of a Tool and Quantitative Validation Study.” *JMIR Med Inform*. 2019 Oct 16;7(4):e15199. doi: 10.2196/15199. PMID: 31621639; PMCID: PMC6913576. https://pubmed.ncbi.nlm.nih.gov/31621639/

14.Lau AYS, Staccini P; Section Editors for the IMIA Yearbook Section on Education and Consumer Health Informatics. “Artificial Intelligence in Health: New Opportunities, Challenges, and Practical Implications.” *Yearb Med Inform*. 2019 Aug;28(1):174-178. doi: 10.1055/s-0039-1677935. Epub 2019 Aug 16. PMID: 31419829; PMCID: PMC6697520. https://pubmed.ncbi.nlm.nih.gov/31419829/

Author Biographies

Thomas O’Hara (tom.ohara@gmail.com) was the lead full stack engineer at Rush University System for Health. O’Hara is currently Python Software Engineer at Altoida Inc.

Anil Saldanha (anil_j_saldanha@rush.edu) is the chief cloud officer at Rush University System for Health.

Matthew Trunnell (mattertrunnell@gmail.com), a self-described data commoner, advises organizations on strategies to enhance the impact of their research-data assets through engineering, stewardship, and data-centered collaboration. Trunnell served as vice president and chief information officer of the Fred Hutchinson Cancer Research center where he led a team of clinical informaticists and software engineers producing clinical data reports and developing reusable clinical data products.

Robert L. Grossman (rgrossman1@uchicago.edu) is the Frederick H. Rawson Distinguished Service Professor in Medicine and Computer Science and the Jim and Karen Frank Director of the Center for Translational Data Science at the University of Chicago. He is also the chair of the Open Commons Consortium, a nonprofit that develops and operates data commons to support research in science, medicine, health care, and the environment.

Bala Hota (bala.hota@gmail.com) was the chief analytics officer at Rush University System for Health. Hota is currently a senior vice president and chief informatics officer at Tendo Systems Inc.

Casey Frankenberger (frankenberger@gmail.com) was the chief research informatics officer at Rush University System for Health. Frankenberger is currently a vice president of business development at C2i-Genomics Inc.

Changes in Patient Characteristics and Practice Outcomes of a Tele-Urgent Care Clinic Pre- and Post-COVID-19 Telehealth Policy Expansions

By Saif Khairat, PhD, MPH; Yuxiao Yao, MSIS; Cameron Coleman, MD, MPS; Philip McDaniel, MA; Barbara Edson, RN, MBA; and Christopher M. Shea, PhD, MPA

Abstract

Introduction

The coronavirus 2019 pandemic (COVID-19) has resulted in major changes in lifestyle practices and healthcare delivery. The goal of this study was to examine changes in practice and service outcomes in a telehealth program before and after the federal and private telehealth policy expansion during the COVID-19 pandemic. These findings are particularly useful to understand what may be needed to overcome telehealth challenges in future disasters.

Methods

We conducted a cross-sectional analysis of virtual visits through a statewide telehealth center embedded in a large academic healthcare system. Primary outcomes of this study were changes in telehealth visits pre- and post-policy expansions among at-riskpopulations.

Results

A total of 2,132 telehealth visits were conducted: 1,530(71.8 percent) patients were female, 1,561(73.2 percent) were between the ages 18-50, 1,576(74 percent) were uninsured, and 1,225(57.5 percent) were from rural regions. The average number of telehealth visits per day increased from 14 to 33 visits post-expansion. A significant change in patient characteristicswas found among senior, uninsured, and rural patients after the telehealth expansion.

There was an 11 percent decrease in telehealth visits from very high vulnerability regions post-expansion compared to pre-expansion. There was a 15 percent decrease in visits resulting in prescription post-expansion (p-value<0.01).

Conclusions

COVID-19 policy expansions expanded telehealth utilization among at-riskpopulations such as senior, uninsured, and rural patients while decompressing hospitals and emergency rooms and maintaining positive patient experiences. Further regulations are needed around virtual visits unintended consequences, software certification, and guidelines for workforce training.

Keywords: Telehealth, Population, Changes, Outcomes, COVID-19

Introduction

The coronavirus 2019 pandemic (COVID-19) introduced major changes in lifestyle practices, and healthcare delivery aimed to minimize the movement and interaction of individuals.[1,2]To "flatten the curve" of COVID-19 cases during the initial phases of the pandemic, the Centers for Disease Control and Prevention (CDC) promoted social distancing through community-based interventions such as working remotely, school dismissals, and the cancellation of large-gatherings.[3]As a result, in March 2020,major North Carolina healthcare systems reduced operations at outpatient clinics by cancelling non-emergent surgical procedures.[4] These changes disrupted the usual ways in which patients seek care.

Studies reported a substantial increase in new telehealth programspost-pandemic.[5-9]Our earlyCOVID-19investigation showed that confirmed COVID-19 case counts were significantly higher in areas with high population density and areas with a major airport.[10]Additionally, patients' gender and geographic location are strong predictors to the choice of telehealth communication medium.[11,12]However, there is lack of knowledge regarding existing telehealth programs and the changes introduced to existing telehealth programs in North Carolina because of the telehealth waivers and the shutdown of healthcare systems.

On March 6, 2020, the US government announced two important regulatory changes related to telehealth to combat COVID-19.[13] First, the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) waived telehealth reimbursement restrictions and privacy protections, allowing coverage for telephone and video encounters on consumer platforms.[14] Second, licensed providers are now permitted to prescribe controlled substances to patients they have not met before, an option that limited the spread of telehealth in the past. Private payers have also waived telehealth restrictions to further encourage individuals to use telehealth.[15]

Telehealth and the digital divide led major concerns on widening the health disparity gap.[16,17]The coverage of audio-only telephone visits by CMS and private insurers[18,19]is particularly important to vulnerable populations such as seniors and rural patients who may not have internet accessibility and can only rely on their phone to seek care. Historically, studies have reported that telemedicine visits yield higher fill rates of prescription when compared to in-person visits.[20,21]It is unclear if there were changes in telehealth use and prescription rates post-CMS telehealth expansion compared to pre-expansion.

The Centers for Disease Control and Prevention (CDC) established a Social Vulnerability Index (SVI) to measure the vulnerability of communities across the US.[22]Therefore, comparing the changesobserved in telehealth use post-CMS policy expansionsto baseline (i.e., pre-telehealth expansions)can provide new insights to policymakers that can help bridge current health disparities.

Emerging viewpoint articles have provided preliminary insights on the importance of telehealth as a new healthcare modality.[23-25] However, to our knowledge, no studies have evaluated the impact of these telehealth policy changes on an existing virtual care practice in North Carolina. In this study, we characterized telehealth practice changein one large healthcare system before and after the CMStelehealth expansion, which was instated on March 6, 2020.

Objective

The goal of this study was to examine practice changes measured as utilization, patient characteristics, and service outcomes in a telehealthpractice before and after the federal and private telehealth policy expansion on March 6, 2020,during the COVID-19 pandemic. These findings are particularly useful to policymakers and organizations to understand what may be needed to overcome telehealth challenges in future disasters.

Materials and Methods

We conducted a cross-sectional analysis of telehealth visits at a major telehealth center embedded in a large academic healthcare system that comprises 11 hospitals and 350 outpatient clinics in the Southeast. During the initial phase of COVID-19 (March through April 2020), in-person visits at the medical center were canceled except for emergency conditions.[26]Consequently, patients with existing in-person visit appointments during March through April were asked to choose between an alternative telehealth visit or to wait for an in-person visit later.Starting the end of April, the healthcare system gradually resumed in-person visits. The study period in which we collected telehealth data was between January 21 and April 19, 2020. We concluded the study in April, which is before the resumption of in-person visits, to reduce the effect of confounding factors when healthcare systems reopened and some telehealth policies began to change. In this study, we defined at risk populations as patients who are over 65 years, uninsured, or living in a rural region.

The telehealth center was launched in 2018 as a virtual urgent care centeroffering 24/7 on-demand access to physicians via video or telephone, thereby providing expanded access to rural and underserved populations as we reported previously.[27] All providers at the center were externally contracted board-certified physicians, not internally employed by the health system and generally not the patient's primary care physician. Virtual care providers were licensed to treat or consult on a wide range of medical conditions including fevers, respiratory infections, and rashes. Encounters for behavioral health conditions were not eligible for virtual visits.

Providers were able to send a prescription to the patient's pharmacy of choice, if clinically indicated, but no laboratory or imaging tests can be ordered. Virtual providers could provide a copy of the encounter documentation and visit notes to the institution's electronic health record, which were visible to the patient and the primary care physician. Patients were charged a fixed fee of $49 USD for the virtual encounter and have the option to submit this charge to their insurance company for reimbursement.

Data Sources

We collected de-identified patient- and visit-level data for all telehealth visits at the virtual care center from January 21, 2020, the date of the first COVID-19 case in the US, through April 19, 2020. All data were extracted electronically from the telehealth system. We compared visit trends before and after the federal telehealth expansion on March 6, 2020. Several major private insurers waived telehealth restrictions on the same day or closely after the federal expansions.[28,29]In this study, we defined pre-telehealth expansion to be between January 21 and March 5, 2020; and post-telehealth to be between March 6 and April 19, 2020.

Patient-level data were self-reported and included demographics, insurance status, and chief complaint. We categorized patients' location as rural or urban using the US Census population estimates of rural classification (less than 50,000 people) and urban classification (more than 50,000 people).[30]

Visit-level data included total time, wait time, visit duration, visit diagnosis, visit modality (telephone vs. video), and whether the visit resulted in a prescription medication sent to a pharmacy (yes/no). Total time was measured as the combination of patient wait time and visit duration. Wait time was defined as the timespan from when a telehealth visit is requested by the patient until the start time of the visit. The visit duration was defined as the time from start to end of the visit.

Outcomes

Primary outcomes of this study were patient characteristics(measured by subgroup analysis ofsex, age, insurance coverage, and location)and practice change(measured by the volume of visits, wait times, visit duration, communication medium, and prescription rates).

Data Analysis

We performed descriptive analysis including subgroup analysis for all telehealth visits during the study period as well as pre/post analysis to evaluate visit trends before and after the federal telehealth expansion (pre-expansion cohort: 44 days, January 21 through March 5; post-expansion cohort: 44 days, March 6 through April 19). We calculated relative changes for the pre/post analysis and performed chi-square testing for statistical significance where appropriate. All data were extracted and analyzed in Microsoft Excel and R statistical programming software.

To understand the telehealth use of patients based on their location, we used ArcGIS® to map ZIP code-level populations as reported in the 2010 US Census Bureau data with telehealth visits by ZIP Code Tabulation Areas (ZCTA). We used the 2018 CDC SVI to assess the patient's neighborhood vulnerability by ZCTA. The CDC SVI score ranges from 0 (lowest vulnerability) to 1 (highest vulnerability). We then mapped the CDC SVI data and visit counts from the telehealth program on the North Carolina map to better understand the change in patients' neighborhood vulnerability pre- and post-expansions. We excluded 58 pre-expansion visits and 51 post-expansion visits from our geospatial analysis because these visits were from out of state addresses.

Results

A total of 2,132 patients visited the telehealth center during the study period, with an average of 21 visits per day. Among all visits, 1,530 (71.8 percent) patients were female, 1,561 (73.2 percent) were between the ages 18-50, 1,576 (74 percent) were uninsured, and 1,225 (57.5 percent) were from rural regions (**Table 1**). A total of 1,453 (68 percent) visits occurred in the 44 days following the federal telehealth expansion.

Patient Demographics

Pre-expansion, the average number of telehealth encounters was 14.4 visits per day; after expansion, the number increased to 33 visits per day, a 229 percent increase (**Table 1**). The change in demand, as measured by proportion of virtual visits, represented heterogeneity across different subpopulations: demand significantly increased 5.6 percent among males (p-value=0.002) and 6.2 percent among young adults (age 18-34) (p-value<0.001) but significantly decreased by 4.9 percent among females and 5.8 percent among pediatric patients (age < 17).

Uninsured patients accounted for a greater proportion of virtual visits after the federal telehealth expansion (1163/1453; 80 percent) as compared to before (414/679; 61 percent), a statistically significant increase (p < 0.001).

Patients living in rural areas accounted for the larger proportion of virtual patients before (415/679; 61.1 percent) and after (810/1453; 55.8 percent) the telehealth expansion. Nevertheless, the portion of patients residing in urban areas increased following the telehealth expansion (643/1453; 44.3 percent) as compared to before (264/679; 38.9 percent), a statistically significant increase (p=0.001).

Telehealth utilization increased substantially post-telehealth expansion, as expected. Pre-telehealth expansion, patients represented 190 (17 percent) unique ZIP codes compared to 265 (24 percent) unique ZIP codes.**Figure 1A**shows the difference in telehealth visits pre and post telehealth policy expansions. The increase in telehealth visits post-expansion occurred in major North Carolina cities such as Raleigh-Durham, Charlotte, Asheville, and Wilmington (shown in red and orange).While a decrease in telehealth visits post-expansion occurred in scattered rural North Carolina regions (shown in blue and green).**Figure 1B** mapped the CDC SVI score to the North Carolina map such that the different shades of red indicated North Carolina areas of high vulnerability, and yellow and orange colors represented low vulnerability regions.

Post-telehealth expansion, the volume of telehealth visits originating from regions with very high vulnerability decreased 11 percent (29 percent to 17 percent) to pre-telehealthexpansion (**Table 2**). In North Carolina, 247 (31 percent) ZIP codes are categorized as high vulnerability followed by 234 (29 percent) categorized as very high vulnerability. Pre-expansion, 236 (38 percent) telehealth visits originated from low vulnerability areas compared to 633 (45 percent) after the expansion.

Practice Change

The average total time (SD) (including wait time and visit duration) for a virtual visit increased from 21.7 (16.8) pre-expansion to 75.5 (129.8) minutes post-expansion. In response, we increased the number of providers from 14 pre-expansion to 32 post-expansion. The number of providers and the average virtual visit total time peaked following the telehealth policy expansion, but total time subsequently decreased to 13 minutes, while the number of providers leveled off around 32 providers per day (**Figure 2**).

Pre-telehealth expansion, the average wait time (SD) was 15.4(6.9) minutes and the average visit duration was 6.3(0.9) minutes. Post-telehealth expansion, the average (SD) wait time was 67.2(128.7) minutes and the average visit duration was 7.6(5) minutes (**Figure 3**). Peak wait times following the telehealth expansion reached 349 minutes.

Post-telehealth expansion, the proportion of patients choosing a telephone visit decreased (581/679, 85.6 percent vs. 1,148/1,453, 79 percent) while the proportion of patients requesting video visits increased (98/679, 14.4 percent vs. 305/1453, 21 percent) following the federal telehealth expansion, a statistically significant change ($p<0.01$) (**Table 1**).

Following the policy change, a smaller proportion of virtual visits resulted in a prescription medication (962/1,453, 66.2 percent) as compared to before the telehealth expansion (531/679, 82 percent) (**Table 1**). This difference reached statistical significance ($p<0.01$).

The distribution of visit diagnoses was similar for virtual visits occurring before and after the federal telehealth expansion. In both cases, the most common diagnoses included: flu, sinusitis, bronchitis, and urinary tract infection. Pre-expansion, three of the top diagnosis (flu, bronchitis, cough) can be labeled as possible COVID-19 cases that may require testing, while post-expansion, there were four of the top five diagnosis (flu, upper respiratory infection, bronchitis, cough) with possible COVID-19 cases.

Discussion

In this cross-sectional study, we evaluated telehealth visits at a major virtual care center during the COVID-19 crisis and observed a significant 225 percent increase in the demand for virtual visits such that the daily volume of virtual visits spiked by 157 percent on March 9, 2020, only three days after the policy expansion bill was passed, as would be expected. This was associated with an increase in wait times of two or more hours from a baseline of ~15 minutes, although visit duration remained essentially the same. The increase in demand and wait times suggest the need for rapid increase in human capacity to deliver telehealth during the initial response to a disaster, which the policy for expanding telehealth coverage could support over time.

We found significant rise in uninsured patients after the policy expansions, which was unexpected. Although we do not have a definitive explanation for this phenomenon, a possible explanation may be that uninsured patients resided in regions with limited access to healthcare and the availability of telehealth during the pandemic allowed them to proactively seek care. Another possibility is that some of the patients in the uninsured category were previous telehealth users who lost their jobs due to economic conditions resulting from the pandemic and lost insurance coverage as a result.[31] Similarly, the decrease in telehealth visits from patients living in highly vulnerable regions is unknown. A possible explanation could be that patients in those highly vulnerable populations chose to use a different telehealth program given the availability of new programs during that time period.

The number of virtual visits with patients over 65 years of age tripled post the policy expansions. Similarly, more males and young adults steered toward virtual care for their health needs. This increase in usage from patients over 65 years was expected given heightened concerns about risk of worse outcomes from COVID-19. Regarding young adults, it is possible that comfort with technology was a driver of increased virtual visits. However, it is not immediately clear why the proportion of male patients increased given that female patients have been reportedly the dominant users of telehealth.[32]

This study shows that despite the surge in virtual visits at our center following the federal telehealth expansion, a substantial smaller proportion of virtual visits resulted in a medication being prescribed. This is encouraging because it suggests that reassurance can be an important component of care delivered virtually and that telemedicine does not necessarily lead to “overmedication” as compared to traditional in-person care. However, not receiving medication as expected by the patient was a reason provided by some patients for their negative ratings of virtual care visits, indicating there may be some patients who need additional reassurance.

As the number of virtual visits increased by 229 percent and wait times reaching 350 minutes, we had to substantially double the number of tele-doctors by a factor of two to meet the increasing demand from patients. This expansion in workforce showed effectiveness when the wait times reduced to average levels pre-telehealth expansion and patient rating improved. The nature of on-demand telehealth services creates a challenge to determine the suitable staffing to meet patient needs. Particularly, the widespread of COVID-19 coupled with the telehealth policy expansion introduced an unprecedented upsurge in patient demand for telehealth. The ability to predict staffing needs is valuable; however, our experience with substantial fluctuation in staffing presents a new telehealth challenge to match between staffing capacity and patient needs.

Training advanced practice providers (APP) and physician assistants (PA) as potential telehealth workforce is one strategy to meet the growing demand.[33] Another suggestion is to train current medical and nursing students to serve as scribes during the telehealth visit to assist with documentation and/or triage. The use of medical scribes can cut physician EHR time and boost productivity and satisfaction; therefore, expanding the use of medical scribes to telehealth use possibly will have similar effect.[34]

Following the federal telehealth expansion on March 6, our data demonstrated a substantial increase in the uptake of virtual care visits among urban patientsand among the number of virtual visits occurring by video. We found that telehealth visits from more vulnerable regions substantially decreased post the expansion. A possible explanation for the significant increase in patients from urban areas, who may have easier access to in-person care facilities, could be shelter-in-place orders, increased public awareness regarding group gatherings, and greater concerns about COVID-19 risk among those living in areas with higher population density. The increase in urban patients also may be linked to availability of broadband internet speed to support video calls. These findings suggest that telehealth policy expansions may worsen health disparities and further widen the digital divide within our communities.

Limitations

This study had several limitations. This study was conducted at a single, online telehealth center at a large academic health system. It is important to recognize that the increase in virtual care visit volume may not be fully attributable to the policy changes, as more patients might have opted for virtual visits regardless of the policy change due to the shutdown of in-person visits. However, the timing of the policy change and the immediate increased demand clearly coincide, and the expanded coverage is promising for handling the capacity demands required with the increased demand. One confounding factor to the study design is the cancellation of in-person visits, which limited our ability to compare virtual vs. in-person visits. A confounding factor to our findings may be the digital bias of telehealth patients, which may not be generalizable to individuals with limited digital knowledge or equipment. Although we used the COVID-19 symptoms defined by WHO in our predictive model, those symptoms are non-specific and overlap with those of flu; therefore, the model may identify some cases as COVID-19 that instead should be classified as a different illness. Also, due to lack of data, the non-linear behavior of number of COVID-19 infections over time was not taken into account in our predictive model, which may simplify the problem.

Policy Implications

Building virtual care capacity remains a work in progress in order to bridge patient expectations with virtual care capabilities.[6] More efforts are needed to adapt and implement virtual care best-practices.[35] The success of virtual care heavily relies on well-trained workforce, ergonomically designed physical space, reliable IT infrastructure, and high-speed internet. Lessons learned from the electronic health records adoption era may be valuable to inform virtual care bestpractices and policymaking.

The policy expansion presented an opportunity for provide care to a broader audience, especially among at-risk populations. We envision that the widespread adoption of telehealth will require additional regulatory measures additional to the established licensure, credentialing, and data privacy and security policies. Currently, there are no health IT certifications for telehealth platforms unlike electronic health record systems that undergo rigorous certification process through the Office of the National Coordinator.[36] Additionally, due to the sudden shift to telehealth, there is a lack in education and training on telehealth bestpractices, a key element to high-quality care. Some providers are self-learning how to care for patients in a virtual space; however, we believe that formal specialty-based telehealth training guidelines are essential for providers with no or limited telehealth experience. Finally, we envision that policymakers will need to further regulate unintended consequences of virtual visits.

Acknowledgements

All authors confirm the content of this manuscript and have all contributed to the work presented in this manuscript.

Conflict of Interest: The authors declare no conflicts of interest.

Funding sources: None.

Notes

1. WHO. WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020. Accessed March 12, 2020, https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020

2. Grennan D. What Is a Pandemic? JAMA. 2019;321(9):910-910. doi:10.1001/jama.2019.0700

3. CDC. Preventing COVID-19 Spread in Communities. Accessed March 12, 2020, https://www.cdc.gov/coronavirus/2019-ncov/community/index.html

4. Kelly A. "UNC Hospitals develops COVID-19 testing kits, responds to pandemic."*The Daily Tar Heel*; 2020. 3/19/2020. Accessed 9/22/2020. https://www.dailytarheel.com/article/2020/03/covid-testing-0320

5. Hamad J, Fox A, Kammire MS, Hollis AN, Khairat S. "Evaluating the Experiences of New and Existing Teledermatology Patients During the COVID-19 Pandemic: Cross-sectional Survey Study."*JMIR Dermatol*. Jan-Jun 2021;4(1):e25999. doi:10.2196/25999

6. Khairat S, Pillai M, Edson B, Gianforcaro R. "Evaluating the Telehealth Experience of Patients With COVID-19 Symptoms: Recommendations on Best Practices" *Journal of Patient Experience*. 2020:2374373520952975. doi:10.1177/2374373520952975

7. Schifeling CH, Shanbhag P, Johnson A, et al. "Disparities in Video and Telephone Visits Among Older Adults During the COVID-19 Pandemic: Cross-Sectional Analysis."*JMIR Aging*. Nov 10 2020;3(2):e23176. doi:10.2196/23176

8. Smith WR, Atala AJ, Terlecki RP, Kelly EE, Matthews CA. "Implementation Guide for Rapid Integration of an Outpatient Telemedicine Program During the COVID-19 Pandemic."*Journal of the American College of Surgeons*. 2020/04/30/ 2020;doi:https://doi.org/10.1016/j.jamcollsurg.2020.04.030

9. Griggs GK. “Innovations in Virtual Care During the Pandemic: Implications for the Future.”*North Carolina Medical Journal*. 2021;82(4):252. doi:10.18043/ncm.82.4.252

10. Khairat S, Meng C, Xu Y, Edson B, Gianforcaro R. “Interpreting COVID-19 and Virtual Care Trends: Cohort Study.” Original Paper. *JMIR Public Health Surveill*. 2020;6(2):e18811. doi:10.2196/18811

11. Schifeling CH, et al., 2020.

12. Khairat S, Liu S, Zaman T, Edson B, Gianforcaro R. “Factors Determining Patients’ Choice Between Mobile Health and Telemedicine: Predictive Analytics Assessment.” Original Paper. *JMIR Mhealth Uhealth*. 2019;7(6):e13772. doi:10.2196/13772

13. CMS. Additional Background:Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge. Accessed April 20, 2020, https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient

14. Representatives Ho. Making emergency supplemental appropriations for the fiscal year ending September 30, 2020, and for other purposes. Accessed March 12, 2020, https://docs.house.gov/billsthisweek/20200302/BILLS-116hr6074-SUS.pdf

15. BCBS. COVID-19 Resources for our Members. Accessed April 6, 2020, https://blog.bcbsnc.com/2020/02/what-you-need-to-know-about-coronavirus/

16. Schifeling CH, et al., 2020.

17. Khairat S, Haithcoat T, Liu S, et al. “Advancing health equity and access using telemedicine: a geospatial assessment.”*J Am Med Inform Assoc*. Jul 24 2019;doi:10.1093/jamia/ocz108

18. CMS. Additional Background:Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge. Accessed April 20, 2020, https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient

19. AHIP. Health Insurance Providers Respond to Coronavirus (COVID-19). Accessed April 20, 2020, https://www.ahip.org/health-insurance-providers-respond-to-coronavirus-covid-19/

20. Ray KN, Shi Z, Gidengil CA, Poon SJ, Uscher-Pines L, Mehrotra A. “Antibiotic Prescribing During Pediatric Direct-to-Consumer Telemedicine Visits.”*Pediatrics*. 2019;143(5):e20182491. doi:10.1542/peds.2018-2491

21. Foster CB, Martinez KA, Sabella C, Weaver GP, Rothberg MB. “Patient Satisfaction and Antibiotic Prescribing for Respiratory Infections by Telemedicine.”*Pediatrics*. 2019;144(3):e20190844. doi:10.1542/peds.2019-0844

22. Control CfD, Prevention. CDC SVI Documentation 2018. Accessed June 2, 2021, https://www.atsdr.cdc.gov/placeandhealth/svi/documentation/SVI_documentation_2018.html

23. Mehrotra A, Ray K, Brockmeyer DM, Barnett ML, Bender JA. “Rapidly Converting to ‘Virtual Practices’: Outpatient Care in the Era of Covid-19.” Catalyst non-issue content. 2020;1(2)doi:doi:10.1056/CAT.20.0091

24. Reeves JJ, Hollandsworth HM, Torriani FJ, et al. “Rapid Response to COVID-19: Health Informatics Support for Outbreak Management in an Academic Health System.” *Journal of the American Medical Informatics Association*. 2020;doi:10.1093/jamia/ocaa037

25. Hollander JE, Carr BG. “Virtually Perfect? Telemedicine for Covid-19.”*New England Journal of Medicine*. 2020;doi:10.1056/NEJMp2003539

26. Kelly A, 2020.

27. Khairat S, Haithcoat T, Liu S, et al., 2019.

28. BCBS. Blue Cross and Blue Shield Companies Announce Coverage of Coronavirus

Testing for Members and Other Steps to Expand Access to Coronavirus Care. Accessed April 21, 2020, https://www.bcbs.com/press-releases/blue-cross-and-blue-shield-companies-announce-coverage-of-coronavirus-testing

29. NTPRC. Telehealth coverage policies in the time of covid-19 to date. Accessed April 21, 2020, https://www.cchpca.org/sites/default/files/2020-03/CORONAVIRUS%20TELEHEALTH%20POLICY%20FACT%20SHEET%20MAR%2017%202020%203%20PM.pdf

30. Ratcliffe M, Burd C, Holder K, Fields A. Defining Rural at the U.S. Census Bureau. 2016.

31. Holmes M. “Running the Numbers: Estimated Changes in Health Insurance Coverage of North Carolinians in the First Six Months of the COVID-19 Pandemic.”*North Carolina Medical Journal*. 2020;81(6):400. doi:10.18043/ncm.81.6.400

32. Khairat S, Liu S, Zaman T, Edson B, Gianforcaro R, 2019.

33. Balestra M. “Telehealth and Legal Implications for Nurse Practitioners.”*The Journal for Nurse Practitioners*. 2018;14(1):33-39. doi:10.1016/j.nurpra.2017.10.003

34. Bates DW, Landman AB. “Use of medical scribes to reduce documentation burden: Are they where we need to go with clinical documentation?”*JAMA Internal Medicine*. 2018;178(11):1472-1473. doi:10.1001/jamainternmed.2018.3945

35. Krupinski EA, Bernard J. “Standards and Guidelines in Telemedicine and Telehealth.”*Healthcare* (Basel, Switzerland). 2014;2(1):74-93. doi:10.3390/healthcare2010074

36. ONC. About The ONC Health IT Certification Program. Accessed April 21, 2020, https://www.healthit.gov/topic/certification-ehrs/about-onc-health-it-certification-program

Author Biographies

Saif Khairat (saif@unc.edu) is an associate professor for the Carolina Health Informatics Program in the Cecil G. Sheps Center for Health Services Research at the University of North Carolina at Chapel Hill.

Yuxiao Yao (yaoyx2020@alumni.unc.edu) is affiliated with the Graduate of School of Information and Library Science ath the University of North Carolina at Chapel Hill.

Cameron Coleman (colemage@med.umich.edu) is affiliated with the University of Michigan.

Philip McDaniel (pmmcdani@email.unc.edu) is a GIS librarian at the Health Services Library at the University of North Carolina at Chapel Hill.

Barbara Edson (barbara_edson@unchealth.unc.edu) is the executive director of the Virtual Care Center at UNC Health.

Christopher M. Shea (chris_shea@unc.edu) is an associate professor in the Gilling's School of Public Health at the University of North Carolina at Chapel Hill.

Are You Using the Right Electronic Health Record?

ByMaria D. Joyce, MBA, CPA; Carl Buising, MD; Juergen A. Klenk, PhD; Michelle Lardner, DNP, RN; Rachael Schacherer, MPP; Jonathan Wachtel, MBA; Rayneisha Watson; and Jon W. McKeeby, DSc, MBA, CPHIMS, CPHI

Abstract

With the enactment of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, hospitals and physician practices across the country converted from a system of paper recordkeeping to fully integrated electronic health records (EHR).[1,2]With financial incentives in hand, there was a rush to market to acquire and implement these systems.Fast-forward 10 years, and it is apparent that the EHR space has significantly evolved in technology, processes, and policies.[3]These changes should make organizations examine their EHR and organizational models and consider if they are using the best EHR to meet theirorganizational needs for the next 20 years.

The National Institutes of Health (NIH)Clinical Center (CC) implemented its EHR in 2004 and, recognizing all of the new participants, technologies, and the advancement of clinical research needs since then, made the decision to embark on a comprehensive business case analysis to evaluate the best solution to meet the CC's and NIH's needs over the next 20 years.The goal was to answer this question: "Given the evolution of the EHR market, is the CC on the best platform to meet its needs now and in the future?"

Keywords: Electronic Health Record, EHR, Business Case

Background

The NIH CC is a biomedical research hospital and the delivery setting for NIH intramural clinical research protocols.The hospital contains 200 inpatient beds, 93 day hospital stations, 15 outpatient care clinics, and more than 1,600 research laboratories.Patients are admitted to the NIH CC for the sole purpose of clinical research as prescribed in a clinical research protocol.The CC supports approximately 1,500 active protocols.The CC admits patients from all over the world for clinical trials and natural history studies.

To support patient care and research, the NIH relies on the Clinical Research Information System (CRIS), first deployed in 2004. It is based on the EHR solution Allscripts' Sunrise Clinical Manager, previouslyowned by Eclipsys. Of note, the CC is the only federal organization that has been certified Stage 7 using the Healthcare Information and Management Systems Society's (HIMSS) Adoption Model for Analytics Maturity (AMAM). This certification is for both inpatient (as of 2015) and outpatient (as of 2018) environments, a designation achieved by only approximately 6.4 percentof hospitals nationwide as of fourth quarter 2017.[4] As an EHR system, CRIS meets the core requirements to support patient care, but it has also been highly customized over the years to link patient medical information to clinical research protocols and meet several other NIH research-specific requirements. These customizations are a result of the different patient care and clinical research workflow requirements associated with the diverse needs of the NIH Institutes and Centers (ICs) and IC investigators.Much has changed since CRIS's implementation.The EHR market has changed substantially in terms of interoperability, expectations for safety, and technology, including artificial intelligence and machine learning, data and predictive analytics, virtual health, and connected applications. Given CRIS's age, uniqueness, end-user challenges, and advancements in the EHR market, the CC conducted this business case analysis.

How to Approach Such an Analysis?

The CC took a very deliberate approach to conduct itsbusiness case analysis, which included three major components:market research, best practice reviews of other federal facilities and academic medical centers (AMCs), and identification of current functionality and gaps.The information obtained from these activities was used to arrive at recommendations for the optimal path forward.

Market Research

A thorough evaluation should be conducted of both emerging technology and currently available EHR systems.Research shows that clinical information system and EHR vendors are beginning to develop capabilities to prepare and capitalize on future market trends. Disruptive trends such as intelligence, Internet of Medical Things (IoMT), and data analytics are reshaping the healthcare industry.[5,6]These technologies support increased clinical decision support, pharmacogenomics, precision medicine, and quality care and patient safety, as well as patient engagement, telehealth, and telemedicine.All of these market trends mentioned are focused on improving the experience for both patients and providers. The EHR of the future will serve not only as a repository of healthcare data but also as a hub for healthcare data management, exchange, advanced analysis, care coordination, patient and provider communication, and data for healthcare and population health research.[7]

For a clinical research hospital such as the CC, a major movement toward virtual care and remote patient monitoring provides capabilities that could be especially transformative, since study participants live all over the world. Cloud-based technology will also be increasingly important as the NIH Intramural Research Program (IRP) scales up with genomics data, artificial intelligence (AI), and voice recognition.

The market research conducted was structured to provide an overview of viable commercial off-the-shelf (COTS)EHR products in the marketplace that could meet the CC's unique needs and provide the best support for theclinical research mission over the next 10 years. The market research process is shown below:

1. Conduct a market scan to identify all viable COTS EHR products.
2. Utilize industry reports such as KLAS, Gartner, financial statements, recent news, and publications to summarize EHR features, market share, financial conditions, and clients.
3. Leveraged internal materials from leading AMC's EHR selection and implementation engagements, and conducted hours of internal interviews with SMEs to identify pros and cons of each product.
4. Develop a summary report of each EHR's functionality, market share, financial condition, and top 10 clients, which includes an analysis of pros or cons for each EHR vendor reviewed.

The market research narrowed the field to three systems capable of meeting the needs of a complex hospital environment.Each of the three presented differing areas of focus:AMCs; the EHR solution for federal facilities (US Department of Defense (DoD) and the US Department of

Veterans Affairs (VA));and one oriented more toward private practice, international markets, and acute care.

Healthcare organizations should regularly evaluate and compare their five to 10 year roadmaps to ensure that their selected vendor appropriately addresses emerging and future health IT trends.

Currently, each of the three EHR platform vendors are differentiated by factors illustrated in **Figure 1**. Vendor A is the market leader within both the acute care and ambulatory markets. Vendors A and B have comparable market shares. However, Vendor A is the leading vendor among AMCs, with several surveyed AMCs highlighting its innovative partnership approach and on-time delivery. Vendor A relies on its fully integrated, homegrown platform, offering an integrated lookandfeel, while Vendors B and C rely on partnerships and acquisitions to provide and support a full suite of EHR platform functionality. According to reaction data from 2018,[8] Vendor A is the leader in EHR physician satisfaction (overall satisfaction for each vendor is 45 percent for Vendor A, 22 percent for Vendor B, and 16 percent for Vendor C).

To develop an initial understanding of each platform's roadmap, the NIH CC held meetings with all three platform vendors at the annual HIMSS conference on February 12, 2019.Dedicated time for these candid conversations was invaluable for gaining insights into each platform's current core functionality, future planned capabilities, and ability to support clinical research, including near- and long-term roadmaps. Discussions indicated that all EHR vendors provide the basic functionality required, with some unique differentiators, such as the ability to support genomics and precision medicine, degree of data aggregation and analytical tools, and visions of the future of healthcare as it relates to health information technology.

Learning FromOthers

When conducting research,there is no substitute for reaching out to similar institutions to learn from their EHR journeys.[9]The NIH CC conducted site visits with multiple AMCs and federal facilities.For each of the selected sites, the CC brought a small team that included those working in the fields ofinformatics andhealth information management, as well as nurses, physicians, pharmacists, and consultants with EHR expertise.

Each site visit was structured as follows:

- An overview of the NIH CC (for context).
- A demonstration of the site's EHR.
- The site's EHR journey that led to the system utilized.
- Specifics regarding clinical research functionality (as applicable).

During these visits, inputs were obtained for benefits and challenges of existing EHR systems, lessons learned implementing their system, best practices employed for process flows, customizations developed (both scope of customizations required for a functionality void and unique requirements of the site), research functionality and applications in use, change management models, and the rationale and criteria used inselecting EHR vendors.Each site had prioritized needs that guided their selection.Some of the primary drivers and insights gained are includedin **Table 1: Site Visit Key Insights**.

In sum, the decision criteria to rank EHR vendors varies for each organization. Among consistently considered criteria are the alignments for: vendors, function, innovation, and support; the ability to support research (either now or in the future); revenue management; and, finally, the vendor’s ability to serve as a partner. Surprisingly, cost was not a major driver. While each site viewed their EHR selection as a critical capital investment, their priority was choosing mission-based support to serve as a backbone in providing high quality and safe patient care.

Knowing What You Need—Now and Then

Research is key to any success. It is also essential when determining the need for a new EHR.[10] Two crucial research tasks already discussed are market research and site visits. The third leg of the stool is an internal assessment: What functionality is currently available, and what will be of critical importance in the future? Conducting this internal assessment at the NIH CC required three audiences for critical input: the Department of Clinical Research Informatics (DCRI, the overarching CC IT department), NIH stakeholders, and NIH leadership.

The DCRI is led by the CC chief information officer and is responsible for clinical informatics, infrastructure and technical operations, user support, IT security, privacy, and project and portfolio management. The DCRI is also responsible for the EHR. They are the subject matter experts for all development, configuration, testing, change management, training, etc. Boards overseeing the DCRI include the Architecture Review Board, Technical Review Board, and Change Management Review Board. These boards supervise any changes made to the system, including patches and upgrades. As such, this was the group critical to identifying the current system environment (all modules and/or interfaces), core system functionality provided, and maintenance required. The DCRI compiled a minimum mandatory capabilities matrix that clearly delineated critical capabilities (such as documentation, order entry, patient management, etc.) and their associated mandatory requirements. The matrix was used to align with current EHR systems identified in market research to validate DCRI’s ability to meet the minimum mandatory requirements. Over the last decade, the DCRI has employed a CRIS users group, nursing leadership forum, medical executive committee, and clinical staff surveys to keep abreast of the evolving needs and future technologies desired by the NIH. The user group was also utilized in the analysis of future state needs.

Stakeholders

An EHR transition is not confined to technical teams. A transition takes networks of clinical subject matter experts to assess and endorse the clinical content that will live within the EHR.[11] Any healthcare organization has many different stakeholders with varying requirements, needs, and expectations of the EHR, its functionality, and data.[12] The NIH stakeholders include: the CC Clinical Department staff; NIH Institute Licensed Independent Practitioners (LIPs) and clinical personnel (research teams, fellows, and informaticists); and IT and customer support. These staff were interviewed in six focus group sessions. In these sessions, several questions were posed, including: What do you like about CRIS? What do you not like about CRIS? What would you like to have incorporated into an EHR in the future? The answers to these and additional questions were documented, consolidated, and grouped into themes.

The NIH leadership included the CC executive team (CEO, COO, CFO, CMO, CNO, and CIO), NIH Institute clinical directors, and key senior level physicians that are prominent CRIS users. The NIH leadership participated in individual interviews with two senior leaders of the project team. They engaged in candid discussions designed to elicit essential EHR needs, now and in the future.

These stakeholder feedback sessions with CC and IC staff led to some valuable insights about CRIS, thecurrent EHR:

- CRIS is a great option for a clinically focused research medical center, and it meets the majority of CC functional needs, but there is room for improvement.
- The lack of a cross-organizational governance structure for clinical processes across protocols impairs knowledge exchange between the CC and the ICs. The existing framework should be optimized to reduce inefficiencies and safety concerns.
- Clinicians recognize that harmonization of clinical workflows is needed to improve business processes and that a training enforcement mechanism is needed to ensure proper levels of knowledge.

Further, the information gathered from all three of these stakeholder groups informed the development of a comprehensive needs and gaps assessment.The market research for each of the identified vendors was then appended to this assessment to evaluate the fit and/or gap for each component.A formal report was produced from the above information, as well as information gleaned from the meetings with each of the vendors at the HIMSS conference, which included system demonstrations, strategic five- to 10-year vendor priorities, and research support.

Arriving at an Answer

The culmination of the analysis conducted was documented in the abovementioned formal report.The report included an executive summary, detailed analysis of the components discussed above (background, market research, best practices reviews, current state, needs/gaps assessment) and recommendations.

Recommendations

1. Maintain and upgrade the current CRIS platform and improve key processes to ensure full system functionality and deploy important new functions.
    a. Develop a strategic plan that aligns with the overall CC strategic plan.
    b. Implement system governance for CRIS and other relevant NIH systems that need to be reformed, including the elimination of duplicate systems to improve accountability, clinical documentation, and patient safety.
    c. Implement a revised training model to ensure that people know how to use basic and future functionality associated with CRIS.
2. Start the procurement process now for a new EHR platform or undertake a significant modernization effort within three to six years. The procurement process would likely take two years, and implementation another two to four years.

The analysis and recommendations for improving the existing CRIS platform and implementing a new EHR system in the future was socialized across the major governing bodies within the NIH:the Medical Executive Committee, Clinical Center Governing Board, and the CC Research Hospital Board.All of these groups embraced the results and concurred with the recommendations.

The NIH CC is now actively working on both recommendations.The DCRI continues to provide new functionality in CRIS to improve patient safety and patient care with enhancements in telehealth, plans of care, and medication reconciliation. This also includes a major Allscripts upgrade.Additionally, the DCRI will soon embark on an updated strategic plan and enhanced data governance, starting first with a data cataloging tool.

The NIH CC has also started work on the development of a procurement strategy and associated procurement documents, with the goal of issuing a solicitation in the next 12 months.

Funding Statement
This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing Interests Statement
The authors have no competing interests to declare.

Contributorship Statement
All authors wrote and reviewed the final manuscript.

As used in this document, "Deloitte" means Deloitte Consulting LLP. Please see www.deloitte.com/us/about for a detailed description of the legal structure of Deloitte LLP and its subsidiaries.

Notes

1. Stark P. (2010). Congressional intent for the HITECH Act. *The American Journal of Managed Care*.12 Suppl HIT:SP24-8. PMID: 21314216. https://www.ajmc.com/view/ajmc_10dechit_stark_sp24tp28.
2. Halamka, J., Tripathi, M. (2017). The HITECH Era in Retrospect. *New England Journal of Medicine377*(10):907-909. https://doi.org/10.1056/NEJMp1709851. PMID: 28877012.
3. D'Amore, J. (2019). 10 Years Since HITECH: The Good, the Bad and the Ugly. *Healthcare IT Today*. https://www.healthcareittoday.com/2019/12/19/10-years-since-hitech-the-good-the-bad-and-the-ugly/.
4. Cohen, J. (2018). How many hospitals are on each stage of HIMSS Analytics' EMR Adoption Model? *Becker's Hospital Review.*https://www.beckershospitalreview.com/ehrs/how-many-hospitals-are-on-each-stage-of-himss-analytics-emr-adoption-model.html?oly_enc_id=7110G3512589E2B.
5. Khatab, Z., Yousef, G. (2021). Disruptive innovations in the clinical laboratory: Catching the wave of precision diagnostics. Critical Reviews in Clinical Laboratory Sciences. 2021 Jul 23:1-17. https://doi.org/10.1080/10408363.2021.1943302.Epub ahead of print. PMID: 34297653.
6. Abdel-Basset, M., Chang, V., Nabeeh, N. An intelligent framework using disruptive technologies for COVID-19 analysis. *Technology Forecast Social Change*, 163, 120431. https://doi.org/10.1016/j.techfore.2020.120431.
7. Stevens, G., De Bosschere, K., Verdonck, P. (2021). Is healthcare ready for a digital future? In M. Duranton et al., editors, *European Network on High-performance Embedded Architecture and Compilation: HiPEAC Vision 2021*, p. 198-205.https://doi.org/10.5281/zenodo.4719708.
8. Reaction Data. (2019)*EHR Satisfaction According to Physicians: The Under-Reported Story*.https://www.reactiondata.com/report/ehr-satisfaction-according-physicians/.
9. Priestman, W., Collins, R., Vigne, H., Sridharan, S., Seamer, L., Bowen, D., Sebire,N.. (2019). Lessons learned from a comprehensive electronic patient record procurement process-implications for healthcare organisations. *BMJ Health&Care Informatics.*

26(1):e000020. https://doi.org/10.1136/bmjhci-2019-000020. PMID: 31072821; PMCID: PMC7062322.

10. Holmgren, A., Kuznetsova, M., Classen, D., Bates, D. (2021). Assessing hospital electronic health record vendor performance across publicly reported quality measures. *Journal of the American Medical Informatics Association*. https://doi.org/10.1093/jamia/ocab120. Epub ahead of print. PMID: 34333626.
11. Otto, F. (2020). 5 Tips for Making the Transition from One EHR to Another As Painless As Possible. *Penn Medicine News*.https://www.pennmedicine.org/news/news-blog/2020/november/5-tips-for-making-the-transition-from-one-ehr-to-another-as-painless-as-possible.
12. Nguyen, L., Bellucci, E., Nguyen, L. (2014). Electronic Health Records Implementation: An evaluation of information system impact and contingency factors. *International Journal of Medical Informatics 83*(11):779-96. https://doi.org/10.1016/j.ijmedinf.2014.06.011.Epub 2014 Jul 22. PMID: 25085286.

Author Biographies

Maria D. Joyce is the chief financial officer at the National Institutes of Health Clinical Center, responsible for maintaining the hospital's fiscal and systems integrity and serving as the principal advisor to the NIH Clinical Center CEO and other senior staff for financial management; management of clinical systems and infrastructure; and evaluation of programs.

Carl Buising (cbuising@deloitte.com) is a managing director in Deloitte's Federal Health practice. He holds an MD from the Uniformed Services University of the Health Sciences and a BS in biology from the University of California at Irvine and is board certified in family medicine.

Michelle Lardner is the senior vice president of clinical informatics at Cancer Treatment Centers of America. Prior to this position, she served as the deputy CIO and chief of clinical informatics for the Department of Clinical Research Informatics at the National Institutes of Health Clinical Center.

Juergen A. Klenk (jklenk@deloitte.com) is a principal and the federal health data and AI lead for Deloitte. He holds a PhD in mathematics and an MS in mathematics and physics from Eberhard-Karls-UniversitätTübingen, Germany.

Rachael Schacherer is the chief of staff to the scientific director at the National Institute of Neurological Disorders and Stroke at the National Institutes of Health.

Jonathan Wachtel (jwachtel@deloitte.com) is a manager in Deloitte's Federal Health practice specializing in health, nonprofit, and life science sectors. He focuses on providing clients with innovative strategic solutions to their clinical, biomedical, and health technology challenges.

Rayneisha Watson (rawatson@deloitte.com) is a PMP-certified executive at Deloitte Consulting LLP with 16 years of experience helping clients achieve their mission through strategic planning, human capital strategies, mission transformation, technology modernization, performance management, and process improvement support.

Jon W. McKeeby has over 30 years' experience in all levels of health IT at the National Institutes of Health Clinical Center. He has been the chief information officer at the NIH CC for the last 15+ years.