

REPORT ON RISKS AND BENEFITS TO HEALTH OF NON-DEVICE SOFTWARE FUNCTIONS

December 2022



**REPORT ON RISKS AND BENEFITS TO HEALTH OF NON-DEVICE SOFTWARE
FUNCTIONS – DECEMBER 2022**

**Submitted Pursuant to
Section 3060(b) of the 21st Century Cures Act**

**U.S. Department of Health and Human Services
Food and Drug Administration**

Executive Summary

Section 3060(a) of the 21st Century Cures Act (herein referred to as the Cures Act), enacted on December 13, 2016 (Pub. L. 114-255), amended the Federal Food, Drug, and Cosmetic Act (herein referred to as the FD&C Act) to exclude certain medical software functions from the definition of device under section 201(h) of the FD&C Act (21 U.S.C. 321(h)). These software functions are specified in section 520(o)(1) of the FD&C Act and the intended uses of such software functions can be summarized as follows: (1) administrative support of a health care facility; (2) maintaining or encouraging a healthy lifestyle and unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; (3) serving as electronic patient records when not intended to interpret or analyze patient records; (4) transferring, storing, converting formats, or displaying data; or (5) unless interpreting or analyzing a clinical test or other device data, providing certain types of limited clinical decision support to a health care provider.

Section 3060(b) of the Cures Act (herein referred to as section 3060(b)) requires that the Secretary of Health and Human Services (HHS) publish a report every two years that examines information available to the Secretary on any risks and benefits to health associated with the software functions described in section 520(o)(1) of the FD&C Act, and provides summary findings regarding the impact of these non-device software functions on patient safety, including best practices to promote safety, education, and competency. This document is the third report pursuant to section 3060(b) since the enactment of the Cures Act.

In an effort to identify new information published since the [Report on Risks and Benefits to Health of Non-Device Software Functions – November 2020](#) (herein referred to as the 2020 Report), the Food and Drug Administration (FDA) collected information from a variety of sources as defined in section 3060(b). This section 3060(b) report includes information from a variety of sources reported on, or pertaining to, United States (U.S.) populations from July 31, 2020, to July 31, 2022. This section 3060(b) report also includes information from comments submitted to the public docket ([FDA-2018-N-1910-0047](#)) from the opening of the docket on July 14, 2022 through the close of the docket August 15, 2022.

FDA analyzed the data and information from the aforementioned sources for new evidence regarding impacts to patient safety, benefits and risks to health, and best practices to promote safety, education, and competency associated with the software functions described in section 520(o)(1) of the FD&C Act.

Using the outlined scope and methodology this report, FDA summarizes the findings from this analysis. In general, the analysis found more benefits than risks to patient safety and health related to these software functions. In addition, this report details best practices related to implementation, training techniques, and use, which could promote safety, education, and competency related to these software functions.

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I. Introduction

Section 3060(a) of the [21st Century Cures Act](#) (herein referred to as the Cures Act), enacted on December 13, 2016 (Pub. L. 114-255), amended the [Federal Food, Drug, and Cosmetic Act](#) (herein referred to as the FD&C Act) to exclude certain software functions from the definition of device under section 201(h) of the FD&C Act (21 U.S.C. 321(h)). These functions are described in section 520(o)(1) of the FD&C Act (21 U.S.C. 360j(o)(1)) and are the focus of this report.

Section 3060(b) of the Cures Act (herein referred to as section 3060(b)) requires a report to be published every two years that examines information available to the Secretary on any risks and benefits to health associated with the software functions described in section 520(o)(1) of the FD&C Act and provides summary findings on the impact of non-device software functions on patient safety, including best practices. Specifically, section 3060(b) states:

The Secretary of Health and Human Services (referred to in this subsection as the “Secretary”), after consultation with agencies and offices of the Department of Health and Human Services involved in health information technology, shall publish a report, not later than two years after the date of enactment of this Act and every two years thereafter, that—

- (1) includes input from outside experts, such as representatives of patients, consumers, healthcare providers, startup companies, health plans, or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary;*
- (2) examines information available to the Secretary on any risks and benefits to health associated with software functions described in section 520(o)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) (as amended by subsection (a)); and*
- (3) summarizes findings regarding the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions.*

The Report on Risks and Benefits to Health of Non-Device Software Functions – December 2022 is the 2022 report pursuant to section 3060(b), and includes findings related to information published since the [Report on Risks and Benefits to Health of Non-Device Software Functions - November 2020](#) (herein referred to as the 2020 Report).

II. Background

The description of non-device software functions defined in section 520(o)(1)(A)-(E) of the FD&C Act (21 U.S.C. 360j(o)(1)(A)-(E)), as amended by the Cures Act, is the subject of this report. Specifically, section 520(o)(1)(A)-(E) of the FD&C Act states:

The term device, as defined in section 201(h), shall not include a software function that is intended—

- (A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions,*

practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

- (B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;*
- (C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—*
 - (i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;*
 - (ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and*
 - (iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;*
- (D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or*
- (E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—*
 - (i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);*
 - (ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and*
 - (iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.*

The Food and Drug Administration (FDA) has issued four final guidances that interpret section 520(o)(1)(A)-(E) of the FD&C Act. The first guidance document was a section 3060 guidance document that provides FDA's interpretation of section 3060(a) of the Cures Act and the types of software that meet and do not meet the device definition in section 201(h) of the FD&C Act, focusing on the first four categories (section 520(o)(1)(A)-(D), paragraphs A through D above). The second guidance document provides clarity to industry and FDA staff on FDA's compliance policy for low-risk, general wellness products that promote a healthy lifestyle (section

520(o)(1)(B)). The third guidance document provides FDA’s policy for medical device data systems (MDDS) that transfer, store, convert formats, and display medical device data or medical imaging data (section 520(o)(1)(D)), as well as FDA’s policy for medical image storage and medical image communications devices. Lastly, on September 28, 2022, FDA announced the availability of a guidance document on clinical decision support (CDS) software ((section 520(o)(1)(E), paragraph E, above). The guidance documents are referenced below to provide clarity related to the non-device software functions included in the scope of this report:

- 1. Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act¹:** This guidance explains the effect of the medical software provisions in the Cures Act on preexisting FDA policy, including policy on mobile medical applications; medical device data systems used for the electronic transfer, storage, display, or conversion of medical device data; medical image storage devices used to store or retrieve medical images electronically; medical image communications devices used to transfer medical image data electronically between medical devices; software that automates laboratory workflow; and low-risk general wellness products.
- 2. General Wellness: Policy for Low Risk Devices²:** Pursuant to section 520(o)(1)(B) of the FD&C Act, software that is intended “for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition” is not a device under section 201(h) of the FD&C Act. This guidance clarifies FDA’s interpretation of section 520(o)(1)(B) of the FD&C Act and its application to general wellness products.
- 3. Medical Device Data Systems³:** Pursuant to section 520(o)(1)(D) of the FD&C Act, software functions that are solely intended to transfer, store, convert formats, and display medical device data or medical imaging data, unless the software function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings, are not devices and are not subject to FDA laws and regulations applicable to devices. This guidance provides FDA’s interpretation of section 520(o)(1)(D) of the FD&C Act and FDA’s current thinking on MDDS, medical image storage devices, and medical image communications devices.

¹ FDA. Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Guidance for Industry and Food and Drug Administration Staff. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act>. Published September 27, 2019.

² FDA. General Wellness: Policy for Low Risk Devices. Guidance for Industry and Food and Drug Administration Staff. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>. Published September 27, 2019.

³ FDA. Medical Device Data Systems, Medical Image Storage Devices, and Image Communications Devices: Guidance for Industry and Food and Drug Administration Staff. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices>. Published September 28, 2022.

- 4. Medical Device Classification Regulations To Conform to Medical Software Provisions in the 21st Century Cures Act, Final Rule⁴:** FDA issued this final rule to amend a series of classification regulations to conform with the medical software provisions of the Cures Act and reflect FDA’s current statutory authority by excluding software functions that no longer fall within the statutory definition of a device. The amendments in the final rule update the “identification” description of eight classification regulations so that the regulations no longer include software functions that the Cures Act excluded from the device definition in the FD&C Act. Specifically, the final rule amended classification regulations to exclude software functions intended to transfer, store, convert formats, or display clinical laboratory test or other device data, results, and findings that do not interpret or analyze such clinical laboratory test or other device data, results, and findings, since these functions are no longer devices (see section 520(o)(1)(D) of the FD&C Act).
- 5. Clinical Decision Support Software⁵:** The purpose of this guidance is to describe FDA’s regulatory approach to CDS software functions and to clarify the types of CDS functions excluded from the definition of device by the criteria outlined in section 520(o)(1)(E) of the FD&C Act. Specifically, CDS functions are excluded from the definition of device by section 520(o)(1)(E) of the FD&C Act if the software functions meet the following four statutory criteria: (1) not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system; (2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines); (3) intended for the purpose of supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition; and (4) intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional relies primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

The CDS software guidance document represents FDA’s current thinking on the aforementioned software functions but does not address which other FDA statutory or regulatory requirements apply to device software functions, including which regulatory requirements may apply to a device software function that is part of a combination product, nor does it address labeling requirements for decision support software disseminated by or on behalf of a drug or biological product sponsor.

⁴ FDA, Medical Devices; Medical Device Classification Regulations To Conform to Medical Software Provisions in the 21st Century Cures Act: Final Rule. <https://www.federalregister.gov/documents/2021/04/19/2021-07860/medical-devices-medical-device-classification-regulations-to-conform-to-medical-software-provisions>. Published April 19, 2021.

⁵ FDA. Clinical Decision Support Software: Guidance for Industry and Food and Drug Administration Staff. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software>. Published September 28, 2022.

III. Methodology

Sources. Information used to generate this report came from a variety of sources as defined in section 3060(b). Sources include interviews with outside experts (i.e., external to FDA), peer-reviewed literature, adverse event report databases, and other “information available to the Department of Health and Human Services (HHS) Secretary” per section 3060(b)(2), including comments received in response to the “Development of 21st Century Cures Act Section 3060 Required Report: Request for Input.”⁶ A list of sources can be found in the Appendix: List of Contributing Sources.

Inclusion/Exclusion Criteria. Parameters for the literature and adverse events searches included information reported on or pertaining to United States (U.S.) populations from July 31, 2020, to July 31, 2022. The date range captured new evidence since the publication of the [Report on Risks and Benefits to Health of Non-Device Software Functions – November 2020](#). Interviews were conducted from July 28, 2022, through August 10, 2022, but information elicited from interviewees about benefits and risks to health, impacts to patient safety, and best practices may have been learned by interviewees prior to July 31, 2020. Similarly, the public comment period for the public docket ([FDA-2018-N-1910-0047](#)) was open from July 14, 2022, and closed on August 15, 2022, but information elicited from respondents may have been learned prior to July 31, 2020.

Definitions. The Cures Act requires information to be reported about the “impacts to patient safety” and “benefits and risks to health.” This report uses the following existing FDA and World Health Organization (WHO) definitions regarding patient safety and health:

- **Impacts to Patient Safety:** A *negative impact* to patient safety is defined as a risk that leads to a serious adverse event (i.e., death, life-threatening, hospitalization, disability or permanent damage, congenital abnormality/birth defect, required intervention to prevent permanent impairment or damage, other serious [important medical events]).⁷ By comparison, a *positive impact* to patient safety is defined as reducing the rate of a serious adverse event.
- **Benefits and Risks to Health:** Health is defined as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.⁸

Analysis Approach. The Cures Act requires a report summarizing findings corresponding to safety, risks and benefits, and best practices categories. Thus, this analysis includes reviews of peer-reviewed literature and information obtained from the additional sources identified above in the Methodology section. The summaries include information and evidence, regardless of the rigor of the design, the grade of study quality, and strength of evidence, in an effort to provide comprehensive findings. Some products identified in this report include both device and non-device functions. Inclusion of a product in this report should not be interpreted as a

⁶ Regulations.gov. 2022 Development of 21st Century Cures Act Section 3060 Required Report; Request for Input. <https://www.regulations.gov/document/FDA-2018-N-1910-0047>. Published July 14, 2022.

⁷ FDA. What is a Serious Adverse Event? <https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event>. Published February 1, 2016.

⁸ World Health Organization. Constitution of WHO: Principles. <https://www.who.int/about/governance/constitution>. Published on April 7, 1948.

determination that the product does not include device functions that would be subject to FDA oversight. Instead, products that may include device functions were included in this report when the results and findings associated with the studies were determined to be relevant to non-device functions in general. When a study was of a product with more than one non-device function, that study was placed in the section of this report that aligned with the function of most interest and relevance to our findings in this report.

FDA organized its findings into three categories across the five software functions, which align to the three requirements for the report required by section 3060(b) of the Cures Act:

1. Impacts to patient safety;
2. Benefits and risks to health; and
3. Best practices to promote safety, education, and competency.

IV. Summary Findings as Required by Section 3060(b) of the 21st Century Cures Act

Many of the findings detailed in this report correspond to positive impacts on patient safety and health benefits related to use of the five software functions. This report identifies only a few reported negative impacts on patient safety and health. Compared with the [2020 Report](#), we observed an increase in peer-reviewed literature with relevant findings and we have noted changes in impacts to patient safety and health between the [2020 Report](#) and the current report across each software function. We acknowledge, however, that given there is no requirement to report adverse events from non-device software, adverse events may be underrepresented in this report.

The sections below provide an overview of the findings for each of the five software functions. These functions are organized into the following three categories to reflect the stated focus of section 3060(b)(2) and (3): Impacts to Patient Safety, Benefits and Risks to Health, and Best Practices to Promote Safety, Education, and Competency. The List of Contributing Sources, outlined in the Appendix, provides details on all sources cited in the section below.

A. Administrative Support of a Health Care Facility

Software functions included in this category are defined in section 3060(a) as intended:

...for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow.

Section 520(o)(1)(A) of the FD&C Act.

Impacts to Patient Safety

FDA received three adverse event reports⁹ related to laboratory workflow applications. The first error occurred after a software update to a culture workshop test where a revised protocol length was not sent to the intended instrument and was automatically changed to its original length. The second error caused samples to revert to “ready for reading” even after selecting “sample read,” which led to delays in workflow. A third error led to a patient’s aspartate aminotransferase test results to being automatically validated due to a missing flag and was reported outside of the laboratory to the patient.

Changes or additions since last published report: New adverse event types. Information presented on this software function includes adverse events related to laboratory workflows that were not reported in the [2020 Report](#).

Benefits and Risks to Health

One study involved researchers examining electronic prescribing (e-prescribing) information from electronic health record (EHR) systems and medical and pharmacy claims data to compare the characteristics of patients who filled all of their initial prescriptions (complete initiation) against patients who did not fill one or more initial prescriptions (incomplete initiation). The researchers used linear and logistic regressions to model costs (i.e., medical costs, pharmacy costs, and total cost of medical and pharmacy services) and binary utilization indicators for the same year and for the following year. The same year, statistical analysis found that having complete medication initiation was associated with statistically significant lower total costs, lower medical costs, lower likelihood of being in the top 5% of total cost, having one or more hospitalizations, and having one or more emergency department (ED) visits. The next year, statistical analysis found that having complete medication initiation was associated with statistically significant lower total costs and lower medical costs. Based on their findings, the researchers note that future studies can use the medication initiation measure from e-prescribing information in EHRs, medical, and pharmacy claims data for population health management programs to advance targeted sub-population interventions and achieve the highest savings.¹⁰

Changes or additions since last published report: New literature. This report presents information describing the positive impact of e-prescribing software on health care costs, a finding not reported in the [2020 Report](#).

⁹ FDA does not substantiate the adverse event reports it receives. Submission of an adverse event report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer, or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause-and-effect relationship and cannot be used to estimate the incidence of these events. Adverse events included in this report were gathered from MedWatch: The FDA Safety Information and Adverse Event Reporting Program: <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program> and Manufacturer and User Facility Device Experience Database - (MAUDE): <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

¹⁰ Chang, H. Y., Kan, H. J., Shermock, K. M., Alexander, G. C., Weiner, J. P., & Kharrazi, H. (2020). Integrating E-Prescribing and Pharmacy Claims Data for Predictive Modeling: Comparing Costs and Utilization of Health Plan Members Who Fill Their Initial Medications with Those Who Do Not. *Journal of Managed Care & Specialty Pharmacy*. 26(10), 1282–1290. <https://doi.org/10.18553/jmcp.2020.26.10.1282>.

Best Practices to Promote Safety, Education, and Competency

Researchers at the Veterans Health Administration (VHA) examined how transitioning their original clinic-based scheduling system to a new resource-based scheduling system affected the optimization of the technology, the efficiency of the scheduling process, and the impact on patient care. The original system relied on schedulers manually determining available resources (e.g., providers, rooms, equipment), which led to issues such as schedulers overbooking the infusion clinic while also preventing VHA from gathering critical data to support provider usage or Veteran demand and assuring reliable and timely access to appropriate services. The researchers observed staff using the two scheduling systems and completed interviews and large-group discussions with schedulers, then compared the two systems' data elements, scheduling functionality, interfaces, and business rules. The new system used resource-based scheduling that monitors availability and utilization of resources or providers and automatically finds open appointments of the appropriate length for the appointment type. The innovations of the new system resulted in time savings when making appointments (e.g., saving up to three minutes per scheduled appointment by auto-populating appointment data fields, reducing specialist appointment scheduling from 10 minutes to five minutes, and recurring appointment scheduling from five minutes to one minute), increased the number of same-day appointments across 12 high-priority specialties, and also led to a 4.56% increase in completed appointments for new Veteran patients and a 5.72% increase for established Veteran patients.¹¹

Another team of researchers from VHA interviewed 23 health care providers to evaluate their perceptions of an event notification intervention at the James J. Peters VA Medical Center in Bronx, New York or the Richard L. Roudebush VA Medical Center in Indianapolis, Indiana. The notification informed primary care teams when a patient from one of these medical centers was discharged from a non-VHA medical center or an emergency department. The notification provided primary care teams (e.g., physicians, nurses, medical assistants) with the non-VHA facility the patient visited and the reason for the visit. The providers largely perceived the notifications as useful to their operations and workflow, helpful in improving practice operations (e.g., timely follow-up to non-VHA care, patient experience), and valuable when transitioning care between health systems. However, some of the providers said the content could be improved (e.g., notifications could include a diagnosis code, more detail on the patient's condition, and treatment provided), and said that adding the discharge notification into the patient's medical record could interrupt workflow.¹²

One public commenter noted that non-device software improves general efficiency, interoperability, and patient care, but added that the proliferation of internet-connected software presents risks to patient safety and privacy. In light of these vulnerabilities, the public commenter emphasized the importance of considering the potential threat of cyberattacks on non-device software and the risks that a cessation of care or theft of sensitive patient information pose to patient safety. Additionally, the public commenter offered recommendations for improving the

¹¹ Ford, J., MacTaggart, P., & Gunnar, W. (2021). Veterans Health Administration Scheduling System: The Path to High Reliability Realization. *Journal of Healthcare Management*. 66(6), 421-430. <https://doi.org/10.1097/JHM-D-20-00257>.

¹² Franzosa, E., Traylor, M., Judon, K. M., Guerrero Aquino, V., Schwartzkopf, A. L., Boockvar, K. S., & Dixon, B. E. (2021). Perceptions of Event Notification Following Discharge to Improve Geriatric Care: Qualitative Interviews of Care Team Members from a 2-Site Cluster Randomized Trial. *Journal of the American Medical Informatics Association*. 28(8), 1728-1735. <https://doi.org/10.1093/jamia/ocab074>.

accuracy and efficiency of workflow when using non-device software for administrative support, including configuring the system to display identity information clearly on all screens and printouts at each step of the workflow, providing users with the ability to track orders in the organization's record system, and ensuring users can easily correct accidental clicks, typos, or drop-down menu choices.¹³

In addition, a government staff member noted a lack of available data related to non-device software for the administrative support of a health care facility but emphasized the potential opportunities for software developers to continue developing and propagating this software to have positive impacts on patient health and safety. They added that while there are similar risks to workflow when comparing paper-based processes and software processes to handle administrative tasks, there are mostly positive benefits derived from using software, such as significant reductions in workflow errors, which can prevent unnecessary delays to treatment and care.¹⁴

Changes or additions since last published report: All information is new since the publication of the [2020 Report](#).

B. Maintaining or Encouraging a Healthy Lifestyle

Software functions included in this category are defined in section 3060(a) as intended:

... for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.

Section 520(o)(1)(B) of the FD&C Act.

Impacts to Patient Safety

Changes or additions since last published report: No changes. The analysis of sources referenced in this report identified no new direct impacts to patient safety. This finding is consistent with the [2020 Report](#), which also reported no direct impacts to patient safety.

Benefits and Risks to Health

One study reviewed the impact of using an on-demand digital platform on health-related quality of life as determined by changes to the patient's "Healthy Days" measure. The Healthy Days measure is a health-related quality of life tool developed by the Centers for Disease Control and Prevention (CDC) that asks patients about their general, physical, and mental health as well as any activity limitations over the past 30 days caused by poor physical or mental health. Researchers observed that use of the digital health platform over the course of one month led to a nearly three-day reduction in the number of unhealthy mental health days and a reduction in the overall number of unhealthy mental health days for 61% of users. These reductions were consistent for both clinical patients (those experiencing symptoms of a condition) and subclinical

¹³ Comment submitted to the Development of 21st Century Cures Act Section 3060 Required Report: Request for Input. <https://www.regulations.gov/document/FDA-2018-N-1910-0047>.

¹⁴ Expert Interviews for the 21st Century Cures Act Section 3060 Required Report. See the Appendix for details.

patients (those not yet experiencing symptoms of a condition). Additionally, both clinical and subclinical users experienced statistically significant reductions in the number of days they reported activity limitations.¹⁵

A team of researchers conducted a systematic review of the Medline, Embase, Cumulative Index to Nursing & Allied Health, and Cochrane Controlled Register of Trials databases for randomized controlled trials (RCTs) that evaluated the impact of a specific wearable activity tracker on healthy lifestyles. The meta-analysis included 37 RCTs from 2007 to 2019 and found that using a wearable activity tracker led to statistically significant increases in daily step count. It also found a statistically non-significant or clinically and statistically non-significant decrease and moderate-to-vigorous physical activity as well as statistically significant decreases in weight and a statistically insignificant decrease in self-reported sedentary behavior.¹⁶

One study reviewed the efficacy of two self-guided, smartphone meditation applications, with participants receiving an application that provided four weeks of awareness training (focused on mindful attention) followed by either four weeks of connection training (focused on cultivating positive relationships) or insight training (focused on understanding the nature of self and internal experience). Participants randomized to both interventions reported improvements such as a reduction in psychological distress (e.g., depression, anxiety, stress); an increase in social connection, mindfulness, self-reflection, and self-understanding; decreased rumination (i.e., repetitive negative thinking); and greater defusion (i.e., the ability to achieve psychological distance from internal experiences).¹⁷

One study assessed the effect of a digital health intervention for smoking cessation that combined a mobile application with an FDA-cleared, over-the-counter carbon monoxide breath sensor and human coaching via in-app text messaging. The mobile application provided participants with the ability to log cigarettes, follow trends in their carbon monoxide values, complete educational and preparatory activities, set a quit date, make a quit plan, undertake short-term practice quits, learn about FDA-approved cessation medications, complete daily check-ins upon quitting smoking, and communicate with their coach. The researchers conducted a follow-up assessment three months after the intervention and found that 35.4% achieved seven-day point prevalence abstinence (PPA) and 31.3% of participants achieved 30-day PPA. Additionally, there was a reduction in cigarettes smoked per day among 52.6% of participants,

¹⁵ Shih, E., Aylward, B. S., Kunkle, S., & Graziani, G. (2022). Health-Related Quality of Life Among Members Using an On Demand Behavioral Health Platform: Pilot Observational Study. *JMIR Formative Research*. 6(7), e35352. <https://doi.org/10.2196/35352>.

¹⁶ Ringeval, M., Wagner, G., Denford, J., Paré, G., & Kitsiou, S. (2020). Fitbit-Based Interventions for Healthy Lifestyle Outcomes: Systematic Review and Meta-Analysis. *Journal of Medical Internet Research*. 22(10), e23954. <https://doi.org/10.2196/23954>.

¹⁷ Goldberg, S. B., Imhoff-Smith, T., Bolt, D. M., Wilson-Mendenhall, C. D., Dahl, C. J., Davidson, R. J., & Rosenkranz, M. A. (2020). Testing the Efficacy of a Multicomponent, Self-Guided, Smartphone-Based Meditation App: Three-Armed Randomized Controlled Trial. *JMIR Mental Health*. 7(11), e23825. <https://doi.org/10.2196/23825>.

and among those who completed the final follow-up assessment, 52.8% reduced their cigarettes smoked per day by more than 50%.¹⁸

One study examined the physical and social effects of a mobile fitness app that included social features (e.g., the ability to create groups) where members can view each other's physical activity and interact on a message board. Participants were assigned to teams based on their geographic location and neighborhood, tracked their workouts in the app, and a subset of the participants completed a post-intervention interview. Although the app did not lead to statistically significant changes in walking minutes or walking miles, there was a statistically significant increase in social connectedness (i.e., the feeling of belonging to a group) but a statistically significant decrease in neighborhood cohesion (i.e., a sense of community and connection with the neighborhood). The authors attributed these trends to walking groups relying more on the online connection generated from the app's chat feature as opposed to meeting in person. Additionally, the study revealed that the psychosocial aspects of the app and walking activities motivated participants, helped relieve stress, and increased feelings of connection with their groups, family, and friends.¹⁹

Another study assessed the impact of a digital platform designed to provide health and well-being resources to local community participants and to foster connectivity among them. The digital platform sent automated text messages to participants to assess their well-being and provide access to community-based health and well-being resources (e.g., health information, Coronavirus Disease 2019 (COVID-19) updates, virtual support, well-being tips). Participants received weekly messages to rate their mood from 0-10 and were sent automatically-generated resources from the platform depending on the response (i.e., those reporting a "high" rating of 7-10 received a link to an uplifting resource, those reporting a "low" rating of 0-3 received links to mental health and well-being resources, and those reporting a "medium" mood rating of 4-6 received links to either an uplifting resource or to the resource homepage). The study found that there was no statistically significant difference in mood among those who reported a high mood rating at baseline. However, there was a statistically significant increase in mood among those who reported a low mood rating at baseline.²⁰

Another study evaluated whether an interactive multimedia program designed to enhance accessibility for cancer patients with low literacy could improve health outcomes. The program presented patients with questions and answers on a touchscreen that promoted readability and accessibility (i.e., through larger text offset with color, by reading the questions to the patient, by translating the questions into another language) and allowed patients to generate checklists of issues they wished to discuss with their providers during their clinic visits. Patients who utilized

¹⁸ Marler, J. D., Fujii, C. A., Galanko, J. A., Balbierz, D. J., & Utley, D. S. (2021). Durability of Abstinence After Completing a Comprehensive Digital Smoking Cessation Program Incorporating a Mobile App, Breath Sensor, and Coaching: Cohort Study. *Journal of Medical Internet Research*. 23(2), e25578. <https://doi.org/10.2196/25578>.

¹⁹ Hollander, J. B., Folta, S. C., Graves, E. M., Allen, J. D., & Situ, M. (2021). A Fitness App for Monitoring Walking Behavior and Perception (Runkeeper): Mixed Methods Pilot Study. *JMIR Formative Research*. 5(3), e22571. <https://doi.org/10.2196/22571>.

²⁰ Ortiz, R., Southwick, L., Schneider, R., Klinger, E. V., Pelullo, A., Guntuku, S. C., Merchant, R. M., & Agarwal, A. K. (2021). Improving Mood Through Community Connection and Resources Using an Interactive Digital Platform: Development and Usability Study. *JMIR Mental Health*. 8(2), e25834. <https://doi.org/10.2196/25834>.

the program demonstrated statistically significantly greater knowledge of their diseases and greater increases in self-efficacy, health beliefs, health-related quality of life, and satisfaction with communication compared with the control group, albeit statistically insignificant.²¹

A study of a mobile health (mHealth) app aimed to assess whether it improved diet and physical activity factors in African Americans. Participants reported their diet and physical activity self-regulation (which surveyed participants' strategies for increasing physical activity and their efforts to track their step counts), social support, perceived barriers, daily fruit and vegetable intake, and moderate physical activity per week at baseline and after 28 weeks. After using the app, participants experienced statistically significant improvements in physical activity self-regulation, two subscales of diet self-regulation (i.e., lower fat and calorie intake as well as nutrition tracking), and daily fruit and vegetable intake. Additionally, the study reported a statistically significant reduction in discouragement received from friends when following a healthy diet and in perceived barriers to following a healthy diet.²²

One study examined the effects of a smartphone app targeted at parents and designed to raise awareness of human papillomavirus (HPV) and its prevention, reduce barriers to HPV vaccination, and enable parents to initiate HPV vaccination scheduling and reminders. The app consisted of four components: a content library on HPV and the HPV vaccine, educational modules and testimonials addressing vaccine barriers, a forum for patients to communicate with providers about the vaccine, and a feature to schedule vaccination appointments and receive tailored reminders. Post-intervention surveys of parents revealed that the app increased parents' intentions of getting their child the HPV vaccine (67%) and increased their knowledge (88%) and awareness (88%) of HPV and of the vaccine. Additionally, parents responded on the utility of all four components, with 94% of parents saying the library was useful, 90% of parents saying the educational modules were useful, 73% of parents saying the communication forum was useful, and 75% of parents saying the appointment scheduler was useful.²³

Changes or additions since last published report: New literature. This report presents information on the impact of mobile phone applications and wearable technologies on mental health, smoking cessation, disease education, and vaccine awareness, which are findings not reported in the [2020 Report](#).

²¹ Peipert, J. D., Lad, T., Khosla, P. G., Garcia, S. F., & Hahn, E. A. (2021). A Low Literacy, Multimedia Health Information Technology Intervention to Enhance Patient-Centered Cancer Care in Safety Net Settings Increased Cancer Knowledge in a Randomized Controlled Trial. *Cancer Control: Journal of the Moffitt Cancer Center*. 28, 10732748211036783. <https://doi.org/10.1177/10732748211036783>.

²² Cyriac, J., Jenkins, S., Patten, C. A., Hayes, S. N., Jones, C., Cooper, L. A., & Brewer, L. C. (2021). Improvements in Diet and Physical Activity-Related Psychosocial Factors Among African Americans Using a Mobile Health Lifestyle Intervention to Promote Cardiovascular Health: The FAITH! (Fostering African American Improvement in Total Health) App Pilot Study. *JMIR mHealth and uHealth*. 9(11), e28024. <https://doi.org/10.2196/28024>.

²³ Becker, E. R., Shegog, R., Savas, L. S., Frost, E. L., Coan, S. P., Healy, C. M., Spinner, S. W., & Vernon, S. W. (2022). Parents' Experience With a Mobile Health Intervention to Influence Human Papillomavirus Vaccination Decision Making: Mixed Methods Study. *JMIR Pediatrics and Parenting*. 5(1), e30340. <https://doi.org/10.2196/30340>.

Best Practices to Promote Safety, Education, and Competency

One study elicited perspectives on whether a healthy lifestyle intervention designed for urban users would be feasible and acceptable to rural users. The researchers assembled focus groups and conducted interviews to assess rural opinions of a diet and physical activity mobile health intervention. There were three major themes from these focus groups and interviews: 1) personal technology is feasible and desirable; 2) challenges persist in implementing mHealth lifestyle interventions in rural communities; and 3) successful mHealth interventions should include personal connections, local coaches, and educational opportunities.²⁴

Another study described the development and acceptability of a mobile app designed to promote uptake of HPV vaccination among adolescents. The researchers developing the content for the app conducted preliminary surveys with parents, pediatric clinicians, and adolescents to gather input on the app and elicit recommendations for additional features. During these interviews, 95% of adolescents indicated they would be willing to use an adolescent-health app if they learned about it from a doctor or nurse rather than from their parents (65%), friends (45%), or teachers (25%). Additionally, 75% of adolescents said they would be more willing to trust the information in the app if it were recommended by doctors or nurses versus their parents (60%) or friends (5%). The researchers then developed the mobile app, which provided information regarding and tracking for the three recommended adolescent vaccines (i.e., the HPV vaccine; the tetanus, diphtheria, and acellular pertussis vaccine; and the meningococcal conjugate vaccine) along with brief stories to provide additional vaccine information and target modifiable parental beliefs associated with HPV vaccine uptake. After using the app, parents and adolescents reported favorable opinions of the app, and the most commonly reported benefits were the ability to track their (or their child's) vaccine schedule, to receive information about vaccines, and to receive information about adolescent health.²⁵

Five studies focused their interventions on specific populations to understand the feasibility and impact of digital health interventions:

One of these studies assessed the acceptability and impact of an mHealth intervention designed in partnership with a community of African American churches to promote cardiovascular health and wellness. The app consisted of 10 core multimedia education modules, delivered by health professionals, on cardiovascular health along with interactive diet and physical activity monitoring and social networking via a group sharing board. The researchers worked with the community to design the app, deploy a 10-week intervention, and assess the effectiveness and participant satisfaction with the app. Participant focus groups revealed several themes, including enthusiasm for the usefulness of the application's self-monitoring features, the value of the application's promotion of a healthy lifestyle through easily accessible information, the easy accessibility of a digital platform for the intervention, improved awareness of the long-term

²⁴ Schoenberg, N., Dunfee, M., Yeager, H., Rutledge, M., Pfammatter, A., & Spring, B. (2021). Rural Residents' Perspectives on an mHealth or Personalized Health Coaching Intervention: Qualitative Study With Focus Groups and Key Informant Interviews. *JMIR Formative Research*, 5(2), e18853. <https://doi.org/10.2196/18853>.

²⁵ Teitelman, A. M., Gregory, E. F., Jayasinghe, J., Wermers, Z., Koo, J. H., Morone, J. F., Leri, D. C., Davis, A., & Feemster, K. A. (2020). Vaccipack, A Mobile App to Promote Human Papillomavirus Vaccine Uptake Among Adolescents Aged 11 to 14 Years: Development and Usability Study. *JMIR Nursing*, 3(1), e19503. <https://doi.org/10.2196/19503>

benefits of maintaining a healthy lifestyle, and a positive influence on their relationships with their providers. Participants also offered recommendations to improve the application. Three recommendations were related to incorporating additional functionalities into the app, including displaying visual rewards or a dashboard summary to show progress, implementing automatic syncing with other diet and physical activity applications, and allowing users to tailor the content to their individual circumstances to increase relevance (e.g., personal messages related to specific cardiovascular disease risk factors such as hypertension or diabetes). Another participant recommendation was to add information to the educational modules related to genetic cardiovascular disease risk, and how cardiovascular risks or symptoms differ in women compared with men.²⁶

Another study examined the differences in acceptability and impact of two versions of a weight loss application among a group of rural men. The basic version of the app provided daily, real-time self-monitoring of weight via manual logging, eating, and activity. The enhanced version of the app offered the aforementioned features along with several additional features. These included customizable personalized reports outlining self-monitoring trends and personalized goal setting, daily text messages prompting self-monitoring and providing content on healthy eating and physical activity, access to a private discussion board within the app, and the ability to sync their weight with a smart scale and upload their weight daily in real time. Participants using both the enhanced and basic versions of the app demonstrated high adherence to self-monitoring, including logging a minimum of 800 daily calories or more at least five days a week (73.4% of enhanced app users and 51.6% of basic app users), tracking steps for four or more days per week (87.8% of enhanced app users and 64.6% of basic app users), and self-weighing at least once weekly (64% of enhanced app users and 46.3% of basic app users). After six months, the mean weight loss for enhanced app users was 7.03 kg, with 42.9% losing more than 5% of their body weight, and the mean weight loss for basic app users was 4.14 kg, with 34.2% achieving more than 5% weight loss. The researchers noted that while both versions of the app were successful in promoting weight loss among rural men, the additional intervention components in the enhanced app were important for maintaining sustained engagement.²⁷

A third study, focused on adolescents, compared the acceptability and effects of a passive monitoring intervention of physical activity with an accelerometer and a blinded heart rate monitor to pairing the same passive monitoring intervention with a chatbot software. The software sent daily messages that prompted adolescents to set exercise goals and report exercise progress and provided feedback on goal attainment. At the end of the 20-day study period, the researchers found that participants in the intervention with the chatbot engaged in a statistically significant 20.84 more minutes of daily moderate-to-vigorous physical activity and a statistically nonsignificant 82 fewer minutes of sedentary behavior than the passive monitoring intervention alone. Additionally, 90% of participants assigned to the intervention with the chatbot reported

²⁶ Brewer, L. C., Kumbamu, A., Smith, C., Jenkins, S., Jones, C., Hayes, S. N., Burke, L., Cooper, L. A., & Patten, C. A. (2020). A Cardiovascular Health and Wellness Mobile Health Intervention Among Church-Going African Americans: Formative Evaluation of the FAITH! App. *JMIR Formative Research*, 4(11), e21450. <https://doi.org/10.2196/21450>

²⁷ Eisenhauer, C. M., Brito, F., Kupzyk, K., Yoder, A., Almeida, F., Beller, R. J., Miller, J., & Hageman, P. A. (2021). Mobile Health Assisted Self-Monitoring is Acceptable for Supporting Weight Loss in Rural Men: A Pragmatic Randomized Controlled Feasibility Trial. *BMC Public Health*, 21(1), 1568. <https://doi.org/10.1186/s12889-021-11618-7>.

being “very satisfied” or “mostly satisfied” with the software, and 85% said the software either “helped a great deal” or “helped somewhat” to more effectively track and promote physical activity.²⁸

A fourth study examined the acceptability and efficacy of a home-based mHealth intervention designed to replace sedentary time with light-intensity physical activity in cancer survivors. Two groups of participants received an activity tracker and a commercially available smartphone app, while one of the groups also received health coaching that provided support to patients on identifying exercises and reviewed the importance of goal setting and self-monitoring with participants. Overall, 79% of participants either “agreed” or “strongly agreed” that the activity trackers were easy to use and indicated that they would use them in the future. Additionally, 93% and 83% of participants said the activity tracker made them more aware of the amount of time they spent sitting and that the tracker motivated them to decrease their sedentary time, respectively. While there were no significant differences between groups in total sedentary time, the number of breaks, number of prolonged sedentary bouts, or amount of physical activity, the group who received health coaching had a statistically significant increase in their daily steps of 1,675 steps per day.²⁹

The fifth study used focus groups and one-on-one interviews with pregnant women, postpartum women, and obstetric health care providers to elicit perspectives on the need for a mobile app designed to increase physical activity during pregnancy and postpartum. Two main themes emerged: recognizing physical activity as critical for weight control and the need for evidence-based exercise information. Participants identified multiple app features to address these themes, including an individualized progress tracker, information on appropriate weight gain tailored to each woman’s needs, activities that can improve or mitigate inappropriate weight gain (as well as having these workouts tailored to the time point of pregnancy or postpartum), a community forum, mental health resources, and push notifications to remind users to move. In addition to all of these suggestions for app features, the participants said the developers need to ensure that the app contains safe and evidence-based physical activity guidance.³⁰

Government staff shared statistics from a study noting the widespread use of mHealth apps.¹⁴ The study showed that half of individuals nationwide have one or more mHealth apps on their smartphone and that 80% used an mHealth app within the past year. These mHealth apps provided various functionalities for different patients, with 2020 data showing that 71% used

²⁸ Cushing, C. C., Bejarano, C. M., Ortega, A., Sayre, N., Fedele, D. A., & Smyth, J. M. (2021). Adaptive mHealth Intervention for Adolescent Physical Activity Promotion. *Journal of Pediatric Psychology*. 46(5), 536–546. <https://doi.org/10.1093/jpepsy/jsaa125>.

²⁹ Blair, C. K., Harding, E., Wiggins, C., Kang, H., Schwartz, M., Tarnower, A., Du, R., & Kinney, A. Y. (2021). A Home-Based Mobile Health Intervention to Replace Sedentary Time With Light Physical Activity in Older Cancer Survivors: Randomized Controlled Pilot Trial. *JMIR Cancer*. 7(2), e18819. <https://doi.org/10.2196/18819>.

³⁰ Tinius, R., Duchette, C., Beasley, S., Blankenship, M., & Schoenberg, N. (2021). Obstetric Patients and Healthcare Providers Perspectives to Inform Mobile App Design for Physical Activity and Weight Control During Pregnancy and Postpartum in a Rural Setting. *International Journal of Women's Health*. 13, 405–432. <https://doi.org/10.2147/IJWH.S296310>

apps to track progress on a health-related goal, 52% used apps to decide how to treat an illness or condition, and 51% used apps to discuss their health with their provider.³¹

Furthermore, health information technology (IT) experts emphasized the importance of evaluating mHealth apps to determine whether they are beneficial to patients and whether they provide evidence-based information. While the experts noted that the apps with greater uptake were those recommended by providers (rather than those that were highly rated on app marketplaces), they noted there is a general lack of standards around how these apps should be developed and brought to market as well as a lack of oversight from the companies that host these apps in their marketplace to assess if the apps are safe or beneficial to patients. They said that mHealth app developers should utilize professional interface designers who understand app best practices, human behavior, and cognitive psychology in order to promote safe and effective use of the apps.¹⁴

Changes or additions since last published report: New literature. All information is new since the publication of the [2020 Report](#).

C. Electronic Patient Records

Software functions included in this category are defined in section 3060(a) as intended:

...to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

“(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

“(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

“(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.

Section 520(o)(1)(C) of the FD&C Act.

Impacts to Patient Safety

FDA received three adverse event reports⁹ that could impact safety. The first adverse event was related to an incorrect patient selection for medication refill because an electronic prescribing system did not sort patients by their corresponding health care provider. As a result, a patient residing in another state was selected for the prescription refill. The error was caught by the prescribing pharmacy after speaking to the patient.

The second adverse event involved medication software containing an error that rendered the software unable to differentiate between ongoing home medications and newly filled prescriptions during a patient’s emergency department visit. This error made home medications

³¹ ONC, Individuals’ Access and Use of Patient Portals and Smartphone Health Apps, 2020. <https://www.healthit.gov/data/data-briefs/individuals-access-and-use-patient-portals-and-smartphone-health-apps-2020>. Published in September 2021.

appear as if they were added to the patient's profile as part of their emergency department treatment. Because this is an inaccurate representation of a patient's medication history, as found by the report, it was noted that it may increase the probability of medication errors and negatively impact patient safety. The issue was not resolved by the manufacturer, and the hospital had to use other sources to gather patient medication history.

The third adverse event was related to migration of medication records from one system to another, where the new system did not display the full name of the medication. The study reported that this resulted in incorrect classification of one medication as another, and duplicated the medications listed in a patient's EHR. The issue was resolved through staff education and system layout changes to display a medication's full name to avoid further errors. These mitigating activities may also apply as a best practice for other EHR systems.

Government staff representatives and health IT experts provided key insight on the impact of EHRs on patient safety. Health IT experts noted that medical errors in EHRs could be partially mitigated by involving patient advocates, caregivers, or guardians with patient EHR data and providing greater transparency into clinical decision-making. A government staff representative said that one way to mitigate these errors would be to use a "retract-and-reorder" (RAR) measure, which is the first health IT measure put forth by the National Quality Forum. A RAR examines the rate at which an incorrect medication order is withdrawn and correctly reordered within an EHR system and allows for examination of current workflows to assess incidence rates, patient safety, and health care quality to establish future best practices.³² Since EHRs can impact patient health and safety in situations involving incorrect data entry, which could be caused by difficult-to-use or confusing interfaces, health IT experts emphasized the need for professional interface designers to assist in the development of EHR systems to avoid potentially significant safety problems with the systems.¹⁴

These health IT experts also stressed the need for interoperability within EHR systems to promote efficiency in health care settings. Particularly during the COVID-19 pandemic, EHR systems required rapid response rates and robust resiliency planning, especially in those hospital systems where the volume of patients is higher compared with volumes in smaller clinical settings, which could result in missed notifications through the EHR. This is evident in a study on diagnostic test results follow-up at the Department of Veterans Affairs (VA) health facilities, which revealed that while critical abnormal test results were verbally relayed to physicians in a timely manner, non-critical abnormal test results were submitted through an EHR system. Because physicians received an overwhelming number of EHR notifications each day, these non-critical abnormal results were sometimes lost or missed when communicated to the physician on duty, thus delaying patient notification and timely follow-up care.³³

³² Udeh C, Canfield C, Briskin I, Hamilton AC. (2021). Association between limiting the number of open records in a tele-critical care setting and retract-reorder errors. *Journal of the American Medical Informatics Association*. 28(8),1791-1795. <https://doi.org/10.1093/jamia/ocab072>

³³ SA, Mushtaq U, Zubkoff L, Murphy DR, Bradford A, Singh H. Why Test Results Are Still Getting "Lost" to Follow-up: a Qualitative Study of Implementation Gaps. (2022). *Journal of General Internal Medicine*. 37(1), 137-144. <https://doi.org/10.1007/s11606-021-06772-y>.

Additionally, health IT scholars noted several concerns related to EHRs that could impact patient safety. Of note, they stated that, in addition to a lack of oversight of EHR systems, there are two major issues that pose a risk to patient safety. The first concern relates to the ongoing issue of software security, evidenced by recent ransomware attacks on health care settings, due to a lack of sophisticated, built-in security measures in EHR systems. This issue is especially true for older software or older EHR systems that have not received a recent update, and therefore are at increased risk of being affected by future ransomware attacks. The second concern relates to pharmacy systems, which could input incorrect medication doses, thereby posing a risk to patient safety when the medication is administered.¹⁴

Government staff providing their insight into the positive impacts of EHRs on patient safety reported a drastic reduction in adverse events based on effective implementation of EHR systems for appropriate workflows.¹⁴ For example, the chances for medical error are higher in non-integrated dental record systems compared with integrated EHR systems, the latter of which allow for more comprehensive care.³⁴ As government staff perform their oversight duties, they identified direct correlations between the implementation of functionalities and standards in EHR systems and measurable improvements in patient care and measurable reductions in patient safety risks and adverse events.¹⁴ For example, a recent study showed that physicians can track their patients after a visit to the emergency department by using the EHRs hospital discharge summaries, visit notes, test results, and new diagnoses in their records. Patient tracking most often occurs if the patient had an unusual or complex case (98%), uncertain diagnosis (89%), and/or if there was concern about a potential error in treatment (48%).³⁵

In addition, a recent study noted that examination of EHRs for hospitalized patients, when matched with data from the nursing staff caring for them, can quantify health care delivery strain on nurses and predict patient mortality or even imminent patient discharge based on the EHR data.³⁶ Another study measured the confidence and performance of Doctor of Pharmacy (PharmD) students when using an EHR system to review and process a set of simulated medication orders and to detect errors in the medication orders. These results were compared with a previous cohort of students who completed the study using a paper-based medication order form. Results showed that the medication verification questions embedded in the EHR led to greater confidence in the PharmD students filling the orders compared with those students who used the paper-based order forms.³⁷ A similar study involved assessing hospital

³⁴ Claman, D. B., Molina, J. L., Peng, J., Fischbach, H., & Casamassimo, P. S. (2021). Accuracy of Parental Self-Report of Medical History in a Dental Setting: Integrated Electronic Health Record and Nonintegrated Dental Record. *Pediatric Dentistry*. 43(3), 230–236. <https://pubmed.ncbi.nlm.nih.gov/34172118/>.

³⁵ Villalba C, Burke RC, Gurley K, Dhaliwal G, Grossman S. (2022). Electronic Health Record-Based Patient Tracking By Emergency Medicine Physicians. *AEM Education and Training*. 6(2), e10732. <https://doi.org/10.1002/aet2.10732>.

³⁶ Lee C, Lawson BL, Mann AJ, Liu VX, Myers LC, Schuler A, Escobar GJ. (2022). Exploratory Analysis of Novel Electronic Health Record Variables for Quantification of Healthcare Delivery Strain, Prediction of Mortality, and Prediction of Imminent Discharge. *Journal of the American Medical Informatics Association*. 29(6), 1078-1090. <https://doi.org/10.1093/jamia/ocac037>.

³⁷ Ives, A. L., Tucker, S. R., & Trovato, J. A. (2020). Using Electronic Health Record Technology to Teach Inpatient Medication Order Verification to Pharmacy Students. *American Journal of Pharmaceutical Education*. 84(8), ajpe7534. <https://doi.org/10.5688/ajpe7534>.

performance measures stratified by EHR vendors and found that no particular vendor was associated with high quality across any performance measure, and that hospital performance was, dependent on how the hospital used the EHR.³⁸ Another study conducted in a hospital setting showed that EHR data can be used to predict and reduce the incidence of hospital-acquired pressure injury (HAPrI) in intensive care unit (ICU) patients.³⁹ In contrast, a predictive study looking at automated collection of vital sign data stored in EHRs (e.g., heart rate, systolic blood pressure, respiratory rate, and pulse oximetry) in a pediatric cardiac intensive care unit highlighted that manual collection of vital signs by health care staff may result in fewer data points compared with automated, continuous monitoring of vital signs. As a result, the study authors suggested that automated collection of vital signs for storage in EHRs records could capture more detailed data for acute events and positively impact patient safety through more accurate representation of the patient's condition.⁴⁰

Changes or additions since last published report: New adverse events, literature, and stakeholder input. This report presents information describing new adverse events and issues with EHR data entry and systems security as patient risks as well as interoperability as a way to benefit patient safety, which are findings not reported in the [2020 Report](#).

Benefits and Risks to Health

Government staff provided research findings on the impact of the Office of the National Coordinator (ONC) for Health Information Technology's 2015 EHR certification requirements.¹⁴ The study found that the implementation of new EHR verifications resulted in fewer duplicate lab and imaging tests in both the outpatient and inpatient settings.⁴¹ Moreover, a research study found that having access to a patient's EHR from an acute care visit in an outpatient setting is important as care providers assess the risk of adverse events, especially for elderly patients who see multiple providers. To reduce the number of adverse events related to transition care among elderly patients, the same study developed and implemented standards to organize details from patient care visits and mitigate variations in guidelines to record their EHR data.⁴² Another study showed that during the COVID-19 pandemic a clinical workflow dependent on EHRs improved both physician adherence to frequently changing treatment guidelines and response rate to

³⁸ Holmgren AJ, Kuznetsova M, Classen D, Bates DW. (2021). Assessing Hospital Electronic Health Record Vendor Performance Across Publicly Reported Quality Measures. *Journal of the American Medical Informatics Association*. 28(10), 2101-2107. <https://doi.org/10.1093/jamia/ocab120>

³⁹ Alderden J, Drake KP, Wilson A, Dimas J, Cummins MR, Yap TL. (2021). Hospital Acquired Pressure Injury Prediction in Surgical Critical Care Patients. *BMC Medical Informatics and Decision Making*. 21(1), 12. <https://doi.org/10.1186/s12911-020-01371-z>.

⁴⁰ Lowry AW, Futterman CA, Gazit AZ. (2022). Acute Vital Signs Changes Are Underrepresented By a Conventional Electronic Health Record When Compared With Automatically Acquired Data In a Single-Center Tertiary Pediatric Cardiac Intensive Care Unit. *Journal of the American Medical Informatics Association*. 29(7), 1183-1190. <https://doi.org/10.1093/jamia/ocac033>.

⁴¹ Pylypchuk Y, Johnson C. (2022). New EHR Certification Requirements and Their Association With Duplicate Tests and Images. *Journal of the American Medical Informatics Association*. 29(8), 1391-1399. <https://doi.org/10.1093/jamia/ocac076>.

⁴² Tremoulet, P. D., Shah, P. D., Acosta, A. A., Grant, C. W., Kurtz, J. T., Mounas, P., Kirchoff, M., & Wade, E. (2021). Usability of Electronic Health Record-Generated Discharge Summaries: Heuristic Evaluation. *Journal of Medical Internet Research*. 23(4), e25657. <https://doi.org/10.2196/25657>.

administering medication per the new guidelines, highlighting the potential of EHRs to improve patient outcomes and decrease patient care disparities.⁴³

Another study examined the effectiveness of using messages through a patient's EHR portal and interactive voice recognition calls to promote influenza vaccination. Participants who used an EHR portal were divided into two groups, with one group receiving a message through their patient portal that provided information about upcoming vaccination clinics and offering online vaccination appointment scheduling, while the other group received usual care, either including or not including notification by phone call. Participants who did not use an EHR portal were also divided into two groups, with one group receiving an interactive voice recognition call that elicited patient self-reports of influenza vaccination, and the other group receiving usual care, either including or not including notification by phone call. For users of the EHR portal, the study found that patients receiving an EHR alert through their portal showed a small but statistically significant improvement in influenza vaccination rates compared with those who did not receive a message through the EHR portal. For those who did not use the EHR portal, the study found no statistically significant difference in influenza vaccination rates between those who received the interactive voice recognition call and those receiving usual care.⁴⁴

Several studies examined trends in EHR use and how EHRs were used by patients and providers. One such study explored patient use of EHRs and found that patients are less likely than physicians to utilize EHR systems since they are not typically required to do so to keep up with their conditions. Further, it found that key factors such as chronic conditions, preventive health behaviors, caregiving status, health knowledge, and issue involvement (i.e., how relevant a specific health issue is to a patient) are the greatest influencers in patient use of EHRs.⁴⁵ In one study, a team of researchers assessed data from EHRs within U.S. Veterans Health Administration to identify and examine clinically significant connections between diagnostic, care process, and outcome variables among patients who had ordered hearing aids. The study found that patient use of EHRs to log self-reported outcomes (in conjunction with demographic data, diagnostic procedure codes, and hearing aid battery orders), can help uncover new hearing aid use patterns and audiological outcomes for patients with hearing loss. Additionally, the study found that the presence of certain comorbid conditions (e.g., Parkinson's disease, diabetes) and prior inpatient admissions were associated with statistically significant lower hearing aid use persistence. From their study, the researchers note that leveraging EHR data for research can serve as a supplement to population-based and epidemiological audiology research and provide

⁴³ Sangal, R. B., Liu, R. B., Cole, K. O., Rothenberg, C., Ulrich, A., Rhodes, D., & Venkatesh, A. K. (2022). Implementation of an Electronic Health Record Integrated Clinical Pathway Improves Adherence to COVID-19 Hospital Care Guidelines. *American Journal of Medical Quality*. 37(4), 335–341. <https://doi.org/10.1097/JMQ.000000000000036>.

⁴⁴ Wijesundara, J. G., Ito Fukunaga, M., Ogarek, J., Barton, B., Fisher, L., Preusse, P., Sundaresan, D., Garber, L., Mazor, K. M., & Cutrona, S. L. (2020). Electronic Health Record Portal Messages and Interactive Voice Response Calls to Improve Rates of Early Season Influenza Vaccination: Randomized Controlled Trial. *Journal of Medical Internet Research*. 22(9), e16373. <https://doi.org/10.2196/16373>.

⁴⁵ Agrawal L, Ndabu T, Mulgund P, Sharman R. (2021). Factors Affecting the Extent of Patients' Electronic Medical Record Use: An Empirical Study Focusing on System and Patient Characteristics. *Journal of Medical Internet Research*. 23(10), e30637. <https://doi.org/10.2196/30637>.

important insights into the various clinical practice patterns, audiologic outcomes, and factors impacting hearing and hearing-related health conditions.⁴⁶

A literature review found that data plausibility (i.e., accuracy) was the most commonly represented quality problem associated with social determinants of health data in EHRs. The study also found that data quality problems result in bias or validity issues and that misclassification bias (i.e., incorrect assignment) was the most frequently identified validity issue. The same study found that mitigation strategies to avoid these issues include: including incomplete data in analyses, using indirect estimation to increase the completeness of datasets and avoid casewise deletion, relying on multiple sources, using validated software tools, and selecting patient addresses (e.g., most recent, birth) thoughtfully.⁴⁷

On a larger scale, using aggregated and de-identified EHR data collected on the same platform from geographically dispersed hospital systems can provide the opportunity for epidemiological surveillance, as demonstrated by a study that rapidly collected data from a large cohort in order to study asthma prevalence using both geographic and demographic data.⁴⁸

A recent retrospective analysis assessed the feasibility of using EHR data to collect and analyze treatments and outcomes of hospitalized patients. The study used seasonal influenza as a use case and leveraged FDA's Sentinel System (a medical product safety surveillance system that collects EHR data to support FDA decision-making) to gather the EHR data. The study found that patients with delayed treatment times (i.e., more than two days) or no treatment experienced more comorbidities and higher rates of cardiovascular and other diseases as a result of their infections than patients treated in a timely manner (i.e., within two days). The researchers note that this methodology can be extended to provide useful information to FDA on patient care, patient characteristics, and medication use.⁴⁹

Changes or additions since last published report: New literature and stakeholder input. This report presents information describing how EHRs can collectively benefit patient health across health care systems, automation of EHR systems, and opportunities to use EHRs for predictive or disease surveillance research, which are findings not reported in the [2020 Report](#).

⁴⁶ Saunders, G. H., Dillard, L. K., Zobay, O., Cannon, J. B., & Naylor, G. (2021). Electronic Health Records As a Platform for Audiological Research: Data Validity, Patient Characteristics, and Hearing-Aid Use Persistence Among 731,213 U.S. Veterans. *Ear and Hearing*, 42(4), 927–940. <https://doi.org/10.1097/AUD.0000000000000980>.

⁴⁷ Cook, L. A., Sachs, J., & Weiskopf, N. G. (2021). The Quality of Social Determinants Data in the Electronic Health Record: A Systematic Review. *Journal of the American Medical Informatics Association*, 29(1), 187–196. <https://doi.org/10.1093/jamia/ocab199>.

⁴⁸ Tarabichi, Y., Goyden, J., Liu, R., Lewis, S., Sudano, J., & Kaelber, D. C. (2020). A Step Closer to Nationwide Electronic Health Record-Based Chronic Disease Surveillance: Characterizing Asthma Prevalence and Emergency Department Utilization from 100 Million Patient Records through a Novel Multisite Collaboration. *Journal of the American Medical Informatics Association*, 27(1), 127–135. <https://doi.org/10.1093/jamia/ocz172>.

⁴⁹ Fuller, C. C., Cosgrove, A., Sands, K., Miller, K. M., Poland, R. E., Rosen, E., Sorbello, A., Francis, H., Orr, R., Dutcher, S. K., Measer, G. T., & Cocoros, N. M. (2022). Using Inpatient Electronic Medical Records to Study Influenza For Pandemic Preparedness. *Influenza and Other Respiratory Viruses*, 16(2), 265–275. <https://doi.org/10.1111/irv.12921>.

Best Practices to Promote Safety, Education, and Competency

Government staff emphasized that EHRs should be interoperable with administrative systems, patient applications, and other compiled data sources to maximize patient benefit and minimize patient risk¹⁴. For example, researchers conducted focus groups with staff at Federally Qualified Health Centers (FQHC) who described that the electronic patient management system used by front office staff to schedule appointments was separate from the EHR system used by clinical staff, and while staff had access to both systems, there were often information gaps regarding patients' disability accommodation needs between administrative and clinical staffs. Researchers noted that integrating the patient management system and EHR could improve patient care and help administrative staff with visit planning.⁵⁰

Health IT experts also recognized interoperability as a key best practice for EHRs, noting the potential for faster clinical decision-making, expediting treatment, and improving quality outcomes over time^{11, 14}. Another study exploring EHR interoperability challenges at FQHCs providing COVID-19 testing, care, and vaccines found that poor data reporting guidelines and missing patient identifiers, among other data, prevented EHRs from including complete patient information. The authors noted these challenges as resulting in “significant barriers to real-time data analytics and efforts to improve health outcomes” for patients.⁵¹ In another study researchers developed an add-on application to EHR systems that assessed efficiency of ambulance staff who managed chronic obstructive pulmonary disease (COPD) cases. The add-on application allowed better presentation of EHR data and intuitive navigation from different displays containing that data in order to decrease cognitive load on ambulance staff. Results from the study found that those using these integrated displays completed more care tasks for their COPD patients (81% tasks completed) compared with those who did not have the add-on application (48% tasks completed), and it was statistically significant.⁵² Additionally, researchers implemented an EHR-integrated application to automate the collection and organization of patient data from various sources and applications for tumor board meetings and found that the integrated application decreased manual preparation time by 45%, allowing providers additional time to review the patient cases themselves.⁵³

⁵⁰ Mudrick, N. R., Breslin, M. L., Nielsen, K. A., & Swager, L. C. (2020). Can Disability Accommodation Needs Stored in Electronic Health Records Help Providers Prepare For Patient Visits? A Qualitative Study. *BMC Health Services Research*. 20(1), 958. <https://doi.org/10.1186/s12913-020-05808-z>.

⁵¹ Romero L, Carneiro PB, Riley C, Clark H, Uy R, Park M, Mawokomatanda T, Bombard JM, Hinckley A, Skapik J. (2021). Building Capacity of Community Health Centers to Overcome Data Challenges with the Development of an Agile COVID-19 Public Health Registry: A Multistate Quality Improvement Effort. *Journal of the American Medical Informatics Association*. 29(1):80-88. <https://doi.org/10.1093/jamia/ocab233>.

⁵² Curran, R. L., Kukhareva, P. V., Taft, T., Weir, C. R., Reese, T. J., Nanjo, C., Rodriguez-Loya, S., Martin, D. K., Warner, P. B., Shields, D. E., Flynn, M. C., Boltax, J. P., & Kawamoto, K. (2020). Integrated Displays to Improve Chronic Disease Management in Ambulatory Care: A SMART on FHIR Application Informed By Mixed-Methods User Testing. *Journal of the American Medical Informatics Association*. 27(8), 1225–1234. <https://doi.org/10.1093/jamia/ocaa099>.

⁵³ Nobori, A., Jumniensuk, C., Chen, X., Enzmann, D., Dry, S., Nelson, S., & Arnold, C. W. (2022). Electronic Health Record-Integrated Tumor Board Application to Save Preparation Time and Reduce Errors. *JCO Clinical Cancer Informatics*. 6, e2100142. <https://doi.org/10.1200/CCI.21.00142>.

However, health IT experts also noted that while interoperability promotes transparency and can improve decision-making, it must have strong privacy protections to safeguard patient data at a time when digital data sources have become more prevalent across all health care settings.¹⁴ A public commenter recommended that health care organizations assess cybersecurity risks for non-device software such as EHRs, which are prone to cybersecurity attacks.¹³¹⁴

One study assessed the steps and time needed to incorporate patient decision aids, or tools that provide patients with evidence-based information and allow patients and providers to discuss care options, into EHR systems. The authors of the study demonstrated that it takes up to 18 months and a six-step process to integrate patient decision aids into EHR systems, thereby delaying patients' access to their EHR data to make health decisions. The researchers also note several facilitators and barriers to the integration of patient decision aids in EHRs. They found that having clinical champions (providers who led investigation of the integration and facilitated discussions between their colleagues and the EHR vendors) on site, including an EHR expert on the implementation team, leveraging evidence-based standards during the setup and maintenance, and opting to not collect protected health information from the patient decision aids all facilitated a smoother integration process. By contrast, the researchers said that utilizing third-party patient decision aids (and not owning the control of the product development process), delays and functionality issues stemming from EHR system updates, and unexpected software-related problems during troubleshooting were the primary barriers to implementation.⁵⁴

Government staff provided a study that examined how different physicians and practice characteristics affect the frequency of using EHRs to report public health information to public health agencies.¹⁴ The study found that although overall rates of public health information reporting were low (approximately one in ten office-based physicians), the use of certified health IT (i.e., EHR technology that is certified by the Office of the National Coordinator for Health Information Technology (ONC) and meets requirements for physicians to participate in the HHS payment program) by primary care physicians was associated with more frequent electronic public health reporting to public health agencies. Physicians using certified health IT were also found to be more likely to record social and behavioral determinants of health than physicians who did not use these EHRs. The authors note that this information from physicians is important to enhancing public health surveillance and identifying populations that need greater assistance.⁵⁵

Health IT scholars noted that both the EHR technology itself and how it is used may impact patient safety and result in negative health consequences.¹⁴ For example, a recent study reported issues with EHR software configuration resulting in up to 40% of patients with positive fecal occult blood tests, indicative of colorectal cancer, not being reported to their physicians as

⁵⁴ Scalia, P., Ahmad, F., Schubbe, D., Forcino, R., Durand, M. A., Barr, P. J., & Elwyn, G. (2021). Integrating Option Grid Patient Decision Aids in the Epic Electronic Health Record: Case Study at 5 Health Systems. *Journal of Medical Internet Research*. 23(5), e22766. <https://doi.org/10.2196/22766>.

⁵⁵ Richwine C., Dustin, C., & Patel, V. (August 2022). Electronic Public Health Reporting & Recording of Social & Behavioral Determinants of Health Among Office-Based Physicians, 2019. ONC Data Brief, no.60. Office of the National Coordinator for Health Information Technology: Washington DC. <https://www.healthit.gov/data/data-briefs/electronic-public-health-reporting-recording-social-behavioral-determinants-health>.

expected in the automated EHR system.⁵⁶ When the issue was corrected, physician follow-up with patients increased significantly. Health IT scholars recommended several strategies to facilitate safe use of EHRs including: utilizing Safety Assurance Factors for EHR Resilience (SAFER) Guides,⁵⁷ a set of nine guides published by ONC allowing health care organizations to implement safety measures related to EHRs, during the development and use of EHRs; enabling all EHR systems to identify and measure problems as they related to patient safety or measurement concepts to mitigate risk as part of the National Quality Forum’s report “Measure Sets and Measurement Systems: Multistakeholder Guidance for Design and Evaluation;”⁵⁸ and making concerted efforts to encourage implementation and adoption of EHR best practices for software safety in addition to dissemination and education of those best practices in various health care settings.¹⁴

Health IT scholars emphasized that oversight and quality assurance practices on EHR systems are not always well implemented.¹⁴ For example, the FDA Safety Innovation Act (FDASIA) Health IT Report⁵⁹ states that adverse events related to EHRs should be reported to a national patient safety center, but because the practice is not yet implemented, there is no aggregated database for safety event reports.⁶⁰

A study in a secondary school setting found that athletic trainers identified a lack of time as a barrier to completing care documentation in EHRs. While it was unclear whether using paper records or EHRs would result in greater efficiency, the researchers recommended leveraging training and education to rectify patient care documentation challenges.⁶¹ Government staff noted that interface design, professional societies, continuing education partners, and other specialty societies with access to clinical staff are important avenues for education on these digital tools, in addition to training with specific EHR systems relevant to individual health care settings.¹⁴

Health IT scholars however, noted that education alone is not the most effective intervention for improving implementation of EHR best practices, and they recommended conducting formal evaluations to gauge user understanding of safe use of EHR systems in addition to developing and disseminating training specific to the user’s health care organization.¹⁴ A study assessing student nurses’ entries in a simulated EHR system during their training found statistically

⁵⁶ Singh, H., Wilson, L., Petersen, L.A. et al. (2009). Improving Follow-Up of Abnormal Cancer Screens Using Electronic Health Records: Trust But Verify Test Result Communication. *BMC Medical Informatics and Decision Making*. 9(49). <https://doi.org/10.1186/1472-6947-9-49>.

⁵⁷ ONC. SAFER Guides. <https://www.healthit.gov/topic/safety/safer-guides>.

⁵⁸ National Quality Forum. Measure Sets and Measurement Systems: Multistakeholder Guidance for Design and Evaluation. https://www.qualityforum.org/Publications/2020/07/Measure_Sets_and_Measurement_Systems_Multistakeholder_Guidance_for_Design_and_Evaluation.aspx.

⁵⁹ FDA. FDASIA Health IT Report. <https://www.fda.gov/about-fda/cdrh-reports/fdasia-health-it-report>.

⁶⁰ Singh, H., Classen, D. C., & Sittig, D. F. (2011). Creating an Oversight Infrastructure For Electronic Health Record-Related Patient Safety Hazards. *Journal of Patient Safety*. 7(4), 169–174. <https://doi.org/10.1097/PTS.0b013e31823d8df0>.

⁶¹ Kasamatsu, T. M., Nottingham, S. L., Eberman, L. E., Neil, E. R., & Welch Bacon, C. E. (2020). Patient Care Documentation in the Secondary School Setting: Unique Challenges and Needs. *Journal of Athletic Training*, 55(10), 1089–1097. <https://doi.org/10.4085/1062-6050-0406.19>.

significant improvements between their first and second assignments and between the second and fourth assignments indicating that training students on EHRs improved their critical thinking skills and readiness prior joining the workforce.⁶² In another study, interns in the intensive care unit who completed a simulated EHR-based learning activity showed decreased variability in their EHR use and increased their efficiency in locating patient information.⁶³

Health IT scholars noted that the use of EHRs involves many stakeholders working together.¹⁴ A study also showed that it is essential that stakeholders, such as vendors, health care providers, health care organizations, health IT departments, and public and private agencies collaborate in implementing best practices for EHR systems to promote patient safety and health IT infrastructure.⁶⁴

Changes or additions since last published report: New literature and stakeholder input. This report presents information describing strategies to monitor and correct inaccurate patient information, data entry errors, or other risks to patient safety; strategies to educate health care providers on and facilitate the use of EHRs; and opportunities to use EHRs for disease surveillance, which are findings not reported in the [2020 Report](#).

D. Transferring, Storing, Converting Formats, or Displaying Clinical Laboratory Test or Other Device Data and Results

Software functions included in this category are defined in section 3060(a) as intended:

...for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings.

Section 520(o)(1)(D) of the FD&C Act.

Impacts to Patient Safety

FDA received three adverse event reports⁹ related to incorrect results being transmitted from software. The first event involved a laboratory's data management software submitting incorrect results to the laboratory's information system, although these incorrect results were not released outside of the laboratory. A second event displayed the wrong patient data and the wrong time the test was done, although these results did not reach the patient. Neither report cites any impact to patient safety resulting from these issues. A third event produced two tests with the incorrect

⁶² Everett-Thomas, R., Joseph, L., & Trujillo, G. (2021). Using Virtual Simulation and Electronic Health Records to Assess Student Nurses' Documentation and Critical Thinking Skills. *Nurse Education Today*. 99, 104770. <https://doi.org/10.1016/j.nedt.2021.104770>.

⁶³ Miller, M. E., Scholl, G., Corby, S., Mohan, V., & Gold, J. A. (2021). The Impact of Electronic Health Record-Based Simulation During Intern Boot Camp: Interventional Study. *JMIR Medical Education*. 7(1), e25828. <https://doi.org/10.2196/25828>.

⁶⁴ Sittig, D. F., Belmont, E., & Singh, H. (2018). Improving the Safety of Health Information Technology Requires Shared Responsibility: It is Time We All Step Up. *Healthcare*. 6(1), 7–12. <https://doi.org/10.1016/j.hjdsi.2017.06.004>.

date of admission and positivity. Although these results did not reach the clinicians or the patients, the error could have resulted in misassociation of patient records.

FDA received one adverse event report⁹ related to a malfunction in image and information management software. The malfunction led to the software failing to upload a patient report and causing the patient report to be inaccessible, which could have led to delays in patient treatment or diagnosis.

FDA received one adverse event report⁹ related to a malfunction in cardiovascular record management software. The software enables clinicians to review diagnostic and non-diagnostic quality images, access their patients' complete cardiovascular records, generate and distribute reports, and store this information in a database. The malfunction caused a patient's heart valve measurements to be mapped incorrectly in the physician-generated reports, which could have led to delays in patient treatment or diagnosis.

FDA received one adverse event report⁹ related to a laboratory software solution providing data management and workflow management functionality, which displayed a known bug impacting culture-workup workflow. A software upgrade was recommended, but it was unable to alter the protocol length as required. As a result, samples were received and processed per the correct protocol length while the system was online, but some samples did not follow the required protocol length when the system was offline. The report did not cite any impact to patient safety resulting from this issue.

Changes or additions since last published report: All information is new since the publication of the [2020 Report](#).

Benefits and Risks to Health

One study emphasized the value of procuring accurate data from diabetes devices to monitor self-management behavior and the glycemic responses of diabetes patients for research purposes. The researchers demonstrated the usability and feasibility of employing off-the-shelf software to retrieve raw personal diabetes device data in formats usable for research. Given the results of the study, the researchers advocated replacing manual data collection, which the researchers note is laborious and prone to data entry errors and misreporting, with clinical download software as the standard for the study of diabetes self-management in order to better understand what self-management behaviors and patient characteristics are correlated with successful outcomes.⁶⁵

In another study, a group of computer scientists developed a platform that supports access to medical device data in real-time and deployed multiple applications within a large health care system, including a medical device dashboard, to find and identify essential information (e.g., device name, location, vendor). After deploying the applications, the team found that the

⁶⁵ Faulds, E. R., Militello, L. K., Tubbs-Cooley, H., & Happ, M. B. (2020). Evaluating Feasibility of Personal Diabetes Device Data Collection for Research. *Nursing Research*. 69(6), 476–482. <https://doi.org/10.1097/NNR.0000000000000464>.

dashboard increased troubleshooting efficiency to minimize downtimes and reduced the troubleshooting workflow time by six times compared with other software.⁶⁶

Another study focused on the development of a platform to improve the efficiency and efficacy of clinical interactions with patients with Parkinson's disease. The platform integrates information from EHRs and patient-reported outcome data and translates them into modular displays to facilitate easy integration into clinical workflows and provide actionable information. When tested, 83% of patients reported that the platform helped facilitate communication with their clinicians, and 65% of patients reported that it helped them better understand their disease trajectory and their clinician's recommendations. Additionally, 75% of clinicians reported that the platform helped them better understand their patients' disease course, 87% of clinicians reported that it supported clinical care recommendations, and 81% of clinicians reported that it helped them communicate with patients.⁶⁷

One study examined the differences in group diagnostic performance and clinician preferences between clinicians using a conventional two-dimensional, non-immersive virtual reality display and a full-immersive virtual reality display in group diagnosis meetings. Researchers formed subgroups from a larger group of 22 medical trainees and had each group review three congenital heart disease cases using each of the display methods and scored each group's diagnostic accuracy. The diagnostic performance for groups using the full-immersive virtual reality display was found to be 54.49% more accurate than the groups using conventional display and 146.82% more accurate than the groups using non-immersive virtual reality display while also being the display preferred by 68% of participants. Additionally, the authors note that the application of the fully immersive virtual reality display has supported improved diagnostic accuracy in group discussions related to congenital heart disease and can improve collaborative performance among clinicians.⁶⁸

Changes or additions since last published report: All information is new since the publication of the [2020 Report](#).

Best Practices to Promote Safety, Education, and Competency

A team of researchers noted that major challenges to the adoption of digital pathology are the transmission, storage, retrieval, and uniform clinical diagnosis using algorithms from slides or images. To overcome these challenges, the researchers developed a prototype solution that relies on the public blockchain infrastructure and established non-fungible token standards to reduce

⁶⁶ Choi, H., Lor, A., Megonegal, M., Ji, X., Watson, A., Weimer, J., & Lee, I. (2021). VitalCore: Analytics and Support Dashboard for Medical Device Integration. ...*IEEE...International Conference on Connected Health: Applications, Systems and Engineering Technologies*. *IEEE International Conference on Connected Health: Applications, Systems and Engineering Technologies*, 2021, 82–86. <https://doi.org/10.1109/chase52844.2021.00016>.

⁶⁷ Brown, E. G., Schleimer, E., Bledsoe, I. O., Rowles, W., Miller, N. A., Sanders, S. J., Rankin, K. P., Ostrem, J. L., Tanner, C. M., & Bove, R. (2022). Enhancing Clinical Information Display to Improve Patient Encounters: Human-Centered Design and Evaluation of the Parkinson Disease-BRIDGE Platform. *JMIR Human Factors*, 9(2), e33967. <https://doi.org/10.2196/33967>.

⁶⁸ Kim, B., Loke, Y. H., Mass, P., Irwin, M. R., Capeland, C., Olivieri, L., & Krieger, A. (2020). A Novel Virtual Reality Medical Image Display System for Group Discussions of Congenital Heart Disease: Development and Usability Testing. *JMIR Cardio*, 4(1), e20633. <https://doi.org/10.2196/20633>.

the costs of storage and transmission and to maintain file integrity. The team leveraged the Interplanetary File System that allows slides or images to be transmitted without being compressed for storage purposes while maintaining high performance and providing record-keeping whenever files are modified. The researchers suggest that following such methods will promote greater adoption of digital pathology, reduce the cost of maintaining a digital pathology infrastructure, and improve the speed of diagnosis.⁶⁹

Another team discussed their experiences developing a clinical data interoperability services module that leveraged an HL7 Fast Healthcare Interoperability Resources application programming interface. The team shared multiple lessons learned about their experience, including engaging leadership and IT staff early in the process to obtain technical unity for development, testing, and integration; establishing linkages to institutional source systems to limit privacy risks and properly manage data permissions; and utilizing active support methods such as education seminars, walk-in clinics, conference calls to field questions, receive feedback and suggestions from users, and make the implementation process more efficient.⁷⁰

One study evaluated the ability of an augmented-reality visualization platform to improve patient education for neurosurgery patients. The study noted that better-educated patients can better manage their care and that the use of virtual and augmented reality in preoperative patient education can lessen preoperative anxiety, improve postoperative satisfaction, and improve clinical outcomes. The researchers had 24 patients use the augmented reality visualization platform concurrently with a neurosurgeon and complete a survey after use. All participants either strongly agreed (79.2%) or agreed (20.8%) that using the platform improved their understanding of their condition, while 95.8% of patients either strongly agreed (66.7%) or agreed (29.7%) that they felt more comfortable with their proposed treatment options after the experience.⁷¹

Changes or additions since last published report: All information is new since the publication of the [2020 Report](#).

E. Certain Clinical Decision Support

Software functions included in this category are defined in section 3060(a):

...unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

⁶⁹ Subramanian, H., & Subramanian, S. (2022). Improving Diagnosis Through Digital Pathology: Proof-of-Concept Implementation Using Smart Contracts and Decentralized File Storage. *Journal of Medical Internet Research*. 24(3), e34207. <https://doi.org/10.2196/34207>.

⁷⁰ Cheng, A. C., Duda, S. N., Taylor, R., Delacqua, F., Lewis, A. A., Bosler, T., Johnson, K. B., & Harris, P. A. (2021). REDCap on FHIR: Clinical Data Interoperability Services. *Journal of Biomedical Informatics*. 121, 103871. <https://doi.org/10.1016/j.jbi.2021.103871>.

⁷¹ Lee, J. J., Klepcha, M., Wong, M., Dang, P. N., Sadrameli, S. S., & Britz, G. W. (2022). The First Pilot Study of an Interactive, 360° Augmented Reality Visualization Platform for Neurosurgical Patient Education: A Case Series. *Operative Neurosurgery (Hagerstown, Md.)*. 23(1), 53–59. <https://doi.org/10.1227/ons.000000000000186>.

(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

Section 520(o)(1)(E) of the FD&C Act.

Impacts to Patient Safety

Numerous studies examined whether incorporating CDS software into EHRs improved adherence to guideline-based treatment for various conditions.

The first study utilized best practice alerts in an EHR to increase the use of guideline-directed medical therapy to treat atherosclerotic cardiovascular disease. The alerts recommended that health care providers follow guidelines established by major U.S. medical societies and prescribe moderate- to high-intensity statins and antithrombotic agents to patients and led to a statistically significant increase in statin use from 67.3% to 71.3% and a statistically significant increase in antithrombotic use from 75.3% to 78.4% after the intervention.⁷²

A second study evaluated the effect of a CDS tool designed to reduce unnecessary blood transfusions and standardize inpatient blood transfusion practices. The tool, which was implemented in a tertiary health system's EHR system, presented health care providers with blood transfusion guidelines published by the Association for the Advancement of Blood & Biotherapies and notified providers when they ordered red blood cell units outside of the recommended guidelines. Use of the CDS tool led to an increase in the percentage of guideline-indicated transfusions from 43.6% to 54.2%.⁷³

A third study evaluated whether the use of illness-specific note templates improved adherence to a hospital's infant sepsis treatment guidance, which recommends that infants at high risk for sepsis (i.e., infants less than 29 days old or infants between 29 and 60 days of age and who are ill or have concerning laboratory findings) be admitted to the hospital and receive a maximum of 36 hours of antibiotics. The illness-specific note templates included the prepopulated phrase "Cultures will be 36 hours at [insert time] on [insert date]" to encourage providers to adhere to

⁷² Vani, A., Kan, K., Iturrate, E., Levy-Lambert, D., Smilowitz, N. R., Saxena, A., Radford, M. J., & Gianos, E. (2020). Leveraging Clinical Decision Support Tools to Improve Guideline-Directed Medical Therapy in Patients With Atherosclerotic Cardiovascular Disease at Hospital Discharge. *Cardiology Journal*. 10.5603/CJ.a2020.0126. <https://doi.org/10.5603/CJ.a2020.0126>.

⁷³ Ikoma, S., Furukawa, M., Busuttill, A., Ward, D., Baldwin, K., Mayne, J., Clarke, R., & Ziman, A. (2021). Optimizing Inpatient Blood Utilization Using Real-Time Clinical Decision Support. *Applied Clinical Informatics*. 12(1), 49–56. <https://doi.org/10.1055/s-0040-1721779>.

the hospital's treatment guidance. The researchers intended the CDS tool to improve adherence by decreasing the percentage of patients who received more than 30 hours of administered antibiotic doses and increasing documentation of the 36-hour phrase. The 36-hour phrase is a statement in an EHR anticipating discontinuance of antibiotics after 36 hours to align with clinical practice guideline-recommendations. Over the course of 33 months, the percentage of patients who received more than 30 hours of antibiotic treatment decreased from 75.6% to 62% and documentation of the 36-hour phrase within clinician notes increased from 4.9% to 75.6%. The researchers note that there was no change in length of stay and there were no reported readmissions following this intervention.⁷⁴

Changes or additions since last published report: New literature. This report identified new evidence describing the impact of software functions intended for certain CDS on medication use, unnecessary treatments, and adherence to treatment guidelines, which are findings not reported in the [2020 Report](#).

Benefits and Risks to Health

One retrospective study examined the effect of implementing a CDS order panel on the rate of inappropriate azithromycin prescriptions, which was a composite metric that included azithromycin prescriptions with an inappropriate indication, unnecessary prescription, excessive or insufficient treatment duration, or inappropriate dosage. The order panel provided real-time education and guidance on appropriate use of azithromycin (i.e., use that followed institutional and FDA guidelines and that was being prescribed to treat bronchitis, sinusitis, community-acquired pneumonia, sexually transmitted infections, and mycobacterium avium complex prophylaxis) at the time of order entry, as well as recommended potential alternatives based on the patient's condition. Following implementation, inappropriate azithromycin prescriptions decreased from 81.4% to 68.8%, unnecessary prescriptions decreased from 67.8% to 55.9%, and prescriptions with inappropriate indications decreased from 69.7% to 61.2%.⁷⁵

Two studies examined the impact of CDS tools on smoking/tobacco cessation. One study examined the utilization and effectiveness of a CDS tool to facilitate patient referrals to smoking cessation services among patients at a plastic surgery clinic and a vascular surgery clinic. The tool was designed as a series of conditional statements for providers to assess smoking status and desire for treatment and generated referral orders or a group therapy flyer if the patient indicated to their provider that they wished to receive treatment. Researchers found that there were no smoking cessation referrals at the plastic surgery clinic or the vascular surgery clinic preintervention but that health care providers used the CDS tool for 95% of patient encounters at the plastic surgery clinic and 50.3% of patient encounters at the vascular surgery clinic. From

⁷⁴ Bauer, S. C., Kaepler, C., Soung, P., Porada, K., Bushee, G., & Havens, P. L. (2021). Using Electronic Health Record Tools to Decrease Antibiotic Exposure in Infant Sepsis Evaluation. *Hospital Pediatrics*. 11(9), 936–943. <https://doi.org/10.1542/hpeds.2021-005883>.

⁷⁵ May, A., Hester, A., Quairola, K., Wong, J. R., & Kandiah, S. (2021). Impact of Clinical Decision Support on Azithromycin Prescribing in Primary Care Clinics. *Journal of General Internal Medicine*. 36(8), 2267–2273. <https://doi.org/10.1007/s11606-020-06546-y>

these encounters, 16.1% and 30.0% of eligible patients at the plastic surgery clinic and vascular surgery clinic, respectively, accepted treatment referrals.⁷⁶

A second study implemented a CDS tool that provided a closed-loop referral pathway (i.e., the sending provider receives a report from the receiving provider after they meet with the patient) between the provider's EHR and a tobacco addiction support treatment service. Upon the provider noting a patient's tobacco use history in their EHR, the CDS tool would automatically generate a referral to tobacco addiction support treatment services that the provider could discuss with the patient and sign if appropriate. The CDS tool also provided an option to generate an after-visit summary to educate patients on the services and what to expect after the referral. The study found that the CDS tool led to 18% of the 1,790 patients electronically referred accepting follow-up services, with 55% of those who accepted follow-up services accepting nicotine replacement therapy.⁷⁷

One study examined how recommendations from a CDS tool could improve the health-related quality of life of lung cancer patients. The study had patients complete questionnaires to self-report their symptoms and one group of patients had their responses inputted into the CDS tool. The CDS tool collected data from patients and from their medical records (e.g., drug allergies, cancer treatment, weight, comorbidities, medications) and utilized symptom management algorithms to generate a summary report for providers. The summary report showed providers the patient's symptom severity, cancer treatment received, supportive care medications taken, alcohol use, drug allergies, and recommendations (including medication adjustments and referrals). Compared with patients who only self-reported their symptoms, the addition of the CDS tool improved clinical management of the study's target symptoms (i.e., pain, anxiety, depression, fatigue, and breathing difficulties), but did not lead to a statistically significant difference in health-related quality of life.⁷⁸

Another study conducted interviews with clinicians to elicit perspectives on the utility of a CDS tool to support chronic non-cancer pain management. The tool displayed information about a patient's current and past treatments, potential new treatment options, risks of potential new treatment options (e.g., opioid use disorder), and trends in symptoms over time. The interviewees expressed optimism that the CDS tool would be useful to support discussions about treatment planning and aggregate critical information from EHRs (e.g., past, current, and potential future treatments). However, the interviewees noted that they were skeptical about the accuracy and relevancy of the underlying EHR data and expressed concern over whether they would have sufficient time to use the tool. To mediate some of their concerns and further improve the tool,

⁷⁶ Stonesifer, C., Crusco, S., & Rajupet, S. (2021). Improving Smoking Cessation Referrals Among Elective Surgery Clinics Through Electronic Clinical Decision Support. *Tobacco Prevention & Cessation*, 7, 14.

<https://doi.org/10.18332/tpc/131823>

⁷⁷ Khanna, N., Klyushnenkova, E., Rao, V., Siegel, N., & Wolfe, S. (2021). Electronic Referrals to the Tobacco Quitline: Implementation Strategies in a Large Health System to Optimize Delivery of Tobacco Cessation to Patients. *Translational Behavioral Medicine*, 11(5), 1107–1114. <https://doi.org/10.1093/tbm/ibaa094>

⁷⁸ Cooley, M. E., Mazzola, E., Xiong, N., Hong, F., Lobach, D. F., Braun, I. M., Halpenny, B., Rabin, M. S., Johns, E., Finn, K., Berry, D., McCorkle, R., & Abraham, J. L. (2022). Clinical Decision Support for Symptom Management in Lung Cancer Patients: A Group RCT. *Journal of Pain and Symptom Management*, 63(4), 572–580. <https://doi.org/10.1016/j.jpainsymman.2021.12.006>.

the interviewees recommended the addition of functionality to facilitate clinical action (e.g., note-writing, order-writing, accessing outside information), making the information provided through the CDS tool more actionable, and improving design with visual cues and interactive features. Interviewees said that including such features in chronic pain treatment may aid in understanding and avoiding high-risk treatment choices (e.g., prescribing opioids to a patient with a history of opioid misuse).⁷⁹

One group of researchers sought to understand factors driving clinician resistance to following evidence-based guidelines provided by CDS software for ordering medical imaging. The researchers surveyed primary care and emergency clinicians and found that the key factor driving this resistance was clinicians wanting to order additional imaging to reduce diagnostic uncertainty, which is not within the scope of the guidelines or recommended by the CDS software.⁸⁰ In another study, researchers implemented a quality improvement initiative aimed at increasing the use of intravenous (IV) fluids for hospitalized patients and patients in emergency departments. The study noted that several publications have suggested that IV balanced fluid infusions lead to improved patient outcomes compared with normal saline infusions, and that fluid prescribing varies considerably between practices. The researchers launched a multi-pronged intervention that included educating clinicians on balanced-fluids versus normal saline and redesigning and implementing a CDS-integrated IV fluid ordering panel. The ordering panel provided active CDS in the form of preselected fluid options that leveraged best practice advisory rules from clinical experts and used patient medication and diagnosis data to identify balanced fluid options and potential contraindications to specific fluid types. While the CDS pre-selected fluid options and prioritized balanced fluids, providers retained the option to order the fluid of their choice. Following implementation of the CDS-integrated ordering panel, use of balanced fluids increased approximately 1.4% per month during the March 2019 to September 2019 period, with the largest increase in emergency medicine (57% increase) and internal medicine subspecialties (18% increase).⁸¹

To promote appropriate vaccination administration, four studies utilized CDS software in their EHRs to notify health care providers if a patient was eligible or if a vaccination dose was unnecessary (i.e., if the patient was up to date on their vaccinations and an additional vaccination may not comply with CDC recommendations). One study's CDS software notified health care providers if they ordered a tetanus vaccination for a patient who had received one within the previous 10 years and found that the software led to a decrease in unnecessary tetanus

⁷⁹ Allen, K. S., Danielson, E. C., Downs, S. M., Mazurenko, O., DiIulio, J., Salloum, R. G., Mamlin, B. W., & Harle, C. A. (2022). Evaluating a Prototype Clinical Decision Support Tool for Chronic Pain Treatment in Primary Care. *Applied Clinical Informatics*. 13(3), 602–611. <https://doi.org/10.1055/s-0042-1749332>.

⁸⁰ Bruno, M. A., Fotos, J. S., Pitot, M., Franceschi, A. M., Neutze, J. A., Willis, M. H., Wasserman, E., Snyder, B. L., Cruciata, G., Stuckey, H. L., & Wintermark, M. (2022). Factors Driving Resistance to Clinical Decision Support: Finding Inspiration in Radiology 3.0. *Journal of the American College of Radiology*. 19(2 Pt B), 366–376. <https://doi.org/10.1016/j.jacr.2021.08.017>.

⁸¹ Spiegel, M. C., Simpson, A. N., Philip, A., Bell, C. M., Nadig, N. R., Ford, D. W., & Goodwin, A. J. (2021). Development and Implementation of a Clinical Decision Support-Based Initiative to Drive Intravenous Fluid Prescribing. *International Journal of Medical Informatics*. 156, 104619. <https://doi.org/10.1016/j.ijmedinf.2021.104619>

vaccinations administered and an absolute risk reduction (i.e., the difference in outcome rates between the control and treatment groups) of 36.7%.⁸²

Two studies focused on increasing influenza vaccination rates. The first of these two studies developed an order group for hospitalized pediatric patients to notify health care providers if the patient had not received an influenza vaccine for the current influenza season and increased the rate of vaccination 3.25 times.⁸³ The other study incorporated CDS functionality into their EHRs to promote appropriate influenza vaccine uptake of patients in the ED and increased the number of eligible vaccinations by 20 times.⁸⁴

The fourth study evaluated the effect of using best practice alerts (i.e., developed using CDC guidelines) on pneumococcal vaccination rates. The best practice alerts informed the provider of their patients' pneumococcal vaccination status and enabled the physician to place an order for the vaccine or to document a refusal and any deferral reasons. The intervention occurred in two phases, with Phase I targeting patients with rheumatoid arthritis and Phase II targeting patients on immunosuppressive medications, and researchers observed vaccination rates increase from 28% preintervention to 61.5% postintervention and 49.6% preintervention to 77.4% postintervention in Phase I and Phase II, respectively.⁸⁵

Changes or additions since last published report: New literature. This report presents information describing the impact of software functions intended for certain CDS on additional health outcomes (e.g., inappropriate antibiotic use and vaccination, lung cancer symptom management, and smoking cessation), which are findings not reported in the [2020 Report](#).

Best Practices to Promote Safety, Education, and Competency

In response to the rapidly changing protocols at the onset of the COVID-19 pandemic, a team of physicians and health technology researchers developed a platform to provide emergency medicine providers with up-to-date information on clinical protocols regarding testing, treatment, and personal protection. The team shared several lessons learned from their efforts to promote success in future CDS development: engaging with leadership with whom there are existing relationships; using a development process that allows for iterative improvements through the incorporation of user feedback; leveraging a common web content management platform to promote usability and easy maintenance; using a flat organizational structure to enable rapid updates when recommendations change; garnering and maintaining “top-down” support by

⁸² Dutta, S., McEvoy, D. S., Stump, T., McCabe, J., Mahendra-Rajah, A., McMurry, R., White, B. A., & Rubins, D. (2021). Clinical Decision Support Reduces Unnecessary Tetanus Vaccinations in the Emergency Department. *Annals of Emergency Medicine*. 78(3), 370–380. <https://doi.org/10.1016/j.annemergmed.2021.02.021>

⁸³ Orenstein, E. W., ElSayed-Ali, O., Kandaswamy, S., Masterson, E., Blanco, R., Shah, P., Lantis, P., Kolwaite, A., Dawson, T. E., Ray, E., Bryant, C., Iyer, S., Shane, A. L., & Jernigan, S. (2021). Evaluation of a Clinical Decision Support Strategy to Increase Seasonal Influenza Vaccination Among Hospitalized Children Before Inpatient Discharge. *JAMA Network Open*. 4(7), e2117809. <https://doi.org/10.1001/jamanetworkopen.2021.17809>

⁸⁴ Buenger, L. E., & Webber, E. C. (2020). Clinical Decision Support in the Electronic Medical Record to Increase Rates of Influenza Vaccination in a Pediatric Emergency Department. *Pediatric Emergency Care*. 36(11), e641–e645. <https://doi.org/10.1097/PEC.0000000000001998>

⁸⁵ Sheth, H. S., Grimes, V. D., Rudge, D., Ayers, B., Moreland, L. W., Fischer, G. S., & Aggarwal, R. (2021). Improving Pneumococcal Vaccination Rates in Rheumatology Patients by Using Best Practice Alerts in the Electronic Health Records. *The Journal of Rheumatology*. 48(9), 1472–1479. <https://doi.org/10.3899/jrheum.200806>

engaging and continually connecting with leadership; and utilizing multiple methods of information dissemination to promote greater uptake by clinicians.⁸⁶

In a different study, researchers compared two types of interventions to identify their effects on optimal dose statin prescribing rates in cardiology practices. An active choice intervention (i.e., an intervention requiring the clinician to accept or decline guideline-directed statin therapy before continuing to input information in the EHR) was compared with a passive intervention (i.e., an intervention that does not require the clinician to accept or decline guideline-directed statin therapy before continuing to input information in the EHR). The researchers hypothesized that the active intervention would significantly increase rates of statin prescribing for patients whereas a passive-choice intervention would not increase rates. Although neither the active choice nor passive-choice interventions led to a statistically significant increase in optimal-dose statin prescribing or any-dose statin prescribing across the entire cohort, adjusted subset analysis of patients with atherosclerotic cardiovascular disease revealed a statistically significant 3.6% increase in statin prescribing in the active-choice intervention whereas the passive-choice intervention led to a statistically insignificant decrease.⁸⁷

Another study utilized deidentified EHR data to develop disease-specific, machine learning, patient-similarity models and precision cohorts for hypertension, type II diabetes, and hyperlipidemia index patients. These precision cohorts consist of patients who closely resemble the characteristics and clinical situation of the index patient and allow clinicians to examine the clinical responses of similar patients to different treatment options administered by other health care providers in the same health system. The study found that for most decision points (i.e., patient and clinician encounters), there were other treatment options that may have led to better outcomes, including 66.8% of decision points for hypertension, 59.0% for type II diabetes, and 83.5% for hyperlipidemia. Of those decision points with potentially better treatment options, the study found that the best practice treatment option would have led to improved outcomes and better-controlled conditions. The study suggests that providing clinicians with data on the effectiveness of other treatment decisions made by their colleagues for similar patients could help identify patient-specific treatment decisions and potentially improve patient outcomes.⁸⁸

One public commenter raised a concern about the possibility of visual or auditory alerts stemming from CDS software leading to alert fatigue and potentially to adverse events. As providers receive more notifications over time, they may become desensitized and ignore important notifications that could potentially prevent adverse events. To combat alert fatigue, the commenter recommended that organizations prepare an inventory of alarm-equipped devices used in high-risk clinical conditions and identify situations where alerts are necessary along with establishing guidelines for when alarms occur and developing tools within CDS software to allow providers to tailor alarm settings.¹³¹³ A second public commenter echoed this concern

⁸⁶ Stark, N., Kerrissey, M., Grade, M., Berrean, B., & Peabody, C. (2020). Streamlining Care in Crisis: Rapid Creation and Implementation of a Digital Support Tool for COVID-19. *The Western Journal of Emergency Medicine*. 21(5), 1095–1101. <https://doi.org/10.5811/westjem.2020.7.48537>

⁸⁷ Adusumalli, S., Westover, J. E., Jacoby, D. S., Small, D. S., VanZandbergen, C., Chen, J., Cavella, A. M., Pepe, R., Rareshide, C., Snider, C. K., Volpp, K. G., Asch, D. A., & Patel, M. S. (2021). Effect of Passive Choice and Active Choice Interventions in the Electronic Health Record to Cardiologists on Statin Prescribing: A Cluster Randomized Clinical Trial. *JAMA Cardiology*. 6(1), 40–48. <https://doi.org/10.1001/jamacardio.2020.4730>

⁸⁸ Tang, P. C., Miller, S., Stavropoulos, H., Kartoun, U., Zambrano, J., & Ng, K. (2021). Precision Population Analytics: Population Management at the Point-of-Care. *Journal of the American Medical Informatics Association*. 28(3), 588–595. <https://doi.org/10.1093/jamia/ocaa247>

related to alert fatigue and recommended that each institution have a committee responsible for configuring alert filters to balance precision and recall. They noted that having no alert filters could cause important alerts being missed due to alert fatigue, but overly restrictive filters could lead to important alerts not being shown. After the initial implementation, the commenters said this committee should meet regularly to review alert log data and adverse-event data to determine if the filters need to be refined.¹³¹³

One study aimed to reduce this potential for alert fatigue by incorporating rapid-cycle randomized testing methods and iteratively improving design choices within CDS tools to promote usability and quality of care. The study highlighted two experiments, one about an influenza alert and the other about a tobacco cessation alert. In the study, researchers combined tools from user-centered design, A/B testing, and implementation science to understand, ideate, prototype, analyze, and improve each iteration of the CDS software. The researchers found that rapid A/B testing combined with rapid-cycle randomized testing methods is a promising approach to efficiently evaluate the usability and acceptability of CDS tools and maximize their impact.⁸⁹

In a different study, a group of researchers studied the implementation process of an EHR-linked CDS tool for prediabetes treatment by interviewing a variety of health care providers and gathering insights into the barriers and facilitators encountered when adopting the tool. The CDS tool identified adults who met the criteria for diabetes screening or laboratory evidence of prediabetes and provided recommendations for care priorities and treatment options. Interviewees noted that strategies they deemed essential to the successful implementation of the CDS tool and overcoming some of those concerns included conducting training prior to implementing the CDS tool and accounting for whether the tool adds time during consultation or competes with different health care providers' priorities.⁹⁰

One study compared the effectiveness of a commercially available CDS tool developed without CDS design best practices with the effectiveness of an enhanced CDS tool that incorporated CDS design best practices and an implementation science framework. Both CDS tools notified providers via their EHR if the patient had a diagnosis of heart failure with reduced ejection fraction and had not been prescribed evidence-based beta blocker therapy. Researchers designed and implemented the enhanced notification using the Practical, Robust, Implementation, and Sustainability Model CDS best practices approach, and further refined the notification by incorporating feedback from clinicians and patients and then conducting design and usability testing. The enhanced CDS tool had a substantially higher adoption rate compared with the

⁸⁹ Austrian, J., Mendoza, F., Szerencsy, A., Fenelon, L., Horwitz, L. I., Jones, S., Kuznetsova, M., & Mann, D. M. (2021). Applying A/B Testing to Clinical Decision Support: Rapid Randomized Controlled Trials. *Journal of Medical Internet Research*. 23(4), e16651. <https://doi.org/10.2196/16651>

⁹⁰ Pratt, R., Saman, D. M., Allen, C., Crabtree, B., Ohnsorg, K., Sperl-Hillen, J. M., Harry, M., Henzler-Buckingham, H., O'Connor, P. J., & Desai, J. (2022). Assessing the Implementation of a Clinical Decision Support Tool in Primary Care for Diabetes Prevention: A Qualitative Interview Study Using the Consolidated Framework for Implementation Science. *BMC Medical Informatics and Decision Making*. 22(1), 15. <https://doi.org/10.1186/s12911-021-01745-x>.

generic CDS tool (62.3% versus 28.8%, respectively), led to more prescription changes (25% for the enhanced tool versus 0% for the generic tool), and was preferred by clinicians.⁹¹

One government staff member emphasized that CDS developers should address safety-related concerns and best practices in the prioritization, development, and authoring phases as well as the design, deployment, and implementation phases.¹⁴ The official shared the Patient-Centered Clinical Decision Support (PCCDS) Learning Network's Analytic Framework for Action (AFA) as literature to support and provide guidance for patient-centered CDS development. The AFA depicts a series of interacting components for developing and disseminating evidence-based PCCDS findings: prioritizing findings; translating findings into intervention types; implementing and operationalizing PCCDS interventions; ensuring that interventions improve decision-making, care and outcomes; aggregating outcomes and effectiveness measures to facilitate learning and gap identification; and understanding how external factors impact PCCDS development, dissemination, and implementation.⁹² The official added that ensuring that CDS engineers and clinical users are appropriately credentialed and certified can promote greater knowledge of and adherence to safe practices.

Multiple public commenters expressed support for FDA's stance on CDS software and noted that it can provide multiple benefits to patient care, including supporting appropriate decision-making and efficient access to current reference information. However, they also emphasized the need to ensure that CDS software uses up-to-date, evidence-based information to inform recommendations and that the software's underlying algorithms are continuously monitored and evaluated to confirm they produce appropriate and accurate recommendations to support providers and enhance patient care.¹³¹⁴

Regarding the content informing CDS software recommendations, one commenter said that promoting safe use of CDS software requires that the software leverage the most current standard-of-care information and accurate underlying algorithms that produce appropriate results to support and improve patient care.¹³¹³ Another public commenter went further, stating that apart from the software malfunctioning, the most significant risk posed by non-device CDS software is delivering inappropriate content and recommendations that are not rigorously reviewed or based on evidence-backed information. They advocated for curating content using a multidisciplinary team of clinical experts, engaging in systematic literature reviews (and weighing the validity of their findings and studies), and assessing medical evidence using formal grading methodology. Additionally, the commenter said the content should be regularly reviewed for quality and updated as needed to align with new evidence.¹³¹⁴

Regarding the underlying algorithms used in CDS software, one public commenter emphasized the importance of providers understanding the logic of the algorithms so that they can make informed decisions on how to incorporate decision-making without solely relying on the

⁹¹ Trinkley, K. E., Kroehl, M. E., Kahn, M. G., Allen, L. A., Bennett, T. D., Hale, G., Haugen, H., Heckman, S., Kao, D. P., Kim, J., Matlock, D. M., Malone, D. C., Page Nd, R. L., Stine, J., Suresh, K., Wells, L., & Lin, C. T. (2021). Applying Clinical Decision Support Design Best Practices With the Practical Robust Implementation and Sustainability Model Versus Reliance on Commercially Available Clinical Decision Support Tools: Randomized Controlled Trial. *JMIR Medical Informatics*. 9(3), e24359. <https://doi.org/10.2196/24359>.

⁹² Marcial, L. H., Richardson, J. E., Lasater, B., Middleton, B., Osheroff, J. A., Kawamoto, K., Ancker, J. S., van Leeuwen, D., Lomotan, E. A., Al-Showk, S., & Blumenfeld, B. H. (2018). The Imperative for Patient-Centered Clinical Decision Support. *eGEMs (Generating Evidence & Methods to Improve Patient Outcomes)*. 6(1), 12. <https://doi.org/10.5334/egems.259>.

algorithms.¹³¹³ Another public commenter expressed support for using algorithms to assist clinicians and noted that they can improve the diagnosis and treatment of an illness, support clinicians in identifying other patient-centric treatment options, and help mitigate the potential for human-generated errors. The public commenter added that the multiple benefits can only be realized if the providers trust the algorithms that they use. Software developers can earn the trust of providers by involving clinicians and end users in the development of these algorithms to ensure that the recommendations and alerts are relevant and are presented at the appropriate point in the clinical workflow. The public commenter also raised concerns about the potential for bias in underlying algorithms and the potential for variable care among demographics. They noted that this bias generally stems from the data sets the algorithms are trained on not being broadly representative of the patient population. Not accounting for the broad spectrum of characteristics that may affect how patients respond to care (e.g., race, ethnicity, gender, geography, sexual orientation, socioeconomic status) could cause the algorithms to be inaccurate when applied to certain groups of patients. Preventing biases and promoting accuracy could take the form of extensive statistical analysis and testing, profiling, and modeling of the training data along with continually monitoring and auditing algorithms to identify and reconcile potential “model drift” (i.e., change occurs in health care workflows, practices, populations, and/or data but is not accounted for by the algorithm and results in the output becoming less accurate over time).¹³¹³

Changes or additions since last published report: New literature. This report includes evidence of best practices to promote safety, education, and competency of software functions for certain CDS, information that was not included in the [2020 Report](#).

V. Appendix: List of Contributing Sources

FDA compiled the following list of contributing sources by the information collection activities it conducted to generate the findings summarized in this report.

Expert Interviews

- Agency for Healthcare Research and Quality – July 28, 2022
- Healthcare Information and Management Systems Society – August 3, 2022
- University of Texas School of Biomedical Informatics – August 9, 2022
- Baylor College of Medicine – August 9, 2022
- Office of the National Coordinator for Health Information Technology – August 10, 2022

Public Comments

- Comments submitted to the 2022 Development of 21st Century Cures Act Section 3060 Required Report Request for Input: <https://www.regulations.gov/document/FDA-2018-N-1910-0047>.

Peer-Reviewed Literature

- Adusumalli, S., Westover, J. E., Jacoby, D. S., Small, D. S., VanZandbergen, C., Chen, J., Cavella, A. M., Pepe, R., Rareshide, C., Snider, C. K., Volpp, K. G., Asch, D. A., & Patel, M. S. (2021). Effect of Passive Choice and Active Choice Interventions in the Electronic

- Health Record to Cardiologists on Statin Prescribing: A Cluster Randomized Clinical Trial. *JAMA Cardiology*. 6(1), 40–48. <https://doi.org/10.1001/jamacardio.2020.4730>.
- Agrawal L, Ndabu T, Mulgund P, Sharman R. (2021). Factors Affecting the Extent of Patients' Electronic Medical Record Use: An Empirical Study Focusing on System and Patient Characteristics. *Journal of Medical Internet Research*. 23(10), e30637. <https://doi.org/10.2196/30637>.
 - Alderden J, Drake KP, Wilson A, Dimas J, Cummins MR, Yap TL. (2021). Hospital Acquired Pressure Injury Prediction in Surgical Critical Care Patients. *BMC Medical Informatics and Decision Making*. 21(1), 12. <https://doi.org/10.1186/s12911-020-01371-z>.
 - Allen, K. S., Danielson, E. C., Downs, S. M., Mazurenko, O., DiIulio, J., Salloum, R. G., Mamlin, B. W., & Harle, C. A. (2022). Evaluating a Prototype Clinical Decision Support Tool for Chronic Pain Treatment in Primary Care. *Applied Clinical Informatics*. 13(3), 602–611. <https://doi.org/10.1055/s-0042-1749332>.
 - Austrian, J., Mendoza, F., Szerencsy, A., Fenelon, L., Horwitz, L. I., Jones, S., Kuznetsova, M., & Mann, D. M. (2021). Applying A/B Testing to Clinical Decision Support: Rapid Randomized Controlled Trials. *Journal of Medical Internet Research*. 23(4), e16651. <https://doi.org/10.2196/16651>.
 - Bauer, S. C., Kaeppeler, C., Soung, P., Porada, K., Bushee, G., & Havens, P. L. (2021). Using Electronic Health Record Tools to Decrease Antibiotic Exposure in Infant Sepsis Evaluation. *Hospital Pediatrics*. 11(9), 936–943. <https://doi.org/10.1542/hpeds.2021-005883>.
 - Becker, E. R., Shegog, R., Savas, L. S., Frost, E. L., Coan, S. P., Healy, C. M., Spinner, S. W., & Vernon, S. W. (2022). Parents' Experience With a Mobile Health Intervention to Influence Human Papillomavirus Vaccination Decision Making: Mixed Methods Study. *JMIR Pediatrics and Parenting*. 5(1), e30340. <https://doi.org/10.2196/30340>.
 - Blair, C. K., Harding, E., Wiggins, C., Kang, H., Schwartz, M., Tarnower, A., Du, R., & Kinney, A. Y. (2021). A Home-Based Mobile Health Intervention to Replace Sedentary Time With Light Physical Activity in Older Cancer Survivors: Randomized Controlled Pilot Trial. *JMIR Cancer*. 7(2), e18819. <https://doi.org/10.2196/18819>.
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