

Structure of Class

- Topics presented in a three day sequence
 - Monday and Wednesday: Problem Based Lecturing
 - Presentation of problem(s)
 - Problem-based lecture
 - Completion of problem(s)
 - Friday: Problem Based Learning in Groups with Facilitated Class Discussion
 - More complex problem distributed on Wednesday
 - Students come to group individually prepared, discuss in group, then discuss as a class (faculty lead facilitated class discussion during which students present)
- Learning
 - Informal group work during PBLecturing
 - Formal group work
 - Assigned groups for all second year classes
 - 24 groups of 5(-6) group members
 - Problem based learning
 - Facilitated class discussion
 - Demonstrate problem solving process
 - Develop consensus on correct thought process(es) and answer(s)

Problems with traditional approach

- Lecture presentation of topic followed by example problem(s)
- Students “memorized” how to work a particular problem
- Problems presented in group work still viewed as “correct” way and memorized
 - problems never engaged students or seemed real to them
- Course content viewed as discrete and disconnected

Topic: Intermittent IV Bolus Dosing

- Peak 1 = D/V
- Trough 1 = $(D/V) (e^{-kt})$
- Peak 2 = $D/V + (D/V) (e^{-kt})$
- Trough 2 = $[D/V + (D/V) (e^{-kt})] e^{-kt}$
 $= (D/V) e^{-kt} + (D/V) (e^{-2kt})$
- Peak 3 = $D/V + [(D/V) e^{-kt} + (D/V) (e^{-2kt})]$
- Trough 3 = $[D/V + (D/V) e^{-kt} + (D/V) (e^{-2kt})] e^{-kt}$
 $= (D/V) e^{-kt} + (D/V) e^{-2kt} + (D/V) (e^{-3kt})$
- Peak ss = $(D/V)[1/(1 - e^{-kt})]$
- Trough ss = Peak ss (e^{-kt})

Traditional "practice" or example problem (case study)

- Quinidine is a drug used to treat cardiac arrhythmias. It is available for IV administration in a solution containing 80 mg/ml
- The pharmacokinetic parameters for quinidine are listed below:
 - Clearance 4.7 ml/min/kg
 - Distribution volume 2.7 L/kg
 - Therapeutic range 2-6 mg/L
- Determine an appropriate IV bolus dosage regimen including maintenance dose, dosing interval, and loading dose for quinidine in a 60 kg patient. (Be sure and check your expected steady-state peak and trough for the dose and interval you recommend.)

Traditional approach

- Student given all of the pertinent information needed to work the problem
 - condition being treated
 - dosage form and strengths available
 - pharmacokinetic parameters
 - therapeutic range
- Student instructed to determine specific information
 - calculate loading dose,
 - maintenance dose,
 - dosing interval
 - check for expected peaks and troughs

PBL problem from clinical setting

- MH has been admitted to the CCU with atrial arrhythmias. You are the clinical pharmacist for that unit. The cardiologist wants to place MH on quinidine and asks you for your recommendations.
- MH is a 80 kg, 50 yo male. His SCr is 1.5 mg/dL.

PBL problem from clinical setting

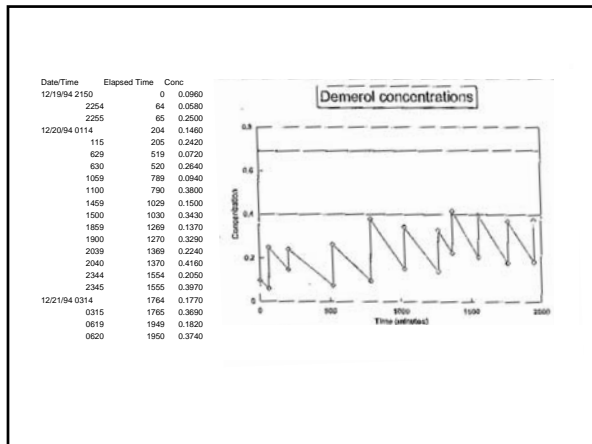
- Student given some information needed to evaluate the situation and some information not needed for this problem
 - Needed
 - condition, drug, age, wt
 - Not needed
 - SCr
- Student must identify information to retrieve, appropriate sources of that information
 - dosage form and strengths available
 - pharmacokinetic parameter estimates
 - appropriate therapeutic range

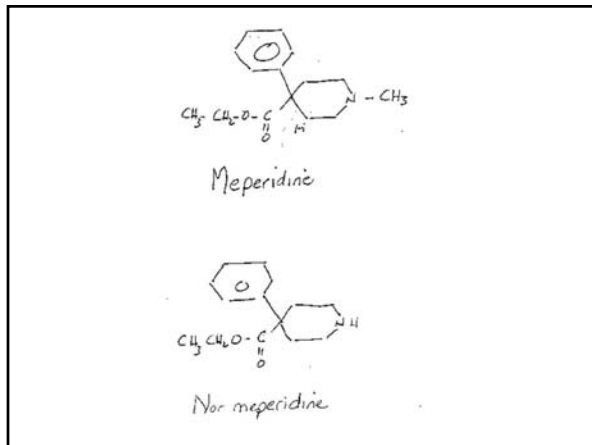
PBL problem from clinical setting

- Student must determine
 - appropriate therapeutic range
 - need for loading dose
- Student must determine necessary calculations to make recommendations
 - loading dose
 - maintenance dose
 - dosing interval
 - check for expected peaks and troughs
- Students must determine if/what follow-up is necessary

Forensic problem

- JJ is a 19yo white female who presented to the emergency room of Shelby Medical Center with severe flank pain and nausea. Following radiologic evaluation, the ER physician diagnosed JJ with renal calculus. She was admitted to the hospital and placed on Phenergan® and Demerol®. On the day following admission JJ's boyfriend ran hysterically into the hallway reporting that JJ was having a seizure.
- You are currently on clerkship as a fourth year pharmacy student and are rounding with the medical team caring for JJ.





Forensic problem

- What questions should the pharmacist ask and answer for the medical team to determine the cause, future prevention and tx of JJ's seizures?
- Do Phenergan® and Demerol® cause seizures at subtherapeutic, therapeutic or toxic concentrations?
- Could a drug interaction or a metabolite be the problem?
- Based upon the dosing of the drugs would her serum conc be adequate to cause seizures?
- Are any medical consults available to address the contribution of the previous MVA and closed head trauma to the seizure?

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Forensic problem

- Patient's actual drug administration
 - complexity of equations
 - accumulation to steady-state
- Ideal drug administration
 - simplification of equations at SS with consistent dose and interval
 - predictability

Legal Issues Related To:



- Admissions Process
- Background Checks
- Random Drug Testing

Admissions: ACPE Requirements¹

- ACPE prohibits discrimination in the admissions process
 - **Guideline 16.6:** admission policy “must ...ensure nondiscrimination as defined by state and federal laws and regulations, such as on the basis of race, religion, gender, lifestyle, sexual orientation, national origin, or disability”

Admissions: Legal Requirements²

- For schools receiving federal funds:(financial aid!)
 - Cannot discriminate based on:
 - Race, color, origin, religion (Title IV Civil Rights Act 1964)
 - Gender (Title IX Education Amendments 1972)
 - Disability (includes learning difficulties; Rehabilitation Act 1973, Section 504)
 - Age (Age Discrimination Act 1975 & some state-specific laws)
- Same basic laws as when hiring employees

Admissions & FERPA²⁻⁴ (Family Educational Rights & Privacy Act 1974)

Mandates that students:

- Be notified of privacy rights
- Have:
 - Access to own educational records
 - Right to challenge information documented in their record
- Give:
 - Consent before any information in their student record is released to others

Allows schools to:

- Release details of campus crime reports WITHOUT a student's consent (since 1992)
- REFUSE access to records of:
 - Prospective students
 - Rejected applicants

Admissions: Our Process

Admissions Committee

- Review all applicant files
- Select those who will be offered an interview based on academic qualifications
 - Our Pre-Pharm students have preference
- Review interview results
- Select candidates for admission
- Candidates notified within ~2 weeks of their status

All Faculty

- Interview candidates in pairs using standardized list of questions (Jan-April)
- Assess written (essay) and verbal (interview) skills
- Individually score candidates, provide relevant comments, recommend: admit/not admit/ further committee review

Admissions: Challenges

- Applicant interview process
 - Must base decisions on appropriate information
 - Ask consistent questions
 - Avoid discriminatory questions
 - Age/Spouse/Children
 - Health status/Gender/Sexual orientation
 - Careful of inappropriate comments/jokes during admissions committee meetings

Your Turn:

Write your thoughts here...we'll discuss later

- **What is your school's greatest challenge regarding legal compliance in the admissions process?**



Student Background Checks: Why Do Them?^{5,6}

- Minimize liability (school and clinical sites)
- Determine if admitted applicants/students:
 - Safe for school & patient care settings
 - Eligible for eventual pharmacist licensure
- As of 2006:
 - 63% SOPs had a BGC policy
 - 33% did BGC at admission; 33% did > 1 time

Student Background Checks: ACPE Requirements¹

- Schools must have statement/policy on criminal BGC (as of 2007; see AACCP policy guidelines)
 - **Guideline 17.4:** “Criminal and other activities that may restrict the student’s ability to access experiential sites or potentially affect the student’s eligibility for future licensure...should be identified....”

Student Background Checks: Legal Issues^{5,6}

- Applicable laws:
 - Federal
 - » Fair Credit Reporting Act 1970
 - » Fair & Accurate Credit Transitions Act 2003
 - State FCRA Equivalents
 - » Often more restrictive than federal law
 - » Some limit use of this information for educational purposes

Student Background Checks: Legal Issues^{5,6}

- Inform applicants of your policy
- Student must be accepted for admission in your program before you can conduct BGC
- BGC may show juvenile offenses, arrested but not charged cases, etc
 - If applicants leave this information off it looks as if they are trying to hide something

Student Background Checks: AACP/PharmCAS^{5,6}

- Pilot study with CERTIPHI began 6/09 (10 SOP)
 - Admission offers reported weekly in PharmCAS
 - Certiphi notified if school requires BGC
 - Applicant notified by Certifphi of need for BGC
 - Applicant completes forms within PharmCAS
 - Report sent to applicant to review - may clarify or challenge information
 - Final report sent to school within ~ 1 week

Student Background Checks: AACP/PharmCAS⁶

- Potential benefits:
 - Standardize process of BGC
 - Allows BGC to be initiated before matriculation
 - Future BGCs processed more quickly
- Estimated costs:
 - Extra \$15 per PharmCAS user (not just those who receive an offer of admission)

Student Background Checks: Our Process

- Were doing online just prior to APPEs
- Now - sign BGC release upon acceptance and conduct via PharmCAS/Certifphi
- Final admission contingent on passing BGC
 - If they refuse BGC, we withdraw the offer
 - If they consent and problems show up on the report, we may withdraw the offer

Student Background Checks: Challenges

- Must have intern license before first IPPE
 - Register with BOP after first day of class (in AL)
 - If license delayed/withheld, interferes with IPPEs
 - Up to 3 months for license if any BGC problems
 - Example: Drug possession charge at age 15
 - Our BOP will now review BGC problems early
- BOP could refuse pharmacist licensure even if they grant intern license

Your Turn:

Write your answer...we'll discuss later

- **What is your school's greatest challenge regarding legal compliance in the admissions process?**



Random Drug Tests: Why Do Them?

- Minimize liability (school and clinical sites)
 - Typical contract language: "Must be actively enrolled in a drug monitoring program"
 - Usually do not specify testing schedule/drugs to check
- Determine if admitted applicants/students:
 - Eligible for eventual pharmacist licensure
 - Safe for school & patient care settings

Random Drug Tests: Legal Requirements²

- Organizations receiving federal funds must (Drug-Free Workplace Act 1988) :
 - Have written policies on drug and substance use/abuse
 - Provide a drug awareness program
 - Make a good-faith effort to maintain a drug-free workplace

Random Drug Testing: Our Process (using PharmCAS/Certiphi)

- Student signs release on admission
- Test everyone randomly twice/yr for pot, crack, cocaine, benzos, narcotics
- Can remove students from testing as needed
- Student has 48 hr to leave sample (~\$35)
 - If positive, student must verify having Rx
 - If cannot, retest done to confirm
 - Once notified, we must notify BOP

Random Drug Testing: Challenges

- Student privacy issues (states, schools view this differently)
- No standard screening list, schedule or response to positive tests (1x only in 4 yr?)
- Potential conflict of interest for testing companies (more frequent testing = more \$)
- If BOP suspends intern license, students cannot complete IPPEs/APPEs

Your Turn:

Write your answer...we'll discuss later

- **What is your school's greatest challenge regarding background testing?**



Discussion Topics

- Admissions Process & Interviews
 - What is involved in the process?
 - Who conducts the interviews?
 - When are they done?
 - Common policies/procedures?
 - Most problematic issues

Discussion Topics

- Background Checks
 - How many schools are using them?
 - What is involved in the process?
 - When are they done?
 - Who pays for them? How much are they?
 - Common policies?
 - Most problematic issues

Discussion Topics

- Random Drug Tests
 - How many schools are using them?
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 - Common policies?
 - Most problematic issues

References



1. ACPE. Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree. Chicago, IL: ACPE, 2006.
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4. Van Dusen V. and Spies A. Student Privacy: Implications for Pharmaceutical Education. AJPE 2003; 67(1):20-30.
5. Certiphi & AACP. Criminal Background Checks on Student Pharmacists (presentation). Available at aacp.org [accessed 6/22/09].

References

6. AACP. Report of the AACP Criminal Background Check Advisory Panel, November 2006. Available at aacp.org [accessed 6/22/09].

Honor Codes and Legal Implications for Colleges/Schools of Pharmacy

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Honor Codes and Legal Implications for Colleges/Schools of Pharmacy

- I. What are the Legal Issues?
- II. Case Examples
- III. Practical Tips

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Some of the Legal Issues

- School of Pharmacy's Policies and Procedures (Student Handbook)
- Codes of Conduct and Vagueness
- Due Process Concerns
- Equal Protection

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Student Handbooks

- Do your institutions have them?
- Are they disseminated to students?
- Acknowledgement of receipt
- Information in Handbook
- IMPORTANT – Policies, Procedures, Codes stated in Handbook must be _____ !

Codes of Student Conduct

Three Major Issues:

- The type of conduct the code will encompass
- The procedures to be used when infractions of the code are alleged
- The sanctions for code violations

Examples.....lying, cheating, stealing, plagiarism, failing to report a violation

- Off-campus activity?

Void for Vagueness

Vague Regulation Requirement:

- The Code must be clear enough for students to understand the standards with which their conduct must comply, and
- The Code must not be susceptible to arbitrary enforcement

Academic vs. Non-Academic Dismissal

- Does it matter from a legal standpoint?
- Can you dismiss a student for “non-academic” reasons?
- Will you be sued?
- What are the courts’ attitude regarding these matters?

Academic Dismissal

“When judges are asked to review the substance of a genuinely academic decision...they should show great respect for the faculty’s professional judgment.”

Academic Dismissal

“Plainly, they may not override it unless it is such a substantial departure from accepted academic norms as to demonstrate that the person or committee responsible did not actually exercise professional judgment.”

Regents of the University of Michigan v. Ewing, 106 S. Ct. 507, 513 (1985).

Due Process

Procedural Due Process

- Standard met “by way of adequate notice, definite charge, and a hearing with opportunity to present one’s own side of the case and with all necessary protective measures” (*Estaban v. Central Missouri State College*, 415 F.2d 1077)

Due Process

Substantive Due Process

- Student must demonstrate “arbitrary and capricious conduct on part of College by showing there was no rational basis for the College’s decision or that dismissal was motivated by bad faith or ill will unrelated to academic performance”

Richmond v. Fowlkes, 228 F.3d 854; 2000 U.S. App. LEXIS 24822.

Equal Protection

- Citizens are protected from “arbitrary or irrational state action” by the Equal Protection Clause
- It is essential that all students be treated equally (Note: This does not mean all students’ results will be the same)

Lack of Professionalism and Student Termination

“Personal hygiene and erratic attendance may be appropriately considered by a medical school as factors bearing on a student’s academic standing in a professional program.”

Board of Curators of the Univ of Missouri v. Horowitz, 435 U.S. 91 (1978)

Violating Student Code and Student Termination

Former student expelled for violating college code (next slide) after pleading nolo contendere to a misdemeanor charge of attempting to obtain a controlled substance with a fraudulent Rx

Student alleged school’s standards were unconstitutionally vague

Violating Student Code and Student Termination

Westark College assumes that, by the act of registering, the student agrees to obey all rules and regulations formulated by the College as listed below and to obey all federal, state, and local laws.

Students are expected to conduct themselves in an appropriate manner and conform to standards considered to be in good taste at all times. This implies a consideration for the welfare and reputation of the College and other students enrolled at the College. Students exhibiting behavior problems not compatible with good citizenship can expect to be reprimanded, have certain restrictions imposed, or be denied the privilege to continue as students.

Violating Student Code and Student Termination

Do you feel this Code of Conduct was “vague?”

The court held that the standards’ reference to “good citizenship” was sufficiently precise to notify the student that her criminal act constituted unacceptable conduct that could lead to expulsion

Agree or disagree?

Violating Student Code and Student Termination

In cases like this (and subsequent case), it is important for the institution to “articulate a reasonable relationship between the off-campus misconduct and the well-being of the college community.”

If institutions meet this criteria, courts “will not overturn a disciplinary action unless they find that the action was arbitrary, an abuse of discretion, or a violation of a student’s constitutional rights” (Kaplan and Lee 2007).

It is important, though, for the institution to state this in its student code.

Violating Student Code and Student Termination

Pharmacy Student Case Example:

- Phrase in question was “detrimental to the interests of the University community”
- Pharmacy student pled guilty to possession of cocaine but claimed that code was vague
- Court stated that a pharmacy student in his last year of pharmacy school was aware that the illegal use and possession of narcotic drugs would violate the law and the Code of Ethics of his profession

Violating Student Code and Student Termination

Lessons from this Case:

- As members of a profession, we may hold our students to higher standards
- Courts may be more willing to “accept much more intrusion into a student’s ‘real world’ experimentation when that student is pursuing a professional degree” (Kiplinger 2006)

Final Thoughts

1. Follow Policies and Procedures, as specified in the Student Handbook (signed Honor Codes)
2. Avoid Vague Language
3. Provide Mechanisms for Students to Report Violators
4. Determine if act makes a detrimental impact on the institution and its mission (this includes off-campus activities)
 - This may or may not be the same for each College/School of Pharmacy

Final Thoughts

5. Make Decisions that are Timely and Communicated to Student
6. Have Evidence to Support Your Decisions (Documentation)
7. Dismiss Students if Warranted (Our Responsibility to Profession)
8. Respect Confidentiality (FERPA)

Helpful References

Board of Curators of the Univ of Missouri v. Horowitz, 435 U.S. 91 (1978).

Estaban v. Central Missouri State College, 415 F.2d 1077 (8th Cir. 1969).

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Kiplinger JW. *Defining Off-Campus Misconduct that "Impacts the Mission": A New Approach*. 4 U. St. Thomas L.J. 87 (2006).

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