Principles of Safe Practice Using an Oncology EHR System for Chemotherapy Ordering, Preparation, and Administration, Part 2 of 2

Lawrence N. Shulman, MD, Robert S. Miller, MD, Edward P. Ambinder, MD, Peter Paul Yu, MD, and John Cox, DO, MBA

Dana-Farber Cancer Institute, Boston, MA; Sacramento Center for Hematology and Medical Oncology, Sacramento CA; Mount Sinai School of Medicine, New York, NY; Palo Alto Medical Foundation, Mountain View, CA; Texas Oncology Methodist Dallas Cancer Center, Dallas, TX

This is the second of a two-part review, concentrating on the ability of oncology electronic health records (EHRs) to enhance patient safety through the chemotherapy ordering and administration process and the standardization of workflow processes in the practice. In part one we outlined broad principles that should be considered when integrating an EHR, and in particular, a chemotherapy ordering module, into practice.[1] We strongly advocate attention to the principles listed in the sidebar, as any fundamental change in a drug ordering process may compromise safeguards that are present in the practice. In this article we endeavor to highlight concrete operational issues that are informed by the use of these principles.

Intersection of Computerized Order Entry and Workflow Policy

Two key concepts raised in part one need to be re-emphasized. The first concept introduced in part one is the importance of workflow. A practice must recognize that chemotherapy ordering safety with EHRs can be impacted not only by the EHR product (the software) but to an even greater extent by the workflow in the clinic.[3] When an existing clinic workflow does not work well with the EHR to be implemented, both should be carefully evaluated. It should not be assumed that the existing workflow is ideal, and changes should be considered that improve safety, efficiency, and compatibility with the EHR.

The second concept is that in order to institute these principles, the practice must have a formal governance structure in place to address the many decisions demanded by the system and the changes in workflow. In large institutions, existing committees such as a pharmacy and therapeutics committee may take on this responsibility. Smaller practices will need to create this process. The committee can be small but should be multidisciplinary, including oncologists, nurses, nurse practitioners, pharmacists, and administrators who are completely engaged in the process. The committee serves to standardize regimens for antineoplastic agents including ancillary medications and to ensure that all orders are supported by credible literature. In addition, the committee analyzes errors and near misses that occur in the practice to alter systems or work flow to reduce the likelihood of subsequent errors. We cannot overemphasize the need to

General Principles for Integrating an EHR Into Practice

Accuracy: Orders should reflect the intent of the ordering clinician and the independent understanding, confirmation and approval of the nurse and pharmacist.

Standardization: All aspects of the ordering process should be standardized.

Automation: Whenever possible, calculations should be performed automatically by the computer system to reduce clinician workload and avoid errors.[2]

Decision Support: The system should contain embedded tools that allow for computerized clinical decision support, including dose ranges, maximum dose thresholds that cannot be exceeded, dose reductions, drug interactions, and allergy alerts.

Flexibility: The system should be able to be modified as current treatments change and new treatments are developed.

Workflow Integration: The system should be designed to be an integrated element of the interdisciplinary process of ordering, preparing and administering chemotherapy.

Safety Over Convenience: When decisions are made concerning the design and functionality of the system, safety concerns should always take precedence over convenience.

Efficiency, Reliability, and Usability: Orders should be able to be entered and communicated to pharmacy and support staff in the same or less time than if done on paper.

optimize clinic workflow and implement a formal system of accountability before the implementation of an EHR.

Standardization of Chemotherapy Regimens and Associated Treatment

Standardization of regimens provides predictability for the entire patient and staff experience in the chemotherapy suite. It supports accuracy, reduces errors, and enhances workflow by decreasing ambiguity. Standardization has been shown to improve safety in the airline industry as well as in medical specialties such as anesthesia.[4] The following practical considerations are best practices that should be considered when creating standard chemotherapy order sets:

1. Chemotherapy orders are to be entered by regimen rather than by individual drug. Regimens are linked to patient diagnosis (eg, the adriamycin, bleomycin, velban, and dacarbazine regimen available only for patients with Hodgkin's Lymphoma). By creating regimen-based orders, the clinic will avoid individual physician variations that do not add value to the process. All regimens are to be evidence based and supported by the primary references for the regimen.

2. Chemotherapy agents are to have dose ceilings above which doses cannot be ordered. This should be an automatic feature of the EHR product, and the ordering physician and pharmacist should be prevented from entering errors.

3. Standard dose modification recommendations are to be embedded in the system as clinical decision support. Referencing the supporting literature for a regimen allows dose modification rules drawn from the experience that validated the regimen's effectiveness to be incorporated into the order set.

4. Regimens will include default antiemetic choices tailored to the specific chemotherapy medications, as determined by standard practice guidelines.[5] These may be modified locally by the practice's governance committee. Standardization of antiemetics can be a strong lever to enhance workflow in the chemotherapy suite, allowing patients to get started on their therapy as the pharmacy is mixing the primary chemotherapy. Standard antiemetic protocols can be created to anticipate second and third drug choices in the event of failure of first-line therapy. Alternative antiemetic agents are available as needed for individual patients.

5. Chemotherapy regimens that require hydration will include standard hydration orders as determined by the practice's committee guidelines. If no hydration is ordered, an order stating "no hydration necessary" must be selected to remove ambiguity about intent, particularly for inpatients or in a teaching clinic where hydration may be ordered by any number of providers including attending physicians, fellows, nurse practitioners, physician assistants, or house staff.

6. When a provider reorders a chemotherapy regimen for a subsequent cycle of therapy, there should be the option of reusing the previous order set (including any dose modifications that were made to that order), or using the original, standard template for that regimen. This means a provider does not need to make the same modifications to a regimen each time the order is written. The EHR will indicate any modifications to the standard order set, identifying the provider who initiated the changes and the reason(s) for the modification.

7. Investigational protocols are ordered using the EHR system. Protocol-mandated dose modifications are to be included as decision support tools in the templates for these regimens. Orders for a specific investigational protocol should only be available to those patients who are registered on that protocol.[6] The EHR will identify drugs that are provided by the study. This allows study medications to be tracked in the clinic, providing appropriate information for pharmacy inventory and accounting purposes.

8. Drugs to treat hypersensitivity reactions to chemotherapy agents will be automatically selected when as-needed medications and built into the order set. This enhances the ability of the staff to respond predictably to rare but anticipated problems in the infusion suite.

9. The EHR should provide a documentation trail that codifies all orders entered and all changes made. The audit trail identifies the time, date, and author of each change made to the original order. In addition, the system will collect data on the reasons for changes of schedule, dose, or drug modification. Many systems do this by providing a series of drop-down menus that prompt the provider for this data. Once entered, this information can be mined to help clinicians monitor clinical practice. Periodic review of this type of information is a critical function of the governance committee.

10. The presentation and categorization of key pieces of clinical information can be standardized to enhance workflow and improve safety. These data elements include pathology, diagnostic imaging, and laboratory reports, as well as surgical and procedure notes. Ideally, outside laboratory reports should be interfaced with the office EHR to allow autopopulation of these results to flow sheets, which will minimize the errors and inefficiencies associated with manual entry.

11. An electronic version of the flow sheet with multiple views, which can be sorted by different fields, printed, and exported, should be at the heart of the oncology EHR. The flow sheet should be autopopulated with key data such as vital signs, including height and weight, and laboratory results. The flow sheet can serve as the place where nursing personnel document not what was ordered, but what was actually

administered. Blood transfusions and other supportive medication administration should be documented here as well so that there is a complete record of patient therapies in one location in the EHR. Nursing staff also document other specifics of therapy administration such as reactions and other clinical events.

12. Other standard elements of the oncologic record that will support an evidence-based chemotherapy ordering process are accurate cancer type and stage, codification of the patient's performance status, and consistent scoring of toxicities associated with therapy. Tumor staging using standardized criteria, such as the American Joint Committee on Cancer TNM Staging System, can be embedded into the system. Drop-down menus that provide staging definitions from the American Joint Committee on Cancer enhance the accuracy of the staging process.[7] Ideally, staging documentation is linked to surgical pathology reports. Patient performance status measurements, using recognized metrics such as the Karnofsky performance score or Eastern Cooperative Oncology Group scale, can also be included. Lastly, toxicities that patients experience as a result of treatment can be codified using standardized nomenclature such as the National Cancer Institute Common Terminology Criteria for Adverse Events grading criteria.[8] The EHR can enhance the documentation of toxicity by the use of drop-down menus with the grading criteria at the point of care, something that is often performed poorly, if at all, using a paper-based chart.

Chemotherapy Ordering and Work Flow Rules

EHR systems bring incredible tools to the clinic, but adopting such systems requires attention to the way the providers interact with it. EHRs must be integrated into an interdisciplinary process of ordering, preparing, and administering chemotherapy. As such, the system facilitates the principle of shared responsibility (where ordering clinicians, infusion room nurses, and pharmacists share the responsibility that orders are correct), redundancy (where the system decreases the likelihood that errors will reach the patient), and minimization of ambiguity (where the system helps ensure that orders reflect the intention of the ordering provider).

When decisions are made concerning the integration of the EHR into the clinic, safety concerns take precedence over convenience. In this process, workflow is always taken into consideration. The governance committee and the personnel of the clinic must develop and adhere to rules of workflow. Of note is that all workflow rules exist with or without the presence of the EHR; however, the EHR can force these rules to be hard wired into the clinic. Examples of best practice workflow rules and the intersection with the EHR are as follows:

1. A certification process is developed to ensure that only qualified and approved clinicians can order chemotherapy. These privileges are reinforced by the EHR system, which will allow access to the order entry components of the system only to clinicians with those rights. In institutional settings, this is a privilege that should be applied for and approved during the credentialing process in the same way clinicians apply for medical staff privileges to perform specific procedures. In smaller practice settings, granting such access rights is in the purview of the governing committee. Similar decisions and monitoring about who can order chemotherapy must be made for trainees (fellows) and physician extenders—nurse practitioners and physician assistants.

2. The EHR system will not allow infusion room nurses or pharmacists to initiate orders or dose modifications. If infusion room nurses determine that dose modifications are needed, they must reject the existing order and request that the ordering clinician re-evaluate them. An agreement must then be reached. The collaborative spirit in the clinic is to resolve all doubt to support a safe environment.

3. The EHR will require the ordering clinician to enter and/or confirm all pertinent data for an order, including the diagnosis, regimen, goal of care (curative or palliative), and patient height and weight.

4. The ordering clinician must enter or confirm criteria needed for treatment (eg, absolute neutrophil count, platelet count, bilirubin), even if those values are available in the practice's computerized laboratory results system. The EHR will make it clear to nursing and pharmacy staff whether or not the current values had been viewed by the ordering physician and were acceptable. Nursing and pharmacy will confirm these values before preparation and administration of chemotherapy.

5. Once orders are entered and the final doses are calculated, the ordering clinician must review and confirm all ancillary medications, hydration, and chemotherapy orders/doses.

6. When infusion room nurses activate chemotherapy orders, they will confirm the height and weight previously determined (remeasuring whenever there is any doubt) and confirm the creatinine (for area-under-the-curve orders). If a height, weight, or creatinine is different from what the ordering provider entered and this results in a 5% or greater change to the chemotherapy dose, then the orders will be rereviewed and reapproved by the ordering clinician before they can be used.

7. Both the infusion room nurse and the pharmacist must confirm and agree with:
- Antiemetic drugs
- Hydration orders
- Chemotherapy agents
- Doses and any modifications

- Treatment criteria (parameters such as absolute neutrophil count, platelet count, and so on)

8. The patient and ordering provider will sign informed consent for all chemotherapy.[9] The nurse who will administer the therapy will confirm that both the patient and the ordering provider have signed the consent form, and that it lists all the chemotherapy medications to be administered.

9. To avoid infusion errors, patients will be positively identified with at least two identifiers. Drugs to be infused will be labeled with those same identifiers. Many EHRs provide tools to support this process (eg, digital pictures of the patient, bar code technology, and so on).

Conclusion

EHRs have the ability to automate many routine processes in clinics. Compared with a paper chart, they allow the categorization of clinical information into formats that permit easier access to multiple users simultaneously. EHRs hold the promise of enhancing our ability to deliver safe and quality oncology care. However, as with any technology, integration into the clinic must be accompanied by a careful assessment of workflow and with great forethought. EHRs are not an out-of-the-box solution that will solve all problems within a clinic. EHR integration into an oncology clinic is a disruptive process. If practices adopt the principles and workflow considerations outlined in these two articles, we believe that a safer environment for our patients will result. These principles and workflow rules may vary with certain systems or in individual practices, but as a whole they form a solid framework for the creation and implementation of computerized systems for chemotherapy ordering, preparation, and administration and the workflow that surrounds these activities.

Commercial vendors who market computerized chemotherapy order entry systems should take these principles into account in the creation and modification of their systems. Institutions and practices should use these principles as criteria for evaluating systems they are considering for purchase.

ASCO is committed to providing oncologists with tools to enhance the safety of patients and assist the oncologist in providing quality cancer care. EHRs have the promise of transforming our practice. ASCO offers an extensive review of the steps and pitfalls of choosing and implementing an EHR in a recently published field guide. *The Oncology Electronic Health Record Field Guide: Selecting and Implementing an EHR* is available through ASCO (www.asco.org/ehrfieldguide).

ASCO members will also find additional resources, including links to online virtual meeting presentations from the ASCO EHR Symposium in September 2007 and to selected articles published in *Journal of Oncology Practice* (www.asco.org/ehr).

Acknowledgment

All authors are members of the Electronic Health Records Workgroup of ASCO.

DOI: 10.1200/JOP.0857501

References

1. Shulman LN, Miller RS, Ambinder EP, et al: Principles of safe practice using an oncology electronic health record system for chemotherapy ordering, preparation and administration (Part 1). J Oncol Pract 4:203-206, 2008

2. DuBeshter B, Walsh CJ, Altobelli K, et al: Experience with computerized chemotherapy order entry. J Oncol Pract 2:49-52, 2006

3. American Society of Clinical Oncology: The oncologist's field guide to selecting and implementing an electronic health record. ASCO 2008. http://www.asco.org/ehrfieldguide

4. Auerbach AD, Murff HJ, Islam SD: Pre-anesthesia checklists to improve patient safety: Making health care safer—A critical analysis of patient safety practices. http://www.ahrq.gov/clinic/ptsafety/chap23.htm

5. Kris MG, Hesketh PJ, Somerfield MR, et al: American Society of Clinical Oncology guideline for antiemetics in oncology: Update 2006. J Clin Oncol 24:2932-47, 2006

6. Goldwein J: Using an electronic health record for research. J Oncol Pract 3:278-279, 2007

7. American Joint Committee on Cancer: TNM staging: The common language for cancer care. http://www.cancerstaging.org

8. National Institutes of Health: Common Terminology Criteria for Adverse Events v3.0. http://safetyprofiler-ctep.nci.nih.gov/CTC/CTC.aspx

9. Michaels D, Cahill M: Informed consent and chemotherapy. J Oncol Pract 1:99, 2005

10. DuBeshter B, Griggs J, Angel C, et al: Chemotherapy dose limits set by users of a computer order entry system. Hosp Pharm 41:136-142, 2006