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Should Sensitive Information From Clinical Trials Be Included in Electronic Medical Records?

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Medical institutions are rapidly moving to ward electronic medical records (EMRs) because of regulatory pressures and perceived benefits in efficiency and quality of patient care. The federal stimulus bill of 2009 included \$36 billion to incentivize medical institutions to adopt EMRs, and President Obama has declared it a goal that every patient have an EMR by 2014.¹

EMRs and Medical Safety

As the impetus to digitize patients' medical information increases, a new concern is emerging: whether to include research information from participants in clinical trials in an institution's EMR. Participants in clinical trials frequently also receive routine medical treatment for other health conditions. Thus, medical information pertaining to diagnosis, treatment, and laboratory and imaging data generated during participation in a study could be important for the participant's personal physicians as they assess symptoms and prescribe treatments.

Perhaps the greatest need to access clinical trial data would occur during acute illness or other emergency treatment situations. Although emergency physicians may face challenges in interpreting symptoms potentially related to an investigational medication with which they are not familiar, the investigator's brochure (IB) for the medication can provide useful information about pharmacokinetics, pharmacodynamics, metabolism, and known adverse effects. Thus, one way to help medically protect study participants receiving routine clinical care from inadvertent adverse events would be to include an electronic version of the IB in the patient's EMR. However, these documents are cumbersome, and industry has reasonable property rights interests in limiting the dissemination of IBs.

Another solution may be to have protocol developers provide a medical précis of the trial, including the diagnosis, drug or intervention, known metabolic pathways and drug interactions, known potential adverse effects, and methods for contacting the principal investigator. Placed in the participant's EMR, this document may satisfy the researchers'

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need to protect intellectual content and provide a measure of additional safety for the clinical trial participant.

Ethical Considerations

For participants receiving care through an institution for a previously recognized condition, this solution appears reasonable. However, this approach raises concerns when considering “sensitive” information from clinical trials, primarily that of psychiatric disorders, substance use, and infectious diseases, but also involving genetic information. Such sensitive information may include data related to psychological well-being, including psychiatric diagnoses and treatments, sexual practices, illegal behaviors, and certain laboratory testing results.² A fundamental problem with including sensitive information in the participant’s EMR is that medical harms are not the only risks participants face in participating in clinical trials. Various kinds of social harms can result to participants through inappropriate release of their medical information.³ Even including a participant’s informed consent form in an EMR would constitute recording sensitive information because that form would contain the diagnosis under study.

Participants in research studies of stigmatizing illnesses are frequently recruited through community sources and often do not receive their standard medical care from the research institution. These research participants fall into a gray area in which they are not patients of an institution’s health care system yet are receiving care in a trial through an institutional-based clinician. From a legal perspective, the risk to the institution if a tort action arises from research participation may be similar to that arising from the provision of routine clinical care.⁴ Thus, to maximize information available to clinicians and health care centers, the institution may be incentivized to include participant data in the medical record.

This institutional concern might not accord with the concerns of clinical trial participants. Social harms from releasing medical records can have negative consequences on participants in several ways. Accessible records of a diagnosed health condition may greatly increase the cost of, or even completely prevent, an individual’s ability to acquire medical, disability, or life insurance. A documented mental illness or a positive test result for illicit drugs may pose serious harms to the participant if those records are subpoenaed during legal action. For example, in divorce proceedings in which child custody is contested, psychiatric records could be used to argue that a patient is less fit to be the custodial parent.⁵ Employment opportunities for the participant also may be adversely affected if psychiatric diagnoses or testing results are released.⁶ For these reasons, confidentiality of mental health information in medical records has long been recognized as vital to the provision of effective psychiatric care.⁷ An additional complication is that state laws vary regarding higher levels of confidentiality required for mental health information.

Patients with mental health conditions may seek clinical trials as a way to receive assessment and treatment for symptoms of concern without leaving a medical trail that could produce social harms. Although precise numbers are lacking, a significant percentage of individuals with mood, anxiety, or substance use disorders who enroll in clinical trials do so because it has heretofore been the only way to receive a form of treatment without leaving an accessible record. Fifty-nine percent of the public is not confident in the security of EMRs and 76% believe it likely that unauthorized persons would have access to their EMRs.⁸ Psychiatrists appear to share similar concerns: at one institution, 83% indicated they would not want their own psychiatric records (if any existed) included in their general EMR.⁹ If participants cannot have confidence that their medical information obtained as part of a research study will remain separate from the regularly accessible medical record, the predictable outcome is that these individuals will avoid entering trials altogether. The

consequences of delayed treatment or nontreatment for depression, anxiety, and substance use disorders are well established: greater likelihood of job loss, marital disruption and divorce, substance abuse, and suicide.

Potential Solutions

A potential solution to these concerns is for the principal investigator to obtain a certificate of confidentiality (COC) from a federal agency. However, COCs offer only a limited sense of increased confidentiality protection. They cannot protect against inadvertent disclosures or malicious use of information in a patient's EMR. Moreover, for a COC to function effectively, an institution's EMR system would need to distinguish between data collected under research vs routine care and appropriately place such data in specially protected sections of the EMR. For example, the laboratory processing of urine drug screening specimens from clinical trials would need specifically to identify "research" vs "routine" results and store the data separately. Few institutional EMR systems currently have this capability.

At its core, the argument over the ethics of including clinical trial data in EMRs comes down to whether the medical risk of not having such information included in EMRs outweighs the social risks. The most appropriate way to manage these competing risks involves the well-established ethical precept of autonomy. The study participants should decide, after fully informed consent and discussion with the study physician, whether they want their trial participation to be included in the institution's EMR. This approach is consistent with the US Food and Drug Administration's recent guidance regarding investigator responsibilities, which states that the investigator should inform the participant's primary care physician about their trial participation, "if the subject has a primary physician *and* [italics added] the subject agrees to the primary physician being informed."¹⁰ Research participants' confidentiality preferences must continue to be respected, especially in a digital age.

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