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Pharmacist perception of opioid overuse for analgesia in the retail setting

Kenneth Jacob Craig
Butler University

Josh Winebough

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Thesis adviser(s) Kimberly Beck 5/8/11
Date

Reader(s) Jane Lewasio 6/3/11
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May 14, 2011

Pharmacist Perception of Opioid Overuse for Analgesia in the Retail Setting

A Thesis

Presented to the Department of Pharmacy

College of Pharmacy and Health Sciences

and

The Honors Program

of

Butler University

In Partial Fulfillment

of the Requirements for Graduation Honors

Kenneth Jacob Craig and Josh Winebaugh, Pharm.D. candidates

May 14, 2011

TITLE

Pharmacist perception of opioid overuse for analgesia in the retail setting.

INTRODUCTION

Opioid analgesics are a class of medications with affinity for receptors in the brain which are naturally targeted by endogenous opioid peptides to exert neuromodulatory action.¹ Long before this target pathway was ever elucidated, ancient cultures had documented use of a naturally occurring plant derivative, opium, which provided the same effects as opioid drugs today. The active alkaloid constituent of opium is morphine. The human body's equivalents of these substrates interact with multiple types of opioid receptors which produce the effects responsible for pain relief. In addition, there are also unwanted side effects including constipation, emesis, and respiratory depression. Contributing to those undesirable factors, are receptor-induced responses such as euphoria, tolerance, and physical dependence which provide a causal link to medication abuse.²

While there have been multiple studies done which evaluate the efficacy of opioids in chronic pain, that determine the pain relief achieved by opioids versus placebo, and those relating structural modifications to potency and receptor specificity, an initial literature search of the relationship of chemical changes to the opioid ring system to overutilization of the analgesics shows a lack of information. The rate of use among the general public is growing at a rapid pace, with certain opioid prescriptions experiencing an 800% rise in fill rate over the past decade alone.³ It has been asserted that this class of medications is the most commonly prescribed in the entire US.⁴ Although that may be true in terms of prescription volume, just greater than 3% of adults are on chronic opioid therapy for treatment of pain not related to

malignancies,⁵ with chronic treatment being defined as consecutive usage for greater than three months time.

NEED FOR THE STUDY

There appears to be a lack of literature on the specific topic of interest, but the focus was to associate professional judgment in the practice setting to a growing crisis noted in the aforementioned studies. Since frequent refills may be linked to dependence or diversion, findings from this study alert physicians and other healthcare providers to make informed decisions when considering analgesic therapy regimens of the double-edged sword balancing legislation, prescribing, and dispensing to best serve patients. Created awareness could help reduce the prevalence of overdose in scheduled analgesics which has been noted and subsequently reviewed by many other previous clinical studies.^{6,7}

Pharmacists are noted as champions for advocating patient safety, and publicizing this data would serve the same purpose.

Unfortunately, permission could not be obtained to collect retrospective chart data on actual patients because of perceived liability. Considering the medications being studied were controlled in nature and the original objective was to ascertain the potential for opioid abuse and overuse, the managers in charge of pharmacy records were highly reluctant to allow participation despite guarantee of anonymity in writing. Instead, the design of the study was altered to gather information regarding pharmacists' perception pertaining to this class of medications to gauge the reality of previous reports regarding explosion of opioid prescribing, abuse, and overdoses.

STUDY OBJECTIVES

This research will help to answer the question, "do practicing retail pharmacists have any qualms about the state of opioid prescribing, legislation, and usage among the public?" To help determine if this premise has been satisfied, the null hypothesis would state "pharmacists, to differing degrees, are comfortable with opioid prescribing, legislation, and usage at present." If the null hypothesis were true, the research question would serve to alleviate fears and concerns raised amongst other research. Conversely, the directional hypothesis supported by this study reads "opioids are rightfully classified as controlled substances in the view of front-line pharmacists due to their high incidence of early fill requests."

METHODS

The data for this study was collected directly from pharmacists' survey responses in the retail setting. Those eligible for inclusion in the survey were either employed by a drugstore chain in Fort Wayne, IN, Indianapolis, IN, or Rockford, IL regions or licensed dispensers in Hardin County, KY.

The goal return for the study was forty responses, to be equally split between each of the four areas. While power was not calculated due to conducting a survey as opposed to a randomized controlled trial, this was theorized to give a random assortment of answers. The respondents would represent three separate states; a metropolitan district, two moderate sized cities, and a small town would be analyzed; and finally it comprises largely chain participants but small retail independents are also included in the study data.

A survey was designed for administration to pharmacists to garner information relevant to the study topic at hand. This was reviewed by Priscilla Ryder, MPH for accuracy and completeness with her expertise in conducting research. For the portion completed by Keny Craig, Pharm.D. candidate, a list of pharmacies inside Hardin County, KY was created. Each of these stores were called to obtain responses from the pharmacist on duty, requiring anywhere from 5-10 minutes of their time. Josh Winebaugh, Pharm.D. candidate, received consent from chain drugstore district managers to distribute a link to Survey Monkey which enabled collection of responses from a diverse range of locations. Although the setup allowed for multiple choice responses for simplicity, some of which were Likert scale, there was ample opportunity to provide additional feedback in the form of open-ended questions expounding on certain options, as well as, an all-encompassing comments section to conclude the survey.

“Other” categories were often options in the survey to include all potential answer choices. Confusion about questions potentially leading to misguided answers was a concern addressed by devising split administration – part by electronic means and the other via telephone with provision of assistance. Electronic means was a trusted, online survey administration site versus the discussion of questions with the responding pharmacist through a phone call. Even offering assistance and additional meaning to questions could be considered “interpretative” and therefore biased. Despite not having a perfect scenario to elicit this information, efforts were made to minimize potential threats to study validity.

In order to provide adequate background and properly define terms, “narcotics” were intended to mean C-II (controlled class 2) opioids versus “other controlled” which would comprise C-III through C-V (controlled classes 3-5) primarily because of differing legislation

between groups. KASPER, INSPECT, and PIL are online reporting systems maintained by individual state boards of pharmacy which compile controlled prescription fill data through use of social security number and/or driver's license to provide unique patient identifiers in an attempt to minimize fraud through use of aliases.

Survey Monkey assembled all electronic records created by the online participants⁸. Josh Winebaugh, later compiled the additional results from the Kentucky arm of the study for a complete statistical analysis and compilation of the solicited feedback other than the directed twelve questions.

Since there may be potential value in the initial design for conducting a retrospective chart review, the proposed data collection sheet is still included as Appendix A. The survey questionnaire is listed in Appendix B.

STATISTICAL ANALYSIS

The multiple choice responses limit the extent of statistical analysis beyond simple percentage component breakdowns. Subgroup analysis is completed for telephone survey versus electronic administration as well as Illinois-Indiana-Kentucky cohorts and provided in chart format for ease of review. Differences may or may not be uncovered to varying degrees and significance will be assessed based on the discrepancies noticed. The intrigue of variations between subgroups relate to true deviations in practice between areas, possibly different training, altered patient populations, or may suggest the presence/absence of overuse and abuse in the given group of interest.

RESULTS

The study in all generated forty-seven data sets. Of these: three were from Rockford, IL (6%), eight from Fort Wayne, IN (17%), nine from Indianapolis, IN (19%), and thirteen from Hardin County, KY (28%). The remaining fourteen electronic respondents selected “other” for area of practice accounting for the last 30% [Table 1].

Table 1 - Participant Demographics

Place of Practice	Number of Participants
Kentucky	13
Fort Wayne	8
Indianapolis	9
Rockford	3
Other	14

Most pharmacists suggested CII “narcotics” were less likely to be abused (19%) than other types of controlled opioids (45%), with 36% attributing equivalent potential for overuse [Figure 1]. But when asked which category typically filled earlier, the majority (62%) assessed no difference. 64% of those surveyed communicated that they denied a patient’s refill request due to early utilization less than 20% of the time [Figure 3]. Over two-thirds of pharmacists (68%) stated that customers used a mix of cash and prescription coverage (state funded Medicare/Medicaid, insurance, discount programs, etc.) to fund their prescription cost. The majority of feedback generated noted that customers termed ‘abusers’ paid with cash, though this only accounted for 19% of answers overall. The remaining 13% cited a mixture of both options [Figure 2]. All three states where pharmacists were interviewed offer an online database with the specific purpose of listing controlled substance fills, although nearly half (49%) of pharmacists used the resource monthly or less often [Figure 4]. Despite the lack of use ascribed above, 68% of pharmacists felt somewhat comfortable or neutral with concern to

ease of use for these systems [Figure 5]. Over half of those completing the survey (57%) indicated they encountered out-of-state controlled prescriptions more often than monthly [Figure 6]. When it came to encountering out-of-state prescriptions for controlled substances, the most common state of origin was Ohio (40% of all pharmacists surveyed encountered prescriptions from this state) [Figure 8]. Of all pharmacists surveyed, 68% were either neutral or somewhat uncomfortable due to prescribing practices and patterns coupled with legislation regarding opioids [Figure 11]. Without hesitation, 77% stated "refill too soon" was the primary rejection in denying a fill for one of these medications [Figure 7].

Figure 1 - Question 1

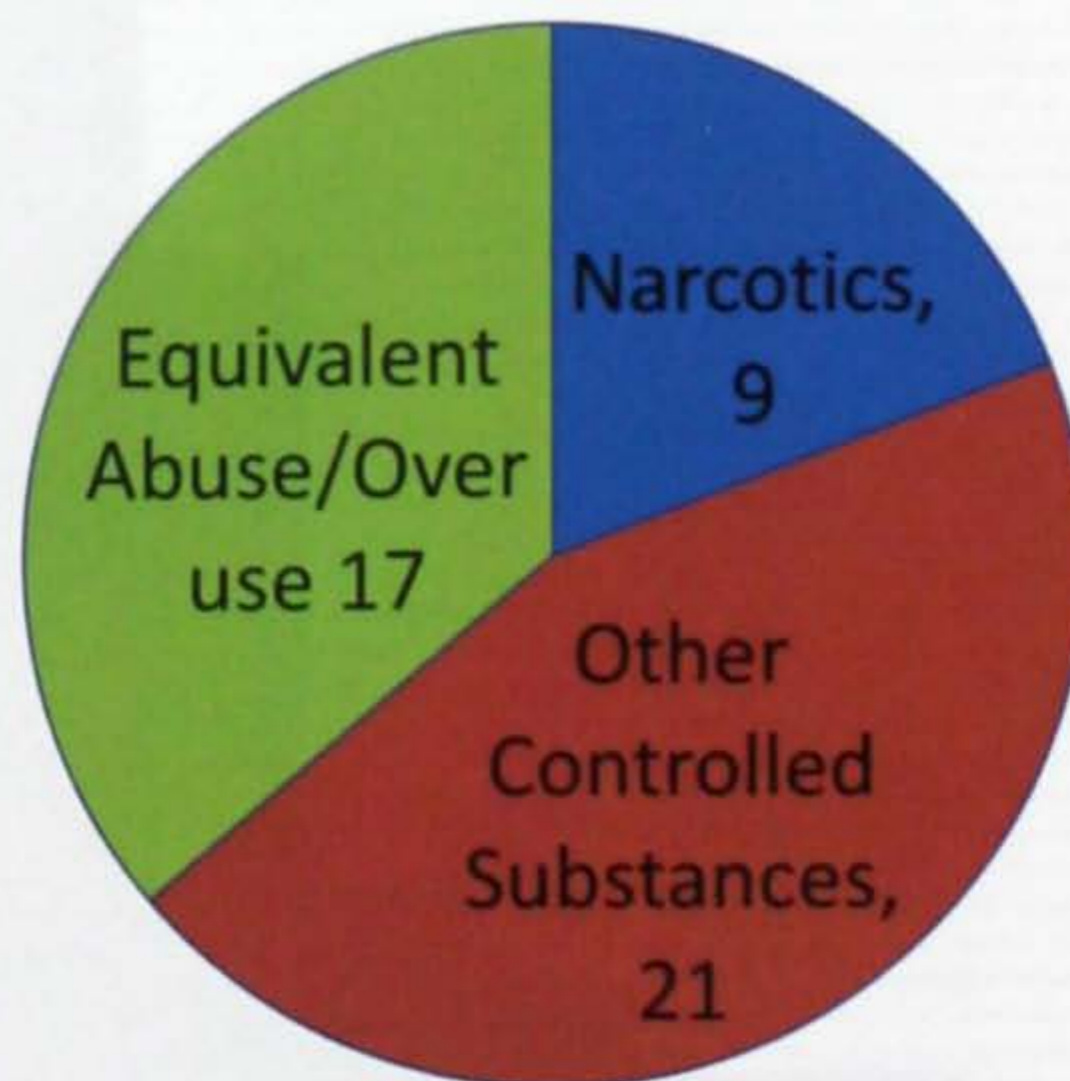


Figure 2 - Question 2

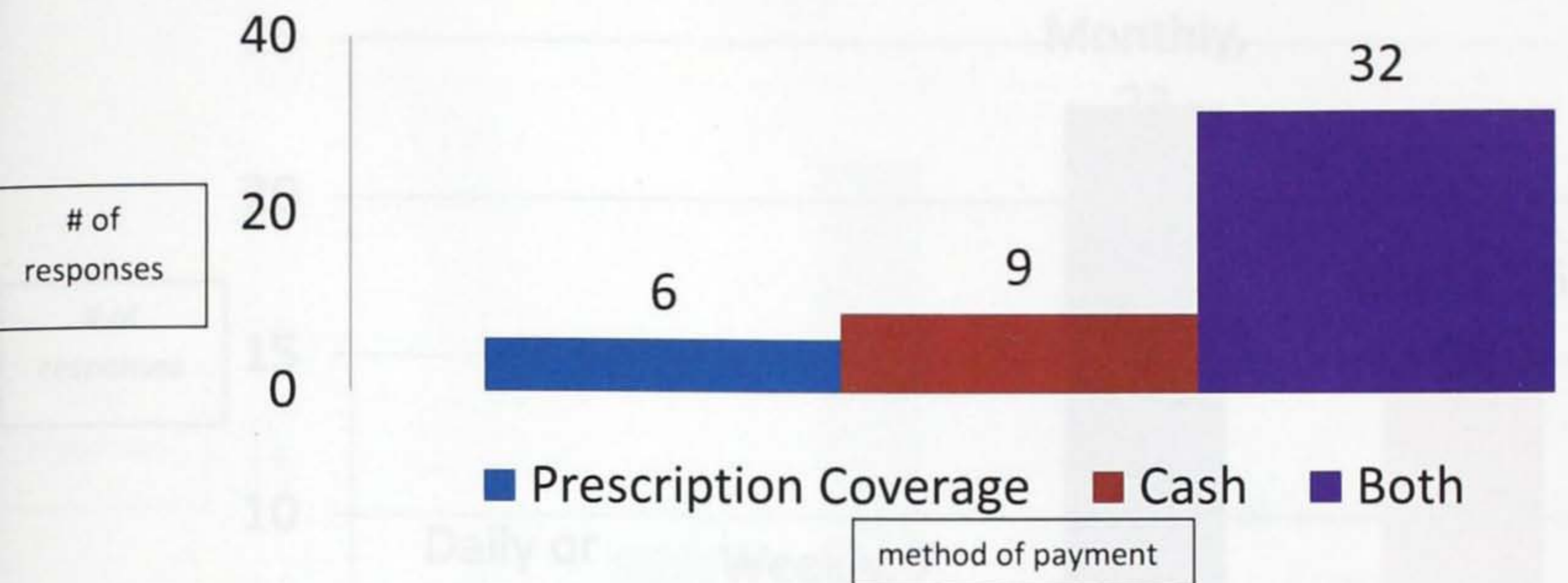


Figure 3 - Question 3

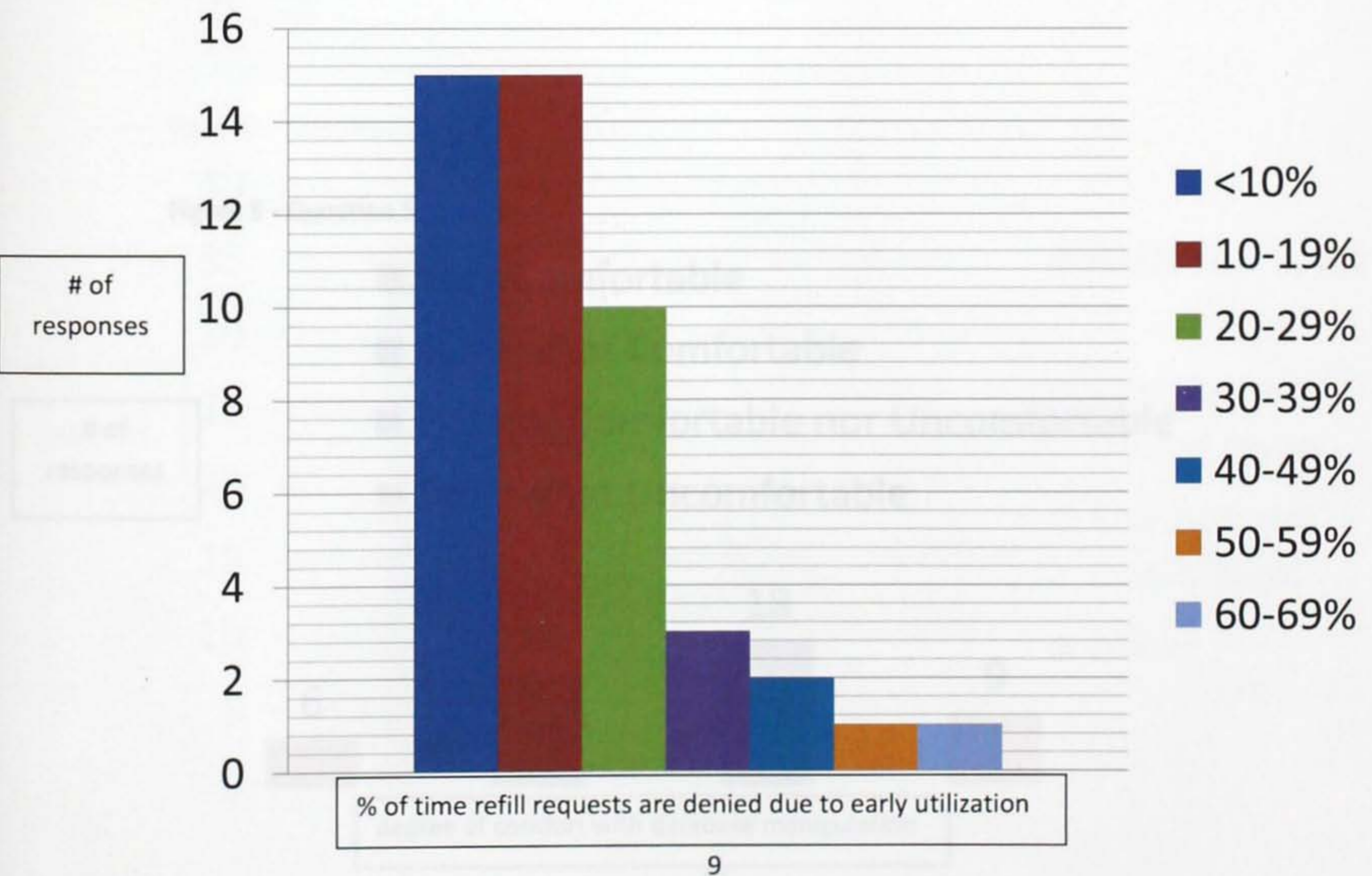


Figure 4 - Question 4

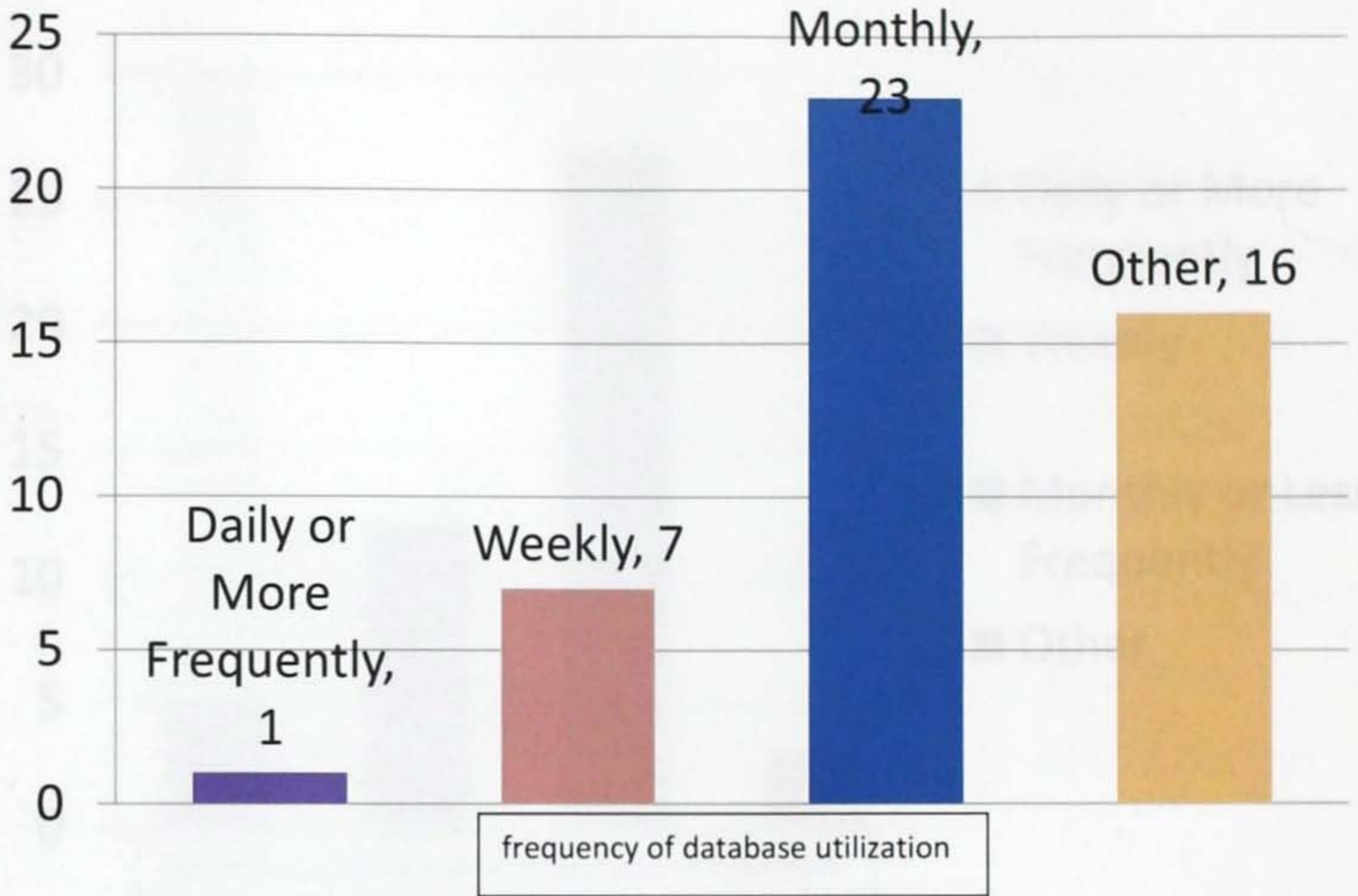


Figure 5 - Question 5

- Very Comfortable
- Somewhat Comfortable
- Neither Comfortable nor Uncomfortable
- Somewhat Uncomfortable

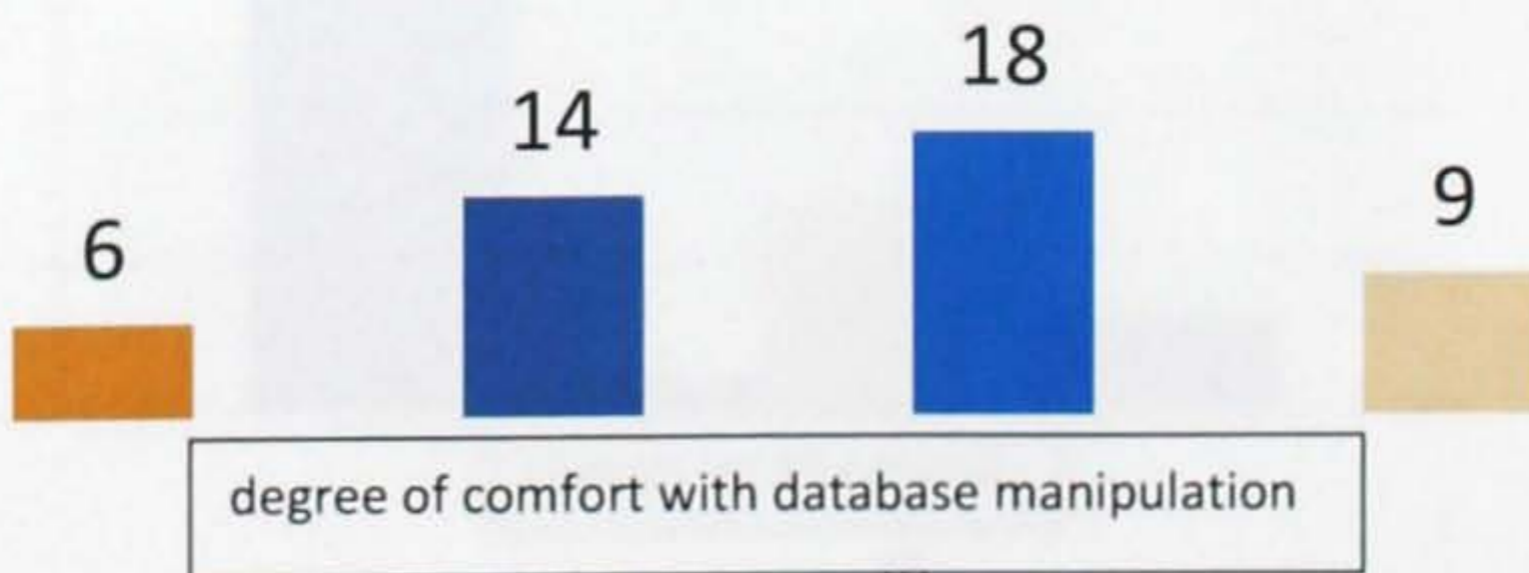


Figure 6 - Question 6

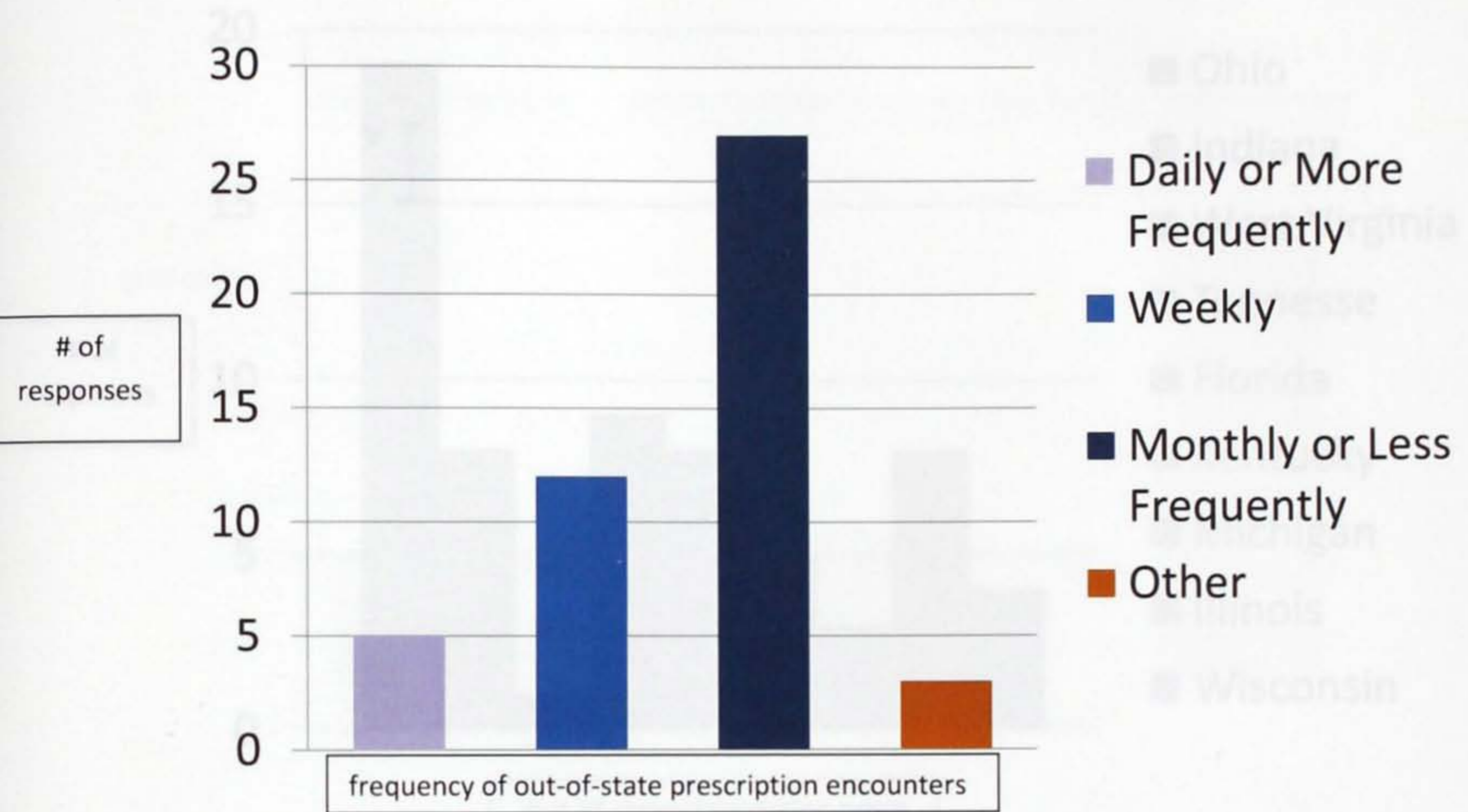


Figure 7 - Question 7

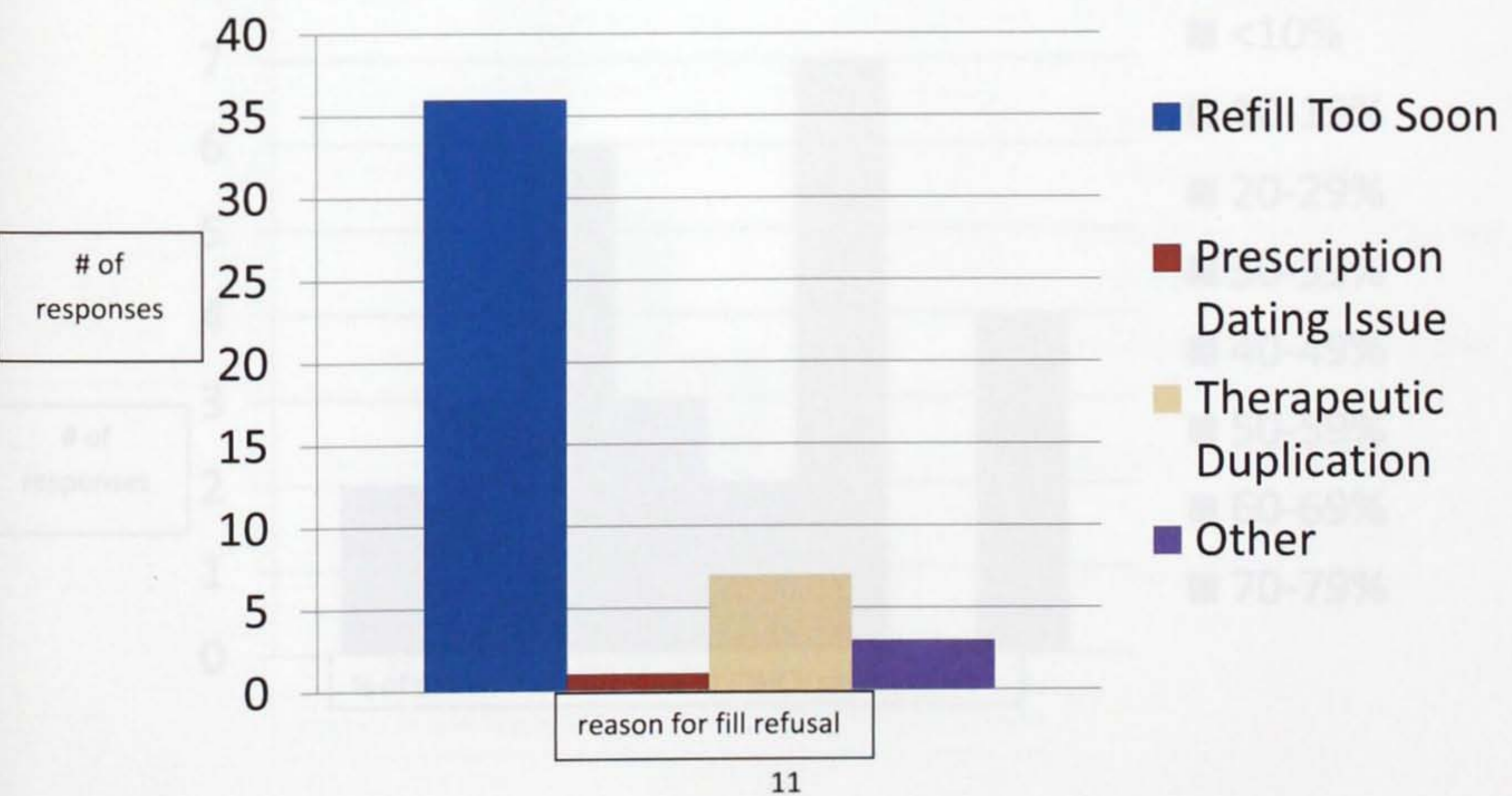


Figure 8 - Question 8

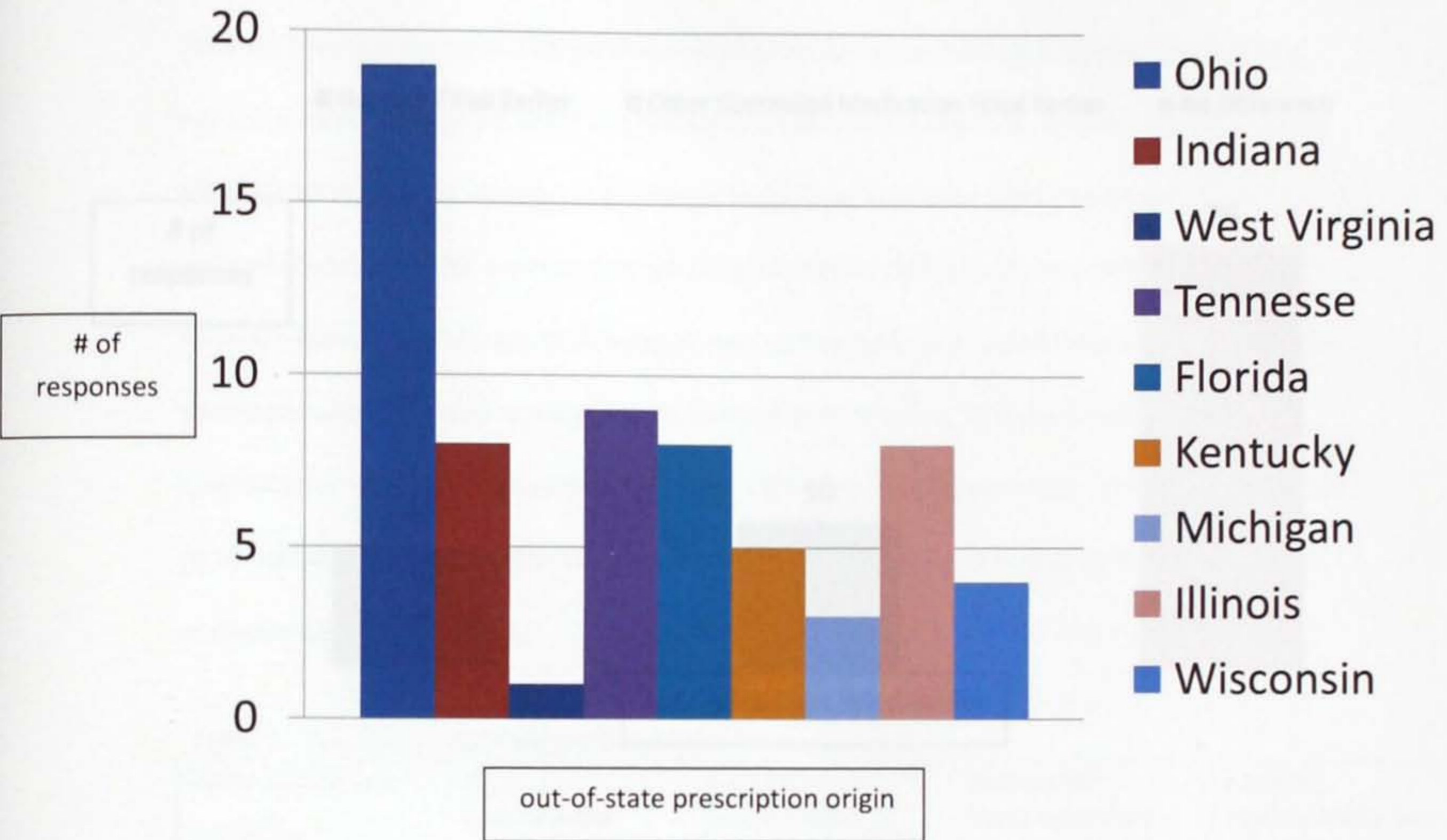


Figure 9 - Question 9 (How many patients on CII + CIII-V opioid analgesic?)

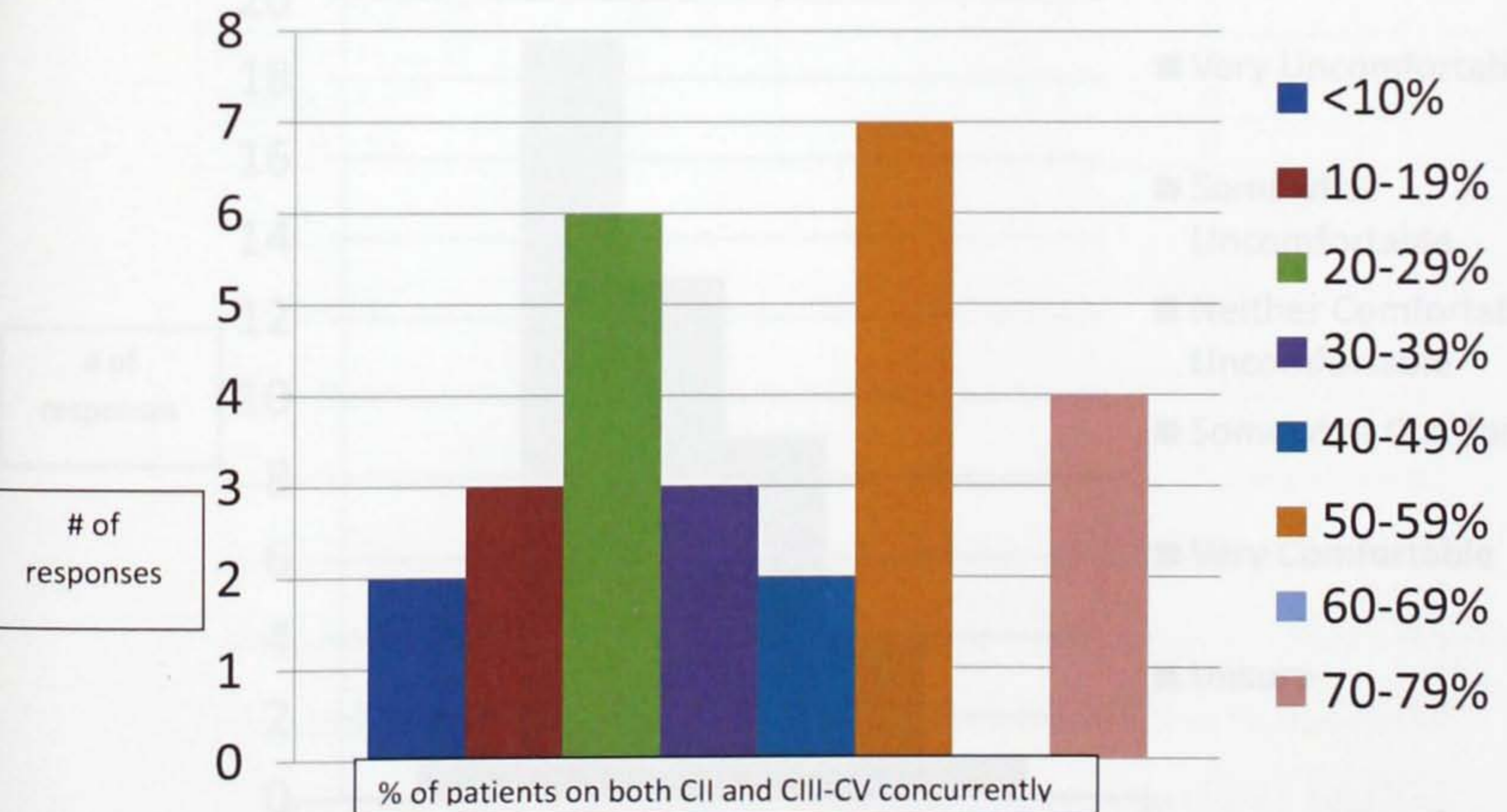


Figure 10 - Question 10 (For those patients qualifying Question 9, which is filled earlier?)

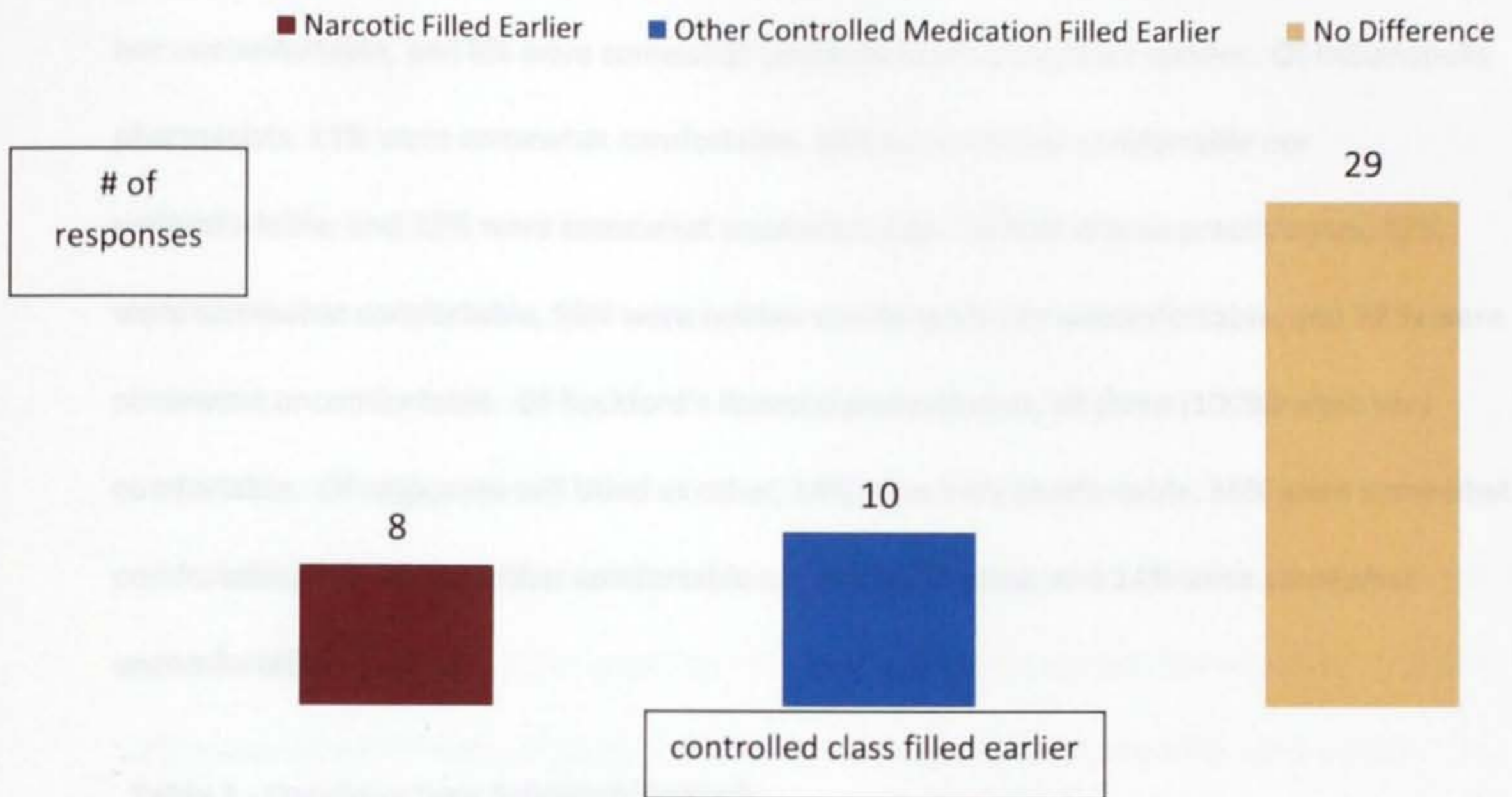
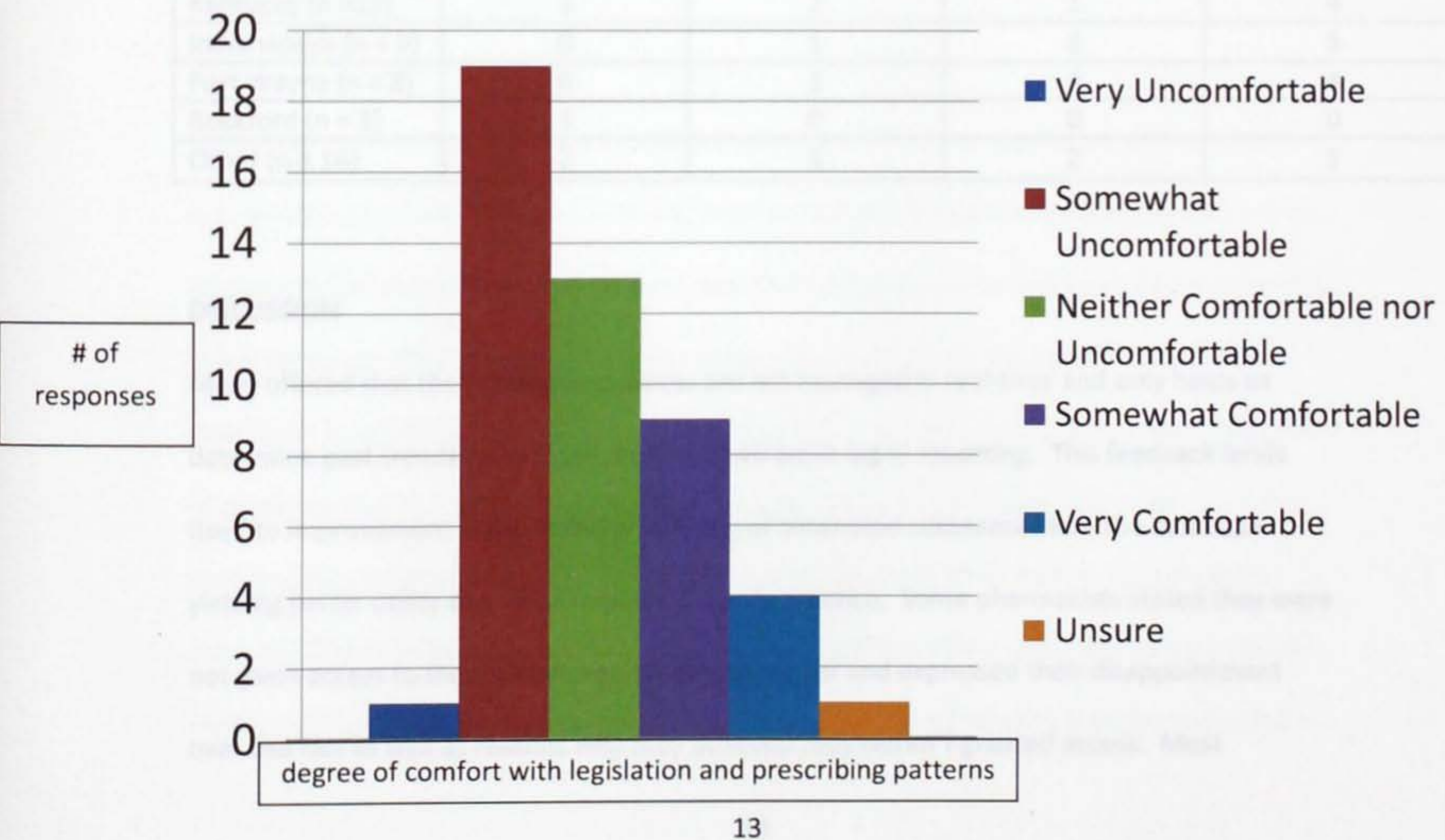


Figure 11 - Question 11



Analyzing subgroups with regards to the use of the electronic databases: Kentucky respondents, 8% were very comfortable, 54% were somewhat comfortable, 30% were neither comfortable nor uncomfortable, and 8% were somewhat uncomfortable using their system. Of Indianapolis pharmacists, 11% were somewhat comfortable, 56% were neither comfortable nor uncomfortable, and 33% were somewhat uncomfortable. Of Fort Wayne practitioners, 12% were somewhat comfortable, 50% were neither comfortable nor uncomfortable, and 38 % were somewhat uncomfortable. Of Rockford’s licensed professionals, all three (100%) were very comfortable. Of responses self titled as other, 14% were very comfortable, 36% were somewhat comfortable, 36% were neither comfortable nor uncomfortable, and 14% were somewhat uncomfortable [Table 2].

Table 2 - Database Ease Subgroup Analysis

Place of Practice	Very Comfortable	Somewhat Comfortable	Somewhat Uncomfortable	Neither Comfortable nor Uncomfortable
Kentucky (n =13)	1	7	1	4
Indianapolis (n = 9)	0	1	3	5
Fort Wayne (n = 8)	0	1	3	4
Rockford (n = 3)	3	0	0	0
Other (n = 14)	2	5	2	5

DISCUSSION

Many offered that the database resources are not managed in real-time and only helps to determine past trends since there is often a two week lag in reporting. This feedback lends itself to improvement in the speed processing of controlled substances into the database yielding better utility and value to pharmacists in practice. Some pharmacists stated they were not given access to these databases by their employer and expressed their disappointment over this fact as well as reasons why they believed they weren’t granted access. Most

prominent among those proposed rationales was the assumption by management team of increased liability through access to the system if patient fills were not being validated on a consistent basis.

While out-of-state prescriptions were often cited in previous research literature as being a tremendous source of abuse, perhaps awareness is to the point where frequency is declining. The reduction in being presented out-of-state opioid prescriptions was attributed to the awareness created by communication from state boards of pharmacy which proves the success of their correspondence. Once pharmacists gained knowledge of the problem, strategies and policies were implemented to create ways to manage their encounter. Some pharmacists did offer comment that many of those out-of-state prescriptions presently seen were in fact legitimate from medical centers or specialty treatments as opposed to the prescription mills which are sensationalized in the media.

STUDY LIMITATIONS

One of the most limiting parameters in looking at the utilization of controlled substances is regulation by the FDA. The governmental examination into a new chemical entity determines its potential for abuse, and is therefore is classified with potential for overuse, thereby alerting pharmacists to restrict the dispensing the respective medications 'too early.' While this evaluation is up to the pharmacist's personal discretion or company policy, it inhibits the ability to study the true overuse in some patients. Another potential limitation will be an independent pharmacy's inability to link other prescriptions filled elsewhere by a particular patient, which may (depending on the patient) underestimate their utilization. Distortion of reality, unintentionally by the pharmacist, may exaggerate in either direction the responses

generated. As mentioned previously there is contradictory bias between potential for confusing electronic questions and guiding pharmacists to achieve desired answers when conducting telephone interview. Another limitation is the minimal amount of specific patient data available (race, diagnosis code, etc.) which tend to be hallmark for classic studies. Since there will be no randomized patient selection in the data collection process, unintentional selection bias may exist.

CONCLUSION

General experience in the retail setting does not make much of this study's findings a shock. At the same time, quantifying data and gathering feedback from professionals who deal with issues on a daily basis is perhaps the most apt route for generating change in areas of concern. Therefore, realizing the repetitive undertone behind many of the responses, especially outside of the multiple choice, underscores the harsh reality of the widespread phenomenon previously described in other studies. This study further attests to the growing epidemic which is blurring the line of treating pain, the fifth vital sign, and ethics of concern for the general wellbeing of patients whom pharmacists vow to serve.

What this study does achieve is it offers constructive suggestions for corrective avenues. Two of the most definitive ways to curb practice and initiate reform would be restructure online databases and enable pharmacists to share information electronically to their peers about out-of-state trends. If significant funding were provided – perhaps by the same companies which manufacture opioids – to allow pharmacies to transmit data real-time to the state databases, there would be a true value to checking them frequently for concerns of opioid overuse with regard to polypharmacy and drug diversion. Concerns about patient privacy are legitimate and

thus the need for tremendous funding. The other possibility rests in communication between pharmacies, chains, or even individual pharmacists to alert peers of trends in out-of-state prescriptions. Early recognition of suspicious orders would greatly reduce incidence of filling prescriptions of questionable legality through dissemination of experience information. Communications was cited in the survey by pharmacists as being beneficial to help reduce frequency of out-of-state encounters and could continue moving forward to prevent future occurrences. Once again, realistic privacy issues are present and care must be exercised not to provide any HIPAA linking information in these proposed alerts. A recommendation not based directly on findings would be to resort back to the previous study design idea. Even though access was not obtained for the original study design, there may be tremendous value in following up with a retrospective chart review to objectively determine the true extent, and not solely perception, of the issues being described above. The associated data collection tool is therefore included in Appendix A.

STUDY SIGNIFICANCE

The information collected will, if successful, gauge the reality of concerns stated in previous research which asserts a growing trend for opioid prescribing and patient practices related to it. Linking the severity of opioid overuse to drug fill patterns may enable physicians and pharmacists to collaborate in order to best serve patients in both relieving their pain while preventing overdose events, including severe constipation, respiratory depression, and even death. This is most applicable to situations of chronic pain in which patients need analgesia for greater than three months duration.

SCHEDULE

- Initial research of primary literature / gather background information relevant to topic --> February 12, 2010
- Development of thesis proposal rough draft --> February 19, 2010
- Thesis proposal submitted to JH 212C --> March 4, 2010
- Abstract rough draft for poster presentation to faculty mentor --> October 1, 2010
- Poster rough draft --> October 11, 2010
- Submit poster presentation abstract to Blackboard's digital drop box --> October 15, 2010
- Present poster on campus in Reilly Room --> October 28, 2010
- Final submission (and approval) of IRB packet --> November 11, 2010
- Collect data during Block 8 (rotational month off) --> November 20, 2010-January 2, 2011
- Complete data analysis during Blocks 10 and 11 --> January 29-March 25, 2011
- Submit presentation abstract to Blackboard's digital drop box + register URC abstract --> February 3, 2011
- Thesis rough draft due to Dr. Beck --> March 18, 2011
- Present study findings at URC on campus --> April 15, 2011 (11AM in PB204)

PRESENTATION

This study was presented twice during the students' final academic year. In the fall of 2010, the rough concept was presented to pharmacy colleagues on campus via a poster presentation in October. In the spring of 2011, the entirety of the findings were presented again on campus but to an open audience publicizing the research done in April at an undergraduate research forum. After final submission, publication into the Honors thesis collection will take place for

display in Irwin Library at Butler University. This will make the work universally available for interlibrary loan, which potentially can be utilized by other universities and experts (as evidenced from past Honors theses) for future work in the field.

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APPENDIX A

Code:

Age (at start of study - January 1, 2009):

Insurer (circle):	state-funded	private	self-pay	vouchers	discount cards	other
Residence (circle)	City (Elizabethtown, Radcliff, etc.)			Rural (surrounding areas)		

Other RX analgesics used:

Medication (circle applicable)	morphine	hydromorphone	hydrocodone	oxycodone
List month-supply fill date 1				
List month-supply fill date 2				
List month-supply fill date 3				
List month-supply fill date 4				
List month-supply fill date 5				
List month-supply fill date 6				
List month-supply fill date 7				
List month-supply fill date 8				
List month-supply fill date 9				
List month-supply fill date 10				
List month-supply fill date 11				
List month-supply fill date 12				
List month-supply fill date 13				

Difference in days between expected and actual fill	-,0,+
First until second	
Second until third	
Third until fourth	
Fourth until fifth	
Fifth until sixth	
Sixth until seventh	
Seventh until eighth	
Eighth until ninth	
Ninth until tenth	
Tenth until eleventh	
Eleventh until twelfth	
Twelfth until thirteenth	

APPENDIX B

1. Do you notice more abuse/overuse potential with opioid narcotics (e.g. oxycodone, morphine, etc.) or other controlled opioids (e.g. hydrocodone, tramadol, etc.)?
 - a. narcotics
 - b. other controlled
 - c. equivalent abuse/overuse

2. Do patients seeking these types of medications tend to use prescription coverage (e.g. third party insurance, discount programs, Medicaid/Medicare), choose to pay cash, or both?
 - a. prescription coverage
 - b. cash
 - c. both

3. How often, as a percentage estimate, do you have to deny patients' access to fill/refill their pain management prescriptions due to early utilization attempts?

4. How often do you typically use KASPR (Kentucky's version), INSPECT (Indiana's version), or PIL (Illinois' version) to inquire about patients records?
 - a. daily or more frequently
 - b. weekly
 - c. monthly or less frequently
 - d. other

5. Do you feel comfortable using the KASPR, INSPECT, or PIL system and what recommendations could you make to improve its usability?
 - a. very comfortable
 - b. somewhat comfortable
 - c. neither comfortable nor uncomfortable
 - d. somewhat uncomfortable

Comments:

6. How often do you encounter out-of-state controlled prescriptions?

- a. daily or more frequently
- b. weekly
- c. monthly or less frequently
- d. other

7. When you're forced to deny filling a pain management prescription, what is the usual cause?

- a. refill too soon
- b. failure to produce ID
- c. out of state origin
- d. prescription dating issues (expired, post-dated, etc.)
- e. therapeutic duplication
- f. other

8. What states other than the one in which you practice do you encounter controlled substance prescriptions from?

9. Approximately what percentage of patients use both a narcotic and another controlled opioid prescription for pain management?

10. From the last question, do you notice patients trying to fill one of the two earlier than the other?

- a. narcotic
- b. controlled
- c. no difference

11. Do you feel put into a difficult situation by prescribing patterns/practices and legislation governing these medications?

- a. very uncomfortable
- b. somewhat uncomfortable
- c. neither comfortable nor uncomfortable
- d. somewhat comfortable
- e. very comfortable
- f. unsure

12. Are there any other pertinent comments you would like to include for this study?