

Primary Care Specialty, Resident Status, and Male Gender Correlate With Controlled Drug Contract Use

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Objective: With prescription drug abuse rising, physicians are often ambivalent about prescribing controlled drugs. To address their concerns, physicians widely use controlled drug contracts (CDC); however, CDC use is poorly studied. This preliminary study characterizes CDC users and identifies factors associated with CDC use.

Method: Data were collected from a Web-based survey of University of Oklahoma College of Medicine medical trainee and faculty attitudes and prescribing practices regarding controlled drugs. Recruited via e-mail, participants submitted responses anonymously for a 6-week period from January through March 2004. Associations between demographic variables and participants' responses were analyzed using χ^2 analysis to determine correlates of CDC use. Demographic variables included training status (medical student, resident, or faculty), age, gender, and faculty specialty. Variables of interest derived from the survey were CDC use, how respondents compared the risks and benefits of controlled drugs, and patient diagnosis.

Results: One hundred ninety-six surveys were submitted, with an estimated response rate of 20% to 30%. CDC use correlated with male gender ($p = .0099$), resident status ($p = .0099$), primary care specialty among faculty ($p = .0001$), and risk/benefit assessment ($p = .04$) but not patient diagnosis ($p = .19$) or participant age ($p = .40$).

Conclusions: Despite limitations, the study findings suggest that a physician's gender, training status, medical specialty, and comparison of the risks and benefits of controlled drugs are factors that determine CDC use.

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Controlled prescription drugs are widely prescribed and may be effective tools for managing symptoms of medical and psychiatric illness. For conditions well known to impair quality of life such as anxiety and pain, these medications can significantly alleviate the burden of suffering.¹ Unfortunately, the prescription of controlled drugs also carries the potential for abuse by some patients. Moreover, prescription drug abuse is now recognized as a growing public health problem.² As a result of this health concern and increased scrutiny of prescribing, controlled drugs are often stigmatized, and physicians may be reluctant to prescribe them. Indeed, barriers to their use are recognized and include the fear of causing addiction, fear of regulatory censure, and a misunderstanding of the definition of addiction.^{3,4} A widely used but poorly studied method of addressing many of the concerns surrounding controlled drugs is the controlled drug contract (CDC).⁵ What is currently known about CDCs derives almost entirely from pain management literature. Studies of the "opioid contract," a CDC applied to opioid analgesics, reveal a number of interesting features of these documents.⁶ Generally, there is significant variability in contract content. An analysis of opioid contracts developed by 39 academic pain centers identified at least 12 different statement categories.⁶ The most common of these statements outlined terms of treatment, proscribed behaviors, and conditions for patient dismissal. Consistently identified contract goals included facilitating informed consent, improving patient care through education, and fostering an agreed-upon course of action.

Other research has sought to clarify the prevalence of the use of opioid contracts. One such study identified the frequency of opioid contract use by practitioners in a family medicine setting at 42%.⁷ In addition, potential problems with drug contracts have been noted, including stigmatization of patients with substance abuse, patients' perceptions of the contract as punitive, and perceptions by prescribers that a signed contract sufficiently assures patient compliance.⁶ Despite their potential problems and some differences of opinion among professionals about their use, these contracts are often viewed as useful tools in the management of chronic opioid prescriptions for some patients.⁸ As evidence of this, the American Academy of Pain Medicine has published a sample patient-physician agreement form for such therapy.⁹

Despite significant contributions in the literature, much is still unknown about these documents. Important questions include whether contracts are efficacious, whether they are binding, and whether they can affect prescriber liability risk.⁶ From a broader perspective, one may ask how these questions would be answered with regard to CDCs as a broad group. Research regarding the general use of contracts may extend our knowledge beyond the management of opioid analgesics to other commonly prescribed controlled drugs such as benzodiazepines. Studies addressing the broader use of such CDCs in medical practice may provide answers supporting the efficacy of formal agreements between practitioners and patients. Preliminary research needs to identify those who use such contracts and the prevalence of CDC use. The drugs and diagnoses associated with CDC use are also important. Furthermore, since there is no evidence definitively establishing CDC efficacy, the factors promoting the use of CDCs should be elucidated. As a preliminary inquiry, this study examines the use of CDCs among medical trainees and faculty members in a large, university-based health system. Initial aims include characterizing CDC users and identifying factors associated with their CDC use.

METHOD

A Web-based survey (Appendix 1) assessing medical trainee and faculty attitudes and prescribing practices regarding controlled drugs was administered to third- and fourth-year medical students, residents, and paid physician faculty at the University of Oklahoma College of Medicine. The participants practice or train in various locations across Oklahoma, and they represent a broad range of primary care and specialty groups. Patient populations served include the urban and rural based as well as the insured and uninsured. This study was approved by the University of Oklahoma Health Sciences Center Institutional Review Board. Survey participants indicated their informed consent by their participation in the study.

Participation was solicited via e-mail, and participants submitted their responses anonymously through a link to a Web-page survey for a 6-week period from January through March 2004. Demographic information gathered included age cohort (5-year increments), gender, and status as medical student, resident (with specialty training program), or faculty (with specialty). Variables of interest were CDC use, the prescriber's comparison of the risks and benefits of prescribing controlled drugs, and the diagnoses for which controlled drugs are most often prescribed. CDC use was indicated on the survey by choosing yes or no. The risk/benefit assessment required the respondent to choose one among several options: risks always outweigh benefits, risks outweigh benefits in most cases, risks and benefits are equal, risks and benefits vary

Table 1. Characteristics of Study Participants

Characteristic	N (%)
Gender ^a	
Male	105 (54.4)
Female	88 (45.6)
Training status ^b	
Medical student	51 (26.0)
Resident	42 (21.4)
Faculty	103 (52.6)
Faculty specialty ^c	
Primary care	51 (52.0)
Medical	30 (30.6)
Surgical	17 (17.3)

^aOne hundred ninety-three of 196 participants identified their gender.

^bAll 196 participants reported their training status.

^cNinety-eight of 103 faculty members identified their practice specialty.

significantly case to case, benefits outweigh risks in most cases, or benefits always outweigh risks. Diagnosis was indicated by write-in.

Associations between demographic variables and participants' categorical responses to survey questions were analyzed using χ^2 analysis. A p value of .05 was considered statistically significant.

RESULTS

A total of 196 surveys were submitted by participants (Table 1). Of this number, 52.6% were faculty, 26.0% were medical students, and 21.4% were residents. Representation by 10-year age cohorts was 37.8% for ages 20 to 30, 24% for ages 31 to 40, 17.3% for ages 41 to 50, 16.8% for ages 51 to 60, and 4% for ages 61 to 70. One hundred ninety-three participants identified their gender. Of this group, 54.4% were male. Ninety-eight faculty members identified their practice specialty. Of this group, 30.6% were medical specialists, 52.0% were primary care physicians (general internal medicine, pediatrics, family medicine), and 17.3% were surgical specialists.

There were no significant differences in gender distribution among training status groups ($N = 193$, $\chi^2 = 5.264$, $df = 2$; $p = .07$) or faculty specialty groups ($N = 97$, $\chi^2 = .529$, $df = 2$; $p = .77$). Similarly, the risk/benefit assessment of prescribing controlled drugs was not significantly different among training status groups ($N = 193$, $\chi^2 = 9.587$, $df = 6$; $p = .14$) or among faculty specialty groups ($N = 98$, $\chi^2 = 6.908$, $df = 6$; $p = .33$). Age distribution was significantly different between faculty, medical student, and resident groups ($N = 196$, $\chi^2 = 168.989$, $df = 18$; $p < .0001$). Medical students and residents were significantly younger than faculty, occupying primarily the age range of 20 to 35 years, whereas most faculty members were in the age range of 31 to 60 years.

Regarding CDC use, residents were significantly more likely than faculty or medical students to use a CDC (Table 2). Among faculty, primary care physicians were

Table 2. Prevalence of Controlled Drug Contract Use

Characteristic	Yes N (%)	No N (%)
Gender ^a		
Male	50 (26.5)	55 (29.1)
Female	26 (13.8)	58 (30.7)
Training status ^b		
Medical student	14 (7.3)	34 (17.8)
Resident	25 (13.1)	17 (8.9)
Faculty	38 (19.9)	63 (33.0)
Faculty specialty ^c		
Primary care	30 (30.6)	21 (21.4)
Medical	6 (6.1)	24 (24.5)
Surgical	2 (2.0)	15 (15.3)

^aN = 189, $\chi^2 = 9.224$; p = .0099.

^bN = 191, $\chi^2 = 9.224$; p = .0099.

^cN = 98, $\chi^2 = 18.314$; p = .0001.

significantly more likely than specialists to use a CDC. Male gender also predicted CDC use. There was a significant difference in how CDC users and nonusers compared the risks and benefits of prescribing controlled drugs (N = 189, $\chi^2 = 8.325$, df = 3; p = .04). CDC nonusers were more likely to see benefits as outweighing risks in most cases, whereas CDC users saw benefits and risks varying more often case by case. CDC use did not correlate with patient diagnosis (N = 188, $\chi^2 = 6.068$, df = 4; p = .19) or with the age of the survey participant (N = 191, $\chi^2 = 9.45$, df = 9; p = .40).

Since gender was a possible confounder, the authors examined its effects on CDC use. When adjustments were made for gender among faculty, differences in CDC use remained in the direction favoring primary care physicians, with a trend (p = .08) in women and a strong correlation among men (p = .0005). Gender adjustments among training status groups, although not reaching statistical significance, favored a trend toward residents (males, p = .05; females, p = .11).

DISCUSSION

This preliminary study demonstrates several findings that may illuminate why and by whom CDCs are used. First, within a medical training context, gender is correlated with CDC use. Males are significantly more likely than females to use a contract. Although the reasons for this finding are not immediately apparent, differences in practice patterns based on gender are reported in the literature. One study¹⁰ reported that female generalists were more likely than their male peers to counsel patients on health behaviors, especially those involving sensitive issues such as sex and drug use. This finding suggests that female physicians are more likely to communicate openly with patients about delicate issues, perhaps using more open, informal approaches to the management of patient behaviors as opposed to using a formal, structured contract.

A second major finding is that primary care faculty use CDCs more often than their specialist colleagues. A probable explanation is that primary care faculty members are more likely than specialists to provide continuous care over time for patients with chronic diseases. Such long-term care may promote a more in-depth doctor-patient relationship, with all of its attendant rewards and potential complications. In this context, CDC use may facilitate a positive and predictable doctor-patient interaction.

Residents use CDCs significantly more often than do faculty and medical students. A potential reason might be a cohort effect. Residents, who are likely to be acquiring knowledge from the most current sources, may be more familiar with a CDC as a recent tool to manage controlled drug prescribing. Resident use of CDCs may also be influenced by the training demands placed upon them. Resident physicians, who shoulder a relatively large proportion of patient care responsibility, are still honing their clinical skills and may find the use of such tools especially helpful in guiding the task of controlled drug management in frequently complex patients. In contrast, faculty, who have acquired clinical competency and experienced judgment, may not feel they require the structured assistance a CDC provides.

Medical students, who train under direct resident and faculty supervision and who typically function at a basic clinical skill level, might be less aware of the availability of or need for a CDC. Furthermore, since medical students do not have prescriptive authority, they are somewhat removed from managing controlled drugs and may have little impetus for using such a tool. Of course, it is important to realize that trainees and faculty alike might use a CDC for its perceived value to the patient, not just for its utility for the user.

How survey respondents compared the risks and benefits of prescribing controlled drugs differentiated between CDC users and nonusers. CDC users more often chose "risks and benefits vary significantly case to case" than did CDC nonusers, who more often chose "benefits outweigh risks in most cases." This finding suggests that physicians who see fewer risks in prescribing controlled drugs may see less need for CDCs, tools that might be viewed as useful in managing liability risks.

Age was not associated with CDC use. Although the differences in age between training status groups were predictable and might be viewed as a possible confounder, the lack of correlation between age and CDC use suggests that age is not a significant factor influencing the use of CDCs.

Taken together, these findings suggest that training status, medical specialty, gender, and the risk/benefit assessment of controlled drugs interact to influence CDC use. Not surprisingly, it appears that CDC use, like most human behaviors, is complex and multiply determined.

The limitations of this study center primarily on sampling issues. First, the sampling method was not random.

This study elicited participation voluntarily via university e-mail using preconfigured contact lists. Self-selection bias is a possibility. Nonresponders may have been uninterested in the survey topic or felt they were too busy to participate, or they could have been prevented from participating by e-mail filters or by nonuse of their university e-mail account. However, on the basis of these selection factors, it is unclear that nonresponders would necessarily differ significantly from responders in their survey responses.

Another issue is the response rate to the survey. Total potential participants were counted at 1419 faculty, residents, and third- and fourth-year medical students. However, as just noted, it is not possible to know how many of these potential participants actually received the e-mail invitation. Furthermore, some faculty may not involve themselves in clinical care of patients and, thus, might have had little impetus to participate. The overall effect of these considerations is to restrict the potential participant pool, perhaps considerably. Consequently, although the response rate may be calculated at 14%, it is likely to be higher. We might reasonably estimate our response rate to be in the 20% to 30% range. Two sources suggest that this response rate is within the range of expectation.¹¹⁻¹² One reports that samples drawn from a consumer e-mail database of those "opting in" for contact will have response rates in the 20% to 50% range¹¹; another source,¹² a review of studies using e-mail surveys, reports an average response rate of 31%. Thus, the response rate to this survey is comparable to those of other online surveys. Nevertheless, prudence suggests interpreting the results of this study carefully. The response rate itself leaves open the possibility that a representative sample may not have been captured. Furthermore, the findings of this study may not be generalizable to settings outside academia.

Despite its limitations, this study contributes appreciably to the literature on controlled drug contracts. It confirms the relatively widespread use of CDCs even without evidence demonstrating their efficacy. More importantly,

this study begins the process of clarifying the factors potentially determining CDC use at least within an academic setting. From a broader perspective, these findings contribute to the knowledge of physician behavior as applied to the complexities of controlled drug prescribing. Further research could function to clarify other factors influencing CDC use, to address whether CDCs have efficacy for the several purposes for which they are used, and to evaluate CDC use outside of academic settings.

Drug names: alprazolam (Xanax, Niravam, and others), buspirone (Buspar and others), modafinil (Provigil).

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Appendix 1 appears on pages 279-280.

Appendix 1. Web-Based Survey Assessing Medical Trainee and Faculty Attitudes and Prescribing Practices Regarding Controlled Drugs^a

Controlled Prescription Drug Survey

(Your completion of this survey is your consent to participate in this study)

- FACULTY Specialty _____
- MEDICAL STUDENT 3rd year 4th year
- RESIDENT PGYI PGYII PGYIII PGYIV PGYV _____ Training Program
- AGE 20–25 26–30 31–35 36–40 41–45 46–50 51–55
- 56–60 61–65 66–70 71–75 76–80 81–85 86–90 91 or above
- MALE FEMALE

1. What group(s) of controlled drugs did you prescribe independently or under supervision at least once in an outpatient or emergency room setting over the past 12 month period? (check all that apply)

- Benzodiazepines Non-benzodiazepine sleep aids
- Opiates Wake-promoting agents
(e.g., Provigil)
- Barbiturates Weight loss promoting drugs
- Stimulants Other (_____)

2. What perspective best describes your own regarding the prescription of controlled drugs? (choose one)

- a. Risks always outweigh benefits
- b. Risks outweigh benefits in most cases
- c. Risks and benefits are equal
- d. Risks and benefits vary significantly case to case
- e. Benefits outweigh risks in most cases
- f. Benefits always outweigh risks

3. In your opinion, what patient behavior best predicts prescription drug abuse? (choose one)

- a. Strong and/or persistent requests for a particular controlled substance
- b. Calling in early for refills
- c. Report of lost or stolen supply of the prescribed substance
- d. Report of a controlled substance as the only effective medication for the problem symptom
- e. Using the drug outside the guidelines of how it was prescribed

4. Based upon your patterns of care for your outpatients, please write in the diagnosis for which you would most likely prescribe a controlled drug. (please write in your answer)

5. What percentage of your outpatients do you estimate abuse controlled drugs that you prescribe for them (independently or under supervision)? (please write in your answer)

_____ %

6. What is the average length of time you continuously prescribe a controlled drug (independently or under supervision) for most of your outpatients receiving such prescriptions? (choose one)

- a. Less than one month
- b. One to six months
- c. Six to twelve months
- d. Greater than twelve months

7. How comfortable in general are you with prescribing controlled drugs (independently or under supervision)? (choose one)

- a. Very uncomfortable
- b. Somewhat uncomfortable
- c. Neither comfortable nor uncomfortable
- d. Somewhat comfortable
- e. Very comfortable

8. In your opinion, what perspective regarding controlled drug prescription best represents that of the majority of the full time faculty who supervise you or with whom you are associated? (choose one)

- a. Risks always outweigh benefits
- b. Risks outweigh benefits in most cases
- c. Risks and benefits are equal
- d. Risks and benefits vary significantly case to case
- e. Benefits outweigh risks in most cases
- f. Benefits always outweigh risks

9. In your opinion, what perspective regarding controlled drug prescription best represents that of the majority of the volunteer faculty who supervise you or with whom you are associated? (choose one)

- a. Risks always outweigh benefits
- b. Risks outweigh benefits in most cases
- c. Risks and benefits are equal
- d. Risks and benefits vary significantly case to case
- e. Benefits outweigh risks in most cases
- f. Benefits always outweigh risks

10. In your opinion, what perspective regarding controlled drug prescription best represents that of the majority of the residents with whom you work? (choose one)

- a. Risks always outweigh benefits
- b. Risks outweigh benefits in most cases
- c. Risks and benefits are equal
- d. Risks and benefits vary significantly case to case
- e. Benefits outweigh risks in most cases
- f. Benefits always outweigh risks

11. In most cases, what factor carries the most weight in helping you decide between controlled and noncontrolled drug options? (choose one)

- a. Treatment efficacy
- b. Potential for abuse or dependency
- c. Patient preference
- d. Training faculty preference
- e. Experience with prescribing

continued

 Appendix 1. Web-Based Survey Assessing Medical Trainee and Faculty Attitudes and Prescribing Practices Regarding Controlled Drugs^a (cont.)

- 12. Please assess the *quality* of the instruction in your training program regarding prescription and management of controlled drugs. (choose one)**
- Excellent
 - Good
 - Fair
 - Poor
- 13. Please assess the *quantity* of the instruction in your training program regarding prescription and management of controlled drugs. (choose one)**
- Too much
 - Just enough
 - Too little
- 14. When prescribing a controlled drug to a patient (independently or under supervision), do you ever use a written controlled drug contract that the patient reads and signs?**
- Yes No
- 15. If you answered no to question #14, what is the primary barrier to using such a document? (please write in your answer)**
- _____
- _____
- 16. If you answered yes to question #14, what benefits do you see to using such a document? What liabilities? (please write in your answer)**
- _____
- _____
- 17. How has using a written controlled drug contract affected your experience of mastery with prescribing controlled drugs (independently or under supervision)? (choose one)**
- Increased
 - No effect
 - Decreased
 - I haven't used the document
- 18. How has using a written controlled drug contract affected your comfort level with prescribing controlled drugs (independently or under supervision)? (choose one)**
- Increased
 - No effect
 - Decreased
 - I haven't used the document
- 19. In your opinion, what percentage of your outpatients in your current training or practice setting has an alcohol or drug abuse problem? (please write in your answer)**
- _____%
- 20. A 45 yo male patient with active panic disorder has a diagnosis of alcohol dependency but has not used alcohol in 5 years. He reports past treatment failures with every SSRI medication available. What would be your next step in the management of this patient's panic symptoms? (choose one)**
- Begin treatment with a high-potency benzodiazepine
 - Obtain a drug screen
 - Confirm previous SSRI trials were of sufficient dose and duration
 - Try another non-SSRI antidepressant
 - Begin treatment with buspirone
- 21. A 21 yo female is diagnosed with anxiety and prescribed alprazolam. She is seen monthly for follow-up. She reports a good response at 3 mg/day for the past 3 months. Two weeks away from her next visit, she calls in to report that her medication was stolen. She requests an early refill. What would be your next step in the management of this patient? (choose one)**
- Refill the medication as requested
 - Refill only enough medication until the next appointment and discuss the situation at the next visit
 - Refuse to refill the medication until the next scheduled appointment and document suspected alprazolam abuse
 - Refuse to refill the medication ever and document suspected alprazolam abuse

^aSurvey Version 2, January 21, 2004.

Abbreviations: SSRI = selective serotonin reuptake inhibitor, yo = year old.