

Introduction to DUR and US DUR Programs

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- Introduction
- Definition of pharmacoepidemiology
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 - Outpatient DUR
 - Inpatient DUR
 - Risk Management
- Conclusions

- **“A desire to take medications is, perhaps, the greatest feature which distinguishes man from other animals.”**

Sir William Osler, 1891

- **“If the whole materia medica, as now used, could be sunk to the bottom of the sea, it would be all the better for mankind, and all the worse for the fishes.”**

Oliver Wendell Holmes
Medical Essays, “Comments and Counter”
Currents in Medical Science

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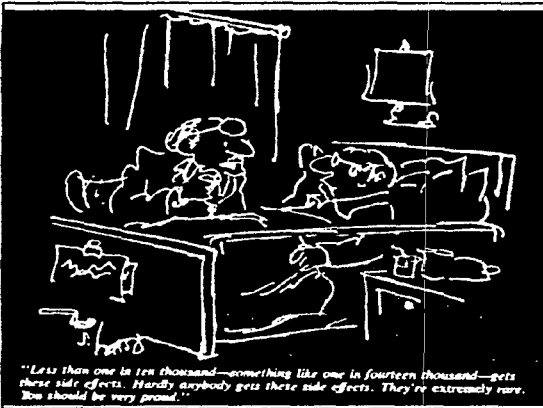
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"Traditional" Pharmacoepidemiology: Definition

- The study of the use and effects of drugs in populations
- Applies the methods of Epidemiology to the content area of Clinical Pharmacology

Pharmacoepidemiology: Unique Characteristics

1. A large population needs to be studied
2. Randomized clinical trials are unlikely to be productive
3. Answers often must be obtained very quickly



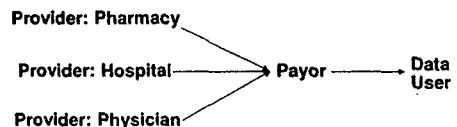
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Data Sources for Pharmacoepidemiology Studies

- Spontaneous case reports of adverse reactions
- Aggregate population-based data sources
- Computerized collections of data from organized medical care programs
- Data collected for pharmacoepi on an ongoing basis
- Existing data collected as part of other ad hoc studies
- Data collected de novo

Computerized Collections of Billing Data: Sources of Data



Definitions

- **Patient safety:** “freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur”

Patient Safety and Medical Errors

- **Iatrogenic injuries:** up to 180,000 US deaths each year, and disability or prolongation of hospital stay in another 1.3 million
- **Medical errors:** 44,000-98,000 annual deaths, more than MVA, breast cancer, or HIV
- **Medical errors:** annual costs of \$17-29 billion

Risks Associated With the Use of Drugs

- **Adverse drug events are the most common iatrogenic causes of patient injuries**



Key Problem of “Historical” Pharmacoepidemiology

- Adverse drug events are the most common iatrogenic causes of patient injuries
- Most are the result of an exaggerated but otherwise usual pharmacological effect of the drug
- Yet, historically these have been ignored by pharmacoepidemiology, as they do not represent a focus of commercial and regulatory interest

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Definitions-1

- Drug utilization studies investigate how often study drugs are used, and in whom

Definitions-2

- Drug utilization review studies are investigations which assess the appropriateness of drug use

Definitions-3

- Drug utilization review (DUR) programs (or DUE programs) are ongoing structured programs designed to improve drug use by intervening when inappropriate drug use is detected, often focusing on drugs of abuse or overuse of drugs

Definitions-4

- Therapeutically-oriented drug utilization review programs are DUR programs which focus primarily on rationalizing prescribing and, thereby, preventing adverse reactions

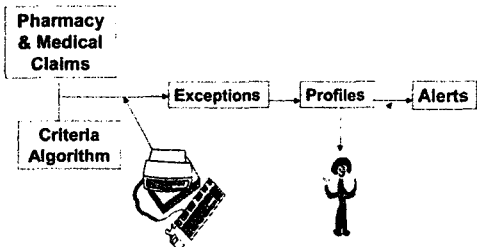
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Types of rDUR Criteria

- Drug-Drug
- Drug-Disease
- Duplication
- Drug-Age
- Drug-Allergy
- Duration
- Refills too soon
- Refills to late
- Drug abuse
- High-cost drug
- Untreated indication

Operation of Outpatient rDUR Programs



Chronology of rDUR

- 1969: Task Force on Rx Drugs (for Medicare): DUR to ↑ quality and ↓ costs is promising; evidence for effectiveness needed before implementation
- 1970: First formal DUR program in Medicaid, focusing on cost

Chronology of rDUR

- 1988: DUR required as part of Medicare Catastrophic Healthcare Act; repealed 1989
- 1990: DUR required for Medicaid
 - Open formularies
 - Estimation of cost savings
- 1990s: ↑ managed care
- Never evaluated for efficacy

rDUR Effectiveness: New Conclusions

- No change in rate of exceptions
- No change in rate of hospitalization in those with exceptions

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Background

- The Hospital of the University of Pennsylvania (HUP) is the major academic teaching hospital for the University of Pennsylvania School of Medicine. It is the first university-based hospital in the country, and includes 701 beds.

Problem-1

- In early 1989 HUP underwent its routine JCAHO accreditation review, and was criticized for the absence of:
 - 1) an adverse drug reaction monitoring program, and
 - 2) a drug usage evaluation program

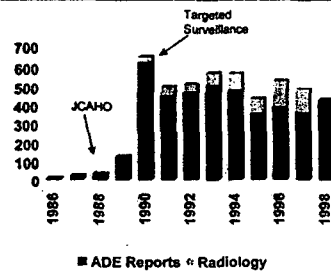
Problem-2

\$

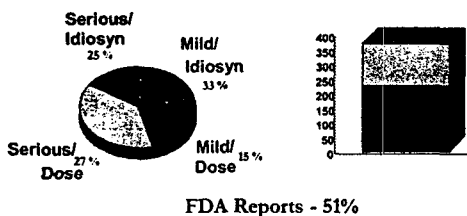
Scope of the New Activity

- Adverse drug reaction reporting
- Drug usage evaluation
- Pharmacy cost containment

ADE Annual Report



Adverse Drug Experiences - 1998



Drug Usage Evaluation Program

- Choose drug(s) for initial evaluation
- Develop criteria for appropriate use
- Develop chart abstracting form
- Identify exposed patients using pharmacy computer
- Conduct chart review
- Analyze data
- Report results to committee
- Design and implement intervention(s)
- Re-evaluate

Sample Inpatient DUEs

- Heparin dosing
- Oral vancomycin use
- Indications for use of meperidine
- Indications for use of broad spectrum antibiotics

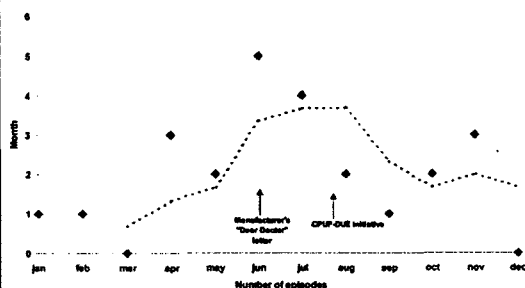
Sample Outpatient DUEs

- Antibiotics used for URI and bronchitis
- Use of Cox 2 inhibitors
- Cisapride drug interactions

Examples of Cost Savings From Inpatient Program

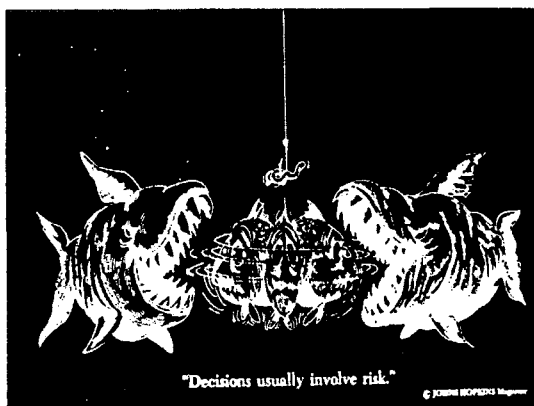
- Antibiotic management program
- Anticoagulation management program
- Restriction of high-dose hydromorphone PCA
- Deletion of zolpidem from formulary

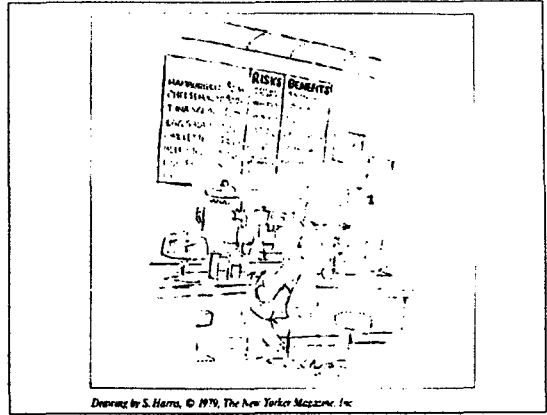
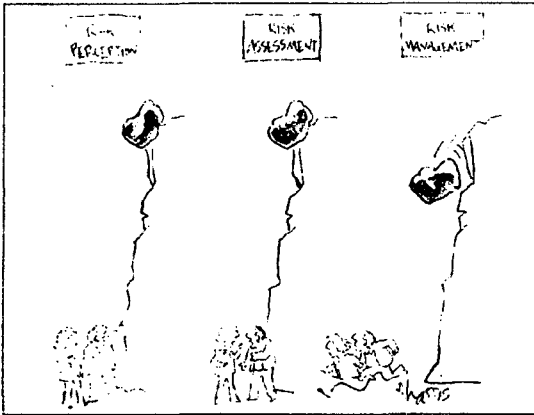
Potential cisapride drug-drug interactions involving outpatient CPUP prescriptions (with trend-line computed by method of moving averages)



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Risk Management

- **Definition:** An endeavor applied to the use of therapeutic agents (including drugs, devices, and biologics) that seeks to assure benefits to patients outweigh risks

Risk Management

- **Broad categories**
 - Informational interventions
 - Active or administrative programs
- **DSaRM**

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