Electronic Health Records in Oncology

Creating a Process to Standardize Regimen Order Sets Within an Electronic Health Record

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Abstract

Purpose: US Oncology uses regimen order sets in clinical practice to treat patients. However, the process to assure accuracy and upkeep of these order sets has not been described. The purpose of this project was to evaluate the regimens housed in the electronic health record, iKnowMed, to determine their appropriateness and accuracy.

Materials And Methods: US Oncology conducted an audit of its standardized regimen library. A utilization review compared chemotherapy regimens in the library and consolidated order sets on the basis of past utilization. Next, internal and external clinical pharmacists were contracted to verify the accuracy, dose, duration, and cycle length of regimens. References cited in the regimen library were evaluated. New or updated references or clinical practice standards were added or modified when necessary. US Oncology corporate pharmacists reviewed the recommendations and discussed findings with an oversight committee. Final proposals were voted on before being incorporated into iKnowMed. An internal database tracking system tool for all reviewed recommendations was created to track and communicate needed changes to the electronic health record.

Results: Out of 511 regimen order sets, 51 were recommended for removal or consolidation. Of the remaining 460 regimen order sets, all had some administrative changes. Specifically, 75% had title changes, 14% had cycle-related changes, 31% had reference updates, and 13% had dosing updates.

Conclusion: Electronic health records systems, such as iKnowMed, can provide standardized order sets for a large oncology network. However, the regimens need to be evaluated routinely using standardized procedures to ensure they are accurate and current.

Introduction

The use of electronic health records (EHRs) is increasing in the United States.¹ EHRs have been shown to reduce medical errors, health care costs, and treatment delays, along with improving office workflow efficiency, enhancing communication between doctors and patients, and promoting continuity of care.² The US Department of Health and Human Services has stated that health information for most Americans should be computerized by 2014.² The Office of the National Coordinator for Health Information Technology sought a budget increase for the Centers for Medicare and Medicaid Services to fund financial incentives for physicians to adopt certified EHRs.³

Use of paper-based patient files and manual input of data into computerized systems can lead to medical errors. An example is a case in 2000 at the Dana-Farber Cancer Institute in Boston.⁴ Gandhi et al⁴ conducted a study of a computerized order entry writing system to identify medication errors and potential adverse drug events at three outpatient infusion centers. A total of 10,112 orders were reviewed (8,008 adult and

2,104 pediatric). Medication errors were found in 306 (3%) of the total number of orders, with 101 (3%) of the chemotherapy orders containing errors. The most common errors were ordering errors (which included prescribing the wrong dosage), dispensing errors, missing chemotherapy parameters, and administration errors. Potential adverse drug events (ADEs) were identified in 237 orders (2.3% of total orders; 77% of the medication errors). Of the potential ADEs, 88 (3%) were related to chemotherapy. Fortunately none were fatal, but 64 (27%) were considered serious and 173 (73%) were considered significant. As a result of the study findings, a new enhanced adult chemotherapy order entry system was developed, and the pediatric unit changed from hand-written orders to regimen- or protocol-specific computerized order templates.

Because of the complexity and potential toxicity of oncology regimens, electronic health records in oncology practice must be different from those of other subspecialties. Generic EHRs rarely include functionalities specific to oncology practice.⁵ Oncology EHRs should include elements for tumor staging, multidisciplinary and data-intensive workflow (pathology, laboratory, and imaging), chemotherapy dosing and administra-

tion, toxicity assessment and management, clinical trial and protocol management, drug inventory management, and survivorship care/advanced care planning.⁶

US Oncology has an oncologist-developed EHR system, iKnowMed (iKM), specifically designed for the oncology physician, practice, and patient. iKM is used by 900 community-based oncologists in 39 states across the United States. It is compliant with requirements of the Health Insurance Portability and Accountability Act and Code of Federal Regulations Title 21, Part 11. Its features include the following: detailed cancer diagnosis and staging content, comprehensive patient history, outcomes reporting, dictation and transcription facilitation, US Oncology's evidenced-based Level I Pathways, graphing of laboratory results, personal health records, clinical trial and protocol support, automated charge capture functionality, and a central regimen library order set repository (Regimen Library). iKM automates chemotherapy dosing, ordering, and scheduling in the patient chart and incorporates all of the documentation for admixture and administration of chemotherapy.

The Regimen Library

The Regimen Library is an up-to-date order set repository of more than 500 referenced chemotherapy regimens. A regimen, or order set, includes the following components: start/end dates; patient demographics, height, weight, and body surface area; drug dosing, infusion and sequencing information; diagnosis; extravasation potential; emetic risk; premedications; growth factors when indicated; supportive care agents (eg, intravenous hydration for cisplatin); and instructions on multipart regimens, tumor characteristics, hypersensitivity medications, and references. Specific drug alerts are displayed for drugs with cumulative dosing (doxorubicin) or maximum dose limitations (vincristine). Regimen order set features and functions were initially designed formally and further developed over time. The original design came from observation of workflow and collaboration with health care providers at the oncology clinic where the iKM application was implemented as beta software. Using rapid design and development techniques, iterations of the feature were delivered and tested with on-site analyst support over a period of several months. The goal was to support a means for nontechnical users to create treatment orders specific to a diagnosis that a physician user could retrieve, modify if needed, and order for a patient with a minimum of interactions. Over time, the software and order sets have evolved on the basis of input from health care provider users. Each set of saved changes to an order set results in a new version that can be tracked over time. The versions are stored and catalogued within iKM for reference.

Within US Oncology, approximately 11,000 new regimens are initiated each month. A multidisciplinary committee, comprising oncologists, pharmacists, and nurses, regularly updates the Regimen Library through an analysis of peer-reviewed literature and FDA-approved indications. All regimens are evaluated for their emetogenic and neutropenic fever potential, and appropriate supportive-care medications are included. The

Regimen Library allows for standardizing patient care, reducing the potential for medication errors and improving the management of adverse effects. As a result, physicians and practices are able to provide personalized care to each cancer patient, while ensuring safety standards of the available chemotherapy regimens.

Collaborative Care Committee

A network of oncology practices must have a formal governance committee to provide oversight and make decisions about the EHR system and workflow.⁷ This multidisciplinary committee should work to standardize order sets and ensure that credible literature is available to support physicians' orders. It should also review medical errors and make changes to the system or workflow to prevent errors from recurring.

At US Oncology, a clinical committee, the Collaborative Care Committee (CCC), was established by the Pharmacy and Therapeutics Committee to evaluate the order sets available within the Regimen Library and govern clinically necessary changes and updates. The mission of this committee is to ensure that the regimens within the Library are accurate, appropriate, and based on the highest level of evidence to deliver quality cancer care. The committee has developed standards to address determining the clinical relevance of existing regimens, adding novel regimens, and other regimen-related issues arising from practices within US Oncology. Recommendations are accepted from the network practices for a regimen to be included in the library. These regimens must be either previously approved by the US Food and Drug Administration or supported by published data.

The group comprises eight physicians, seven clinical pharmacists, two nurses, iKM representatives, and US Oncology corporate clinical pharmacy representatives. The iKM committee members facilitate incorporating clinical concepts into the available EHR platform. The group is organized into the following eight disease groups: (1) hematology and hematologic malignancies; (2) breast cancer; (3) gastrointestinal cancers; (4) genitourinary cancers; (5) lung cancers; (6) gynecologic cancers, melanoma, sarcomas; (7) head and neck cancers and any other cancers; and (8) supportive care agents. Members of these subgroups make recommendations to the full CCC regarding regimens pertaining to their specific disease of interest. The committee meets formally on a quarterly basis; however, monthly communication includes voting on regimen updates or addressing other needed regimen-specific issues. The strength of the CCC lies in the leadership of the multidisciplinary group involved. This is largely a volunteer, practice-based committee dedicated to standardizing the regimen ordering content with the ultimate goal of maximizing patient safety.

Materials and Methods

Purpose of the Audit

The Regimen Library audit was conducted in two phases. Phase I was primarily a utilization review to evaluate the usage of order

sets and determine which regimens could be consolidated or removed; phase II verified the accuracy of the remaining regimens against the documented references.

Utilization Review

To begin the audit process, regimens that could be consolidated on the basis of duplicative regimen components were identified. An initial review was performed to calculate how frequently each regimen was used between January and October 2009. Regimen utilization was reviewed by the disease groups for current clinical relevance for each disease type. Determination by the CCC of what should be kept or removed occurred over a 1-month period (February-March 2010). Fifty-one duplicative or outdated regimens were removed from the Library. For example, before the audit, all published versions of fluorouracil-leucovorin-oxaliplatin (FOLFOX) were available. On the basis of feedback from the CCC, FOLFOX regimens were condensed to one default version. In addition, multiple versions of rituximab-cyclophosphamide-doxorubicin-vincristine-prednisone (*R-CHOP*) and doxorubicin-bleomycin-vinblastine-dacarbazine (*ABVD*) were available as a result of differing numbers of cycles. These regimens were consolidated, and a default cycle number was identified.

Audit

During phase II, the goal was to determine the relevance and appropriateness of all remaining order sets by evaluating the clinical elements in comparison with published references. Network practices are able to modify and customize order sets beyond the basic literature-based regimens in the Library. Unique order sets created by practices are visible only to those practices and were not included in this audit. In addition to updating the Library, other elements such as the Infusion Time Table (ITT) and Supportive Care template were expanded and revised. The ITT is a standardized table based on published literature that offers recommended admixture (eg, compounding, drug-fluid combinations) and administration guidelines (routes of administration). It also includes extravasation potential and specific nursing and pharmacy information. The Supportive Care template provides basic guidance on recommended standards of supportive care agents for certain drugs and drug combinations. This includes antiemetics, prevention of infusion-related reactions, hypersensitivity medications, pre- and posthydration, electrolyte and vitamin supplementation, growth factors, and other regimen-specific supportive care agents. A “regimen” was further refined to represent a specific drug combination intended for a specific disease state. For example, there is one carboplatin/paclitaxel regimen for non-small-cell lung cancer and a separate one for ovarian cancer. Other examples include separate versions of topotecan for small-cell lung cancer versus ovarian cancer or gemcitabine for breast cancer versus pancreatic cancer. The use of brand names and chemotherapy acronyms were eliminated, except where use of the generic could increase confusion with alternative agents. For example, Abraxane was retained instead of the generic nab-paclitaxel to reduce confusion with paclitaxel. Some acronyms were kept in

instances of well-known and multidrug combinations, such as rituximab-CHOP.

Additional standardization was also adopted regarding the wording used for continuous intravenous infusions based on the duration of infusion. For example, a distinction was made between whether patients return to clinic daily for pump refills (eg, a 24-hour continuous infusion daily for 3 days) or whether they are given quantity sufficient for the cycle (eg, a 72-hour continuous infusion).

Audit Process

The audit process comprised three parts: part 1 was the external regimen evaluation; part 2 was the review of auditor recommendations; and part 3 was the incorporation of the changes into iKM.

Part 1, the performance of the audit, was conducted by eight external clinical pharmacists hired on a contract basis from academic medical centers. These pharmacists were involved in just the initial portion of the audit. They reviewed each regimen within a disease state and compared it with the cited reference. The goal was to review each order and verify the drugs, doses, days of administration, cycle length, and number of cycles against the referenced literature. On the basis of that comparison, the auditors submitted proposals for change based on a specific citation or standard clinical practice and also included recommendations to add additional references to the Library (Appendix Table A1).

In part 2, the auditors' proposed changes were reviewed internally by corporate pharmacists and the practice-based CCC disease groups. The corporate pharmacists partnered with data analysts to create a database tool for the purpose of tracking the following changes: the initial changes recommended by the auditors, comments provided by the disease groups, and final approval by the full CCC (Figure 1).

Part 3 involved implementation of the order set changes into iKM. This was accomplished by collating the complete findings from the CCC and communicating those changes to the iKM team via the database. Corporate- and practice-based pharmacists provided a final review for accuracy during the iKM testing phase before release into the active Regimen Library repository. The final step in implementation included sending a communication document to the practices regarding the anticipated updates.

Results

As a result of this audit, more than three quarters of regimens required title changes, which, if not effectively communicated, could result in practitioner frustration and workflow delays. Other findings of the remaining 460 regimens include 14% requiring cycle-related changes, 31% requiring reference updates, and 13% requiring dosing updates.

A multipronged approach was undertaken as a recommendation from the CCC. A document was prepared and sent out to all network healthcare providers detailing the changes to the regimen titles for ease of searching (Appendix Table A2). In

Disease	Regimen Title (iKM Regimen Name)	Audit: New Regimen Title	Current Information	Changes Recommended
Breast	TC (Taxotere-Cyclophosphamide) D1 Q21	Docetaxel + Cyclophosphamide (TC)	1. Title: TC (Taxotere-Cyclophosphamide) D1 Q21 2. Reference	1. Title: Docetaxel-Cyclophosphamide (TC) 2. Reference update: Jones SE, et al. JCO;24: 5381-5387, 2006
Breast	TCH (Taxol (D1)-Carboplatin (D1) - Herceptin (Wkly)) Q21 (Herceptin only)	Paclitaxel (D1) + Carboplatin (D1) + Trastuzumab (Weekly) (TCH) Q21 days (Trastuzumab only)	1. Title: TCH (Taxol (D1)-Carboplatin (D1) -Herceptin (Wkly) Q21 (Herceptin only) 2. Drug: Herceptin 3. Regimen instructions: Remove current	1. Title: TCH: Paclitaxel (D1)-Carboplatin (D1)-Trastuzumab (QWk) Q21 days (Trastuzumab only) 2. Drug: List as 'trastuzumab' not 'herceptin' 3. Regimen instructions: To be given with TCH: Paclitaxel (D1)-Carboplatin (D1)-Trastuzumab (QWk) Q21 days (Paclitaxel + Carboplatin only)
Breast	TCH (Taxol (D1)-Carboplatin (D1) - Herceptin (Wkly)) Q21 (TC only)	Paclitaxel (D1) + Carboplatin (D1) + Trastuzumab (Weekly) (TCH) Q21 days (Paclitaxel + Carboplatin only)	1. Title: TCH (Taxol (D1)-Carboplatin (D1) -Herceptin (Wkly) Q21 (TC only) 2. Admin days: 1,1 3. Regimen instructions: Remove current	1. Title: TCH: Paclitaxel (D1)-Carboplatin (D1)-Trastuzumab (QWk) Q21 days (Paclitaxel + Carboplatin only) 2. Regimen instructions: To be given with TCH: Paclitaxel (D1)-Carboplatin (D1)-Trastuzumab (QWk) Q21 (Trastuzumab only)
Breast	Vinorelbine (30 mg/m ²) QW	Vinorelbine	1. Title: Vinorelbine (30 mg/m ²) QW 2. Dose: 30 mg/m ²	1. Title: Vinorelbine (25 mg/m ²) QWk 2. Dose: Decrease to 25 mg/m ² (dose not tolerated in study)
Breast	Vinorelbine-Herceptin (Herceptin only)	Vinorelbine + Trastuzumab (Trastuzumab only)	1. Title: Vinorelbine-Herceptin (Herceptin only) 2. Drug: Herceptin 3. Regimen instructions: Remove current	1. Title: Vinorelbine-Trastuzumab (Trastuzumab only) 2. Drug: List as 'trastuzumab' not 'herceptin' 3. Regimen instructions: To be given with: Vinorelbine-Trastuzumab (Vinorelbine only)
Breast	Vinorelbine-Herceptin (Vinorelbine only)	Vinorelbine + Trastuzumab (Vinorelbine only)	1. Title: Vinorelbine-Herceptin (Vinorelbine only) 2. Dose: 30 mg/m ² 3. Cycles: 16 4. Regimen instructions: Remove current	1. Title: Vinorelbine-Trastuzumab (Vinorelbine only) 2. Dose: 25 mg/m ² (per reference) 3. Cycles: 6 (references doesn't specify) 4. Regimen instructions: To be given with Vinorelbine-Trastuzumab (Trastuzumab only)

Figure 1. Example of the database created to track audit changes. D, day; Q21, every 21 days; QWk, weekly.

addition, links were posted on multiple intranet sites and within the iKM EHR application.

Discussion

The objective of this initiative was to conduct an audit of the Regimen Library contained within US Oncology's EHR iKM, with the following goals: evaluate the usage of order sets; remove duplicative or unused regimens; address the relevance and appropriateness of regimens by evaluating the clinical elements versus the published literature; and finally, review and communicate changes to US Oncology network practices.

Chemotherapy ordering, preparation, and administration are high-risk procedures¹ and should be based on established guidelines and best practices. However, many oncologists create order sets customized according to their own or their patient's needs, as no source has been identified as the definitive reference guide for chemotherapy regimens.

By using the iKM EHR system, which contains both patient records and the Regimen Library, the CCC, comprising physicians, pharmacists, nurses, and iKM representatives, was able to better regulate available order sets. As a result, clinicians now

have access to more accurate and up-to-date regimens supported by evidence-based medicine, with the goal of improving patient safety and patient care. In the absence of a single reference source for chemotherapy regimens, the iKM Regimen Library can be used by oncologists as a reference guide for chemotherapy regimens.

EHRs such as iKM can also be used to address drug safety issues, such as carboplatin area-under-the-curve recommendations from the FDA and international organizations such as ASCO and the American Society of Hematology. An established clinical regimen committee can address such safety concerns and order set "standards" when the literature is inconsistent or an approach is outdated. Examples include carboplatin dosing based on area-under-the-curve versus milligrams per square meter, paclitaxel infused over 24 hours versus 3 hours, and how and when bleomycin test dosing is performed.

The optimal frequency for a formal review of regimens is not established; however, continued review and refinement of regimens is necessary to ensure that the most accurate and up-to-date cancer treatment is provided to patients.

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Appendix

Table A1. Sample Audit Check List

List Item
Tumor Type
Regimen title
Drug
Dose
Days of administration
Cycle length (days)
Cycle number
Correct cited reference for tumor type
Premedications required
Additional supportive care medications
Hypersensitivity medications required
Infusion times
Order of administration
Continuous IV wording
Duplicate regimen in need of removal

Abbreviation: IV, intravenous.

Table A2. Sample of Regimen Name Changes Resulting From the Audit

Old Regimen Name	New Regimen Name
Colon cancer	
5FU (300 mg/m ² /d CIV)	Fluorouracil (CIV)
5FU-Leuc (Weekly-Low)	Fluorouracil (Bolus) + Leucovorin (Weekly-Low)
5FU-LV (De Gramont)	Fluorouracil (Bolus + CIV) + Leucovorin (De Gramont)
5FU-LV (De Gramont)-Bevacizumab	Fluorouracil (Bolus + CIV) + Leucovorin (De Gramont) + Bevacizumab
5FU-LV (Mayo)	Fluorouracil (Bolus) + Leucovorin (Mayo)
5FU-LV (Mayo)-Bevacizumab	Fluorouracil (Bolus) + Leucovorin (Mayo) + Bevacizumab
5FU-LV (Roswell Park)	Fluorouracil (Bolus) + Leucovorin (Roswell Park)
5FU-LV (Roswell Park)-Bevacizumab	Fluorouracil (Bolus) + Leucovorin (Roswell Park) + Bevacizumab
Cetuximab (D1, 8, 15, 22, 29, 36)-Irinotecan (D1, 8, 15, 22) Q42D	Cetuximab (D1, 8, 15, 22, 29, 36) + Irinotecan (D1, 8, 15, 22) Q42D
Cetuximab QW	Cetuximab QW
Cetuximab-Irinotecan	Cetuximab + Irinotecan Q21D
FLOX	Fluorouracil (Weekly Bolus) + Oxaliplatin (FLOX)
FOLFIRI (5FU CIV over 46 h)	Fluorouracil (CIV) + Irinotecan (FOLFIRI)
FOLFIRI-Bevacizumab	Fluorouracil (CIV) + Irinotecan (FOLFIRI) + Bevacizumab
FOLFOX 4	Regimen removed
FOLFOX 4-Bevacizumab	Fluorouracil (Bolus + CIV) + Oxaliplatin (FOLFOX 4) + Bevacizumab
FOLFOX 6	Regimen removed
FOLFOX 6, Modified	Fluorouracil (Bolus + CIV) + Oxaliplatin (FOLFOX 6, Modified)
FOLFOX 6-Bevacizumab	Fluorouracil (Bolus + CIV) + Oxaliplatin (FOLFOX 6) + Bevacizumab
FOLFOX 6-Bevacizumab, Modified	Fluorouracil (Bolus + CIV) + Oxaliplatin (FOLFOX 6, Modified) + Bevacizumab
FOLFOX 7	Regimen removed
Irinot 125/m ² D1, 8, 15, 22	Irinotecan (D1, 8, 15, 22) Q42D
Irinotecan (350 mg/m ²) Q21	Irinotecan Q21D
Vectibix 6 mg/kg Q14D	Panitumumab
XELIRI (CAPIRI) 200 mg/m ² Q21	Capecitabine + Irinotecan (XELIRI/CAPIRI)
XELOX/CAPOX	Capecitabine + Oxaliplatin (XELOX/CAPOX)
XELOX/CAPOX-Bevacizumab	Capecitabine + Oxaliplatin (XELOX/CAPOX) + Bevacizumab
Head and neck cancer	
New regimen	Cetuximab
New regimen	Cisplatin (D1) + Docetaxel (D1) + Fluorouracil (D1-4) Q21D

Abbreviations: d, D, day; CIV, continuous intravenous infusion; Q42D, every 42 days; QW, weekly; Q21, Q21D, every 21 days.