Generating Clinical Notes for Electronic Health Record Systems

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Summary

Clinical notes summarize interactions that occur between patients and healthcare providers. With adoption of electronic health record (EHR) and computer-based documentation (CBD) systems, there is a growing emphasis on structuring clinical notes to support reusing data for subsequent tasks. However, clinical documentation remains one of the most challenging areas for EHR system development and adoption. The current manuscript describes the Vanderbilt experience with implementing clinical documentation with an EHR system. Based on their experience rolling out an EHR system that supports multiple methods for clinical documentation, the authors recommend that documentation method selection be made on the basis of clinical workflow, note content standards and usability considerations, rather than on a theoretical need for structured data.

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1. Background

Healthcare providers documenting patient care delivery can use any of a spectrum of different documentation methods, including handwriting on paper, dictating note contents into a recording device from which they can later be transcribed and using any of various computer-based documentation (CBD) systems [1]. Creating clinical notes, herein called *clinical documentation*, consists of a process in which healthcare providers record the observations, impressions, plans and other activities arising from episodes of patient care, and generally occurs with each interaction between patients and the healthcare system. The notes that result from clinical documentation are generally intended to produce an objective record of a patient's history, physical findings, medical reasoning, and patient care [2-4]; to recount the care and procedures that individual patients receive in case of potential future arbitration [5]; to justify the level of reimbursement for given services; to determine the quality of care provided to patients [6-10]; to provide clinical data for research; to apply computerized decision support algorithms [11, 12]; and, to allow data mining for real time process improvement and quality monitoring [13-18]. Because EHR system adoption relates in part to how well such systems support clinical documentation [19-23], healthcare providers must consider how their documentation needs align with the capabilities of an electronic health record (EHR) system.

While healthcare providers value flexibility and workflow efficiency [24], many clinical documentation systems described in the biomedical literature place higher value on structuring the data entry to support subsequent machine readability. Structured entry systems generally emphasize compliance with data formatting and content requirements [1, 25, 26], help healthcare providers be thorough [25, 27, 28] and generate categorical data that can be reused for other needs (e.g., research, automatic coding or billing of clinical encounters). Many structured entry systems have been developed [1, 18, 25, 29-47]. However, structured entry systems typically have not enjoyed long-term or widespread adoption [26, 48]. McDonald [26] and Ash [49] have demonstrated that structured entry adoption may be hampered by user interface complexity, inflexibility for documenting unforeseen findings, lack of integration with other clinical applications, and deficiencies in the underlying data model.

The authors' institution approached the challenge of incorporating clinical documentation into the local EHR system with the belief that healthcare providers should be able to choose from a broad palette of documentation methods, based on clinical workflow, document content standards and usability considerations. Three major goals for integrating clinical documentation in this way were:

1. that it would allow a variety of documentation methods to contribute notes to the EHR system,
2. that all healthcare providers could view any clinical note in the EHR system, regardless of the documentation system they use in their own practice, and,
3. that adoption of a specific documentation method would not become a barrier to the completeness of data within the EHR system.

Supported documentation methods include handwritten or other paper notes scanned into a digital format, transcribed dictated notes and notes entered directly into any of several CBD systems.

2. Objectives

This manuscript presents a case study outlining the authors' experiences integrating clinical notes generated using various clinical documentation methods into their local EHR system, and discusses the lessons learned. The authors' perspectives have additionally been formulated through their collective experiences developing and evaluating clinical note capture tools over a span of more than thirty years, including recent efforts to integrate and evaluate clinical documentation systems in various healthcare settings [1, 25, 32-34, 45, 50-53].

3. Case Study

In 2000, the Vanderbilt University Medical Center (VUMC) initiated a program to expand its existing EHR system with the goal of incorporating any clinical document into the patient chart regardless of how it was created [50]. The new program was designed to build upon prior implementation of clinical provider order entry, [54] a simple template-centric CBD system [55] and a relatively more limited EHR system that provided results reviewing primarily for laboratory and radiology testing [52]. To be included in the expanded EHR system, clinical documents were required only to be formatted to contain a metadata header that included the patient medical record number, name, document type (and subtype, if appropriate), date of clinical service (and time of service, if available), and a globally unique document identifier code. Document types and subtypes referred to the function the note serves, such as "clinic note" or "discharge summary". This simple inclusion requirement allowed documents generated from any header-compliant documentation method to be used for clinical documentation into the EHR system.

A variety of clinical documentation methods became available to healthcare providers using the EHR system at the VUMC. The authors categorize these documentation methods below based on the input method they support, the degree to which the notes they produce are created using templates, and whether the notes are structured or standardized. The authors define "templates" as note outlines that have empty spaces that prompt users to enter missing information and that contain standard text. Templates have long been used in CBD systems [1, 16, 18, 25, 30, 32, 37, 44, 56-62]. The authors define "structure" as having a predefined or conventional syntactic organization, and "standardized" as complying with a predefined semantic standard. In the current manuscript, CBD systems supporting direct input of structured and machine-readable data into notes are collectively called "structured entry" systems for the sake of simplicity. The documentation method categories supported by the VUMC EHR system include:

1. scanning of documents originally created on paper,
2. notes generated through a process of dictation and transcription,
3. notes typed using a relatively unstructured CBD system,
4. notes entered using a structured entry system without a standardized terminology, and
5. notes entered using a structured entry system with a standardized terminology.

▶Table 1 summarizes the primary documentation methods available at the VUMC.

Assisted Documentation Methods

Document scanning
Using tools to scan paper-based notes into digital image files, handwritten notes, drawings on paper, patient-generated documents and paper-copy records from other medical sites are all scanned into digital files and uploaded into the EHR system. Scanning also is used to incorporate external data such as faxes, medical records from referring physicians, patient logs (e.g., home blood pressure readings) and pictures into an EHR system. Once scanned, the electronic documents can be tagged with brief comments for indexing, and have standard header information about the author, note type and the date of service added electronically.

Dictation with Transcription
Dictation is a multi-step documentation method in which a healthcare provider speaks the contents of a clinical note into a recording device, and a transcriptionist produces the note from listening to the recording. The transcriptionist can be a human, a specialized computer program or a combination of the two. By local institutional policy, the transcription step is followed by a third step in which the healthcare provider must review the typed note for errors and finalizes it for inclusion in the medical record within a time window that varies based on the patient's acuity and the type of note being documented.

Computer Based Documentation Methods

Computer-based documentation is defined as any documentation method in which the healthcare provider interacts with a computer program that in turn generates notes. Numerous CBD systems exist with diverse user interfaces, functional characteristics, target audiences and track records. They can be built for general purpose or highly specialized for specific tasks, and used to document in a single step or over the course of a clinical encounter [1, 11, 18, 23, 25, 29-45]. CBD systems can have diverse workflow and user interface characteristics. For example, they can be integrated into EHR systems; they can allow users to work from templates; and they can use various input modalities, such as mouse clicks, keyboard typing or via a touch screen. As above, a specialized class of CBD systems called Structured Entry systems allow users to document clinical care by selecting or modifying categorical concepts that are typically organized into templates. Structured entry systems are typically designed to capture structured and machine-readable data directly from the healthcare provider in real time, [63] to produce data that can facilitate automated reminders and alerts while providing an infrastructure for clinical other uses (e.g., automated billing, research, quality assurance).

The following CBD systems have been implemented into the institution's clinical environment, from the least to the most structured and standardized.

Type New Document

"Type New Document" is a blank text box into which clinicians may type clinic, hospital progress, procedure or consultation notes. This tool provides plain-text formatting, does not offer templates, and has no ability to reuse data or text from other parts of the EHR system. Notes can be saved as drafts to be completed at a later time. Type New Document, as its name implies, requires a high reliance on typing, but is easily accessed, learned and used.

Messages

Messages can be sent electronically among healthcare providers and patients using a toolset within the EHR and patient portal systems. Such messages are typically sent serially to several healthcare providers, with each adding text appropriate to their role in the message. For example, a patient may send a message to her physician's practice requesting a referral to a dermatologist to evaluate a worrisome mole. The physician's nurse may screen the message, and add text stating that the patient is overdue for her diabetic hemoglobin A1C testing. The physician could then ask for the dermatology referral and order the overdue lab testing. The nurse would then call or send a message to the patient, and then save to the EHR system the composite note containing all the sequential entries. Each entry into the evolving message is digitally signed and time-stamped. All message notes are written in a simple text editor, without templates and require a high reliance on typing. Patients can access completed communications via a patient portal system.

StarNotes

"StarNotes" is a CBD system that uses typed text entry, and was developed at VUMC as a component of the EHR system. StarNotes was first developed in 2001 as a web version update of a prior client-based CBD system [55] that had been in use at VUMC since 1997. StarNotes permits template-driven entry of various categories of clinical notes by any healthcare team member. StarNotes includes a text editor that allows the user to mark-up and modify an existing template by typing or "pasting" text, either freehand or from categorical lists of predefined text. StarNotes enables both automated and manual importing of data elements, including patient name, gender, age, laboratory results, allergies, problem lists and medication lists, from linked EHR applications. Notes are typically template-based, and prior notes can be made to serve as a template for subsequent notes.

Structured Entry

Two structured entry tools that do not map to a standardized interface terminology (i.e., "Star-Forms" and "StarFields") are available to EHR users at VUMC. Both consist of customized web-based forms and web-pages that allow users to enter data in response to templates. These tools are embedded completely within the EHR system and can accept input via a number of webform elements, including check boxes, radio buttons, lists, text fields and dynamic selection of text pre-

sented in the user interface. A commercial nursing documentation system comprises a third structured documentation system in wide use in the inpatient setting; this system takes template-based entry into structured forms and then submits both the granular data and summary reports as portable document files (PDFs) to the EHR system. These systems are used for documenting categorical or stereotypical information, such as vital signs, nursing exams and treatments, administrative data and clinical reviews of systems. Documentation into these systems is largely mouse-based with typing required to complete the forms. Because these tools' major focus is to facilitate complete and concise documentation of categorical data, the structured data captured by these systems has generally not been aligned with or mapped to a standard reference terminology.

Quill

"Quill" is a structured entry system designed to permit easy documentation of categorical information through flexible templates that are mapped to standard clinical terminologies [1]. Quill's user interface allows input primarily by using "point-and-click" entry, however typed free text and keyboard shortcuts also are permitted. Documentation in Quill involves using a specialized interface terminology based on, but evolved from, a clinical terminology developed by project members as part of the National Library of Medicine Quick Medical Reference/Internist-1 project [64, 65]. The Quill engine and interface terminology also allow documentation through web forms that resemble StarForms, above. Quill is used at VUMC in the Cardiology, Cardiac Surgery and Neurology outpatient clinics for physician and nurse documentation, and in the Emergency Department for recording encounters with the triage nurse.

4. Observations

Over 65 million notes were stored in VUMC EHR system during the period 1999-2008, inclusive, with 50.1 million stored during 2004-2008. Scanned documents included notes from a diverse set of sources, and not all represented clinical notes. The top scanned note categories included clinical notes (35%, encompassing clinic notes, discharge summaries, correspondence among healthcare providers and with patients and nursing notes), then administrative documents (28%, encompassing insurance information, signed consent forms, HIPAA notification forms, release of information requests, return to work notices and requests for consultation), orders and prescriptions (19%) and results from testing (10%, encompassing laboratory test results, radiology interpretation and pathology results). Statistics for the specific documentation methods described above during the five-year period 2004-2008, inclusive, are reported in ▶Table 2, with scanned documents limited to those representing clinical notes (i.e., excluding administrative documents, orders, prescriptions, testing results).

5. Discussion

Documenting clinical care challenges busy healthcare providers. Clinical documentation typically occurs in chaotic settings while healthcare providers must simultaneously balance multiple information sources and competing tasks (such as evaluating the patient, ordering tests and medications, orchestrating subsequent care, etc) [19, 48-50, 66-69]. Healthcare providers resent forces that decrease the amount of time available for patient care and for their personal needs [70, 71]. Any documentation method that interrupts the clinical workflow or is inefficient may reduce healthcare provider's willingness to use it [48]. In addition, healthcare providers value the ability for a documentation method to permit them to document efficiently in a complex workflow, to balance standardized structure with ample flexibility to document unforeseen findings, and to be expressive when documenting findings and impressions [20, 24]. Together, the importance of these attributes suggests that documentation methods should enable providers to record the correct and necessary narrative content efficiently and should fit into and support busy workflows.

The VUMC promoted methods that allowed clinical notes to be captured into the local EHR system using a wide variety of documentation generation methods. The authors believe that this suc-

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cess has resulted from the combination of using an EHR system that incorporates documents meeting a fairly simple formatting requirement and the availability to local healthcare providers of a spectrum of documentation methods. Requiring that healthcare providers select from only a small number of documentation systems, or emphasizing documentation system structure over usability and workflow fit may have compromised the degree of CBD system adoption, the completeness of patient records in the EHR system and the willingness of those healthcare providers who find value in structured entry to adopt the EHR system.

The VUMC experience is consistent with Lorenzi's four "Cornerstones of Medical Informatics," [51] which state that EHR systems be able to:
1. represent data and knowledge so that complex relationships can be visualized;
2. avoid causing cognitive overload when presenting data;
3. use the most appropriate information technology tool for specific needs; and
4. integrate information tools into natural work processes.

This framework suggests that methods for clinical documentation should provide interfaces that allow users to retain their sense of how narrative and objective data interrelate, use a familiar visual layout, allow structured clinical data to come from both structured and narrative documents, and fit into a clinical workflow. While structured entry systems that allow automatic data reuse require that developers create specialized interface terminologies, human adoption of CBD systems requires an emphasis instead on narrative expressivity, efficiency, flexibility and being situated in a typical workflow [24, 48, 55]. Systems optimized to acquire structured data from healthcare providers may have user interfaces that are unfamiliar, inflexible or inefficient, and place the burden of structuring the data on a busy healthcare provider rather than leveraging specific computer programs to extract the data from the human-input clinical narrative [72].

This inclusive approach to supporting documentation in the local EHR system has conferred several benefits. First, because the system supports a variety of document types and aggregates notes using relatively simple tagging in the documents' header, the VUMC was able to extend this platform to support health information exchange in a recent project [73-75]. This exchange was able to incorporate documents created in other systems by simply applying the standard set of categorical tags to the header of each document. Second, as the VUMC explores the potential for genome- and phenome-wide association studies [79], investigators have been able to construct a "synthetic derivative" of clinical documents in the EHR system. The synthetic derivative includes all EHR system text and categorical documents, shifts and distorts dates of service and de-identifies structured data, and retains only tagged information for images (including scanned documents) [76]. Because the VUMC EHR system contains a wealth of unstructured documents, investigators developing the synthetic derivative have been able to create a rich data source for associating patient phenotypes with haplotype and genomic patterns, using both standard terminology mapping and natural language processing techniques [77, 78]. In summary, the relatively open framework for incorporating clinical documentation into the EHR system has facilitated the collection of information from a variety of disparate clinical enterprises, and has resulted in a resource that VUMC researchers are able to exploit for health information exchange and high-dimensionality data research.

The authors' experience evokes several likely workflow-based documentation scenarios. For example, a structured documentation tool may be the most appropriate for relatively simple tasks, repetitive documentation, or when addressing diagnoses common to the clinical domain using the tool. Examples may include vital sign entry, patient questionnaires, review of systems or recording vaccinations. The regularized input imposed by a structured documentation system should be well matched to the relatively fixed content, sequence and structure of such tasks. For more complex or variable tasks, such as describing a patient with a rare disease or a patient with multiple problems, a healthcare provider may require a more expressive or flexible documentation tool such as dictation or typing-intensive documentation tools. When possible, scanning should be reserved for those tasks difficult to replicate with electronic tools (such as drawing pictures), archiving data received from outside institutions, or when electronic capture tools present a significant hindrance (user, workflow, or cost barriers) to use of an EHR system.

For example, at the authors' institution, StarForms and StarFields are widely used for outpatient nursing assessments, for inpatient bedside procedure documentation and for intensive care unit

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progress notes. Throughout the outpatient setting, many healthcare providers document their patient clinic visit notes using StarNotes or with dictation and transcription. Documents brought in by patients or sent from outside hospitals, or written by healthcare providers on paper (such as by those who have not adopted a CBD system or in the case that the note included a drawing) are scanned in and uploaded to the EHR system. Despite these common trends in usage, there exist numerous clinical settings where different healthcare providers use different documentation methods according to personal preference and skillsets. For example, one provider may chose to write notes using StarNotes, another using StarForms and another on paper with the expectation that it will be scanned all within a single clinic.

6. Limitations

The recommendation that documentation method selection be made first on the basis of clinical workflow, note content requirements and usability considerations rather than on a theoretical need for structured data is based on the success implementing that approach at the VUMC. It is possible that the observed successes in rolling out a diverse set of documentation methods were the result of other factors, such as local culture or unmeasured incentives or drivers. The degree to which the local context shaped the insights described in the manuscript are unknown and may impact whether they are locally relevant or broadly generalizable to other settings.

In addition, while the authors propose that EHR systems should be designed to incorporate clinical documents produced using any of a variety of documentation methods, they stop short of prescribing for healthcare providers a means of identifying the best documentation approach for a given task, person, or workflow. The biomedical literature lacks an evidence base that would guide specific recommendations about how to match documentation method with task, person or workflow, and so the current paper stops short of providing formal guidance on how this should be done. Developing a research program to address this gap is an important area for future research.

7. Conclusion

The authors report the integration of multiple approaches for documenting clinical care into a single EHR system. Based on this and prior experiences, the authors recommend that healthcare providers be able to chose the most appropriate and usable documentation method based on clinical workflow and note content requirements, rather than be required across the board to use one particular method – such as a structured CBD system that forces categorical data entry. With the goal of choosing the best documentation approach for a given task, person, and workflow, the authors believe that healthcare providers will be best served by having available a spectrum of documentation methods during clinical practice. Individual healthcare providers may chose their documentation methods based on a balance between their comfort with the system and the content of the task they are trying to accomplish, rather than just adopting a "one-size-fits-all" documentation method. For situations where workflow and note content requirements lend themselves to relatively formulaic clinical documentation, such as with problem list entry, intake assessments and recording the review of systems or physical examination, a structured entry system may be appropriate. This approach facilitates electronic capture of clinical information, while also providing early adopters with tools that support structured entry and data aggregation, without imposing this level of complexity on the entire enterprise. With this approach, barriers to documentation tool use will be minimized.

Implications of results for practitioners
Provider acceptance of EHR systems has been hampered by the challenge of integrating structured computer-based clinical documentation. Healthcare providers and EHR system users should use the documentation method best matched to the clinical workflow and note content needs rather than emphasize structured documentation systems across the board. EHR system developers should ensure that the systems can incorporate notes generated using a variety of different documentation methods.

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Human Subject Research Approval
The Vanderbilt Institutional Review Board approved this project was as being compliant with institutional and national ethical standards for research involving humans. Summary counts of notes generated by each documentation method are reported.

Conflict of Interest
The manuscript describes the electronic health record (EHR) system and computer based documentation (CBD) systems developed and deployed at the Vanderbilt Medical Center; a version of that EHR system and of some of the CBD systems have been commercialized by a third party. Authors Rosenbloom, Stead, Giuse, Lorenzi and Johnson receive periodic distributions as one-time inventors of that system. This process is tightly monitored by the Vanderbilt University Medical Center Office for Technology Transfer and by the Vanderbilt Office for Faculty Affairs.

Table 1 Characteristics of the different documentation methods available at the Vanderbilt University Medical Center

Documentation Method	Primary Note Entry Modality	Template Use Frequency	Innately Produces Structured Data
Assisted Documentation methods			
Scanned documents	Variable	Variably	No
Dictation	Spoken	Occasionally	No
Computer Based Documentation Methods			
Type New Document	Typing	None	No
Message	Typing	None	No
StarNotes	Typing	Typically	Rarely
StarForms	Typing, Clicking	Always	Typically
StarFields	Clicking	Always	Typically
Nursing Forms	Typing, Clicking	Always	Typically
Quill	Clicking	Always	Typically

Table 2 Number of notes stored per year by documentation method, and total yearly patient encounters.

Documentation Method	Year				
	2004	**2005**	**2006**	**2007**	**2008**
Assisted Documentation Methods					
Scanned Documents*	90,868	130,266	194,328	285,217	317,268
Dictation	361,652	434,393	388,176	341,603	442,123
Computer-Based Documentation Methods					
Type New Document	95,376	96,318	149,640	158,676	233,307
Message	576,000	-**	9,015,319	10,326,978	11,688,633
StarNotes	321,600	393,970	775,267	841,164	1,383,036
StarForms	60,650 ***	137,469	363,475	638,482	1,391,693
StarFields	-**	31,588***	410,228	813,656	1,258,933
Nursing Forms	-**	3,481***	407,772	540,447	469,900
Quill	22,548	75,926	139,511	156,384	150,476
Total*	1,528,694	1,303,411	11,843,716	14,102,607	17,335,369
Individual Patient Encounter Volume					
Inpatient	41,068	45,153	49,257	51,243	52,348
Outpatient	1,121,907	1,210,937	1,335,825	1,470,656	1,557,088
Emergency	64,684	72,024	77,001	83,315	84,196

* numbers include only scanned documents categorized as clinical notes

** data unavailable for this year

*** year includes months from prior to this method's implementation

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