

Integration of Prescription Drug Monitoring Programs (PDMP) in Pharmacy Practice: Improving Clinical Decision-Making and Supporting a Pharmacist's Professional Judgment

Article Synopsis:

Enforcement action against pharmacists is most prevalent when pharmacists fail to exercise corresponding responsibility. This cross-sectional study examined the relationship between pharmacists' use of Indiana's PDMP and dispensing practices of controlled substance prescriptions (CSP). Changes in dispensing, to dispense fewer CSPs, were attributed to PDMPs increasing access to patient drug histories by 53% of pharmacists. The study found that PDMP users were more likely to report refusing to dispense a CSP. Consistent use of PDMPs in pharmacy practice leads to more refusals of CSPs. Increased access to patient information facilitates pharmacists' ability to detect prescription drug abuse and diversion.

ABSTRACT

1

2 **BACKGROUND:** Pharmacists have shared responsibility to investigate the validity of controlled
3 substance prescriptions (CSPs) that raise red flags and subsequently exercise their right to refuse
4 to dispense a CSP if its validity cannot be verified. Improving access to clinical practice tools,
5 such as prescription drug monitoring programs (PDMPs), may increase availability of a patient's
6 drug history, which is critical to making informed clinical decisions about dispensing CSPs.

7 **OBJECTIVES:** The purpose of this study was to examine how integration and consistent use of a
8 PDMP in pharmacy practice impacts pharmacists' dispensing practices related to CSPs.

9 **METHODS:** A cross-sectional study examined pharmacists' knowledge and use of Indiana's
10 PDMP (INSPECT) and dispensing practices of CSPs. Three outcome measures were analyzed
11 using multiple logistic regression in order to examine the relationship between PDMP use and
12 pharmacists' controlled substance dispensing behaviors.

13 **RESULTS:** Pharmacists were 6.4 times more likely to change their dispensing practice to dispense
14 fewer CSPs if they reported INSPECT provided increased access to patient information.
15 Pharmacists who always use INSPECT refused an average of 25 CSPs annually compared to an
16 average of 7 refusals for pharmacists not using INSPECT. Pharmacists using INSEPCT
17 consistently (at every visit) were 3.3 times more likely to refuse to dispense more CSPs than
18 pharmacists who report never using INSPECT.

19 **CONCLUSION:** Integration of PDMPs in pharmacy practice may improve a pharmacist's ability
20 to make informed clinical decisions and exercise sound professional judgment. Providing
21 clinical practice tools to both prescribers and pharmacists is important to preventing drug
22 diversion and prescription drug abuse in the United States. Future research should focus on

23 understanding the barriers and challenges to successful integration of PDMPs in pharmacy
24 practice.

25 INTRODUCTION

26 In 2015, the Center for Disease Control and Prevention (CDC) reported that drug deaths
27 related to prescription opioids have remained stable since 2012. This may suggest that the
28 United States is gaining some ground in regards to fighting the epidemic of nonmedical use of
29 prescription drugs. However, there remains a significant amount of work to be done to improve
30 the prevention and treatment of substance abuse.¹ In 2007, the CDC reported that every 19
31 minutes someone dies from an unintentional prescription drug overdose in the United States,
32 which resulted in 27,000 deaths in 2007 alone.² If the number of deaths related to prescription
33 drug abuse is not alarming enough, the CDC reports that for every unintentional overdose, “9
34 persons are admitted for substance abuse treatment, 35 visit emergency departments, 161 report
35 drug abuse or dependence, and 461 report nonmedical uses of opioid analgesics”.² Prescription
36 drug abuse is by no means a new problem in the United States. However, the continued growth
37 and the current scale of the problem has reason to raise serious concern.³ The distribution of
38 opioid drugs has increased by over 7 times between 1997 and 2007.² Unfortunately, with this
39 increase in distribution of opioid drugs comes an increased risk of drug diversion. Drug
40 diversion occurs when prescription drugs are used for recreational purposes, and thus are
41 “diverted” from their original purpose.^{4,5} Although, drug diversion can occur at various stages
42 of the prescribing and dispensing process, the pharmacist may be the “last line of defense”.^{4,5}

43 Federal regulation 21 C.F.R. § 1306 requires that prescriptions for controlled substances
44 be issued for legitimate medical purposes by individual practitioners acting in the usual course of
45 their professional practice.^{4,5} That same law imposes responsibility on pharmacists who fill the

46 prescriptions. If pharmacists knowingly fill improper or invalid prescriptions, they, as well as the
47 prescribers, can be held accountable.^{5, 6} Similarly, state law requires pharmacists performing
48 their duties to exercise professional judgment that is in the best interest of their patients' health.
49 Before honoring prescriptions, pharmacists are required to take reasonable steps to determine
50 whether a prescription has been issued in compliance with state law.⁴ According to federal
51 regulation 21 C.F.R. § 1306, a pharmacist may refuse to fill a prescription if professional
52 judgment suggests filling it would be contrary to law, be against the best interest of the patient,
53 aid or abet an addiction or habit, or be contrary to the health and safety of the patient.⁴
54 Unfortunately, making a clinical decision to refuse to dispense a controlled substance may prove
55 difficult for many pharmacists due to a variety of factors that block or inhibit their ability to
56 make an evidence-based clinical decision such as lack of patient information or lack of evidence-
57 based resources.⁷

58 In recent decades, Prescription Drug Monitoring Programs (PDMPs) have become more
59 prominent across the United States. A PDMP is a statewide electronic database that collects
60 detailed data on controlled substance prescriptions (CSPs) in a state.^{8, 9} As of 2013, 49 states
61 had enacted legislation to develop PDMPs, and 48 states have implemented these programs.⁸
62 PDMPs can help identify major sources of prescription drug diversion such as prescription fraud,
63 forgeries, doctor shopping and improper prescribing and dispensing practices.¹⁰ PDMPs have
64 proven to be invaluable tools in fighting the growing prescription drug abuse epidemic in the
65 United States by reducing drug diversion of controlled substances and improving clinical
66 decision-making through increased access to detailed patient drug histories for both prescribers
67 and dispensers.¹⁰

68 In 2004, the State of Indiana expanded previous legislation and secured grant funding to
69 establish the Indiana Scheduled Prescription Electronic Collection and Tracking Program
70 (INSPECT), Indiana's PDMP, in order to provide an additional clinical resource to ultimately
71 improve providers' clinical-decisions by expanding access to their patients prescription drug
72 histories. An INSPECT report summarizes all CSPs a patient has been prescribed and includes
73 information regarding the practitioner(s) who prescribed the controlled substance as well as the
74 pharmacy and pharmacist who dispensed the CSP.¹¹ Although, a growing body of evidence
75 suggests that incorporation of PDMPs are effective in increasing clinical-decision making by
76 providing greater access to patient drug information, nearly 30% of providers in Indiana report
77 not using INSPECT, according to a 2012 study conducted by the Indiana University Center for
78 Health Policy (CHP).^{10, 12} While Indiana pharmacists were significantly more likely to have
79 heard of INSPECT they, unfortunately, were not more likely to have reported using the program
80 in their pharmacy practice.¹²

81 Pharmacists may be considered the "gatekeepers" of the controlled substances that have
82 had such an impact on the prescription drug abuse epidemic in the U.S. As the "last line of
83 defense," pharmacists are challenged with ensuring that patients being treated for legitimate
84 chronic pain have access to their CSPs, while identifying CSPs that have not been prescribed for
85 a valid medical purpose.⁸ Furthermore, pharmacists have the responsibility to investigate the
86 validity of CSPs that raise red flags, resolve these red flags, and ultimately exercise their right to
87 refuse to dispense a CSP if the validity of the prescription cannot be verified.

88 PDMPs are valuable clinical resources that provide pharmacists with additional
89 information regarding their patients. This increased access to patient data facilitates pharmacists
90 ability to detect prescription drug abuse and diversion.¹³ In a study conducted by Fleming et al.,

91 pharmacists were prompted to use a PDMP in order to confirm suspicions of forgery related to
92 CSPs.¹³ Another study examined variations in pharmacy practice between users and non-users of
93 PDMPs. This study suggested that PDMP users were less likely to discuss concerns of suspicion
94 of drug diversion with the patient, but were as likely to contact the provider, refer the patient
95 back to the provider, and refuse to fill the prescription.¹⁴ The results from these two studies
96 suggest that utilization of PDMP data to investigate CSPs when there is a question to their
97 validity may increase a pharmacist's level of confidence to take action and to exercise
98 corresponding responsibility.¹³

99 The purpose of this study is to examine how integration and consistent use of a PDMP in
100 pharmacy practice impacts pharmacists' dispensing practices related to CSPs. The study aims to
101 determine if the use of INSPECT as a clinical resource in pharmacy practice: (1) promotes a
102 change in practice to dispense fewer CSPs, (2) increases the likelihood of a pharmacist to report
103 having refused to dispense a CSP, (3) and whether and to what extent more consistent use of
104 INSPECT influences a pharmacist's total annual refusals of CSPs. As more and more evidence
105 suggests that PDMPs are effective in reducing drug diversion and improving clinical decision-
106 making, it is believed that pharmacists who report more consistent use of INSPECT in their
107 pharmacy practice will be more likely to refuse dispensation of CSPs as a result of increased
108 access to patient information that provides the data necessary to support their professional
109 judgment.¹⁰

METHODS

110

111 **Study Design**

112 *Survey & Data Collection*

113 The study population included 10,606 providers who were identified by the IPLA as a
114 pharmacist in the State of Indiana who held a valid license to dispense controlled substances in
115 2012. This cross-sectional study examined survey data collected from Indiana pharmacists
116 through the *IPLA INSPECT Knowledge and Use Survey*.¹² The survey was developed through a
117 collaborative effort between representatives from IPLA, the Indiana State Prescription Drug
118 Abuse Prevention Task Force Education Committee, and the Indiana University Purdue
119 University – Indianapolis (IUPUI) Center for Health Policy (CHP). The web-based survey was
120 designed to gather information on pharmacists' practice characteristics and behaviors as well as
121 key information about their knowledge and use of INSPECT. At the request of the CHP, IPLA
122 sent an initial electronic invitation to all eligible practitioners as well as 3 follow-up reminders to
123 complete the survey. The study was sanctioned by the Indiana Board of Pharmacy, and the study
124 design and methods was reviewed and approved by Indiana University Institutional Review
125 Board.

126 Of the 10,606 eligible pharmacists, a total of 1,582 completed the survey yielding an
127 overall response rate of 15%. Due to the relatively low response rate for this survey, basic
128 demographics of the study sample were compared to Indiana's 2012 Pharmacist Workforce Data
129 to ensure the sample was representative of Indiana's total pharmacist population.¹⁵ Table 3
130 illustrates the demographic characteristics for both the study sample and Indiana's pharmacist
131 workforce in 2012. The table also includes other demographic and practice characteristics
132 collected from the survey, which are relevant to this study. The sample exhibited similar

133 characteristics to Indiana's 2012 Pharmacist workforce in regards to age, years practicing, and
134 gender.

135 **Study Variables**

136 The study contained 3 primary outcome measures, which include (1) dispensation
137 change, (2) refused dispensations, (3) and annual refusals. Operational definitions for the
138 outcome measures are included in Table 1. Contextually relevant demographic and practice
139 characteristics were included in all analysis as covariates to control for factors that may influence
140 the relationship between the primary outcome measure and the dependent variable.

141 One important practice characteristic that is commonly included in pharmacy research is
142 degree type (PharmD, MPharm, BPharm). This measure is typically included to control for
143 variations in education and training that may influence pharmacists' attitudes beliefs, practice
144 characteristics as well as clinical knowledge. Degree type was not available in the data for this
145 study. Instead, a new variable, training period, was generated to capture the important
146 characteristics associated with variations in professional training. Training period is a 3 level
147 categorical variable that indicates at what period in time the pharmacist went through training
148 and was calculated based on the number of years in professional practice. Pharmacists practicing
149 today were trained in one of three distinct cohorts, which are bound by events relating to the
150 adoption of the Doctorate of Pharmacy as the sole entry degree for the profession. The
151 parameters for training period are described in Table 2. Training period was incorporated as a
152 covariate in all the statistical models for this study in order to control for variations in education
153 and training.

154 **Data Analyses**

155 All statistical analyses were performed using SAS Statistical Software 9.4[®]. The 3
156 outcome variables were assessed with determination of odds ratio (OR) estimates and 95% Wald
157 confidence intervals (CIs). Descriptive statistics (frequencies, means, and standard deviations)
158 were performed when appropriate. Practice and demographic characteristics as well various
159 independent response variables were analyzed using independent samples t tests or one-way
160 analysis of variance (ANOVA).

161 *Multiple Logistic Regression*

162 In order to perform a binary logistic regression, the outcome measure dispensation
163 change was dichotomized into, 'dispensed fewer' or 'dispensed more', CSPs. The primary
164 independent variable of interest was whether or not respondents indicated that INSPECT was a
165 factor leading to their dispensation change. Backward elimination was used to fit the model and
166 to include all conceptually relevant independent variables in order to reduce possibility of a
167 suppressor effect within the model.¹⁶ These variables were removed one by one and the
168 procedure determined the contribution of each variable at each step. All significant independent
169 variables identified through this process were retained in the multiple regression analysis. The
170 same process was followed for the other two (2) outcome measures. Refused dispensation, a
171 binary variable, was analyzed in similar fashion using a binary logistic regression model to
172 determine if reported use of INSPECT increased the likelihood of a pharmacist reporting at least
173 one (1) refusal in the past 12 months.

174 The last outcome measure, annual refusals, was analyzed to determine to what degree
175 various practice characteristics, such as the frequency of INSPECT use, influences a
176 pharmacist's reported number of annual CSP refusals. The annual refusal data were categorized

177 into five (5) groups due to a non-normal distribution of the data which was revealed by execution
178 of Kolmogorov-Smirnov test for normality ($D=.24$, $P<.01$). As a result, these data were
179 analyzed using a multiple ordinal logistic regression model.

180 **RESULTS**

181 **Demographics**

182 The majority of respondents reported working in an outpatient setting (73.9%) compared
183 to an inpatient setting as reported in Table 3. There were more male (54.4%) than female
184 respondents. The mean age of respondents was 46.9 years of age. The average years practicing
185 was 20.8 years with more than half the respondents having 20 or more years of experience.
186 Nearly all respondents reported having heard of INSPECT (94.3%) prior to receiving the survey.
187 However, only 71.8% of the respondents who had heard of INSPECT reported using it.

188 **Change in Dispensation Practice of CSPs**

189 A total of 506 (37.6%) respondents indicated that they had changed their dispensing
190 practice related to CSPs in the last 12 months. Of those who reported changing their dispensing
191 practices, significantly more respondents (74.7%) reported a change to dispense fewer CSPs (X^2
192 = 183.0, $p < .0001$) compared to those who reported a change to dispense more CSPs.

193 Respondents were also asked to report on the factors that led to the dispensation change. The
194 frequencies for the various factors leading to a dispensation change are provided in Table 4. The
195 most frequently reported factors leading to a change in dispensing practice of CSPs were:

- 196 (1) New professional practice standards and protocols
- 197 (2) INSPECT providing greater access to patient prescription drug history
- 198 (3) Increased professional awareness of risks, benefits, and other solutions.

199 As illustrated by these data, in table 4, more than half (53%) of pharmacists reporting a change in
200 their dispensing practice attribute the change to INSPECT increasing access to patient
201 prescription drug history. Pharmacists were 6.4 times more likely to report a dispensation
202 change to dispense fewer CSPs, if they also reported that increased access to patient prescription
203 drug history through INSPECT was a factor leading to the change (OR = 6.4, 95% CI, 3.437 –
204 11.862).

205 **Refused Dispensation of CSPs**

206 Significant variations in pharmacists' decision to refuse to dispense a CSP existed within
207 several practice and demographic characteristics including pharmacy setting, gender, training
208 period, and use of INSPECT. These data are provided in Table 5. Outpatient pharmacists were
209 21 times more likely to have refused to dispense a CSP compared to inpatient pharmacists (OR =
210 20.9, 95% CI, 11.007 – 39.836). Practitioners who trained in Cohort 1 were 2.4 times more
211 likely to refuse to dispense a CSP compared to pharmacists trained in Cohort 3 (OR = 2.4, 95%
212 CI, 1.343 – 4.218). In other words, pharmacists trained after full implementation of the
213 Accreditation Council for Pharmacy Education (ACPE) new accreditation and standards
214 guidelines were more confident in refusing dispensing a CSP. Also, male pharmacists were 2.5
215 times more likely to have reported refusing dispensation of a CSP in the past 12 months
216 compared to females (OR = 2.5, 95% CI, 1.454 – 4.204). Multiple logistic regression analysis
217 indicated that pharmacists who reported using INSPECT were significantly more likely to have
218 refused dispensation of a CSP compared to practitioners who did not use INSPECT (OR = 2.2,
219 95% CI, 1.339 – 3.693).

220 **Annual Refusals of CSPs**

221 Pharmacists may be more likely to refuse to dispense a CSP if using INSPECT, but the
222 study aimed to further examine the relationship between consistent use of INSPECT and the
223 magnitude of refusals reported by pharmacists. Table 6 provides the mean number of refusals
224 based on key practice and demographic characteristics. Pharmacists who reported never using
225 INSPECT only refused to dispense 6.9 CSPs on average per year. However, pharmacists who
226 have completely integrated INSPECT into their professional practice and report always using the
227 program, refused to dispense 24.8 CSPs on average per year. The multiple logistic regression
228 model demonstrated that practitioners who reported using INSPECT “Periodically” or “At every
229 visit” were statistically more likely to refuse to dispense more CSPs than pharmacists who
230 reported never checking INSPECT ($OR_{periodically} = 3.0$, 95% CI, 1.351 – 6.763; $OR_{everyvisit} = 3.3$,
231 95% CI, 1.307 – 8.465).

232 **DISCUSSION**

233 Reducing prescription drug abuse in the United States is a multifaceted and intricate
234 process that must be addressed from multiple perspectives. One of the major driving forces
235 responsible for prescription drug abuse is the rise in opioid prescribing rates throughout the U.S.
236 The number of opioid prescriptions dispensed by retail pharmacies has increased consistently
237 since 1991.¹⁷ General prescribing practices, high-volume prescribing, or even pill mills directly
238 influence the increasing rates of opioid prescriptions being dispensed by retail pharmacies.¹⁷
239 Regardless of the original source of these prescriptions, pharmacists share responsibility with the
240 prescriber to ensure that these prescriptions are issued for a valid medical purpose.

241 DEA regulation 21 C.F.R. 1306.04 defines corresponding responsibility and understands
242 that pharmacists play an integral role in preventing the diversion of controlled substances.⁶

243 Under this regulation, pharmacists are instructed to “exercise their professional judgment to
244 determine whether a prescription for a controlled substance was issued for a legitimate reason”.⁵
245 Unfortunately, pharmacists frequently find themselves in precarious situations where they must
246 determine if a controlled substance prescription was issued for a legitimate medical purpose by a
247 practitioner acting in the usual course of professional practice. Many times pharmacists in these
248 situations have few resources and have limited access to patient information needed to make
249 sound clinical-decisions. Maxwell et al., suggested that the limited access to patient information
250 fundamentally hampers pharmacists’ abilities to make informed clinical-decisions.¹⁸

251 The Department of Health and Human Services (DHHS) identified ‘clinical practice
252 tools’, such as PDMPs, as 1 of 8 primary domains necessary to preventing prescription drug
253 abuse.¹⁷ PDMPs may alleviate, to some degree, pharmacists’ lack of access to patient
254 information. One of the primary purposes of PDMPs is to increase access to patient prescription
255 drug histories, which are critical to making informed clinical-decisions and exercising good
256 professional judgment. According to the PDMP Center for Excellence, evidence continues to
257 suggest that PDMPs are valuable tools for providers that ultimately may improve clinical
258 decision-making and help reduce diversion of controlled substances.¹⁰

259 This study set out to explore the use of Indiana’s prescription drug monitoring program as
260 a support tool for improving clinical decision-making among pharmacists. It also examined the
261 influence PDMPs have on CSP dispensing behaviors. The results from this study suggest that the
262 use of INSPECT may lead to a reduction in CSP dispensing, which is illustrated by an increased
263 likelihood of pharmacists to modify their dispensing practice to dispense fewer CSPs as a result
264 of increased access to a patient’s drug history. This also suggests that PDMPs may, in fact,

265 provide more information to pharmacists that may help to inform and support their professional
266 judgment to exercise corresponding responsibility.

267 Not only did the use of INSPECT result in a reported reduction of dispensed controlled
268 substances by pharmacists, but pharmacists were more likely to report refusing to dispense CSPs
269 if they used INSPECT. In this regard, our data suggest that the use of INSPECT may facilitate
270 pharmacists to exercise corresponding responsibility. We suspect that this is due to PDMPs
271 providing greater access to patient information that serves as evidence to support their
272 professional judgment to refuse to dispense a CSP in the event they are unable to resolve an
273 identified red flag while processing a prescription.

274 Additionally, more consistent use of INSPECT was significantly more likely to result in a
275 higher number of refusals to dispense controlled substances by a pharmacist. Practitioners who
276 reported using INSPECT periodically or at every visit were significantly more likely to refuse to
277 dispense a CSP as compared to pharmacists who reported never using INSPECT. This finding
278 further exemplifies the notion that the integration and consistent use of INSPECT in pharmacy
279 practice may provide pharmacists with the information necessary to be confident in their
280 professional judgment and clinical decisions.

281 The findings from this study are consistent with findings from previous studies which
282 concluded that PDMPs increase a pharmacist's level of confidence in their clinical decisions and
283 professional judgment.^{13, 14} This study adds a unique dimension to the growing body of literature
284 surrounding prescription drug diversion and abuse, as the majority of current literature examines
285 the overall effectiveness of PDMPs and the role of prescribers in reducing drug diversion and
286 prescription drug abuse.¹⁰ Less research is available regarding the impact PDMPs have on
287 pharmacists' dispensing practice relating to CSPs. This study was one of the first known studies

288 to quantify pharmacists' professional judgment to refuse to dispense a CSP by examining the
289 number of refusals reported by pharmacists.

290 **Study Limitations**

291 As PDMPs are now implemented in 49 states, there is a need for research that is capable
292 of evaluating their effectiveness in reducing drug diversion throughout the country. Many states
293 have started to evaluate these programs, but there are some limitations. The primary limitation
294 to this study was response bias. Issues of drug diversion and prescribing or dispensing practices
295 are considered to be controversial by many providers. Pharmacists may be hesitant to disclose
296 information regarding dispensing practices due to fear of legal ramifications. It is likely that
297 response bias may result in an overestimate of pharmacists reported number of refusals of CSPs.
298 However, the *IPLA INSPECT Knowledge and Use Survey* was administered as an anonymous
299 survey to help limit the potential response bias. Furthermore, the response rate for the survey
300 was low and may be a limitation to the study. However, measures were taken to compare
301 Indiana's pharmacist workforce to the study's sample in order to determine if the sample was
302 similar to that of Indiana's pharmacist workforce. Lastly, the study was conducted within one
303 state, Indiana. Therefore the generalizability of these findings to other states may be a limitation.
304 In light of these limitations, the study findings should still be considered due to their implications
305 and consistency with previous literature.

306 **CONCLUSION**

307 The Drug Enforcement Agency states that enforcement action against pharmacists is
308 most likely to occur when pharmacists fail to exercise corresponding responsibility.⁵
309 Unfortunately, the interpretation of what constitutes "exercising corresponding responsibility" is,
310 to some degree, up for discussion. The DEA does indicate that pharmacists must identify and

311 resolve red flags prior to dispensing a controlled substance. Red flags arise as a result of pattern
312 prescribing, fraudulent prescriptions, paying cash, or geographic anomalies, to name a few. Yet,
313 lack of access to complete patient information as well as segmented relationships between
314 pharmacists and physicians make resolution of red flags a time consuming and tedious task.
315 These challenges may actually make exercising corresponding responsibility for pharmacists
316 quite difficult. However, this study suggests that pharmacists who consistently use prescription
317 drug monitoring programs in their pharmacy practice are over 3 times more likely to refuse
318 controlled substance prescriptions as compared to those pharmacists who do not use a PDMP as
319 a clinical practice tool. Implementing policies, strategies, and practices that support pharmacists
320 in fulfilling their duty to “exercise his/her independent judgment when determining whether a
321 prescription was issued for a legitimate medical purpose by a practitioner acting in the usual
322 course of professional practice”⁵, are vital to reducing diversion of prescription drugs. Future
323 research should focus on understanding the barriers and challenges to successful integration of
324 PDMPs in pharmacy practice.

325 **Acknowledgements**

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327 acknowledge the collaborative effort between the Indiana Professional Licensing Agency, the
328 Indiana State Prescription Drug Abuse Prevention Task Force Education Committee, and the
329 Indiana University Purdue University – Indianapolis (IUPUI) Center for Health Policy (CHP)
330 which led the development of the *IPLA Knowledge and Use Survey* used in this study. The
331 content is solely the responsibility of the authors and does not necessarily represent the official
332 views of the Indiana Board of Pharmacy or the aforementioned collaborators.

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Table 1

Operational definitions for study outcome measures

Outcome Measure	Operational Definition
Dispensation Change	<i>Dispensation change</i> is binary variable that identifies if a pharmacist reported a change in dispensing practice to dispense fewer or more controlled substances in the past 12 months. (dispense fewer=1, dispense more=0)
Refused Dispensation	<i>Refused dispensation</i> is a binary variable that indicates if a pharmacist reported refusing to dispense a controlled substance within the past 12 months. (Yes=1, No=0)
Annual Refusals	A pharmacist's total number of reported refusals to dispense a controlled substance within the past 12 months was an ordinal categorical variable with 5 categories. <i>Category 1:</i> < 1 refusals per year <i>Category 2:</i> 1-5 refusals per year <i>Category 3:</i> 6-10 refusals per year <i>Category 4:</i> 11-20 refusals per year <i>Category 5:</i> > 20 refusals per year

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Table 2
Parameters used to determine training period cohorts

<i>Training Period</i>	<i>Description</i>
Cohort 1	Pharmacists trained after complete transition to the PharmD as the sole entry degree for the pharmacist profession and full implementation of ACPE's ¹ new accreditation standards.
Cohort 2	Pharmacists trained during the transition to the Doctor of Pharmacy (PharmD) as the sole professional practice degree for pharmacy in the United States and after the adoption of ACPE's new accreditation standards in 1997.
Cohort 3	Pharmacists trained prior to the adoption of ACPE's ¹ <i>Implementation Procedures for Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Education</i> . New accreditation standards and guidelines were adopted in June of 1997.

338 ¹ Accreditation Council for Pharmacy Education

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Table 3

Descriptive statistics for key demographic and practice characteristics of study sample

Demographic Characteristic	IPLA INSPECT Survey Sample	2012 Indiana Pharmacist Workforce Data	Statistic
	N (%)	N (%)	
Age (years)	Mean ± SD, 46.9 ± 13.7	Mean ± SD, 46.3 ± 12.4	P > .05
Years Practicing	Mean ± SD, 20.8 ± 14.0	Mean ± SD, 20.3 ± 12.9	P > .05
Gender			X ² = .417, P > .05
Female	833 (54)	4963 (58)	
Male	699 (46)	3645 (42)	
Race/Ethnicity (n=1523)^a			
White/non-Hispanic	1,408 (93)		
Asian American/ Pacific Islander	52 (3)		
Black/non-Hispanic	28 (2)		
American Indian/ Alaska Native	6 (0)		
Hispanic/Latino	15 (1)		
Training Period			
Cohort 1	412 (27)		
Cohort 2	483 (31)		
Cohort 3	630 (41)		
Pharmacy Setting			
Inpatient	353 (26)		
Outpatient	1,000 (74)		
Heard of INSPECT			
Yes	1,469 (94)		
No	88 (6)		
Used INSPECT			
Yes	1,043 (72)		
No	410 (28)		
Frequency of INSPECT			
At every visit	73 (8)		
Periodically	799 (78)		
Never	39 (4)		

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Table 4
Frequency of factors which led to a change in dispensing practice of controlled substance prescriptions

What factors led you to change your dispensing practices? (N=497)	N (%)
New professional practice standards and protocols	276 (56)
INSPECT providing greater access to patient prescription drug history	263 (53)
Increased professional awareness of risks, benefits, and other solutions	249 (50)
Increased state or federal guidelines and recommendations	193 (39)
Change in my patient mix	121 (24)
I am afraid of legal ramifications	103 (21)
Increased law enforcement activity	65 (13)
Increased referrals from other physicians/providers for treatment of chronic pain patients	63 (13)
Increased patient awareness of risks and benefits	38 (8)
Increased referrals from other physicians/providers for treatment of acute (surgical/traumatic/short-term) pain patients	37 (7)
Other	72 (15)

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Table 5
Pharmacists reported refusal to dispense a controlled substance prescription by key demographic and practice characteristics

Characteristic	Refused to Dispense	Did Not Refuse to Dispense	Total Responses	X ²	P-Value
	N (%)	N (%)			
Pharmacy Type			1,222	233.1	< .0001
Inpatient	217 (70)	94 (30)			
Outpatient	896 (98)	15 (2)			
Gender			1,305	12.6	0.0004
Female	639 (88)	85 (12)			
Male	546 (94)	35 (6)			
Training Period			1,337	13.0	0.0015
Cohort 1	330 (88)	46 (12)			
Cohort 2	386 (90)	45 (10)			
Cohort 3	500 (94)	30 (6)			
Have you ever used INSPECT?			1,254	57.2	< .0001
Yes	890 (95)	51 (5)			
No	252 (81)	61 (20)			

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Table 6
Pharmacists reported annual refusals to dispense controlled substance prescriptions by key demographic and practice characteristics

Characteristic	Mean (SD)	Statistic	P Value
Pharmacy Type		-10.36	< .0001
Inpatient	2.6 (5.3)		
Outpatient	21.2 (25.6)		
Gender		-2.01	0.045
Female	15.7 (22.7)		
Male	18.6 (25.5)		
Training Period		3.21	0.041
Cohort 1	19.4 (26.2)		
Cohort 2	18.4 (25.2)		
Cohort 3	15.5 (22.3)		
Frequency of INSPECT Use		5.68	0.004
Never	6.9 (13.1)		
Periodically	18.6 (23.9)		
At Every Visit	24.8 (27.3)		

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352 **REFERENCES**

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