

## Transition From Paper to Computerized Pharmacist Clinical Decision Support

To the Editor:

The progress of electronic pharmacy clinical decision support has been limited because of problems of interoperability between and within electronic medical records (EMRs). EMRs in use in hospitals are predominantly first-generation EMRs with 1970-style hierarchical databases that predate the advent of relational database systems (RDBSs). These non-RDBSs require the creation of computer applications, application program interfaces, for an external application to access the data stored in these non-RDBSs.

This is the root cause of the data silos and data islands problem, where data are isolated to a single organization or abandoned to a single unit within an organization. Hospital pharmacy faces this issue as data are trapped in the EMR. First-generation EMR providers adopted the enterprise business model, where the customer relies on that single EMR for all its information. Thus the very design of the first-generation EMRs supports the lack of interoperability; there was never any intention to share the data with any outside entity. This is a shrewd business model to maintain a local monopoly on the data.

Most computer applications providing pharmacist clinical decision support (RxCDS) require the user to type in the data because the EMR will not share them. Fortunately, EMRs are good at generating printed reports. Where there are printed paper reports, there was once a text file, e.g., MyReport.txt. Most hospital pharmacies periodically have a pharmacist patient profile report generated to be used in the event of EMR downtime. Likewise, most hospital nursing departments have something to use for patient data as a backup to EMR failure.

We electronically mined EMR pharmacy downtime reports intended as printed paper reports to collect patient-specific data for use in an RxCDS application. The data automatically populate into the RxCDS.

First, we found a pharmacist patient profile file and a prior 12-hour patient lab file on our local area network. Next, we had our Information Technology Department increase the frequency of the reports to generate them every two hours, so we are never more than two hours behind in the data. This eliminates the largest obstacle to the progress of an RxCDS application: A data source is now available. Why create an RxCDS application to discover the 30 patients in your hospital who require renal dosing if you have to type in all the information for 300 patients! Application developers or programmers, either external or internal to the hospital, can map the data to an existing RxCDS or create a new RxCDS. Ideally a pharmacist who is also an application developer or programmer can be found.

Our RxCDS is used for pharmacokinetic (PK) dosing of aminoglycosides and vancomycin; automating clinical pharmacy protocols for renal dosing, anticoagulation, and total parenteral nutrition (TPN); government regulatory compliance; *ad hoc* searches for patients on specific drugs or with recent specific laboratory tests; and providing patient pharmacy profiles, labs, and prescription label printing during planned or unplanned EMR downtime.

The RxCDS is a productivity tool. Pharmacists spend no time typing existing data into the RxCDS, so there are no data-entry errors. Vancomycin/aminoglycoside and heparin dosing are both faster and accurately reflect clinical protocols. TPN patients are found quickly, nutritional metrics calculated, and current labs displayed. Our data is filtered to discover duplicate prescriptions or overlapping as-needed indications so that the pharmacist can correct those orders and avoid potential medication administration errors as well as avoid government regulatory fines. Patients on recalled or unavailable drugs can be found quickly. Screening to find patients who might require a pharmacist's intervention can be done quickly; the relevant clinical pharmacy protocol is displayed with a suggested course of action. Any actual intervention made by the pharmacist can either be recorded into the RxCDS or copied and pasted into the EMR.

*Ad hoc* observational studies can be created to investigate medication issues. As an advantage to lowering bias in studies, the application decides, based on our inclusion criteria, if a patient is included or excluded: There is no cherry-picking of data.

Our argatroban dosing protocol required a dose reduction for patients on continuous renal replacement therapy (CRRT); even though the drug is not renally cleared, CRRT was suggested as a predictor of hepatic failure. We created a small application to search our data and collected 30 relevant patients. In about three-quarters, the results of liver-function tests (LFTs) were elevated, but not in the other one-quarter, who we may have been underdosing. A good suggestion was to order LFTs to monitor for possible dose adjustments. As a byproduct, we were surprised to discover that CRRT patients had a mortality rate of 70%.

Some of our pharmacists use another PK dosing model instead of our RxCDS PK function. It was recently noted in morbidly obese patients that vancomycin regimens were significantly different between the two models. We created a small application to search our data and collected 10 relevant patients. We determined that using an adjusted weight for patients whose actual weight was more than 1.5 times their ideal body weight was best for our RxCDS vancomycin PK model; otherwise it uses actual patient weight. This change has been completed in the RxCDS. The other model (which we cannot change) seems to underdose by estimating a longer half-life in obesity.

The health care work environment in general is "high touch" and "low tech;" hospital pharmacy is no different. We love our paper and have suffered with the introduction of new technology. We have endured the challenges of first-generation EMR implementations. We prefer to stay with our current EMR to avoid going through the pain of a conversion. The centralized enterprise business model is very seductive.

There is another, perhaps better model—the federated model, a decentralized collaboration of processes. The idea is to use "best of breed" processes in a modular structure. You own the model; the model does not own you. There is no monopoly. If one of the subprocesses fails, you replace it with another. The entire business is not brought down; there is no downtime. This allows competitive free enterprise to create a new product or service.

## LETTERS TO THE EDITOR

We need to add modular computer subprocesses to hospital pharmacy, such as RxCDS. Any vendor providing a module for functionality not in the EMR needs to have an interface (e.g., HL7) to the data held captive in the EMR. Our RxCDS simply uses data from text files. Microsoft has marketed Amalga to hospitals as a solution to move data from the EMR into Microsoft SQL, an RDBS. Any modern computer application, like our RxCDS, can access data from an RDBS. In time, it is hoped that second-generation EMRs with RDBSs will be the norm in hospital pharmacy. But for now we all must find a useable source of hidden EMR data to advance our hospital pharmacy information systems.

Albert D. Stewart, PharmD, MBA  
Clinical Pharmacist  
St. Joseph Health Systems  
Irvine, California

## Extending Patents With New Indications

*To the Editor:*

In your November issue, Stephen Barlas expresses his dissatisfaction with a Food and Drug Administration, Congress, and court system that refused to give AstraZeneca the tools to prevent the generic manufacturer of Crestor from selling it for the indication of homozygous familial hypercholesterolemia.<sup>1</sup> However, he fails to see the overarching issue here. The drug was going off patent. The company was trying to effectively extend that patent by coming up with a “new indication” and locking out the generic. In fact, the indication is just a rare form of high cholesterol, a “disease” that this product, the generic, and all the competing drugs already treat. To effectively prohibit the generic from being used for the same purpose as the brand version would be a gift to the drug company, and probably unnecessary, since I am sure this drug was already being tried by doctors treating someone with high cholesterol.

The law is fine as it is. We don't need to allow drug companies to shut out generics by using these sleight-of-hand tricks.

Lorne Basskin, PharmD  
Professor, Health Economics  
Brown University School of Professional Studies  
Providence, Rhode Island

## REFERENCE

1. Barlas S. The push for additional orphan drugs. Can the FDA do more to encourage their development? *P T* 2016;41(11):667.