

Student Responses to Legal and Ethical Scenarios in Drug Information

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Abstract

Objectives: To assess student knowledge and ethical decision-making regarding legal and ethical principles and their application to drug information practice scenarios and to describe an active learning strategy designed to engage students in a large group lecture classroom based forum.

Methods: Students are provided 6 drug information practice based scenarios and are asked if they would provide information/counseling to the inquirer based on the background provided. The scenarios are intended to stimulate classroom discussion and interactivity and focus on a legal and/or ethical obligation of pharmacists in the practice of drug information.

Results: The survey instrument is a written questionnaire that is used as a participation required quiz although individual answers are not graded. Results from the class are presented in aggregate for each question. One thousand and ten students have completed the exercise from 2004 to 2013.

Conclusions: This exercise incorporates active learning into a drug information course and assesses student knowledge and decision-making on legal and ethical themes such as balancing patient interests, discerning differences based on inquirer, and professional/legal liability.

Keywords: Drug information; Active-learning; Law; Ethics

Introduction

Ethics instruction has a long history in pharmacy education and has an equally long history of discussions of the most effective methods of approach as an excerpt from a 1953 issue of the American Journal of Pharmaceutical Education attests and up to the present day [1,2]. A national survey was published in 2004 that examined the ethical reasoning of student pharmacists in two different years of the curriculum and found variations in moral development based on geography, year placement in the curriculum and compared to other health professions; this did not examine pedagogies [3]. There was also an examination of the pharmacy literature concerning ethics education in 1980 as the “clinical pharmacy” transition was beginning and making the case that new roles for pharmacists would pose new ethical challenges and that pharmacy education should address these needs proactively [4].

More recently ethical issues have surfaced that affect all health professionals, not the least of which are pharmacists. Much of the controversy has centered around professional obligations versus conscientious objection [5,6]. Topics of these controversies include emergency contraception, provision of drugs for capital punishment and euthanasia, among many others [5,6].

Apart from a chapter in several editions of a standard drug information text concerning ethical aspects of drug information practice, there is very little information in the professional literature regarding ethical concerns in drug information practice [7,8]. There is even less information regarding the developing pharmacist and their ethical training concerning these issues, topics and methods. This study addresses that deficit and provides information about how first-year student pharmacists view common ethical dilemmas in drug information practice that also occur in general pharmacy practice. The purpose of this study is to assess student knowledge and ethical decision-making regarding legal and ethical principles and their application to drug information practice scenarios and to describe an active learning strategy designed to engage students in a large group lecture classroom based forum.

Materials and Methods

First year student pharmacists in the PHA 1225: Drug Information course at Palm Beach Atlantic University (2004-2006) and the PYDI 5130: Drug Literature I course at Auburn University (2007-2013) were provided a paper-based quiz containing 6 clinical practice based scenarios and were asked if they would provide information/counseling to the requestor based on the information provided. The first practice based scenario was adapted from a drug information textbook exercise with questions two through six adapted from actual questions provided to a drug information service [9]. The quiz is provided in Questionnaire 1. The students are asked to circle either “Yes” or “No.” The survey instrument is used as a participation required quiz for classroom assessment although individual answers are not graded. Students are not penalized for not responding to individual questions. The quiz takes approximately 5-8 minutes of student time and is completed during the typical class meeting. The results of the quizzes are aggregated and anonymized for analysis and reporting for the next class period. In the subsequent class period the instructor presents the legal and ethical issues pertaining to the practice of drug information; the scenarios along with the aggregate results from the students are presented in order to stimulate active learning and classroom discussion.

Results are reported as proportions with descriptive statistics for each of the scenarios provided. Each of the provided scenarios focuses on an element of legal obligation, ethical consideration, or both and are

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designed to promote student reflection as well as classroom discussion and interaction between the instructor and students. This project was approved by the Auburn University Institutional Review Board.

Results

A total of 1010 student pharmacists have completed the quiz since 2004. Palm Beach Atlantic University had 181 participants from 2004 to 2006 and Auburn University had 829 participants from 2007 to 2013.

Question number 1 focused on drug identification for a minor

patient and was adapted from a drug information textbook [9]. The yearly and total student responses to this question are provided in Table 1. Overall, nearly 89% of students responded that they would provide drug information in the scenario of identifying a drug product for a mother who finds something in their minor child's desk drawer. Students are trained in the relevant privacy components of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in the Pharmacy Law course as well as during the Introductory Pharmacy Practice Experience portion of the curriculum; however, many students are typically unaware of the provisions of state law that outline

DRUG LITERATURE I QUIZ SpXXXX:

Please answer the following questions under the premise of "Would you provide drug information to the caller in the following circumstances?"

1. A parent calls to request identification of a medication belonging to her 15-year old daughter (found in the child's desk drawer) [9]

Yes	No
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2. A man calls requesting verification of the information his MD has given him on the possible adverse effects of beta-blocker therapy. This information is not complete and, in your estimation, the caller should know more about the adverse effects of beta blockers.

Yes	No
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3. A woman calls requesting information on a diet patch allegedly "approved for weight loss" which she has recently purchased. She states the product name and ingredients and asks if you agree that they are valuable for weight loss. The patch is a homeopathic product and not FDA approved.

Yes	No
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4. A man calls before his pre-employment physical exam asking how long marijuana would remain detectable in the urine.

Yes	No
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5. A woman calls requesting information on drugs that could be taken to interfere with the results of a polygraph test.

Yes	No
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6. A 22-year old woman calls requesting guidance because she has been taking a drug known to you to be highly teratogenic when taken during pregnancy. She specifically asks if the drug will harm her baby and states that she is contemplating abortion as she is 2 months pregnant.

Yes	No
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Questionnaire 1: Scenario Quiz.

Year	Yes n (%)	No n (%)
2004	54 (89%)	7 (11%)
2005	58 (91%)	6 (9%)
2006	50 (85%)	9 (15%)
2007	102 (96%)	4 (4%)
2008	110 (92%)	10 (8%)
2009	93 (87%)	14 (13%)
2010	99 (77%)	30 (23%)
2011	102 (90%)	11 (10%)
2012	121 (94%)	8 (4%)
2013	110 (90%)	12 (10%)
Total	899 (89%)	111 (11%)

Table 1: Student Responses to Information Request Scenario 1.

the health privacy protections of minors. In Alabama §22-8-4 and subsequent §22-8-6 of the Alabama Code provides specific guidance regarding health information and privacy of minors between the ages of 14 and 19 years old [10,11]. In particular, minor patients between the ages of 14 and 19 years old can consent to medical care regarding “pregnancy, venereal disease, drug dependency, alcohol toxicity, or any reportable disease.” The Academy of Pediatrics has also provided guidance on minors providing consent for both emergency and non-emergency care [12,13]. All of this information is discussed in the context of providing drug information in real patient care settings.

The second question in the quiz presented a scenario where a physician has provided incomplete information regarding a drug therapy and a pharmacist is asked to provide additional information and counseling to the patient. The yearly and total student responses to this question are provided in Table 2. In this instance 97% of the students polled responded that they would provide information to the patient/requestor. This scenario provides the opportunity to discuss the concept of the “learned intermediary” and present case law where pharmacists were liable in similar practice situations [14]. A topic that is typically brought up when discussing this scenario is the possibility that the physician declined to provide this information for a legitimate reason. This then leads the class into a review on the systematic approach to responding to a drug information request, paying particular attention to collecting appropriate background information from the patient [15]. They can then determine whether it is necessary to provide additional information to the patient or to decline to add the information for appropriate reasons or to consult the prescribing physician if necessary.

Question number three asked if students would provide information regarding a homeopathic product that is allegedly “approved for weight loss.” For this scenario 75% of the students responded that they would provide information to the requestor. When the 25% of students who responded in the negative were asked to provide a rationale for their refusal, a recurring comment was that the students were simply unfamiliar with the concepts of homeopathy. Due to this unfamiliarity, they decided to not provide information at all in an abundance of caution as not to potentially provide incorrect or only partially correct information to the patient. Once the basic principles of homeopathy are discussed in class, many of the students who were initially reluctant to provide information changed their minds and were more willing to discuss the product with the patient. Many students who were initially inclined to provide information expressed negative opinions of the merits of possible homeopathic remedies and would counsel the patient not to use the product. The yearly and total student responses to this question are provided in Table 3.

The fourth scenario dealt with a request where a caller requests information on how long marijuana will remain detectable in the urine prior to his pre-employment physical. For this scenario only 42% of students responded that they would provide information. The classroom discussion resulting from this scenario typically focused on students presuming that the caller is intending to circumvent pre-employment drug testing to gain employment. Students who responded that they would provide information for this requestor typically support their decision by citing that the information is also widely available on the internet so if they decline the inquirer can still acquire the information, so “why not”? Students who responded that they would not provide information felt that they would not want to be a responsible party to someone circumventing pre-employment screening, particularly if this person were to have a job of some public responsibility, with a common example being cited as “a school bus driver.” For the purposes of classroom discussion, the question scenario was altered to make the inquirer the employer themselves or a law enforcement officer. In both of those modifications students expressed that they were more likely to provide information since they felt there was less opportunity for conflict of interest or being party to a person circumventing drug testing for personal gain. The yearly and total student responses to this question are provided in Table 4.

The fifth scenario presented a woman requesting information on what drugs could be taken to interfere with a polygraph test. This scenario presented similar ethical issues as the fourth scenario in that the students typically interpreted that question as a person trying to avoid the consequences of negative behavior. The yearly and total student responses to this question are provided in Table 5. For this scenario only 30% of students responded that they would provide information to the requestor. The classroom discussion was similar to scenario number 4 with students not wanting to participate due

Year	Yes n (%)	No n (%)
2004	57 (95%)	3 (5%)
2005	57 (89%)	7 (11%)
2006	52 (99%)	6 (1%)
2007	105 (99%)	1 (1%)
2008	119 (99%)	1 (1%)
2009	104 (99%)	1 (1%)
2010	127 (98%)	2 (2%)
2011	112 (99%)	1 (1%)
2012	128 (99%)	1 (1%)
2013	118 (97%)	3 (3%)
Total	979 (97%)	26 (3%)

Table 2: Student Responses to Information Request Scenario 2.

Year	Yes n (%)	No n (%)
2004	35 (58%)	25 (42%)
2005	42 (66%)	22 (34%)
2006	41 (72%)	17 (28%)
2007	87 (82%)	19 (18%)
2008	90 (75%)	30 (25%)
2009	79 (73%)	30 (27%)
2010	106 (82%)	23 (18%)
2011	92 (81%)	21 (19%)
2012	99 (77%)	30 (23%)
2013	91 (75%)	31 (25%)
Total	762 (75%)	248 (25%)

Table 3: Student Responses to Information Request Scenario 3.

Year	Yes n (%)	No n (%)
2004	22 (37%)	37 (63%)
2005	27 (42%)	37 (58%)
2006	23 (40%)	35 (60%)
2007	58 (54%)	48 (44%)
2008	48 (40%)	72 (60%)
2009	42 (39%)	65 (61%)
2010	72 (56%)	57 (44%)
2011	37 (32%)	78 (68%)
2012	50 (39%)	79 (61%)
2013	44 (36%)	78 (64%)
Total	423 (42%)	586 (58%)

Table 4: Student Responses to Information Request Scenario 4.

Year	Yes n (%)	No n (%)
2004	14 (24%)	45 (76%)
2005	20 (31%)	44 (69%)
2006	12 (21%)	45 (79%)
2007	40 (39%)	62 (61%)
2008	36 (30%)	84 (70%)
2009	31 (29%)	76 (71%)
2010	58 (45%)	71 (55%)
2011	25 (22%)	89 (78%)
2012	30 (23%)	99 (77%)
2013	36 (30%)	86 (70%)
Total	302 (30%)	701 (70%)

Table 5: Student Responses to Information Request Scenario 5.

Year	Yes n (%)	No n (%)
2004	37 (62%)	23 (38%)
2005	49 (77%)	15 (23%)
2006	35 (61%)	22 (39%)
2007	85 (80%)	21 (20%)
2008	101 (84%)	19 (16%)
2009	78 (67%)	39 (33%)
2010	110 (85%)	19 (15%)
2011	80 (81%)	19 (19%)
2012	103 (80%)	26 (20%)
2013	79 (65%)	43 (35%)
Total	757 (77%)	227 (23%)

Table 6: Student Responses to Information Request Scenario 6.

to potential liability concerns. For classroom discussion the scenario was again modified to make the requestor a lawyer or law enforcement officer. In both of those modifications students expressed they would be more willing to provide information since it was potentially in assistance of the legal process.

The final scenario presented a woman calling the pharmacist to request guidance since she is pregnant and has been taking a known teratogen. The scenario specifically states that she is contemplating an abortion. In this scenario 76% of the 1010 respondents stated that they would provide information to the requestor. During the classroom discussion, many of the students who responded that they would provide information felt that it was the patient's right to the know of the potential dangers to the fetus and that the final determination of abortion respected patient autonomy. Students who responded that they would decline to provide information typically stated that their conscience would have been burdened if they provided information to a patient that directly resulted in an abortion. This led to classroom consideration of healthcare provider "conscience clauses" or moral

objections and the various limits and implications. The yearly and total student responses to this question are provided in Table 6.

Discussion

This educational exercise allows students to identify and weigh various legal and ethical principles in the provision of information in their clinical practice. The scenarios provided were mostly drawn from real inquires placed to a drug information center. The exercise also allowed for the reinforcement of other concepts discussed in the drug information course, such as collecting appropriate background information from a requestor. As demonstrated in the classroom discussions, student answers might change depending on who the requestor is and what the intent of that requestor is with the information provided. The scenarios also show that students are hesitant to provide information in areas where their knowledge is lacking so as not to accidentally mislead patients.

The data was reasonably consistent over the 10 years of data collection, not indicating a trend of changing opinion for any scenario. For four of the six scenarios, the fluctuation was 24%, one question was 19% and one was 10% as to positive responses.

A limitation to analysis was being unable to reliably compare responses between the two schools of pharmacy. Data collection was too uneven (three years for Palm Beach Atlantic University and seven years for Auburn University). Another limitation was being unable to quantify the change of response if the scenario changed (eg, a patient asking about interfering drugs for a polygraph test versus a law enforcement officer). Also, there is no data to allow comparative assessments of pedagogies as this is the only approach measured for this activity.

This classroom activity allows student pharmacists to begin to contemplate scenarios to which they will be potentially exposed in practice, both as an intern/extern and practicing pharmacist once graduated. The interactive portion of the class after collecting baseline data, allows expansion of the concepts and further exercise of ethical considerations that likely would not occur if only a passive approach was utilized.

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