Original Article

Evaluating Incorporation of Drug Restrictions into Computerized Drug Order Entries after Transition to an Electronic Health Record

Ryan Rodriguez, PharmD, BCPS^{*}; Benjamin Staley, PharmD, BCPS[†];
and Randy C. Hatton, PharmD, FCCP, BCPS[‡]

Abstract

Background: Incorporation of drug restriction policy into electronic drug order entries (DOEs) can promote responsible medication use and resource utilization when implemented systematically.

Objective: To identify drugs that require further incorporation of formulary restriction policy into their DOEs after migration to an electronic health record with computerized prescriber order entry (CPOE).

Methods: After transition to CPOE, test orders for formulary restricted drugs were entered in the CPOE environment. Data were collected about rationale for drug restriction, type of formulary restriction, presence of incorporation of restriction policy into the DOE, and whether incorporation was consistent with a recommended method. Restricted drugs requiring revision of policy incorporation into their DOEs were analyzed to create a prioritized task list based on rationale for the restriction.

Results: Of all restricted drugs, 63.6% (287/451) did not have restriction policy incorporated into their DOEs consistent with the recommended method and therefore required revision. Eighteen percent (81/451) of restricted drugs had no incorporation of restriction policy in their DOEs. Safety was the rationale for restriction in 21% (17/81) of these, which received highest priority for revision. When drugs were orderable but restricted, 61.9% (78/126) lacked optimal incorporation of policy in DOEs to promote adherence. When drugs were not orderable, 64% (206/322) did not provide guidance to formulary alternatives in DOEs when they should have.

Conclusion: After transition to CPOE, almost two-thirds of all analyzed restricted drugs lacked optimal incorporation of formulary restriction policies in their DOEs. DOEs with restrictions related to safety reasons were among those most frequently requiring revision. Some DOEs can better promote adherence and provide guidance to prescribers through revision. Predefined, systematic implementation strategies should be used during changes in computerized drug use processes.

Key Words—American Recovery and Reinvestment Act, computerized physician order entry, electronic medication alerts, hospital formularies, informatics, medical order, policy

Hosp Pharm—2013;48(7):568–573

In 2009, the United States government provided incentive to implement electronic health records (EHR) via the Health Information Technology for Economic and Clinical Health (HITECH) Act. The

HITECH Act aimed to reduce health care costs and increase patient safety by decreasing redundant and unnecessary tests and procedures, paperwork, and administrative costs.¹ Under this act, hospitals receive

^{*}Clinical Assistant Professor, Drug Information, University of Illinois at Chicago; [†]Clinical Specialist, Quality Improvement & Accreditation, Shands Hospital at the University of Florida, Gainesville; [‡]Director, Drug Information and Pharmacy Resource Center, Clinical Professor, University of Florida College of Pharmacy, Shands Hospital at the University of Florida, Gainesville. At the time of writing, Dr. Rodriguez was PGY-2 Resident, Drug Information at Shands Hospital. Corresponding author: Ryan Rodriguez, Drug Information Group, University of Illinois at Chicago, 833 S. Wood Street, Suite 164, Chicago, IL 60612; phone: 312-413-8363; e-mail: rwrodrig@uic.edu

financial incentives for adoption of an EHR system that is used in a meaningful manner to improve health care quality. Institutions and practitioners were faced with short timelines to implement EHR and meet criteria and deadlines to benefit from HITECH incentives.^{1,2} The abbreviated timeline may have resulted in insufficient planning for some institutions to ensure safe and effective adoption of EHR.

In May 2011, Shands Hospital at the University of Florida transitioned from a pharmacy-based medication order entry system (Horizons Med Manager [HMM; McKesson, Alpharetta, GA]) to a hospitalwide EHR with computerized prescriber order entry (CPOE) (Epic Systems, Verona, WI). Upon order entry in HMM, pharmacists were provided pop-up text notifications describing formulary restriction policies and actions required to enter an electronic order from the written medical record. This provided guidance for appropriately entering data in order entry fields and for communicating with prescribers. With Epic, prescribers would enter an electronic drug order to be verified by pharmacists, who would modify data entry and communicate with prescribers as appropriate. New methods to incorporate formulary restriction policies into computerized drug order entries (DOEs), thereby promoting safe medication use, were available with Epic.

COMPUTER-BASED GUIDANCE

Epic functionality provided guidance to prescribers at the time of order entry, promoting adherence to drug-specific formulary restrictions. An alternative medication alert (AMA) can be part of the DOE; it provides information in a pop-up window when a drug is ordered. AMAs can also include hyperlinks to the DOE of other drugs; most often this is a preferred formulary alternative (termed *AMA with link* and *AMA without link*). Required questions or optional questions that require user input (free-text or radio buttons) can be included in the DOE to document that specific criteria for restricted drug use have been met. Dose limits can restrict prescribers from exceeding a maximum ordered dose, number of administrations, or maximum concentration in the DOE. Text notifications within the DOE can provide detailed information explaining drug restrictions and criteria for use that are not able to be incorporated in an interactive computerized format requiring user input.

Previous work has documented the value of CPOE decision support in driving institutional medication use policy. Westphal and colleagues showed that the rate of physician noncompliance with institutional guidelines for pneumonia antibiotic therapy decreased from 18.3% to 7.3% ($P < .001$) after implementation of a computerized

display of treatment guidelines upon physician order entry.³ Additionally, Traugott and colleagues showed that CPOE guidance, when effectively offered to prescribers, improved therapeutic drug monitoring.⁴ Inclusion of vancomycin therapeutic drug monitoring criteria in a CPOE environment increased the percentage of appropriate vancomycin level orders from 58% to 68% ($P = .02$). These findings support provision of electronic guidance to prescribers as a useful method to promote adherence to policy and appropriate resource utilization.

EPIC FUNCTIONALITY AND SHANDS FORMULARY

The new EHR system with CPOE was felt to offer greater functionality to incorporate formulary policy into DOEs than the previous system at Shands Hospital at the University of Florida. The formulary at Shands incorporates detailed drug use policy and formulary restrictions and utilizes various types of formulary restrictions to streamline safe medication use processes (Table 1).

Drugs may be nonformulary (NF), meaning they are not readily available for use, but may be purchased. NF drugs may additionally be not available (NFNA), meaning they will not be purchased. Patients may or may not be permitted to take their own NF medications (NFNA CAN use own or NFNA can NOT use own, respectively), as determined by drug-specific factors (eg, injectable drugs and controlled substances are generally not permitted). High-priority nonformulary (HPNF) drugs are not readily available for use due to distribution system or cost restrictions, but have processes in place for rapid acquisition when needed. Therapeutic interchange designations exist for many NF drugs, allowing automatic substitution with a product deemed therapeutically equivalent by the Pharmacy and Therapeutics (P&T) Committee. Drugs may be added to the formulary with restrictions, including designations of criteria for use (CFU), requiring that certain situations be fulfilled to permit use. This includes the subdesignation *dose restriction*, which limits the number, strength, or duration of doses. All of these designations promote specific use within Shands' medication use system and are referred to collectively as *drug restrictions*.

Each type of formulary restriction requires 1 of 2 general courses of pharmacist action. Adherence to specific policy should be ensured when restricted formulary drugs are ordered, whereas guidance to available alternatives should be offered to prescribers when NF drugs are ordered. Each designation status could be incorporated into DOEs and its resultant action streamlined by using a standardized, most appropriate Epic

Table 1. Recommended method for incorporating different formulary restriction policies into drug order entries

Drug restriction type	Description of drug restriction	Availability of formulary alternative	Drug use process requirement	Recommended method to incorporate restriction
Interchange	Ordered medication is substituted with preferred formulary alternative	Yes	Provide guidance to prescriber	AMA with link to order formulary alternative
NFNA, CAN use own	Ordered medication not readily available, will not be purchased, patients CAN use own supply	Yes	Ensure adherence to specific policy	Required reason documenting the necessity of continuing therapy
		No	Provide guidance to prescriber	AMA with link to order formulary alternative
NFNA, can NOT use own	Ordered medication not readily available, will not be purchased, patients may NOT use own supply	Yes	Provide guidance to prescriber	AMA with link to order formulary alternative
		No	Provide guidance to prescriber	AMA without link
Criteria for use	Specific criteria required for use	Yes	Ensure adherence to specific policy	Required questions documenting fulfillment of criteria
Dose limit	Maximum dose may not be exceeded	Yes	Ensure adherence to specific policy	Dose restriction defaulting to standardized amount
High priority nonformulary	Ordered drug not readily available due to restricted distribution or cost, but may be purchased	Yes	Provide guidance to prescriber	AMA with link to order formulary alternative
		No	Ensure adherence to specific policy	Required reason documenting the necessity of therapy

Note: AMA = alternative medication alert; NFNA = nonformulary and not available.

functionality. Therefore, we created a predefined consensus guide recommending the most appropriate method for incorporating each type of formulary restriction into a drug's respective DOE (Table 1).

Even though Epic offered a greater potential to improve computerized methods of promoting adherence to formulary restriction policies compared to the previous system, the rapid adoption at Shands limited its ability to ensure that optimal methods were in place to promote adherence with formulary restriction policy. Therefore, inadequate incorporation of formulary policies into DOEs was suspected. The objective of this analysis was to identify and prioritize for revision those drugs that required further incorporation of formulary restriction policy into their DOEs.

METHODS

Drugs that were restricted between January 2004 and September 2011 were identified by reviewing the Shands' *Drugs and Therapy Bulletin*, an institutional publication describing formulary changes made after each P&T Committee meeting. After the May 2011

go-live, mock orders for restricted drugs were ordered in a test CPOE environment that fully reflected the live CPOE environment. This simulated the prescriber order entry process at admission and during the hospital stay. Data were collected about rationale for drug restriction, type of formulary restriction, presence of incorporation of restriction policy into the DOE, and whether incorporation was consistent with a recommended method determined by consensus of medication safety, drug information, regulatory, and information technology pharmacists (Table 1).

Types of formulary restriction were ranked according to importance to create a prioritized task list for revision. From highest to lowest priority, rationale for restriction included safety issues, availability of a preferred formulary alternative, supply issues, cost issues, convenience of operations, and other. Drugs with dual formulary designations (NF with approved interchange to an alternative) were classified as interchange, because automatic pharmacist interchange is the usual course of implementation. Data were analyzed using descriptive statistics.

RESULTS

A total of 451 drugs were analyzed. Of these, 18% (81/451; **Tables 2** and **3**) had no incorporation of restriction policy in their DOE. The rationale for restriction was based on availability of a preferred alternative (n = 18; 22.2%), safety issues (n = 17; 21.0%), cost issues (n = 14; 17.3%), supply issues (n = 11; 13.6%), other (n = 11; 13.6%), and convenience of operations (n = 10; 12.3%) (**Table 2**).

Drug restriction policy was incorporated consistent with the recommended method in 36.4% (164/451) (**Table 3**) of all drugs. Therefore, restriction policy was incorporated but required revision for 45.6% (206/451) of drugs to agree with the recommended method to incorporate policy into the DOE. Among drugs restricted by the highest prioritized rationale (safety), restriction policy was incorporated as recommended in 42.3% (47/111) of drugs, with the remainder having no incorporation (n = 17; 15.3%) or incorporation requiring revision (n = 47; 42.4%).

Table 3 describes methods of incorporation of formulary restriction policy into DOEs for drugs with different drug use process requirements. Some restricted drugs could be ordered as long as specific restriction policy was followed. For these, 61.9% (78/126) of drugs either did not have restriction policy incorporated into their DOEs (n = 45; 35.7%) or required revision of incorporated policy (n = 33; 26.2%), indicating some aspect of the requirement for drug use could have been circumvented. Conversely, guidance to formulary agents is required for restricted drugs that should be replaced with a formulary alternative. In these cases, 64% (206/322) of drugs either did not have restriction policy incorporated into their DOEs (n = 27; 10.6%) or required

revision of incorporated policy (n = 172; 53.4%), which indicates that more guidance was needed to encourage use of preferred formulary products.

DISCUSSION

This study's primary finding was that almost two-thirds of all analyzed restricted drugs lacked optimal incorporation of formulary restriction policies in their DOEs after conversion to CPOE. Additionally, the drug restrictions that were made based on safety rationale were among those most frequently not incorporated or inadequately incorporated into their respective DOEs and thus required revision to be consistent with the preferred method to optimize drug use processes.

The American Society for Health-Systems Pharmacy (ASHP) Section of Pharmacy Informatics and Technology provides guidelines for pharmacy planning for CPOE implementation in hospitals and health systems.⁵ Components of the planning stage are defining the desired medication use process and determining CPOE functionality to achieve this goal. These processes require systematic and standardized planning for CPOE implementation. The proportion of drugs with formulary restriction policy optimally incorporated into their DOEs after Shands' transition to Epic could have been increased by a more methodical adherence to this recommendation.

ASHP also recommends the establishment of post go-live metrics. This study provides a quantification of the efficiency of the first post go-live build-in encouraging adherence to drug use policy. This evaluation will serve as a comparator for future changes in technology and policy.

Several notable restrictions for high-risk drugs were identified in this analysis. Among these was the lack of a requirement to document fulfillment of dofetilide

Table 2. Drugs requiring further incorporation of formulary restriction policy into drug order entries after transition to an electronic health record^a

Rationale for restriction	Drugs with restrictions, n	Restriction policy incorporated as recommended, n (%)	Restriction policy not incorporated, n (%)	Restrictions incorporated but requiring revision, n (%)
Alternative preferred	140	65 (46.4)	18 (12.9)	57 (40.7)
Safety concerns	111	47 (42.3)	17 (15.3)	47 (42.4)
Cost	65	24 (37)	14 (21.5)	27 (41.5)
Supply issues	59	12 (20.3)	11 (18.6)	36 (61.1)
Convenience of operations	40	7 (17.5)	10 (25)	23 (57.5)
Other	36	9 (25)	11 (30.6)	16 (44.4)
Total	451	164 (36.3)	81 (18)	206 (45.7)

^aPercentages reported as proportions of each rationale for restriction.

Table 3. Incorporation of formulary restriction policy into drug order entries with different process requirements after transition to an electronic health record^a

Process requirement	Type of drug restriction	Restriction policy incorporated as recommended, n (%)	Restriction policy not incorporated, n (%)	Restrictions incorporated but requiring revision, n (%)
Promote adherence to drug-specific policy ^b	Criteria for use (n=106)	45 (42.4)	38 (35.9)	23 (21.7)
	HPNF (n=15)	2 (13.3)	6 (40)	7 (46.7)
	Dose restriction (n=5)	1 (20)	1 (20)	3 (60)
Provide guidance to prescriber ^c	NFNA, CAN use own drug (n=131)	33 (25.2)	11 (8.4)	87 (66.4)
	NFNA, can NOT use own drug (n=97)	15 (15.5)	7 (7.2)	75 (77.3)
	Interchange (n=94)	68 (72.4)	16 (17)	10 (10.6)
	Other (n=3)	0	2 (66.7)	1 (100)
	Total (n=451)	164 (36.4)	81 (18)	206 (45.6)

Note: HPNF = high-priority nonformulary; NFNA = nonformulary and not available.

^aPercentages reported as proportions of each type of formulary restriction.

^bDecisions permitting medications to be ordered, but requiring adherence to drug-specific formulary restriction policy.

^cDecisions preferring the use of a formulary alternative.

criteria for use, which previously required a unique paper order form. Although we identified this, an independent medication safety team concurrently identified and resolved the issue during this audit. Additionally, many chemotherapy drugs that required a unique paper form did not provide prescribers with this warning, as was the case with the majority of other chemotherapy drugs.

Some inadequate incorporation of restriction policy could have allowed violation of Shands' patient's own medication policy, which prohibits the use of patients' own controlled substances or injectables. For example, when additional guidance could be offered to prescribers via an AMA with a link to a formulary alternative for drugs designated NFNA not permitting use of patients' own medication, 63.9% (62/97) of these drugs did not have policy optimally incorporated into their DOEs and required revision. Epic allowed these drugs to be ordered as long as a required reason for continuing the medication was specified. This permission applies by default to any drug designated as nonformulary in a master Epic formulary. However, these medications should not be administered, therefore they should not be orderable. Guidance to alternatives via AMAs could avoid administration of patients' own medication where this would constitute a violation of institutional policy.

Additionally, 17% (16/94) of drugs with therapeutic interchange did not guide prescribers to the preferred formulary product when they entered an NF product. By definition, therapeutic interchange establishes an automatic substitution of a preferred formulary agent for an NF agent; therefore, all interchanges should utilize an

AMA with link to guide prescribers to the preferred formulary product.

A passive strategy of not creating DOEs for NF medications was identified for some drug restrictions (20/451; 4.4%), based on the rationale that the NF drug would not be visible to prescribers. This is inconsistent with incorporation of policy into other DOEs, where the NF drug is listed but guidance is provided via an AMA. The place of this strategy among the recommended methods is being debated among medication safety, drug information, regulatory, and information technology pharmacists at Shands to determine its effectiveness.

A general standardization and simplification scheme can provide a consistent process that promotes safe and replicable medication use systems.⁵ However, in this analysis, various methods of incorporating restriction policy into DOEs were utilized within each formulary restriction type.

Drug restrictions based on safety that were not incorporated into their respective DOEs received highest priority and were submitted first to the information technology team based on the predefined ranking of rationale for restriction. Periodic reassessment is being planned.

CONCLUSIONS

After transition to CPOE, almost two-thirds of all analyzed restricted drugs lacked optimal incorporation of formulary restriction policies in their DOEs. DOEs with restrictions related to safety reasons were among those most frequently requiring revision. Some DOEs

can better promote adherence and provide guidance to prescribers with revision. Predefined, systematic implementation strategies should be used during changes in computerized drug use processes.

ACKNOWLEDGMENTS

The authors report no funding sources, no conflict of interest, and no financial, institutional, or consultant sponsorship related to this study.

The authors acknowledge Eleanor Lawton and Alex Hollwey for their assistance in data collection.

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