Article

The Ethics of Emergent Health Technologies: Implications of the 21st Century Cures Act for Nursing

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Abstract

The 21st Century Cures Act, passed in December 2016 by the United States Congress, is a public law aimed at accelerating the time it takes to get pharmaceutical drugs and medical devices into the market, in addition to shifting connected review processes from randomized controlled trials to real-world efficacy tests. As of December 2019, efforts are underway to introduce a "Cures Act 2.0" bill, with particular attention to the implementation of digital health within health systems. Research on the development of emergent health technologies is nascent; research examining health technology implications of 21st Century Cures Act for the health care workforce is nonexistent. This article fills a crucial gap in public awareness, discussing ethical implications of the 21st Century Cures Act and centering nursing. Nursing is a profession frequently acknowledged as practicing on "the front lines of care" and frequently responsible for the trialing of products in clinical settings. The article summarizes and evaluates key components of the 21st Century Cures Act related to health technology development. Discrete health technologies addressed are (a) breakthrough devices, (b) digital health software, and (c) combination products. It then connects these provisions to ethical considerations for nursing practice, research, and policy. The article concludes by discussing the relevance of emerging digital health technologies to the crafting of a "Cures 2.0" bill, with particular attention to this moment in light of digital care precedents set during the COVID-19 pandemic.

Keywords

digital health, ethics, health policy, nursing, 21st century cures act, health equity

On December 13, 2016, former President Obama signed H.R. 34, The 21st Century Cures Act, into law after it was passed with unanimous bipartisan support in the United States Congress. The Act was the result of 2 years of congressional work by the Federal Energy and Commerce Committee drafting plans to increase federal funding for medical innovation. While opposed by patient safety lobbyists and others concerned about loosening evaluation standards for pharmacologic drugs and medical devices, the statute allocated $6.3 billion to the National Institutes of Health and United States Food and Drug administration (FDA) for advancing the discovery, research, and development of innovative cures (Lupkin, 2016; Mendoza, 2017). Containing wide-ranging implications for oncology and pharmacotherapy innovation, the Act also enabled the FDA to develop new evaluation frameworks for vetting digital health products (21st Century Cures Act. Public Law 114-255, 2016).

Since the passage of the public law, the FDA has begun developing guidelines for medical device and drug manufacturers. These activities have dovetailed with a surge of private sector investment in health technologies, particularly those powered by artificially intelligent software (Kesselheim & Hwang, 2016). In 2019, U.S. Congress members Fred Upton and Diana DeGette

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requested public input for the initiation of a Cures 2.0 Act, stating that there was more work to be done following passage of the initial law, particularly with regard to digital health and implementation science. They noted, "Recognition of digital platforms as sources of medical services combined with reforms to how digital products may be covered and reimbursed for by payors such as Medicare will be critical to realizing this potential" (DeGette & Upton, 2019, p. 1). These statements seem particularly true in light of March 6, 2020, when the U.S. Centers for Medicare and Medicaid broadened reimbursement for telehealth services in response to COVID19. While implemented as part of a temporary emergency plan, these actions set a precedent for digitized care provisioning and may influence future policymaking for digital health following containment of the pandemic (Centers for Medicare and Medicaid Website, 2020; Public Law H.R. 6074, 2020). To date, no known nursing organizations have provided input to U.S. Congress members Upton and DeGette in drafting Cures 2.0 legislation.

While a framework has been proposed by the FDA, standardized procedures for including real-world data within postmarket assessment activities are still evolving. Scholarship within the last 4 years has broadly analyzed risks and benefits of shifting toward increased reliance on real-world data with attention to patient safety (Klonoff, 2019; Schwartz, 2017; Wechsler, 2017). There has been little discussion, however, about the implications of the 21st Century Cures Act for health professions responsible for ensuring patient safety and fidelity to research protocols with regard to the trialing of digital health products in clinical settings. Nursing is one of these professions, with a range of connected roles encompassing clinical care, health care administration, and research. Existing scholarship on the 21st Century Cures Act in relationship to nursing focuses on precision health and the roles that nurses must play in advancing it (Starkweather et al., 2018). To date, there has been little study of this law with regard to digital health production, and none that discusses these digital health aspects in relationship to nursing professions specifically. A more robust discussion of this law in relationship to digital health and nursing is required.

The purpose of this article is twofold: to summarize and evaluate key components of the 21st Century Cures Act dealing with health technology development and to discuss the relevance of emerging digital health technologies to ethical considerations for nursing practice, research, and policy. Specific technology categories discussed are (a) breakthrough devices, (b) digital health software, and (c) combination products. The article concludes by considering these issues in connection with the drafting of a "Cures 2.0" and digital care precedents being set during the COVID-19 pandemic.

Breakthrough Devices

As defined in section 515B of the United States' *Food, Drug, and Cosmetic Act*, breakthrough devices: (a) provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions than what is currently available and (b) represent breakthrough technologies for which no approved or cleared alternatives exist. These devices must offer significant advantages over existing, approved or cleared alternatives including the potential—compared with existing approved alternatives—to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance) or establish long-term clinical efficiencies. Finally, the availability of these devices on the marketplace must be in the best interest of patients (Breakthrough Devices Program Report to Congress, 2019; Federal Food, Drug, and Cosmetic Act. Public Law 116-22, 2019). An example of a recently approved breakthrough device is an artificially intelligent software product that scans the eye for amyloid-plaques to aid in the diagnosis of Alzheimer's disease. The device constitutes a "breakthrough" relative to existing methods for Alzheimer's diagnosis, which rely solely on the review of clinical symptoms in crafting the diagnosis (Optina Diagnostics, 2019).

The 21st Century Cures Act created a breakthrough device approval pathway to mimic the one previously created for breakthrough drugs. Based on the Act's general guidelines, once FDA designates a medical device as a "breakthrough device," the product is fast-tracked for evaluation within 60 days. The accelerated breakthrough path signals an important clarifying function of the Act—defining what breakthrough devices are relative to other types of devices. Since the passage of the Act, FDA has further outlined details of the qualifying process for breakthrough designation and has issued a template for company use when applying for the designation (Letourneau et al., 2016; 21st Century Cures Act. Public Law 114-255, 2016).

Given the hastened timeline for both designation and approval, this pathway provides an incentive for device manufacturers to seek breakthrough designation. Since these devices are designed for urgent and unmet patient needs, their expedited availability should be a net positive for patients and device manufacturers. Nevertheless, the increased number of products coming onto the market may also create a heightened need for postmarket surveillance (Brown et al., 2016). The statute does not stipulate what postmarket surveillance procedures should look like for breakthrough products considered to be digital health technologies—that is, containing primarily software-based functions. Currently, assessment

activities may take place within the same companies producing the breakthrough medical device products which raises questions regarding how FDA considers the integrity of the evidence produced. As part of FDA's mission to reimagine its evaluation process for digital health, it created a pilot program for nine participating companies of varying size and organizational structure to help define key performance metrics and quality indicators to be used during digital health company evaluation. To date, several of the products produced by participating companies have achieved breakthrough device designation (Digital Health Software Precertification Pilot Program Website, 2019; Sczabo, 2019).

Digital Health Software

Digital health software termed Software as a Medical Device has historically encompassed everything from downloadable mental health applications that track mood to the electronic health records (EHRs) with certain capabilities used throughout health systems following passage of the Health Information Technology for Economic and Clinical Health Act of, 2009. Given the heterogeneity of the area, as well as vendor confusion regarding what needed FDA clearance and approval, the 21st Century Cures Act served a clarifying function. The Act delineated what types of software are *not* considered medical devices. As of 2016, these five categories of software include medical device data systems, clinical decision support, EHRs, administrative support software, and general wellness/lifestyle software. This delineation among types of products helps companies predict with more certainty if their product will have to undergo an FDA process, and, if so, how long it may take to do so. Time-to-market predictability is an appealing data point for potential investors in early stage products where there is increased uncertainty and risk of failure and financial loss in setting out to develop the product in the first place.

Digital health software commonly involves projects using artificial intelligence for care delivery and human health. While the hope is that these types of software products will improve care and alleviate clinician burden, the FDA has not decided who will vet and designate third parties to perform postmarket surveillance procedures for health system infrastructural products.

In the same way that a risk-based schema indicates the type of evaluation necessary for different medical devices, products that are categorized as low risk but crucial for clinical decision-making support will need to be carefully monitored for reliability. While the Cures Act exempted EHRs from regulatory consideration as Software as a Medical Devices, in 2019 FDA commissioner Scott Gottlieb announced that congress would need to create separate legislation to specifically regulate them. This followed on the heels of several injuries and six deaths occurring as a result of "health information technology malfunction" (Ying, 2019). While the Cures Act may have clarified definitional categories in a way that was helpful to manufacturers developing heath technology products, the outcomes for patients and providers may not have been as unanimously beneficial. These public risks deserve heightened attention and explication.

Combination Products

Combination products are hybrid products that blur the line between drug, device, and/or biologic therapies. This emerging area includes many (although not all) products considered to be "digital therapeutics," such as the ingestible sensor for tracking medication adherence designed by Proteus Digital Health, a privately held company that has raised almost $500 million in venture capital (Comstock, 2016; Crunchbase.com, 2017). Pursuant to the 21st Century Cures Act, the FDA created an Office of Combination Products with primary responsibilities of developing regulation and guidance for this area (Office of Combination Products Website, 2019). Whereas previously these products underwent two (drug and device) approval processes, now there is a dedicated office and staff, and a single application process for manufacturers. The office defines a product as primarily constituting a drug or device and then sends it for evaluation by the appropriate FDA-designated entity. Manufacturers can challenge decisions about the FDA's designation as drug or device. As part of the Act, companies and FDA officials are required to meet in the early stages of product development in order to decide how to evaluate it, a stipulation that is designed to encourage developers and streamline clearance (Office of Combination Products Website, 2019; Ropes and Gray, 2016; 21st Century Cures Act. Public Law 114-255, 2016).

At this point, there are no constraints on the way combination products can be marketed to nurses. Nurses are frequently targeted by pharmaceutical sales personnel and often influence prescribing activities, a phenomena well-documented in research examining nurse-industry relations (Grundy, Fabbri et al., 2016; Grundy, Bero, et al., 2016; Grundy & Malone, 2017; Jutel & Menkes, 2008). Since combination products may be marketed through existing pharmaceutical sales channels, there is an increased need for nursing education about the appropriateness and risks surrounding their uptake within health systems. The marketing of these products stands to impact institutional decision making as well as individual practice. Even in pragmatic trials, nurses are responsible for the care and advocacy of patients, fidelity to research protocols, and knowledge

regarding Good Clinical Practice standards for conducting human subjects research in clinical settings. Specific areas of attention include protection of research participants and appropriate utilization of participatory design strategies such that populations recruited for research participation equitably benefit from the development and deployment of trialed products.

In July 2019, the FDA published its finalized guidelines for postmarketing safety reporting of these products. While particular procedures for detailing the significance of an adverse event and timeline associated with required reporting to the FDA are detailed, the document does not describe what a recall process should look like for combination products with significant software components (Office of Combination Products Website, 2019). Due to the iterative nature of developing software-based products, existing recall procedures will need to be significantly reimagined by regulatory agents. Nurses involved in the trialing of these products in clinical settings are responsible, however formally or inadvertently, for assessing the severity of unintended events. Since emergent health technologies pose unknown risks to care delivery, health systems should ensure that existing reporting procedures for "unintended consequences" include and solicit the reporting of ethical concerns. This may be facilitated by improving the ease of reporting procedures such that clinicians are encouraged to voice their concerns rather than work around them.

The 21st Century Cures Act's collective changes help delineate combination products from other sorts of products. The Act's changes also reduce submission burden for software developers, establish a separate review group for considering combination products, and create guidelines for collaboration with manufacturers. They reflect the consistent effort to make health technology products more available to consumers. Given that the FDA's evaluation guidelines are still being developed for these products, and that in cutting-edge fields with few experts, manufacturers may be playing significant roles in the regulatory process, nurses have an important role to play by ensuring the FDA learns promptly about postmarket issues with these products. Looking to other areas such as blood testing and genomic sequencing where past regulatory conflicts have informed policy could be useful for establishing best ethics practices (Clayton, 2019; Cortez, 2018; Mandl & Manrai, 2019).

Nursing Practice, Research, and Policy

While Clinical Research Nurses may be well appraised of digital health implications of the 21st Century Cures Act, it is critical to introduce these topics to a wider audience in light of their patient safety and marketing considerations. Particularly with regard to digital precedents being set in the United States during COVID19, nurses have a responsibility to shape the regulatory landscape informing safe, equitable, and timely care to patients. As such, this section summarizes key ethical considerations for nursing practice, research, and policy and offers suggestions for ways to improve the treatment of these topics within health systems.

Nursing Practice

In a climate where effectiveness testing is not required prior to the sale of many products, nurses on the ground will be tasked with vetting the integrity of patient data these products produce, including whether and how product data get factored into clinical decision making. For this reason, at a grassroots level, nurses must introduce "digital considerations" as a topic within ethics committees and ensure that they are given proper consideration across clinical environments. In settings where these conversations have not been introduced across disciplines, nursing can work to make the topics more visible. One way to increase visibility about ethical considerations of digital health implementation is to set up "digital experience teams" to proactively gather information about how digital products are impacting care and clinical work experiences. These teams may gather on-the-ground feedback from clinicians and disseminate this feedback regularly across practice environments, reporting on the topics as they would other care improvement issues and escalating concerns to leadership as needed. This can be done as a consistent effort within individual clinical units and would advance the visibility of patient safety and workforce concerns surrounding digital care.

In addition to on-the-ground digital experience teams, the voluntary collaboratives informing digital health product uptake need to include nurses who are apprised of the ethical considerations of health technology development. In the current regulatory climate, cross-organizational collaboratives such as the Accelerated Digital Clinical Ecosystem (ADviCE) (http://advicehealth.org) are setting implicit standards for digital health implementation within health systems. As of April 2020, ADviCE's core team of collaborators did not include anyone from the field of nursing.

Research

Nursing research can go a long way toward advancing the ethical consideration of digital health products. In addition to incorporating digital experiences into care improvement activities, there is a need for empirical work that centers the ethical implications of health technology development in varied ways. Research on the

ethical consideration of emerging health technologies is nascent, as is policy analysis regarding the effects of digital health uptake within health systems. Centering these concepts within nursing research should enable readier translation of ethical recommendations to clinical contexts. General areas deserving of more thorough analysis include how and in what ways nurses respond to commercial influences on health care, how the integrity of evidence produced by patient devices is considered within clinical contexts, and how and in what ways health equity is affected by digital update within health systems. Two specific recommendations for closer examination highlighted here involve the trialing of breakthrough devices and EHR audit log data.

While it will take time before any of the current breakthrough devices are incorporated into standard health system practices, many are being trialed within clinical settings. There is little guidance for how to vet these types of products, and for anticipating the way that they may alter the delivery of patient care, both in terms of quality and equity for patients, as well as burden to clinical staff. Nurses are often the staff members charged with implementing recruitment and or retention practices for trialing these types of products within clinical settings. For this reason, nursing research is particularly well-suited for studying the ways these products are being taken up in practice. Nurse researchers who explicate the impact of such emergent health technologies on equitable care provisioning, quality of care, and patient safety will offer a meaningful contribution to the evolution of health innovation in the United States.

Similarly, with regard to ways that EHRs are both creating and surfacing issues throughout the health care workforce (Adler-Milstein et al., 2020), a timely opportunity presents itself to investigate EHR audit log data for ways to improve care. Current scholarship focuses heavily on the ways EHRs are contributing to physician burnout; however, their use impacts the clinical practice of many allied health professions. Research is needed to investigate how these data can surface inequities in care practices that demand attention and amelioration.

Policy

The Cures Act not only expedites the approval processes for health technology products but also it further outlines the definitions of these rapidly emerging product categories thereby streamlining procedures to lower manufacturing costs, shorten development timelines and position technology developers to raise early-stage funding. Specifying more clearly what it means to be a breakthrough product, a piece of software that is *not* exempted from FDA review, and/or a combination product also better enables start-up companies to understand the rules by which they have to play. For these reasons, the Act is very favorable to innovation, and will, over time, have a cascading effect that benefits the technology labor force, potentially creating more knowledge-based jobs as product companies grow following FDA product approval. What is presently unknown is how and in what ways these changes will benefit the health care workforce tasked with working directly with patients. As companies further integrate their products within health care settings, nurses working in direct patient care will closely interface with the technology that augments care delivery and, in the absence of ethical frameworks guiding them, be forced to form their own ad-hoc ways to preserve patient benefit. As such, nurses have a crucial role to play in policy formation for and public awareness about emergent health technologies.

In a climate, where commercial drivers of technology uptake are closely aligned with regulatory activities (Martin, 2020), and where a temporary relaxation of regulatory restrictions is occurring because of a global pandemic, it is important to take up the ethical consideration of emerging health technology products. Policymakers and the public need to be informed about risks and benefits of the Cures Act as they relate to effectiveness testing of forthcoming products on the market, patient safety considerations, and the crafting of a Cures 2.0 bill to advance digital care provisions. In this effort, nursing organizations have the power to raise the visibility of these issues to U.S. Congress members who are drafting legislation and to make clear their ubiquitous support of the public's interest.

In addition to raising the visibility of these issues to the public and lawmakers, nursing leadership within institutions can initiate policies to provide low-burden, formal opportunities to clinicians on the front lines of care to provide feedback about the functionality of the software they use on a daily basis. During a time when clinician workflows are changing rapidly, and when many nursing roles are shifting to remote care activities, it crucial to clarify pathways of communication in order for clinicians to voice concerns. These pathways would present a considerable opportunity for nurses to advocate for structural solutions to technology problems. Doing so would help ensure that precedents set during crisis situations elevate rather than hinder the provisioning of high quality, equitable care.

From a health system perspective, digital health centers within institutions need to incorporate ethical considerations of products in vetting clinical software prior to purchase, in building robust and transparent implementation guidelines, and in developing appropriate postimplementation assessments to ensure that the software is effective in improving care. The role of institutional ethics and purchasing committees may need to

expand to address more fully these unique products, particularly now. Nurses, as the most trusted health professionals, are powerfully situated to spearhead these changes and can set the ethical precedents now that will carry forward into future care provisioning.

Conclusion

Current regulatory changes for breakthrough devices, digital health software, and combination products constitute significant aspects of the 21st Century Cures Act, dealing with technology aimed to impact human health. Extended provisions to advance digital health are at the center of forthcoming bills to revise it, and provisions are already being made in the United States to utilize digital care alternatives during COVID19. In a regulatory climate heavily focused on implementation (Cortez, 2019), it will fall to those working in clinical environments to proactively identify how and in what ways these technologies impact care, particularly since postmarket surveillance procedures are in their infancy. Crafting formal ways to capture how and for whom these products affect care delivery is as crucial for institutions as it is for the public interest. To that end, nursing has the opportunity to take up ethical considerations of these products as central to its mission both within and across institutions and to work in a timely manner to raise these issues with policymakers.

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