

PHA5255 Medications Use Process
Study Questions
Revised 11-8-03

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Week 1 Study Questions

1. In what sense was the death of Katherine LaStima an accident? Not an accident?
 - a. Summarize the events that lead to the death of Katherine LaStima. Organize these into a chain of causality, starting from the proximate (immediate) cause, then what caused that, etc.
 - b. Discuss the assertion that Katherine died from the natural course of asthma.
 - c. Who could have prevented her death? How?
 - d. How could the death of the “next Katherine” be prevented (or its probability be reduced?) What would be the advantages and disadvantages of punishing those responsible?

2. How severe is the problem of PDRM? How widespread is it?
 - a. What are typical, median incidence and prevalence of ambulatory PDRM, PDRA and inpatient PDRM?
 - b. How does the prevalence of PDRA compare to the prevalence of hospital admissions for selected other diseases? What is the practical significance of this comparison?
 - c. What is the basis of these numbers, i.e., what are two main research methods in these studies?
 - d. How, do you think, would the research method affect the results

3. According to research studies, what stage or step in the typical ambulatory medications use process may generate the most drug related hospital admissions?

4. According to research studies, what stage or step in the typical inpatient medications use may generate the most "errors" in medications use?
5. The article by Donald Berwick, *A User's Manual for . . . the . . . Quality Chasm Report*, describes the social context of medical care, medications use and this course --
 - a. What (who) wrote *Crossing the Quality Chasm*?
 - b. Were there precedents to that report or did it surprise the world, "out of the blue"?
 - c. What was the motivation for writing it, e.g., was it requested by the government or a political party?
 - d. What is the "underlying framework" (levels) of *Crossing the Quality Chasm*?
 - i. How are the four levels related?
 - ii. Which of these does *Crossing the Quality Chasm* put above the others? (Berwick calls it "True North.")
 - iii. State an example of a relationship between this "true north" level and each other level. Your example should be related to pharmacy practice or medications use, and can either describe a present problem or a possible change at that level.
 - e. Give an example for the "old" and the "new" rules, in particular #4, #5 and #6.
 - i. First of all, what are rules #4,5, and 6?
 - ii. Give examples related to pharmacy practice or medications use. (Hint. See Chapter15 of PME-IDO.)
 - f. What is a "toxic financing scheme?" Give an example related to pharmacy practice or medications use.

Week 2 Study Questions

1. Describe a model to explain the causes of PDRM. Define the basic concepts in the model (DTP, DRM, error, etc.) and how they relate to each other.
 - a. define *adverse drug reaction*, *adverse drug event*, and *drug related morbidity*. How do they differ?
 - b. Define *error*.
 - c. what are some of the more important limitations of "error" as an explanation of DRM?
 - d. What is latency? What are two types of latent precursors? What is the distinction between them?
 - e. What is the relationship between latent injury and a DTP?
2. What is system failure? How is it different from error?
2. Name and describe the four criteria for preventability.
3. Give an example of a PDRM indicator and analyze it (explain how it would satisfy each criterion for preventability).
4. Sometimes the objective of a drug therapy system is stated as, "preventing DRM," and sometimes as "promoting definite outcomes intended to improve a patient's quality of

life." compare and contrast the two ideas. Do they say essentially the same thing?

Week 4 Study Questions

1. What does pharmaceutical care “look like” on a patient and practice level?
 - a. describe the TOM (pharmaceutical care) "flow diagram" model of cooperative, systematic pharmaceutical care.
 - b. Where are the main points of cooperation? Cooperation with whom?
 - c. what is the logic of the ordering of steps in the process? For example, why does the monitoring plan come before dispensing? If all steps were carried out, but not necessarily in order, what difference might it make in patient outcomes?
2. What are the most important structural differences between a medications use process and medications use system?
 - i. if you looked at a diagram how could you distinguish them quickly?
 - ii. How would this distinction explain success or failure in many activities, e.g., frying a hamburger (or even a veggieburger)?
3. Discuss an example of a *clinical* indicator (per Chapter 10) for a common drug therapy problem.
 - a. Give an example of the step in care where a pharmacist compares a clinical indicator to a therapeutic objective.
 - b. Compare and contrast "DTP" and "clinical indicator."
 - c. Compare and contrast the SOAP process and clinical dialog.
 - d. In what way does clinical dialog in a community pharmacy have a similar purpose to a medical record in a hospital?

Week 5 Study Questions

1. Describe and apply the principles that might help to prevent PDRM in individual patients. (One way to apply them is to describe how they are related to preventing specific DRM.)
2. What is the basis of these five principles? Describe support for them from the literature reviewed in Chapters 2-3.
3. What are initiators, co-therapists and facilitators?
4. The concepts of *initiators*, *co-therapists* and *facilitators* are similar to *physician*, *pharmacist* and *patient*. How does *initiator* differ from *physician*, etc. Why use the less familiar term?

Week 6 Study Questions

1. Who are the people in medications use?
 - a. What are initiators, co-therapists and facilitators?
 - b. The concepts of *initiators*, *co-therapists* and *facilitators* are similar to *physician*, *pharmacist* and *patient*. How does *initiator* differ from *physician*, etc. Why use the less familiar term?
2. Describe various objectives of medications use and their corresponding perspectives
 - a. describe illness and disease with respect to . . .
 - i. their effect on cooperation and disagreement within the initiator--cotherapist--facilitator triad.
 - ii. their function in the practice of medicine
 - b. what are the three basic forms of professional relationship described in chapter 4?
 - c. what is “therapeutic” about a therapeutic relationship? Consider the Homer deBrave exercise in Case 1. Give a hypothetical example of how a therapeutic relationship could contribute to improved outcomes for Mr. DeBrave, compared to the other two types of relationships.

Weeks 7-9 (Environment of Medications Use)**Week 7 Study Questions (10-8-03)**

1. Offer a definition for “managed care” including its purported goals as well as its “real” goals.
2. Who do MCOs contract with? If you decided to work for Eckerd, what is the relationship between Eckerd and a MCO? (Think about this relationship from a variety of perspectives.)
3. Why is managed care important to pharmacists and the organizations that they work for? Would you advise an independent pharmacy to drop a managed care plan if they were not happy with the reimbursement they were receiving for providing pharmacy services?
4. Describe the earliest beginnings of managed care in the United States.
5. Discuss the concept of prepaid financial arrangements and how it is different from fee-for-service payments. Define the terms capitation payment, fee-for-service payment and discounted fee-for-service payment. Compare and contrast these terms and identify the payer and payee (in terms of employer, insurance company, MCO, physicians, pharmacist, hospital, etc.).
6. Define the terms PCP, gatekeeper, closed and open panel, and multispecialty group practice.
7. Describe the characteristics of Preferred Provider Organizations in terms of network arrangements, payment structure between employer, PPO and/or insurance company, and providers. Who bears the financial risk in a PPO arrangement?
8. Compare and contrast HMOs with PPOs. Name and compare/contrast the four major types of HMOs. Rank order these MCO types in terms of intensity of controls.

Study Questions for Week 8 (Part 1, 10/14)

1. Describe change in enrollment in PPOs, HMOs, and traditional indemnity insurance during the past twenty years. In terms of all insured Americans, what percentage is enrolled in these different types of MCOs today? Which MCO types are most likely to be the dominant players during the remainder of this decade?
2. For members enrolled in a HMO, which type of HMO has the largest market share?
3. Which states have the highest HMO penetration rate and how does Florida compare?
4. Discuss Medicare and Medicaid Managed Care, especially in the context of Florida. In Florida Medicaid, what are the differences between Medipass and the HMO option (hint: go to the website for the Agency for Health Care Administration in Florida)?
5. Give an example of a capitation rate paid by an employer to a managed care organization or insurance company. What health care services would that capitation cover? Give an example of a capitation payment paid by a MCO to a primary care medical group and discuss how a medical group could reimburse PCPs, specialists, and other providers. Discuss whether capitation payments are used for pharmacy services and, if not, how these services are paid.
6. Why has the annual percentage change in prescription drug costs been in the double digits recently? Is the average percentage increase larger for brand name drugs compared to generic drugs?
7. What is AWP and how is it determined? How is AWP different from “dispensing fee?” What is an example of a typical prescription reimbursement fee and can it vary from insurance payor A to insurance payor B?
8. What is the relationship between age and number of prescriptions dispensed annually?
9. Describe the differences between NCQA, URAC and JCAHO (Hint: go to their websites)?
10. Describe the purpose of HEDIS and give an example of several performance indicators included in HEDIS? Are any related to pharmacy? How is the data for these indicators collected? How are they used?

Study Questions for Week 8 (Part 2, 10/15)

1. How have prescription drug costs changed during the past twenty years and what predictions might be made for the next ten years?
 - a. What is the approximate average retail price of a prescription? What is the average reimbursement rate?
 - b. When a pharmacy sells a prescription to a consumer, on average, about what percentage goes to the pharmaceutical manufacturer, to the wholesaler, and to the pharmacy?
 - c. What does the trend line for utilization of drugs look like in terms of its slope and what are the approximate average prescriptions per member per year dispensed today? How does the trend line change based on patient demographics?
2. What proportion of medical care costs are for pharmaceuticals and how does the trend line look from 1990 to 2010?

3.
 - a. Approximately how many retail prescriptions are dispensed annually in the United States?
 - b. What is the annual cost in the United States for retail prescriptions? Show the trend line and identify the annual cost based on 2000 data.
 - c. Identify and describe the components that help to explain the rise in prescription costs from year to year.
 - d. Does the 80/20 rule apply to pharmaceutical costs/patient for a typical PBM?
4. Identify the role of PBMs in implementing strategies used by managed care to influence medications use.
 - a. Offer a definition for pharmacy benefit management companies (PBM).
 - b. Who are PBM's clients?
 - c. What services are typically provided by PBMs?
 - d. Name the three largest PBMs.
 - e. Describe how PBMs provide patients access to pharmaceuticals.
 - f. Discuss the financial arrangements between a PBM and its network pharmacies and how PBMs reach decisions about the composition of their networks.
5. Discuss vertical integration based on Dr. Segal's lecture and its implications to formulary design.

Study Questions for Week 9 (10/21)

1. Describe the role of drug formularies in managed care.
 - a. How are formularies prepared in MCOs?
 - b. What are some advantages and disadvantages of formularies?
 - c. Define the following terms concerning drug formularies: open; closed; partially closed, positive, negative, generic substitution; therapeutic interchange.
2. Discuss the concepts of tiered co-payments; prior authorization, preferred and excluded drug products; and limits on the number of prescriptions, quantity of drug, or day's supply per prescription.
 - a. Why do MCOs use copayments?
 - b. Explain how a preferred drug differs from a non-preferred drug. Who determines which medications fall into each category and what factors are considered in this assignment?
 - c. What is RxHub and what might be its impact on the pharmaceutical distribution channel? How might it affect the role of pharmacists?
 - d. What are some advantages and disadvantages of drug cap programs?

3. Discuss Utilization Controls on Physicians
 - a. Discuss prior authorization and drug utilization reviews (DUR) including the role of OBRA 90 in the area of DURs.
 - b. Discuss physician profiling activities and some examples of profiling measures involving drug therapy.
4. Discuss disease management and pharmaceutical care.
 - a. Discuss what is intended by the statements “recognition that large variations in medical practice exists” and “the gap between actual medical practices and evidence-based best practices.” Give some examples from the literature to explain these ideas.
 - b. Define disease management.
 - c. Define Clinical Practice Guidelines and their intended purpose.
 - d. What is the role of MCOs, PBMs, and pharmacists in implementing practice guidelines?

Study questions for weeks 10-11, Access, Cost and Quality

1. Be able to define cost, access and quality of health care and to show that you can use the definitions.
2. What are the dimensions of the “quality cube”? Give examples of important intersections of quality “domains” and “components,” e.g., continuity of process.
3. What are some sources for quality standards?
4. How can the quality of drug therapy be assessed? What are the limitations of DUE from this perspective?
5. What is efficient drug therapy? What are the differences among efficacy, effectiveness, and efficiency?
6. What is an incremental cost analysis? How is one calculated? How is one interpreted?
7. Apply the formal (four-criterion) definition of preventability to the circumstances that lead to drug withdrawals (scenarios 1 2 or 3) :
 - a. briefly state each preventability criterion and discuss its application to the events that lead to drug withdrawal.
 - b. what is the relationship between the withdrawal scenarios proposed in chapter 5 and preventability of DRM?
 - c. summarize the general scenario(s) describing drug withdrawals. How does this reflect on the drug approval process?
8. What argument would you make to a managed care executive in favor of efficient drug

therapy and against drug cost (or prescription benefit) minimization? What do the New Hampshire medicaid studies show about drug cost minimization?

9. What is optimality? Be able to give a precise definition or description of optimal drug cost that is consistent with the definition of optimality, p. 111 and the Glossary.
10. Under what conditions (if any) can quality of care be improved without either increasing total expenditures or decreasing access to care?
11. What are the four basic elements of “quality improvement”?
12. What are the strengths and limitations of the food and drug “product law” approach to drug quality?

Study Questions for Week 11(b) & 12(a) M.U.S. Performance Information

1. What information is required to control PDRM in populations?
2. What is an indicator?
3. What types of indicators are used in medications management?
4. What is the basic information needed to define an indicator?
5. Distinguish between rate based and sentinel indicators in terms of the information needed to define them.
6. Explain how indicator rationale and scope are used to interpret indicator data.
7. What is indicator validity? How can it be expressed numerically?
8. What is indicator reliability? How can it be expressed numerically?
9. What is a PDRM indicator (aka medications management system performance indicator)?
 - a. How is a PDRM indicator validated?
 - b. What do PDRM indicators contribute to a medications management system?
10. What is the definition of preventability upon which PDRM indicators are based?

Week12 (Outline of a Med Use System, Lecture 14)

1. Medications Use System
 - a. What are the *two* major components of a “medications use system?”
 - b. What is the collective name for a pharmaceutical care system within a medications management system?
 - c. Where do “pharmaceutical care system” and “medication management system” fit into the four system levels described by Berwick and the IOM?
2. What are three ways to describe a system?
3. What is the definition of a system?
4. What six attributes (elements) characterize a *specific* system?
 - a. Why is purpose the primary attribute?
 - b. How does the definition of inputs and outputs influence “processes”?
 - c. Give a major example of “information flow” and state its function relative to other attributes.
 - d. How can we define the environment in terms of influence?
5. Describe, in general terms, the relationship between a pharmaceutical care system and a medications management system. *Compare* the steps and *contrast* the “object” that each is intended to control. (See text p 226-7, 285-7)

Study Questions- Week13 (Lecture 15, Medication Management System)

1. What is the purpose of Focus-PDCA and similar techniques?
 - a. What does the acronym, “FOCUS-PCDA” stand for? Describe each step and give examples.
 - b. What is a “Shewhart” or “Deming” cycle?
 - c. On what bases could we “find” a process to improve?
 - d. What “variations” do we try to understand the causes of?
 - e. Compare/contrast error analysis (sentinel event analysis) and continuous improvement of quality (QI).
2. Describe the organization, appearance and uses of an Ishikawa (Fishbone) diagram
3. Describe the organization, appearance and uses of a cause and effect tree diagram. What are the five whys?
4. What is a control chart?
 - a. What is the function of a control chart?
 - b. What are control limits?
 - i. What is the statistical logic of calculating them?
 - ii. What is the statistical logic of using them?
 - iii. It is usually said that a process is “in control” when its outputs are within

control limits. Should exceptions to this rule be made when the outputs being charted are PDRM? Why?

Study Questions Week 14 (Effects of Systems on Cost and Quality)

1. Critically assess the studies summarized chapter 9, Tables 9.2 and 9.3. What do they tell you, and what is their significance, from the perspective of. . .
 - a. A community, ambulatory care or hospital pharmacy practitioner.
 - b. A community, ambulatory care or hospital pharmacy manager
 - c. A managed care executive
 - d. A systems theorist
 - e. A practicing physician
2. Compare and contrast the Swiss Cheese model and the simulation model from the perspective of systems theory.
 - a. What is their objective?
 - b. How are they similar?
 - c. How are they different?
3. What do Parts 1 and 2 of the simulation represent?
4. How does the simulation represent decisions and actions in medication use? What was the main simplifying assumption used in the simulation?

Study Questions Week 15 (Prescribing Improvement)

1. Describe four fundamental criteria for appropriate prescribing.
2. A medical philosopher commented that therapy based only on objective scientific standards is "wrongheaded"? Discuss your understanding of this point.
3. What are the relative advantages and disadvantages of explicit and implicit prescribing criteria? How can the respective advantages be combined?
4. What is drug use evaluation (DUE)?
 - a. describe the steps in retrospective DUE.
 - b. compare and contrast the *scope of DUE* and the *quality of medications use*.
5. Prescribing influence and improvement methods can be divided into "direct" and "indirect" approaches or methods. Of the two broad approaches, . . .
 - a. Why are educational approaches "indirect"?
 - b. Why are prescribing restrictions "direct"?
 - c. Give examples of each and briefly describe them
 - d. Which has the stronger research support?
 - e. Which has the clearer theoretical basis?

- f. What are “unintended consequences” of some prescribing interventions?

Study Questions Week 16 (The Way Forward)

1. What are the main stages in the adoption of an innovation?
2. What are the main issues in the adoption of an innovation?
3. Which stage do you believe the greatest (or the present) obstacle to adoption of Medications Use Systems is? Why?
4. Which issue do you think is the greatest obstacle to adoption of pharmaceutical care?
5. Name some constituencies in the adoption of Medications Use Systems.
6. Describe the significance of performance indicators as part of a strategy to broaden adoption of medications use systems (MUS).
 - a. What is the NIMP defense? Is it related to denial? How (not)? (p. 350 & 359)
 - b. theoretically, why would the NIMP defense be the “fundamental obstacle” in the adoption of MUS? (p. 358)
 - c. How could performance indicators be a powerful means for overcoming the NIMP obstacle?
 - d. how could performance indicators illustrate the effectiveness of an MUS, as a supplement or alternative to large-scale randomized controlled trials?
7. Give an example of the acquiescence (“boiled frog”) defense as it might be used by a pharmacy organization.
8. What is a “quality tax”? How might new standards, e.g., requiring pharmacies to provide pharmaceutical care or QI programs, reduce the “quality tax”?

Practice questions

The following questions are intended to help you study and to familiarize you with the types of questions that will be on the exams. Some multiple choice questions (mcqs) will require recall of facts or relationships but *other mcqs will require you to reason*. Word limits will be given for short answer and essay questions to guide you. Within reason, longer answers would not be penalized. Many questions on the exam will be based on a case, probably one from the textbook or from lab. Please also see the comments at the end of this document.

Caveats:

In these practice questions, you might be able to figure out the answer to one question from the information given in another question. The questions on the exam will not have this problem. Many, perhaps all, actual questions on the exam will be different from these practice questions. Therefore, learn why a particular answer to each question

would be correct or incorrect. Learning the correct answers per se would be an inadequate study strategy.

- Match up the following acronyms for adverse effects of drug therapy with the description that is closest to being correct.

ADR	a. caused by the use of drugs. Includes overdose and, in effect, other errors in use
ADE	b. caused by the use of drugs or the non-use of drugs when a valid indication is present. In effect, includes errors in both use and non-use.
DRM	c. caused by drugs at normal doses. In effect, error is excluded as a cause

- An error (by the patient, caregiver or professional) is a necessary prerequisite for preventability. True or false? Explain briefly.
- What is the relationship between error and preventability? For example, in order for a Drm to be preventable, is it necessary that somebody committed an error?
- Most drm are caused by bad drugs, bad patients, bad physicians, or bad luck. True or false? Explain your answer briefly.
- In the case of Katherine LaStima, state one example of a latent injury and one example of a latent failure.
- Match up the concept in column a with the description in column b and briefly explain your answer.

Column A	column B
a.Theoretical DTP	1. An elderly patient who has a new prescription for a long-acting benzodiazepine (LBD)
b.Potential DTP	2. Prescribing long-acting benzodiazepines (BD) for elderly patients
c.Actual DTP	3. An elderly patient who is occasionally dizzy and disoriented
d. Manifest problem	4. An elderly patient who has been taking LBD at bedtime for sleep, who is occasionally dizzy and disoriented in the morning

It has been stated that illness is primary experience and disease is secondary experience.

- Discuss this statement -- develop an argument for or against its accuracy. (50 words)
- Describe ways in which this can affect a patient's cooperation in his/her own care. (50 words)

9. In the triad of initiator--co-therapist--facilitator, what is the difference between the functions of a cotherapist and a facilitator? (25 words)
10. Chapter 10 includes an example of a clinical dialog between Mrs. LaDichosa and a pharmacist. Case 3 also concerned a clinical dialog.
- at what step in the therapeutic outcome monitoring process described in Case 3 (Mr. Hammer) would these dialogs occur?
 - name and briefly describe some other steps in that cycle where clinical dialog with the patient would be likely to occur.
 - name and briefly describe some steps in that cycle where clinical dialog with the patient would be *unlikely* to occur. (Hint – to answer b and c well you would have to know what the purposes and steps of clinical dialog are and how clinical dialog differs from an ordinary conversation.)
11. It has been claimed that the order of steps in pharmaceutical care is dictated by logic. In the therapeutic outcome monitoring process described in case 3 (mr. hammer), what is the logical justification (if any) for the location of step 4 "design a monitoring plan" before step 5 "dispense and advise" and after step 3 "evaluate therapeutic plan."?
12. A co-therapist function is to medications use as _____ is to driving.
- planning a trip
 - steering
 - arriving at a destination
 - following a road map
13. Suppose a clinic pharmacist is monitoring a patient's total phenytoin serum levels. The phenytoin is being used long-term for its anticonvulsant effect. Assume that the usual therapeutic range is 5-20 :g/ml, usually 10-20 :g/ml. On a particular occasion, the patient has a level of 8 :g/ml. According to the theory of pharmaceutical care, the most appropriate basis on which the pharmacist should judge the acceptability of this result is
- according to normal therapeutic range
 - according to the therapeutic objective for this patient
 - according to the patient's response
 - a and b
 - b and c
- (Hints: this question is not about phenytoin. Also, it asks about theory, not what you think normal practice might be.)
14. In systems language, what does the patient's phenytoin level represent? (Choose the most accurate and precise response).
- outcome
 - clinical indicator
 - neither

15. Match up the *concepts* in Column a to the following terms: (a) subjective, (b) objective, (c) primary, (d) secondary, (e) ideal, (f) real, (g) general, (h) specific, (i) an experience, (j) a behavior, (k) an objective measure of a subjective experience, (l) a justification of behavior, (m) multi-dimensional, (n) a connection to a patient, (o) a connection to scientific knowledge. Note that every term applies to at least one concept, some terms may apply to more than one concept, and not every concept need receive the same number of terms.

Column A (Concepts)	Column B (Terms).
illness is .	
disease is . . .	
sickness is . .	
health-related quality of life is . .	

One way to do this exercise is to write one or more sentences with the terms, e.g., "illness is a subjective,"

The following table summarizes the results of a decision analysis done on anti-emetic therapy. Economic consequences of ineffective therapy include prolonged stay in the clinic, increased care (staff time), and occasional hospitalization. Other consequences of ineffective therapy mainly involve severe patient discomfort and inconvenience.

Therapy	Drug Cost (D)\$	Expected Effectiveness (E)*	Increment in E (ΔE)	Expected Total Cost of Therapy (C) \$**	Increment in C (ΔC) \$	Incremental Cost (ΔC)/e
A	\$80.00	7.0	0.3	\$100.00	\$30.00	\$100.00
B	\$19.00	6.7	1.7	\$70.00	\$20.00	\$11.76
C	\$35.00	4.5	-0.5	\$60.00	\$10.00	(\$20.00)
D	\$25.00	5.0	n/a	\$50.00	n/a	n/a

* subjective and objective ratings of antiemetic effectiveness within 24 hours following chemotherapy.

Maximum possible effectiveness = 8, minimum effectiveness = 0.

** from decision analysis as described in the text.

16. Given the decision analysis, . . .
- which therapy minimizes expected value of drug cost?
 - which therapy minimizes expected value of total cost?
 - which therapy maximizes expected effectiveness?
 - why is) C for drug B \$20.00?
 - which therapy should be excluded from consideration?
 - what is the cost per unit of additional effectiveness for drug b?
 - since the total cost of therapy includes drug cost, explain why the correct answers to question b above can be different from the correct answer to question a.

The following 3 questions refer to the description of Donald Ashwell's death in Chapter 5.

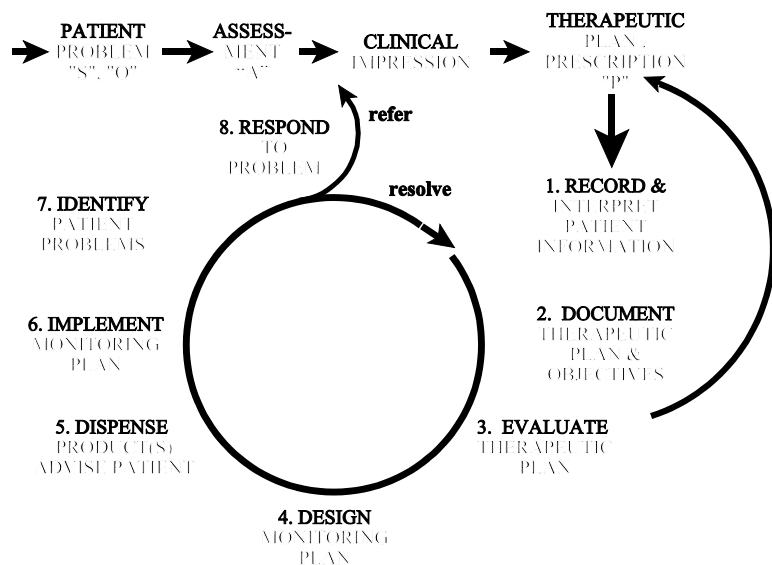
17. According to the theory of PDRM presented in this course, the death of Donald Ashwell
- was not a DRM, because he died from the natural course of his disease
 - was not preventable, because Ashwell's DTP could not be foreseen to possibly result in harm.
 - a and b
 - was a DRM, because it was a failure of drug treatment.
 - was preventable, because the treatment failure could be foreseen to possibly result in harm
 - d and e
- (In order for an alternative to be correct all of it has to be correct.)
18. The death of Donald Ashwell most clearly illustrates a violation of principle 2 (access). However, other principles were also violated in this case. Describe how the care of Donald Ashwell might be related to principle 5 (systems management)? (25 words)
19. In the case of Donald Ashwell,
- What was the principal DTP?
 - What was the resulting DRM?
 - State at least two bases on which you can distinguish the DTP from the DRM
 - Was the DRM preventable? Use the definition of preventability to make your case.
20. Quality of health care can be increased without increasing total expenditures . . .
- Only if access is reduced
 - If efficiency is increased
 - Both of the above
 - Neither of the above. Quality improvement must increase total expenditures
21. Would the prevention of PDRM necessarily increase the total expenditure for health care goods and services in a population? Why (not) ?
22. Suppose a clinic pharmacist is monitoring a patient's total phenytoin serum levels. The phenytoin is being used long-term for its anticonvulsant effect. Assume that the usual

- therapeutic range is 5-20 mcg/ml, usually 10-20 mcg/ml. On a particular occasion, the patient has a level of 8 mcg/ml. In systems language, what does the patient's phenytoin level represent? (Choose the most accurate and precise response).
- Outcome
 - Feedback
 - Therapeutic plan
 - Therapeutic objective
 - Performance indicator
23. Describe the four “quality tools” needed to manage patient care activities within a system
- Define performance guidelines/criteria, database, indicators and standards.
 - Describe how they relate and how are they used together to manage a system.
 - Quality improvement is defined as data-driven. What data should drive a medications management system.? Give an example.
 - Should an indicator be based on a guideline or vice versa? Why?
 - Would you say that *guidelines* are used to detect system performance problems or that *indicators* are used to detect system performance problems?
24. Guidelines . . .
- Are useful to detect system performance problems
 - Are descriptions of certain aspects of high quality system performance.
 - (a) and (b)
 - Neither (a) nor (b)
 - Neither (a) nor (b). Guidelines refer only to professional practice and are not related to system performance.
25. What information is required to control PDRM in populations?
- what is an indicator?
 - what types of indicators are used in medications management?
 - What is the basic information needed to define an indicator?
 - distinguish between rate based and sentinel indicators in terms of the information needed to define them.
 - explain how indicator rationale and scope are used to interpret indicator data.
 - What is indicator validity? How can it be expressed numerically?
 - What is indicator reliability? How can it be expressed numerically?
 - what is a PDRM indicator (aka medications management system performance indicator)?
 - each PDRM indicator has a specific rationale. In addition, they all have a common underlying rationale. What is the general rationale for the PDRM indicators described in this course?
 - How were the PDRM indicators validated?
 - What do they contribute to a medications management system?
 - What are the other essential informational components of a medications management system?

26. Describe the steps in the FOCUS-PDCA process
- describe the *purpose* of the FOCUS-PDCA process
 - list and briefly explain each step.
 - given data suggesting many problems with medications use, what are some criteria that can be used to “find” a process to improve?
 - what is the relationship between the nominal group process (NGP) and an Ishikawa diagram? For example supply the missing words: NGP is used to _____ root causes and an Ishikawa diagram is used to _____ them. (See Text chapter 11).
 - be able to define *special* and *random* variation in a control chart. Be able to interpret a control chart including identifying probable “out of control” values.
27. Consider the following indicator:
- Definition: patient with more than one active nonsteroidal anti-inflammatory prescription (overlapping refills for two or more NSAIDS for 2 months or longer.)
- Denominator: all patients receiving care during data collection period
- Type: rate
- Data source: pharmacy computer
- Scope: process of drug therapy; drug use management
- is this a process or outcome indicator? Why?
 - suppose that this is intended to be a sentinel indicator. What (if any) essential component(s) is (are) missing?
 - in addition, if this were intended to be a rate-based indicator, what (if any) essential component(s) is (are) missing?
28. Suppose that the above indicator was intended to be a rate-based PDRM indicator. Data were collected for this indicator for six months. Then a pharmaceutical care system was instituted, six months after the institution of pharmaceutical care system data were again collected for six months.
- What aspect of a TOM process would theoretically affect this rate the most?
 - Would you expect the rate (numerator/denominator) rise or fall? Why?
29. A pharmacy benefits manager developed some performance indicators and applied them to a database containing patient records for the company’s medicare managed care program. Then he selected a random sample of cases with indicator positives and negatives and gave summaries of those patients’ medical records to a panel of pharmacists and physicians qualified to judge the subject of the indicators. The *CHF* indicator counted the following events: a patient admitted to a hospital or emergency department (ed) with decompensated congestive heart failure (CHF) when he had a history of chf and no record of regular use of ace inhibitor or beta blocker. The expert panel performed 35 chart abstracts and reviews. Here are the results for the CHF indicator:

	Medical Record Review		
CHFM Indicator	MRR Positive (S+)	MRR Negative (S-)	Total
Indicator Positive (I+)	a 14	b 6	a+b 20
Indicator Negative (I-)	c 3	d 12	c+d 15
Total	a+c 17	b+d 18	n 35

- 30. What kind of indicator is this?
 - a. process
 - b. outcome
 - c. medication system performance (hybrid)
 - d. can't decide because there is not enough information
- 31. Calculate the accuracy, specificity, sensitivity (etc.) of this indicator.
- 32. Express accuracy, specificity, sensitivity (etc.) in words. What do they actually mean?
- 33. Suppose that the rate of the CHFM indicator in the population reviewed was 1.8% (18 per 1000 patient-years). Further suppose that 75% of the patients with CHF who did not receive appropriate management required emergency care for cardiac decompensation. Interpret this information in plain English, for example, as you would explain to the head of the managed care program.



- 34. What are the main limitations of U.S. Federal drug law for improving the safety and effectiveness of medications use?
- 35. In Figure 1, match each system element or function (a-d) with the step(s) with

Figure 1

which it is most closely associated.

- a. command signal
- b. comparator
- c. initiator
- d. feedback loop (control Information)

Match to . . .

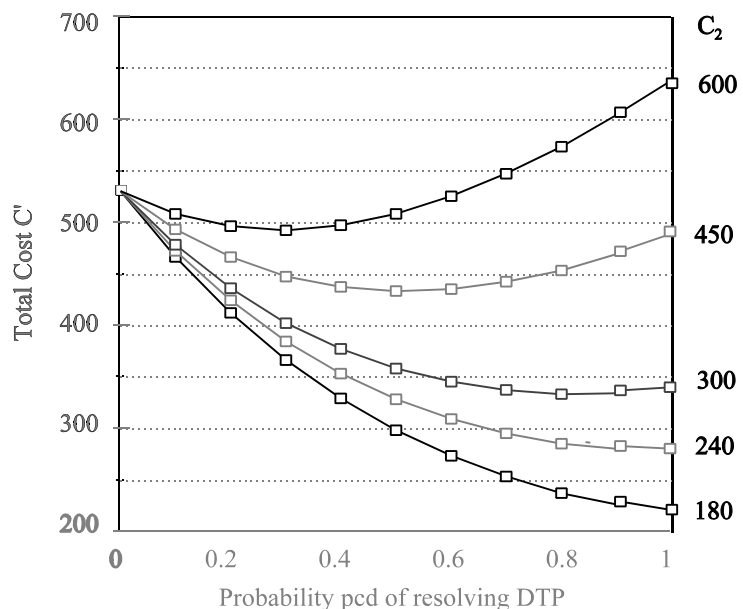
- (1) "Assessment "A"
- (2) step 3
- (3) step 6 - 8
- (4) step 7, specifically
- (5) step 1

In the following item, indicate whether each statement is true or false.

36. The system simulations described in chapter 9
- a. tracked the appearance and disappearance of dtp.
 - b. were a refinement of the swiss cheese model.
 - c. represented both initial therapy and continuing therapy.
 - d. were based on the model of drm developed in chapter 3.
 - e. supplemented empirical research studies of system effectiveness.
 - f. assumed that initiators have high error rates
37. What is the overall relevance to systems theory of the studies summarized chapter 9, Tables 9.2 and 9.3?
- a. increasing pharmacist involvement in medications use may be a cost-effective way to improve prescribing.
 - b. increased participation by pharmacists as cotherapists in medications use is often acceptable to facilitators.
 - c. adding system elements such as feedback and monitoring to a medications use process may improve patient outcomes, reduce costs, or both.
 - d. physician acceptance of pharmacists' advice is a key issue in acceptance of pharmaceutical care systems.

Figure 2 is taken from chapter 9.

38. What is the correct label for the "x" axis? (If it were not given)
39. What is the correct label for the [left-hand/right-hand] Y axis? (If it were not given)
40. In your own words, what is Figure 2



the most important point demonstrated by Figure 2?

41. Interpret the control chart shown in Figure 3. According to the theory of control charts presented in this course, . . .
 - a. which month's data (if any) clearly indicate that system performance has significantly degraded? Why?
 - b. which month's data (if any) clearly indicate that the manager should implement corrective action? Why?
 - c. which months show special variation?
 - d. if the manager implemented system change at some time during the first 12-18 months, when could he conclude that the change had been effective? Why?

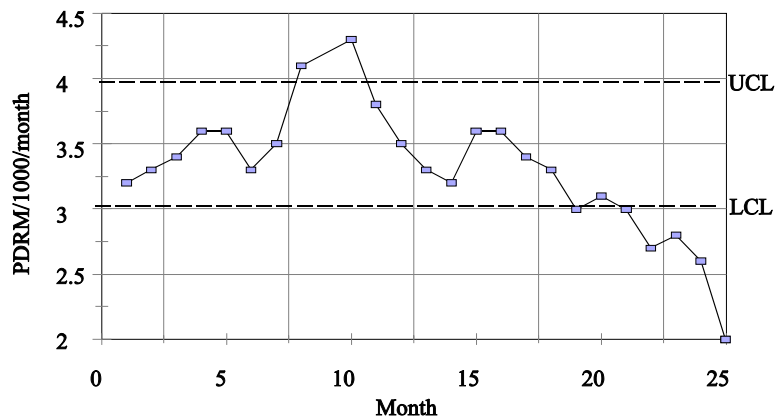


Figure 3. Control Chart

Medications Use Systems

General Comments on Study Strategy

Successful strategies in this course may differ from what you are used to. The exams in this course are based primarily on the course text and lab exercises. Class time is used mainly to discuss the most difficult and most important aspects, but does not present encyclopedic detail. The details, for example in the tables in Chapters 2, 3, 6 and 9, are there to support some main points. You should review the data as part of your critical reading of these chapters, but you should not expect to see questions with that level of detail on an exam.

For example, we would expect you to know the *range* and *median* of PDRA prevalence from Table 2.1, because the problem statement of the course depends on those facts. We would not, however, expect you to remember what study had the highest or lowest prevalence.

Exams will require you to know the key facts, principles and relationships that serve as the basis of the course and tie it together. The amount of factual information, however, is small compared to most courses in the sciences. Unlike some other courses, you do not have to memorize your way through this course. You may have to memorize some definitions, but normally it will be more important to know what the definition means, and how it differs from similar terms, than to remember exact words without fully understanding what they mean. Memorizing facts will get you to “first base,” i.e., quizzes, but not much further.

Writing successful exams in this course will require recall of key information, plus analysis, interpretation, evaluation and integration. These are similar to the skills you need to do well in the labs, and in actual practice. Lab exercises provide experience and practice in using and discussing the main points. The lab discussions are intended to further this experience and practice with these skills. This is why we go to the expense and trouble of having labs but don't grade your work in every lab.

Most people cannot hope to memorize “everything” in this course without discrimination. It will be much more effective to study for exams if you can see a “big picture” of medications use, and then use the big picture to guide your studying. The questions for each week outline the big picture, and the sub-questions lead back into the details. Some of the subquestions are close to possible exam questions. Following the weekly questions are a number of “practice questions.”

You could get lost in all the data and discussions of these chapters unless you use the main points as a guide. It would be very wise for you to know the answers to the study guide questions as you finish each week of the course. That would greatly reduce the amount of study time just before the exam. Also, questions to clarify your understanding are very welcome during class.

General (Objectives of the Course)

By the end of this course you should be able to critically describe and discuss the “big picture”:

- a. Describe the major quality (safety and effectiveness) failures in medications use.
- b. Describe likely causes of these quality failures.
- c. Identify the steps or decisions in the medications use process where these causes

- frequently occur.
- d. Explain general theories or principles of how to improve quality of medications use systems, e.g., Swiss Cheese Model and simulation refinements.
 - e. Describe a medications use system. Compare and contrast a pharmaceutical care system and a medications management system. Identify the functions of essential elements.
 - f. Describe the rationales for and obstacles against the adoption of medications management systems; describe actions that various stakeholders could take to implement quality improvement.
 - g. Describe at least one example of how “caring” or a therapeutic relationship could have improved patient outcomes.