

Improving Patient Safety and Increasing Pharmacist Interventions with the Use of Clinical Decision Support Software from VigiLanz

The John Muir Medical Center – Concord Campus Experience with VigiLanz

Real Time Monitoring for Adverse Drug Events

The John Muir Medical Center - Concord Campus (JMCC) is a 259-bed acute care facility that serves Contra Costa and southern Solano counties in California. The medical center has long been recognized as a preeminent center for cancer care and cardiac care, including open heart surgery and interventional cardiology. In 2006 it made the decision to contract with VigiLanz Corporation to install its Dynamic PharmacoMonitoring System™ (DPM) platform and the Dynamic PharmacoVigilance System® (DPV) module which identifies and prevents adverse drug events in real time. John Russillo, Clinical Pharmacy Coordinator, was no stranger to tracking and intervening on patient safety issues. He had for some time been using the tools currently available at his hospital to maximize what his pharmacy staff could do to reduce adverse drug events. Minimizing any harm from using pharmaceuticals was a high priority, and pursued with intensity. After a thorough search of other vendor solutions, he and his staff chose the VigiLanz DPM platform and DPV. He would easily be able to write his own rules within DPV to follow any drug/lab combination. In addition, DPV also comes with a rule library of over 1000 rules, which can be used as is or altered by the client to meet the requirements of their institution. The VigiLanz installation team guaranteed a ninety day installation process and would install the VigiLanz DPM servers and platform within the four walls of the hospital. Since the Concord campus IT system already met the VigiLanz DPM data requirements, minimal IT hours were needed for this implementation. VigiLanz would remotely monitor and service the system resulting in minimal burden on their IT department.

The System Described

The Clinical Pharmacy Coordinator was now able to monitor clinical events automatically using DPV that were previously unavailable. In addition, he liked the fact that he would be able to eliminate the current manual process of matching trending lab values to specific drugs and subsequent order changes on a patient by patient basis. This process was extremely tedious, was consuming three hours of pharmacist time daily, and did not eliminate the chance for errors due to oversight or inconsistent review. With DPV, he would now have a system that would automatically watch the flow of pharmacy, lab, and ADT information for each patient and signal with an activation of a rule, any situation where a threshold had been crossed or a dangerous trend in lab values was present. Pharmacy staff could track and intervene in all these activations by simply using DPM's web based user interface. They would also receive e-mail notifications regarding activations. From there, the pharmacist could intervene immediately or monitor the activation over time, allowing a specified time period for physicians to fix the problems themselves before the pharmacists might need to act. Unlike other alerting systems, VigiLanz has incorporated a Good Medical Practice Interval into all of its rules-based engines. This allows an activation of a rule to be satisfied by following the rule satisfaction criteria embedded in the

rule. This dramatically reduces noise and false positive results, and enables activations to be averted automatically if the rule satisfaction criteria are met within the designated period of time.

Monitoring Drugs and Physiology

The Clinical Pharmacy Coordinator and his team implemented rules that monitored abnormal levels or worrisome trends in INR, liver function tests, platelet counts, or serum levels of drugs while on certain key drugs. Renal dosing was also a large part of the pharmacists' work load. Adjustments to the rule satisfaction criteria that are built into all DPV rules enabled JMCC to write a large set of rules that matched specific drug doses to specific Creatinine Clearance (CrCl) values. CrCl was calculated automatically from Serum Creatinine, age, weight and height in accordance with their existing CrCl algorithms. If a CrCl result was out of line with the drug dose ordered, it would trigger the rule and create an activation. Prior to the DPM implementation, renal dosing (review and changes) alone took nearly 3 hours a day of manual processing by a pharmacist.

If a specific lab test was ordered and a specific drug was prescribed, a rule could be written simply linking a lab and a drug. In addition, rules could be written linking many drugs and/or having multiple labs within select ranges. Rule filters could be added for age, gender, weight, unit and even physician. All of these rules could be then managed using a friendly user interface, resulting in monitoring of any drug and lab combination. No programming or scripting languages are used or required. The user can also manage the rule library without any IT support.

Once rules are put into production, they are immediately available to run against the defined patient population. The rule engine runs in real time quietly in the background, continuously looking for new incoming data that would trigger rules which would then become activations. Simultaneously it re-evaluates existing activations where the Good Medical Practice Interval has not yet expired. The Clinical Pharmacy Coordinator could now take the best practices for his hospital and build them into DPV rules, thus completely automating a once manual and tedious process. His pharmacy staff could then log into the DPM and view and acknowledge activations, as well as run the many useful reports that the DPM has to offer.

Adding New Data Sources to the DPM

JMCC also wanted to build rules around Pyxis medication cabinet pulls when the drug was being used as an antidote to identify potential adverse drug reactions (ADRs). DPV was already pulling Pyxis data into its database in real time so the ability to create such rules was readily available.

The DPM architecture allows a hospital to add additional data sources. A good example of this flexibility is that the Clinical Pharmacy Coordinator would like to add rules utilizing clinical data such as QT intervals with labs and drugs. Once this clinical data is made available to the DPM, he will be able to easily write applicable rules.

JMCC is currently running 264 DPV rules, with new ones being developed and added on a weekly basis. Since the DPV runs on its own set of servers and is not required to integrate back into any existing system, it runs through these rules in a matter of

seconds. System processing does not affect performance of other hospital IT systems, as the VigiLanz DPM is not required to integrate back into any existing systems.

Solving the Over Alerting Problem

A major obstacle in the use of automated alerting solutions is the issue of over alerting, resulting in alert fatigue. DPV contains multiple features that were designed to reduce the problem of over alerting an already vigilant staff.

Supporting the Clinical Pharmacy Coordinator's efforts to address specific patient needs, these features enable one to eliminate future activations of an individual patient for a specific rule. When the pharmacist is aware of a clinical situation and does not need more reminders, a rule can be either turned off or suppressed for an individual patient. If suppressed, one can specify that the rule fire again for the patient but only if there is a specified percentage increase or decrease in the lab result. This feature can be implemented with a mouse click when acknowledging activations.

Learning the System

What was the impact on the staff pharmacists and the learning curve for an enterprise solution such as DPV? The Clinical Pharmacy Coordinator noted that it took one hour per pharmacist to teach them how to search, view, and acknowledge DPV activations and make it part of their daily work flow. This is significantly less than the typical 8-16 hour time commitment required for other software solutions.

An Opportunity for a Study: Comparisons Before and After the DPV Implementation

JMCC went live on December 18th, 2007 with the DPM platform. Since JMCC had been very active in ensuring safe medication practice prior to the DPV installation, there were processes and data that could be compared before and after. Prior to the implementation of DPV, identification of situations requiring clinical interventions by pharmacists came from manually searching through lab trend reports and drug lists, and from the computerized pharmacy order system that identified some abnormal labs only upon drug order entry. Once a pharmacist decided to intervene, the intervention was logged into the tracking software provided by the pharmacy system, and placed into one of 27 categories and followed daily until the case was closed.

Upon implementation of DPV, the work flow changed. DPV automatically monitors its data feeds 24/7 for any changes in drug or lab data. When a DPV rule was activated, the pharmacists who were logging into the system decided what needed to be followed up on with further action. This was all easily accomplished using the DPV activation screen. When viewing this screen, the pharmacy drug administrations and the specific lab results that triggered the rule are graphically displayed, along with pertinent patient information and location. All other pharmacy orders and labs can be viewed with the click of a mouse, along with any other activations that may have fired for the patient. Those activations that need follow up are entered into the pre-existing hospital clinical intervention tool with an intervention category assigned to it. The 27 intervention categories had been used

in this hospital for some time and were not changed when DPV was installed. What did change is that most opportunities for intervention before DPV were found by manually comparing a patient's lab trends with drug therapy. This is now done automatically and has led to more opportunities to intervene in patient safety issues, with less error and less time spent in the process.

Results

Table I shows (2) time periods: September-November 2006, before the VigiLanz implementation, and January-March 2007, during which time VigiLanz was live. December, 2006 was a transition month and is excluded. Overall, with DPV in place the number of pharmacy interventions increased from 2,369 to 3,061. Total patient days were 13% less in the pre-implementation period reflecting seasonal variation in patient census. Correcting for the variation in patient days yields 294 additional interventions done during the VigiLanz time period, an increase of 15.9%.

The time spent on interventions went from 50,060 minutes to 58,962 minutes. However, the manual sorting through lab trends and drug doses which took 3 hours daily was no longer necessary after DPV was deployed. Adding this to the 50,060 minutes needed pre-VigiLanz for the interventions themselves adjusts this to 66,260 minutes.

DPV created 1,598 activations that were acknowledged by pharmacy staff during the first quarter of 2007. This activity takes an average of 3 minutes per activation acknowledged. This added 4,794 minutes of time bringing the VigiLanz total to $58,962 + 4,794 = 63,756$ minutes. This resulted in a reduction of 3.8% less time spent by pharmacists during the time period DPV was in production.

The pharmacist intervention literature was reviewed for studies that compiled the number of interventions and the drug costs saved from these interventions. When a study did have such data and took place within the USA, we included the study¹⁻¹⁰ in attempting to get some consensus as to the value of a clinical intervention. Saved drug costs are a one dimensional valuation of pharmacist interventions; but since it can be reasonably valued in economic terms we choose it as a cost measure of how the VigiLanz DPM system impacted JMCC (see Table II).

Table I

Intervention Counts and Minutes Compared

	From 09/01/06 THRU 11/30/06		From 1/01/07 THRU 03/31/07	
	COUNT	MINUTES	COUNT	MINUTES
Admissions	2498		2677	
Patient days	12408		14194	
Drug Lab Monitoring	1	10	6	270
Med error f/u	149	2950	106	1540
ADR minor severity	1	15	16	500
ADR moderate severity	68	3295	89	3515
ADR screening	90	2815	153	4240
ADR Severe severity	0	0	2	100
Critical intervention by RPh	5	80	11	205
Dose consideration	198	3139	262	4132
Drug interaction	156	3920	183	4800
Drug consult patient specific	58	2220	52	1450
Aminoglycoside dosing	11	165	9	185
Aranesp dosing/monitoring	35	600	43	730
Argatroban dose monitoring	1	110	2	220
Arixtra dose monitoring	3	105	1	30
Ativan dose monitoring	13	585	22	550
Heparin dose monitoring	63	1530	59	1175
IVIG dose monitoring	4	65	2	20
Levofloxacin dosing	584	6175	685	8329
Lovenox dose monitoring	494	6900	563	8227
Pepcid dose monitoring	22	205	55	595
Phenytoin dosing	53	1545	70	2290
Vitamin K dose monitoring	41	330	24	190
Vancomycin dose monitoring	157	2184	173	2870
Duplicate med alert	25	350	28	345
Improved patient care	21	280	15	210
Kinetics consult	103	4053	108	3434
Monitoring	325	6434	418	8810
TOTALS	2369	50060	3157	58962
Adjusted Total*		66260	2746	63756
Change			377	
% Change Adjusted			15.90%	-3.80%
Drug Cost Savings**			377*82.23 = \$31,700	

* Pre DPV, the number of minutes logged for interventions (50,060), plus the minutes needed to manually prepare the data (16,200) came to an adjusted total of 66,260 minutes. Post DPV deployment, the minutes needed to acknowledge rule activations (4,794) was added to the total minutes (58,962) for an adjusted total of 63,756 minutes. Finally, post DPV deployment, the intervention count (3,157) was reduced by 13% to 2,746 to reflect the increase in patient days during the Jan/Feb/March time period.

**The Drug cost savings/intervention was derived from the review of 10 published studies consisting of 12 sets of data conducted in the USA ¹⁻¹⁰ where drug cost savings/interventions could be determined. The total number of interventions (40,318) and drug cost savings (\$3,358,226) summed from the ten studies yielded an average savings of \$82.23 per intervention. There were 377 more interventions during the VigiLanz time adjusted for patient days. This yields an increased drug cost savings of \$31,700 for the quarter due to VigiLanz implementation.

Studies of Drug Cost Savings with Pharmacy Interventions

Table II

Interventions	Drug Cost Savings (DCS)	Savings/Intervention	First Author	Year Published
855	\$30,677	\$35.88	Catania & Catania ⁴	1988
2150	\$1,029,776	\$478.97	Lada P ⁵	2007
4151	\$372,384	\$89.71	Gandhi PJ ⁷	2001
983	\$94,368	\$96.00	Hatoum HT ³	1988
4648	\$487,833	\$104.96	Mutnick AH ²	1997
310	\$79,723	\$257.17	Chuang LC ¹⁰	1994
332	\$18,030	\$54.31	Miyagawa CI ¹	1986
170	\$3,739	\$21.99	Catania & Yee ⁹	1990
292	\$4,644	\$15.90	Catania & Yee ⁹	1990
24873	\$1,085,560	\$43.64	Yanchick JK ⁸	2000
239	\$21,300	\$89.12	Crowson K ⁶	2002
1315	\$130,192	\$99.01	Crowson K ⁶	2002
Total I	Total DCS	Totals DCS/Totals I		
40318	\$3,358,226	\$82.23		

Conclusions

Implementation of DPV has resulted in increased efficiency and an increased yield in clinical interventions by the pharmacy staff at JMCC. DPV is a valuable monitoring tool for their patients in their efforts to minimize possible harm from drug therapy. The staff accomplished 15.9% more interventions in 3.8% less time after DPV was installed. This hospital was already intensively involved in medication use monitoring before the DPM system implementation and the Clinical Pharmacy Coordinator understood exactly what he wanted from this tool. This meant that the concepts surrounding a 'do no harm' philosophy were already in place. Associated with this was a deep understanding of drug safety issues based upon literature evidence. What they were missing was a tool that could bring a high level of real time automated monitoring to their daily clinical tasks. What would have happened in a hospital that was not already at the forefront of patient safety issues is conjecture, but one would suspect that the increase in pharmacist's interventions would be even more dramatic.

How does a user value the utility of such a tool? Let's start with the data that was obtained at JMCC. Assume the figure of drug cost savings of \$82.23 per intervention. Following the DPV implementation, there were 377 additional interventions for the quarter, adjusted for the patient day differential. Multiplying these two figures, one obtains a dollar cost savings of \$31,700 or \$126,800 on an annualized basis. Pharmacy productivity was also increased. Beyond direct drug cost savings and staff productivity, there are other cost savings that accrue to a hospital outside of the pharmacy. Literature regarding total dollar cost savings for the prevention of preventable adverse drug events has been readily available since the late 1990s.¹¹ The most widely used cost figure is by Bates, et. al. This states the cost at \$5,800 (2007 dollars), reflecting a prolonged length of stay, the associated facility, personnel, and diagnostic expenses beyond the direct drug costs. Despite the body of research quantifying these costs, this figure remains controversial, and depending upon patient and payer mix, may be partially passed on to the insurers.

How does one value the clinically significant rare events that DPV uncovered that might have never been identified except for the use of an automated real time system? While these relatively few events would be statistically small, they are quite significant from patient safety and legal liability points of view.

However, we believe that forcing patient safety efforts into dollar cost savings is an overloading of the economic model. There are other important issues at stake here. For example, if a patient dies because monitoring of a drug serum level is lax, and this death is never litigated, there is actually a perverse cost savings from that death because of a shorter length of stay. Yet, all would agree, that from a basic medical ethical precept of 'do no harm', this death is a serious failing.

We would argue that good pharmacy/medical care where harm from drug use is minimized stands on its own merit without further justification. As commendable as it is to detect Adverse Drug Events (ADEs), it should be the goal of every medical institution to prevent or minimize the occurrence of preventable ADEs. Since an automated, real time monitoring system can add dollar cost savings of more than \$100,000 annually and improve pharmacy staff productivity, it is a useful justification for the tool, albeit reflecting only a fraction of the overall value to the institution and patient.

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