Implementing a Real-Time Electronic Data Capture System to Improve Clinical Documentation in Radiation Oncology

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Abstract

Purpose: Electronic health records (EHRs) often store information as unstructured text, whereas electronic data capture (EDC) using structured fields is common in clinical trials. We implemented a web-based EDC system for routine clinical care, and describe our experience piloting this system for breast cancer patients receiving radiation therapy.

Methods: Our institution uses dictation for clinical documentation in a centralized EHR; a separate radiation therapy-specific record-and-verify system contains prescriptions, schedules, and treatment documentation. The implemented EDC system collects patient, tumor, and treatment characteristics using structured data fields and merges it with data from the radiation therapy system to generate template-based notes in the EHR. Mean times to create notes using dictation versus EDC were compared. Users were surveyed about their experience. Acute toxicities were captured using the EDC system, and reported.

Results: The EDC system has been used by 25 providers for 1,296 patients. In the most recent month, 978 clinical notes were generated. The average clinician documentation time over a typical course of radiation was reduced from 22.4 minutes per patient with dictation, to 7.1 minutes with EDC. The user survey response rate was 100%, with 92% of respondents being either satisfied or very satisfied with their experience. The worst acute toxicities were mostly grade 1 (51%) or grade 2 (43%), with rare grade 3 (3%) events.

Conclusions: We implemented an EDC system for routine clinical use in the breast radiation therapy service that resulted in significant time-savings for clinical documentation and prospective population of a database to facilitate outcomes reporting.

Key Words: Radiation oncology, electronic data capture, electronic health records

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INTRODUCTION

Phase III randomized controlled trials remain the gold standard for comparing new treatment regimens against the standard of care, to advance clinical oncology knowledge. However, these studies are time consuming and resource intensive; as a result, less than 5% of all oncology patients are enrolled in randomized controlled trials [1,2]. Retrospective studies can be performed more readily, but they often require manual review and coding of patient charts. Although they may result in interesting hypothesis-generating findings, these studies are often limited by selection, recall, and other biases that reduce their generalizability.

Electronic health records (EHRs) are being used increasingly, with estimates that they are being adopted by as many as 80% of physicians [3]. The Health Information Technology for Economic and Clinical Health (HITECH) Act continues to provide a substantial financial incentive for an evolving definition of "meaningful use" of EHRs in the United States [4].

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Although these systems can improve the efficiency and completeness of clinical documentation, the rich clinical data are often captured as unstructured free-text, which means subsequent retrospective chart reviews must be used to glean clinical insight. In contrast, electronic data capture (EDC) systems are often used in randomized controlled trials to capture data in a structured format, through electronic case-report forms, but the collection fields are limited to trial-specific data elements, and they are completed in addition to routine documentation.

We sought to implement a web-based EDC system for routine clinical care, using structured data entry to improve the ease of clinical documentation, and simultaneously populate a patient database to facilitate outcomes reporting. The pilot group for this system was our breast radiation oncology service. The goals of this study were to describe the implementation of the clinical tool, report on its initial impact in terms of efficiency gains, and provide proof-of-concept for future outcomes research.

METHODS

Information Systems

An overview of the information systems used at our comprehensive cancer center is depicted in Figure 1. An EHR that was developed in-house serves as the centralized repository for clinical documentation that includes clinical notes, radiology images and reports, pathology records, scanned outside documentation, and radiation treatment plans. Various departments commonly rely on specialty-specific software to manage their own workflow and generate appropriate internal documentation, with selected documents being deposited into the EHR for all providers to access.

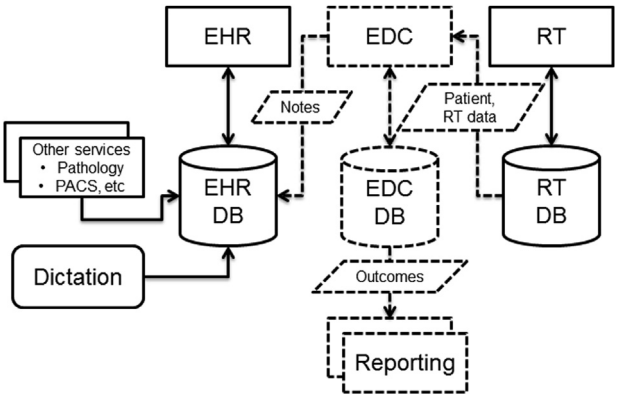

Fig 1. Diagram of information systems at our cancer center. *Dashed lines* denote new functionality implemented as part of the EDC system. EDC = electronic data capture; EHR = electronic health record; RT = radiation therapy system of record; DB = database.

The radiation oncology department uses MOSAIQ (Elekta, Stockholm, Sweden) as its record-and-verify system, which includes a patient database, simulation orders, radiation prescriptions, treatment plans, treatment documentation, and clinical schedules. Clinical notes are usually dictated on the telephone, transcribed by an ancillary service, imported into the EHR as preliminary documents, and edited by the dictating provider before finalization. For each patient treated by the radiation oncology department, clinical documentation in the EHR includes the following: (1) a detailed initial consultation note; (2) a simulation note describing the treatment simulation procedure; (3) a treatment planning note documenting the proposed treatment plan; (4) a quality assurance (QA) note from weekly staff physician review of treatment plans; (5) weekly on treatment visit (OTV) notes documenting acute side effects; (6) a treatment summary at completion of therapy; and (7) routine follow-up notes tracking disease outcomes and late toxicities.

The implemented EDC system operates as an intermediary between MOSAIQ and the EHR (Figure 1). Initial patient and clinical information entered into MOSAIQ is asynchronously imported into the EDC to pre-populate a web interface for additional structured data entry by the provider. The combined data are used to generate documentation in the EHR based on predefined note templates and are stored in the EDC to pre-populate subsequent notes. These structured data additionally serve as a prospectively generated database to facilitate outcome reporting. The exchange of data is protected by secure sockets layer-encrypted network communications, database- and application-level security, and logging of all personal health information views.

Implementation Process

A radiation oncologist (one of the investigators) collaborated with an institutional information technology group to design an intuitive and responsive web interface for the EDC system, by analyzing and identifying opportunities to optimize the clinical workflow. The interfaces captured structured data by maximizing the use of drop-down menus, selection boxes, and radio buttons while minimizing catch-all fields labeled "Other" with corresponding free-text. The web pages were

designed to dynamically hide and show data elements using context-driven logic.

For example, after the user specifies that the patient received neoadjuvant chemotherapy, the system captured both a pretreatment clinical stage and a subsequent posttreatment pathologic stage with a "yp" designation. Previously entered data were used to pre-populate future notes in accordance with institutional practices, to reduce data-entry time. For instance, patients specified as having left-sided breast cancer, on the initial consult form, had "deep inspiration breath hold," a treatment delivery technique used preferentially for left-sided breast cancer cases, to minimize irradiation of the heart; these were selected by default for the simulation note, but could be edited by the clinician as needed.

The EDC system was released in a stepwise fashion, approximately in ascending order of documentation complexity: QA notes, treatment summaries, simulation notes, planning notes, and OTV notes. The rationale for this release schedule was to facilitate user acceptance by first offering notes that reduced workload for resident and midlevel practitioners, who were additionally asked to enter the information required to generate the detailed consultation note. Although providers were encouraged to use the EDC for documentation as functionality became available, they retained the flexibility to continue dictating notes. For the pilot implementation, the treated disease site was limited to the breast (or chest wall) and draining lymphatics, thus excluding patients who received palliative treatment to distant metastatic sites.

Statistical Analysis

Descriptive statistics were used to describe EDC adoption, patient characteristics, and acute treatment toxicities, spanning the period from pilot usage in February 2014 until January 31, 2015. An anonymous survey querying user experience on a Likert scale of 1-5 was administered using REDCap (research electronic data capture) tools [5] that are hosted at our institution. The time required to create various note types using dictation or the EDC was recorded using a stopwatch in an unblinded process, and mean values were compared using Mann-Whitney U tests. Two-sided P values $<.05$ were considered statistically significant. An estimated total documentation time per patient was calculated using the expected number of notes for a typical course of treatment based on existing workflow. This research was approved by our institutional review board and quality assurance and improvement board.

RESULTS

Clinical Workflow

At the time of initial consultation, the patient's demographics were entered into MOSAIQ, and the consultation note continued to be dictated and transcribed. If the patient elected to receive treatment, the preliminary radiation prescription was recorded in MOSAIQ. Patient-specific disease and treatment characteristics were entered into the EDC system through a consult form. This one-time task was the sole additional documentation added to the pre-existing workflow. The data fields that were captured include: tumor characteristics (laterality, clinical stage, pathologic stage, histology, grade, hormone receptor status); chemotherapy details (regimen, timing); surgery details (primary surgery type, nodal surgery extent, reconstruction details, margin status); and radiation details (treatment intent, planned targets). For example, 30 distinct data elements were collected for a typical early-stage breast cancer patient treated with breast conservation therapy. These fields were used to automatically generate a short clinical vignette that functioned as the patient identifier in all subsequent notes.

At each following step when clinical documentation was required, the provider filled in additional structured data fields, and the EDC generated an appropriate note in the EHR. At the time of simulation, the fields that were captured included patient positioning, wire markers, immobilization, use of breath hold, and tolerance of simulation. Planning notes were created from the clinical vignette and the prescription in MOSAIQ, with additional annotation of special treatment procedures. As the proposed radiation treatment plan was discussed at weekly QA meetings, providers recorded the suggested changes, if any, and documentation of the outcome for each patient was completed in real time during discussions with the patient. During weekly OTVs, providers reviewed subjective complaints, physical examination findings, objective toxicities using the Common Toxicity Criteria [6] (CTC, version 4.0), and changes in treatment course, if any, and made the appropriate selections in the EDC system. The number of fractions and dose delivered to date were extracted from MOSAIQ. At the end of treatment, summary data, such as start date, end date, number of treatment fractions, and dose delivered, were obtained from MOSAIQ, to generate a pre-populated treatment summary document. All of these events were tracked in a patient "dashboard," named the "Event Manager," for quick access to longitudinal documentation.

Adoption of EDC

The EDC system was implemented and released in a stepwise approach. Pilot usage by providers began in February 2014, with the consult form and QA note. Over the subsequent six months, additional documentation tools were gradually tested and released, and the EDC system was made available to the breast radiation oncology service, at our main cancer center and several regional care centers. As of January 31, 2015, the system had been used regularly by 12 staff physicians, and a total of 13 resident physicians and midlevel providers. The EDC system has generated more than 6,018 total notes for 1,296 patients, including 978 notes for 145 patients during the most recent month. Patient, tumor, and treatment characteristics for the first 1,000 patients are listed in Table 1.

All 25 users were surveyed regarding their experience, with a response rate of 100% (Table 2). Overall satisfaction was categorized as "satisfied" or "very satisfied" by 23 (92%) respondents. Additionally, most respondents rated the ease of data entry as "good" or "excellent" (84%), and either "agreed" or "strongly agreed" that use of EDC improved documentation efficiency (96%), accuracy (84%), completeness (72%), and workflow (92%). Although users maintained the option to continue to dictate, the rate of using EDC "(almost) all the time" was high for simulation (91%), treatment planning (91%), OTV documentation (82%), and treatment summary (91%) notes.

Documentation Timing Comparison

Seven users provided timing data for dictation, and five of those users additionally provided timing data using the EDC system (Table 3). The additional consult form that was required as part of the EDC required an average of 2.5 minutes to complete. Each subsequent note type was completed an average of 1.3-3.7 minutes faster using the EDC system, compared with dictation ($P < .001$). Notes regarding QA were completed during the QA meeting and were not considered to be added documentation time. Some providers used a tablet to access the EDC system in the patient room, to complete the OTV documentation in real time, which was similarly considered not to be added time. The estimated total documentation time required per patient for a typical course of breast radiotherapy was an average of 22.4 minutes for dictation, compared with 7.1 minutes using EDC.

Acute Toxicities

All 381 patients who had at least 4 completed OTV notes were included in an analysis of acute toxicities. The

Table 1. Patient, tumor, and treatment characteristics for initial 1,000 patients

Patients (n = 1,000)			New Diagnosis (n = 955)			Tumors (n = 1,022)			Tumors (n = 1,022)		
Gender			Stage			Histology			Surgery		
Female	993	(99)	0	94	(10)	DCIS	96	(9)	Lumpectomy	646	(63)
Male	7	(1)	IA	305	(32)	IDC	776	(76)	Mastectomy	358	(35)
			IB	20	(2)	ILC	75	(7)			
Age (y)			IIA	145	(15)	IDC/ILC	20	(2)	Sentinel node only	510	(50)
<40	90	(9)	IIB	152	(16)	Other	55	(5)	Axillary dissection	418	(41)
40-49	181	(18)	IIIA	85	(9)				No nodal surgery		
50-59	315	(32)	IIIB	34	(4)	Histologic grade					
60-69	298	(30)	IIIC	92	(10)	Low	119	(12)	Surgical margin		
≥70	116	(12)	IV	28	(3)	Intermediate	475	(46)	Negative	854	(84)
						High	418	(41)	Close (<2 mm)	130	(13)
Laterality			Neoadjuvant therapy						Positive	16	(2)
Left	492	(49)	Chemotherapy	334	(35)	Receptors					
Right	486	(49)	ypT0N0	68	(7)	ER+	811	(79)	Radiation target		
Bilateral	22	(3)	ypTisN0	20	(2)	PR+	696	(68)	Partial breast	35	(3)
						Her2+	145	(14)	Whole breast	610	(60)
Diagnosis						TNBC	134	(13)	With low axilla	84	(8)
New	955	(96)							With SCV	112	(11)
Recurrence	45	(5)							With IM	105	(10)
									Chest wall	332	(32)

Note: Values are n (%). DCIS = ductal carcinoma in situ; IDC = invasive ductal carcinoma; ILC = invasive lobular carcinoma; ER = estrogen receptor; PR = progesterone receptor; TNBC = triple negative breast cancer; SCV = supraclavicular; IM = internal mammary.

Table 2. Responses from user-experience survey (n = 25)

Survey item	Likert Scale Rating (%) 1	2	3	4	5
Ease of data entry	0	8	8	52	32
Improved documentation efficiency	0	0	4	36	60
Improved documentation accuracy	0	0	16	40	44
Improved documentation completeness	0	0	28	16	56
Improved documentation workflow	0	4	4	28	64
Overall satisfaction	0	0	8	28	64

Note: Responses on 5-point Likert scale: 1 = poor, strongly disagree, very dissatisfied; 3 = neutral; 5 = excellent, strongly agree, very satisfied.

overall worst toxicity experienced was most commonly grade 1 (51%) or grade 2 (43%), with rare grade 3 (3%) events. The most common grade 2 event was dermatitis (38%), followed by hyperpigmentation (10%), fatigue (7%), and breast (or chest wall) pain (6%). The grade 3 events were comprised of a 1% incidence of each of the following: dermatitis, fatigue, and pain.

DISCUSSION

In this study, we implemented a web-based EDC system to capture structured data from clinical encounters, with the goals of improving the efficiency of clinical documentation and prospectively populating a research database. We found the system to be practical for routine clinical use, and estimated a reduction in total documentation time from 22.4 to 7.1 minutes per patient, during a standard course of breast radiation treatment.

With the current emphasis on delivering value-based health care, an EDC system such as the one described can assist in both reducing cost and quantifying value. By extracting structured data from various systems, and reusing information previously entered in the EDC, to populate template-based notes, the time spent on documentation was reduced by 68%, or 15.3 minutes per patient. Assuming 200 patients are treated per physician per year, the absolute total time-savings using the EDC would be 50 hours per physician per year on documentation. Another measure of cost-savings could be realized with a reduction in reliance on transcription services for dictated notes. Outcomes research in the form of acute toxicities, late toxicities, and patient outcomes serves as the foundation for quantification of delivered value. As proof-of-concept for future outcomes research, we generated a report of acute toxicities, based on OTV notes. As follow-up data are gathered through the EDC system, we expect to generate reports of late toxicities and disease outcomes.

An additional benefit of template-based note generation is the standardization of data capture across the practice. Review of the collected data elements with billing specialists could help ensure that data capture is adequate to maintain compliance with billing codes and future standards, such as the International Classification of Diseases, 10th edition. In addition to basic outcomes reporting, the EDC database provides an opportunity for further analysis or initiatives. For example, a report on patient demographics lends insight into the practice's patient population and practice patterns. Finally, one could link data from the EDC system to other structured data in the EHR, such as medication lists and laboratory values, to identify potential prognostic or predictive factors in clinical outcomes [7].

An alternative approach to upfront structured data entry is leveraging natural language processing (NLP) to extract data from unstructured clinical documentation [8]. This approach has been evaluated in various research settings, such as with outcomes data from radiology reports [9], staging and margin information from pathology reports [10], or machine-learning techniques to identify new clinical insights [11]. Although these approaches are still under investigation, advances in

Table 3. Mean times to create clinical notes, using dictation versus electronic data capture

Method/Purpose	Estimated No. Notes Per Patient	Dictation No. Notes Timed	Dictation Mean Time Per Note	Dictation Time Per Patient	Electronic data capture No. Notes Timed	Electronic data capture Mean Time Per Note	Electronic data capture Time Per Patient	Difference Time Per Patient	Difference *P* Value
Consult form	1	N/A	N/A	N/A	23	2.5	2.5	−2.5	N/A
Simulation	1.4	20	3.3	4.6	33	0.6	0.9	3.7	<.001
Treatment planning	1	17	2.5	2.5	27	0.7	0.7	1.8	<.001
Quality assurance	1	15	2.1	2.1	N/A	N/A	N/A	2.1	N/A
On treatment visit	5	80	1.8	9.0	39	0.5	2.5	6.5	<.001
Treatment summary	1	13	4.2	4.2	32	0.5	0.5	3.7	<.001
Total				22.4			7.1	15.3	

Note: Times are given in minutes. N/A = not applicable.

NLP can serve as a complementary technology. For example, NLP could be used to analyze the dictated consultation note and pre-populate elements in the EDC, or otherwise provide structure to inevitably unstructured elements in the EHR, to supplement prospectively collected structured data from the EDC.

The implemented EDC addresses a unique challenge in the field of radiation oncology, in which clinical data are often separated into two components: a comprehensive EHR, and a radiation-specific record-and-verify system. Clinical documentation often requires accessing several systems to retrieve the needed information, all of which can be combined into one interface using the EDC. As a bridge between the EHR and the radiation therapy record-and-verify system, the EDC may satisfy the national objective of having interoperable EHR technology, as set forth in the passage of the Medicare Access and CHIP [Children's Health Insurance Program] Reauthorization Act of 2015, which repealed Medicare's sustainable growth rate formula [12]. This interoperability may explain the observed time-savings in this study, whereas general studies of EHRs may demonstrate higher levels of user dissatisfaction, along with a negative impact on clinical operations and/or documentation time [13,14]. To our knowledge, the most similarly described system was an EHR implemented approximately 20 years ago at the University of North Carolina, which was a joint effort among transcriptionists and physicians to code patient charts at the time of dictation, to capture structured data [15,16]. In contrast, the described EDC leverages a web application, to allow direct provider data entry from the increasing number of web-enabled devices.

As this EDC implementation was specific to the breast radiation oncology service, a pertinent question is its generalizability to other disease sites and practices. Our current plans are to use this initial experience and adopt similar customized templates for other disease sites within the radiation oncology department, and for integration with our new hospital electronic medical record, EpicCare (Epic Systems Corporation, Verona, Wisconsin). This approach requires that the following be defined: data elements to collect for the consult form; toxicities to evaluate during weekly OTVs; and templates for note generation. In its current implementation, the EDC extracts data directly from the MOSAIQ database and integrates them with our in-house institutional EHR. We hope to adapt this system to other practice environments, a process that requires a formal application programming interface provided by the radiation record-and-verify system.

This study has several limitations. One is the relatively short follow-up time since implementation of the system; longer-term maintenance tasks, such as updating data-entry screens and note templates, are only starting to emerge. In addition, we did not capture provider time spent editing notes after transcription or EDC. Qualitatively, our providers reported a decreased burden of reviewing notes generated by the EDC system, and they endorsed this benefit as another advantage of using EDC. Another limitation is that we compared use of EDC to our baseline practice of dictating notes, and the efficiency gains may be lower compared with those of EHRs that include the functionality of using template-based notes with data-driven elements. Finally, as the system matures, we will need to coordinate with medical and surgical oncology colleagues to ensure comprehensive outcomes for data collection.

In summary, we implemented a web-based EDC tool as a means to capture structured data for patients in the breast radiation oncology service. The result was significant time savings for clinical documentation and prospective population of a database for future outcomes research. Additional experience is needed to determine how easily this system can be generalized to other radiation oncology disease sites and practices.

TAKE-HOME POINTS

- We implemented a web-based EDC system that integrated hospital-based EHRs with a radiation-specific record-and-verify system for routine clinical use.
- Overall satisfaction was expressed by 92% of EDC system users.
- An estimated reduction of clinical documentation time from 22 to 7 minutes for a typical course of breast radiotherapy was achieved using EDC, compared with dictation.
- The EDC system provides prospective population of a database for future outcomes research, with acute toxicities reported as a proof-of-concept.

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