OpenNotes and Patient Safety: a Perilous Voyage into Uncharted Waters

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LEGAL LANDSCAPE FOR OPENNOTES REQUIREMENTS AND THE HARM PREVENTION EXCEPTION

The OpenNotes movement began in 2010 when three medical centers initiated an exploratory study to investigate the effects of inviting patients to view their primary care visit notes via online portals.^[1] The results indicated that providers did not spend significantly more time or effort with the “opening” of patient notes.^[2] Patients reported that open notes helped them feel more in control of their care and increased their medication adherence.^[2] However, 26–36% of patients also reported privacy concerns in the initial inquiry.^[2] Subsequent publications regarding OpenNotes have echoed the patients’ positive sentiment on efficacy; however, their privacy concerns were never fully ameliorated by subsequent publications and legislation.^[3–5] Despite the documented concerns, the OpenNotes movement grew in popularity and stakeholders began to advocate for legislation requiring widespread open note accessibility.

The 21st Century Cures Act represented a bipartisan effort to streamline the drug and medical device approval process, bring treatments to market faster, implement improvements in mental health and substance abuse policy, and provide additional research funding.^[6] The law mandated increased electronic health system interoperability and greater patient access to their personal health information via online portals.^[6] It also prohibited individuals or entities from blocking a person’s access to their electronic health information (EHI).^[6] The Cures Act Final Rule delineated eight exceptions to the information-blocking provision, including privacy and preventing harm (safety). In compliance with the preventing harm exception, a provider must believe that the information will cause “harm to the life or physical safety of the individual or another person”^[7] to block the release of that information to the patient.

VULNERABILITIES IN CURRENT EHI PRIVACY AND SAFETY PROTECTIONS

While patients now have greater access to their EHI, they also face greater risk of others accessing their private health information. Within the limited scope of the harm prevention exception, health care facilities have attempted to block the release of potentially harmful EHI. However, hasty implementation has left holes in patient privacy and safety protections, thus bringing the early concerns surrounding OpenNotes to fruition. Some systems use “blanket blocks,” which automatically block the release of certain types of visit notes into the patient health portal for specific specialties such as pain clinics, psychiatry, and social work. These “blanket blocks” represent a sincere but inadequate effort to protect vulnerable patients from threats to privacy and safety.

These “blanket blocks” neglect the complex ways individuals interact with health systems. They ostensibly protect the privacy and safety of individuals with stigmatized health issues such as psychiatric and substance use disorders. However, these individuals often interact with health systems in multifaceted ways; patients seek care in many different settings. One of the principal utilities of electronic health records is to streamline care across interactions within the health system. To block information only in specific environments, instead of blocking information on sensitive topics across all interactions, runs counter to the very logic underlying the technology.

Current harm prevention practices also fail to address the needs of marginalized and vulnerable groups, putting them at risk for a disproportionate burden of harm. For example, adolescents who try to access reproductive and sexual health services, especially LGBTQIA+ youth who disclose their gender identity or sexual orientation to providers outside of adolescent-only settings, are not protected by current note-blocking provisions. If disclosures are discovered by family members without patient consent, these pediatric patients could face mental or physical abuse, family ostracization, homelessness, and/or loss of access to necessary health services. People with socially stigmatized mental health diagnoses are also at increased risk of experiencing a harmful breach of privacy which could impact their relationships, employment, or housing status.

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Individuals experiencing interpersonal abuse, including domestic violence, elder abuse, child abuse, or human trafficking, are also at disproportionate risk for harm. Abusive partners or traffickers may have access to their victims' portals. If abuse disclosures are recorded in visit notes, and the notes are released into the patient portal, their abuser may be able to see the notes. This breach of privacy could result in the patient no longer being allowed to access healthcare services or escalate existing emotional or physical abuse. Survivors of domestic violence may also be at risk if a record of them seeking reproductive and sexual health services (birth control, STI status, past pregnancies, losses, or terminations) is released into their patient portal and seen by their abuser. This may result in emotional or physical violence or coercion to discontinue accessing care or treatments. Further, detailed, confidential safety plans may be breached, putting patients in danger at their most vulnerable time, just as they are reaping the benefits of the entire care team being aware and coordinating such plans. Members of these vulnerable communities merit protection and deserve to have their unique needs considered when making healthcare policy.

RECOMMENDATIONS

Due to the transient nature of mental and physical health status, the universal vulnerability to aging, and the high prevalence of IPV, privacy and safety concerns surrounding the EHI have the potential to impact all patients at some point in their lives. For this reason, concrete steps need to be taken to ensure the privacy and safety of all patients when releasing notes. Healthcare leaders must make a concerted effort to retrain providers on safe practices when using OpenNotes, and build safeguards into protocols and software to prevent breaches in privacy from occurring. This will protect patients from possible threats to their privacy and safety. Health systems must also create or amend policy to ensure that proper informed consent is obtained for the use of online patient portals.

Health care institutions should:

1. Create procedures for healthcare personnel to explain that visit notes, including medications lists/histories, are available through their patient portal; reinforce that patients may ask that any note not be released; and disclose that notes are viewable by anyone with access to the patient portal
2. Increase the rigor of consent procedures for creating online patient portals, and increase the rigor of credentials required to access patient portals
3. Build provider-side functions into the EHR to facilitate safe practices and trauma-informed care when charting, including creating confidential note templates for

domestic violence, child abuse, human trafficking, elder abuse, and sexual assault reporting

4. Explicitly encourage the use of proxy portal access for minors' guardians or elderly patients' caretakers during visits with patients, instead of allowing them to access the patient's account directly

Providers can also incorporate the following safety practices into patient interactions:

1. Implement a list of "ABR—Ask Before Releasing" sensitive topics which providers must always double-check with patients before releasing
2. Carefully review auto-populated portions of the note and portions cut and pasted from other notes, including medications lists, with the patient and ask if they wish for those to appear without restriction in their patient portal
3. Inform adolescents about their health care rights and confidentiality protections under state law, as well as the information their parents can see and access through the patient portal during a time when parents leave the exam room¹

In summary, OpenNotes mandates are well intentioned as gateways to empowerment and self-efficacy for some patients but also carry significant safety concerns that disproportionately affect vulnerable groups including minors, those with stigmatized health conditions, and victims of violence. In this paper, we have suggested a number of safeguards that are key to ensuring the safety of these groups and of all patients. We urge widespread implementation of these recommendations.

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Declarations:

Conflict of Interest: The authors declare that they do not have a conflict of interest.

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¹For more information on these recommendations, a full list of ABR topics, and other patient safety and privacy materials, please visit <https://www.med.unc.edu/beacon/open-notesafety/>.

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