

# Evidence in Context: Integrating Evidence and Value Into Coverage Policy

**Session 10.**                      **Tuesday, December 7, 2004, 2:45 p.m. – 4:15 p.m.**

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**Panelists:**                      **Duane Thurman, Health Care Authority  
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# Introduction

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- How best to manage the evidence-based medicine decision making process and competing stakeholder interests?
- Concentrated special interests versus diffuse public interests

# Evidence-based Prescription Drug Program

- In June 2003 the legislature created the Washington State Evidence-based Prescription Drug Program (Senate Bill 6088).
- Coordinated effort by Health Care Authority's Uniform Medical Plan, Medicaid Fee for Service, and Labor & Industries' Workers' Compensation Program.
- Goal: to develop a statewide evidence-based "preferred drug list" to control prescription drug costs without reducing quality of care.

# Evidence-based Prescription Drug Program

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- Components of the Program
  - Washington Preferred Drug List
  - Pharmacy & Therapeutics Committee
  - Endorsing Practitioner – Therapeutic Interchange Program

# Washington Preferred Drug List

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- The Preferred Drug List is a list of drugs selected by the agencies to be used as the basis for their purchase of prescription drugs.
- The list currently consists of 13 therapeutic drug classes and is expected to be increased to 25 to 30 drug classes by the end of 2006.
- The agencies began using the list in January 2004.

# Pharmacy & Therapeutics Committee

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- The Committee has 10 members that include 4 physicians, 4 pharmacists, 1 physician's assistant, and 1 advanced registered nurse practitioner.
- The Committee meets quarterly.
- The Committee reviews reports prepared by the Evidence-based Practice Center at Oregon Health Sciences University to determine if there is a significant difference in the safety and efficacy of drugs within a therapeutic class.
- The Committee then makes a recommendation to the agencies as to which drugs are equally safe and efficacious in a particular class.
- The agencies then select the preferred drug, or drugs, based on an analysis of net cost savings to the state.

# Endorsing Practitioner – Therapeutic Interchange Program

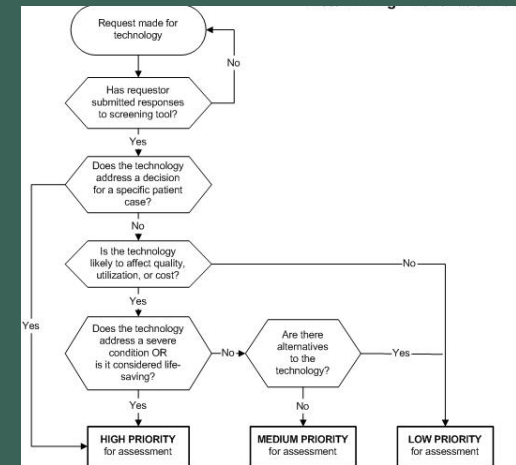
- An “endorsing practitioner” is a Washington prescriber who has reviewed the preferred drug list and has notified the health care authority that he or she has agreed to allow therapeutic interchange of a preferred drug for any non-preferred drug in a therapeutic class on the preferred drug list.
- Pharmacists will automatically interchange the preferred drug for any non-preferred drug prescribed by these practitioners and notify the prescriber of the change unless:
  - the Rx is for a "refill" of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug; or
  - the endorsing practitioner indicates “dispense as written” on an Rx for a non-preferred drug.
- In these situations the pharmacist will dispense the non-preferred drug as prescribed.

# Health Technology Assessment (HTA) in WA

To develop a **common process** among state agencies for evaluating health technologies, which include devices, durable medical equipment, procedures, diagnostics, and off-label drug use

# WA's Common HTA Process

- Manufacturers, practitioners, and patients request technology
- Prioritize by quality, utilization, and cost



The screenshot shows the FDA's 510(k) Database search page. At the top, it features the FDA logo and the text "U.S. Food and Drug Administration" and "Department of Health and Human Services". Below this is the "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH" header. The main content area is titled "Search 510(k) Database" and includes a search form with various fields: Panel (dropdown), Product Code (text), 510K Number (text, with "K" entered), Applicant Name (text), Device Name (text), Type (dropdown), Decision (dropdown), Decision Date (date range), and Sort by (dropdown, set to "Decision Date (descending)"). There are also checkboxes for "Cleared/Approved IVD Products" and "Third Party Reviewed", and a dropdown for "Expedited Review". At the bottom, there are buttons for "Search", "Clear", "10 Records per Report Page", and "Go to Simple Search".

- Consider guiding principles:

a. FDA approval

b. scientific evidence shows technology improves health outcomes

c. technology is likely to improve outcomes as much or more than alternatives

# WA's Common HTA Process



From:

<http://144.32.150.197/scripts/WEB.CXE/NHSCRD/start>

- Find and use high quality health technology assessments
- Search journals for evidence
- Apply evidence hierarchy
- Consider non-published information
- Adhere to the quality checklist if creating an HTA
- Use HTA to inform coverage decisions and to develop guidelines for medical necessity



From:

[www.ncbi.nlm.nih.gov/entrez/query.fcgi](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi)

# Next Steps: a Range of Options

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**Forming a group that discusses technologies & decisions**

**Developing website to post information**

**Joint purchasing of HTA**

**Developing a centralized HTA capacity**

# HTA in WA as a Priority of Government

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- Plays a role in providing access to appropriate health care and improving the efficiency of current services
- Develop, coordinate, and centralize health planning and information across state health activities to eliminate duplication of effort and leverage resources and information

# Staying Power of HTA in WA

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# Opposition to Evidence-Based Medicine

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- What happens when researchers get the “wrong” scientific results, contrary to someone’s financial interests?
- Tactics, players, and impacts
- Societal implications
- Lessons

# Many Stories: Common Themes

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- Legal, administrative, political attacks against findings contrary to financial interests
- Controversial treatments already in use, had market share
- Attacks bypass genteel peer-review
- Goal to discredit findings, intimidate investigators, preempt time & resources, eliminate funding



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# **Bruce Psaty and Calcium Channel Blockers**

**(UW internist)**

# Bruce Psaty: Start of a Controversy

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- $\text{Ca}^{++}$  Channel drugs for HTN: higher risk of MI than older, cheaper drugs
- 1995: Paper at Epi and Prevention Council of the AHA in San Antonio; seemed innocuous, but hostile Q&A piqued journalists' interest
- Blindsided with faxes, calls; recommended JNC guidelines
- Fax to Med School Dean from Pfizer; call to Public Health Dean from state legislator

# Bruce Psaty: the Context

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- 20% of hypertensive patients taking Ca<sup>++</sup> Channel Blockers
- Heavily marketed; growing market share; 15 times more expensive than older alternatives known to reduce stroke, CHF, MI
- Bayer: kickback program to pharmacies: \$35 for every new Rx for their drug. In 1994, paid \$605,000 fine

# Bruce Psaty: The plot thickens

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- Blistering “Dear Doctor” letter distributed nationally; Bayer not identified as sponsor
- Pressure public health Dean: don’t publish
- FOI request from Pfizer: “all records, reports, data, analyses, correspondence, and any other documentation related to design, conduct, results, conclusions. Includes protocols, individual data, data sets, stat. calculations, correspondence, meeting minutes, notes of Psaty, other staff, faculty...”

# Bruce Psaty: The Denouement

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- Subsequent work confirmed initial case-control study, inc. RCT's and meta-analyses
- Canadian study of the controversy: 96% of authors supporting Ca<sup>++</sup> Channel drugs had financial ties to drug makers vs. 44% of neutral or critical authors
- Silver lining: “Pfizer did more to promote the findings of our unwanted study than I could have done on my own. Maybe Bayer too. I don't want to give Pfizer all the credit.”

# Lessons

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- Outcomes research: financial implics, more politicized than basic science
- Political, legal and marketing discourse; groups with money and power can shape questions & answers
- Harassing scientists: disincentive to research in controversial areas
- Support investigators under attack
- Commercial pressures are one reason it's hard to practice EBM

# Summary Points

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- Why do we need evidence-based medicine (EBM) to help inform health policy and coverage decisions?
  - Resources are limited
  - Competing resource needs
  - Significant “opportunity costs” for health care
  - Critical to develop appropriate mechanisms to prioritize health care resources in order to
    - Improve health outcomes
    - Control health expenditures
    - Potentially redirect savings to needed resources

# Summary Points (con't)

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- Science/evidence is one input to EBM policy formulation and coverage decision making
- Other inputs include:
  - Stakeholder interests and values
    - Provider groups
    - Firms that supply technology
    - Patient advocacy groups
- Managing competing external interests is critical to success of EBM policy/decision-making process

# Discussion Questions

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1. What are major challenges in performing evidence-based decision making?
  - Legislators and staff
  - Health care agency staff

# Discussion Questions

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2. What strategies might work best to manage competing interests in order to ensure evidence is used most effectively?

# Discussion Questions

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## 3. How to weight competing interests?

- Science
- Financial interests
- Patient advocacy groups
- Providers

# Discussion Questions

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4. What factors would be critical to enhance evidence-based decision making in the future?

- Tracking health outcomes across agencies
- Development of effective information technology and data systems
- Individual agency versus centralized organization support for evidence-based decision making
- Credible professional and scientific advisory function