Evidence-based Practice Center Technical Brief Protocol

Project Title: *Documentation Burden*

I. Background and Objectives

    Physician job satisfaction and burnout are urgent challenges currently facing the U.S. healthcare system, especially given the effects of the COVID-19 pandemic.[1] There are multiple contributors driving these issues, but documentation burden is commonly cited as a key factor.[2] Many physicians report that electronic health records (EHRs), electronic prescribing, electronic patient portals, and computerized physician order entry (CPOE) lead to information overload, frequent interruptions/distractions, and a change in the content of professional work to tasks less connected to meaning and purpose.[2, 3] Greater time spent on administrative tasks is associated with decreased career satisfaction and increased burnout,[4] and greater use of EHRs and CPOE is associated with increased burnout.[3] EHR usability is generally poor, and physician assessment of poor EHR usability is strongly associated with burnout.[5] In addition, clinical documentation requirements often cannot be completed during the work day,[6-8] and "work outside of work" is a strong driver of physician burnout.[9]

    Although the adoption of EHRs in the United States has increased since the mid 2000's, clear definitions and metrics for documentation burden are lacking.[10, 11] Documentation burden has been described largely in the context of specific clinical documentation tasks. For example, a summary of organizational interventions targeting reduced job demands, improved job resources, and improved clinical workflows is provided by Sinsky and colleagues.[9] These include eliminating multiple unnecessary documentation requirements, aligning EHR functions with clinical workflows, reducing inbox message volume, streamlining documentation involving verbal orders, and reducing the work associated with prior authorization. Additional interventions include team support for documentation and shifting to annual prescription renewals from more frequent intervals.

    Metrics for these interventions are often simplistic, for example the number of messages or time spent on documentation. Expanded and more granular metrics have been introduced through the American Medical Association's Joy in Medicine Health System Recognition Program.[12] These include the Work Outside of Work (WOW) metric based on time outside of patient scheduled hours, Time on Inbox, Time on Encounter Note Documentation, and Total EHR Time.

    In part because established definitions and metrics for documentation are not well developed, published literature applying these metrics is limited and has not been systematically collated to date. Evidence for validity metrics measuring documentation burden is often lacking or not reported clearly, scalability is not demonstrated, and key strengths and weaknesses are not well delineated. These challenges and controversies collectively highlight the need for a summary of the literature and an evidence map across different clinical fields and types of health professionals to increase the understanding of how best to measure and report documentation burden. This understanding would then support the evaluation of interventions designed to

minimize documentation burden to reduce burnout, promote job satisfaction, increase efficiency, and improve the quality of patient care.

Beyond these issues, metrics related to documentation burden have been intended for application primarily to physician work experiences, and documentation burden for other healthcare professionals has not been described well. Whether measures of documentation burden apply fairly and equitably across clinical disciplines, job roles, and demographic factors such as gender identity is also unclear. For example, documentation burden differs across specialties and is often reported to be greater for women clinicians than for men. Metrics for documentation burden must accurately reflect these important differences, and assessment of validity in the domains of reliability, consistency, and expected relations with other variables is needed.

As identified above, documentation burden is an important issue across healthcare job roles. The National Academy of Medicine report on clinician well-being clarified that approaches to mitigate documentation burden for one job role should not simply shift it to another job role that likely already faces substantial documentation burdens of its own.[2] Understanding the experiences and unique documentation demands across job roles would help clarify the extent to which current metrics satisfactorily capture these burdens to inform needs and assess initiatives to reduce documentation burden.

Additional factors of interest related to documentation burden include how the burden differs by practice setting and specialty. Documentation burden differs across specialties for physicians,[7] but the specific contributors to these differences across types of documentation requirements are not well understood. Similarly, documentation demands comparing academic and private practice settings, inpatient and outpatient settings, public and private hospital organizations, and rural and urban facilities have not been elucidated. These unanswered questions illustrate the scope of the challenge and need to review how documentation burden differs based on job role, demographics, practice setting, specialty, and geographic location. The patient perspective on clinician work and associated distress is rarely included in discussions of documentation burden. Important considerations might include whether patients see value in documentation tasks that healthcare professionals view as onerous or low value. Alternatively, patients might express preference for more face-to-face interactions with healthcare professionals if these were the result of efforts to reduce documentation burden.

Beyond gaining a better understanding of how patients view clinical documentation burden on clinicians and themselves, it is important to better understand the extent to which patients contribute to documentation demands. Patients increasingly contribute to required documentation in their clinical care, such as in previsit questionnaires or followup questions after visits. How patients use patient portals to communicate with clinicians (thereby generating additional documentation requirements), how often paperwork is brought by patients to clinicians to complete and how much time and cognitive effort this requires, and how impactful patient expectations of documentation management (e.g., timeliness, level of detail, who the response should come from) all merit further exploration.

Purpose of the Review

This Technical Brief will evaluate multiple aspects relating to documentation burden, including metrics, validity across settings and clinician populations, and patient perspectives. Collating and assessing evidence across these domains will inform efforts by health systems and standard-setting bodies to alleviate documentation burden and promote job satisfaction and well-

being in medicine. This work will be used by the American Medical Informatics Association (AMIA) in alignment with the 25x5 Task Force's vision of a "U.S. healthcare workforce free of documentation burden and focused on patient care and improved patient outcomes."

II. Guiding Questions

Description/Overview of measurements of documentation burden:
1) What metrics of documentation burden that have been developed or used (including metrics broadly – quantitative and qualitative)?
    a) For which settings, populations, and intended uses were the metrics developed?
    b) How have these metrics been applied?
    c) Is there published information available on validity of the metrics?
    d) What are the key strengths and weaknesses of different metrics that have been used?
2) What are the different perspectives on the appropriateness of different metrics of documentation burden that have been applied/proposed (e.g., scalability, resource intensiveness to collect, equitable across populations)?
3) What are the perceptions of documentation burden from the perspective of people in different clinical roles (e.g., doctor, nurse, etc.) and patients/caregivers?

Factors influencing documentation burden:
4) What is the role of patients in documentation burden?
5) What is the role of setting (i.e., rural vs. urban, hospital, outpatient, academic institution, etc.) in documentation burden?

III. Methods

We will search peer-reviewed published literature and gray literature. Findings will be synthesized with additional information identified from Key Informant (KI) interviews. We will create evidence tables and figures that addresses the Guiding Questions (GQs).

1. Data Collection:

A. Discussions with Key Informants

We plan to recruit six to nine KIs with different expertise, backgrounds, and professional affiliations. We will initially schedule one or two group conferences, each separated by two sections: one for patient advocates and one for healthcare providers, researchers, policymakers, and EHR vendors. The section for patient advocates will focus on their perspectives of documentation burden in physician-patient interactions and, subsequently, its effects on outcomes and quality of care. The section with healthcare providers, researchers, policymakers, and EHR vendors will seek input on the GQs and their experience, opinions, and challenges related to documentation burden.

We will use an interview guide to facilitate the group conferences. The conferences will be led by clinical and research experts on the team , who will document responses using real-time transcription and audio recording. The conference will be conducted according to KIs' preferred method (i.e., over the phone or via video conference). We will identify key points and produce a

meeting summary. The meeting summary will be sent to KIs for verification and clarification. Potential questions for KIs are listed below:

Questions for healthcare providers, researchers, policymakers, and EHR vendors

a. We plan to conduct a comprehensive search and evaluate all existing metrics of documentation burden and those under development. Do the KIs know of any specific metrics that we should focus on?
b. What concerns do patients and caregivers have about documentation burden? What concerns do providers and policymakers have about documentation burden?
c. What metrics/outcomes would be important to patients and caregivers when we evaluate the impact of documentation burden? What metrics would be important to providers and policymakers?
d. We plan to evaluate documentation burden by clinical roles. There are many different roles that we need to categorize to facilitate analysis. We are considering the use of these 3 categories: physician/nurse practitioner/physician assistant, nurse, and other professionals. Do the KIs have suggestions for this categorization or recommendations for modifications to it?
e. To evaluate the validity of the metrics, multiple methods may exist. Do the KIs know of any specific evaluation methods that are more acceptable in the field.
f. We plan to evaluate the metrics of documentation burden in terms of validity, settings, intended uses, involved clinical roles, scalability, feasibility, resources, and equity. Do the KIs have suggestions about other factors that we should investigate?
g. EHR adoption was sporadic and limited until the mid-2000's. Literature prior to this is likely highly irrelevant. Which date do the KIs suggest we use as a start date for the inclusion of published studies?
h. What important studies would the KIs suggest that we consider?

Questions for patient advocates

a. How do patients and caregivers view EHRs and their implication on physician-patient encounters?
b. Would the patients and caregivers view the EHR negatively if they knew the EHR would bring additional stress to healthcare providers? What concerns do patients and caregivers have about documentation burden?
c. What outcomes or metrics would be important to patients and caregivers when we evaluate the impact of documentation burden?

B. Gray Literature search.

We will search the following sources for gray literature: U.S. Food and Drug Administration, ClinicalTrials.gov, Health Canada, U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), conference proceedings, web search engines (Google), and websites of Federal and State Government, patient advocate groups, EHR vendors, and professional societies. In addition, a Supplemental Evidence and Data for Systematic Reviews (SEADS) portal will be available to collect additional study-specific information from industry stakeholders, professional societies, and researchers. A Federal Register Notice will be posted for this review.

C. Published Literature search.

We plan to conduct a comprehensive database search, including Embase®, Epub Ahead of Print, In-Process & Other Non-Indexed Citations, MEDLINE® Daily, MEDLINE®, Cochrane Central Registrar of Controlled Trials, Ovid® Cochrane Database of Systematic Reviews, and Scopus® from the year 2000 to the present. We have developed a preliminary database search strategy (Appendix A) and found that these databases can adequately identify the relevant literature. We will use relevant systematic reviews and meta-analyses to identify additional existing and new literature. Reference mining of relevant publications will be conducted. The search strategy will be peer-reviewed by an independent information specialist. An experienced librarian will conduct the search. All citations identified through the process will be imported to a reference management system (EndNote® Version X9; Thomson Reuters, Philadelphia, PA).

For abstract screening, we plan to use a validated Natural Language Processing (NLP) algorithm developed by DistillerSR® (Evidence Partners Incorporated, Ottawa, Canada). Each abstract will be screened by one human reviewer and the NLP technique with constant surveillance of possible misclassified citations for quality control. Consensus for inclusion and conflicts will be advanced for full-text screening. Independent reviewers, working in pairs, will screen the full-text version of eligible references. Discrepancies between the reviewers will be resolved through discussions and consensus. If consensus cannot be reached, a third reviewer will resolve the difference.

We will apply the following inclusion and exclusion criteria for the studies identified in the literature search (Table 1). We will limit the literature search to studies published after the year 2000.

Table 1. PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Settings)

PICOTS Elements	Inclusion Criteria	Exclusion Criteria
Population	Healthcare professionals, including but not limited to: • Physicians • Nurses • Other professionals	• Any healthcare professional without direct patient contact
Interventions (Exposure)	• EHR • Electronic prescribing • Electronic patient portals • Computerized physician order entry	• None
Comparators	• None	• None
Outcomes	Metrics of documentation burden, including but not limited to: • WOW • Time on Inbox • Time on Encounter Note Documentation • Excessive workload • Time on EHR • Administrative tasks • Fragmentation of workflow • Physician-patient interaction	• None
Timing	• All	• None
Settings	• Any clinical settings	• None

PICOTS Elements	Inclusion Criteria	Exclusion Criteria
Study design	- RCTs - Comparative observational studies - Surveys - Qualitative studies - Mixed-method studies - Systematic review or meta-analysis	- In vitro studies - Erratum - Editorials - Letters - Case studies/case reports - Narrative reviews
Publications	- Studies published in English as peer reviewed full-text articles - Published after the year 2000	- Foreign language studies - Conference abstracts

Abbreviations: EHR = electronic health record; RCT = randomized clinical trials; WOW = Work Outside of Work

2. Data Organization and Presentation:

A. Information Management

We will develop a standardized data extraction form to extract study characteristics (author, year, study design, inclusion and exclusion criteria, study settings, population, metric of documentation burden and its validity, strength and weakness, users' perspectives, and related items for addressing the GQs). The standardized form will be tested by all study team members using randomly selected studies. We will supplement the extracted information with data derived from KIs and gray literature. DistillerSR® will be used to create data extraction forms and facilitate data extraction.

B. Data Presentation

Metrics of documentation burden and validity of the metrics will be summarized in searchable evidence tables and depicted visually. We will highlight intended uses of these metrics, strengths and weakness, different perspectives from clinical roles and patients/caregivers, and factors affecting the use. Additional information extracted from KIs will be synthesized and presented narratively.

IV. References

1. Shanafelt TD, West CP, Dyrbye LN, et al. Changes in burnout and satisfaction with work-life integration in physicians during the first 2 years of the COVID-19 pandemic. Mayo Clin Proc. 2022 Dec;97(12):2248-58. doi: 10.1016/j.mayocp.2022.09.002. PMID: 36229269.

2. National Academies of Sciences, Engineering, and Medicine; National Academy of Medicine; Committee on Systems Approaches to Improve Patient Care by Supporting Clinician Well-Being. Taking action against clinician burnout: a systems approach to professional well-being. Washington (DC): National Academies Press; 2019.

3. Shanafelt TD, Dyrbye LN, Sinsky C, et al. Relationship between clerical burden and characteristics of the electronic environment with physician burnout and professional satisfaction. Mayo Clin Proc. 2016 Jul;91(7):836-48. doi: 10.1016/j.mayocp.2016.05.007. PMID: 27313121.

4. Rao SK, Kimball AB, Lehrhoff SR, et al. The impact of administrative burden on academic physicians: results of a hospital-wide physician survey. Acad Med. 2017 Feb;92(2):237-43. doi: 10.1097/ACM.0000000000001461. PMID: 28121687.

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12. American Medical Association. Joy in Medicine ™: Health System Recognition Program. 2023. https://www.ama-assn.org/practice-management/physician-health/joy-medicine-health-system-recognition-program. Accessed on July 26 2023.

V. Definition of Terms

AMIA	American Medical Informatics Association
AHRQ	Agency for Healthcare Research and Quality
CPOE	Computerized Physician Order Entry
EPC	Evidence-based Practice Center
EHR	Electronic Health Record
GQ	Guiding Question
KI	Key Informant
MHRA	Medicines and Healthcare Products Regulatory Agency
NLP	Natural Language Processing
PICOTS	Populations, Interventions, Comparators, Outcomes, Timing, and Settings
RCT	Randomized Clinical Trial
SEADS	Supplemental Evidence and Data for Systematic Reviews
U.K.	United Kingdom
U.S.	United States
WOW	Work Outside of Work

VI. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

VII. Key Informants

Within the Technical Brief process, KIs serve as a resource to offer insight into the clinical context of the technology/intervention, how it works, how it is currently used or might be used, and which features may be important from a patient of policy standpoint. They may include clinical experts, patients, manufacturers, researchers, payers, or other perspectives, depending on the technology/intervention in question. Differing viewpoints are expected, and all statements are crosschecked against available literature and statements from other KIs. Information gained from KI interviews is identified as such in the report. KIs do not do analysis of any kind nor contribute to the writing of the report and will not review the report, except as given the opportunity to do so through the public review mechanism.

KIs must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as KIs and those who present with potential conflicts may be retained. The Task Order Officer and the Evidence-based Practice Center (EPC) work to balance, manage, or mitigate any potential conflicts of interest identified.

VIII. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the draft report are considered by the EPC in preparation of the final report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and may be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $5,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

IX. EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than $1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than $1,000 will usually disqualify EPC core team investigators.

X. Role of the Funder

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