Issue Brief 18

Documenting Diagnosis: Exploring the Impact of Electronic Health Records on Diagnostic Safety

Agency for Healthcare Research and Quality

PATIENT SAFETY

This page intentionally left blank.

Issue Brief 18

Documenting Diagnosis: Exploring the Impact of Electronic Health Records on Diagnostic Safety

Prepared for:
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract Number HHSP233201500022I/75P00119F37006

Prepared by:
MedStar Health National Center for Human Factors in Healthcare, Columbia, MD
Georgetown University School of Medicine, Washington, DC
Kristen Miller
Raj Ratwani
Bat-Zion Hose
Josh Biro

Oregon Health & Science University, Portland, OR
Jeffrey A. Gold

Center for Innovations in Quality, Effectiveness and Safety (IQuESt)
Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine, Houston, TX
Hardeep Singh

AHRQ Publication No. 24-0010-3-EF
August 2024

This project was funded under contract number HHSP233201500022I/75P00119F37006 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. The authors are solely responsible for this document's contents, findings, and conclusions, which do not necessarily represent the views of AHRQ. Readers should not interpret any statement in this product as an official position of AHRQ or of the U.S. Department of Health and Human Services. None of the authors has any affiliation or financial involvement that conflicts with the material presented in this product.

Suggested citation: Miller K, Biro J, Gold JA, Hose B-Z, Singh H, Ratwani, R. Documenting Diagnosis: Exploring the Impact of Electronic Health Records on Diagnostic Safety. Rockville, MD: Agency for Healthcare Research and Quality; August 2024. AHRQ Publication No. 24-0010-3-EF.

Introduction on Diagnostic Documentation

The electronic health record (EHR), an essential aspect of health information technology (health IT), serves multiple critical functions in modern healthcare. As a real-time information tool for longitudinal patient care, the EHR serves as a centralized digital repository to collect, preserve, and access patient data, including structured values, clinical notes, and interpretations of radiology and pathology tests.[1]

While this comprehensive documentation is essential, EHR functionality has extended beyond record keeping. For clinicians, the EHR is a central platform for aggregating, organizing, and visualizing diagnostic information. It facilitates clinical reasoning, record management, and communication with the care team.

Advanced tools for knowledge sharing and generation provide decision support through alerts and embedded clinical decision support (CDS) systems that have a significant role in diagnostic safety. EHRs enhance patient safety both directly and indirectly by improving data documentation, ensuring data completeness, and supporting the long-term sustainability of patient records.[2]

The potential value of the EHR to support improved patient outcomes, enhanced patient safety, and reduced costs has only been partially realized as current EHRs present both challenges and opportunities.[3-5] An often overlooked potential benefit of EHR adoption is its role in documenting the diagnostic process and essential variables related to the patient's diagnostic journey. Diagnosis serves as the cornerstone of patient care, providing a roadmap for treatment, monitoring, and decision making.

Errors in the diagnostic process can occur at various stages, from initial patient presentation to the final diagnosis, and can stem from multiple sources such as cognitive biases, communication failures, and system-level issues.[6-9] Documentation of diagnoses varies significantly by provider, practice, and disease, leading to challenges in diagnostic accuracy, clinical variation and management, and communication with patients and care team members.[10-13]

In the digital era, accurate and comprehensive diagnosis documentation within EHRs is paramount, not only for the continuity of care but also for ensuring patient safety, quality of care, and effective healthcare delivery. Documentation tools such as templates, smart phrases, and voice recognition software provide features to increase the quality and utility of clinical documentation. However, these tools require appropriate management, guidelines, and oversight ranging from internal policies and procedures to federal regulatory compliance.

The 2017 narrative review "The Impact of Electronic Health Records on Diagnosis" explored how the EHR facilitates diagnosis and improves the diagnostic process, as well as the major ways it is problematic.[14] This issue brief reviews the history of documentation legislation, including rules and regulations, and outstanding challenges and best practices to improve documentation. It also identifies future developments and opportunities for improvement, including emerging technology-based strategies to improve the traditional documentation process.

History of EHR Documentation Legislation

The EHR has evolved as the result of various influences across academia, industry, and government. Existing and emerging health IT legislation has driven significant EHR adoption, regulation, and optimization. In this section, we describe the historical progression of legislation and regulations that affect diagnostic documentation, tracing its evolution from early initiatives to contemporary federal regulations.

This review includes:

- The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009,[15,i]
- Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012,[16]
- The 21st Century Cures Act of 2016,[17] and
- Regulation CMS-1693-F from the Centers for Medicare & Medicaid Services (CMS) in 2021.[18]

Collectively, these laws and regulations promote implementation and use of the EHR. They also represent an evolution in understanding the emerging sociotechnical challenges and complexities healthcare organizations face in implementing regulations effectively, facilitating or limiting the potential benefits of health IT. Regulations affect diagnostic documentation by promoting standardization, interoperability, and patient engagement, thereby potentially enhancing diagnostic safety.

The HITECH Act, part of the American Recovery and Reinvestment Act,[19] provided incentives to stimulate "meaningful use" of the EHR through adoption by healthcare systems and individual care providers, infrastructure development, and improvements in healthcare delivery.[15] As a result of HITECH and associated efforts, health IT has revolutionized how care is delivered, but evidence is mixed on hospital productivity, physician productivity, and quality improvement.[20-22]

FDASIA expanded the FDA's authority to protect and advance public health through changes in the drug and device review process, promoting innovation, increasing stakeholder involvement, and enhancing safety.[16] Specifically, Section 618 directed multiple federal agencies, including the FDA, Office of the National Coordinator for Health Information Technology (ONC), and the Federal Communications Commission to develop a proposed strategy and recommendations for an appropriate risk-based regulatory framework for health IT.

The regulatory framework proposed through FDASIA was an important first step in identifying the types of risks posed by health IT that impact patient safety. Data capture and clinical documentation were identified as key health management functions and categorized as clinical software.

The 21st Century Cures Act included a number of provisions specific to interoperability, health information exchange, and improvements to the EHR.[17] Created based on the 21st Century Cures Act, the ONC's Cures Act Final Rule[23] focused on healthcare systems and clinical practices, healthcare providers, technology developers, and patients.

Compared with previous legislation, the 21st Century Cures Act includes multiple components that directly impact documentation integrity. The rule finalizes modifications to the 2015 health IT certification criteria to advance interoperability, enhance health IT certification, and reduce burden and costs. The final rule also

---

[i]More information on this legislation is available from the Office of the National Coordinator for Health Information Technology at https://www.healthit.gov/topic/laws-regulation-and-policy/health-it-legislation.

added criteria to make patient's electronic data more accessible via a third-party app (e.g., Apple Health Kit). Patient access is required to be free of charge and include progress notes prepared by the clinical team. Early research indicates that the OpenNotes initiative, engaging patients through shared clinical notes, increases organizational transparency and patient engagement.[24]

Lastly, in addition to recommendations on EHR certification and interoperability, the legislation allows physicians to officially delegate clinical documentation to a scribe who is not a physician as long as the physician reviews, verifies, and signs the documentation. The 21st Century Cures Act ultimately prioritizes ease of access to records and the transparency of clinical notes to patients and other care providers.

On January 1, 2021, CMS changed the requirements for outpatient evaluation and management (E/M) coding, including eliminating history and physical examination documentation.[18] This rule (CMS-1693-F) introduced significant revisions to the documentation requirements for E/M services, particularly for office/outpatient visits. Instead of relying on comprehensive documentation of history, examination, and medical decision making (the traditional three key components), CMS allowed healthcare providers to choose between two documentation options for E/M office visits.

With the first documentation option, providers could base code selection primarily on the complexity of medical decision making involved in patient care (medical decision making). With the second, providers could choose an E/M code based on total time spent with the patient, including face-to-face and non-face-to-face time on the date of the encounter (time-based documentation). The goal of the rule was to reduce administrative burden, improve flexibility for healthcare providers, and focus more on patient care rather than documentation requirements.

Recent studies have found small reductions in documentation time following these coding requirements, but the magnitude of reduction was modest and not clinically meaningful.[25,26] Authors of these studies suggest that even if total documentation time is not dramatically reduced, the new requirements could reduce physicians' cognitive burden[ii] and improve their work experience.[26,27]

Multiple federal and state laws and regulations govern nearly every facet of medical records, including content, security, retention, access, and disposal. These include the Health Insurance Portability and Accountability Act,[28] Medicare Access and CHIP Reauthorization (MACRA),[29] and Merit-Based Incentive Payment System (MIPS).[30]

To meet MIPS requirements, clinicians often need to ensure that their clinical documentation accurately captures relevant data points for reporting purposes. Compliance may involve implementing structured documentation templates, using CDS tools, and optimizing EHR workflows to facilitate data capture and reporting.

In addition, MACRA's emphasis on interoperability encourages the exchange of health information between different healthcare providers, necessitating EHR systems to support seamless data sharing and integration. Collectively, the evolution of EHR regulations contributes to diagnostic safety with considerations of privacy, security, interoperability, standardization, quality reporting, performance metrics, billing, coding accuracy, clinical decision making, and care coordination.

[ii]More information on cognitive burden is available in *Issue Brief 17: Cognitive Load Theory and Its Impact on Diagnostic Accuracy* at https://www.ahrq.gov/diagnostic-safety/resources/issue-briefs/dxsafety-cognitive-load.html.

Challenges and Opportunities for Improvement in Diagnostic Documentation

Accurate and robust documentation affects the standard of care. Better access to clinical information provides crucial insights for the care team and key considerations for diagnosis and treatment. Enhanced documentation enables well-organized availability of meaningful, accurate, and complete health records. Such records can improve the quality of care delivered, improve coordination and communication across care teams and with patients, and support the execution of integrated decision support.[31-33] However, these benefits are only achieved with documentation integrity, which requires an accurate and complete health record.

EHR usability has been directly associated with diagnostic error issues[34,35] and has not supported the development of higher levels of situational awareness.[36] Challenges and opportunities arise in optimizing complex user interfaces, improving inefficient workflows, and optimizing interoperability by applying human factors and design principles, CDS, and personalization or customization (as appropriate).

Systems designed to use medical terminology or international medical coding systems rather than free text can prevent inaccurate information.[37] Potential added functionality to assist with documentation includes templates, standard phrases and paragraphs, and automated object insertion to improve efficiency of data capture, timeliness, legibility, consistency, and completeness.[38] In addition, giving patients access to clinical notes has shown various advantages, such as heightened control over their health condition, increased involvement, better medication adherence, and heightened accountability among clinicians.[39,40]

Diagnostic uncertainty, a concept that has yet to be adequately operationalized in medical practice, is a natural part of medicine and more common in primary care than any other specialty.[41-43] Providers may encounter diagnostic uncertainty, where the patient's symptoms or clinical presentation do not clearly indicate a specific diagnosis. Notably, no diagnostic code exists for "I don't know." In such situations, providers may need to rely on provisional or working diagnoses, which can make it challenging to assign an accurate International Classification of Diseases, 10th Revision (ICD-10) code.

ICD-10 codes are highly detailed and specific, often requiring providers to choose from a vast array of codes that correspond to different diagnoses, conditions, and symptoms. Without a definitive diagnosis, providers may struggle to accurately select the most appropriate code from the extensive list of options.

A review of clinical documentation evaluated two signs of diagnostic uncertainty, identifying diagnostic uncertainty with moderate reliability. The first was the use of direct expression (e.g., use of question marks, differential diagnoses, and vocabulary such as "probably, maybe, likely"). The second was indirect inference (e.g., absence of documented diagnosis at the end of a visit, ordering of multiple consultations or diagnostic tests).[44]

Approximately 80 percent of data within the EHR is unstructured text, including visual data (e.g., endoscopy, laparoscopy), biosensor data from monitors and devices, audio data, and clinical notes (e.g., progress notes, discharge summaries, diagnostic test reports).[45,46] Although much of the data in a patient's EHR is coded, important information about the patient's care and management are often hidden in unstructured clinical notes. This practice makes it challenging and time consuming for physicians to review during their typical clinical workflow.

The use of free text within clinical notes is integral to clinical documentation as it enables clinicians to capture a comprehensive perspective of an individual, extending beyond structured data entry. Within clinical and progress notes, clinicians articulate their current evaluation, including their reasoning, and outline future steps in diagnosis or treatment. EHR-integrated interventions can target key diagnostic processes, including but not limited to:

- Dashboards to identify at-risk patients,[47]
- Diagnostic timeouts for clinicians to reassess the working diagnosis,[47]
- Patient-facing questionnaires to gather patient concerns,[47]
- Initiatives that allow patients to review diagnoses and problems documented in the EHR for accuracy,[48,49]
- More robust mechanisms for followup for tracking diagnostic information and communication,[50] and
- Innovative ways for the healthcare team to communicate and collaborate on not only the initial encounter but also results of diagnostic tests and referrals.[51]

The goal of these initiatives is to transform the EHR from a billing and communication tool for clinicians to a central form of communication among clinicians, patients, and care partners.

The concept of documentation integrity includes not just the content and information included but also information governance, authorship validation, amendments, and record corrections. Preserving documentation integrity is critical to maintain the highest levels of care and patient safety, reduce fraud and abuse, and reduce the risk of a malpractice lawsuit.[52,53] Documentation features such as template-driven drop-down boxes or lists provide rigid structures that support standardization that may prevent clinicians from telling a patient's complete story.

Research has found that clinicians experience incredible rates of stress and burnout as a result of the cognitive load required for adequate clinical documentation and record keeping.[54] Furthermore, because hospitals are reimbursed based on diagnosis-related groups, they face financial pressures within coding practices to maximize reimbursement or perceived performance.[55-57]

Clinicians have adapted to navigating the requirements for adequate documentation to secure reimbursement. Physicians often resort to copying and pasting previous notes, making minor modifications, which may inadvertently contribute to the proliferation of unnecessary and irrelevant data. Future regulations must support clinicians in creating high-quality documentation while recognizing systematic "defensive medicine" and "return on investment" challenges. Existing quality and reimbursement programs must adjust their data collection and quality measurement practices to ensure that reported data and reimbursement accurately represent the patient population under treatment, rather than solely reflecting the completeness of coded data.

The Future of Diagnostic Documentation

The future of clinical documentation is likely to be influenced by advancements in technology, using artificial intelligence (AI), machine learning (ML), and natural language processing (NLP); patient-facing initiatives such as Open Notes; and improved teamwork and care coordination. Future advancements in clinical documentation can address a range of factors, including increased provider volumes, clinician burnout, and clerical burden (especially documentation of care and order entry).

Once viewed as a technology of the future, AI is currently being tested, trialed, and implemented at healthcare organizations nationwide to reduce the burden of documentation.[58,59]

Ambient AI scribes use novel generative AI techniques such as automatic speech recognition and NLP to capture real-time patient-provider conversational interactions and assemble them into a structured note. Initial investigations into ambient AI scribes have found promising results—reducing clinicians' burden and the amount of time spent constructing notes while simultaneously improving the experience of both clinicians and patients.[60]

In freeing providers to spend more time and interact more directly with patients, ambient AI scribes may improve providers' diagnostic ability. However, ambient AI scribes also introduce new risks that may lead to diagnostic error. AI-generated notes may be inaccurate, inconsistent, and biased, hindering providers' diagnostic ability.[61-63] While the strong benefits of this new technology may lead to rapid implementation, it is imperative to carefully consider the consequences it may have on diagnostic safety to mitigate any added danger.

ML can significantly improve diagnostic safety through:

- Enhanced pattern recognition (e.g., analyzing large datasets to identify patterns that may not be apparent to human clinicians),[64]
- ML-powered CDS to provide real-time recommendations based on patient data,[65]
- Electronic trigger tools to identify signals of diagnostic error,[66] and
- Predictive analytics to help prioritize diagnostic testing and interventions.[67,68]

More specifically, NLP, a type of ML, can be used to enhance clinical documentation through clinical note summarization and analysis. NLP is defined as any computer-based algorithm that manages, enhances, and converts natural language to a form suitable for computational analysis.[69] NLP technologies can "read" unstructured documentation and convert it into discrete data, including automatically summarizing lengthy clinical notes and documentation, extracting key findings, diagnoses, and treatment plans to create concise and structured summaries.

Clinical summarization tools can improve documentation efficiency, enhance readability, and facilitate information retrieval for providers, supporting better clinical decision making and patient care.[70] Studies show that NLP has better sensitivity than ICD codes at identifying common patient symptoms, particularly when the symptom burden is high.[71]

Because NLP technologies can analyze free-text notes to extract relevant diagnostic information, such as symptoms, findings, and provisional diagnoses, specially designed NLP algorithms can glean important insights from notes. By automatically identifying and coding diagnoses from unstructured text, NLP streamlines the documentation process, reduces manual effort, and improves the accuracy and consistency of diagnosis documentation.

NLP techniques can perform semantic analysis of clinical notes to identify key concepts, relationships, and contextual information related to diagnoses. By mapping clinical terms to standardized medical terminologies (e.g., SNOMED CT, ICD-10), NLP facilitates the recognition and normalization of diagnoses, ensuring consistency and interoperability in clinical documentation.

Lastly, NLP-powered CDS systems can assist providers in documenting diagnoses by offering real-time suggestions, alerts, and recommendations based on the patient's clinical data and documentation. NLP

decision support tools can help providers consider differential diagnoses, adhere to clinical guidelines, and ensure thorough and accurate diagnosis documentation. Examples illustrating future implications for clinical practice include a model to predict in-hospital mortality using notes in the first 24 hours of a patient admission[72] and a model to identify prediabetes discussions in clinical documentation.[73]

Patients play a role in both providing and reviewing data to ensure its accuracy and completeness. Still, the completeness of a patient's record depends on information entered, not just the design. Records could be inaccurate if a patient withholds information, such as symptoms or family history, or providers unintentionally omit relevant information.

Government initiatives, beginning with legislation in 2009, incentivized health systems to offer patients electronic access to their own data via secure electronic patient portals.[74] Opportunities continue to emerge for patients to review their data to ensure accuracy and facilitate shared decision making.[75] With the growing awareness of the importance of patient input in achieving diagnostic excellence, there is great interest in the utility of patient access to their notes. Codified by the 21st Century Cures Act, "the open notes" movement now legislates immediate patient access to their notes.

Open Notes is an international movement designed to promote transparency in healthcare and is endorsed by the American College of Physicians.[76] Studies show that when patients read their notes, they identify a large number of errors, especially related to diagnosis.[24,77,78] Common errors include mistakes in diagnoses, medical history, medications, physical examination, and test results, notes on the wrong patient, and errors on which side of the body was the site of the injury or symptom.

Patient engagement with their notes is not universal, with significant disparities observed.[79,80] One factor is the complexity and structure of standard medical notes. Numerous studies suggest that typical notes are not at an appropriate reading level for most patients and patients often misconstrue or misinterpret even some of the most standard phrases in their notes.[81-84] However, expecting providers to manually change their documentation practice is not only unreasonable but will likely increase providers' already heavy documentation workload.

The rapid advancement of large language models now affords the ability to automate the creation of simplified patient-centric notes from existing provider documentation without negatively affecting provider documentation burden. Preliminary studies suggest it is not only feasible, but in controlled settings, also improves patient comprehension of the documented information.[60] Future studies will be needed to determine the scalability of this technology and the impact of automated conversion of standard notes on patient engagement with their EHR.

The National Academies of Sciences, Engineering, and Medicine (NASEM) report I*mproving Diagnosis in Healthcare* described successful diagnosis in the 21st century. It is a team-based, patient-centric model leveraging the knowledge and skills of all interprofessional staff and expanding the diagnostic team to include pathologists, radiologists, allied health professionals, medical librarians, and others.[6,85]

Encouraging collaboration among members of the care team, including physicians, nurses, specialists, and allied health professionals, promotes a multidisciplinary approach to diagnosis documentation. Effective communication among care team members fosters a shared understanding of the patient's clinical presentation, diagnostic evaluation, and treatment plan. By facilitating open dialogue and information exchange, communication helps align the care team's efforts and priorities, leading to more cohesive and coordinated clinical documentation in the EHR.[86]

Collaborative documentation allows each team member to contribute their unique perspectives, clinical insights, and expertise to ensure comprehensive and accurate documentation of the patient's diagnosis. Expanding the diagnostic team will bring both challenges and opportunities for improving diagnostic documentation by facilitating effective teamwork. Implementing administrative changes, such as providing documentation assistance and fostering empowered teamwork, can alleviate the burden on clinicians by redirecting data entry responsibilities.

Conclusion

Clinical documentation has transitioned from paper-based records to digital formats, driven by regulatory initiatives and technological advancements. Diagnostic documentation is crucial for diagnostic safety as it ensures accurate and comprehensive recording of patient information, which supports effective clinical decision making and continuity of care. Detailed documentation enhances patient safety by reducing the risk of diagnostic errors and facilitating timely interventions.

EHR data are vital for quality metrics and performance evaluations, driving improvements in healthcare practices. Comprehensive EHRs provide a rich dataset for future research, enabling studies that can uncover patterns, improve diagnostic processes, and advance medical knowledge.

The field of clinical documentation is vast, covering aspects such as safety, effectiveness, equity, patient-centeredness, timeliness, and efficiency. Each of these domains offers opportunities for indepth study. However, specific knowledge about diagnostic errors within clinical documentation is limited, indicating a need for further research to enhance our understanding in this area.

Ongoing developments, including the integration of AI and advanced big data approaches, open notes initiatives, and enhanced teamwork among care teams, are poised to reshape the future of diagnosis documentation. Through continued innovation and collaboration, the future of diagnosis documentation in EHRs will reflect accurate, comprehensive, and patient-centered care.

References

All web pages were accessed June 26-27, 2024.

1. Centers for Medicare and Medicaid Services. Electronic Health Records. Last modified September. https://www.cms.gov/priorities/key-initiatives/e-health/records.
2. Tubaishat A. The effect of electronic health records on patient safety: a qualitative exploratory study. Inform Health Soc Care. 2019;44(1):79-91. https://pubmed.ncbi.nlm.nih.gov/29239662/.
3. Howe JL, Adams KT, Hettinger AZ, Ratwani RM. Electronic health record usability issues and potential contribution to patient harm. JAMA. 2018;319(12):1276-1278. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5885839/.
4. Ratwani RM, Savage E, Will A, Fong A, Karavite D, Muthu N, Rivera AJ, Gibson C, Asmonga D, Moscovitch B, Grundmeier R. Identifying electronic health record usability and safety challenges in pediatric settings. Health Affairs. 2018 Nov 1;37(11):1752-1759. https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0699.
5. Kruse CS, Mileski M, Vijaykumar AG, Viswanathan SV, Suskandla U, Chidambaram Y. Impact of electronic health records on long-term care facilities: systematic review. JMIR Med Inform. 2017;5(3):e7958. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5640822/.
6. Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; National Academies of Sciences, Engineering, and Medicine. Improving Diagnosis in Health Care. Washington, DC: National Academies Press; 2015. https://www.ncbi.nlm.nih.gov/books/NBK338596/.
7. Chimowitz MI, Logigian EL, Caplan LR. The accuracy of bedside neurological diagnoses. Ann Neurol. 1990;28(1):78-85. https://pubmed.ncbi.nlm.nih.gov/2375637/.
8. Gupta A, Harrod M, Quinn M, Manojlovich M, Fowler KE, Singh H, Saint S, Chopra V. Mind the overlap: how system problems contribute to cognitive failure and diagnostic errors. Diagnosis. 2018;5(3):151-156. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6743477/.
9. Giardina TD, Haskell H, Menon S, Hallisy J, Southwick FS, Sarkar U, Royse KE, Singh H. Learning from patients' experiences related to diagnostic errors is essential for progress in patient safety. Health Aff (Millwood). 2018;37(11):1821-1827. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8103734/.
10. Cohen GR, Friedman CP, Ryan AM, Richardson CR, Adler-Milstein J. Variation in physicians' electronic health record documentation and potential patient harm from that variation. J Gen Intern Med. 2019;34:2355-2367. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6848521/.
11. Martin S, Wagner J, Lupulescu-Mann N, Ramsey K, Cohen AA, Graven P, Weiskopf NG, Dorr DA. Comparison of EHR-based diagnosis documentation locations to a gold standard for risk stratification in patients with multiple chronic conditions. Appl Clin Inform. 2017;8(03):794-809. whttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC6220706/.
12. Militello LG, Arbuckle NB, Saleem JJ, Patterson E, Flanagan M, Haggstrom D, Doebbeling BN. Sources of variation in primary care clinical workflow: implications for the design of cognitive support. Health Informatics J. 2014;20(1):35-49. https://pubmed.ncbi.nlm.nih.gov/24105625/.
13. Hodgson T, Burton-Jones A, Donovan R, Sullivan C. The role of electronic medical records in reducing unwarranted clinical variation in acute health care: systematic review. JMIR Med Inform. 2021;9(11):e30432. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8663492/.

14. Graber ML, Byrne C, Johnston D. The impact of electronic health records on diagnosis. Diagnosis. 2017;4(4):211-223. https://pubmed.ncbi.nlm.nih.gov/29536944/.
15. Health Information Technology for Economic and Clinical Health (HITECH) Act, Pub. L. No. 111-5, 123 Stat. 226(2009). https://www.congress.gov/111/plaws/publ5/PLAW-111publ5.pdf.
16. Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. 112-144, 126 Stat. 993(2012). https://www.congress.gov/112/plaws/publ144/PLAW-112publ144.pdf.
17. 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033(2016). https://www.govinfo.gov/content/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf.
18. Centers for Medicare and Medicaid Services. Physician Fee Schedule Final Rule, CMS-1693-F (2019). https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-federal-regulation-notices-items/cms-1693-f.
19. American Recovery and Reinvestment Act, Pub. L. No. 111-5, 123 Stat. 115(2009). https://www.congress.gov/111/plaws/publ5/PLAW-111publ5.pdf.
20. Mennemeyer ST, Menachemi N, Rahurkar S, Ford EW. Impact of the HITECH Act on physicians' adoption of electronic health records. J Am Med Inform Assoc. 2016;23(2):375-379. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7784315/.
21. Lin Y-K, Lin M, Chen H. Do electronic health records affect quality of care? Evidence from the HITECH Act. Inf Sys Res. 2019;30(1):306-318. https://doi.org/10.1287/isre.2018.0813.
22. Kim H, Lee J. The impact of health IT on hospital productivity after the enactment of HITECH Act. Appl Econ Lett. 2020;27(9):719-724. https://doi.org/10.1080/13504851.2019.1644433.
23. Department of Health and Human Services. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. 85 Federal Register 25642 (2020). https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification
24. Bell SK, Delbanco T, Walker J. OpenNotes: how the power of knowing can change health care. NEJM Catalyst. 2017;3(5).
25. Apathy NC, Hare AJ, Fendrich S, Cross DA. Early changes in billing and notes after evaluation and management guideline change. Ann Intern Med. 2022;175(4):499-504. https://www.acpjournals.org/doi/10.7326/M21-4402.
26. Maisel N, Thombley R, Overhage JM, Blake K, Sinsky CA, Adler-Milstein J. Physician Electronic Health Record Use After Changes in U.S. Centers for Medicare & Medicaid Services Documentation Requirements. Paper presented at JAMA Health Forum, 2023.
27. Sinsky CA. 2021 E/M Coding Change: Making Sense of Unexpected Findings. Ann Intern Med. 2022;175(4):602-603.
28. Health Insurance Portability and Accountability Act, Pub. L. No. 104-191 110, Stat. 1936(1996). https://www.govinfo.gov/content/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf.
29. HR 2—114th Congress: Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87(2015). https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf.

30. Kim A. Re: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements. Policy Commons 2019. https://policycommons.net/artifacts/1688445/re/2420093/.
31. Adane K, Gizachew M, Kendie S. The role of medical data in efficient patient care delivery: a review. Risk Manag Healthc Policy. 2019:67-73. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6486797/.
32. El-Kareh R, Hasan O, Schiff GD. Use of health information technology to reduce diagnostic errors. BMJ Qual Saf. 2013;22(Suppl 2):ii40-ii51. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3786650/.
33. Schiff GD, Bates DW. Can electronic clinical documentation help prevent diagnostic errors? New Engl J Med. 2010;362(12):1066-1069. https://www.nejm.org/doi/10.1056/NEJMp0911734.
34. Dixit RA, Boxley CL, Samuel S, Mohan V, Ratwani RM, Gold JA. Electronic health record use issues and diagnostic error: a scoping review and framework. J Patient Saf. 2023;19(1):e25-e30. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9983735/.
35. Krevat SA, Samuel S, Boxley C, Mohan V, Siegal D, Gold JA, Ratwani RM. Identifying electronic health record contributions to diagnostic error in ambulatory settings through legal claims analysis. JAMA Network Open. 2023;6(4):e238399-e238399. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10105306/.
36. Savoy A, Patel H, Murphy DR, Meyer AN, Herout J, Singh H. Electronic health records' support for primary care physicians' situation awareness: a metanarrative review. Hum Factors. 2023;65(2):237-259. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9969495/.
37. Vimalachandran P, Wang H, Zhang Y, Heyward B, Whittaker F. Ensuring Data Integrity in Electronic Health Records: A Quality Health Care Implication. Paper presented at 2016 International Conference on Orange Technologies (ICOT), 2016.
38. Weir C, Hurdle J, Felgar M, Hoffman J, Roth B, Nebeker J. Direct text entry in electronic progress notes. Methods Inf Med. 2003;42(01):61-67. https://pubmed.ncbi.nlm.nih.gov/12695797/.
39. Mannhardt N. Improving Patient Access and Comprehension of Clinical Notes: Leveraging Large Language Models To Enhance Readability and Understanding. Cambridge: Massachusetts Institute of Technology; 2023. https://dspace.mit.edu/bitstream/handle/1721.1/152654/mannhardt-niklasm-meng-eecs-2023-thesis.pdf.
40. Mishra VK, Hoyt RE, Wolver SE, Yoshihashi A, Banas C. Qualitative and quantitative analysis of patients' perceptions of the patient portal experience with OpenNotes. Appl Clin Inform. 2019;10(01):010-018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6327733/.
41. Bhise V, Rajan SS, Sittig DF, Morgan RO, Chaudhary P, Singh H. Defining and measuring diagnostic uncertainty in medicine: a systematic review. J Gen Intern Med. 2018;33:103-115. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5756158/.
42. Simpkin A, Schwartzstein R. Tolerating uncertainty—the next medical revolution? New Engl J Med. 2016;375(18):1713-1715. https://www.nejm.org/doi/10.1056/NEJMp1606402.
43. Malterud K, Guassora AD, Reventlow S, Jutel A. Embracing uncertainty to advance diagnosis in general practice. Br J Gen Pract. 2017:244-245. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5442924/.

44. Bhise V, Rajan SS, Sittig DF, Vaghani V, Morgan RO, Khanna A, Singh H. Electronic health record reviews to measure diagnostic uncertainty in primary care. J Eval Clin Pract. 2018;24(3):545-551. https://pubmed.ncbi.nlm.nih.gov/29675888/.
45. Liang J, Tsou C-H, Poddar A. A Novel System For Extractive Clinical Note Summarization Using EHR Data. Paper presented at Proceedings of the 2nd Clinical Natural Language Processing Workshop, 2019.
46. Kong H-J. Managing unstructured big data in healthcare system. Healthc Inform Res. 2019;25(1):1-2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6372467/.
47. Garber A, Garabedian P, Wu L, Lam A, Malik M, Fraser H, Bersani K, Piniella N, Motta-Calderon D, Rozenblum R, Schnock K, Griffin J, Schnipper JL, Bates DW, Dalal AK. Developing, pilot testing, and refining requirements for 3 EHR-integrated interventions to improve diagnostic safety in acute care: a user-centered approach. JAMIA Open. 2023;6(2):ooad031. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10172040/.
48. Blease C, McMillan B, Salmi L, Davidge G, Delbanco T. Adapting to transparent medical records: international experience with "open notes." BMJ. 2022;379.
49. Bell SK, Dong ZJ, Desroches CM, Hart N, Liu S, Mahon B, Ngo LH, Thomas EJ, Bourgeois F. Partnering with patients and families living with chronic conditions to coproduce diagnostic safety through OurDX: a previsit online engagement tool. J Am Med Inform Assoc. 2023;30(4):692-702. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10018262/.
50. O'Malley AS, Draper K, Gourevitch R, Cross DA, Scholle SH. Electronic health records and support for primary care teamwork. J Am Med Inform Assoc. 2015;22(2):426-434. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4394968/.
51. Cifuentes M, Davis M, Fernald D, Gunn R, Dickinson P, Cohen DJ. Electronic health record challenges, workarounds, and solutions observed in practices integrating behavioral health and primary care. J Am Board Fam Med. 2015;28(Supplement 1):S63-S72. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7304941/.
52. Bowman S. Impact of electronic health record systems on information integrity: quality and safety implications. Perspect Health Inf Manag. 2013;10(Fall):1c. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3797550/.
53. Quinn MA, Kats AM, Kleinman K, Bates DW, Simon SR. The relationship between electronic health records and malpractice claims. Arch Intern Med. 2012;172(15):1187-1189.
54. Yan Q, Jiang Z, Harbin Z, Tolbert PH, Davies MG. Exploring the relationship between electronic health records and provider burnout: a systematic review. J Am Med Inform Assoc. 2021;28(5):1009-1021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8068439/.
55. Papanicolas I, Woskie LR, Jha AK. Health care spending in the United States and other high-income countries. JAMA. 2018;319(10):1024-1039. https://pubmed.ncbi.nlm.nih.gov/29536101/.
56. Kosar CM, Loomer L, Thomas KS, White EM, Panagiotou OA, Rahman M. Association of diagnosis coding with differences in risk-adjusted short-term mortality between critical access and non–critical access hospitals. JAMA. 2020;324(5):481-487. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7403917/.

57. Sjoding MW, Iwashyna TJ, Dimick JB, Cooke CR. Gaming hospital-level pneumonia 30-day mortality and readmission measures by legitimate changes to diagnostic coding. Crit Care Med. 2015;43(5):989-995. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4617210/.
58. Elation Health Team. 1 in 3 Primary Care Providers Have Already Tried AI Scribe Tools, Outlook Is Cautiously Optimistic; 2023. https://www.elationhealth.com/resources/media-coverage/ai-release.
59. Nuance Communications. Nuance Announces General Availability of DAX Copilot Embedded in Epic, Transforming Healthcare Experiences With Automated Clinical Documentation; 2024. https://www.prnewswire.com/news-releases/nuance-announces-general-availability-of-dax-copilot-embedded-in-epic-transforming-healthcare-experiences-with-automated-clinical-documentation-302037590.html.
60. Tierney AA, Gayre G, Hoberman B, Mattern B, Ballesca M, Kipnis P, Liu V, Lee K. Ambient artificial intelligence scribes to alleviate the burden of clinical documentation. NEJM Catalyst Innov Care Deliv. 2024 Feb 21;5(3). https://catalyst.nejm.org/doi/full/10.1056/CAT.23.0404.
61. Abràmoff MD, Tarver ME, Loyo-Berrios N, Trujillo S, Char D, Obermeyer Z, Eydelman MB, Considerations for addressing bias in artificial intelligence for health equity. NPJ Digital Medicine. 2023;6(1):170. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10497548/.
62. Xiao D, Meyers P, Upperman JS, Robinson JR. Revolutionizing healthcare with ChatGPT: an early exploration of an AI language model's impact on medicine at large and its role in pediatric surgery. J Pediatr Surg. 2023;58(12):2410-2415. https://pubmed.ncbi.nlm.nih.gov/37544801/.
63. Goodman KE, Paul HY, Morgan DJ. AI-generated clinical summaries require more than accuracy. JAMA. 2024;331(8):637-638.
64. Daskivich TJ, Abedi G, Kaplan SH, Skarecky D, Ahlering T, Spiegel B, Litwin MS, Greenfield S. Electronic health record problem lists: accurate enough for risk adjustment? Am J Manag Care. 2018;24(1):e24-e29. https://pubmed.ncbi.nlm.nih.gov/29350512/.
65. Vasey B, Ursprung S, Beddoe B, Taylor EH, Marlow N, Bilbro N, Watkinson P, McCulloch P. Association of clinician diagnostic performance with machine learning–based decision support systems: a systematic review. JAMA Netw Open. 2021;4(3):e211276-e211276. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7953308/.
66. Zhao B, Zhang R, Chen D, et al. A Machine-Learning-Based Approach for Identifying Diagnostic Errors in Electronic Medical Records. IEEE Transactions on Reliability; 2023.
67. Ibrahim MS, Saber S. Machine learning and predictive analytics: advancing disease prevention in healthcare. J Contemp Healthc Analytics. 2023;7(1):53-71. https://publications.dlpress.org/index.php/jcha/article/view/16.
68. Badawy M, Ramadan N, Hefny HA. Healthcare predictive analytics using machine learning and deep learning techniques: a survey. J Electric Syst Inform Technol. 2023;10(1):40.
69. Yim W-w, Yetisgen M, Harris WP, Kwan SW. Natural language processing in oncology: a review. JAMA. 2016;2(6):797-804. https://pubmed.ncbi.nlm.nih.gov/27124593/.
70. Richter JG, Thielscher C. New developments in electronic health record analysis. Nat Rev Rheumatol. 2023;19(2):74-75. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9761741/.
71. Chan L, Beers K, Yau AA, Chauhan K, Duffy A, Chaudhary K, Debnath N, Saha A, Pattharanitima P, Cho J, Kotanko P. Natural language processing of electronic health records is superior to billing codes to identify symptom burden in hemodialysis patients. Kidney Int. 2020;97(2):383-392. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7001114/.

72. Cooley-Rieders K, Zheng K. Physician documentation matters. Using natural language processing to predict mortality in sepsis. Intelligence-Based Med. 2021;5:100028.
73. Schwartz JL, Tseng E, Maruthur NM, Rouhizadeh M. Identification of prediabetes discussions in unstructured clinical documentation: validation of a natural language processing algorithm. JMIR Med Inform. 2022;10(2):e29803. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8914791/.
74. Ricciardi L, Mostashari F, Murphy J, Daniel JG, Siminerio EP. A national action plan to support consumer engagement via e-health. Health Aff (Millwood). 2013;32(2):376-384. https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.1216.
75. Delbanco T, Walker J, Bell SK, Darer JD, Elmore JG, Farag N, Feldman HJ, Mejilla R, Ngo L, Ralston JD, Ross SE. Inviting patients to read their doctors' notes: a quasi-experimental study and a look ahead. Ann Intern Med. 2012;157(7):461-470. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3908866/.
76. OpenNotes. 2024; https://www.opennotes.org.
77. Blease CR, Bell SK. Patients as diagnostic collaborators: sharing visit notes to promote accuracy and safety. Diagnosis (Berl). 2019;6(3):213-221. https://pubmed.ncbi.nlm.nih.gov/31039128/.
78. Bell SK, Mejilla R, Anselmo M, Darer JD, Elmore JG, Leveille S, Ngo L, Ralston JD, Delbanco T, Walker J. When doctors share visit notes with patients: a study of patient and doctor perceptions of documentation errors, safety opportunities and the patient–doctor relationship. BMJ Qual Saf. 2017;26(4):262-270. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7255406/.
79. Rodriguez JA, Clark CR, Bates DW. Digital health equity as a necessity in the 21st Century Cures Act era. JAMA. 2020;323(23):2381-2382. https://doi.org/10.1001/jama.2020.7858.
80. Brewer LC, Fortuna KL, Jones C, Walker R, Hayes SN, Patten CA, Cooper LA. Back to the future: achieving health equity through health informatics and digital health. JMIR mHealth uHealth. 2020;8(1):e14512. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996775/.
81. Kayastha N, Pollak KI, LeBlanc TW. Open oncology notes: a qualitative study of oncology patients' experiences reading their cancer care notes. J Oncol Pract. 2018;14(4):e251-e258. https://ascopubs.org/doi/10.1200/JOP.2017.028605.
82. Earnest MA, Ross SE, Wittevrongel L, Moore LA, Lin C-T. Use of a patient-accessible electronic medical record in a practice for congestive heart failure: patient and physician experiences. J Am Med Inform Assoc. 2004;11(5):410-417. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC516248/.
83. Gee PM, Paterniti DA, Ward D, Miller LMS. e-Patients perceptions of using personal health records for self-management support of chronic illness. CIN: Comput Inform Nurs. 2015;33(6):229-237. https://pubmed.ncbi.nlm.nih.gov/25899440/.
84. Sarkar U, Karter AJ, Liu JY, Adler NE, Nguyen R, Lopez A, Schillinger D. The literacy divide: health literacy and the use of an internet-based patient portal in an integrated health system—results from the Diabetes Study of Northern California (DISTANCE). J Health Commun. 2010;15(S2):183-196. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3014858/.
85. Graber ML, Rusz D, Jones ML, Farm-Franks D, Jones B, Cyr Gluck J, Thomas DB, Gleason KT, Welte K, Abfalter J, Dotseth M. The new diagnostic team. Diagnosis (Berl). 2017;4(4):225-238. https://pubmed.ncbi.nlm.nih.gov/29536943/.
86. Kawamoto K, Anstrom KJ, Anderson JB, Bosworth HB, Lobach DF, McAdam-Marx C, Ferranti JM, Shang H, Yarnall KS. Long-Term Impact of an Electronic Health Record-Enabled, Team-Based, and Scalable Population Health Strategy Based on the Chronic Care Model. Paper presented at American Medical Informatics Association Annual Symposium Proceedings, 2016 (p. 686).

AHRQ Pub. No. 24-0010-3-EF
August 2024