Improving Quality of Care and Outcomes: Applications of Pharmacoeconomics and Value-Based Frameworks

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Financial Disclosure and Resolution

Under guidelines established under the Standards for Integrity and Independence in Accredited Continuing Education, disclosure must be made regarding relevant financial relationships with ineligible companies within the last 24 months.

No experimental or off-label drugs, therapies and/or devices that have not been approved by the FDA will be discussed during this seminar.

|	Nature of Relevant Financial Relationship	
Name of Ineligible Company(ies)	What was received?	For what role?
Pfizer, Otsuka, Janssen	Research Grant Funding	Principal Investigator
Funding was awarded to the University of Oklahoma Health Sciences Center. All three financial relationships have ended. Financial relationships have been mitigated by Dr. Skrepnek agreeing to only present peer-reviewed, published data and recommendations that have been approved, adhere to balanced and objective evidence-based guidelines, and attest that any recommendations are evidence-based and free of commercial bias. He has agreed to teach to the competencies identified by the learning objectives and present the source and type or level of evidence to participants. Additionally, he has attested that his presentation will not include discussion of products or services from the above listed ineligible companies. Presentation slides were reviewed for content validation and bias by the OU College of Pharmacy Office of Continuing Education.		

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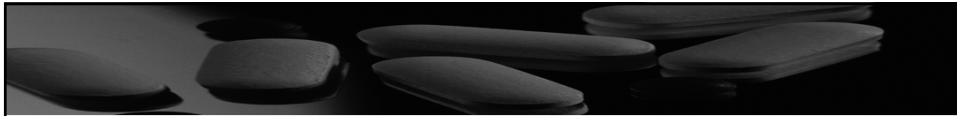
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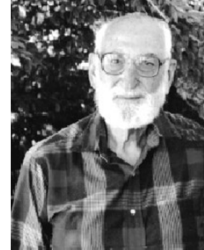
"People have a big problem understanding the relationship between quality and systems...

System management doesn't get taught in [the health sciences]...

There's lip service to quality and, goodness knows, propaganda, but real commitment is in short supply"

Donabedian A. Evaluating the quality of medical care. Milbank Memorial Fund Quarterly 1966;44:166-206.

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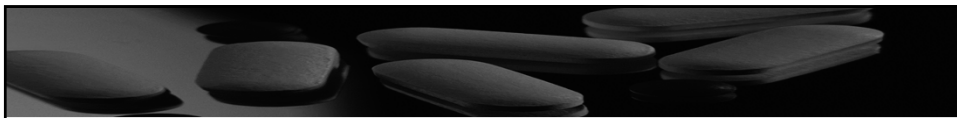
Professional Practice Gap

Fail safe healthcare systems require a concerted interdisciplinary and interprofessional approach to both identify and remove underlying system errors and to establish mechanisms for continuous improvement.

Principals of pharmacoeconomics and outcomes research may be employed to improve the medication use process, particularly with its focus upon population-based approaches to optimize economic, clinical, and humanistic outcomes.

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The Concentration of Health Care Spending

The top 5% of the population involves ~50% of costs

(which is also an 80:20 rule)

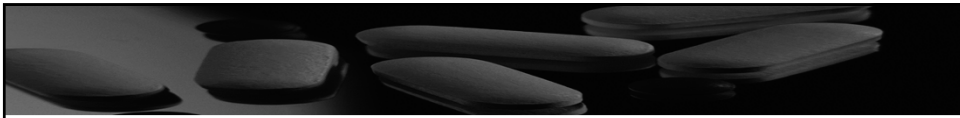Note: Dollar amounts in parentheses are the annual expenses per person in each percentile. Population is the civilian noninstitutionalized population, including those without any health care spending. Health care spending is total payments from all sources (including direct payments from individuals, private insurance, Medicare, Medicaid, and miscellaneous other sources) to hospitals, physicians, other providers (including dental care), and pharmacies; health insurance premiums are not included.
Source: Kaiser Family Foundation calculations using data from U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey (MEPS),.

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Other outcomes?

Several ways to evaluate:
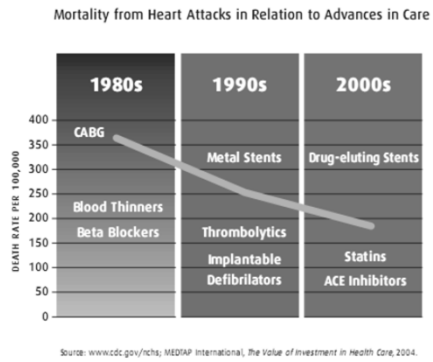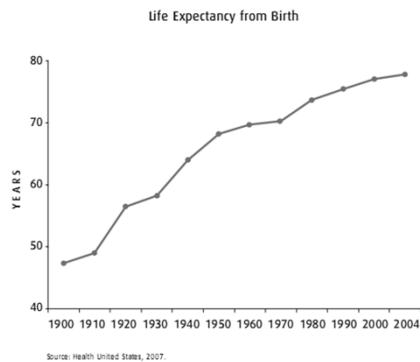
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Advances in Innovation

- From 1970-2000...

  The increased life expectancy from health care innovations added ~$3.2 trillion *per year* to the nation's economy in terms of productivity gains

  (GDP$_{1970}$ ~ $3 trillion)
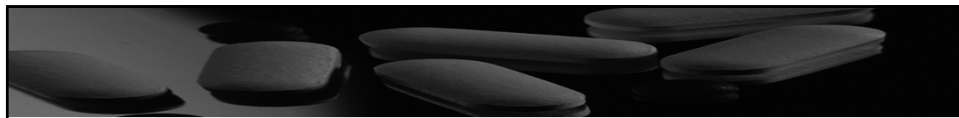
Where We Would be without Advances in Health Care Since 1980

>940,000 more deaths

>4.6 million more disabled persons

>406 million more hospital inpatient days

Source: Adapted from Luce, BR et al. The Return on Investment in Health Care: From 1980 to 2000. Value in Health. 9(3):146-156, 2006.

Source: Murphy KM , Topel RH. The Value of Health and Longevity. J Polit Econ 2006 114(9): 871-904.
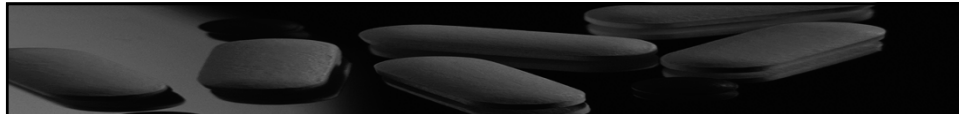
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2023 Scheffe CE Seminar Outline

I. "To Err is Human"
II. Drug-Related Problems
III. Economic Burden
IV. Incidence and Prevalence
V. Quality in Health Care
VI. Value-Based Frameworks

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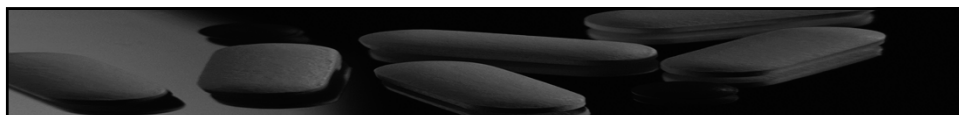
Learning Objectives

At the completion of this activity, pharmacists will be able to:

1. Summarize general principals of value, cost-effectiveness analyses, and value-based frameworks

2. Define and quantify the incidence, prevalence, and impact of medical errors, medication errors, drug-related problems, adverse drug events, and adverse drug reactions

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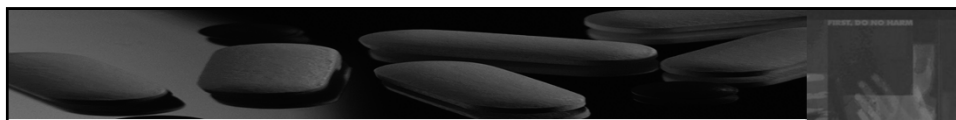
Definitions

- Error; Medical Error; Medication Error
- Error of Commission; Error of Omission
- Drug-Related Problem (DRP)
- Adverse Drug Event (ADE)
- Adverse Drug Reaction (ADR)
- Pharmacoeconomics
- Cost-Effective
- Value-Based Framework

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"To Err is Human"
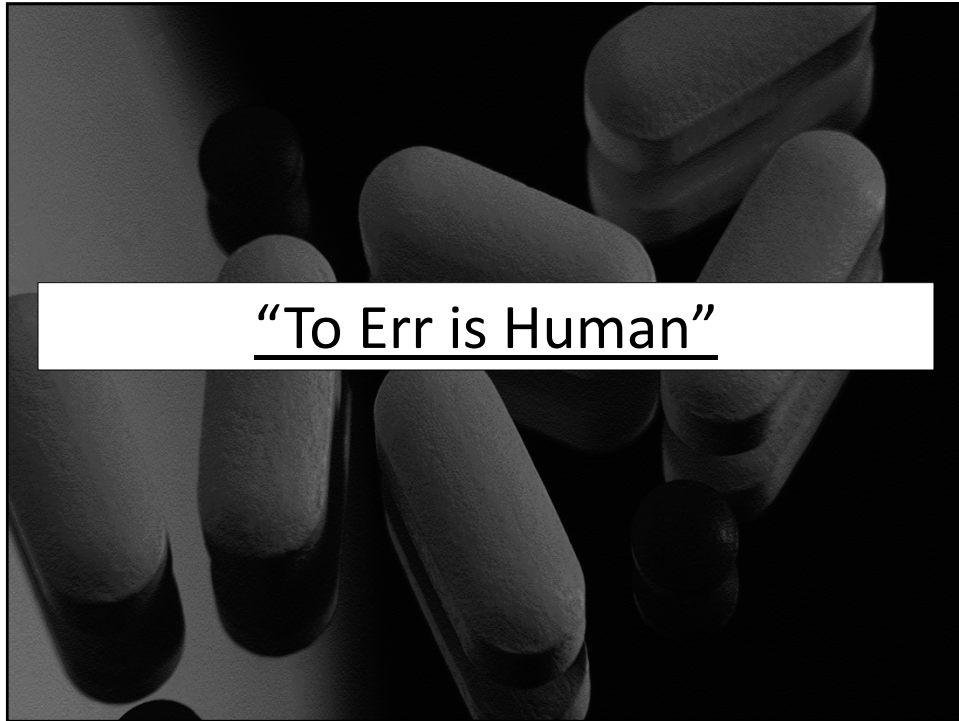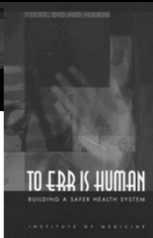
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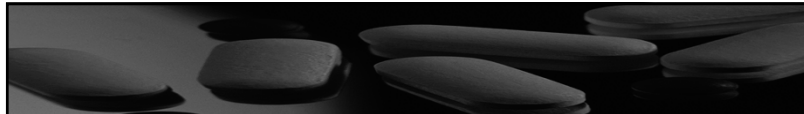
Patient Safety

- Institute of Medicine (2000)
  - *Mortality* Associated with Medical Errors
    - Between 44,000-98,000 deaths per year in the 1990s were caused by medical errors in hospitals in the U.S., ranking between the 4th to 7th leading cause of death (and exceeding deaths attributed to breast cancer, AIDS, or highway accidents)[A]
    - The most current estimates suggest medical errors rank as the 3rd leading cause of death (9.5% of all deaths, >250,000 annually)[B]
  - *Morbidity* Associated with Medical Errors
    - >1 million individuals annually [A,B,C]
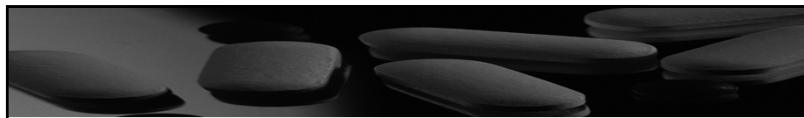
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Patient Safety

- Institute of Medicine (2000)
  - Approximately <u>one-fifth</u> of all medical errors in hospital settings were deemed to be drug-related, and <u>over half of these drug-related errors were considered preventable</u>[A]

    - Follow-up investigations indicated that medication errors were the most common inpatient medical error, impacting >1.5 million persons[F]
    - The IOM placed medication error reduction as a priority area within numerous reports following[A,G,H,I]
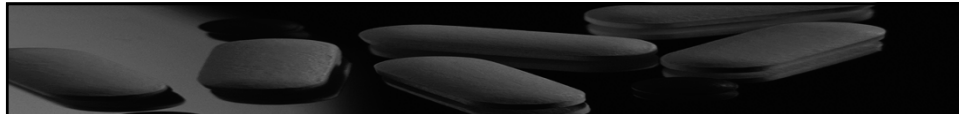
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Patient Safety

- Institute of Medicine (2000)
  - Why do errors occur?[A]
    - Complex systems and processes, and lack of system-wide organizational design

      - "Not bad people in health care"...rather, "Good people working in bad systems"
      - Poor communication, unclear lines of authority
      - Disconnected systems, siloes
      - More advanced, powerful interventions and more intensive care
      - Advancing case-mixes, rare conditions, comorbid diseases

    - Disparate competencies, education, and training
    - Human and social factors
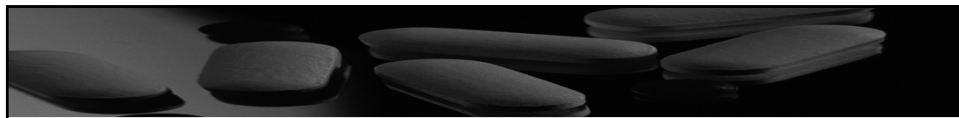
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Six Aims Targeted by the Institute of Medicine (IOM)
to Improve Health Care Systems

- Safe : Avoiding injuries to patients from the care that is intended to help them.

- Effective : Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).

- Patient-centered : Providing care that is respectful of and responsive to individual patient preferences needs, and values and ensuring that patient values guide all clinical decisions.

- Timely : Reducing waits and sometimes harmful delays for both those who receive and those who give care.

- Efficient : Avoiding waste, including waste of equipment, supplies, ideas, and energy.

- Equitable : Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

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Institute of Medicine Tactics to Improve Medication Safety

- Adopt a system-oriented approach to medication error reduction
- Implement standard processes for medication doses, dose timing, and dose scales in a given patient care unit
- Standardize prescription writing and prescription rules
- Limit the number of different kinds of common equipment
- Implement physician order entry
- Use pharmaceutical software
- Implement unit dosing
- Have the central pharmacy supply high-risk intravenous medications
- Use special procedures and written protocols for the use of high-risk medications
- Do not store concentrated solutions of hazardous medications on patient care units
- Ensure the availability of pharmaceutical decision support
- Include pharmacists during rounds of patient care units
- Make relevant patient information available at the point of patient care
- Improve patient knowledge about their treatment

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Free from Harm

Accelerating Patient Safety Improvement
Fifteen Years after *To Err Is Human*
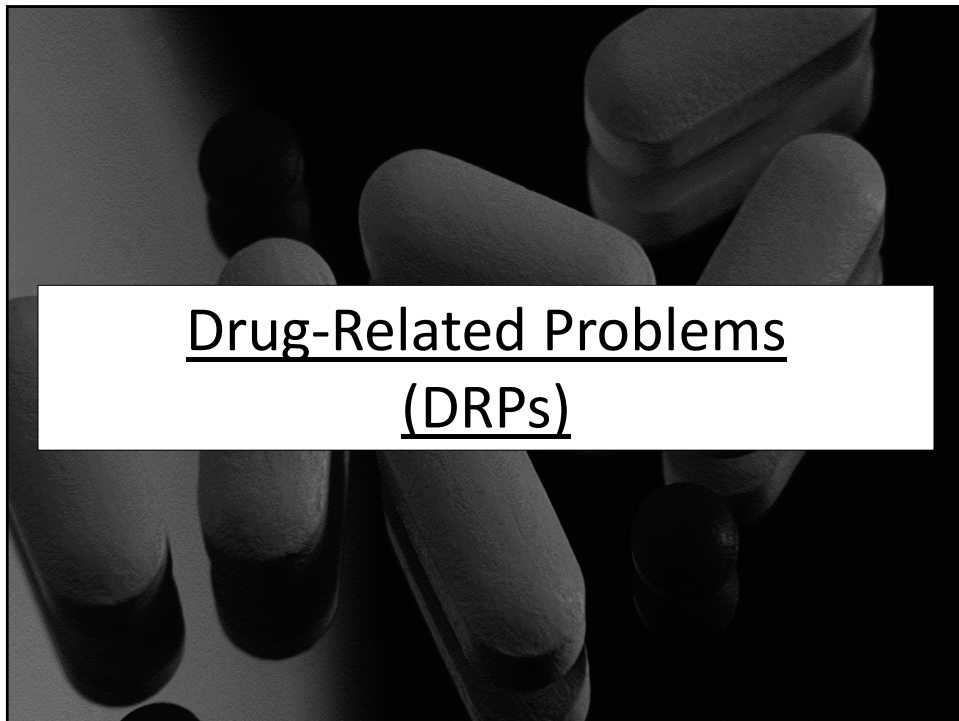
Report of an Expert Panel Convened by
The National Patient Safety Foundation

NPSF
National Patient Safety Foundation®
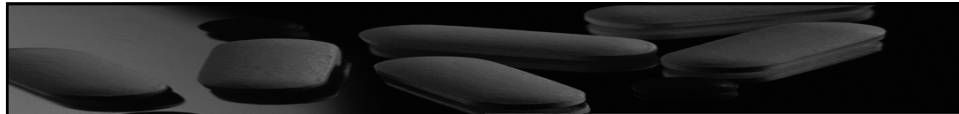
"Despite some improvement in patient safety in the United States, the pace and scale of improvement has been disappointingly slow and limited.

Patients continue to experience harm when interacting with the health care system and, consequently, much more needs to be done.

The problem of making health care safer is far more complex than initially understood."[J]

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Drug-Related Problems (DRPs)

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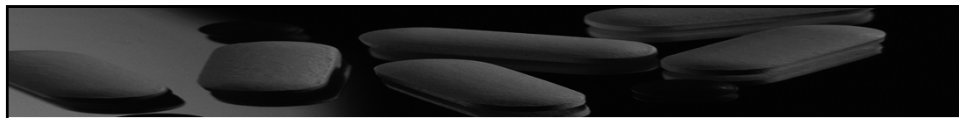
Medical Errors

◆ *Medical Errors* involve a broad characterization within healthcare, often defined simply as:

> "The failure of planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)."[A]

Error of Commission[I,S]
    Example: filling for a drug with a 'known' fatal drug-drug interaction; misfills

Error of Omission[I,S]
    Example: failing to prescribe a drug for a patient's underlying disease state

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Medical Errors

Concerning **errors of omission** (e.g., *failing to prescribe a drug for a patient's underlying disease state*), McGlynn and colleagues (2003) estimated that **over 50% of patients do not receive recommended preventative, acute, or chronic care in the United States**

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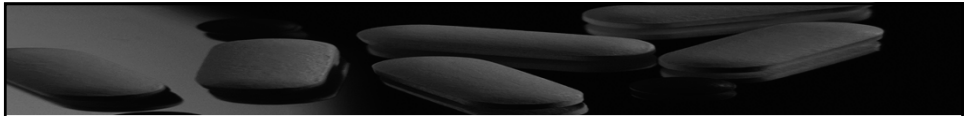
(Patient) NonAdherence

🔹 Initial research reported that >5.5% of hospital admissions were directly associated with patient nonadherence[AP,AQ]

Disease State	Mean Adherence	95th% CI	Number of Studies
HIV	88.3 %	(78.9-95.2)	8
Arthritis	81.2 %	(71.9-89.0)	22
GI disorders	80.4 %	(73.9-86.2)	40
Cancer	79.1 %	(75.9-84.2)	65
Seizures/Brain disorders	78.4 %	(52.4-95.7)	9
Genitourinary and STDs	77.0 %	(65.4-89.6)	17
Dermatologic disorders	76.9 %	(66.5-85.9)	11
Cardiovascular disorders	76.6 %	(73.4-79.8)	129
ENT and mouth disorders	76.1 %	(68.6-82.8)	30
Blood disorders, excluding leukemia	75.6 %	(45.9-95.7)	7
OB-GYN	74.8 %	(64.2-84.2)	19
Infectious Disease	74.0 %	(67.5-80.0)	34
Opthalmic Disorders	72.6 %	(61.8-82.3)	15
ESRD	70.0 %	(56.8-81.6)	15
Pulmonary Disease	68.8 %	(61.1-76.2)	41
Diabetes	67.5 %	(58.5-75.8)	23
Sleep Disorders	65.5 %	(54.3-75.8)	16

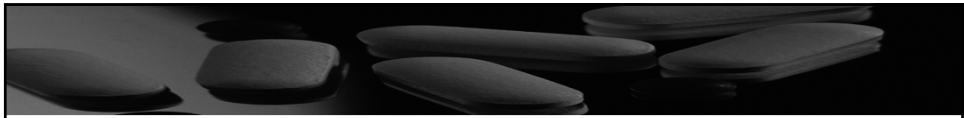Source: DiMatteo MR, Variations in Patients' Adherence to Medical Recommendations: A Quantitative Review of 50 Years of Research. Medical Care 2004;42:200-209.

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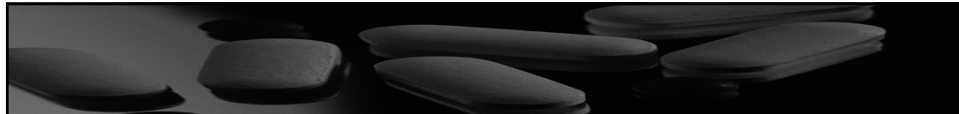
Differing Levels of Clinical Evidence: Exploring Communication Challenges in Shared Decision Making

Quentin W. Smith[1], Richard L. Street Jr.[1,2], Robert J. Volk[1,3], and Michael Fordis[1]

The *British Medical Journal* posted on their website, *Clinical Evidence*, the results of an analysis of randomized controlled trials focusing on harms and benefits of 3,000 medical treatments. The effectiveness of each treatment was rated based on six criteria: (a) beneficial, (b) likely to be beneficial, (c) trade-off between benefits and harms, (d) unlikely to be beneficial, (e) likely to be ineffective or harmful, and (f) unknown effectiveness. The results were striking. Only about a third of the treatments were shown to be beneficial (11%) or likely to be beneficial (23%). Another 7% were rated as trade-offs between benefits and harms, with 6% rated unlikely to be beneficial and another 3% rated likely to be ineffective or harmful (Clinical Evidence, 2012). The authors at *Clinical Evidence* rated the remaining 50% of medical treatments as being of unknown effectiveness. The challenge that evidence ratings like these pose for clinicians is not new.

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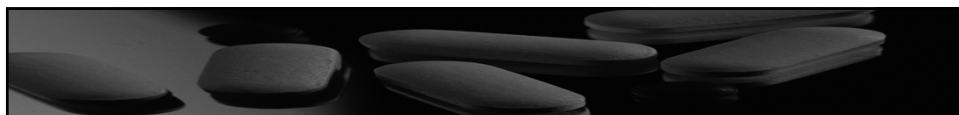
Medication Errors

- *Medication Errors* are considered a specific subcategory of *Medical Errors*, and are often defined as:

  > "Any error in the process of prescribing, dispensing, or administering a drug, whether there are adverse consequences or not."[L]

- Medication errors may be either:

  A) Coincidental in nature; or

  B) May relate to the circumstances associated with the utilization of a given drug
  - That is, medication errors may involve events that are preventable or those that revolve around the broader medication use system.[M,N]

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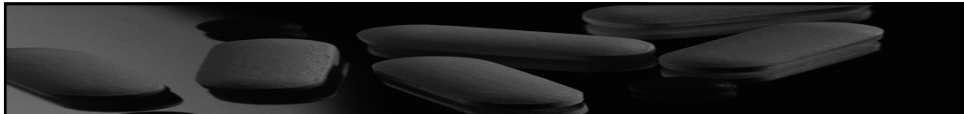
Drug-Related Problems (DRPs)

- A *Drug-Related Problem* is defined as:

  > "A circumstance that involves a patient's drug treatment that actually, or potentially, interferes with the achievement of an optimal outcome."[O]

- DRPs are perhaps the most general description of medication errors, and includes:
  - A) Medication errors;
  - B) Adverse drug reactions (ADRs);
  - C) Adverse drug events (ADEs);
  - D) Nonadherence; and
  - E) Treatment failures.[P]

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Drug-Related Problems (DRPs)

◈ DRPs have been categorized as inappropriate medication use through either *commission* or *omission* including:

1) An untreated indication;

2) Drug use without indication;

3) Improper drug selection;

4) Subtherapeutic dosage;

5) Overdosage;

6) Failure to receive drugs;

7) Drug interactions;

8) NonAdherence; or

9) Adverse drug reactions.[Q]

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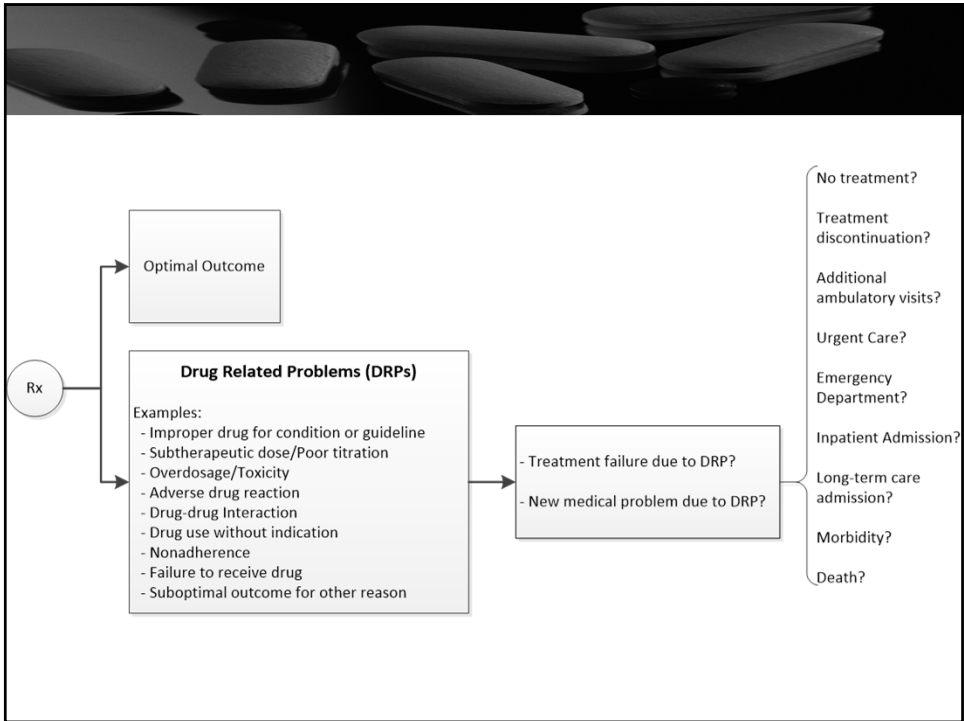
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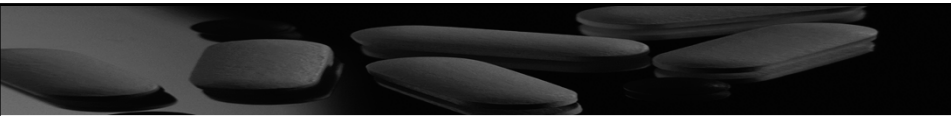
Adverse Drug Reactions (ADRs)

- A more specific term than DRPs, an *Adverse Drug Reaction* (ADR) is defined by the World Health Organization (WHO) as:

> "A response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function."[R]

- An ADR purports that a causal relationship exists between the use of the drug and a subsequent toxic or side effect[S]

  - An ADR may actually exclude 'error' within various definitions[S]
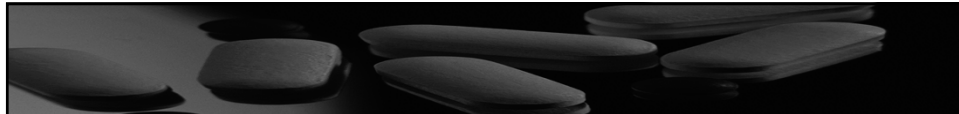
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Adverse Drug Events (ADEs)

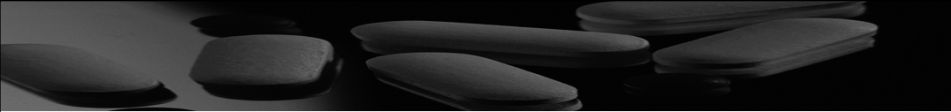- An *adverse drug event* (ADE) *differs* from an ADR in that an ADE involves an injury or iatrogenic outcome either during or after the use of a medication and does not necessarily purport a cause-effect relationship.[M,T,U,V]
  - Explained differently, an ADE is often used to describe harm that results from medication use (that can include an ADR) which may be expected from the utilization of a drug PLUS those effects associated with error or improper use[L]
  - All ADRs are considered ADEs, although the opposite does not necessarily hold true (i.e., not all ADEs are ADRs, because ADEs include 'error or improper use')[W]
  - An ADE may also be specified as either *preventable* (e.g., dispensing misfill) or *nonpreventable* (e.g., certain side effects or adverse drug reactions)[S]

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Adverse Drug Events (ADEs)

- A *potential* ADE (or *"near miss"*) involves a medication error wherein an injury or deleterious event *had the potential to occur but was subsequently avoided or circumvented*[S]

- A *potential ADE* is defined by the IOM as:
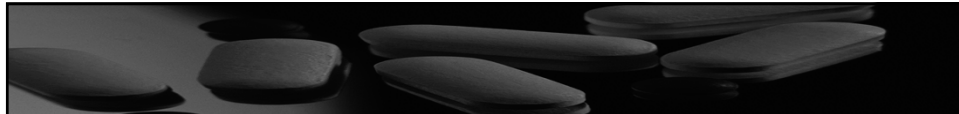
> "An act of commission or omission that could have harmed the patient but did not do so as a result of chance, prevention, or mitigation."[A]

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Economic Burden

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Economic Burden of DRPs (annual)

Inpatient/Acute Care

- Initial estimates for 'preventable' medication errors *only* = $19 billion (2023$)[X]
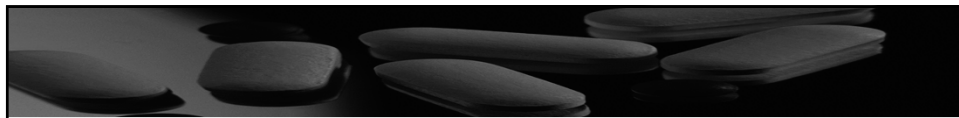
Ambulatory Care/Community

- Initial estimates: annual cost of drug-related morbidity and mortality in ambulatory care settings = ~$160 billion (2023$)[Y]; Updated estimates = ~$302 billion (2023$)[Z]

Long-Term Care/Nursing Homes

- Current estimate = ~$17 billion (2023$)[AA]
  - ~$2.25 spent on drug-related problems for every $1.00 used for medications[AA]

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Economic Burden of DRPs (annual)

Overall

- The economic burden of illness estimate of medical errors across all settings when considering both patient morbidity and mortality is estimated to be >$1.42 trillion (2023$)[AB]

- Note: A large and systematic under-reporting is present
  - Voluntary reporting systems designed to measure errors have been purported to underestimate the true number of ADEs or medication errors by up to 90%

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Incidence and Prevalence
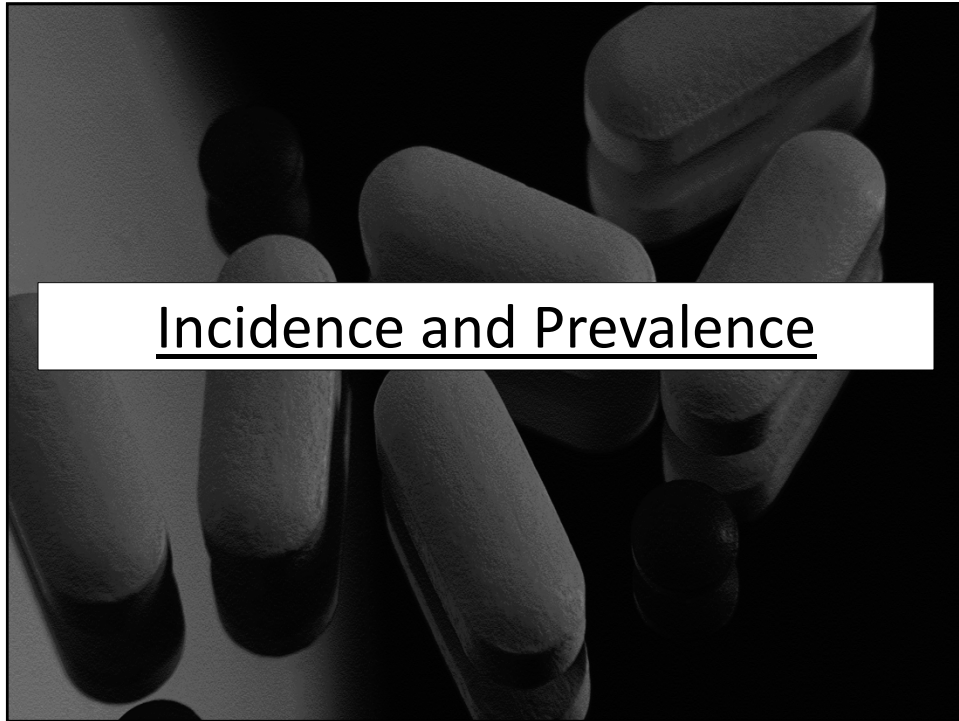
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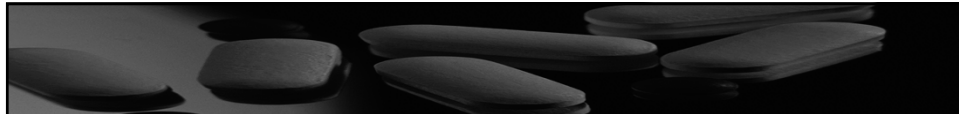
Incidence and Prevalence

Inpatient/Acute Care

- Medical Errors[AC,AD]

  - The most robust estimate single estimate suggests that complications related to pharmacotherapy occurred in 19.0%

  - Preventable medical errors occurred in 58.0%

  - Negligence accounted for 27.6%

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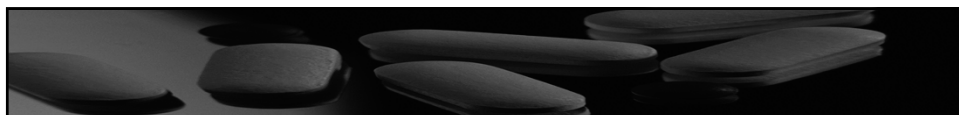
Incidence and Prevalence

Inpatient/Acute Care (cont.)

- Medication errors generally range from 1.7 to 59.0%[A]

  - Prescribing errors accounted for an additional 0.3 to 2.6%[P]

  - Preventable ADEs are estimated to range from 28.0 to 56.0% and higher[C,M,AE,AF]

  - ADRs have been estimated to be associated with between 0.3 to 7.0% of hospital admissions[AG,AH,AI]

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Incidence and Prevalence

Ambulatory Care/Community

- ADRs generally range from 2.6 to 50.6% in outpatient care[AJ]
  - The occurrence of medication errors is increasing at a higher rate in community settings than within hospitals[AK,AL,AM]

Long-Term Care/Nursing Homes

- ADEs have been estimated to occur at a rate of 277 adverse drug events per 1,000 person years[AN,AO]

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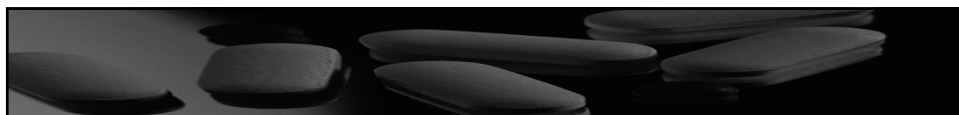
Specific Populations

Pediatrics

- Medication errors often exceed 3x that of adults[S]
  - Dosing errors most common[AR,AS,AT]
  - Most error-prone settings involving pediatric or neonatal intensive care units[AU,AV]
  - Intuitively, fundamental pharmacokinetic and pharmacodynamics differences are present[S]

- Overall medical errors, relative to non-error pediatric cases suggest similar risk
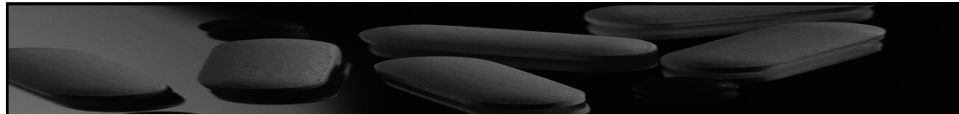 - Pediatric cases involving medical errors are associated with 2x to 18x increased risk of death and 2x to 20x times higher charges[AW]

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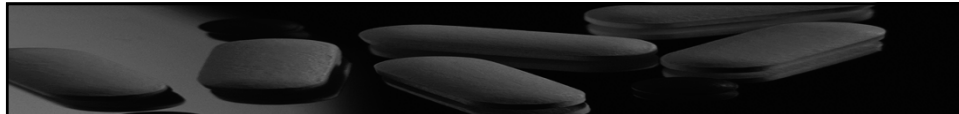
Specific Populations

Older Adults

- ADEs have been estimated to occur at a rate of 50.1 adverse drug events per 1,000 person years among Medicare recipients in outpatient settings[AN,AO]

- Preventable ADEs have been estimated 13.8 preventable events per 1000 person years in outpatient settings[AO]
  - Some 3.0 to 11.0% of hospital admissions have been found to be related to ADEs in older adults[AX]
  - Notably, >75% of older adults utilize prescription medications and >80% use nonprescription drugs frequently[AY,AZ,BA]

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Other Considerations

Drug-Drug Interactions (DDIs)

- When the number of drugs prescribed reaches 8, the risk of DDIs approaches ≥90%
- Common drugs associated with DDIs: narrow therapeutic index drugs, antiarrhythmics, antihypertensives, diuretics, chemo agents

Standards of Care: Adherence to Guidelines

- Older persons often less likely to receive appropriate medications, especially involving:
  - Antihypertensives, aspirin, statins
  - Anticoagulants
  - Heart failure treatments
  - Mental health pharmacotherapy

45

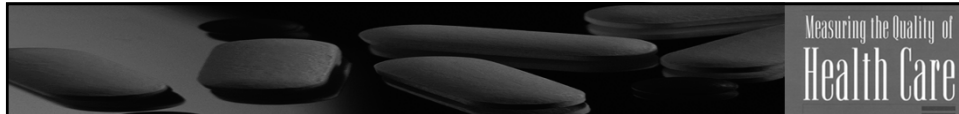## *Quality in Health Care*

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Quality in Health Care

The Institute of Medicine (IOM), 1999

Quality of care is "the degree to which <u>health services</u> for individuals and populations increase the likelihood of <u>desired health outcomes</u> and are consistent with the <u>current professional knowledge</u>"

Key attributes
- Health services:
  - incorporates both treatment and prevention
- Desired health outcomes:
  - includes those sought by patients/consumers
- Current professional knowledge:
  - involves changing and evolving standards of care

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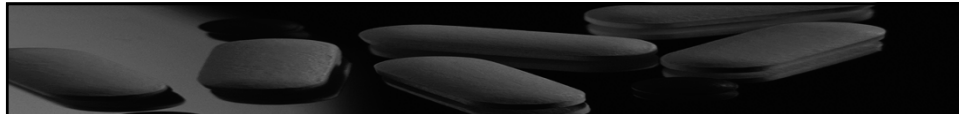
Quality in Health Care

Selected Indicators and Dimensions of Quality in Health Care

- Safety
- Appropriateness
- Patient/caregiver experience
- Respect and caring
- Timeliness
- Acceptability
- Access
- Continuity
- Availability
- Prevention/early detection
- Technical quality/proficiency/competence

- Health outcomes
- Health improvement
- Effectiveness
- Efficiency
- Affordability
- Availability of information
- Consumer participation/choice
- Equitability
- Sustainability

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Quality in Health Care

General Solutions to Improve Quality in Health Care[A,S]

1. Broad reform (versus incremental change)

2. Organizational and systems redesign

3. Stakeholders alignment (e.g., appropriate incentives)

4. Increasing the appropriate use of technologies

5. Interprofessional and team-based provision of care (includes the patient themselves)

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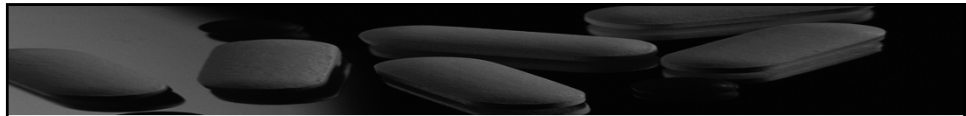*Quality Assurance: Practical Tools and Resources*

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Quality in Health Care

◆ Fail safe healthcare systems require a concerted interdisciplinary and interprofessional approach to both identify and remove underlying system errors and to establish mechanisms for continuous improvement.[G]

◆ Pharmacoeconomics and outcomes research may also be employed to improve the medication use process, particularly with its focus upon population-based approaches to optimize economic, clinical, and humanistic outcomes.[S,W,BJ]

> **If You Can't Measure It, You Can't Manage It**
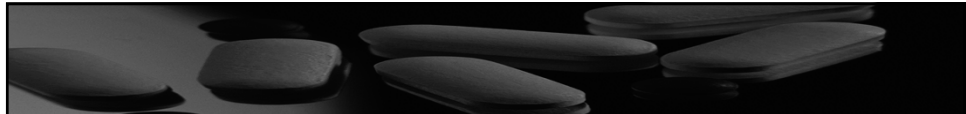
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Summary of questions appearing on the Medication Appropriateness Index (MAI)

1. Is there an indication for the drug? (3 points)
2. Is the drug effective for the condition? (3 points)
3. Is the dosage correct? (2 points)
4. Are the directions correct? (2 points)
5. Are clinically significant drug-drug interactions present? (2 points)
6. Are clinically significantly drug-disease interactions present? (2 points)
7. Are the directions practical? (1 point)
8. Is the drug the least expensive alternative? (1 point)
9. Is there unnecessary duplication? (1 point)
10. Is the duration of therapy acceptable? (1 point)

Overall score range: 0 to 18
(higher scores associated with adverse health outcomes)

Sources: Hanlon et al. J Clin Epidemiol 1992;45:1045-1051. Samsa et al. J Clin Epidemiol 1994;47:891-896. Hanlon et al. Ann Pharmacother 2004;38:9-14.

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Quality in Health Care

⬥ Practical, Disease Specific Example (Patient NonAdherence)

▪ Improved patient adherence in diabetes, hypertension, and cholesterol via CMS' Quality Measures Report was associated with $27–$47 billion in **avoided** health care costs between 2013-2018

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Quality in Health Care

Selected Quality Assurance/Quality Indicator/Performance Measure Resources

▪ **National Committee for Quality Assurance (NCQA)**
  - Healthcare Effectiveness Data and Information Set (HEDIS)
  - Consumer Assessment of Healthcare Providers and Systems (CAHPS + HCAHPS)

▪ **Pharmacy Quality Alliance (PQA)**

▪ **Centers for Medicare and Medicaid Services (CMS)**
  - CMS Measure Inventory Tool (CMIT)
  - Medicaid Child and Adult Core Value Set

▪ **Agency for Healthcare Research and Quality (AHRQ)**
  - Pediatric Quality Measures Program (PQMP)

▪ **Health Utilization Management Accreditation (URAC)**

▪ **United States Preventative Services Task Force (USPSTF)**

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www.ncqa.org/hedis

55

www.pqaalliance.org/pqa-measures

56

cmit.cms.gov

57

www.medicaid.gov/medicaid/quality-of-care/quality-of-care-performance-measurement/index.html

58

www.ahrq.gov/pqmp

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www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations

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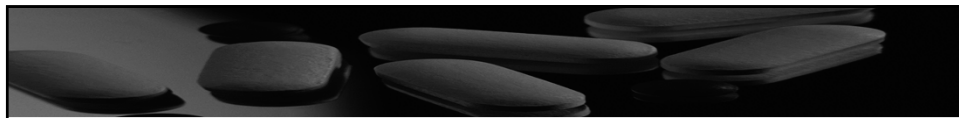
What to do?

◆ Easy, simple solutions?

- ▪ EMRs, Computer systems?
- ▪ Big data?
- ▪ Advanced decision support, AI?
- ▪ More point of care systems?

> <u>Consistent failure</u> has been observed without the appropriate integration and adoption of comprehensive analytic approaches (e.g., training in the field of pharmacoeconomics and outcomes research)[S]
>
> - The Institute for Safe Medication Practices (ISMP) found that approximately 1/3 of <u>serious</u> errors are not detected by existing computers or current processes; numerous other analyses support the general premise[S,BA,BC,BD,BE,BF,BG,BH]

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Quality in Health Care

Improving the Medication Use Process

- ▪ Desired Outcome: Minimize and prevent drug-related problems
  - – Involving the structure and process of health care

> If pharmacists were available only for dispensing, less than 60% of patients have been estimated to achieve optimal outcomes (i.e., no DRP)

- ▪ Desired Outcome: Maximize clinical, economic, and humanistic outcomes through efficient structures/processes

> One method = Pharmacoeconomics

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Quality Assurance: The Role of PharmacoEconomics

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Pharmacoeconomics: A Comprehensive Framework

"…<u>comprehensively</u> identifies, measures, and compares the costs (resources consumed) and consequences (clinical, monetary, and humanistic) of pharmaceutical products and services"

Nature of the discipline
- Economics, finance
- Risk analysis
- Decision sciences
- Epidemiology
- Social sciences
- Statistics
- Clinical evaluation
- Health service evaluation

Input —Innovation→ Outcome

-------------------- VERSUS --------------------

Input —Standard of Care→ Outcome

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Pharmacoeconomics: A Comprehensive Framework

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Pharmacoeconomics: A Comprehensive Framework
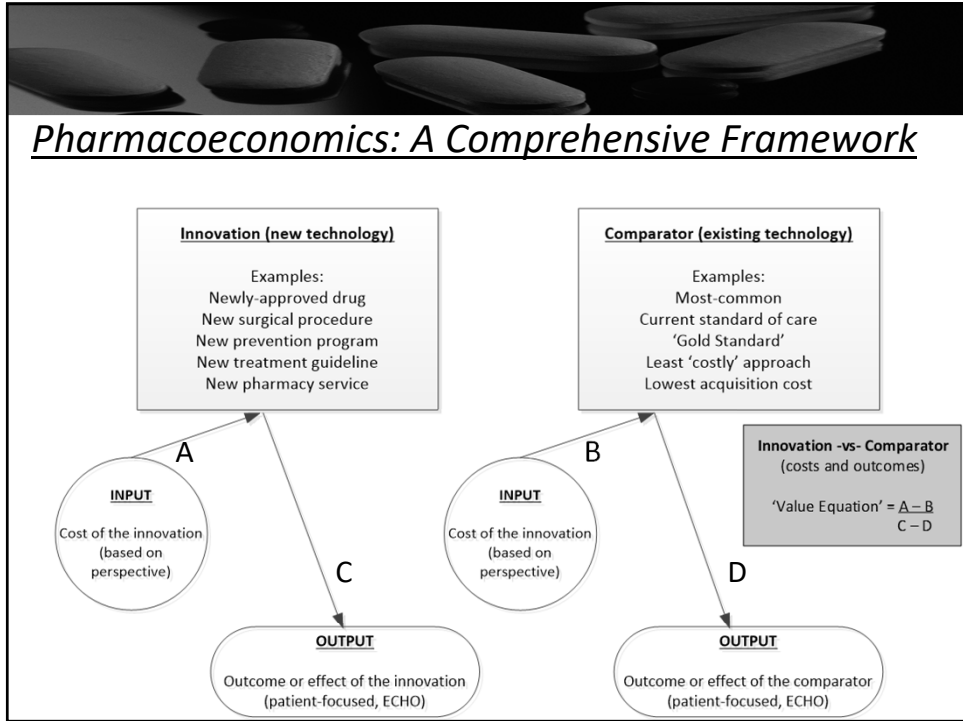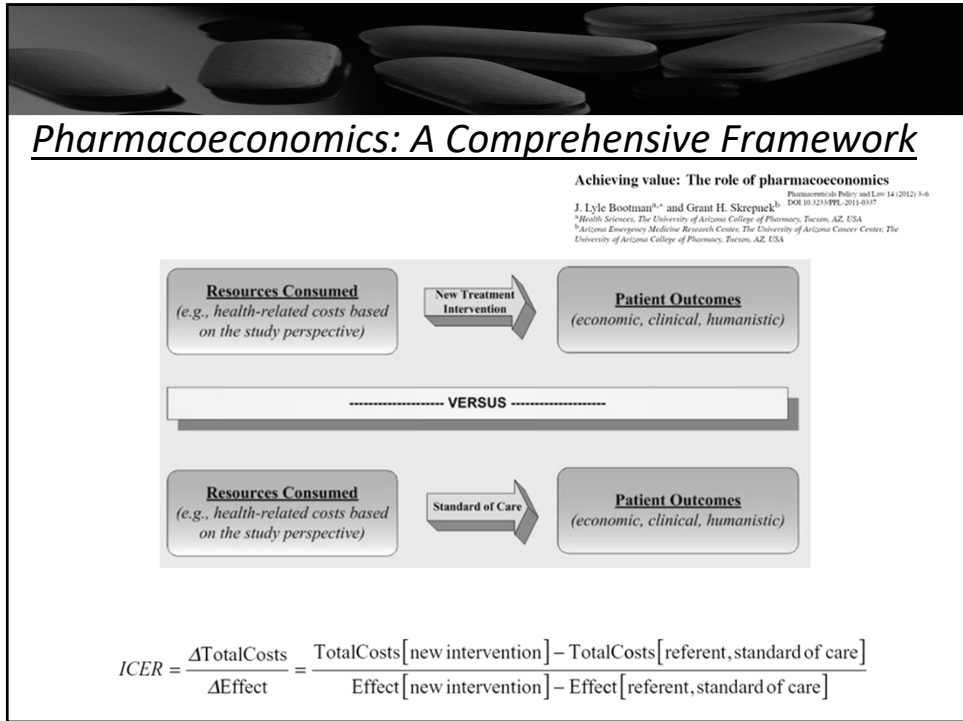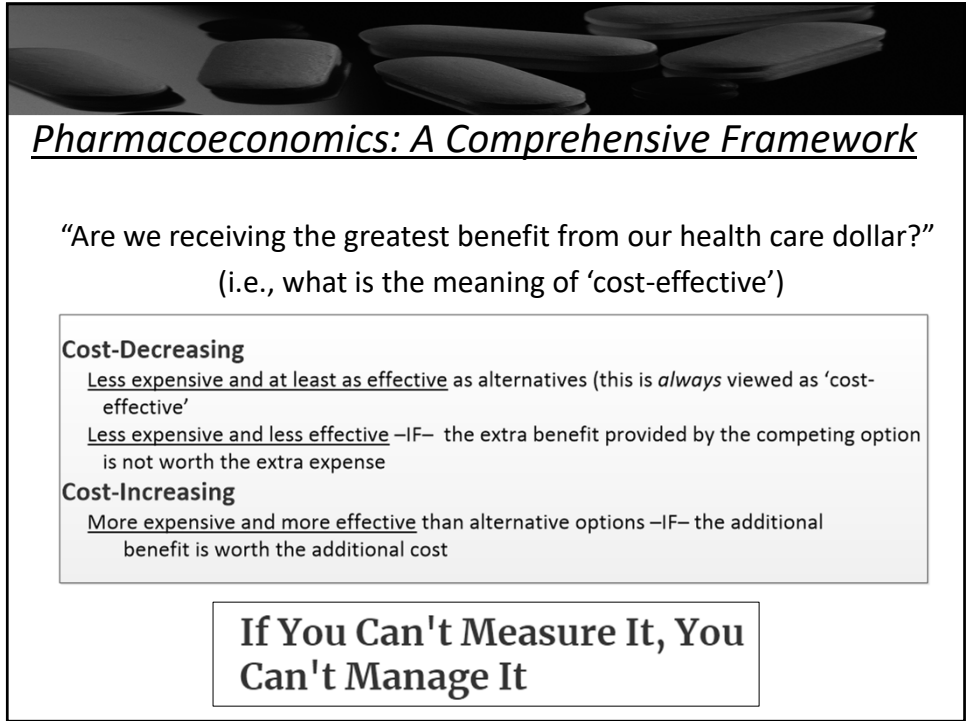
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Pharmacoeconomics: A Comprehensive Framework
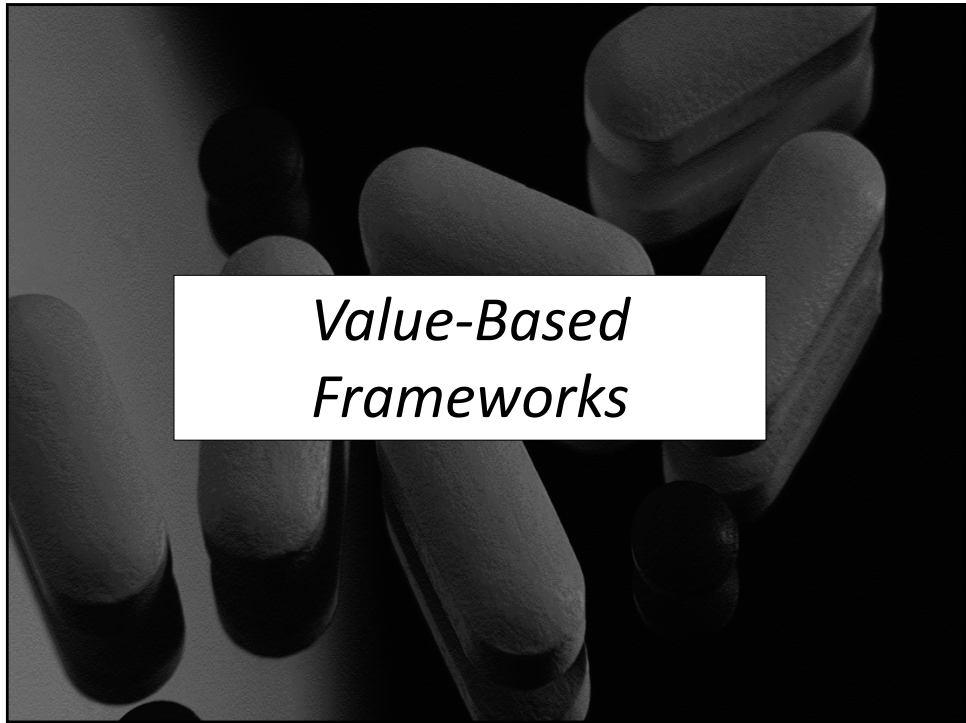
"Are we receiving the greatest benefit from our health care dollar?"
(i.e., what is the meaning of 'cost-effective')

Cost-Decreasing
  Less expensive and at least as effective as alternatives (this is *always* viewed as 'cost-effective'
  Less expensive and less effective –IF– the extra benefit provided by the competing option is not worth the extra expense
Cost-Increasing
  More expensive and more effective than alternative options –IF– the additional benefit is worth the additional cost

If You Can't Measure It, You Can't Manage It

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Value-Based Frameworks

68

National Health Expenditures (NHE)

Rx drugs = 9% of health care spending

(Physician and Clinical + Hospital services = 52% of health care spending)

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Value-Based Frameworks

◆ Selected payment and reimbursement models for providers and products

- Pay for Performance (P4P)
- Capitation, Risk-sharing
- Expanded bundling (currently extended through 2025 through CMS)
- Accountable care organizations (ACOs), population health
- Direct contracting with employers
- Direct-to-consumer retainer fees, 'concierge' practices
- Value-based purchasing (e.g., Medicare's Merit-Based Incentive Payment System, MIPS)
- Academy of Managed Care (AMCP) Format for Formulary Submissions (i.e., "dossiers")

AMCP Format 4.1 Revision

Format for Formulary Submissions

Guidance on Submission of Post-Approval and Pre-Approval Clinical and Economic Information and Evidence
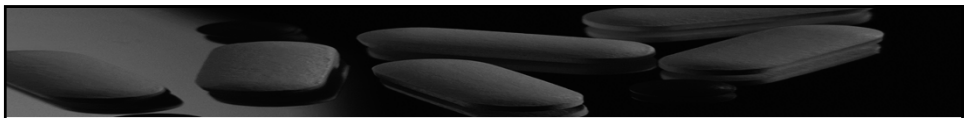
72

Value-Based Frameworks

- ✧ Caveats of 'cost containment' policies ('bending the cost curve')
  - ▪ Over time, no long-term evidence (i.e., virtually zero) suggests that more traditional 'cost controls' have worked to control long-run costs in any sector, time frame, or country
    - • The focus in health care has historically been on controlling 'unit costs' (e.g., implementing limits on 'more expensive' products or services)
    - • Without appropriate competitive incentive mechanisms, cost containment policies typically fail to achieve their intended goals

  - ▪ The effects of price controls
    - • Empirical findings are abundantly clear and entirely consistent
      - – *What might happen when a price control is placed on product/service (i.e., unit cost control) -if- the payment falls below the actual cost of production?*

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Value-Based Frameworks

- ✧ Nomenclature and Definitions[BK,BJ]
  - ▪ No consensus on terminology is present for value-based frameworks
    - • A single definition remains elusive (and will be unlikely to emerge)
    - • Definitions vary based upon the stakeholder's point of view
      - – Access? Cost? Quality?
      - – Patient? Provider? Payer?

  - ▪ Overall, the goals of value-based frameworks intend to parallel those of pharmacoeconomics (i.e., efficiency, Iron Triangle of Health Policy)

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The US healthcare value chain.
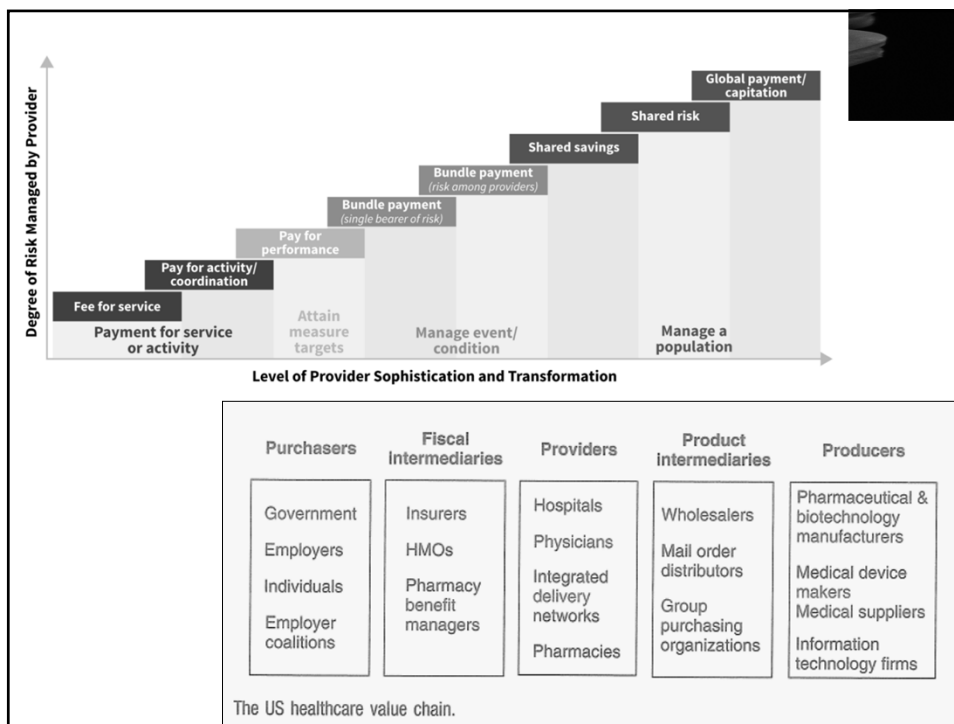
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Value-Based Frameworks

- Recommendations for value-based framework development[BK,BJ]
  - Payment reform and incentive systems
    (e.g., based upon known economic principles of consumer behavior, competition, risk management, and efficiency)
  - Interoperability, systems integration, and partnerships
  - Enabling technology and advanced analytics
  - Population health management
  - Stakeholder engagement
  - Others

UNDERSTAND SHARED HEALTH NEEDS OF PATIENTS

DESIGN SOLUTION TO IMPROVE HEALTH OUTCOMES

INTEGRATE LEARNING TEAMS

MEASURE HEALTH OUTCOMES AND COSTS

EXPAND PARTNERSHIPS

Strategic framework for value-based health care implementation to achieve better patient outcomes.

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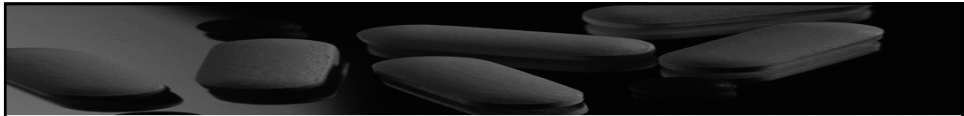
Value-Based Frameworks

◆ Review of selected value frameworks[BI,BL]

⊞ <u>American Society of Clinical Oncology, ASCO</u>
- Developed beginning in 2007, in part, to capture specific attributes of cancer-related care and outcomes
  - Also considers frameworks from the National Cancer Center Network (NCCN) and European Society for Medical Oncology (ESMO), though recommendations do not necessarily correlate perfectly (R = 0.67-0.71)
- Weighs most heavily toward clinical benefit (overall survival > progression-free survival) and considers treatment toxicity plus out-of-pocket costs

Death or Debt? National Estimates of Financial Toxicity in Persons with Newly-Diagnosed Cancer

THE AMERICAN JOURNAL of MEDICINE

Adrienne M. Gilligan, PhD,[a,b] David S. Alberts, MD,[c] Denise J. Roe, DrPH,[d] Grant H. Skrepnek, PhD[e,f] Vol 131, No 10, October 2018

[a]The University of North Texas Health Sciences Center, College of Pharmacy, Fort Worth; [b]Truven Health Analytics, an IBM Company, Houston, Texas; [c]The University of Arizona, The University of Arizona Cancer Center, Tucson; [d]The University of Arizona, Mel and Enid Zuckerman College of Public Health, Tucson; [e]University of Oklahoma Health Sciences Center, College of Pharmacy, Oklahoma City; [f]The University of Oklahoma Health Sciences Center, Peggy and Charles Stephenson Cancer Center, Oklahoma City.

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ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO OPEN SCIENCE FOR OPTIMAL CANCER CARE

ORIGINAL RESEARCH

Assessment of the clinical and cost-effectiveness evidence in the reimbursement decisions of new cancer drugs

G. Chauca Strand[1*], C. Bonander[1], N. Jakobsson[2], N. Johansson[1,3] & M. Svensson[1,4]

[1]Health Economics and Policy, School of Public Health and Community Medicine, Institute of Medicine, University of Gothenburg, Gothenburg, Sweden; [2]Karlstad Business School, Karlstad University Faculty of Arts and Social Sciences, Karlstads Business School, Karlstad; [3]University Health Care Research Center, Faculty of Medicine and Health, Örebro University, Örebro, Sweden; [4]Department of Pharmaceutical Outcomes and Policy, University of Florida, Gainesville, Florida, USA

Available online 28 August 2022

Background: This study aimed to describe the clinical and cost-effectiveness evidence supporting reimbursement decisions of new cancer drugs and analyze the influence of trial characteristics and the cost per quality-adjusted life years (QALYs) on the likelihood of reimbursement in Sweden.
Patients and methods: Data were extracted from all appraisal dossiers for new cancer drugs seeking reimbursement in Sweden and claiming added therapeutical value between the years 2010 and 2020. The data were analyzed using descriptive statistics, and logistic regression models were also used with the cost per QALY, study design, comparator, and evidence on final outcomes in the clinical trials as predictors of reimbursement.
Results: All 60 included appraisals were based on trial evidence that assessed at least one final outcome (overall survival [OS] or quality of life [QoL]), although rarely as a primary outcome. Of the appraisals with a final decision (n = 58), 79% were approved for reimbursement. Among the reimbursed drugs, only half had trial evidence demonstrating improved OS or QoL. Only one drug had trial evidence supporting improvements in both OS and QoL. The average cost per QALY for reimbursed cancer drugs was estimated to be 748 560 SEK (€73 583). A higher cost per QALY was found to decrease the likelihood of reimbursement by 9.4% for every 100 000 SEK (€9830) higher cost per QALY (P = 0.03). For cost-effectiveness models without direct evidence of improvements in final outcomes, a larger QALY gain was observed compared with those with evidence mainly relying on intermediate and surrogate outcomes.
Conclusions: There are substantial uncertainties in the clinical and cost-effectiveness evidence underlying reimbursement decisions of new cancer drugs. Decision makers should be cautious of the limited evidence on patient-centered outcomes and the implications of allocating resources to expensive treatments with uncertain value for money.
Key words: reimbursement, health technology assessment, decision making, cancer drugs

Approximately 50% of reimbursed cancer drugs had trial evidence of improved overall survival or improved quality of life

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Value-Based Frameworks

◆ Review of selected value frameworks (cont.)

❖ Institute for Clinical and Economic Research, ICER

- Stated focus, beginning in 2014:

  1) Comparative clinical effectiveness

  2) Incremental cost-effectiveness (including long-run, exceeding 5 or more years)

  3) Relevant contextual considerations

  4) Other benefits or disadvantages (e.g., extending beyond measured clinical outcomes)
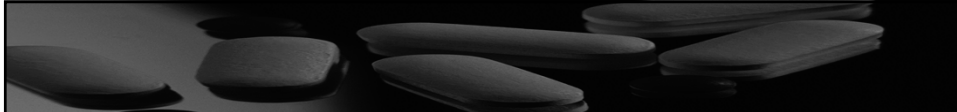
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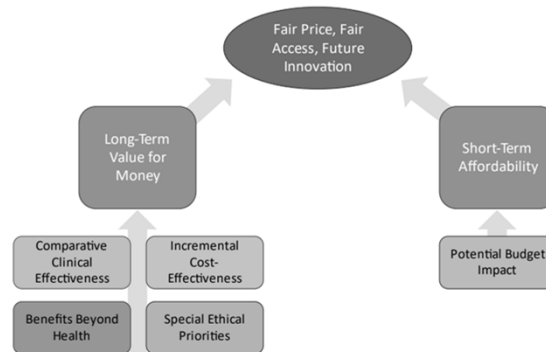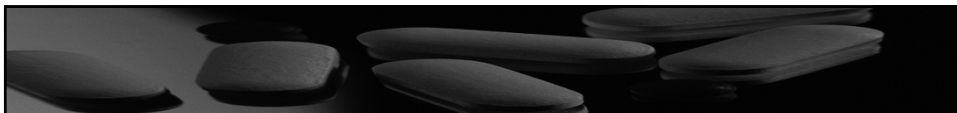
80

Value-Based Frameworks

◆ Review of selected value frameworks (cont.)

▫ Patient Perspective Value Framework, PPVF (Avelere Health & FutureCures)
  - Explicitly incorporates patients' perspectives of value (i.e., needs, attitudes/beliefs, expectations, financial trade-offs)
  - Does not necessarily focus upon systemwide costs, but rather patient/family financial obligations

▫ Payer Perspectives (Prime Therapeutics)
  - Adapts the Institute for Clinical and Economic Research framework
  - Considers two primary factors: long-term value of treatment (i.e., clinical outcomes, comparative effectiveness, total cost of care, adherence/persistency) and 2) short-term pharmacy spend (including budget impact and forecasting models)

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Value-Based Frameworks

◆ Review of selected value frameworks (cont.)

▫ Others
  - American College of Cardiology/American Heart Association, ACC-AHA
  - Memorial Sloan Kettering Drug Abacus, MSKD
  - Advanced Medical Technology Association, AdvaMed
  - International Society of Pharmacoeconomics and Outcomes Research, ISPOR
  - Deloitte (with AdvaMed)
  - Accenture (with Boston Scientific)
  - Boston Consulting Group (with Harvard Business School)
  - Mckinsey
  - European Network for Health Technology Assessment

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Concluding Comments

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Clinical Pearls

- **Drug-related problems** constitute large and often preventable clinical and economic burdens, regardless of care setting; numerous areas exist for pharmacists to continue to provide benefit and value in health care (e.g., drug safety, outcomes, patient and provider adherence, special populations)

- **Pharmacoeconomics**
  - Provides <u>the</u> comprehensive and robust framework to assess and ensure safe, effective, and efficient medication use systems
    - 'If you can't measure it, you can't manage it'
  - Identifies gaps in current healthcare delivery models in acute, ambulatory and community, and long-term care
    - Which empirical findings are associated with treatment failures and other poor outcomes (i.e., that require intervention points)?
  - Provides scientific information to support continued and innovative roles for pharmacists to improve patient care and the healthcare system
    - Heightened awareness and transparency (e.g., cost of illness)
    - Demonstrations of cost-effectiveness

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Concerning health care in the United States, which of the following is correct:

An estimated 90% of the cross-sectional variance in health spending across developed nations is explained by the GDP (gross domestic product) alone

Approximately 80% of healthcare expenditures are consumed by 20% of individuals

Health care reform has historically focused on reducing 'unit costs' of expensive products or services

More than one of the above is correct

None is correct

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The 'Iron Triangle of Health Policy' used to guide efficiency in health care considers which three components:

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Post-Assessment Question 3 - Answer
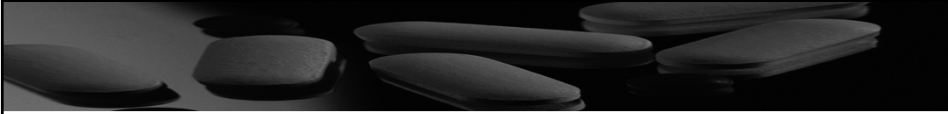
Which of the following can be considered to be 'cost-effective':

A. Less costly and more effective   (*always* cost-effective)
B. More costly and more effective   (can be cost-effective)
C. More costly and less effective   (*never* cost-effective)
D. Less costly and less effective   (can be cost-effective)
E. More than one of the above can be considered to be 'cost-effective'

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Grant H. Skrepnek, Ph.D.
The University of Oklahoma Health Sciences Center   44

References

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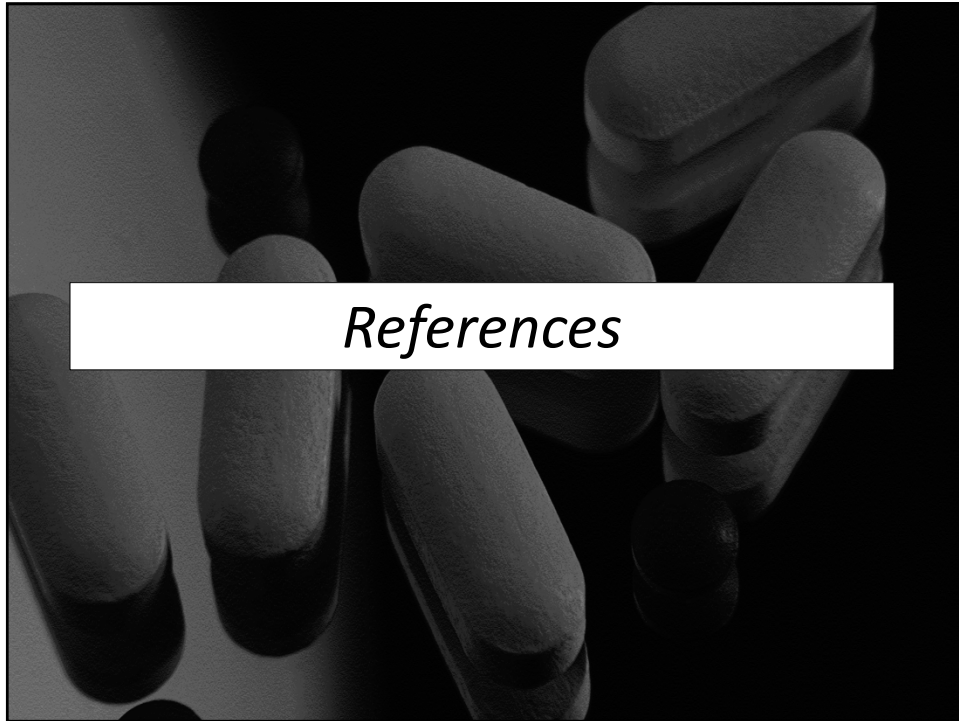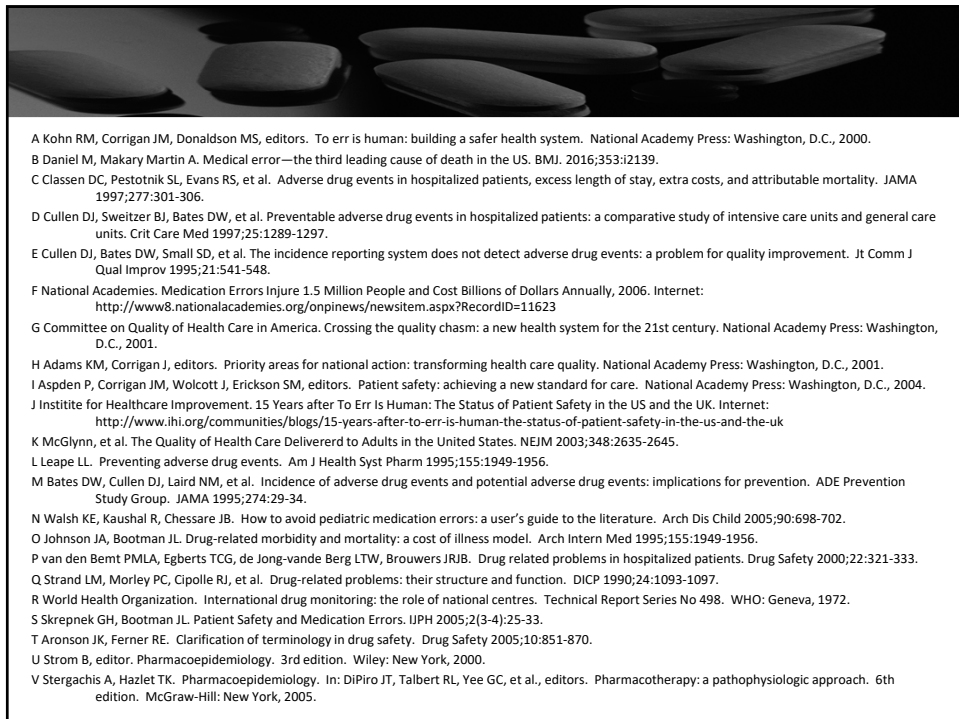
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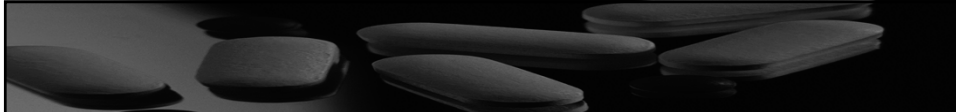
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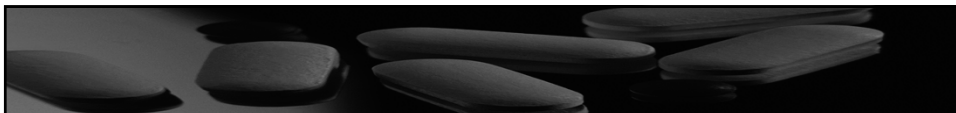
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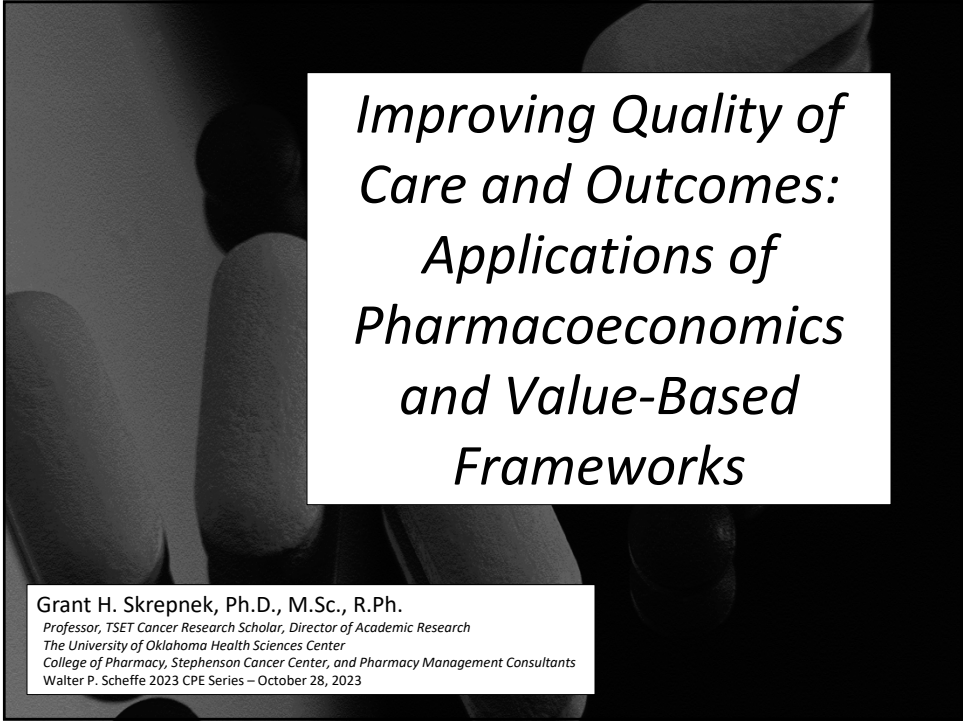
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