Clinical documentation: composition or synthesis?

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Published Online First 19 July 2012 ABSTRACT

Objective To understand the nature of emerging electronic documentation practices, disconnects between documentation workflows and computing systems designed to support them, and ways to improve the design of electronic documentation systems. **Materials and methods** Time-and-motion study of resident physicians' note-writing practices using a commercial electronic health record system that includes an electronic documentation module. The study was conducted in the general medicine unit of a large academic hospital.

Results During the study, 96 note-writing sessions by 11 resident physicians, resulting in close to 100 h of observations were seen. Seven of the 10 most common transitions between activities during note composition were between documenting, and gathering and reviewing patient data, and updating the plan of care. **Discussion** The high frequency of transitions seen in the study suggested that clinical documentation is fundamentally a synthesis activity, in which clinicians review available patient data and summarize their impressions and judgments. At the same time, most electronic health record systems are optimized to support documentation as uninterrupted composition. This mismatch leads to fragmentation in clinical work, and results in inefficiencies and workarounds. In contrast, we propose that documentation can be best supported with tools that facilitate data exploration and search for relevant information, selective reading and annotation, and composition of a note as a temporal structure.

Conclusions Time-and-motion study of clinicians' electronic documentation practices revealed a high level of fragmentation of documentation activities and frequent task transitions. Treating documentation as synthesis rather than composition suggests new possibilities for supporting it more effectively with electronic systems.

INTRODUCTION

Clinical documentation is a vital part of modern medicine. It has a number of benefits for the immediate care of the patient and numerous advantages for medical practice at large. Clinical documentation can serve as a cognitive aid assisting clinicians in synthesizing a patient's case, highlighting its salient properties, and otherwise facilitating sense making and reasoning.¹ Additionally, it can aid a clinical team in developing a shared understanding, and coordinating the work on the case.² At the same time, secondary use of captured clinical documentation—a vast, rich collection of data on problems, treatments, outcomes, and associated costs—can help to transform the healthcare system into a "learning" vehicle to generate new knowledge across a wide spectrum of clinical and health policy domains.³⁴

Electronic documentation—a process of composing clinical notes using electronic notewriting tools provided by most of the modern electronic health record (EHR) systems-is redefining both the process of clinical documentation and the purpose of the clinical note.⁵ ⁶ It is expected to enhance communication among clinicians, reduce error rates, improve documentation efficiency, and help prevent diagnostic errors.⁷ Time saving, in particular, is one of the main motivating factors behind the adoption of electronic documentation, even if it may not directly translate into improvements in patient care.⁸⁻¹⁰

Despite the largely optimistic expectations, evaluation studies of electronic documentation to date have produced mixed results. Electronic documentation has been shown to facilitate transitions of care,¹¹ improve quality of hospice care,¹ and provide a successful vehicle for decision support.¹³ A recent study by Amarasingham¹⁴ showed that a higher degree of automation of a hospital documentation system leads to a significant reduction in the odds of inpatient death for all causes, and a lower rate of mortality. However, other researchers question the benefits of electronic support for documentation. For example, studies examining the time-saving potential of electronic documentation have produced contradictory results; some of them showed improvement¹⁵ ¹⁶ while others showed an increase in documentation time.¹⁷ ¹⁸ Many features that became pervasive in electronic note writing, such as automated fill-in and copy-and-paste,¹⁹ often result in unintended and potentially dangerous consequences. Much has been written about the deteriorating quality of the electronic note, ridden with mindless repetition of copied and pasted content, and outdated and erroneous information. $^{6\ 20-23}$ Frequent results of such health information technology-related 'unintended consequences' include reduced efficiency, lower quality of care, increased probabilities for medical errors,^{24–26} and increased tensions between clinicians and administrators.²

While there is a growing attention to the potential unintended consequences of electronic documentation, the root causes for such consequences are poorly understood. One reason proposed in recent literature is the mismatch between existing documentation practices and user interfaces and application flow of electronic systems that support them.^{28–31} In particular, researchers noted an increase in the rate of transitions between clinical activities that indicates a higher degree of fragmentation of clinical work after introduction of EHR systems that included electronic support for documentation.²⁸

In this paper, we report the results of a time-and-motion study that examines the nature of emerging practices for electronic documentation, and specifically for composition of formal (such as admission, discharge, and daily progress notes) and informal notes written for a single patient (such as sign-out notes). Previous time-and-motion studies of electronic documentation focused primarily on quantifying its impact on physicians' work, particularly on time spent documenting.³² In contrast, our goal was to clarify emerging practices of electronic documentation, and to identify ways to improve the design of electronic systems that support them. Our specific questions included (1) When, and in what circumstances, do clinicians write notes? (2) What are the general steps of note composition? Are there common patterns of transitions between these steps? (3) How does the EHR system they use facilitate or inhibit this process? And, finally, (4) What is the degree of fragmentation of electronic documentation activities? Previously, Hripcsak et al used audit logs of authoring and viewing of clinical notes to determine how much time is spent on documentation, and examined viewing of notes by members of clinical teams.³³ Our study extends that work using complementary methods-namely, direct observations.

METHODS AND MATERIALS Empirical settings

We conducted the study in June–July, 2010 at New York-Presbyterian Hospital/Columbia University Medical Center, a large teaching hospital in New York City. The hospital has over 2300 beds and discharges over 110 000 patients a year with an average length of stay of 6.4 days.³⁴

We conducted the study in the general medicine unit of the hospital. The unit is separated into two sections, each including one or two attending physicians and three or four clinical teams; each team consists of a first-year resident (intern), a second or third-year resident, and a medical student.

New York-Presbyterian deployed a commercial EHR system (Allscripts Sunrise, Allscripts Corp, Chicago, Illinois, USA) in 2004. The system includes a number of modules, separated into tabs, such as Results, Flow sheets, and Orders. The documentation module allows entry using structured templates that suggest components of a note to be filled in by the note's author, or as a free-text narrative. It supports composition of different types of notes; some of them become a part of the patient record (ie, admission, discharge, and daily progress notes); others provide informal support for communication (ie, sign-out notes, used to facilitate transitions of care between shifts or during internal transfers). The module includes several enhancements to facilitate note composition-for example, Smart Paste³⁵ allows clinicians to automatically pull desired patient data from the EHR and insert it into the note. In addition, many clinicians continue to use WebCIS, an older EHR system that does not include a computerized physician order entry At the time of the study, WebCIS was no longer used for entering notes; however, it was still used for viewing notes and other patient data. When the study was conducted, most licensed independent practitioners (physicians, nurse practitioners, and physician assistants) entered their notes directly into the EHR via keyboard and mouse rather than by dictation.

Study design

For the purposes of this paper, we define documentation as preparation and composition of a clinical note, whether the note is formal (ie, legal clinical documents such as an admission note) or informal (ie, internal working documents such as a sign-out note). All types of notes seen in the study were written for a single patient. Various practices exist for sign-out notes; however, in our study sign-out notes were composed for each patient individually, which justified their inclusion in the study.

The purpose of this study was to clarify emerging work patterns related to electronic documentation, understand if and how existing health information technology systems may support or hinder these practices, and provide insights into improving the design of electronic documentation functionalities. During the course of the study, an experienced observer (LM) shadowed participants for the duration of their shift, capturing their note-writing activities and other clinical activities that occurred immediately before and after note writing. The observer's expertise included a variety of qualitative research methods, including ethnographic observations (observations of clinical work practices, such as in Mamykina and Wolf³⁶), open-ended interviews, and focus groups; and a variety of analytical methods, including Grounded Theory and conversational analysis. The study included close to 100 h of observations; we recorded 96 note-writing sessions by 11 residents (five first-year residents and six second- and third-year residents) over 11 days. Temporal data on the activities were collected whenever possible. We used informal interviews with study participants as member checks to confirm the findings and their interpretation. The study was approved by the institutional review board of Columbia University Medical Center; all participants consented to the study before the observations.

Taxonomy of clinical activities

In time-and-motion studies, the activities observed by researchers are often captured using a predefined taxonomy. The accuracy of the taxonomy and its suitability for a particular work environment have a significant impact on the results. The taxonomy we adopted for this study was initially developed by Overhage et al³⁷ and later refined by Pizziferri et al.³² It is recommended by the Agency for Healthcare Research and Quality for collecting time-and-motion data in clinical workflow studies. A pilot test with four participants (two first-year residents and two second-year residents) indicated the need to modify this taxonomy in several ways. First, it needed more finegrained subcategories for describing documentation practices, which led to restructuring of the existing categories. In addition, since all note-writing activities observed during the study were performed electronically, it needed a way to reflect the use of the local EHR for documentation.

To deal with these requirements, we made a number of changes to the original taxonomy and developed a custom activity capture tool for iPad. First, we separated all note-writing activities into two categories: "electronic documenting" and "paper documenting." Notably, these categories did not include informal mental notes, observations, and to-do lists that are frequently captured during a day (these were captured primarily within "paper use without documentation (WD)" category discussed below). Because at our study site all formal documentation was done electronically, "paper documenting" did not contain any activities. We also created two additional categories: "computer use WD" (eg, looking up patient data in an EHR, or writing an order using a computerized physician order entry), and "paper use WD" (eg, looking up patient data in a paper chart, or hand writing a to-do list). In addition, within the "computer use WD" and the "electronic documenting" category we included activities that reflected the specific features of the local EHR system, such as "flow sheets" (for computer use WD)

and "Smart Paste: vital signs" (for electronic documenting). The modified taxonomy is included in appendix A.

In our iPad tool, we introduced the ability to capture multiple activities simultaneously, which became particularly important for capturing electronic documentation practices. It allowed us to record the time spent on the overall note writing, while capturing other activities that took place while the note composition was still in progress.

Data analysis

To analyze the data collected in the time-and-motion study, we extended a methodology developed by Zheng *et al*³⁸ that consists of multiple analytical tools to visualize and uncover hidden regularities embedded in the sequential execution of patient care tasks in a clinical workflow. This method also allows the assessment of workflow fragmentation—a measure delineating frequency of task switching which is a salient signal of work efficiency, in addition to the identification of other common workflow patterns.

RESULTS

In the empirical study, we observed a total of 96 note-writing sessions. The types of notes observed are reported in table 1. Not surprisingly, the time spent each day (each first-year resident write 6-10 such notes a day) and the time taken for each note is greatest for daily progress notes as first-year residents are slower writers than their more experienced colleagues. Sign-out notes are just as frequent; however, they take considerably less time per note, and by extension each day. In contrast, admission and discharge note are written less often. As a result, while they still take a considerable time for each note, their averaged time per day is less.

In the following sections, we present our empirical results according to the three research questions that motivated the study—namely, "when do physicians document?" "what are common transitions between steps in note writing?", and "what is the context for documentation?"

When do physicians document?

Analysis of the temporal distribution of note-writing activities showed that the participants roughly fell into three temporal patterns (described below); all three had their advantages and limitations. These patterns were later confirmed through member checks.

► *Early documenter*: Physicians in this category tended to complete their progress notes in the morning, immediately after patient visits (and occasionally before these visits) and before rounds. The participants of the study explained that this approach helped them to mentally synthesize patient cases, and crystallize their salient features for presentation during rounds.

 Table 1
 Types of notes observed during the study and time spent on different types of notes, from the time the note was created to the time it was submitted or saved as draft

	Number	Average time	Average time
Type of note	observed	per day (min)	per note (min)
Daily progress notes	40	49.6	13.4
Sign-out notes	40	9.2	4.0
Admission notes	10	10.4	12.1
Discharge notes	6	1.2	8.6
Total	96		

- ► *Thorough documenter*: Physicians in this category tended to write their daily notes at the end of a shift, upon completion of the discussions and activities pertaining to the patient. The participants believed that this approach produces more thorough notes, as they include information that becomes available throughout the day.
- ► Opportunistic documenter: Whereas many second- and thirdyear residents fell into the first two categories, some novices had a less structured approach to note writing. Their notes were often started in the morning, but interrupted by more pressing needs. Instead of waiting until the end of the day, these residents continued writing notes opportunistically throughout the day.

What are common transitions between steps in note writing?

We recorded 1081 activities that physicians engaged in while writing notes. This suggests that for the 96 notes observed in the study, physicians transitioned on average over 10 times while writing a note. For each of these notes we looked at what activities physicians engaged in while writing the note (from the time they started note writing until they saved or submitted a note, or were terminally interrupted). In addition, we looked at the frequencies of common transitions between activities that were captured in sequence.

Table 2 shows the categories of activities physicians engaged in while writing notes, with a particular focus on activities within the "electronic documenting" category. Not surprisingly, the most frequent transitions were between activities within the "electronic documenting" category. However, it also shows that for each note physicians in the study, on average, looked elsewhere in their EHR close to four times, and at least once in their paper-based memos. In addition, it was not uncommon for physicians to reach out to their colleagues with questions either in person or over the phone. Within "electronic documenting", typing was a predominant activity, with electronic enhancements such as copy and paste and Smart Paste following closely behind.

This analysis of transitions showed that the vast majority of them (792 out of 1018 (77.8%)) were between activities within the "electronic documenting" category, and activities within other categories. The 10 most frequently occurring transitions between activities that happen while physicians write notes are displayed in table 3. The last column, "Support", shows the relative frequency of these transitions per hour over the total number of hours in the study. The table shows that only three of the 10 most common transition categories (Nos 1, 5, and 10) are between activities *within* the "electronic documenting" category.

Table 2	Frequency o	f activities	physicians	engage in
while write	ting notes			

Category	Count (average per note)	
Electronic documenting	4.9	
Typing	2.2	
Copy/paste	0.8	
Smart Paste: notes	0.2	
Smart Paste: common labs	0.2	
Smart Paste: templates	0.2	
Smart Paste: vital signs	0.2	
Computer use WD	3.7	
Paper use WD	1	
Phone	0.4	
Talking	0.4	

WD, without documenting.

No	Transition	Support (No/h)
1	Electronic documenting (copy/paste) $ ightarrow$ Electronic documenting (typing)	1.14
2	Electronic documenting (typing) \rightarrow Computer use WD (EHR: documents (read))	0.55
3	Computer use WD (EHR: WebCIS) \rightarrow Computer use WD (WebCIS: notes)	0.5
4	Paper use WD (sign-out to do (read)) \rightarrow Electronic documenting (typing)	0.45
5	Electronic documenting (smart paste $-$ notes) \rightarrow Electronic documenting (copy/paste)	0.41
6	Electronic documenting (typing) \rightarrow Paper use WD (sign-out to do (read))	0.41
7	Computer use WD (EHR: documents (read)) \rightarrow Computer use WD (EHR: documents (read note))	0.41
8	Computer use WD (EHR: patient lst) \rightarrow Computer use WD (EHR: documents (read))	0.36
9	Computer use WD (EHR: documents (read note)) \rightarrow Electronic documenting (copy/paste)	0.36
10	Electronic documenting (create progress note) \rightarrow Electronic documenting (Smart Paste: templates)	0.36

 Table 3
 Ten most common transitions

EHR, electronic health record; WD, without documenting.

All the other common transitions are *between* categories, such as from "electronic documenting" to "paper use WD," and from "electronic documenting" to "computer use WD."

Closer inspection of the between-category transitions shows that most of them are for data assembling (such as in Nos 2, 3, 6, and 9). For example, while composing a note, the physician might search for patient data residing elsewhere in the EHR or on paper. Alternatively, these transitions indicate cases when note composition triggered new activities related to patient care. For example, while documenting a patient's medication list in a progress note, the physician might recall a decision to change the dosage of a particular medication prescription, and immediately make the necessary updates to the orders.

Figure 1 shows a subset of the observed note-writing sessions. The visualization confirms that with a few exceptions, note writing necessitates frequent rapid transitions between the documenting activities (such as typing and copying/pasting) and activities in many other categories (such as "computer use WD" and "paper use WD").

What is the context for documentation?

This question dealt with the activities that physicians engage in immediately before and immediately after documenting. The results are presented in table 4. Most of the activities shown in table 4 belong to the "computer use WD" category, suggesting that note writing is a part of a series of activities pertaining to patient care that are completed with the use of the EHR. Specifically, many of the before documenting activities are related to researching a patient's case and gathering patient data, whereas after documenting activities include other types of work, such as updating medication orders or to-do lists.

Note-writing practices

In addition to capturing activities using the taxonomy and the iPad tool, the observer kept written notes about the context in which these activities were performed, allowing several note composition practices to be highlighted. For example, several physicians consistently opened two different EHR applications simultaneously in two separate windows, using one for viewing patient data, and another one for composing a note. In other cases, physicians printed, or manually copied data from the EHR or other clinical information systems onto paper to have the data available throughout the note composition, thus diminishing the potential of electronic systems to reduce the use of paper. Finally, during member checks, some participants indicated that they used automated fill-in features, such as Smart Paste, to include much of the available patient data into the current note just to have it handy while writing the assessment and plan section.

DISCUSSION

Fragmentation of clinical documentation

Previously, researchers have noted that inefficient design of computerized systems increasingly leads to fragmentation of clinical work, forcing physicians to rapidly switch between activities and tasks.^{2 28 39} Such fragmentation may adversely affect the quality of clinical work and its outcomes. Further, it may increase physicians' mental load and result in more frequent interruptions, thus presenting a substantial risk to patient safety.^{23 24 28 40 41}

In electronic documentation, we define fragmentation as a high frequency of transitions between activities belonging to different categories. Our study showed an average number of transitions of over 10 per note. Moreover, most common transitions seen in the study were between typing notes and other activities, such as viewing notes written by other clinicians, and one's own informal notes written on paper.

These findings, particularly the high rate of transitions between activities in the "electronic documenting" and "computer use WD" categories, suggest that note writing is fundamentally a *synthesis* activity. As a general rule, we found that physicians do not write their notes from memory but review various sources of patient data, and interpret and synthesize these data.

At the same time, the note-writing module of the EHR system used by the physicians in this study, and that of many other EHR systems, includes a set of tools that support *uninterrupted composition*. Its user interface is optimized for composing and editing notes and does not provide an integrated view of the note-writing environment and other EHR modules, such as flow sheets and orders. As a result, physicians in our study rapidly switched back and forth between viewing patient data and existing documentation, and writing their own thoughts and impressions.

Furthermore, analysis of the activities before and after documenting shows that note writing is an integral part of *sensemaking*⁴² critical to patient care, which includes researching a patient's case, updating the care plan, and summarizing the status of the patient. Any separation of these activities creates artificial boundaries, which might be responsible for the workflow fragmentation seen in this study.

Fragmentation creates workarounds and inefficiencies

Previous studies have suggested that suboptimal design of EHR systems often leads to "fragmented displays" and "hidden

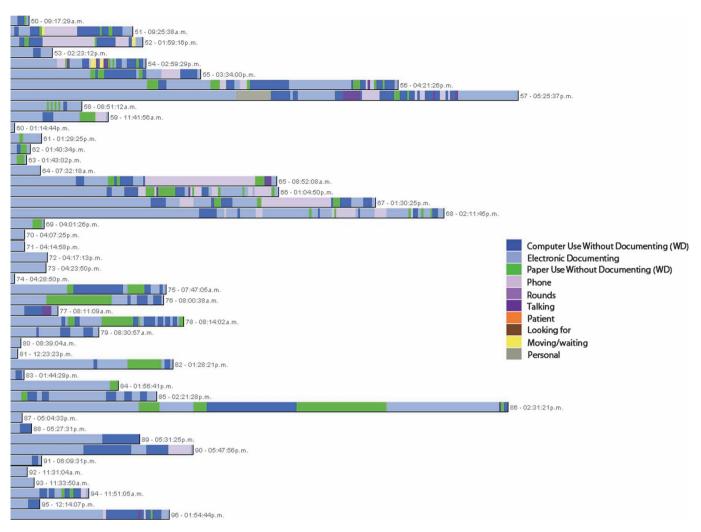


Figure 1 Activities while documenting. Each row represents a note, segmented into activities that were captured from the time users began composing a note until the time the note was completed (or saved as draft).

information".^{24 39} In order to synthesize a patient's case, clinicians need to switch rapidly between different areas of their EHRs to gather relevant information. The inevitable cost is overload of working memory and loss of context, conditions that often result in the increased possibility of information loss and error.³⁹ The common result of this practice is an overly long and often unreadable note that duplicates data already available elsewhere in the system.⁴³

In our study we saw a number of workarounds physicians used to compensate for the inefficiency of their EHR. Although these practices may save time, and reduce the cognitive workload that results from dealing with fragmented information, they also have significant associated limitations and risks. For example, manual transfer of data from an EHR onto paper simply for the sake of having these data available while composing a note can lead to errors and mistakes. Similarly, relying on printed data while composing notes can result in physicians relying on outdated information.

Documentation as synthesis

Conceptualizing clinical documentation as an information synthesis activity rather than a composition activity has direct implications for the design of electronic support for documentation in EHR systems. Viewing note writing as composition calls for a set of techniques that focus on improving the composition process—for example, the introduction of templates⁴⁴ or structured data entry.⁴⁵ In contrast, viewing clinical documentation as synthesis suggests that the focus of electronic documentation should be on tools that accelerate sense making. Researchers in cognitive science usually discuss these within three broad families: (1) tools that support data exploration, and search for relevant information—for example, using information visualization techniques applied to a patient record, such as Graphical Summary of Patient Status⁴⁶ and LifeLines⁴⁷; (2) tools that support selective reading and annotation—for example, through highlighting and tagging⁴⁸ ⁴⁹; and (3) tools that support composition of a document as a temporal structure that grows and is updated over time.⁵⁰ ⁵¹

Although each of these components has been previously explored by researchers in different fields, there are few examples of integrated sense making environments that could guide the design of tools for electronic clinical documentation. For example, Entity Workspace,⁵⁰ designed to support knowledge workers in different domains, allows its users to search through an extensive body of documents, selectively highlight and annotate relevant parts of the text as they read, and integrate and manipulate their notes in composition of a summary document. For medical sense making, Smart Forms⁵² incorporate many of the components we listed above, thus achieving closer integration between documentation and decision-making.

 Table 4
 Ten most common activities before documenting and 10 most common activities after documenting

No	Activity (before)	Frequency
1	Computer use WD (EHR: patient list)	37
2	Computer use WD (EHR: documents (read))	28
3	Paper use WD (sign-out: to do (write))	15
4	Computer use WD (EHR: orders (read))	10
5	Computer use WD (EHR: orders (write))	8
6	Paper use WD (sign-out: to do (read))	8
7	Computer use WD (EHR: WebCIS)	6
8	Moving/waiting (walking)	6
9	Computer use WD (WebCIS: data)	6
10	Computer use WD (EHR: documents (read note))	4
No	Activity (after)	
1	Computer use WD (EHR: patient list)	34
2	Paper use WD (sign-out to do (write))	17
3	Computer use WD (EHR: documents (read))	15
4	Computer use WD (EHR: orders (read))	14
5	Computer use WD (EHR: orders (write))	9
6	Moving/waiting (walking)	9
7	Computer use WD (EHR: clearing flags)	6
8	Talking (other residents)	6
9	Paper use WD (sign-out to do (read))	6
10	Computer use WD (EHR: WebCIS)	5

EHR, electronic health record; WD, without documenting.

Wilcox *et al*⁵³ developed a prototype clinical documentation environment, activeNotes. This integrates note composition with information retrieval on demand: the system uses terms entered by the note writer as key words and searches for relevant data in the EHR. These emerging approaches establish a new direction for supporting clinical documentation as synthesis and provide physicians with appropriate cognitive support. However, few of these tools have been integrated into everyday clinical practice, leaving ample space for new research and design initiatives to improve electronic clinical documentation. Such tools are particularly important owing to the continuing evolution of a clinical note as a cognitive aid, communication tool, financial statement, and a legal record of the delivered patient care.

Limitations

This study has a number of limitations. First, it was conducted in one unit of a teaching hospital with a limited number of participants. All the participants were resident physicians in training and the study did not focus on ambulatory settings, more familiar to the majority of practicing physicians in the USA. It also focused on documentation supported by a particular EHR system. Therefore, the results may have limited generalizability to other settings, types of clinicians, and other EHR systems. Our own research and that of other investigators suggests that nurses, physicians in small practices, surgeons, and clinical specialists, among many others, have different attitudes and approaches to documentation. Similarly, different computing systems may lead to variation in electronic documentation styles. For example, direct dictation remains a common practice among physicians; however, physicians participating in our study did not use dictation at all. Further research is required to develop a more comprehensive picture of documentation practices and the impact of EHR systems on these practices.

In addition, patient care is inherently discontinuous and interruptions occur, with numerous interwoven activities

competing for clinicians' attention, electronic documentation being only one of them. While we argue for reducing unnecessary transitions, many interruptions that occur during clinical work are appropriate and necessary.

Finally, the activities were captured using a predefined taxonomy; activities outside the available categories were captured as "other" without further detail. Third, the accuracy of the empirical data depended on the observer's ability to follow up the study participants and keep accurate track of their activities. These limitations, however, are inherent in the nature of the methods chosen for this research.^{32 38 54}

CONCLUSION

A time-and-motion study of physicians' electronic documentation practices showed a high level of fragmentation of documentation activities and frequent task transitions. This may lead to an increased load on working memory, increased probabilities of errors, and, as a result, a number of workarounds to compensate for limitations of computerized systems. This finding provides further empirical evidence that conceptualizing clinical documentation as composition does not match real documentation practices. Treating documentation as synthesis rather than composition suggests new possibilities for supporting it more effectively with electronic systems.

Contributors All authors designed the study. LM designed and developed the iPad tool, conducted the observations, and analyzed the captured data, and drafted and revised the paper. KZ developed tools used for the analysis of the observational data, and together with LM analyzed the data. DV provided feedback on the design of the iPad tool, and revised and edited the paper. PDS together with LM developed the new taxonomy, provided feedback on the iPad tool and revised and edited the paper. GH advised on the design of the new taxonomy, study design, data analysis, and revised the draft paper. There are no collaborators beyond the coauthors of the paper.

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Competing interests None.

Patient consent The study involved no direct patient contact and required no patient consent. All participating clinicians consented in accordance with requirements of Columbia University Medical Center Institutional Review Board.

Ethics approval Ethics approval was provided by Columbia University Medical Center (CUMC).

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