DESIGN AND IMPLEMENTATION OF A COMPUTERIZED INFORMATICS TOOL TO FACILITATE CLINICIAN ACCESS TO A STATE'S PRESCRIPTION DRUG MONITORING PROGRAM DATABASE

By

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CHAPTER I

INTRODUCTION

In the mid-1990's, experts in pain management began raising concerns about inadequate relief of pain for patients at all points within the health care system(1). These efforts culminated in the establishment of six standards by the Joint Commission which directed practitioners and health care organizations, in part, to "…recognize the right of individuals to appropriate assessment and management of pain…[and to] establish policies and procedures that support the appropriate prescribing or ordering of effective pain medications.(2)"

Perhaps not unexpectedly, in the ten-year span from 1997 to 2007, the number of opioid prescriptions quadrupled nationally, accompanied by a seven-fold increase in the quantity of prescribed opioids, from 96 mg of morphine-equivalent-dose per capita to 700 mg per capita, enough to therapeutically dose every person in the US for 3 uninterrupted weeks(3, 4).

Paralleling the increase in drug supply, prescription drug abuse emerged as a major socioeconomic problem throughout the United States and has been described as both an epidemic and "the Nation's fastest growing drug problem(5)." Prescription drug overdose deaths, primarily involving opioid analgesics, have nearly tripled since 1995, and have eclipsed the combined rates of heroin- and cocaine-related death. In 2009, prescription opioid overdose overtook motor vehicle accident as a cause of death(3).

People who take high doses of opioids (≥ 100 mg of morphine equivalent dose per day) are at significantly higher risk of overdose and death(6). Opioid overdose occurs disproportionately in those

who visit a single doctor but have large prescribed daily dose and in those who visit multiple doctors to secure a cumulative high daily dose. Each of these sub-groups comprise only 10% of the people who have opioid prescriptions, yet each accounts for 40% of the overdoses(3). In addition, the "doctor-shopper" subgroup is responsible for significant diversion of pharmaceuticals, in turn sold by drug dealers and in open-air drug markets(7).

Many authorities believe that state prescription drug monitoring programs (PDMP) can play a considerable role in identifying individuals at risk for overdose and in reducing prescription drug diversion(3, 5, 8-10). PDMPs are state-run electronic databases that store information about DEA-Scheduled drugs prescribed within the given state. Currently, forty-three states have operational PDMPs and 6 additional states have enabling legislation to establish programs(11). Depending on state legislation and statute, data can be accessed by authorized prescribers, dispensers, law enforcement personnel, and licensing/credentialing bodies. PDMPs allow better targeting of opioid prescriptions by helping clinicians identify prescription drug misuse, confirm compliance with pain contracts, and verify proper prescription filling in high-need patients(9, 12).

The impact of PDMPs on the prescription drug crisis can only be realized if the databases are actually queried. It is clear that PDMPs are underutilized. Regarding the Ohio PDMP, one survey found that although 89% of the 95 respondents were aware of their state's PDMP, less than 59% had ever queried it(13). Online data from the Oregon PDMP indicates that in the month of December 2012, a typical month within the report, only 41% of those physicians and physician assistants with PDMP access accounts performed queries (1,333 querying users among 3,291 authorized), with an average of 13 queries per user, one query every 1.5 work days(14). In addition, state registration rates for authorized users are generally low, ranging from 5 to 39%(15). In the Oregon PDMP report, only 3,291 physicians and PAs have PDMP access accounts from among 14,675 potential users (22%)(14). Poor integration of the PDMP query process into the clinician workflow further impedes routine use. In a survey to determine why an

available PDMP is not queried, 73% of prescribers were prevented by time constraints, 29% claimed difficulty navigating the PDMP website, and 28% couldn't remember their logon password(10).

Ideally, access to the PDMP should occur seamlessly from within the electronic health record (EHR), supplying clinician credentials and patient demographics and displaying filtered query results within the EHR user interface(15). However, currently there is no application-programming interface (API) that would allow a PDMP to work with a health enterprise's EHR. In fact, the wording of the state's enabling legislation may rigidly establish how PDMP data is to be accessed, precluding data-sharing via an API(16).

To overcome the access barriers of the Tennessee PDMP, we designed a computerized informatics tool to query the Tennessee Controlled Substances Monitoring Database (TN-CSMD) from within the Vanderbilt University Medical Center (VUMC) EHR, without the use of an API. This approach was reviewed and endorsed both by the executive director and by the legal counsel of the Tennessee Board of Pharmacy, designated by statute as the administrator of the TN-CSMD. The EHR-integrated PDMP query tool was placed into limited clinical use by emergency department (ED) clinicians on October 25, 2011, after approval by VUMC's legal counsel and the VUMC Office of Privacy. We then evaluated whether implementation of the integrated query tool increased the PDMP query rate.

This paper represents the first reported integration of the query process for a state prescription drug-monitoring program (PDMP) with a hospital's electronic health record (EHR). The specific aims were 1) to develop a computer interface for sending a query to, and receiving prescription drug information from, the TN-CSMD from within the hospital's electronic health record, without the use of an application programming interface (API), unfortunately prohibited by the language of the authorizing legislation for the PDMP; 2) to evaluate whether the availability of such an EHR-integrated PDMP query tool increases the screening rate for prescription opioid abuse in emergency department (ED) patients,

and 3) to determine whether such screening affects opioid provision for patients during ED care and upon discharge.

CHAPTER II

DEVELOPMENT OF THE EHR-INTEGRATED PDMP QUERY TOOL

Accessing the Tennessee PDMP Prior to Integrated Query Tool Implementation

For an authorized user to query the Tennessee PDMP in an EHR use environment, the clinician-user must leave the EHR, open an internet browser window and navigate to the Tennessee PDMP website (https://www.tncsmd.com), enter state-issued user name and user-selected password, enter patient demographic information including name and date-of-birth, select the report format, select the query time frame, acknowledge authorization to access data, and activate the submit button [Figure 1].

After the query is initiated, a pause of 30-60 seconds can be expected for PDMP database search and return of prescription data file. If data is found, the user selects a hyperlink to download the prescription file in the user-selected format (PDF or Excel). Once the file is downloaded, the user can open the file and review the contents for prescription activity, with prescriptions listed in reverse chronological order. Data available on each prescription includes the prescriber code, drug identity, fill date, quantity dispensed, pharmacy code, and new or refill indicator. The time required to complete the Tennessee PDMP query is approximately 3 minutes, longer if data is incorrectly entered or certain data fields are not completed or checked. The user is engaged in a single task and tethered to the workstation throughout the query process.

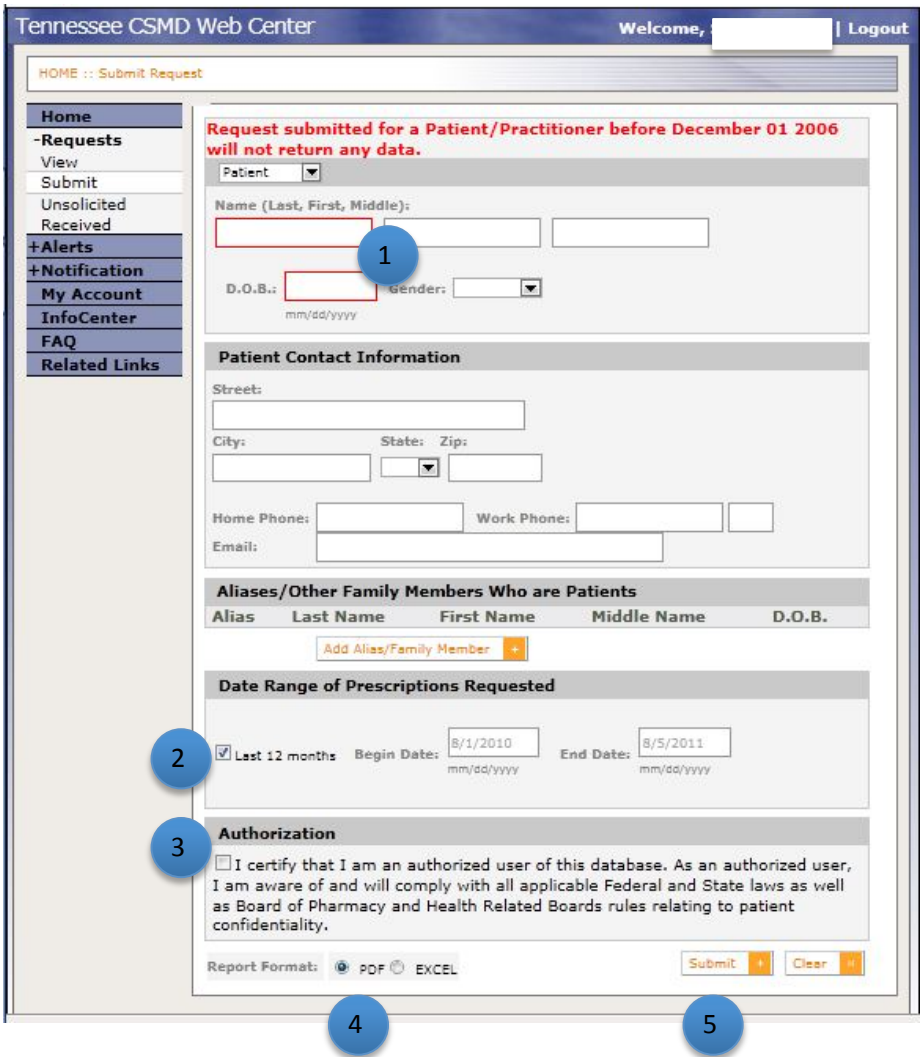

Figure 1: Submitting Query to Tennessee PDMP

Decoding PDMP Server-Client Web Traffic

The first step in developing the integrated PDMP query tool was to determine the message content and format expected by the Tennessee PDMP server, for which we used Fiddler® (http://www.fiddler2.com), a free-ware web debugging proxy which logs all HTTPS traffic between web browser and server. By examining the transaction log for a PDMP query [Figure 2], we were able to encode the client-side messages to mimic the transactions that would occur had a person been entering data directly from the web browser.

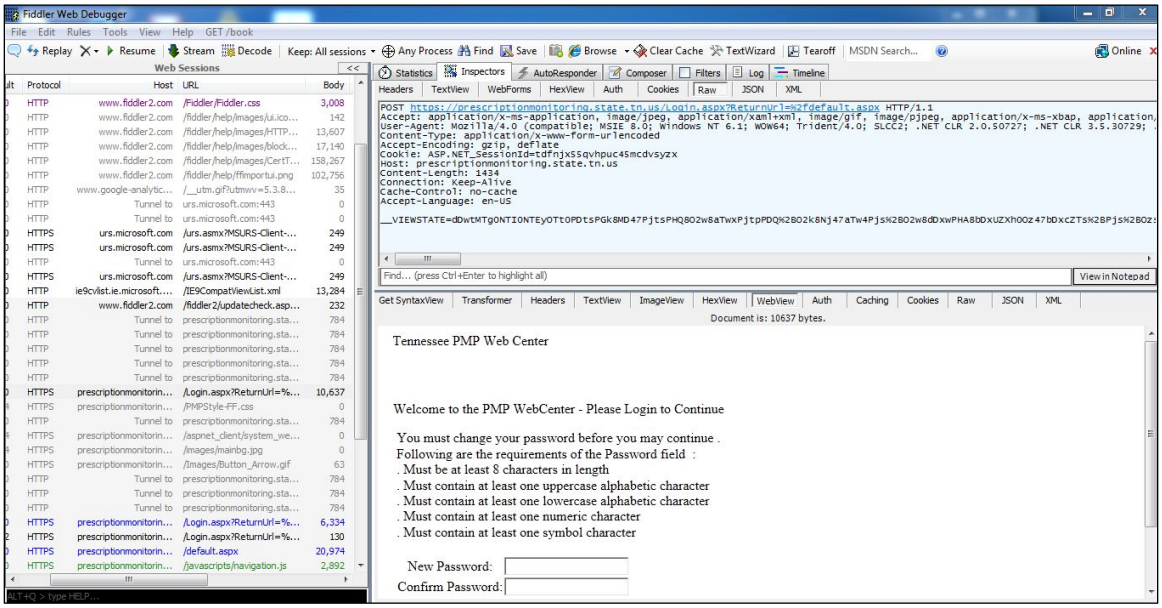

Figure 2: Sample Fiddler® PDMP Traffic Log

We used Perl (http://www.perl.org), an open-source programming language with robust text processing capabilities, along with the LWP-User Agent Perl module, to construct the query scripts used to post the appropriate user credentials and patient demographics to the PDMP server. Perl leverages regular expressions (REGEX) to capture data from within text (e.g., from within the server-client transactions of the PDMP) and store that data in programmed variables. It is the content of these variables that comprise the POST message to the PDMP website, as well as store the URL addresses to which messages are to be sent and from which data is to be retrieved.

EHR-Integrated PDMP Query Tool Design

The PDMP username and password were stored on the EHR server, in a MySQL database table keyed to the unique EHR user name, such that logging on to the EHR would provide the integrated PDMP query tool with access to the EHR user's PDMP credentials. The PDMP credentials were entered by the user and stored in the database table on first use of the integrated query tool, with verification of credentials confirmed by transaction with the PDMP server. The integrated PDMP query tool retrieved

patient demographics from within the EHR via the admit-discharge-transfer (ADT) system and stored them in a Perl hash variable. Following is the resultant formatted POST message response variable to be sent by the user agent module to the Tennessee PDPM server, where the correct uniform resource locator (URL) for the PDMP database server is stored in the variable '$pmp_url2' and patient demographic information is stored in the other variables denoted by an initial '$':

```
$response = $ua->post($pmp_url2,
                      {
                        '__EVENTTARGET'            => '',
                        '__EVENTARGUMENT'     => '',
                        '__VIEWSTATE'               => $viewstate_submit,
                        '_requestType'               => 'Patient',
                        '_name:_lastName'          => $request{lastName},
                        '_name:_firstName'         => $request{firstName},
                        '_name:_middleName'      => $request{middleName},
                        '_dob:_date'                => $request{dob},
                        '_Gender:_codes'          => $request{gender},
                        '_address:_location'      => $request{address},
                        '_address:_city'           => $request{city},
                        '_address:_state::_ddlState' => $request{state},
                        '_address:_zip:_zip'      => $request{zipcode},
                        '_homePhoneNum:_phoneNumber' => $request{homePhone},
                        '_workPhoneNum:_phoneNumber' => $request{workPhone},
                        '_workPhoneNum:_extension'   => $request{workExtension},
                        '_email:_email'           => $request{ptEmail},
                        '_fromDate:_date'        => $start_date[$index],
                        '_toDate:_date'           => $today[1],
                        '_authorization'         => 'on',
                        '_reportFormat:_actions'    => $request{reportFormat},
                        '_submit'                => 'Submit',
                      });
```

If there was data on the PDMP data server, the prescription data file was retrieved in both PDF format (to facilitate subsequent viewing by user), and Excel format, which was then run through a data parser program. The prescription data parser script used REGEX to extract relevant prescription data, including counts of unique pharmacies, unique prescribers, drug identities, controlled substance prescriptions, and opioid prescriptions, as well as data on date of the most recent controlled substance prescription. This data was stored temporarily in MySQL database tables, keyed to case number, unique to each patient encounter, and to the EHR user name, unique to each user. Query time, calculated from server system time, was also stored in order to limit data persistence in the EHR. The PDF file was further processed to prevent printing.

The query to the PDMP and retrieval of returned data was initiated from within the EHR interface using two separate computer gateway interface (CGI) scripts, one to initiate the query [Figure 3] and the second to retrieve the data after sufficient time elapsed for the query to complete [Figure 4]. The second CGI script would generate a screen message for the user, either 1) indicating that not enough (or too much) time had elapsed since the query, or 2) displaying a summary of the PDMP report, from the parsed data, containing last prescription date, number of different prescribers, number of different dispensers/pharmacies, number of controlled substance and opioid prescriptions filled over time interval (default: 12 months) and containing a hyperlink to permit viewing of the PDMP report [Figure 5].

With this approach, the time to complete a query is still approximately 3 minutes, but the time required for the user to be engaged in tasks is reduced to two 5-second intervals. In addition, the user is presented with a brief summary of pertinent prescription data designed to allow decision making without the need to open and review the complete PDF file [See Figure 7 for integrated query tool schematic].

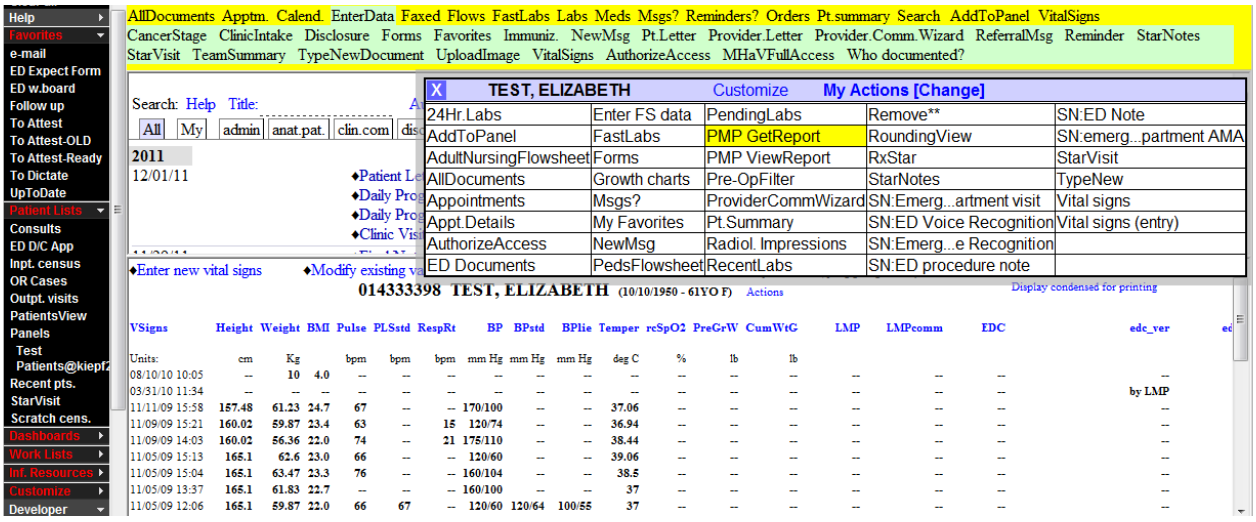

Figure 3: Initiating PDMP Query from within EHR interface (*PMP GetReport* link)

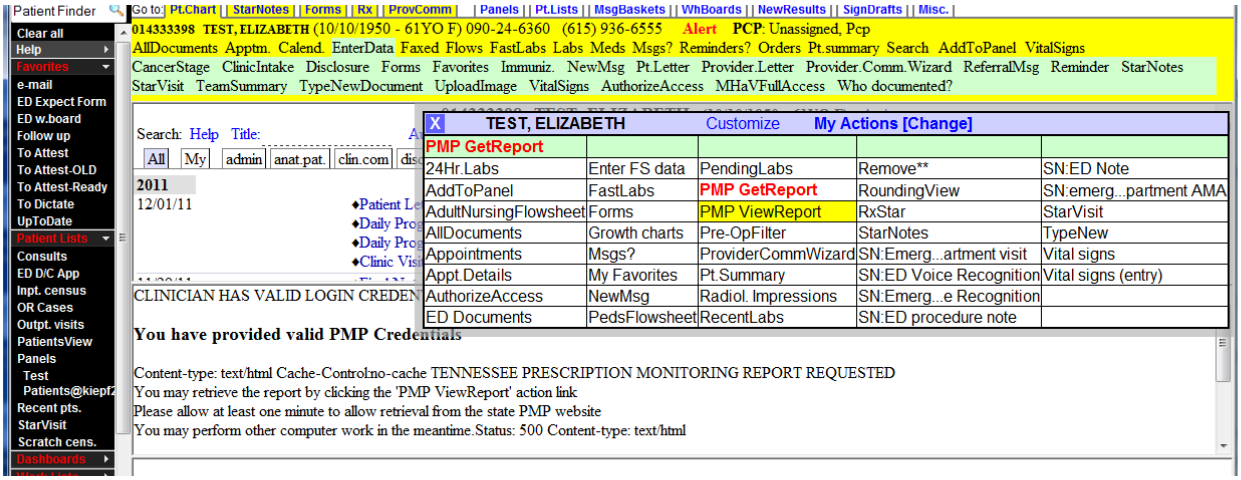

Figure 4: Retrieving and Viewing PDMP Report from within EHR interface (*PMP ViewReport* link)

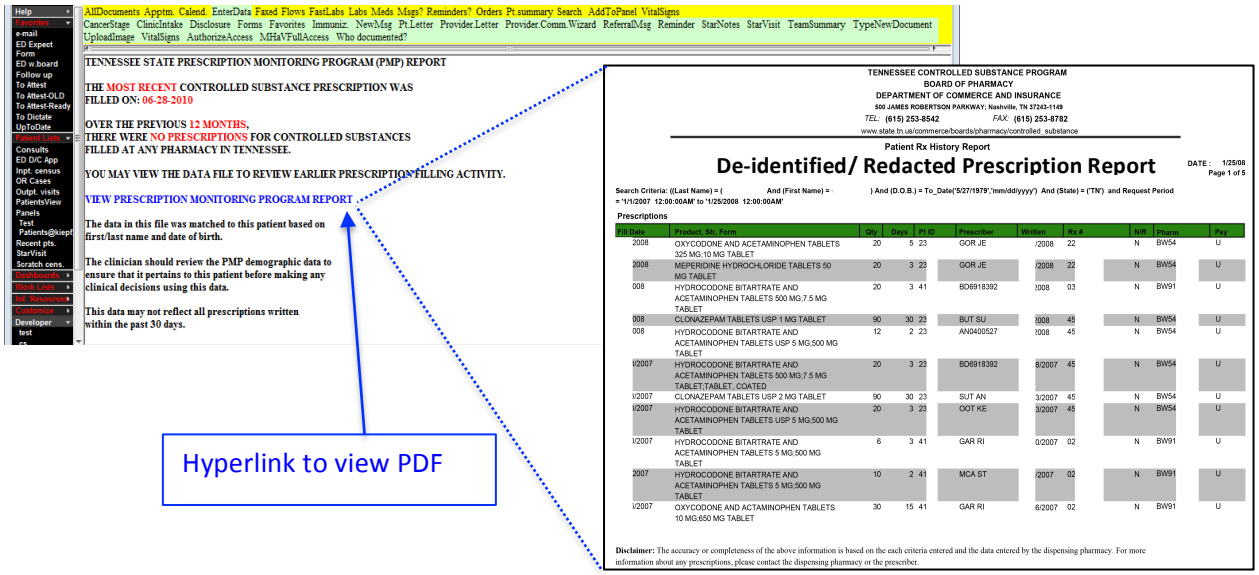

Figure 5: Filtered Prescription Report Screen, link to PDMP Report PDF

When accessing the Tennessee PDMP from the web browser at the time of this study, practitioners received the following admonition [Figure 6]:

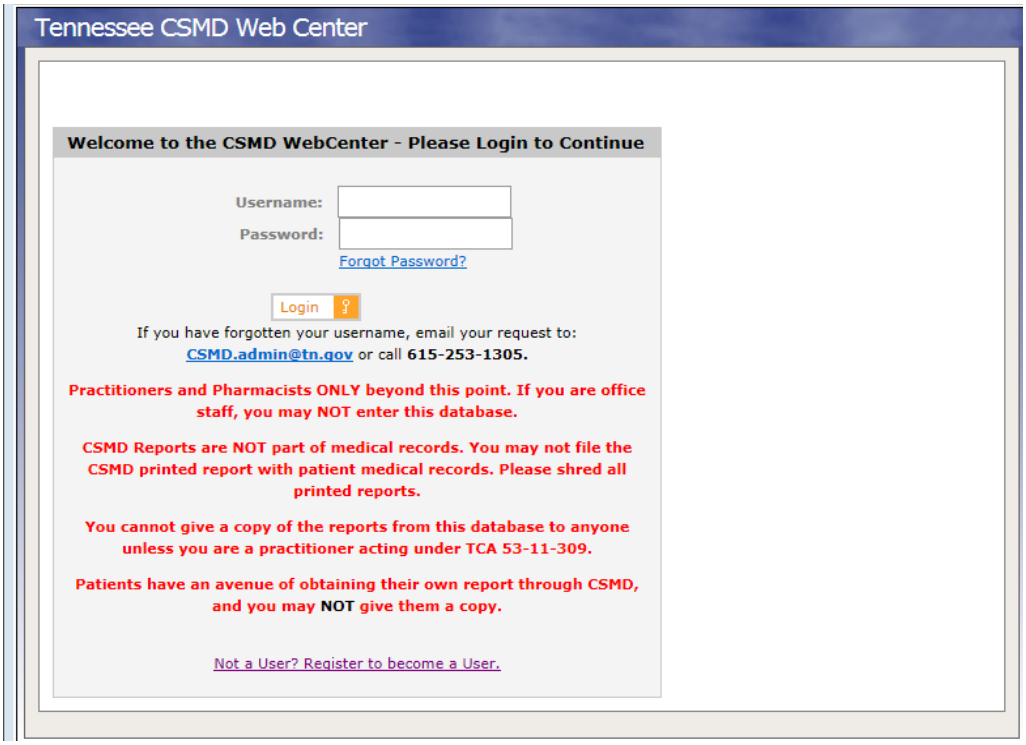

Figure 6: Tennessee Controlled Substances Monitoring Database Login Screen (www.tncsmd.com, screen capture 1/22/2012)

The EHR-integrated PDMP query tool design complied with the following Tennessee Board of Pharmacy mandates:

1) *Data cannot be incorporated into the medical record*. Data was deleted from the server 60 minutes after query, whether viewed or not.

2) *Data can only be accessible to the PDMP-credentialed clinician who was caring for the patient and initiated the query*. Accessing the PDMP from within the EHR ensures that the clinician has patient-care responsibilities per privacy-use requirements of the medical

center. Data was stored and subsequently retrieved keyed to the user's EHR login credentials. EHR record access was tracked for each user per medical center guidelines.

3) *Report cannot be printed or provided to the patient.* When the PDF was retrieved from the PDMP site, the report was re-configured to render it unprintable.

The EHR-integrated PDMP query tool is capsulized in the schematic that follows [Figure 7].

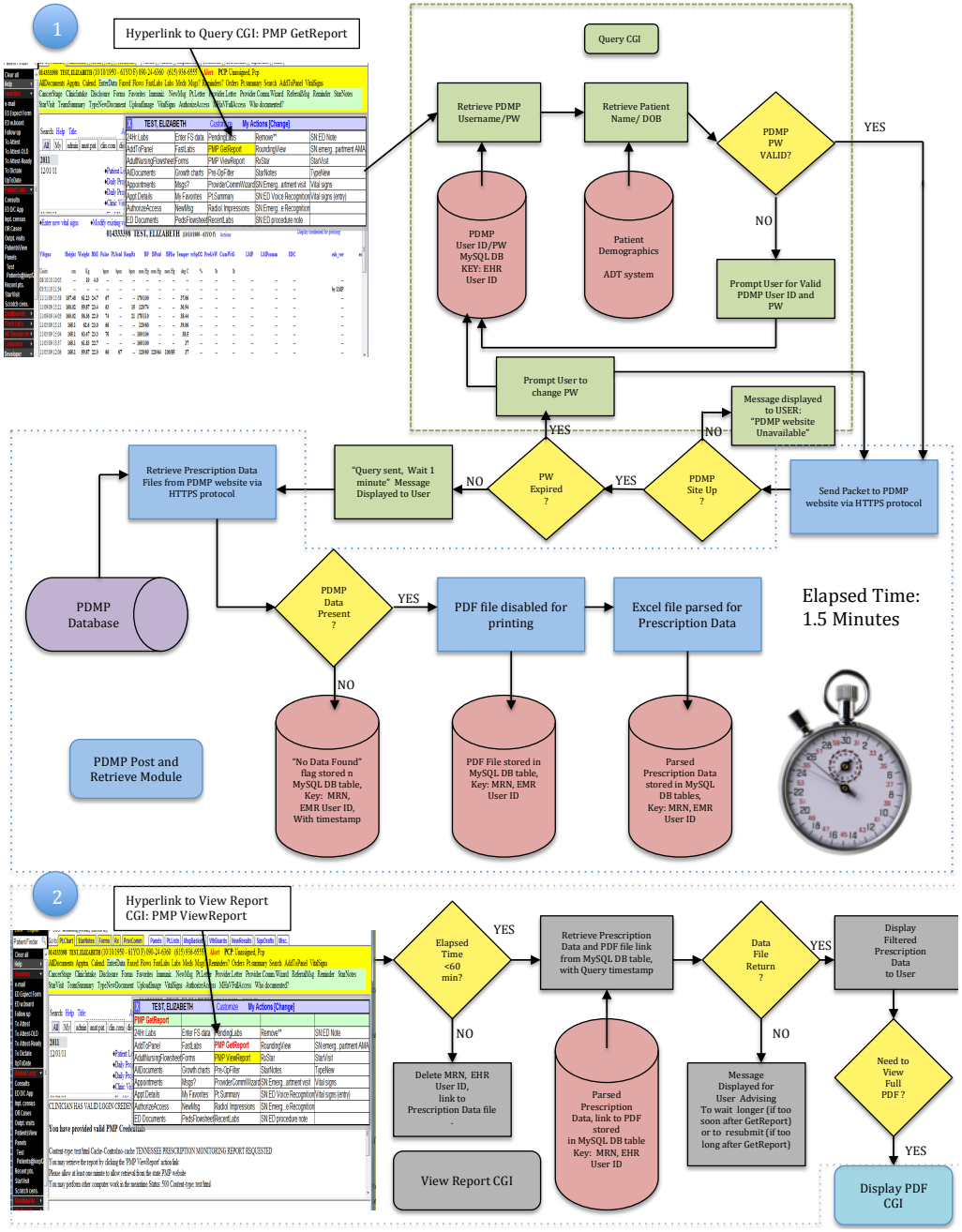

Figure 7: Schematic flow-diagram of EHR-integrated PDMP Query Tool

CHAPTER III

EVALUATION OF THE EHR-INTEGRATED PDMP QUERY TOOL

Quasi-Experimental Repeated Intervention Study

The evaluation study was reviewed and approved by the institutional review board as an expedited review. Because only de-identified patient data was saved for study and because the PDMP prescription data represented an existing data collection, the institutional review board waived informed consent from patients. Consent was obtained from the participating ED attending physicians.

Setting: Emergency department of Vanderbilt University Medical Center, a Level 1 trauma center with 65,000 annual ED visits.

Participants: Twenty-eight experienced ED attending physicians with active credentials for the Tennessee Controlled Substances Monitoring Database. Physicians work 8-hour shifts within 1 of 3 areas of the ED: 1) A-pod for critical illness and trauma, 2) B-pod for less acute illness and initial psychiatric evaluation, or 3) Team Triage, where the ED physician performs initial assessment and order entry during times of high triage volume, as well as primary evaluation for drug/alcohol treatment intake and minor medical problems.

Study Design: Quasi-experimental repeated pre-post intervention study, with alternating 2-week periods of non-availability/ availability of the EHR-integrated PDMP query tool, repeated once, i.e., no tool/tool/no tool/ tool.

Participating ED attending physicians were educated about the study and use of the EHR-integrated PDMP query tool by way of an educational session after a faculty meeting, informational email with PowerPoint slideshow, and face-to-face meetings with the principal investigator. Prior to each

change in tool availability at the 2-week interval mark, participants were alerted with daily emails on 3 successive days, with delivery and read receipts. Participants were instructed that they were free to use the tool at their clinical discretion during periods of integrated query tool availability, and further that they were also free to use the PDMP access method of their personal preference, using either the integrated query tool or accessing the PDMP from the web browser. During weeks of integrated query tool unavailability, the only option for PDMP query was via the web browser. Integrated query tool availability was programmed to occur automatically, based on server system date. During study intervals when the query tool was not available, activating the EHR hyperlink 'Get PMPReport' would display a message to the study participant that, per study design, the tool was not available until 'x' date, and would remind the participant that he/she could still query the PDMP using the web browser.

Throughout the 8-week study, patient record identifiers for patients evaluated by study physicians and discharged from the ED were automatically placed into an electronic ED discharge queue housed within the EHR server. A Perl script running in the background would retrieve the structured ED discharge summary corresponding to the record identifier, and use REGEX to parse the summary for whether the patient reported use of opioids in home medications, whether the patient received opioids during ED care, and whether the patient received opioids at ED discharge, and if so the discharge opioid name and prescribed quantity.

The PDMP prescription data, including any patient identifiers, were deleted from the temporary query tool database one hour after query. During the 8-week study however, the data involving study participating ED attending physicians were first copied to a dedicated study database maintained on the EHR server. The study data were keyed to unique identifiers generated by applying a one-way cryptographic hash algorithm to the identifiers for the query tool (medical record number, case number, EHR User ID) that generated unique 32-bit numbers for each identifier. In this way, the same MRN maps to the same one-way hash value, but the original MRN cannot be practically re-generated, even if one is

aware of the specific cryptographic hash algorithm. This method effectively created a de-identified data set to which both prescription data from the PDMP and data from the EHR could be added, while still referring to the same patient and same participating ED attending. Only one query per case number was stored in the study database, such that if different study physicians (e.g., physician in triage and physician in acute care pod) initiated a PDMP query during the same ED visit, only the last query would be represented in the study database.

For purposes of the study, we also programmed a small module within the integrated query tool to parse the ED triage note and extract the intake pain score (1-10); this information was stored in the study database as well. In addition, we logged the counts for when retrieved filtered data was actually viewed by the user, and counts for when the PDF data file was opened and reviewed.

At the conclusion of the 8-week study, participating clinicians were asked to log on to the Tennessee Controlled Substances Database and print a record of their queries, from 9/1/2011 through 4/30/2012. Those dates encompassed a period before the study when the integrated tool was not available (9/1/2011-10/24/2011), a period before the study when the tool was available for clinical use (10/25/2011-1/22/2012), the study period, and a period after study completion, when, because of a redesign of the state PDMP browser interface, the integrated query tool became non-functional pending programming revision (3/19/2012 – 4/30/2012). The queries that were generated by use of the integrated query tool were formatted differently than queries that were manually performed from the web browser, and so it was possible to distinguish manual queries from query tool-generated ones. Query counts for each participating physician were entered into an Excel spreadsheet, for each date of the study. In addition, query counts were obtained for the above noted pre-study and post-study intervals.

We reviewed the online scheduling tool that is used for scheduling ED physicians to determine shift location (i.e., A-pod, B-pod, Team Triage) and hours worked during each of the above pre-study, study, and post-study intervals. Similarly, patient counts for each attending during worked shifts were

obtained from the electronic ED whiteboard registration log function, which maintains a record of patient assignment for each clinician, keyed to their EHR User ID. By knowing the PDMP query counts and clinician's patient census and hour counts for each day, we were able to calculate a query frequency (queries/ hour worked) and query rate (queries/ patient) for each clinician for all intervals.

Post-Study Survey of Participating ED Attending Physicians

We designed and administered a post-study evaluation survey using REDCap electronic data capture tools hosted at Vanderbilt University. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources(17). The survey consisted of 16 structured questions and 2 open-response questions covering clinical experience, prior experience with the Tennessee PDMP, features used by clinician to identify controlled substance prescription abuse, and participant opinions of the EHR-integrated PDMP query tool. Participants received an e-mail invitation for survey participation containing a link to the survey. RedCAP tracked participation and collated survey results anonymously.

CHAPTER IV

RESULTS OF EVALUATION STUDY AND POST-STUDY SURVEY

Quasi-experimental Repeated Intervention Study Results

Twenty-eight ED attending physicians participated in the study. During the 8-week study period, study physicians evaluated 5,630 patients during 3,712 hours of clinical care in the ED (1.52 patients/hour). For study intervals 1 and 3 with no EHR-integrated PDMP query tool availability, physicians saw 2,786 patients (1428 patients interval 1, 1358 patients interval 3) during 1840 hours (920 hours each interval), for an average of 1.51patients/ hour. During intervals 2 and 4, when the integrated query tool was available, participating physicians saw 2,844 patients (1414 patients interval 2, 1430 patients interval 4) in 1872 clinical hours (1000 hours in interval 2, 872 hours in interval 4) for an average of 1.52 patients/hour. Because physicians had different academic and clinical responsibilities, with some spending some of their clinical time at the children's hospital and/or VA hospital, there was significant variability from interval to interval for shifts worked for individual physicians, with some working no clinical hours in the adult ED during an interval.

Primary Outcome—Effect of integrated query tool on query rate/ frequency

Study physicians queried the PDMP 73 times during study intervals when the integrated query tool was unavailable, for a rate of 0.026 queries per patient and frequency of 0.040 queries per hour, or approximately 1 patient queried every 3 shifts/clinician. Physicians queried 169 times with the integrated query tool, for a query rate of 0.060 queries per patient and query frequency of 0.090 queries/ hour (1 query every 1.4 shifts). In only 3 instances did physicians use manual query when the integrated query tool was available. Individual physician query behavior is depicted in Figures 8 and 9.

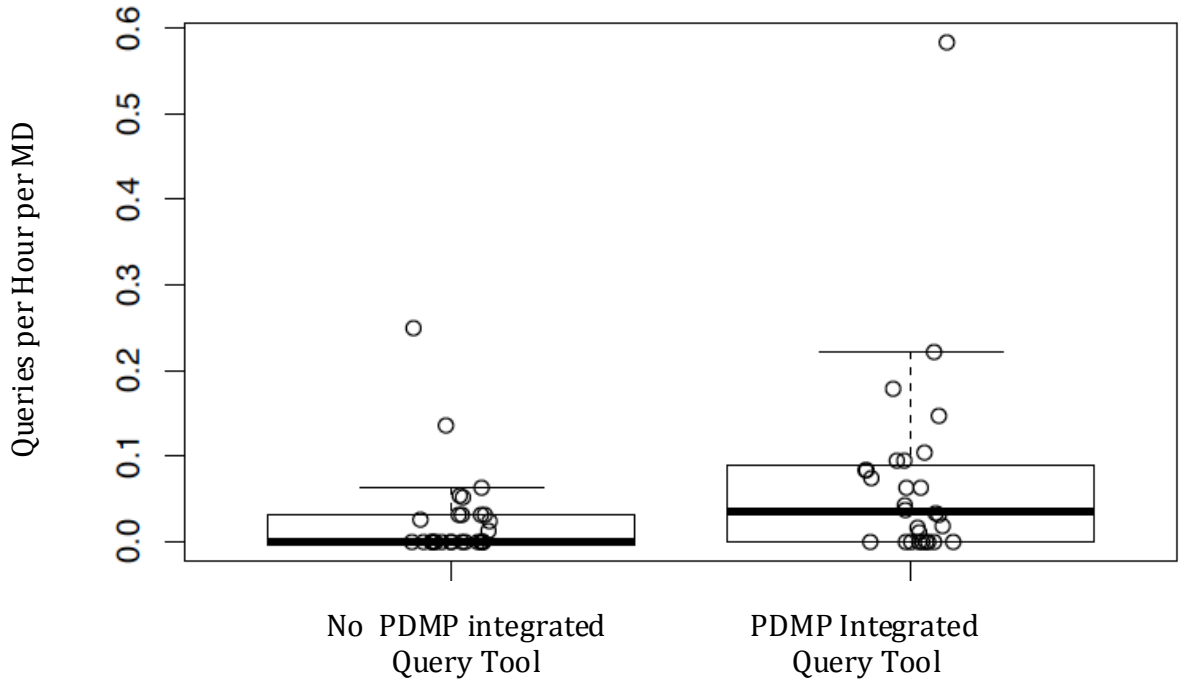

Figure 8: Box plot of Frequency of PDMP Query per hour (combined study intervals)

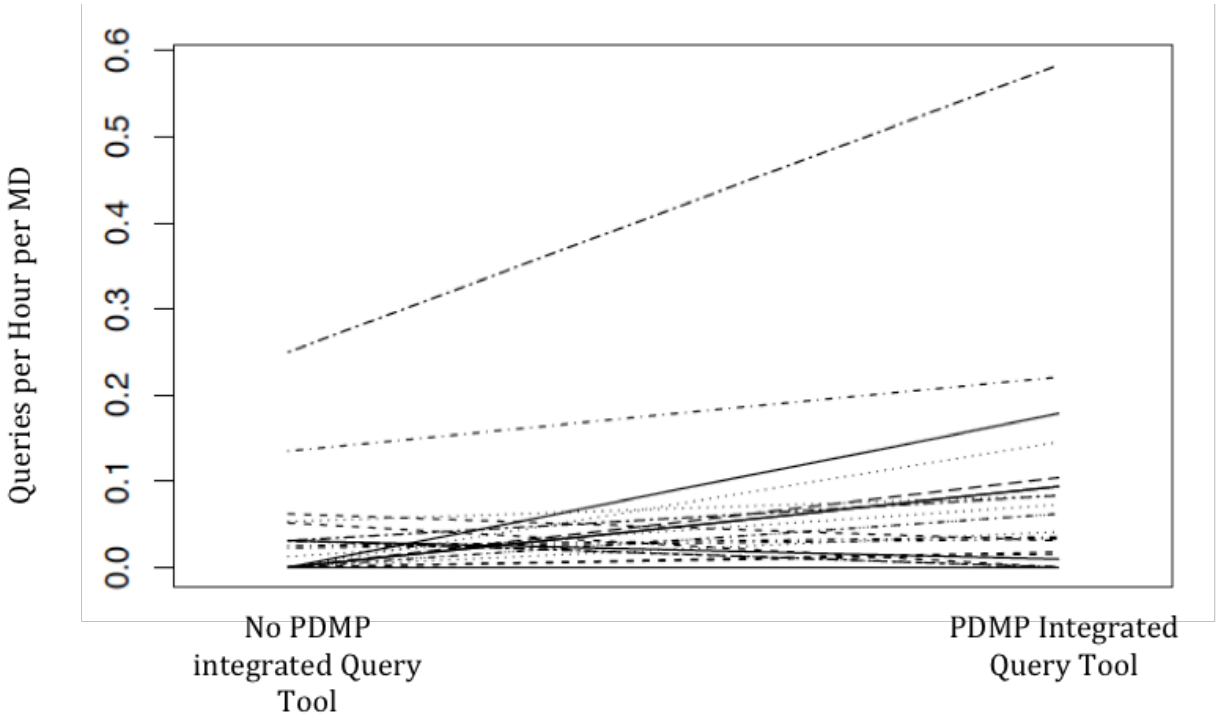

Figure 9: Spaghetti plot of individual user query frequency

Prior to the study (9/1/2011-10/24/2011), before development of the integrated query tool, physicians queried the PDMP 175 times during evaluation of 5,553 patients over 3,096 hours, rate 0.031 per patient, frequency 0.057. For the period after study completion (3/19/2012 – 4/30/2012), when the integrated query tool was again unavailable, study physicians initiated 123 queries for 4,272 patients during 2400 hours, yielding a query rate of 0.029 per patient and query frequency of 0.051 per hour. After the integrated query tool was placed into clinical practice (10/25/2011-1/22/2012), study physicians queried the PDMP 661 times during the evaluation of 9,200 patients over 5,736 hours, for a query rate of 0.072 and query frequency of 0.12.

Physicians were more likely to check the PDMP during the intervention period when the EHR-integrated query tool was available (median 2.09, IQR 0-4.8) compared to the control period, when only web-browser access to the PDMP was available (median 0, IQR 0-1.8) (p=0.008 by Wilcoxon Signed Rank test). Summary statistics for the primary study objective are provided in Table 1.

Table 1: Summary Statistics for Query Rate. *a*, *b*, *c* represent lower, median, and upper quartiles for continuous variables *x*±*s* represents *X* ± 1 SD

	No PDMP Query Tool N=28				**PDMP Query Tool Available N=28**			
	a	*b*	*c*	*x*±*s*	*a*	*b*	*c*	*x*±*s*
Query%	0.0	0.0	1.8	2.0±4.7	0.0	2.1	4.8	5.5±12.9

We assessed the association between EHR-integrated query tool availability and the number of PDMP queries using a longitudinal negative binomial regression model. The incident rate ratio with 95% confidence interval comparing integrated tool availability to non-availability was 3.88(2.13-7.05) (p< 0.001).

Secondary Outcome—Effect of PDMP query on prescribing behavior

There were 2,793 patients for whom discharge data was captured by the integrated query tool during study intervals 2 and 4. This differs from the 2,844 patients as determined from the ED whiteboard registration log function. Psychiatric patients transferred to the medical center psychiatric hospital did not generate discharge summaries, and so were not reflected in the study database but were counted in the physician patient census.

During interval 2 and 4, when the integrated query tool was available, prescription data was obtained for 154 unique case numbers. There were no duplicate medical record numbers among these 154 patients, indicating that there were no queries of the same patient during a different encounter. Of these 154 PDMP screened patients, the data was never reviewed in 31 instances (20%). Of those 123 patients for whom the filtered data screen was reviewed, the complete PDMP report PDF was viewed in 71 (58%).

Of the 2,734 patients with discharge prescription data, physicians provided an opioid discharge prescription for 755 (28%); for the 2,639 patients for whom no PDMP query was performed, physicians provided discharge opioid prescriptions to 711 (27%) and for the 71 PDMP-queried patients (with ED discharge prescription data and PDMP data viewed by study physician), physicians prescribed discharge opioids for 31(44 %). Regarding provision of opioids during the ED stay (n= 2,610), opioid analgesics were administered to 917 (35 %) patients, including 873 (35%) of 2,520 patients not queried in the PDMP database and 30 of 67 (45%) who were queried and had PDMP data review by physician [Table 2].

Table 2: Contingency Table for Provision of Opioids in ED or at Discharge vs. PDMP Query status, Pearson's Chi Square

	No Query		Query		p-value
No ED Opioids	65%	$1647/2520$	51%	$37/67$	p <0.0001
ED Opioids	35%	$873/2520$	49%	$30/67$	α = 0.05 DF = 1
No D/C Opioids	73%	$1928/2639$	54%	$40/71$	p = 0.002 α=0.05
D/C Opioids	27%	$711/2639$	46%	$31/71$	DF=1

We evaluated prescription data characteristics that correlated with provision of ED and discharge opioids in the 71 patients for whom both prescription data was reviewed and discharge data was captured. None of the evaluated filtered-data had a significant effect on provision of opioids during ED care [Table 3] or at ED discharge [Table 4]. We did not capture the time of PDMP data viewing relative to opioid dispensing during ED care and were therefore unable to determine the instances when ED opioid administration preceded PDMP query; our analysis simplistically assumes that query occurred prior to drug administration. It is certainly true, however, that all data was viewed prior to ED discharge prescriptions.

Table 3: Effect of Filtered-View Prescription Data on Provision of Opioid During ED Evaluation

Prescription Attribute	**Low**	**High**	**Δ**	**Effect**	**S.E.**	**Lower 0.95**	**Upper 0.95**	**Wald Statistics**		
								X^2	*d. f.*	*p*
Number of Scripts	0	17	17	-0.14	0.34	-0.80	0.52	0.17	1	0.68
Odds Ratio				0.87		0.45	1.69			
Days since last fill	28	184	156	-0.05	0.14	-0.32	0.22	0.12	1	0.73
Odds Ratio				0.95		0.73	1.25			
Number of Pharmacies	0	4	4	-0.31	0.42	-1.13	0.51	0.54	1	0.46
Odds Ratio				0.73		0.34	1.86			
Number of Prescribers	0	6	6	0.34	0.38	-1.04	0.47	0.81	1	0.37
Odds Ratio				1.41		0.35	1.60			
							Total	1.06	4	0.900

Results of post-study survey of ED attending physician participants

Twenty-five of the 28 study physicians returned surveys. The majority of respondents (68%) had more than 6 years of post-residency clinical experience. Prior to clinical availability of the EHR-integrated PDMP query tool (10/25/2011), six clinicians (24%) did not recall their PDMP-access password, which decreased only minimally after the study, with 5 failing to recall the access password.

Table 4: Effect of Filtered-View Prescription Data on Provision of Opioid Prescription at ED Discharge

Prescription Attribute	Low	High	Δ	Effect	S.E.	Lower 0.95	Upper 0.95	Wald Statistics		
								X^2	*d. f.*	*p*
Number of Scripts	0	17	17	0.5	0.35	-0.18	1.18	2.05	1	0.15
Odds Ratio				1.64		0.83	3.25			
Days since last fill	28	184	156	-0.02	0.12	-0.25	0.22	0.02	1	0.89
Odds Ratio				0.98		0.78	1.24			
Number of Pharmacies	0	4	4	-0.24	0.44	-1.09	0.62	0.29	1	0.59
Odds Ratio				0.79		0.34	1.86			
Number of Prescribers	0	6	6	-0.29	0.38	-1.04	0.47	0.55	1	0.46
Odds Ratio				0.75		0.35	1.60			
							Total	2.16	4	0.70

Respondents acknowledged that they used the PDMP relatively infrequently prior to the advent of the integrated query tool, with 2 indicating they never queried and an additional 9 (36%) admitting less than 1 query in 5 shifts. The 5 most frequent users of the PDMP database claimed 1 or 2 queries per 8-hour shift. After introduction of the integrated PDMP query tool, no respondent indicated that they never queried, 4 (16%) queried fewer than 1 in 5 shifts, 10 (40%) respondents reported 1-2 queries per shifts, and 4 (16%) estimated >2 queries per shift.

When asked whether anything prevented the clinician from querying the Tennessee Controlled Substances Monitoring Database more frequently, prior to the integration of the PDMP query process with the EHR user interface, survey respondents identified the following barriers to database query, as discrete choices: 13 (54%) indicated that the process took too much time; 10 (42%) selected that they were unable to remember the PDMP password and/or login; 5 (21%) felt that the state PDMP website required too much navigation to get the data, and 3 were unable to reliably find the web site. Only 6 (25%) felt that they queried the PDMP database as much as they considered clinically indicated.

In response to a question about patient characteristics that prompted a PDMP query, most respondents indicated patient behavior (n=23, 92%), request for specific opioid (n=21, 84%) and review of past medical history (n=21, 84%), with allergy list (n=13, 52%) and medication list (n=14, 56%) indicated by fewer participants, and patient appearance noted least frequently (n=3, 12%).

Regarding PDMP report features that made participants concerned that a patient may be misusing prescription opioids, respondents noted number of filled prescriptions (n=23, 92%), number of different pharmacies (n=18, 72%), prescription overlap, i.e., new prescription before prior prescription should be exhausted (n=21, 84%), number of different prescribers (n=22, 88%), and non-disclosed opioid prescriptions (n=21, 84%) most frequently. Less frequently noted were geographic location of pharmacy, specific opioid identity, and quantity of pills prescribed.

Respondents were asked to identify features of the EHR-integrated PDMP query tool that they found helpful/ useful. The most frequently identified feature was the decreased time to PDMP data acquisition (n= 21, 84%) and freedom from remembering PDMP login credentials (n=18, 72%); eleven participants (44%) noted the filtered view of the prescription data. Only one respondent indicated that non-printing of the report for data privacy was a helpful feature.

All participants agreed that the state PDMP was either an extremely valuable, indispensible modality to combat drug abuse (n=15, 60%) or a somewhat valuable adjunct to verify suspicious prescription-filling behavior (n=10, 40%). No respondent viewed the PDMP as of limited or no value or as a source of potential patient harm by leading to withholding of indicated pain medication.

When queried about the impact on their clinical practice caused by pending Tennessee legislation to mandate PDMP review prior to controlled substance prescription, three physicians (12%) opined that it would have a significant impact, likely resulting in fewer controlled substance prescriptions and 21 (84%) thought that it would have some impact on time demand but that they would still prescribe controlled substances if clinically indicated; only one provider felt that the legislation would have no impact.

Further, 60% of survey participants (n=15) indicated that an EHR-integrated query process would be imperative if such legislation were enacted and the remaining 40% felt that it would be important but that they could get by with difficulty.

Finally, participants were asked for comments/ suggestions for further implementation of the integrated PDMP query tool, which yielded the following 4 responses:

> "It is a really great tool and if available, I would use it for every patient I saw"
>
> "If we had to look each time we prescribe controlled substances, it would be imperative to have a link/short cut like [you] have implemented. Also, I must say the one kink is that once you click 'GetReport' it takes too long to get to view the report. That would need to be enhanced. It is a great tool. In fact, so great that now I have forgotten my password and can't get into the website like I used to…"
>
> "Needs to be supported institution wide"
>
> "Outstanding addition; miss not having it readily available"

There were two questions that were discovered to have faulty branching logic and were never presented to the survey participants: 1) which of the features of the Tennessee Controlled Substances Monitoring Database in identifying possible controlled substance misuse? ; 2) what features of the integrated PDMP query tool did you not like?

CHAPTER V

DISCUSSION

In response to the action plan issued by the Obama Administration to combat the prescription drug abuse epidemic(5), the Office of the National Coordinator for Health Information Technology (ONC) collaborating with the Substance Abuse and Mental Health Services Administration (SAMHSA) contracted with the MITRE Corporation (McLean, VA) to determine avenues for improving PDMP access by leveraging health information technology (IT). The MITRE Corporation in turn developed the project entitled *Enhancing Access to Prescription Drug Monitoring Programs Using Health Information Technology* and convened work groups composed of individuals from the healthcare community, industry, trade and advocacy groups, and state and federal government. The project action plan was first presented on June 30, 2011(18) and the final work group report was released August 17, 2012(15).

Among the top seven recommendations of the work group were three with direct relevance to this project: 1) "create a common application programming interface (API) for PDMP system level access, …to supplement the stand-alone web portals that exist today for user-level access"; 2) "integrate access to the PDMP data into the clinical workflow—PDMP information should be integrated in EHR and pharmacy systems to varying degrees of sophistication depending on resources and expertise available"; and 3) "define a standard set of data that should be available in PDMP reports(15)." Expanding on those recommendations, the Workflow study group expressly recommended that:

> "Dispensers and prescribers should be granted access to the PDMP system by signing in to the User System…authentication should not interfere with the User's workflow…. dispensers and prescribers should have the ability to click a link in their User System that would allow them to more efficiently access a patient's PDMP data. The link should automatically populate …name, date of birth, address (situational), gender (situational). …Users could provide better patient care if they were able to view this data in the context of the patient's history in the User System. Prescribers and dispensers are more likely to view the PDMP information and use it to make clinical

> decisions when the information is clearly visible in their normal workflow. Therefore, PDMP data should be integrated in EHR and pharmacy systems. Prescribers and dispensers should not be overwhelmed with a cluttered display of PDMP data. Instead, instead they want to view only the most relevant information…[with] the option to view the full list of information."(15)

The design and programming of our integrated query tool began in October 2010 and was placed into limited clinical use in October 2012; although the design preceded the expert workgroup report by almost 2 years and implementation by a year, it is important to analyze our work with that framework in mind. Our tool encompassed all of the above recommendations, within constraints imposed by the Tennessee Board of Pharmacy.

The EHR-integrated PDMP query tool essentially doubled the query rate to the Tennessee Controlled Substances Database in our population of ED patients. The tool was well regarded by the participating ED attending physicians as an enhancement to their workflow; yet query rates were still low, at 6%. In an urban ED population, the incidence of drug seeking patients can be conservatively estimated at 1.5 to 4.2%(19, 20). Although the study was not designed to capture whether a clinician believed that a given patient was abusing prescription drugs, nearly half of the PDMP-queried patients, 3% of the total, did not receive opioids at the time of ED discharge [Table 2]. This implies that clinicians either 1) clinically identified and queried the PDMP for most or all of the drug-seekers presenting to the ED, missing few or none, and provided discharge opioids to every non-drug seeker or 2) failed to query a number of prescription drug abusing patients, choosing not to discharge patients on opioids for other clinical reasons. Anecdotally, the primary investigator, using the tool liberally during development, uncovered prescription abuse in several patients whom he had not clinically suspected of prescription abuse and for whom previous ED providers with PDMP access credentials had recently provided opioid prescriptions. Even before introduction of the integrated PDMP query tool, 20% of survey respondents indicated that they queried the PDMP as often as clinically warranted.

In our study, users were required to initiate the query and then retrieve the query results. In 20% of the cases, the query results were not viewed. In order to better realize the potential for PDMPs and to increase capture rates of prescription opioid abusing patients, a better integrated query tool design would be one that enables an automatic query based on certain patient-specific triggers. Such triggers could include triage or clinic registration, intake pain score, opioid computer order entry, or opioid electronic prescription generation. In addition, rather than relying on the user to retrieve data, our study indicates that filtered prescription data should be automatically presented to the user in a way that works well with work flow. This approach, in fact, is the one advocated by the Enhanced PDMP Access Using IT Work Groups(15) Our decision to not incorporate an automatic trigger was a concession to the Tennessee Board of Pharmacy attorney; our initial plan was to automatically initiate a query at the time of ED triage, on patients with a pain score above 5. Our decision to use a second hyperlink to retrieve data was a pragmatic one based on the primary investigator's programming skills; it would be a trivial matter for a skilled programmer to automate the display of filtered prescription data.

In the spring of 2012, the Tennessee Legislature passed the Prescription Safety Act of 2012, which mandates that, beginning January 1, 2013, all prescribers in the state must obtain credentials to query the Tennessee Controlled Substances Monitoring Database. In addition, the Act requires that practitioners prescribing more than 7 days of controlled substances must query the database prior to issuing a prescription, effective April 1, 2013.(21). The EHR-integrated PDMP query tool would be well suited for integration into the electronic prescription writing process, an enhancement that most of our survey respondents identified as "imperative".

The IT Work Groups recommended development of electronic data filters to identify patients-at-risk for misusing or diverting prescription drugs, such as the number of outstanding prescriptions, the number of dispensers, and the number of prescribers, much as we did in this study. However, our integrated PDMP query tool and PDMP report parser is able to capture not only prescription data from

the PDMP but can also abstract data from the electronic health record as we did with triage pain scores, home opioid use, ED opioid provision, and structured ED discharge data. In addition, we programmed additional integrated query tool modules, not used in this study, to determine polar-arc distances from the latitude and longitude coordinates corresponding to the zip-codes of dispensing pharmacy location, patient home address, ED hospital location, and prescriber location. We also envision capturing allergy data, specifically to opioids and non-opioid (e.g. non-steroidal anti-inflammatory drugs). The combined PDMP prescription data and EHR patient-specific data can be saved in de-identified database tables indexed by unique cryptographic-hash patient identifiers, as we did for this study. If such de-identified data is then expert-reviewed and classified for prescription drug abuse (yes/no), the data can be used to generate robust and sophisticated prediction algorithms, using machine learning techniques. This would allow patient stratification for probability of drug abuse to further aid in the identification of prescription abusing and/or diverting patients.

Study Limitations

The most significant limitation of the study arises from the reliance on a web debugging proxy to code the integrated PDMP query tool. Since tool function is dependent on correct interpretation of server-client messages, any change in the server interface can render the tool inoperative, requiring the tool to be reprogrammed. With an API supplied by the vendor, any changes in server-side function would then be updated in the API by the vendor and distributed to users.

As our study was about to begin, after institutional review board approval, the state PDMP program announced a pending upgrade to the PDMP website with a timetable that would truncate our study or require interruption of the study, re-programming, and resumption, a process that would complicate the study design. Fortunately, because of some delays in the State's implementation of the new database, we were able to complete the study without interruption. However, at this time, the

integrated PDMP query tool is non-functional until it can be re-programmed to correctly interpret the server-client transactions of the revised PDMP database. In addition, during the transition to the new database and new web interface, the state PDMP did not save data for 2 weeks. This data lapse occurred during interval 4, when the integrated tool was available, such that, although we were not able to recover the counts for PDMP query via the review query mechanism on the PDMP website, we did capture the study physicians PDMP queries via the integrated PDMP query tool.

Though the Tennessee Board of Pharmacy attorney opined that an API was not authorized by the original legislation, the language of the revised Prescription Safety Act of 2012 does appear to give more discretion to the PDMP committee of the Board of Pharmacy(21), engendering hope that an API-based query integration could be developed in the future.

While it appears that the use of the integrated PDMP query tool was statistically associated with increased provision/prescription of opioids [Table 2], one must consider that presumably all of the patients for whom the PDMP was queried were candidates for opioids; conversely, even though pain is the number one reason that patient's present for ED evaluation, the proportion of patients with pain complaints relative to patients not having pain is unknown in our study. We did capture pain score in those patients for whom the integrated query tool was run; that was programmed with consideration of future patient-at-risk prediction algorithms. For this study, it would have been more valid to capture pain scores from the ED discharge queue, so that similar populations were compared.

This study was conducted in the ED, a high interest area for prescription drug abuse and an area of interest for the PDMP-IT Work Groups. The generalizability of our results to other areas of the hospital is unclear. Similarly, the applicability of the integrated PDMP query tool to other health enterprises, other EHR systems, or other states PDMPs also is not clear. However, the vendor (Optimum Technology Inc., Columbus OH, www.otech.com) for the Tennessee CSMD is also the vendor for 9 other states and one would expect the web interface to be the same or similar in those states.

CHAPTER VI

CONCLUSIONS

We report the first development and implementation of a query process for a state PDMP that is integrated with a medical center electronic health record user interface. Our tool design anticipated future Office of National Health Coordinator for Health IT work group recommendations. Use of the integrated query tool led to doubling of the rate and frequency of PDMP queries and was highly regarded by users as an enhancement to their workflow. However, as implemented, the integrated PDMP query tool was still underused and 20% of query reports were never reviewed; we agree with the Health IT Work Groups assertions that patient-specific triggers should initiate the query and that data should be displayed automatically within the user workflow after tool-initiated data retrieval.

We also incorporated the capture of de-identified data from the PDMP and the EHR into the PDMP query process; such data can then be used to develop sophisticated algorithms for stratifying patients-at-risk for prescription drug abuse.

Our integrated query tool does not require an API, which at the time of development was precluded by the wording of the state's PDMP statute, as interpreted by the Board of Pharmacy. In the future and based on the ONC Health IT Work Groups recommendations, it is likely that APIs will be incorporated into state PDMPs. However, since the wheels of the legislative process sometimes turn slowly, our approach may have ongoing applicability in the near term if not longer.

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