U.S. FOOD & DRUG ADMINISTRATION
Center for Devices and Radiological Health

Report on Risks and Benefits to Health of Non-Device Software Functions

December 2024

REPORT ON RISKS AND BENEFITS TO HEALTH OF NON-DEVICE SOFTWARE FUNCTIONS – December 2024

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 fourth 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 - December 2022 (herein "the 2022 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, 2022, to July 31, 2024. This section 3060(b) report also includes information from comments submitted to the public docket (FDA-2018-N-1910) from the opening of the docket on June 18, 2024 through the close of the docket on July 18, 2024.

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 in this report, FDA summarizes the findings from this analysis. In general, there was more information available for this report than for previous reports. Similar to the 2022 Report, 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 design, 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—*
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> *(1) includes input from outside experts, such as representatives of patients, consumers, health care 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;*
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> *(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*
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> *(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.*

This Report on Risks and Benefits to Health of Non-Device Software Functions – December 2024 is the 2024 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 – December 2022 (herein "the 2022 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[1];

(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) issued four final guidances and one final rule that interpret section 520(o)(1)(A)-(E) of the FD&C Act. The four guidance documents and one final rule are referenced below to provide clarity related to the non-device software functions included in the scope of this report:

[1] For example, a wearable fitness tracker that encourages a user to be active is considered within scope, while a wearable device intended to reduce symptoms of a particular disease (e.g., reducing pain as a result of arthritis) is considered out of scope, of the non-device software function of maintaining or encouraging a healthy lifestyle.

1. **Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act[2]:** 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 Devices[3]:** 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 Classification Regulations To Conform to Medical Software Provisions in the 21st Century Cures Act, Final Rule[4]:** 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).

4. **Medical Device Data Systems[5]:** 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

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[2] 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.

[3] 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.

[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. 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.

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 medical device data systems, medical image storage devices, and medical image communications devices.

5. **Clinical Decision Support (CDS) Software[6]:** 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 health care 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.

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 reports, 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."[7] Details about the sources can be found in Appendix B: 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, 2022, to July 31, 2024. The date range captured new evidence since the publication of the

[6] 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.
[7] Regulations.gov. FY24 Development of 21st Century Cures Act Section 3060 Required Report: Request for Input. https://www.regulations.gov/docket/FDA-2018-N-1910. Published June 18, 2024.

Report on Risks and Benefits to Health of Non-Device Software Functions – December 2022. Interviews were conducted from May 15, 2024, through June 25, 2024, but information elicited from interviewees may have been learned by interviewees prior to July 31, 2022. Similarly, the comment period for the public docket (FDA-2018-N-1910) was open from June 18, 2024, and closed on July 18, 2024, but information elicited from respondents may have been learned prior to July 31, 2022.

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]).[8] 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.[9]

Analysis Approach. The Cures Act requires a report summarizing findings corresponding to safety, risks and benefits, and best practices categories. The summaries include information and evidence gathered from the sources listed above and outlined in Appendix B: List of Contributing Sources, 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 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.

[8] FDA. What is a Serious Adverse Event? https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event. Published February 1, 2016.
[9] World Health Organization. Constitution of WHO: Principles. https://www.who.int/about/governance/constitution. Published on April 7, 1948.

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

Similar to the previous reports, many of the findings detailed in this report correspond to positive impacts on patient safety and health benefits related to the use of the five software functions, and only a few reported negative impacts on patient safety and health. Compared with the 2022 Report, we observed an increase in the amount of relevant peer-reviewed literature with relevant findings and we have noted changes in impacts to patient safety and health between the 2022 Report and this 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.[10]

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 Appendix B: List of Contributing Sources, provides details on all sources cited in the section below.

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

The evidence below for administrative support of a health care facility's impact on patient safety was gathered from an adverse event report.

[10] There are additional considerations related to adverse event reporting. For adverse event reports that are used to inform impacts to patient safety, reports that contain incomplete information about the nature of the malfunction do not qualify fully and are thus not included in this report. Also, 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 two sources: 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).

FDA received one adverse event report[10] involving a radiology management system failing to send the proper scheduling requests. When a user added protocol notes to one exam and selected another exam before saving their protocol changes for the first exam, the first exam was not sent to the appropriate queue for scheduling. Although there was no report of patient harm, the reporter noted this could have led to a scheduling delay and adversely affected patient care.

Changes or additions since last published report: New adverse event report. This report presents a new adverse event related to scheduling software, which is new since publication of the 2022 Report.

Benefits and Risks to Health

The evidence below on the benefits and risks to health associated with administrative support of a health care facility was gathered from peer-reviewed literature (including various focus areas).

Multiple studies evaluated the use of health platforms to improve care management and planning. [11,12,13,14] For example, one study[11] evaluated the usability and acceptability of a mobile health platform consisting of a web-based family services case management system and a mobile app for mothers with substance use disorder. The participating mothers praised the app's educational materials as well as the ability to schedule appointments and communicate with their providers through the app. Other researchers[12,13] conducted a retrospective analysis following the deployment of a patient-facing advance care planning platform. The platform enabled patients to create a plan by selecting their life-sustaining medical treatment preferences and generating appropriate legal documentation. Another study[14] sought to improve postpartum primary care engagement and reduce patient administrative burden and information gaps by implementing an intervention bundle that included default scheduling of postpartum primary care appointments, tailored messaging in texts and patient portal messages about the importance of regular primary care appointments following delivery, and appointment reminders designed to promote adherence. In general, these studies concluded that these platforms could enhance communication between patients and providers and improve patient engagement in their care.

A university hospital evaluated the accuracy, visibility, and turnover of an electronic health record (EHR)-integrated inventory management system. The EHR-integrated system actively monitored feedback (e.g., loading/unloading of pharmaceuticals, dispensing, return) and use of the EHR-integrated system led to a 6.02% increase in inventory accuracy over the traditional

[11] Isaacs, K. R., Bajracharya, E., Taylor, S., Chang, K., Washio, Y., Parker, T., Paul, D. A., & Ma, T. X. (2023). Usability and acceptability testing of a Plan of Safe Care in a mobile health platform. *Frontiers in Psychiatry*, *14*, 1182630. https://doi.org/10.3389/fpsyt.2023.1182630.

[12] DiJulio, B., Firth, J., & 2015. (2015, September 30). *Kaiser Health Tracking Poll: September 2015*. KFF; KFF. https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-september-2015/.

[13] Roberts, R. L., Mohan, D. P., Cherry, K. D., Sanky, S., Huffman, T. R., Lukasko, C., Comito, A., Hashemi, D., Menn, Z. K., Fofanova, T. Y., & Andrieni, J. D. (2024). Deployment of a Digital Advance Care Planning Platform at an Accountable Care Organization. *Journal of the American Board of Family Medicine: JABFM*, *36*(6), 966–975. https://doi.org/10.3122/jabfm.2023.230133R2.

[14] Clapp, M. A., Ray, A., Liang, P., James, K. E., Ganguli, I., & Cohen, J. (2024). Increasing Postpartum Primary Care Engagement through Default Scheduling and Tailored Messaging*: A Randomized Clinical Trial*. *medRxiv: The Preprint Server for Health Sciences*, 2024.01.21.24301585. https://doi.org/10.1101/2024.01.21.24301585.

system. The authors noted these improvements are essential for optimizing patient care and improving the financial management of pharmacies.[15]

Multiple articles[16,17] assessed the potential for software solutions to help identify language barriers for patients and prompt a referral for an interpreter. In the first, researchers conducted 49 interviews with various health care professionals and staff to elicit their feedback on potential risks and benefits of using artificial intelligence (AI) to identify patients with language barriers and connect them with in-person interpreters. Interviews elicited several perceived benefits, including increased awareness of in-person interpreters and improved ability to overcome clinician bias. Interviewees acknowledged potential AI-related risks (e.g., transparency, patient stigmatization), but the authors concluded this method can improve clinician knowledge and training on the use of in-person interpreters and help address health disparities, quality, and safety.[18] The second article evaluated the implementation of a language subsection within a hospital's EHR system that enabled clinicians to trigger a notification[19] to highlight the need for an interpreter. The implementation led to increases in the recognition of patients in need of interpreter services during triage, the utilization of interpreters for patients in need of services, and in the documentation of interpreter use within the EHR.[20]

Researchers working on an initiative to address health disparities in Kansas designed a novel data collection system for community health workers. The system integrates program activities and provides details on partner organizations supporting medical and social needs, community outreach events, information about client encounters, and care plans. Users were able to locate pertinent information through the system's interface and could develop queries to search for organizations and facilitate client referrals. The system also generated automated notices for overdue actions and generated population-level summaries of their clients and their progress toward their goals and in their care plan. The authors noted this system will help to improve the

[15] Shi, L., Wei, W., Smith, A., & Abbasi, G. (2024). Implementation and evaluation of an EHR-integrated perpetual inventory system in a large tertiary hospital oncology pharmacy. *American Journal of Health-System Pharmacy: AJHP: Official Journal of the American Society of Health-System Pharmacists*, *81*(12), 546–554. https://doi.org/10.1093/ajhp/zxae022.

[16] Gupta, K. M., Campeggio, D., Madu, C., Callahan, J. M., Jenicek, G., Ortiz, P., & Zorc, J. J. (2023). Improving Identification of Interpreter Need in the Pediatric Emergency Department. *Pediatrics*, *151*(3), e2022057330. https://doi.org/10.1542/peds.2022-057330.

[17] Barwise, A. K., Curtis, S., Diedrich, D. A., & Pickering, B. W. (2024). Using artificial intelligence to promote equitable care for inpatients with language barriers and complex medical needs: clinical stakeholder perspectives. *Journal of the American Medical Informatics Association: JAMIA*, *31*(3), 611–621. https://doi.org/10.1093/jamia/ocad224.

[18] Barwise, A. K., Curtis, S., Diedrich, D. A., & Pickering, B. W. (2024). Using artificial intelligence to promote equitable care for inpatients with language barriers and complex medical needs: clinical stakeholder perspectives. *Journal of the American Medical Informatics Association: JAMIA*, *31*(3), 611–621. https://doi.org/10.1093/jamia/ocad224.

[19] Articles and adverse event reports may use "alert" and "notification" interchangeably. For consistency, this report will use alert to refer to time-sensitive situations and notifications will be used for non-time-sensitive situations.

[20] Gupta, K. M., Campeggio, D., Madu, C., Callahan, J. M., Jenicek, G., Ortiz, P., & Zorc, J. J. (2023). Improving Identification of Interpreter Need in the Pediatric Emergency Department. *Pediatrics*, *151*(3), e2022057330. https://doi.org/10.1542/peds.2022-057330.

understanding of community health workers' workflow and support changes to health policy that can expand and sustain the community health workforce.[21]

A team of researchers evaluated the accuracy of diagnosis codes in administrative claims and EHRs compared to a retrospective medical record review. The researchers assembled a sample of 669 patients who recently had an eye care visit and compared patients' vision and eye disorder information from their medical records to their EHR and billing claims data. Accuracy was high in both the administrative claims and EHRs across multiple conditions (e.g., diabetic retinopathy, glaucoma, cataracts) but poor for several other conditions (e.g., blindness and low vision, orbital and external diseases). The authors noted this study validates the use of payment claims and EHR data to survey vision and eye health within study populations.[22]

Changes or additions since last published report: New literature. This report presents information on the benefits of health platforms and other technological solutions on improving care management, risks associated with AI, as well as other information that is new since publication of the 2022 Report.

Best Practices to Promote Safety, Education, and Competency

The evidence below for best practices to promote safety, education, and competency related to administrative support of a health care facility was gathered from peer-reviewed literature (including various focus areas) and stakeholder input collected from public commenters and during interviews with experts.

As part of a quality improvement initiative, a team of researchers surveyed 19 representatives from emergency medicine residency programs to elicit information on their shift scheduling practices and their satisfaction with their current scheduling method. Most respondents (17) used a software to assist with scheduling, and there was greater perceived resident and scheduler satisfaction when using scheduling software. Factors associated with software selection included cost, long-term program use, and preference toward utilizing the same platform used for faculty and attending physician scheduling. The common pain points included suboptimal algorithms used by scheduling software, steep learning curves to use the software, and cost. The authors noted these pain points could offer opportunities for software developers to improve their offerings and thus the user experience. One such opportunity cited by the authors is integrating AI technology into scheduling software to help mitigate the administrative burden and to help improve resident schedule satisfaction.[23]

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[21] Acharya, H., Sykes, K. J., Neira, T. M., Scott, A., Pacheco, C. M., Sanner, M., Ablah, E., Oyowe, K., Ellerbeck, E. F., Greiner, K. A., Corriveau, E. A., & Finocchario-Kessler, S. (2024). A Novel Electronic Record System for Documentation and Efficient Workflow for Community Health Workers: Development and Usability Study. *JMIR Formative Research*, *8*, e52920. https://doi.org/10.2196/52920.

[22] Wittenborn, J. S., Lee, A. Y., Lundeen, E. A., Lamuda, P., Saaddine, J., Su, G. L., Lu, R., Damani, A., Zawadzki, J. S., Froines, C. P., Shen, J. Z., Kung, T. H., Yanagihara, R. T., Maring, M., Takahashi, M. M., Blazes, M., & Rein, D. B. (2023). Validity of Administrative Claims and Electronic Health Registry Data From a Single Practice for Eye Health Surveillance. *JAMA Ophthalmology*, *141*(6), 534–541. https://doi.org/10.1001/jamaophthalmol.2023.1263.

[23] Nwanaji-Enwerem, J. C., Ehrhardt, T. F., Gordon, B., Meyer, H., Cardell, A., Selby, M., Wallace, B. A., Gittinger, M., & Siegelman, J. N. (2024). Considering Burnout and Well-Being: Emergency Medicine Resident Shift Scheduling Platform and Satisfaction Insights from a Quality Improvement Project. *Healthcare (Basel, Switzerland)*, *12*(6), 612. https://doi.org/10.3390/healthcare12060612.

During an interview, life sciences experts also expressed their belief that AI is a promising tool for many administrative functions, such as producing first draft of administrative documents for human review. However, they also acknowledged that AI is not currently at a place where it can engage in independent analysis of these administrative functions.[24] One public commenter cited an article that discussed the use of generative AI to draft replies to patient messages and evaluated its effect on physician time answering messages. The study found that the use of generative AI significantly increased time spent reading messages and the length of replies while having no effect on reply time.[25] The commenter believed this article showed the potential for generative AI to help support administrative functions but also highlighted areas of improvement (e.g., improved reasoning for recommending a clinical visit) that warrant future studies.[26]

A team of researchers evaluated the implementation of the Veterans Affairs (VA) Health Connect, an initiative the VA underwent to modernize the software and technological infrastructure used in its call centers. Veterans could call a toll-free number to contact VA Health Connect, which then connected veterans to virtual services in four areas: scheduling and general inquiries; pharmacy support; clinical triage; and virtual visits. The researchers conducted interviews with 29 clinical and administrative leads responsible for the modernization effort to identify the factors that affected the deployment of VA Health Connect as well as considerations for future initiatives. Interviews elicited several primary takeaways for organizations who plan to undergo complex initiatives, including the importance of understanding current staffing, hiring, and training processes; obtaining local buy-in from leaders; and anticipating future information technology (IT) needs to prevent delays. The authors encouraged others considering similar modernization initiatives to anticipate likely obstacles, communicate with stakeholders early and often, and provide flexibility to make sure local needs are met.[27]

One team of researchers reviewed the terminology and concepts needed to understand real-time prescription benefit tools and identified considered for implementation, barriers to adoption, and directions for future research. Real-time prescription benefit tools retrieve patient- and medication-specific information from pharmacy benefit managers, payors, or retail pharmacies and presents to the clinicians at the point of prescribing. The authors noted these tools can help to provide timely prescription benefit information and help providers choose the most financially appropriate medications for patients. However, the authors noted there is a need for research on out-of-pocket costs for patients, determinants for medication adherence, and the impact of cost-effective prescribing practices on clinical outcomes. The authors also encouraged health care organizations to develop system-level metrics to evaluate the performance, impact, and

[24] Expert Interviews for the 21st Century Cures Act Section 3060 Required Report. See the Appendix for details.
[25] Unlu, O., Shin, J., Mailly, C. J., Oates, M. F., Tucci, M. R., Varugheese, M., Wagholikar, K., Wang, F., Scirica, B. M., Blood, A. J., & Aronson, S. J. (2024). Retrieval Augmented Generation Enabled Generative Pre-Trained Transformer 4 (GPT-4) Performance for Clinical Trial Screening. *medRxiv: The Preprint Server for Health Sciences*, 2024.02.08.24302376. https://doi.org/10.1101/2024.02.08.24302376.
[26] 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-1910-0291.
[27] Gray, C., Lerner, B., Egelfeld, J., Robinson, J., Urech, T., & Vashi, A. (2024). What Should Healthcare Systems Consider When Modernizing Call Centers? Early Considerations From the Veterans Health Administration. *Journal of Healthcare Management / American College of Healthcare Executives*, *69*(3), 205–218. https://doi.org/10.1097/JHM-D-23-00053.

potential unintended consequences of these tools and their recommendations. Although they acknowledged the promise that these tools offer for lowering prescription costs, the authors noted more research is needed to optimize these tools and improve their adoption among providers. They advocated for careful guidance from the clinical community and a concerted effort to understand the impact that these tools can have on patient-, provider-, and system-related outcomes.[28]

Changes or additions since last published report: New literature and stakeholder input. This report presents information on how best to integrate AI technology into software related to administrative support, the importance of developing metrics to evaluate performance, impact, and potential unintended consequences, as well as other information that is new since publication of the 2022 Report.

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 2022 Report, which also reported no direct impacts to patient safety.

Benefits and Risks to Health

The evidence below of the benefits and risks to health for maintaining or encouraging a healthy lifestyle was gathered from peer-reviewed literature (including various focus areas) and stakeholder input collected from public commenters.

Multiple studies focused on exercise capacity and physical activity, with a particular focus on the effects of wearable activity trackers on driving that capacity.[29,30,31] Most of the studies confirmed

[28] Wong, R., Mehta, T., Very, B., Luo, J., Feterik, K., Crotty, B. H., Epstein, J. A., Fliotsos, M. J., Kashyap, N., Smith, E., Woreta, F. A., & Schwartz, J. I. (2023). Where Do Real-Time Prescription Benefit Tools Fit in the Landscape of High US Prescription Medication Costs? A Narrative Review. *Journal of General Internal Medicine*, *38*(4), 1038–1045. https://doi.org/10.1007/s11606-022-07945-z.

[29] Beckie, T. M., Sengupta, A., Dey, A. K., Dutta, K., Ji, M., & Chellappan, S. (2024). A mobile health behavior change intervention for women with coronary heart disease: A randomized controlled pilot study. *Journal of Cardiopulmonary Rehabilitation and Prevention, 44*(1), 40–48. https://doi.org/10.1097/HCR.0000000000000804.

[30] Alvarez, G., Sanabria, G., Jia, H., Cho, H., Reynolds, N. R., Gradilla, M., Olender, S., Mohr, D. C., & Schnall, R. (2023). Do Walk Step Reminders Improve Physical Activity in Persons Living With HIV in New York City? - Results From a Randomized Clinical Trial. *The Journal of the Association of Nurses in AIDS Care*: JANAC, 34(6), 527–537. https://doi.org/10.1097/JNC.0000000000000427.

[31] Okobi, O. E., Sobayo, T. O., Arisoyin, A. E., Adeyemo, D. A., Olaleye, K. T., Nelson, C. O., Sanusi, I. A., Salawu, M. A., Akinsete, A. O., Emore, E., Ibeneme, C. N., Odoma, V. A., Busari, A. K., & Okobi, E. (2023). Association Between the Use of Wearable Devices and Physical Activity Among US Adults With Depression and Anxiety: Evidence From the 2019 and 2020 Health Information National Trends Survey. *Cureus*, 15(5), e39521. https://doi.org/10.7759/cureus.39521.

that use of wearables and wearable-related interventions led to an initial increase in exercise and physical activity, but use decreased over time. For example, one study[32] that explored the relationship between wearable activity trackers and moderate-to-vigorous physical activity found those who wore trackers daily were more likely to report more activity, but only 17 minutes more than the non-daily wearers.

Meta-analyses of data from 19 studies revealed that active video game technology had a moderately positive effect on physical activity.[33] [34] [35] [36] For instance, one study focused specifically on gamification between low-, medium-, and high-steppers based on an initial activity assessment where one group had a "gamification" factor included (i.e., were updated regularly with standings and comparisons to their fellow participants).

Researchers reviewed multiple studies that explored impacts on weight control and loss and demonstrated the effectiveness of mobile health tools in promoting healthy behaviors and improving weight control and physical activity in women. The review found that these effects were consistent across various ethnic and racial groups and sex-specific risk factors. The authors concluded that, while there is a noticeable impact of digital health interventions on women's healthy behaviors, there is a need to address digital equity (e.g., subpopulations may be unable to take advantage of digital tools due to cost).[37]

Multiple other studies also assessed the impact of digital weight management tools.[38,39] In one of those studies, those in the intervention group received weekly interactive voice calls and text messages through a digital platform, which included tailored behavior changes goals, prompts

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[32] De La Torre, S. A., Pickering, T., Spruijt-Metz, D., & Farias, A. J. (2024). The frequency of using wearable activity trackers is associated with minutes of moderate to vigorous physical activity among cancer survivors: Analysis of HINTS data. *Cancer Epidemiology, 88*, 102491. https://doi.org/10.1016/j.canep.2023.102491.

[33] Swartz, M. C., Lewis, Z. H., Deer, R. R., Stahl, A. L., Swartz, M. D., Christopherson, U., Basen-Engquist, K., Wells, S. J., Silva, H. C., & Lyons, E. J. (2022). Feasibility and Acceptability of an Active Video Game-Based Physical Activity Support Group (Pink Warrior) for Survivors of Breast Cancer: Randomized Controlled Pilot Trial. *JMIR cancer, 8*(3), e36889. https://doi.org/10.2196/36889.

[34] Hatfield, D. P., Must, A., Kennedy, W., Staiano, A. E., Slavet, J., Sabelli, R. A., Curtin, C., Bandini, L. G., Nauta, P., Stuetzle, C., & Bowling, A. B. (2023). GamerFit-ASD beta test: adapting an evidence-based exergaming and telehealth coaching intervention for autistic youth. *Frontiers in Pediatrics*, 11, 1198000. https://doi.org/10.3389/fped.2023.1198000.

[35] Wentz, J. R., & Wilhelm Stanis, S. (2024). Physical Activity and Social Comparison: The Importance of Group Composition in an Employee Fitbit Intervention. *Health Promotion Practice*, 25(3), 409–416. https://doi.org/10.1177/15248399231160152.

[36] Moller, A. C., Sousa, C. V., Lee, K. J., Alon, D., & Lu, A. S. (2023). Active Video Game Interventions Targeting Physical Activity Behaviors: Systematic Review and Meta-analysis. *Journal of Medical Internet Research, 25*, e45243. https://doi.org/10.2196/45243.

[37] Azizi, Z., Adedinsewo, D., Rodriguez, F., Lewey, J., Merchant, R. M., & Brewer, L. C. (2023). Leveraging digital health to improve the cardiovascular health of women. *Current cardiovascular risk reports, 17*(11), 205–214. https://doi.org/10.1007/s12170-023-00728-z.

[38] Vidmar, A. P., Salvy, S. J., Wee, C. P., Pretlow, R., Fox, D. S., Yee, J. K., Garell, C., Glasner, S., & Mittelman, S. D. (2023). An addiction-based digital weight loss intervention: A multi-centre randomized controlled trial. *Pediatric Obesity, 18*(3), e12990. https://doi.org/10.1111/ijpo.12990.

[39] Miller, H. N., Gallis, J. A., Berger, M. B., Askew, S., Egger, J. R., Kay, M. C., Finkelstein, E. A., de Leon, M., DeVries, A., Brewer, A., Holder, M. G., & Bennett, G. G. (2024). Weight Gain Prevention Outcomes From a Pragmatic Digital Health Intervention With Community Health Center Patients: Randomized Controlled Trial. *Journal of Medical Internet Research*, 26, e50330. https://doi.org/10.2196/50330.

for goal tracking, and training materials and coaching/feedback. No significant weight loss differences were found between intervention and usual care participants. Researchers concluded that, given the lack of differences, digital interventions could be considered an option for clinicians to suggest to patients based on their preferences.

Another group of researchers explored the effects of a mobile health intervention on weight change outcomes in youth. The intervention was a commercially available program that included virtual health coaching and an integrated mobile app for monitoring diet and physical activity. 3,500 participants enrolled in the program, and participants experienced a decrease in body mass index over 31 weeks. Researchers noted the importance of conducting additional research with a control group to better understand the impact of the program on weight change outcomes in young men and women.[40]

Two articles examined effects on quality of life. One study assessed the feasibility and acceptability of a mobile health app to provide health-related quality of life (HRQOL) support for caregivers of cancer patients. Participants were mailed wearable fitness trackers to record physical activity, heart rate, and sleep during the 120-day study period and downloaded a mobile app that prompted them to complete HRQOL assessments at baseline, 30 days, and 120 days. Though underpowered, improvements in most HRQOL domains were identified. Overall, researchers concluded the app is a promising method for providing HRQOL support.[41].[42]

In another study researchers aimed to evaluate the effects of promoting resiliency on healthy lifestyles.[43] For instance, one study focused on the impact of a three-week, daily resiliency practice via a smartphone app on the professional quality of life, physical activity, and happiness levels of health care workings in a neonatal intensive care unit setting. Researchers evaluated participants pre- and post-intervention utilizing appropriate score instruments. Overall scores at the end of the study showed statistically significant improvement in burnout, secondary trauma stress, and happiness scores. Other scores for exercise and compassion also improved, but were not statistically significant. Use of a gratitude journal, as well as exercise and mindfulness interventions, also generally improved scores.[44]

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[40] Jelalian, E., Darling, K., Foster, G. D., Runyan, T., & Cardel, M. I. (2023). Effectiveness of a Scalable mHealth Intervention for Children With Overweight and Obesity. *Childhood Obesity, 19*(8), 552–559. https://doi.org/10.1089/chi.2022.0154.

[41] Koblick, S. B., Yu, M., DeMoss, M., Liu, Q., Nessle, C. N., Rozwadowski, M., Troost, J. P., Miner, J. A., Hassett, A., Carlozzi, N. E., Barton, D. L., Tewari, M., Hanauer, D. A., & Choi, S. W. (2023). A pilot intervention of using a mobile health app (ONC Roadmap) to enhance health-related quality of life in family caregivers of pediatric patients with cancer. *Mhealth, 9*, 5. https://doi.org/10.21037/mhealth-22-24.

[42] Victoria-Castro, A. M., Martin, M. L., Yamamoto, Y., Melchinger, H., Weinstein, J., Nguyen, A., Lee, K. A., Gerber, B., Calderon, F., Subair, L., Lee, V., Williams, A., Shaw, M., Arora, T., Garcez, A., Desai, N. R., Ahmad, T., & Wilson, F. P. (2024). Impact of Digital Health Technology on Quality of Life in Patients With Heart Failure. JACC. *Heart Failure, 12*(2), 336–348. https://doi.org/10.1016/j.jchf.2023.09.022.

[43] Elledge, D. K., Lee, S. C., Stewart, S. M., Pop, R., Trivedi, M. H., & Hughes, J. L. (2023). Examining a Resilience Mental Health App in Adolescents: Acceptability and Feasibility Study. *JMIR Formative Research*, 7, e38042. https://doi.org/10.2196/38042.

[44] Peterson, N. E., Thomas, M., Hunsaker, S., Stewart, T., & Collett, C. J. (2024). mHealth Gratitude Exercise Mindfulness App for Resiliency Among Neonatal Intensive Care Unit Staff: Three-Arm Pretest-Posttest Interventional Study. *JMIR Nursing*, 7, e54561. https://doi.org/10.2196/54561.

Multiple articles reported effects on mindfulness and if there were any effects on living a healthy lifestyle.[45,46] For example, in one study,[47] a group of researchers sought to determine if a smartphone mindfulness app could address burnout among acute care nursing staff. Participants who completed the intervention showed significantly decreased levels of personal burnout and stress along with increased mindfulness. However, there were no observed differences in levels of resilience. The researchers expressed the findings suggested a brief mindfulness-based intervention may have a positive impact.

One public commenter noted that even though general wellness products present low risk, there is still the potential for some risk, and if the software does not provide measurable benefits to health, it only presents risk and can lead to limited trustworthiness for the intended user.[26]

Changes or additions since last published report: *New literature and stakeholder input.* This report presents information on the benefits of wearables and wearable-related interventions on physical activity, weight management, and other general health behaviors, as well as other information that is new since publication of the 2022 Report.

Best Practices to Promote Safety, Education, and Competency

The evidence below for best practices to promote safety, education, and competency related to maintaining or encouraging a healthy lifestyle was gathered from peer-reviewed literature (including various focus areas), and stakeholder input collected from public commenters and during interviews with experts.

[45] Pascual, K., Fredman, A., Naum, A., Patil, C., & Sikka, N. (2023). Should Mindfulness for Health Care Workers Go Virtual? A Mindfulness-Based Intervention Using Virtual Reality and Heart Rate Variability in the Emergency Department. *Workplace Health & Safety, 71*(4), 188–194. https://doi.org/10.1177/21650799221123258.
[46] Truhlar, L. M., Durand, C., Cooper, M. R., & Goldsmith, C. W. (2022). Exploring the effects of a smartphone-based meditation app on stress, mindfulness, well-being, and resilience in pharmacy students. American journal of health-system pharmacy: *AJHP: Official Journal of the American Society of Health-System Pharmacists*, 79(23), 2159–2165. https://doi.org/10.1093/ajhp/zxac240.
[47] Brouwer, K. R., Melander, S., Walmsley, L. A., Norton, J., & Okoli, C. (2024). A Mindfulness-Based Intervention for Acute Care Nursing Staff: A Pilot Study. *Journal of Jolistic Nursing: Official Journal of the American Holistic Nurses' Association*, 42(1), 24–33. https://doi.org/10.1177/08980101231181004.

Eleven articles reported impacts on physical activity in various populations.[48,49,50,51,52,53,54,55,56,57] The authors noted across the various studies that mobile health combined with multiple emerging technologies can potentially improve physical activity, particularly mobile apps that featured personalized goal setting, selective feedback, motivational messages, and interactions with clinicians could provide benefits to patients. For instance, researchers in a study[58] recruited children to test the usability of a mobile app health intervention designed to encourage healthy eating and active living. Students were asked to assess the usability and effectiveness of the app, with results used to refine the app prototype and identify ways to make the app a truly useful tool. The majority of participants gave a strongly favorable evaluation for usability measures and reported that tailored, motivational messages were enjoyable, taught them something new, and enabled behavior change.

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[48] Mahmood, A., Kim, H., Kedia, S., & Dillon, P. (2022). Wearable Activity Tracker Use and Physical Activity Among Informal Caregivers in the United States: Quantitative Study. *JMIR mHealth and uHealth*, 10(11), e40391. https://doi.org/10.2196/40391.

[49] Atluri, N., Mishra, S. R., Anderson, T., Stevens, R., Edwards, A., Luff, E., Nallamothu, B. K., & Golbus, J. R. (2024). Acceptability of a Text Message-Based Mobile Health Intervention to Promote Physical Activity in Cardiac Rehabilitation Enrollees: A Qualitative Substudy of Participant Perspectives. *Journal of the American Heart Association*, 13(2), e030807. https://doi.org/10.1161/JAHA.123.030807.

[50] Sangameswaran, S., Casanova-Perez, R., Patel, H., Cronkite, D. J., Idris, A., Rosenberg, D. E., Wright, J. L., Gore, J. L., & Hartzler, A. L. (2024). Improving physical activity among prostate cancer survivors through a peer-based digital walking program. AMIA. Annual Symposium proceedings. *AMIA Symposium*, 2023, 608–617.

[51] Gao, Z., Ryu, S., Zhou, W., Adams, K., Hassan, M., Zhang, R., Blaes, A., Wolfson, J., & Sun, J. (2023). Effects of personalized exercise prescriptions and social media delivered through mobile health on cancer survivors' physical activity and quality of life. *Journal of Sport and Health Science*, 12(6), 705–714. https://doi.org/10.1016/j.jshs.2023.07.002.

[52] Monroe, C. M., Cai, B., Edney, S., Jake-Schoffman, D. E., Brazendale, K., Bucko, A., Armstrong, B., Yang, C. H., & Turner-McGrievy, G. (2023). Harnessing technology and gamification to increase adult physical activity: a cluster randomized controlled trial of the Columbia Moves pilot. *The International Journal of Behavioral Nutrition and Physical Activity*, 20(1), 129. https://doi.org/10.1186/s12966-023-01530-1.

[53] Shah, N., Borrelli, B., & Kumar, D. (2023). Perceptions about smartphone-based interventions to promote physical activity in inactive adults with knee pain - A qualitative study. Disability and rehabilitation. *Assistive Technology*, 1–8. Advance online publication. https://doi.org/10.1080/17483107.2023.2272854.

[54] Monroe, C. M., Zosel, K., Stansbury, M., Younginer, N., Davis, R. E., Dutton, G., Newton, R. L., Jr, Cai, B., & West, D. S. (2024). A focus group study among insufficiently physically active African American adults regarding technology-delivered team-based gamification for physical activity promotion. *mHealth*, 10, 3. https://doi.org/10.21037/mhealth-23-44.

[55] Garcia, D. O., Valdez, L. A., Aceves, B., Bell, M. L., Rabe, B. A., Villavicencio, E. A., Marrero, D. G., Melton, F., & Hooker, S. P. (2022). mHealth-Supported Gender- and Culturally Sensitive Weight Loss Intervention for Hispanic Men With Overweight and Obesity: Single-Arm Pilot Study. *JMIR Formative Research*, 6(9), e37637. https://doi.org/10.2196/37637.

[56] Garcia, L., Ferguson, S. E., Facio, L., Schary, D., & Guenther, C. H. (2023). Assessment of well-being using Fitbit technology in college students, faculty and staff completing breathing meditation during COVID-19: A pilot study. *Mental Health & Prevention*, 30, 200280. https://doi.org/10.1016/j.mhp.2023.200280.

[57] Wing, D., Godino, J. G., Baker, F. C., Yang, R., Chevance, G., Thompson, W. K., Reuter, C., Bartsch, H., Wilbur, A., Straub, L. K., Castro, N., Higgins, M., Colrain, I. M., de Zambotti, M., Wade, N. E., Lisdahl, K. M., Squeglia, L. M., Ortigara, J., Fuemmeler, B., Patrick, K., … Bagot, K. S. (2022). Recommendations for Identifying Valid Wear for Consumer-Level Wrist-Worn Activity Trackers and Acceptability of Extended Device Deployment in Children. *Sensors* (Basel, Switzerland), 22(23), 9189. https://doi.org/10.3390/s22239189.

[58] Lin, C. A., Vosburgh, K. L., Roy, D., & Duffy, V. B. (2023). Usability Testing an mHealth Program with Tailored Motivational Messages for Early Adolescents. *Nutrients*, 15(3), 574. https://doi.org/10.3390/nu15030574.

Multiple articles reported the effects of gamification on physical activity.[59,60] In one of those studies, a group of researchers investigated the effect of wearable device leaderboards on the number of steps taken by users to determine the effectiveness of "gamification" on physical activity. For example, researchers found that participation in leaderboards led to a 3.5% increase in the users' physical activity. Additionally, users who were previously more sedentary showed a 15% increase in the number of steps. In general, there is potential for wearable technologies and mobile health to be utilized to motivate positive behavioral changes.

During expert interviews, government health care experts noted that users have a variety of preferences in how they learn or engage with apps. Literature has shown that gamification can be helpful in engaging with different communities, particularly when engaging younger users, and that there is a strong interest in gamification and simulated learning to supplement wellness and training.[24] The government health care experts referred to federal facilities like the SimLEARN National Simulation Center as examples of groups who are working to integrate gamification into various digital health technologies.[61] However, gamification does pose some risks. Biomedical research experts noted during their interview that while apps or services may ask age when signing up for them, there remains a risk that underage users could obtain access or make health decisions inappropriately, or even make information accessible to a company in such a way that it violates policies or laws.[24]

Multiple studies explored effects on weight loss.[62,63, 64] Weight loss has been shown to have a positive impact on clinical outcomes, but there have been challenges in identifying and implementing effective, sustainable, low-cost programs to promote healthy eating and regular exercise to achieve weight loss. For instance, a group of researchers[65] studied how weight loss coaches having access to self-monitoring data might improve long-term outcomes for participants in behavioral weight loss programs. The study was divided into two phases, with participants provided a smart scale, an activity tracker, and an app tied to the activity tracker for monitoring diet. At the end of phase one, participants had high adherence to self-monitoring of weight, diet, and exercise, but for phase two, researchers noted a drop-off in self-monitoring among all participants. Researchers noted that individuals who established consistent and

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[59] Wang, J., Fang, Y., Frank, E., Walton, M. A., Burmeister, M., Tewari, A., Dempsey, W., NeCamp, T., Sen, S., & Wu, Z. (2023). Effectiveness of gamified team competition as mHealth intervention for medical interns: a cluster micro-randomized trial. NPJ digital medicine, 6(1), 4. https://doi.org/10.1038/s41746-022-00746-y.

[60] Hydari, M. Z., Adjerid, I., & Striegel, A. D. (2023). Health Wearables, Gamification, and Healthful Activity. *Management Science*, 69(7), 3920–3938. https://doi.org/10.1287/mnsc.2022.4581

[61] VA Center for Care and Payment Innovation. (n.d.). *SimLEARN*. VA Center for Care and Payment Innovation; U.S. Department of Veterans Affairs. https://www.innovation.va.gov/simlearn/.

[62] Lee, C. Y., Robertson, M. C., Johnston, H., Le, T., Raber, M., Rechis, R., Oestman, K., Neff, A., Macneish, A., & Basen-Engquist, K. M. (2022). Feasibility and Effectiveness of a Worksite-Weight-Loss Program for Cancer Prevention among School-District Employees with Overweight and Obesity. *International Journal of Environmental Research and Public Health*, 20(1), 538. https://doi.org/10.3390/ijerph20010538.

[63] Tincopa, M. A., Patel, N., Shahab, A., Asefa, H., & Lok, A. S. (2024). Implementation of a randomized mobile-technology lifestyle program in individuals with nonalcoholic fatty liver disease. *Scientific Reports*, *14*(1), 7452. https://doi.org/10.1038/s41598-024-57722-7.

[64] Crane, N., Hagerman, C., Horgan, O., & Butryn, M. (2023). Patterns and Predictors of Engagement With Digital Self-Monitoring During the Maintenance Phase of a Behavioral Weight Loss Program: Quantitative Study. *JMIR mHealth and uHealth*, 11, e45057. https://doi.org/10.2196/45057.

regular self-monitoring patterns early had higher success rates, but the continued challenge of self-monitoring remains. They also noted that the decrease in weight self-monitoring may indicate that strategies are not driven by logistical concerns, but rather by underlying reactions to weight self-monitoring.

Many studies focused on app design with various populations and its effectiveness on increasing willingness to adopt potentially beneficial wearable and mobile technologies to maintain a healthy lifestyle.[66,67,68] In one study,[69] researchers interviewed teens and caregivers in urban communities with significant socioeconomic and health disparities to determine perspectives on the usefulness of mobile health interventions to address behavioral needs. Researchers sought to utilize human-centered design methods to identify the specific needs of teens with overlapping adversities, and/or marginalized identities to improve upon the potential of mobile health applications. Six dominant themes emerged from the interviews, with researchers focusing in on four: 1) health and wellness concerns, 2) barriers, 3) use of smartphones, and 4) impact of smartphones. The researchers noted many of the teens (and caregivers) expressed an openness to using mobile health apps, but that there were still barriers around access and privacy and that any apps will need to moderate exposure to harm from other applications and smartphone tools. Overall, the researchers identified useful perspectives about mobile health, and suggested that continued and deliberate collaboration with teens and caregivers across the deployment process is key to assisting previously underserved communities.

During expert interviews, biomedical research experts also noted the importance of demographic diversity. They noted that diversity in demographic data is not only important for the validity across various studies, but that such data needs to be captured from a variety of individuals to create baselines and represent the totality of users. Particularly when developing new software and tools, the lack of diversity can limit not just the education and training process, but also uptake. Health care quality experts expanded on this, emphasizing that this is not always evident to software developers. They pointed out that engaging with a diversity of patients, patient representatives, families, and caregivers is key to developing effective interventions including general wellness apps, and thus should be considered during development.[24]

One public commenter shared sentiment related to empirically tested apps, especially given the prevalence of general wellness apps. They noted that when software is not required to be reviewed for commonly accepted benchmarks of trust (e.g., equity, accessibility, usability,

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[66] Kopka, M., Camacho, E., Kwon, S., & Torous, J. (2023). Exploring how informed mental health app selection may impact user engagement and satisfaction. *PLOS Digital Health, 2*(3), e0000219. https://doi.org/10.1371/journal.pdig.0000219.

[67] Choi, S., Sajib, M. R. U. Z., Manzano, J., & Chlebek, C. J. (2023). mHealth technology experiences of middle-aged and older individuals with visual impairments: Cross-sectional interview study. *JMIR Formative Research, 7*, e52410. https://doi.org/10.2196/52410.

[68] Fowe, I. E., & Boot, W. R. (2022). Understanding older adults' attitudes toward mobile and wearable technologies to support health and cognition. *Frontiers in Psychology, 13*, 1036092. https://doi.org/10.3389/fpsyg.2022.1036092.

[69] Stiles-Shields, C., Reyes, K. M., Archer, J., Lennan, N., Zhang, J., Julion, W. A., & Karnik, N. S. (2022). mHealth Uses and Opportunities for Teens from Communities with High Health Disparities: A Mixed-Methods Study. *Journal of Technology in Behavioral Science*, 1–13. Advance online publication. https://doi.org/10.1007/s41347-022-00278-y.

privacy, security), software users are forced to invest significant time and resources vetting different solutions or establishing their own evaluation criteria. Similarly, they noted that it is important for developers to validate their software against certain benchmarks to differentiate themselves from similar software offerings in a crowded software market.[26]

Changes or additions since last published report: *New literature and stakeholder input.* This report presents information on preferences for how people learn or engage with general wellness apps, app design and effectiveness related to increasing willingness to use wearable and mobile technologies, and barriers and challenges to using apps, as well as other information that is new since publication of the 2022 Report.

Electronic Patient Records[70]

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

The evidence below for electronic patient records' impact on patient safety was gathered from adverse event reports.

FDA received one adverse event report[10] involving an EHR system failing to properly combine patient and encounter records. FDA also received an adverse event report[10] involving an EHR extension designed to display and add clinical data in diagnostic and treatment decisions. When a user saved, signed, refreshed, or remove a note section, the EHR displayed an error message, and users could lose unsaved changes. Another adverse event report[10] involved an EHR displaying the incorrect demographic data for a patient, which the reporter noted could affect patient care if clinical decisions are based on incorrect demographic information. Although there were no direct patient impacts, the reporters noted these could have led to patient harm if clinical care decisions were made on incorrect or incomplete patient information.

[70] To the extent possible, FDA has reviewed the EHRs discussed in the literature to confirm they meet applicable criteria outlined in section 520(o)(1)(C)(i)-(iii) of the FD&C Act (21 U.S.C. 360j(o)(1)(C)(i)-(iii)), including certification under the ONC Health IT Certification Program.

FDA received one adverse event report[10] related to a data management system displaying an incorrect patient's name in the EHR. This led to a misdiagnosis and clinicians conducting an improper surgery on a patient.

Changes or additions since last published report: New adverse event reports. This report presents new adverse events related to certain, complex EHR functionality (e.g., medication ordering), which is new since publication of the 2022 Report.

Benefits and Risks to Health

The evidence below for the benefits and risks to health of electronic patient records was gathered from peer-reviewed literature (including various focus areas) and stakeholder input collected during interview with experts.

A review on the use of EHRs for multiple sclerosis clinical care and research found pairing real-world data to clinical trial data is challenging due to the lack of standardized collection methods for physician and patient-reported outcomes. However, the researchers noted toolkits can promote structured clinical documentation and said allowing patients and clinicians to view patient-reported data can promote integration of the patient's perspective, reduce burden related to clinician data entry, and improve patients' engagement in their care. The authors offered praise for one standardized data collection method that included disease-specific data entry to streamline clinical practice and improve data collection and completeness. They noted proper implementation and validation of EHR data can potentially improve analysis of large sample sizes and the integration of clinician- and patient-reported outcomes.[71] Multiple interviewees discussed similar topics. Health care technology experts noted aggregating EHR data from across health care systems has made it more convenient for patients and providers to view and validate information.[24] Life sciences experts also praised the enhanced potential of aggregated EHR data for clinical research.[24]

Two studies reviewed efforts to improve the patient experience and involvement in EHR use. One review found patient-centered EHRs were associated with greater use of recommended care services and improved disease knowledge, patient involvement, treatment adherence, and self-management/self-efficacy. The authors identified benefits related to active features (i.e., those where the patient performs an action directly and engages with the EHR). The authors concluded their findings support greater adoption of patient-centered EHRs but believe further research is needed to assess differences across diseases and health outcomes.[72] Another study noted patient voice can help researchers generate new discoveries on patient care, offer insights for diagnostic decision support, and provide evidence to support informed and accurate diagnoses. One area the authors noted patient voice can be found and used effectively is through patient portal messages. The authors offered support for the OurNotes movement,

[71] Swetlik, C., Bove, R., & McGinley, M. (2022). Clinical and Research Applications of the Electronic Medical Record in Multiple Sclerosis: A Narrative Review of Current Uses and Future Applications. *International Journal of MS Care*, *24*(6), 287–294. https://doi.org/10.7224/1537-2073.2022-066.

[72] Brands, M. R., Gouw, S. C., Beestrum, M., Cronin, R. M., Fijnvandraat, K., & Badawy, S. M. (2022). Patient-Centered Digital Health Records and Their Effects on Health Outcomes: Systematic Review. *Journal of Medical Internet Research*, *24*(12), e43086. https://doi.org/10.2196/43086.

where clinicians and patients collaborate to create notes, and said this concept can help to capture patient perspectives and incorporate them directly into the EHR.[73]

Another study evaluated whether enabling patient transfer of demographic, medical condition, and medication date from the EHR into a registration form improved the accuracy and completeness of patient profiles. Stakeholders who provided input on the integration emphasized the importance of clearly conveying information of individual choice and revocability of permission to interested patients, and advocated for sharing information on the time needed to complete a research profile and sharing details on privacy options. Participants that used the EHR-connected research profile entered more conditions and medications in their profile than those that used the non-EHR-connected research profile, and the majority of participants preferred the EHR-connected profile creation method.[74]

Another research team developed an EHR-based surveillance network that links symptom, clinical, laboratory, and disposition data to enable surveillance of acute respiratory infections in emergency departments (EDs). Case data from a network of 24 EDs is automatically populated in a database where it is analyzed, parsed, and aggregated in a cloud platform before being transmitted to the Centers for Disease Control and Prevention (CDC). Data from this network enabled the detection of new outbreaks, improved understanding of the magnitude and distribution of infections, allowed researchers to follow the natural history of infections, and provided a resource to evaluate control strategies. The researchers also noted that the methodology used to develop this network extended the existing clinical research to capture data at scale while providing continuous oversight and input by providers and academics.[75]

Changes or additions since last published report: New literature and stakeholder input. This report presents information on the benefits of aggregating data and incorporating the patient voice into EHRs, the potential impact of missing data and non-standardized data collection methods, as well as other information that is new since publication of the 2022 Report.

Best Practices to Promote Safety, Education, and Competency

The evidence below for best practices to promote safety, education, and competency related to electronic patient records was gathered from peer-reviewed literature (including various focus areas) and stakeholder input collected during interviews with experts.

One group of researchers sought to improve veterans' access to a patient portal that provides them with access to their EHR, hosts their patient health information, and offers methods of communication with their providers. The researchers identified several barriers to the

[73] Payne, T. H., Lehmann, C. U., & Zatzick, A. K. (2023). The Voice of the Patient and the Electronic Health Record. *Applied Clinical Informatics*, *14*(2), 254–257. https://doi.org/10.1055/s-0043-1767685.
[74] Cheng, A. C., Dunkel, L., Byrne, L. M., Tischbein, M., Burts, D., Hamilton, J., Phillips, K., Embry, B., Tan, J., Olson, E., & Harris, P. A. (2023). ResearchMatch on FHIR: Development and evaluation of a recruitment registry and electronic health record system interface for volunteer profile completion. *Journal of Clinical and Translational Science*, *7*(1), e222. https://doi.org/10.1017/cts.2023.654.
[75] Kline, J. A., Reed, B., Frost, A., Alanis, N., Barshay, M., Melzer, A., Galbraith, J. W., Budd, A., Winn, A., Pun, E., & Camargo, C. A., Jr (2023). Database derived from an electronic medical record-based surveillance network of US emergency department patients with acute respiratory illness. *BMC Medical Informatics and Decision Making*, *23*(1), 224. https://doi.org/10.1186/s12911-023-02310-4.

registration process and offered recommendations to address these barriers. The authors emphasized the criticality of conducting local reviews of patient portal registration processes and suggested that future researchers view errors as opportunities to improve their processes, engage with all members of the care team, and identify and coordinate with a champion who can offer feedback that can promote the sustainability of initiatives.[76]

Another study combined a literature review and stakeholder interviews with global outreach experts to identify critical EHR data elements and process steps for clinicians conducting outreach trips to low- and middle-income countries. The combined efforts led to the researchers identifying 111 data elements and 27 process steps. The authors noted that collecting patient data via an EHR can improve patient safety and outcomes, increase adherence to clinical practice guidelines, and enhance quality improvement efforts. They advocated for a culture of electronic data collection, measurement, and improvement to help promote care. The authors believe this culture and the use of validated data elements and process steps can promote more robust collection and monitoring of critical patient data.[77]

One team of researchers shared lessons learned from a current state workflow assessment intended to inform transition to a new EHR system. The authors advocated for assembling a multi-professional team with diverse experience and engaging with all levels of facility leadership to accurately outline the workflow. They also suggested that stakeholders utilize qualitative content analysis to identify themes and inform improvement efforts. In addition, the authors recommended that clinical sites develop a plan to guide integration and a training program for project teams.[78]

Military health experts suggested that health care systems consider change management strategies and investing time and resources into preparing end-users for potential changes when updating EHR systems. They emphasized the importance of building end-user competency from within and leveraging internal champions that are formally trained in the effective use of the EHR and can support training initiatives by connecting with their peers and preparing the next generation of users to use these tools effectively.[24]

Experts also acknowledged the importance of choosing the appropriate EHR software that meets their needs and can integrate properly into the clinical workflow. One suggestion that government health care experts provided during their interview was to establish a clearinghouse or testing center where clinicians could test different EHR software to determine which fits their needs. They noted this can help to prevent software from being live-tested on staff while they practice, which could impact the quality of care, and also help to improve the integration of the

[76] Roberto, C., Keiffer, M., Black, M., Williams-Suich, C., & Grunewald, K. (2022). Improving Patient Access to the My Health*e*Vet Electronic Patient Portal for Veterans. *Federal Practitioner: For the Health Care Professionals of the VA, DoD, and PHS*, *39*(12), 476–481. doi:10.17288/fp.0331.

[77] Shapiro, L. M., Chang, J., Fox, P. M., Kozin, S., Chung, K. C., Dyer, G. S. M., Fufa, D., Leversedge, F., Katarincic, J., & Kamal, R. (2022). The Development and Validation of Data Elements and Process Steps for an Electronic Health Record for Hand Surgery Outreach Trips. *Journal of Hand and Microsurgery*, *15*(5), 358–364. https://doi.org/10.1055/s-0042-1749465.

[78] Watson, C. H., Masalonis, A., Arnold, T., Chumbler, N. R., & Plew, W. (2023). Methods and Lessons Learned from a Current State Workflow Assessment following Transition to a New Electronic Health Record System. *Perspectives in Health Information Management*, *20*(2), 1c. https://pubmed.ncbi.nlm.nih.gov/37293479/.

EHR into existing processes.[24] Military health experts also emphasized the importance of integrating the clinicians perspective into the integration of the EHR into the workflow, and they noted that gathering this input and incorporating it into their EHR rollout was critical for their own integration efforts.[24]

Another team of researchers shared insights from their experience integrating a COVID-19 tracker application into a health system's EHR. The authors said their use of the Health Level 7 (HL7)'s Fast Healthcare Interoperability Resources (FHIR) standard provided additional data structure and semantics, which improved data transfer speed and made the implementation of FHIR APIs smoother and more efficient. However, the authors also noted that several implementation barriers arose due to only partial implementation of current FHIR standards in the EHR, the developers' inexperience with the FHIR standards and API-driven integration, and FHIR standard gaps. Despite these challenges, the authors believe the FHIR standard is promising for use in integrating patient engagement applications into EHRs. The authors suggested more complete implementation of FHIR standards could increase the use of patient-generated health data in clinical decision-making. Specifically, the authors called for the adoption of event notifications from EHRs to patient apps and for improved integration of patient-generated health data into EHRs.[79]

During their interview, health care technology experts spoke on the importance of standards. They emphasized the importance of not only certifying that EHRs meet standards during development, but also to test and verify that they continually test that they meet standards once implemented. As such, the experts said that it is critical that all health care IT stakeholders follow appropriate standards to ensure data quality.[24] The health care technology experts also noted that HHS has taken steps to help promote the use of both legally mandated and voluntary consensus standards through their Health IT Alignment Policy.[80] Another resource that health care quality experts pointed to during their interview was the Office of the National Coordinator for Health IT (ONC) Safer Guides, which are a series of guides that identify recommended practices to optimize the safety and safe use of EHRs.[24] As of this report, there are nine published guides.[81] The health care quality experts noted these guides help to enhance safety and ensure that clinicians utilize EHRs properly.[24]

A study noted there was significant inconsistency between the EHR data and patient interview findings, and more information was reported during patient interviews. They noted multiple factors can affect the documentation of symptoms in the EHR. The authors expressed their belief that using solely EHR data can lead to biases and inaccurate diagnoses and that patient interviews are an important source of information for emerging or new diseases, exposures, and

[79] Lobach, D. F., Boxwala, A., Kashyap, N., Heaney-Huls, K., Chiao, A. B., Rafter, T., Lomotan, E. A., Harrison, M. I., Dymek, C., Swiger, J., & Dullabh, P. (2022). Integrating a Patient Engagement App into an Electronic Health Record-Enabled Workflow Using Interoperability Standards. *Applied Clinical Informatics*, *13*(5), 1163–1171. https://doi.org/10.1055/s-0042-1758736.

[80] Office of the National Coordinator for Health IT. "HHS Health IT Alignment Policy." *HealthIT.gov*, Office of the National Coordinator for Health IT, www.healthit.gov/topic/hhs-health-it-alignment-policy.

[81] Office of the National Coordinator for Health IT. "SAFER Guides." *HealthIT.gov*, Office of the National Coordinator for Health IT, 2018, www.healthit.gov/topic/safety/safer-guides.

public health-related investigations.[82] Another study noted unstructured free text notes can be rife with documentation errors and advocated for reinforcing clinicians' appropriate EHR use as well as improving their EHR use experience.

Changes or additions since last published report: New literature and stakeholder input. This report presents information on reviewing and testing EHR software, the importance of change management strategies and choosing the appropriate EHR software that meets clinical needs, as well as other information that is new since publication of the 2022 Report.

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

The evidence below for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results' impact on patient safety was gathered from adverse event reports.

FDA received two adverse event reports[10] related to medical imaging software displaying patient data for a previous patient when a user attempted to begin viewing a new patient. The reporters said there was no direct patient harm, but they noted this could have adversely affected patient care if a provider based a clinical decision on the incorrect information.

FDA received two adverse event reports[10] related to a visual data system that provided high-definition video to surgeons within the operating room. The first error involved a portion of the video image not appearing, and the second error involved the image appearing too small during procedure preparation. There was no direct patient harm resulting from these errors, but the reporters acknowledged that the lack of appropriate visibility have put patients at risks.

FDA received three adverse event reports[10] that involved the association of images and image data with incorrect patients. Two errors occurred with multimedia integration and communication incorrectly associated information from an imaging sharing system with another patient. In the third error, the software did not store the correct date and time when retrieving results from bedside medical devices. There were no reports of patient harm related to these

[82] Soto, R. A., Vahey, G. M., Marshall, K. E., McDonald, E., Herlihy, R., Chun, H. M., Killerby, M. E., Kawasaki, B., Midgley, C. M., Alden, N. B., Tate, J. E., Staples, J. E., & Investigation Team, C. (2024). The role and limitations of electronic medical records versus patient interviews for determining symptoms, underlying comorbidities, and medication usage for patients with COVID-19. *American Journal of Epidemiology*, kwae079. Advance online publication. https://doi.org/10.1093/aje/kwae079.

errors, but the reporters noted these errors could have led to patient harm if a clinical decision was made on incorrect patient information.

FDA received one adverse event report[10] related to cardiovascular image management software. Providers were unable to export a patient's study data from the software, which delayed clinician assessment and patient care.

FDA received several adverse event reports[10] related to mobile applications that connect to glucose monitors and allow patients to view trends in their blood sugar levels. One report involved the application not refreshing as frequently as designed, which the reporter noted could have affected the accuracy of the information shown that patients use to make decisions on their insulin dosing. Another report involved the application displaying the incorrect units for the patient's blood sugar level, which may have led to the patient experiencing a hyperglycemic episode. In addition, there were more than 24 reports related to the application experiencing issues when attempting to connect the application to the patient's glucose monitor. Of these, 15 events led to patients experiencing hypoglycemic episodes, with three of these events requiring hospitalization and advanced care and two of these events leading to the patient fainting. Ten events led to patient experiencing hyperglycemic episodes, but no reports indicated any harm requiring medical intervention.

Changes or additions since last published report: *New adverse event reports.* This report presents new adverse events related to a cloud-based automated library, a visual data system, and mobile applications that connect to glucose monitors and allow patients to view trends in their blood sugar levels, which is new since publication of the 2022 Report.

Benefits and Risks to Health

The evidence below for the benefits and risks to health of transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results was gathered from peer-reviewed literature (including various focus areas) and stakeholder input collected during interviews with experts.

A team of researchers tested whether the implementation of a data integration, storage, and visualization software improved patient outcomes in cardiac intensive care units. The software collected data from intensive care unit monitors and devices and interfaced with the EHR to display and visualize aggregated data. Analyses revealed that hospitals using the software had statistically significant greater reductions in cardiac arrests, unplanned admissions, and postoperative length of stay than the hospitals that did not use the software.[83]

During an interview, biomedical research experts noted that the ability to automatically transfer, store, or convert data can help make data more consistent, enhance how information is presented to providers, and reduce the possibility of mistakes.[24] Life sciences experts noted this software can also efficiently transfer and display laboratory test results in a patient's EHR, which

[83] Gaies, M., Olive, M. K., Owens, G. E., Charpie, J. R., Zhang, W., Pasquali, S. K., Klugman, D., Costello, J. M., Schwartz, S. M., & Banerjee, M. (2023). Methods to Enhance Causal Inference for Assessing Impact of Clinical Informatics Platform Implementation. *Circulation. Cardiovascular Quality and Outcomes*, *16*(2), e009277. https://doi.org/10.1161/CIRCOUTCOMES.122.009277.

they said can reduce administrative burden and streamline clinician workflow.[24] Government health care experts expressed similar views during their interview, stating that integrating patient data into a single source can provide clinicians with a better understanding of the patient and their history to improve their decision-making ability.[24]

A group of researchers sought to advance a stroke-oriented learning health care system by establishing a comprehensive repository of stroke data from a hospital network's EHR system. The group developed a series of data pipelines to convert EHR data into analyzable formats. The authors noted this methodology yielded a comprehensive and accessible research database that can help to accelerate stroke research and improve poststroke patient care and outcomes.[84] Similarly, a team of researchers developed a clinical research datamart where a health system's rehabilitation-related EHR data are converted to meet the parameters of a common data model to facilitate rehabilitation research and included a user interface that allowed users to visualize data and standardize terminology to support large-scale analytics and clinical data analyses. The authors stated this approach can help to advance precision rehabilitation research, link health system data and experiences with external evidence to improve patient care and facilitate the use of real-world evidence for the development and implementation of health interventions to support patient outcomes.[85]

Another study reviewed the potential benefits of using population health management platforms that aggregate, transform, and store data (e.g., EHR data, medical device data, PRO data). The authors noted such an approach can improve the integration of PROs with clinical data and the utilization of this information to support patient care. They also said this approach can help overcome many of the technical and governance barriers that exist. The authors recommended future integration teams prepare clear documentation of data provenance, develop comprehensive data dictionaries, and establish record linkage mechanisms.[86]

Despite the benefits of this software function, multiple experts identified potential risks during interviews. Government health care experts noted that, while integration is a definite benefit, being unable to integrate all necessary data into one location with this software can lead to providers potentially making ill-informed diagnostic decisions. They noted aggregating patient information supports clinical care and said this software function will become more critical as the population matures and the number of providers struggles to keep pace.[24] However, biomedical research experts emphasized the importance of security, as any movement or storage of patient data can lead to the unintended release of patient health information.[24]

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[84] Potter, T. B. H., Pratap, S., Nicolas, J. C., Khan, O. S., Pan, A. P., Bako, A. T., Hsu, E., Johnson, C., Jefferson, I. N., Adegbindin, S. K., Baig, E., Kelly, H. R., Jones, S. L., Britz, G. W., Tannous, J., & Vahidy, F. S. (2023). A Neuro-Informatics Pipeline for Cerebrovascular Disease: Research Registry Development. *JMIR Formative Research*, *7*, e40639. https://doi.org/10.2196/40639.

[85] Oniani, D., Parmanto, B., Saptono, A., Bove, A., Freburger, J., Visweswaran, S., Cappella, N., McLay, B., Silverstein, J. C., Becich, M. J., Delitto, A., Skidmore, E., & Wang, Y. (2023). ReDWINE: A clinical datamart with text analytical capabilities to facilitate rehabilitation research. *International Journal of Medical Informatics*, *177*, 105144. https://doi.org/10.1016/j.ijmedinf.2023.105144.

[86] Espinoza, J., Tut, M., Shah, P., Kingsbury, P., Nagaraj, G., Meeker, D., & Bahroos, N. (2023). Integrating REDCap patient-reported outcomes with the HealtheIntent population health platform: proof of concept. *JAMIA Open*, *6*(3), ooad074. https://doi.org/10.1093/jamiaopen/ooad074.

Changes or additions since last published report: *New literature and stakeholder input*. This report presents information on the benefits of automatically integrating, storing, and visualizing data and converting formats to support health outcomes, risks associated with security and not appropriately integrating data into one location, as well as other information that is new since publication of the 2022 Report.

Best Practices to Promote Safety, Education, and Competency

The evidence below for best practices to promote safety, education, and competency related to transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results was gathered from peer-reviewed literature (including various focus areas) and stakeholder input collected during interviews with experts.

One study aimed to modify a platform to reduce the complexity of querying and loading EHR data. The authors developed an application that imports patient data (e.g., medical record number, start date) and meta-data (e.g., path, type) into the platform and populates tables within a data repository. The authors noted this methodology allowed staff to direct their focus toward preparing queries rather than loading the data, which reduced their cognitive load and enabled staff with limited technical expertise to prepare queries.[87]

A team of researchers covered several initiatives intended to overcome challenges associated with organizing, sharing, integrating, and using of health care data and shared best practices from each case study. One initiative was a health technology platform that collected, aggregated, and converted the formatting of clinical data to make it compliant with Health Insurance Portability and Accountability Act guidelines and to ensure it conformed to a common data model capable of supporting queries. Lessons learned from this initiative included the value of a robust cloud architecture to enable frequent data updates; the importance of proper integration into providers' workflow; and the potential utility of adopting standard EHR data specifications to reduce burdens associated with unstructured data. Another initiative was a clinical, imaging, and genomic data repository that automated the aggregation, deidentification, formatting, and upload of data. A lesson learned from this initiative was the value of a data-sharing taxonomy that considered the accessibility, size, elements, and computing power needed to gather and share large amounts of data.[88]

One group of researchers developed the technical architecture of a data hub capable of combining multiple EHR data feeds to enhance public health surveillance. This architecture supported secure file sharing and connection, secure data storage, large-scale data analyses, and data visualization. The researchers noted coupling of consolidated clinical document architecture records with laboratory reporting feeds can help to improve the analytic power of

[87] Wagholikar, K. B., Ainsworth, L., Zelle, D., Chaney, K., Mendis, M., Klann, J., Blood, A. J., Miller, A., Chulyadyo, R., Oates, M., Gordon, W. J., Aronson, S. J., Scirica, B. M., & Murphy, S. N. (2022). I2b2-etl: Python application for importing electronic health data into the informatics for integrating biology and the bedside platform. *Bioinformatics (Oxford, England)*, *38*(20), 4833–4836. https://doi.org/10.1093/bioinformatics/btac595.

[88] Sweeney, S. M., Hamadeh, H. K., Abrams, N., Adam, S. J., Brenner, S., Connors, D. E., Davis, G. J., Fiore, L. D., Gawel, S. H., Grossman, R. L., Hanlon, S. E., Hsu, K., Kelloff, G. J., Kirsch, I. R., Louv, B., McGraw, D., Meng, F., Milgram, D., Miller, R. S., Morgan, E., … Srivastava, S. (2023). Case Studies for Overcoming Challenges in Using Big Data in Cancer. *Cancer Research*, *83*(8), 1183–1190. https://doi.org/10.1158/0008-5472.CAN-22-1277.

public health data sets. They also emphasized the importance of standards that outline the structure of data sharing and semantic representation of information.[89]

During interviews for this report, multiple experts discussed the current regulatory landscape related to data transfer, storage, and format conversion. Health care technology experts noted that there are differences between federal and state laws in this space and that developers have sought clarity from the different, non-FDA regulators on applicable standards and how they can ensure compliance with all applicable regulations.[24] As regulations are passed and standards are established, information services experts said it is important that organizations educate developers on these new standards and inform them of the standards applicable to their work.[24] One education method that health care quality experts suggested was developers and implementers developing direct trainings in small groups. Although they noted this approach can be labor-intensive and difficult to accomplish at scale, they said this has been the most successful method they used when educating these groups on standards.[24]

Multiple expert interviewees also discussed the importance of standards when developing software intended to transfer, store, or convert the formatting of data. Biomedical research experts emphasized the importance of developers using and adhering to existing standards when planning and designing software solutions, and that resources are publicly available that support the standardization of this software.[24] One such example shared by information services experts was ONC's United States Core Data for Interoperability, which is a standardized catalog of health data classes and data elements designed to enable interoperable health information exchange across U.S. health care systems.[90] This standardization is especially important for terminology and units when transferring data between platforms, and these experts noted that ensuring this information is consistent can limit potential risks.[24] Information services experts added standards help make communication consistent and improve interpretability. However, they also said there can still be variability among existing standards (e.g., fields may be optional, data entry may be inconsistent, codes may vary between institutions), which creates potential for flexibility. While they acknowledged the potential benefits of flexibility, the experts said this lack of standardization can limit accuracy and efficiency when integrating data from multiple sources, and thus said it is more important for data to be structured even if some flexibility must be sacrificed.[24]

Changes or additions since last published report: *New literature and stakeholder input*. This report presents information on educating developers on the standards applicable to their work, the value of a data-sharing taxonomy, and the balance between structure and flexibility, as well as other information that is new since publication of the 2022 Report.

[89] Hota, B., Casey, P., McIntyre, A. F., Khan, J., Rab, S., Chopra, A., Lateef, O., & Layden, J. E. (2022). A Standard-Based Citywide Health Information Exchange for Public Health in Response to COVID-19: Development Study. *JMIR Public Health and Surveillance*, *8*(9), e35973. https://doi.org/10.2196/35973.

[90] Office of the National Coordinator for Health Information Technology. "United States Core Data for Interoperability (USCDI)." *HealthIT.gov*, Office of the National Coordinator for Health Information Technology, July 2024, www.healthit.gov/isp/united-states-core-data-interoperability-uscdi.

Certain Clinical Decision Support (CDS)

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—*
>
> > *(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

The evidence below for certain CDS' impact on patient safety was gathered from adverse event reports.

FDA received one adverse event report[10] related to a CDS tool not providing an appropriate notification.[10] The error occurred with a CDS tool intended to notify providers of potential drug-allergy interactions. The tool lacked proper mapping of certain allergy substances when entered as a certain code, which led some drug-allergy notifications to not properly trigger. The reporter said there was no direct patient impact, but noted this could lead to a serious injury or delay patient care.

FDA received two adverse event reports[10] related to CDS software that supported medication order checking. The first error occurred when the CDS software sent an incorrect medication identifier, which led to incorrect prescription order checking. There was no direct patient impact, but the reporter noted this could have led to inappropriate prescribing. The second error occurred when a provider scanned two medications with the same formulations but different delivery mechanisms (i.e., extended-release vs immediate-release). The software did not display an incompatibility warning to notify the provider the scanned product did not match the order. This did not affect a patient, but this error could have led to incorrect medication administration.

Changes or additions since last published report: *New adverse event reports.* This report presents new adverse events related to a CDS tool not providing an appropriate notification and CDS software that supported medication order checking, which is new since publication of the 2022 Report.

Benefits and Risks to Health

The evidence below for the benefits and risks to health of certain CDS was gathered from peer-reviewed literature (including various focus areas).

Multiple studies assessed the effects of CDS tools on tobacco cessation.[91,92] One study assessed the effects of a CDS tool that notified clinicians when a patient was a current tobacco user and indicated readiness to quit. Clinicians participated in training to reinforce the importance of discussing and addressing tobacco use history and received a notice that prompted them to identify whether they documented a tobacco assessment and plan, if they discussed the health risks of tobacco use and advised the patient to quit, or that tobacco use issues were not discussed. After adjusting for age, gender, practice site, and patient location, clinicians that used the notification feature saw a significant increase in their patients' tobacco cessation compared to clinicians in the control group.[91] A second tobacco cessation study reviewed EHR activity metrics to monitor the effects of two CDS tools. The first prompted clinicians to consider completing a tobacco screening and the second prompted providers to consider discussing tobacco support and referring appropriate patients to a tobacco cessation clinic. The researchers offered recommendations to improve the adoption, efficacy, and accuracy of these tools while reducing their burden on clinicians; including identifying clinician champions to support the implementation of CDS tools, requiring documentation of the reason(s) for ignoring a notification, and setting a maximum number of notices for each encounter.[92]

Multiple studies assessed the effects of CDS tools that sent notifications.**Error! Bookmark not defined.**[93,94] One study assessed the impact of a CDS tool that provides education on the indications for a urine culture and provided a reminder, consistent with clinical guidelines, suggesting removal of a catheter prior to collecting a sample from a patient with a catheter present for longer than seven days. Regression analysis demonstrated a statistically significant decrease in the number of urine culture orders and antibiotic use for urinary tract infections.[95] Another study evaluated the impacts of an EHR-based CDS tool designed to promote guideline-recommended cancer risk management. The CDS tool identified care gaps in each patient's cancer risk management activities along with their due date and recommended frequency. The

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[91] Drake, L. A., Suresh, K., Chrastil, H., Lewis, C. L., & Altman, R. L. (2022). Improving Tobacco Cessation Rates Using Inline Clinical Decision Support. *Applied Clinical Informatics*, *13*(5), 1116–1122. https://doi.org/10.1055/a-1961-9800.

[92] Chen, J., Cutrona, S. L., Dharod, A., Bunch, S. C., Foley, K. L., Ostasiewski, B., Hale, E. R., Bridges, A., Moses, A., Donny, E. C., Sutfin, E. L., Houston, T. K., & iDAPT Implementation Science Center for Cancer Control (2023). Monitoring the Implementation of Tobacco Cessation Support Tools: Using Novel Electronic Health Record Activity Metrics. *JMIR Medical Informatics, 11*, e43097. https://doi.org/10.2196/43097.

[93] Yarrington, M. E., Reynolds, S. S., Dunkerson, T., McClellan, F., Polage, C. R., Moehring, R. W., Smith, B. A., Seidelman, J. L., Lewis, S. S., & Advani, S. D. (2023). Using clinical decision support to improve urine testing and antibiotic utilization. *Infection Control and Hospital Epidemiology*, *44*(10), 1582–1586. https://doi.org/10.1017/ice.2023.30.

[94] Lau-Min, K. S., Bleznuck, J., Wollack, C., McKenna, D. B., Long, J. M., Hubert, A. P., Johnson, M., Rochester, S. E., Constantino, G., Dudzik, C., Doucette, A., Wangensteen, K., Domchek, S. M., Landgraf, J., Chen, J., Nathanson, K. L., & Katona, B. W. (2023). Development of an Electronic Health Record-Based Clinical Decision Support Tool for Patients With Lynch Syndrome. *JCO Clinical Cancer Informatics*, *7*, e2300024. https://doi.org/10.1200/CCI.23.00024.

tool was highly sensitive (96.4%) and specific (91%) in identifying patients with existing gaps in their cancer risk management care, and clinicians believed the tool positively impacted their patient care. Identified areas for improvement included incorporating CDS reminders in other areas of the EHR, building in CDS logic that enabled easier updates, and applying guideline recommendations across populations of interest.[96]

A team of researchers assessed the effects of a CDS tool on patient admissions for cellulitis. The CDS tool recognized when a clinician inputted a clinical impression or diagnosis code for cellulitis and presented a series of image-based patient and rash characteristics to support the clinician as they developed their differential diagnosis. Based on the clinician's selections, the CDS would present image-based listings of likely diagnoses and of the most dangerous diagnoses in a variety of skin tones. Although engagement with the CDS tool was low among clinicians, there was a statistically significant absolute reduction in the need for admissions by clinicians that used the tool.[97]

One study evaluated the implementation of a notification feature that informed providers when patients were physically inactive (according to scores on a physical activity questionnaire) and offered recommendations for physical activity counseling. Clinicians opened and signed between 2% and 65% of all notifications per month and rejected between 2% and 22% of all notifications per month. Clinicians noted the notification feature was easy to navigate, prompted conversations with their patients, and did not disrupt clinical care.[98]

One study tested the usability and effectiveness of a CDS-enhanced EHR order set used in outpatient antibiotic prescribing for community-acquired pneumonia and urinary tract infections. The CDS tool included orders embedded in the patient's discharge workflow to help providers choose the correct antibiotic and send passive notifications to display informational resources. Providers were more satisfied with and preferred the usability of the CDS-enhanced EHR to their current order system, and there was a reduced rate of usability errors with the use of the CDS-enhanced EHR. Use of the CDS-enhanced EHR was associated with improved adherence to antimicrobial stewardship guidelines and reduced the rate of decision-making errors when ordering antibiotics.[99]

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[96] Lau-Min, K. S., Bleznuck, J., Wollack, C., McKenna, D. B., Long, J. M., Hubert, A. P., Johnson, M., Rochester, S. E., Constantino, G., Dudzik, C., Doucette, A., Wangensteen, K., Domchek, S. M., Landgraf, J., Chen, J., Nathanson, K. L., & Katona, B. W. (2023). Development of an Electronic Health Record-Based Clinical Decision Support Tool for Patients With Lynch Syndrome. *JCO Clinical Cancer Informatics*, *7*, e2300024. https://doi.org/10.1200/CCI.23.00024.

[97] Dezman, Z. D. W., Lemkin, D., Papier, A., & Browne, B. (2023). The impact of a point-of-care visual clinical decision support tool on admissions for cellulitis in the University of Maryland medical system. *Journal of the American College of Emergency Physicians Open, 4*(3), e12969. https://doi.org/10.1002/emp2.12969.

[98] McCarthy, M. M., Szerencsy, A., Taza-Rocano, L., Hopkins, S., Mann, D., D'Eramo Melkus, G., Vorderstrasse, A., & Katz, S. D. (2024). Implementing a Clinical Decision Support Tool to Improve Physical Activity. *Nursing Research*, 10.1097/NNR.0000000000000714. Advance online publication. https://doi.org/10.1097/NNR.0000000000000714.

[99] McGonagle, E. A., Karavite, D. J., Grundmeier, R. W., Schmidt, S. K., May, L. S., Cohen, D. M., Cruz, A. T., Tu, S. P., Bajaj, L., Dayan, P. S., & Mistry, R. D. (2023). Evaluation of an Antimicrobial Stewardship Decision Support for Pediatric Infections. *Applied Clinical Informatics*, *14*(1), 108–118. https://doi.org/10.1055/s-0042-1760082.

Three studies focused on the association between the use of CDS software and medications related to sexual health. One study assessed changes in pediatric providers' knowledge and their likelihood to initiate preexposure prophylaxis (PrEP) after exposure to a CDS tool that presented several options (e.g., opening PrEP order set, referring the patient to an internal PrEP provider, sending the patient educational modules) to a provider when they ordered a human immunodeficiency (HIV) test for a patient. There were statistically significant increases in providers self-reported knowledge of PrEP and their likelihood of prescribing PrEP or referring patients for PrEP. Participating providers agreed the CDS was an effective educational tool and helped them understand what PrEP was and who would benefit from using it.[100] A second study assessed whether a dedicated PrEP nurse or CDS tools increased PrEP counseling and prescriptions. Both interventions increased HIV prevention counseling, but neither increased PrEP prescriptions.[101] A third study integrated gonorrhea treatment, HIV screening, and CDC PrEP prescribing guidelines into an EHR-based CDS tool. Patients that met certain criteria caused the CDS tool to recommend the clinician consider an STI order set that offered recommendations for tests, provided PrEP prescription options, presented CDC guidelines-based medication recommendations, and provided a link to gonorrhea treatment guidelines. The CDS tool showed high rates of use but did not demonstrate significant differences in the number of patients treated or prescribed PrEP. Clinicians noted they did not change their treatment or screening recommendations based on the tool's suggestions.[102]

A research team compared the effectiveness of a physician-facing CDS tool to patient-directed education in the promotion of appropriate opioid use for chronic pain. The CDS tool sent notifications when a provider entered an order yielding a potential total daily dose beyond an evidence-based threshold and when a provider ordered opioids and benzodiazepines together. Patient education materials included information on opioids and their alternatives, the potential benefits of multi-modal treatment, and how to prepare for health care visits. Use of the patient education materials was associated with nearly three-fold greater odds in achieving the highest patient-provider communication satisfaction compared to use of the CDS tool. However, use of the CDS tool resulted in a 38% lower odds ratio for prescribing high doses of opioids compared to the patient education arm. The authors concluded both strategies performed well and that

[100] Chan, C. T., Carlson, J., Lee, T., Vo, M., Nasr, A., & Hart-Cooper, G. (2022). Usability and Utility of Human Immunodeficiency Virus Pre-exposure Prophylaxis Clinical Decision Support to Increase Knowledge and Pre-exposure Prophylaxis Initiations among Pediatric Providers. *Applied Clinical Informatics*, *13*(5), 1141–1150. https://doi.org/10.1055/a-1975-4277.

[101] Wang, R., Fruhauf, T. F., Sao, S. S., Gingher, E. L., Martin, S. J., & Coleman, J. S. (2023). Clinic-based interventions to increase preexposure prophylaxis awareness and uptake among United States patients attending an obstetrics and gynecology clinic in Baltimore, Maryland. *American Journal of Obstetrics and Gynecology*, *229*(4), 423.e1–423.e8. https://doi.org/10.1016/j.ajog.2023.07.046.

[102] Karki, S., Shaw, S., Lieberman, M., Pérez, A., Pincus, J., Jakhmola, P., Tailor, A., Ogunrinde, O. B., Sill, D., Morgan, S., Alvarez, M., Todd, J., Smith, D., & Mishra, N. (2024). Clinical Decision Support System for Guidelines-Based Treatment of Gonococcal Infections, Screening for HIV, and Prescription of Pre-Exposure Prophylaxis: Design and Implementation Study. *JMIR Formative Research*, *8*, e53000. https://doi.org/10.2196/53000.

health systems can consider their available resources, expertise, and bandwidth when determining the most effective communication strategy for their stakeholders.[103]

A team of researchers worked with a group of primary care providers to help guide the design of a CDS tool intended to promote evidence-based care for prediabetes. The CDS tool sent a non-interruptive notification when a provider enters a diagnosis code for prediabetes in a patient's EHR or when a patient's glycemic test results were in the prediabetes range. The notification displayed relevant patient information (e.g., recent weight and body mass index measurements, glucose readings) and presented providers with options to add a prediabetes code to the patient's problem list, prescribe metformin, order A1c testing, and refer patients to health educator counseling. Providers preferred the non-interruptive notification, as they felt inundated with the number of notifications they received in their EHRs and regularly circumvented or deferred notifications, so they could continue patient care. Although uptake was relatively low, providers that used the CDS saw statistically significant increases in the rate of HbA1c lab test orders, and in health educator counseling referrals and attendance.[104]

Multiple studies used CDS tools to help reduce unnecessary testing. One hospital system implemented a CDS tool in their lumbar puncture order sets to conserve resources and reduce the potential for false positives from polymerase chain reaction tests. The updated order sets included recommendations designed to reduce initial cerebrospinal fluid testing and encourage focused testing based on initial test results and clinical suspicion. There was a statistically significant decrease in the number of polymerase chain reaction tests following implementation of the CDS tool.[105] Another study used a CDS tool to reduce the rate of inappropriate testing for clostridioides difficile. The authors created and launched notification features across 11 hospitals to provide context-relevant notifications to the provider if the patient had been administered a laxative within the last 48 hours, if they recently received a positive clostridioides difficile test, or if they recently received a negative clostridioides difficile test. Use of the CDS tool led to a beneficial 27.3% decrease in test orders.[106]

Changes or additions since last published report: *New literature.* This report presents information on the benefits of CDS tools that send various types of notifications to physicians to

[103] Spiegel, B. M. R., Fuller, G., Liu, X., Dupuy, T., Norris, T., Bolus, R., Gale, R., Danovitch, I., Eberlein, S., Jusufagic, A., Nuckols, T., & Cowan, P. (2023). Cluster-Randomized Comparative Effectiveness Trial of Physician-Directed Clinical Decision Support Versus Patient-Directed Education to Promote Appropriate Use of Opioids for Chronic Pain. *The Journal of Pain*, *24*(10), 1745–1758. https://doi.org/10.1016/j.jpain.2023.06.001.

[104] O'Brien, M. J., Vargas, M. C., Lopez, A., Feliciano, Y., Gregory, D. L., Carcamo, P., Mohr, L., Mohanty, N., Padilla, R., Ackermann, R. T., Persell, S. D., & Feinglass, J. (2022). Development of a novel clinical decision support tool for diabetes prevention and feasibility of its implementation in primary care. *Preventive Medicine Reports*, *29*, 101979. https://doi.org/10.1016/j.pmedr.2022.101979.

[105] Lyman, K. A., Madill, E., Thatikunta, P., Threlkeld, Z. D., Banaei, N., & Gold, C. A. (2023). An Electronic Health Record Intervention to Limit Viral Testing of Cerebrospinal Fluid. *The Neurohospitalist*, *13*(2), 173–177. https://doi.org/10.1177/19418744231152103.

[106] Krouss, M., Israilov, S., Alaiev, D., Tsega, S., Talledo, J., Chandra, K., Zaurova, M., Manchego, P. A., & Cho, H. J. (2023). SEE the DIFFerence: Reducing unnecessary C. difficile orders through clinical decision support in a large, urban safety-net system. *American Journal of Infection Control*, *51*(7), 786–791. https://doi.org/10.1016/j.ajic.2022.11.003.

improve their patient care, help reduce unnecessary testing, help improve sexual health-related outcomes, as well as other information that is new since publication of the 2022 Report.

Best Practices to Promote Safety, Education, and Competency

The evidence below for best practices to promote safety, education, and competency related to certain CDS was gathered from peer-reviewed literature (including various focus areas) and stakeholder input collected from public commenters and during interviews with experts.

During interviews for this report, experts across the health care ecosystem recognized the potential for AI to improve care quality and patient outcomes. Life sciences experts noted AI can facilitate CDS functions and improve upon existing technology by retrieving information from patient records (e.g., handwritten notes) that would otherwise be difficult to access. They noted this enabled access to essential patient information and presented it in an accessible way for providers to efficiently and effectively identify critical patient information.[24] In addition, a health care quality expert noted that providers appreciate when AI bots review information from patients and feel more confident when the outputs are aligned with their clinical opinion. Health care quality experts also noted that providers want AI to be personalized to their work and in the recommendations it provides. They also noted patients want to know when and where AI is used in their care and that they want to be confident in their data's security.[24]

However, many experts also expressed caution about the integration of AI within CDS during interviews for this report. Health care information services experts said AI can generate inappropriate recommendations but provide incorrect information with confidence (i.e., backed by sources but based on unreliable information), which can affect the accuracy of clinical decision-making.[24] Biomedical research experts noted that presenting data or recommendations in a manner that can be misinterpreted or without proper context presents the risk of inappropriate decision-making.[24] Health care information services experts emphasized the importance of listing the sources the software used to generate recommendations and allowing clinicians to review these sources to determine its reasoning. One system these experts used to document the strength of recommendations from CDS software is the Grading of Recommendations Assessment, Development and Evaluation system, which rates the quality of evidence and evaluates potential uncertainties to determine the strength of recommendations. The experts also stressed the importance of CDS developers implementing appropriate constraints on AI models to limit potential biases that can develop if they are trained on a broad dataset or on unreliable sources.

In order to be proactive about regulating the use of AI in CDS software, health care technology experts noted during their interview that an executive order called upon government agencies within HHS to form a task force whose purpose is develop a regulatory structure to oversee the utilization of AI in health care.[107] Other government agencies have put forth formal rules to help improve the standardization of regulation for generative AI in health care (e.g., ONC's "Health

[107] The White House. (2023, October 30). *FACT SHEET: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence*. The White House; The White House. https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/30/fact-sheet-president-biden-issues-executive-order-on-safe-secure-and-trustworthy-artificial-intelligence/.

Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing"[108]). The experts also noted regulators are working to balance protecting patients and promoting innovation in this area, but they emphasized the potential risk generative AI models could present if used within CDS.[24]

One study examined common CDS software malfunctions related to a medication's route of administration and offered recommendations to limit these errors. The authors presented a series of CDS malfunctions that occurred where certain notifications did not send appropriately due to errors in the software's interpretation of a patient's medication regime or route of administration. Based on these malfunctions, the authors offered several recommendations to avoid or detect these types errors, including conducting audits on the software's logic related to route of administration, creating reports to monitor the availability of new formulations of medications, and using user feedback tools to identify and respond to potential issues.[109] During an interview for this report, a health care quality expert acknowledged the potential risk of misinterpreting medication orders from CDS software. They suggested including the five rights (i.e., right patient, drug, time, dose, route of administration) within medication orders to make it easier for providers to validate the information is correct before placing an order.[24]

One group of researchers drew findings from the Agency for Healthcare Research and Quality's Patient-Centered Outcomes Research CDS Initiative to gather lessons learned about publicly available, standards-based CDS software. A main theme from the initiative was the importance of clinician trust in the CDS software, and participants noted developers can increase trust by providing accessible information to help users understand and assess the software's logic, validity, and utility. Findings from the initiative supported a collaborative approach (e.g., guideline developers, clinical experts, CDS developers) when translating CDS logic into publicly available supporting materials. The researchers noted additional transparency and understandability can help address hesitancy from health systems who desire more information on CDS outcomes and return on investment to justify its cost and effort. In addition, the researchers noted publicly available CDS can benefit from iterative improvements and refinements from public users, but they also advocated for incorporating feedback loops where CDS developers receive feedback from other sources to make improvements and address issues. The initiative also found lower-resourced settings require extra support (e.g., additional funding, detailed implementation guides) to effectively implement and benefit from CDS.[110]

One study aimed to identify data elements useful in finding and limiting the sending of irrelevant drug-allergy notifications. The researchers found that 91% of these notifications were overridden, with a statistically significant difference in the percentage of possible notifications

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[108] Health and Human Services Department. (2024, January 9). *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing*. https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and.

[109] Wright, A., Nelson, S., Rubins, D., Schreiber, R., & Sittig, D. F. (2022). Clinical decision support malfunctions related to medication routes: a case series. *Journal of the American Medical Informatics Association: JAMIA, 29*(11), 1972–1975. https://doi.org/10.1093/jamia/ocac150.

[110] Dhopeshwarkar, R. V., Freij, M., Callaham, M., Desai, P. J., I Harrison, M., Swiger, J., A Lomotan, E., Dymek, C., & Dullabh, P. (2023). Lessons Learned from a National Initiative Promoting Publicly Available Standards-Based Clinical Decision Support. *Applied Clinical Informatics*, *14*(3), 566–574. https://doi.org/10.1055/s-0043-1769911.

that were dismissed (95.9%) and the percentage of definite matches that were dismissed (88%). Based on their analysis, the authors estimated that 53.5% of notifications (for those with a prior administration record and a definite match) could potentially be averted with minimal risk. The authors believed that limiting notifications can benefit prescribers by reducing the incidence of false-positive notices and allowing them to pay more attention to clinically important warnings.[111]

One public commenter also noted that studies have shown many clinicians ignore many of the CDS software notices they receive (e.g., low relevance, inappropriate timing) and concluded that these notices can be improved and optimized to provide additional benefits to clinicians.

One study evaluated how different versions of a notification feature performed in eliciting responses from providers. Providers received one of three versions: an interruptive notification that appeared after opening the patient's chart, an interruptive notification that appeared prior to closing the patient's chart, and a passive notification that only expanded if the provider chose to view it. The proportion of encounters resulting in meaningful responses were 94.8% of the "interruptive on open" notifications, 90.1% of the "interruptive on close" notifications, and 19.7% of the passive notifications. However, "interruptive on open" was much more likely to elicit a deferral response than either of the other two types of notifications, and although participants were less likely to interact with the "Optional Persistent" notification, 98.3% of participants who did interact with that notification provided a meaningful response. Despite these differences, the authors acknowledged each notification method has utility.[112]

A group of primary care clinicians took part in a survey to assess their interest in using CDS for prostate-specific antigen testing and identify features that may facilitate their uptake and adoption. Among the results, when surveyed on functions of a CDS system, 88% of the clinicians agreed or strongly agreed it should fit within their existing workflow, 90% agreed or strongly agreed it should provide patient-specific support, and 72% agreed or strongly agreed CDS use should be optional.[113]

A similar study aimed to identify the factors that influenced the adoption, implementation, and maintenance of ED clinicians' use of a CDS tool that provided clinicians with optional evidence-based decision support to assist with opioid use disorder diagnosis, assess withdrawal severity, and evaluate a patient's readiness to begin treatment. Interviews with clinicians revealed that their adoption, implementation, and maintenance of adoption and use of the tool were associated with organizational culture and commitment, training and support, the ability to connect patients to ongoing treatment, and the ability to tailor implementation to each ED. Clinicians believed adoption and maintenance of CDS could be improved if they could create

[111] Colicchio, T. K., & Cimino, J. J. (2023). Beyond the override: Using evidence of previous drug tolerance to suppress drug allergy alerts; a retrospective study of opioid alerts. *Journal of Biomedical Informatics*, *147*, 104508. https://doi.org/10.1016/j.jbi.2023.104508.
[112] Musser, R. C., Senior, R., Havrilesky, L. J., Buuck, J., Casarett, D. J., Ibrahim, S., & Davidson, B. A. (2024). Randomized Wof Electronic Health Record Alert Types in Eliciting Responses about Prognosis in Gynecologic Oncology Patients. *Applied Clinical Informatics*, *15*(2), 204–211. https://doi.org/10.1055/a-2247-9355.
[113] Harper, J., Hunt, T., Choudry, M., Kapron, A. L., Cooney, K. A., Martin, C., Ambrose, J., & O'Neil, B. (2023). Clinician interest in clinical decision support for PSA-based prostate cancer screening. *Urologic Oncology*, *41*(3), 145.e17–145.e23. https://doi.org/10.1016/j.urolonc.2022.11.015.

local workflows and tailor the CDS tool to fit the resources, staffing, and unique characteristics of their work site.[114]

One public commenter said that even though proper use of CDS software poses little risk to patients, CDS should never replace clinicians' independent professional judgement. They said the most significant risk associated with non-device CDS software is the potential for the delivery of unreliable or out-of-date content or recommendations. However, they noted this risk can be mitigated by adopting a rigorous process for creating and deploying content and engage clinicians throughout the software development lifecycle to seek feedback on improving content and the user experience. Best practices offered by the public commenter included creating a multidisciplinary team of clinical experts to curate and validate content for the clinical knowledge systems that support CDS software and conducting regular reviews of content to ensure the software bases its recommendations on the most current information. The public commenter also said CDS developers should highlight these mitigation strategies and best practices as key features of their software and stress their importance when training clinicians on the use of such software. They also emphasized the value of transparency when working to build trust with clinicians, including having developers share details of the editorial process and the basis for recommendations.[26,115]

A team of researchers proposed using academic detailing (i.e., health IT experts conducting personal visits to clinicians) to promote correct understanding of a CDS tool and to identify factors that influenced its implementation. Researchers interviewed clinicians to assess the factors that impacted their use of the CDS tool. Interview findings demonstrated that academic detailing is a promising method to promote correct understanding of CDS tools and to identify factors that impact its implementation. The interviewees also praised its ability to inform real-time implementation and design adjustments so the tool can best fit into clinicians' dynamic work environment.[116]

Two teams of researchers conducted scoping reviews to assess the current state of CDS software in their respective fields. The first team evaluated the use of CDS software in community pharmacies. The primary finding from the review was the lack of research examining the use of CDS software in in community pharmacies. The authors suggested this lack of research and the prevalence of proprietary CDS systems in large national chain pharmacies may have hindered further research and improvement in this area. The second team reviewed

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[114] Simpson, M. J., Ritger, C., Hoppe, J. A., Holland, W. C., Morris, M. A., Nath, B., Melnick, E. R., & Tietbohl, C. (2023). Implementation strategies to address the determinants of adoption, implementation, and maintenance of a clinical decision support tool for emergency department buprenorphine initiation: a qualitative study. *Implementation Science Communications*, *4*(1), 41. https://doi.org/10.1186/s43058-023-00421-7.

[115] Section 520(o)(1)(E)(iii) of the FD&C Act requires that CDS software that is excluded from the device definition must be 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 rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient."

[116] Barton, H. J., Maru, A., Leaf, M. A., Hekman, D. J., Wiegmann, D. A., Shah, M. N., & Patterson, B. W. (2024). Academic Detailing as a Health Information Technology Implementation Method: Supporting the Design and Implementation of an Emergency Department-Based Clinical Decision Support Tool to Prevent Future Falls. *JMIR Human Factors*, *11*, e52592. https://doi.org/10.2196/52592.

literature available on CDS software for nurses in palliative care. Although the articles discussed many potential benefits of CDS software (e.g., improve the quality of care, guide end-users toward evidence-based interventions, efficiently seek consultations), the authors research does not adequately cover all potential needs of patients (e.g., psychosocial, cultural, spiritual needs). As such, the authors called on future developers to build in prompts that guide patient discussions about these needs and encouraged researchers to evaluate how this functionality could help clinicians support patients. In addition, the authors advocated for future research to examine the effects of CDS software on health care processes and clinicians' workflow.[117]

Researchers conducted a series of interviews with primary care providers to elicit their thoughts on a CDS tool that provided pain- and opioid-related risks, benefits, and information on possible treatments for chronic pain patients. Providers said implementing the CDS tool into the EHR was the ideal channel as it was convenient and allowed them to be more directly involved in entering patient data. Providers noted many of the tool's features (e.g., access to the Prescription Drug Monitoring Program, appointment history, treatment tracker) were valuable, but the utility of each feature could vary based on its implementation into the workflow. They suggested that reducing the number of clicks and training medical assistants, nurses, and patients to enter information could improve the tool's integration into their workflow. They also suggested that future CDS implementers proactively address clinical capacity, resources, and organizational support.[118]

As noted in the literature, displaying information in accessible and interpretable formats is integral. Biomedical research experts shared similar views during an interview for this report, specifically noting how important it is for CDS software to only collect pertinent information, both to secure information and to filter out irrelevant information. The experts said that developers need to make it clear to end-users where the data came from, how it was extracted, and why it is relevant. They added that having information presented in an accessible format and training users has an appreciable benefit for patients and providers. The experts also noted that collaboration with IT teams is necessary to ensure not only ensure data accuracy but also to train staff on the usefulness and limitations of software outputs.[24]

Changes or additions since last published report: *New literature and stakeholder input.* This report presents information on how to best use AI to facilitate CDS functions, improve notifications to better serve physicians, validate CDS data and logic, as well as other information that is new since publication of the 2022 Report.

[117] Santos, F. C. D., Snigurska, U. A., Keenan, G. M., Lucero, R. J., & Modave, F. (2023). Clinical Decision Support Systems for Palliative Care Management: A Scoping Review. *Journal of Pain and Symptom Management*, *66*(2), e205–e218. https://doi.org/10.1016/j.jpainsymman.2023.03.006.

[118] Mazurenko, O., McCord, E., McDonnell, C., Apathy, N. C., Sanner, L., Adams, M. C. B., Mamlin, B. W., Vest, J. R., Hurley, R. W., & Harle, C. A. (2023). Examining primary care provider experiences with using a clinical decision support tool for pain management. *JAMIA Open*, *6*(3), ooad063. https://doi.org/10.1093/jamiaopen/ooad063.

V. Appendix

Appendix A: Table of Abbreviations

Abbreviation	Definition
AI	Artificial Intelligence
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
ED	Emergency Department
EHR	Electronic Health Record
FD&C Act	Federal Food, Drug, and Cosmetic Act
FHIR	Fast Healthcare Interoperability Resources
HHS	Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HRQOL	Health-Related Quality of Life
ICU	Intensive Care Unit
IT	Information Technology
PrEP	Preexposure Prophylaxis
PRO	Patient-Reported Outcome
STI	Sexually Transmitted Infection
VA	Veterans Affairs
WHO	World Health Organization

Appendix B: 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

- Office of the National Coordinator for Health Information Technology - May 15, 2024
- Agency for Healthcare Research and Quality - May 20, 2024
- Biomedical Advanced Research and Development Authority - May 22, 2024
- Wolters Kluwer - May 29, 2022
- Tempus - May 29, 2024
- Veterans Health Administration/Office of Patient Safety - May 30, 2024
- Veterans Health Administration/Office of Connected Care - June 18, 2024
- Office of the Assistant Secretary of Defense for Health Affairs (Federal Electronic Health Record Modernization office) - June 25, 2024

Public Comments

- Comments submitted to the FY24 Development of 21st Century Cures Act Section 3060 Required Report: Request for Input: https://www.regulations.gov/docket/FDA-2018-N-1910.

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