

Evidence-Informed Health Policy: Limiting Rationing and Increasing Health Value for Dollar

NCSL

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1

The State Dilemma

States in political vise:

- Advocates and industry want maximum service
- Taxpayers want to limit expenditures
- Highest demand during economic downturn
- States are the safety net for low income persons
- It's not **IF** they ration but how they **LIMIT** rationing

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2

State Response to Tightening Vise

- Generally:
 - Reducing Eligibility for State Medical Assistance
 - Cutting Provider Payments
 - Cutting Categories of Care
- Some:
 - Recognize Technology, Practice and System Factors that Reduce Value and Drive Cost
 - Demanding Higher Standard of Evidence for Payment
 - Seeking Pragmatic, High Quality, Independently Produced, Comparative Effectiveness Research

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3



Why Do We Need Evidence-informed Policy?

“Professional good intentions and plausible theories are insufficient for selecting policies and practices for protecting, promoting and restoring health.”

Iain Chalmers

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66-48

DR. BENJAMIN SPOCK

BABY AND CHILD CARE

The most widely recommended handbook for parents ever published—
Authoritative, illustrated, indexed

Over 19,000,000 copies sold

The Complete Book POCKET BOOKS

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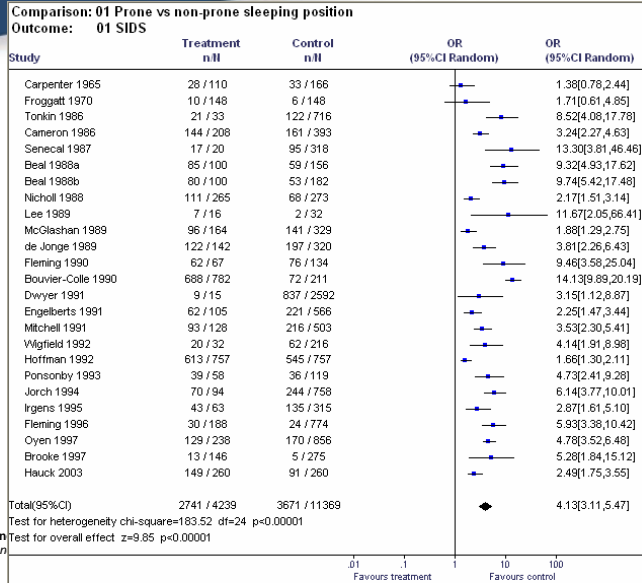
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I think it is preferable to accustom a baby to sleeping on his stomach from the start if he is willing. He may change later when he learns to turn over.

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Telling Parents That Babies Should Sleep On Their Stomachs



Estrogen + Progestin for Prevention After WHI and HERS

	1992	2002
CHD	Suspected benefit ⊕○○○	Confirmed harm ⊕⊕⊕⊕
Hip fracture	Suspected benefit ⊕○○○	Confirmed benefit ⊕⊕⊕⊕
Colorectal cancer	Suspected benefit ⊕○○○	Confirmed benefit ⊕⊕⊕⊕
Breast cancer	Suspected harm ⊕○○○	Confirmed harm ⊕⊕⊕⊕
Stroke	Suspected harm ⊕○○○	Confirmed harm ⊕⊕⊕⊕
Thrombosis	Suspected harm ⊕○○○	Confirmed harm ⊕⊕⊕⊕
Gall bladder disease	Suspected harm ⊕○○○	Confirmed harm ⊕⊕⊕⊕

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CRASH
Corticosteroid Randomisation
After Significant Head Injury

NEWS Autumn 2004

**CRASH trial: 10,008 patients –
the largest head injury trial ever**

THE LANCET

Volume 364 Number 9442 October 9–15, 2004 www.thelancet.com

“The administration of corticosteroids to brain-injured patients has seemingly caused more than 10 000 deaths during the 1980s and earlier.”

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State Experience Using Evidence-informed Policy

- Vendor Supplied Research
- US Preventive Services Task Force
 - Results, methods and example
- AHRQ Effective Health Care Program
- Drug Effectiveness Review Project
 - State’s own motion, direct application
- Medicaid Evidence-based Decisions

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DERP

- Established in 2003
- Self-governed collaboration of 10 states and CADTH
- Administered by Center for Evidence-based Policy
- Research conducted by federally designated EPCs

DERP

- Systematic reviews based on USPSTF methods
- Public input on Key Questions
- Global literature search
- Solicit industry research
- Appraisal of research
- Synthesis of best quality research
- Universal peer review
- Final product in public domain

DERP Transparency

- Draft KQs posted and comments incorporated
- Full disclosure of methods and sources
 - Which studies included and why
 - Which studies not included and why
 - All industry submissions
- Universal peer review w/ comments public
- Final report in public domain

Reports Completed by DERP

- 2nd Generation Antidepressants
- 2nd Generation Antihistamines
- Alzheimer's Drugs
- Angiotensin Converting Enzyme Inhibitors
- Angiotensin II Receptor Antagonists
- Anti-Epileptic Drugs
- Anti-platelet Drugs
- Controller Drugs for Asthma
- Atypical Antipsychotics
- Quick Relief Medications for Asthma
- Beta Adrenergic Blockers
- Calcium Channel Blockers
- Combination Drugs for Hypertension & Hyperlipidemia
- Constipation Drugs
- Newer Diabetes Drugs
- Renin Angiotensin Aldosterone System Drugs
- Drugs to treat ADHD
- Hepatitis C Drugs
- Hormone Replacement Therapy
- Long-acting Opiates
- MS Drugs
- Neuropathic Pain Drugs
- Newer Antiemetics
- Newer Insomnia Drugs
- NSAIDS
- Oral Hypoglycemics
- Overactive Bladder
- Proton Pump Inhibitors
- Skeletal Muscle Relaxants
- Statins
- Targeted Immune Modulators
- Thiazolidinediones
- Topical Calcineurin Inhibitors
- Triptans
- 59 updated reports completed

DERP Results

- Good evidence, no significant differences (PPIs)
- No good comparative evidence (Opioid Analgesics)
- Good evidence, marginal differences (Triptans)
- Good evidence, significant clinical differences (Beta Blockers)
- Even classes with good evidence often have significant gaps (subpopulations)

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Medicaid Evidence-based Decisions (MED)

- Evolved to meet policy needs
 - Focused on interventions of all kinds
 - Diagnostics
 - Devices
 - Procedures
 - Programs
- Range of research products
 - Few new systematic reviews
 - Time and resources are limited
 - Poor evidence base
 - Existing high quality SR available

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Sample Reports Completed by MED

- Role of Percutaneous Coronary Intervention in Patients with Stable Angina
- Autism Treatment for Children and Adolescents
- Breast MRI- Risk Assessment Models
- Prior Authorization (PA) Imaging Cervical Spine
- PA Imaging Dementia
- PA Imaging Headaches
- PA Imaging Knee Pain
- PA Imaging Low Back Pain
- PA Imaging Shoulder Pain
- PA PET in Malignancy
- PA Screening US in Pregnancy
- Effectiveness of Diabetes Prevention Programs
- Prevention and Non-Surgical Treatments for Overweight and Obese Adults
- Arthroscopy of Knee for Osteoarthritis
- Chronic Pain Interventions for Lower Back Pain
- Opioids for the Management of Acute Pain
- Spinal Surgery
- Stereotactic Radiosurgery and Intensity Modulated Radiation Therapy
- Dental Radiographs for Diagnosing Caries
- Examining the Scope of Practice for Dental Hygienists and Assistants
- Orthodontics for Children and Adolescents
- Disease Management Programs (3 Reports)
- Early Periodic Screening and Diagnosis Treatment (4 Reports)
- Telehealth and telemetric monitoring (2 reports)
- Sleep Disorders in Children
- Alcohol Abuse
- Smoking Cessation in Pregnancy
- Substance Abuse
- Transplant Centers of Excellence
- Vacuum Wound Closures
- Total Participant Inquiries = 40

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17



MED Results

- Significant Savings on high tech imaging
 - CT angiography
 - Imaging billing practices
- Self-monitoring of blood glucose
- Autism guidelines
- Vacuum wound closures
- Knee arthroscopy, lavage and debridement
- Durable medical equipment

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18



Terbutaline for Preterm Labor

The screenshot shows the FDA website interface. At the top, it says "U.S. Department of Health & Human Services" and "www.hhs.gov". Below that is the "FDA U.S. Food and Drug Administration" logo and a search bar. A navigation menu includes "Home", "Food", "Drugs", "Medical Devices", "Vaccines, Blood & Biologics", "Animal & Veterinary", "Cosmetics", "Radiation-Emitting Products", and "Tobacco Products". The main content area is titled "Drugs" and "FDA Drug Safety Communication: New warnings against use of terbutaline to treat preterm labor". A sidebar on the left lists various drug safety topics. The main text includes a "Safety Announcement" dated [02-17-2011] and a paragraph explaining the FDA's warning against the use of terbutaline for preterm labor. The Oregon Health & Science University logo is visible in the bottom right corner of the screenshot.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Drugs

Home > Drugs > Drug Safety and Availability

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Drug Safety and Availability

- Drug Alerts and Statements
- Importing Prescription Drugs
- Medication Guides
- Safe Use Initiative
- Drug Safety Communications
- Drug Shortages
- Postmarket Drug Safety Information for Patients and Providers
- Information by Drug Class
- Medication Errors
- FDA Drug Safety Newsletter
- Drug Safety Podcasts
- Drug Recalls

FDA Drug Safety Communication: New warnings against use of terbutaline to treat preterm labor

Safety Announcement
Additional Information for Patients
Additional Information for Healthcare Professionals
Data Summary
References

Safety Announcement

[02-17-2011] The U.S. Food and Drug Administration (FDA) is warning the public that injectable terbutaline should not be used in pregnant women for prevention or prolonged treatment (beyond 48-72 hours) of preterm labor in either the hospital or outpatient setting because of the potential for serious maternal heart problems and death. The agency is requiring the addition of a **Boxed Warning** and **Contraindication** to the terbutaline injection label to warn against this use. In addition, oral terbutaline should not be used for prevention or any treatment of preterm labor because it has not been shown to be effective and has similar safety concerns. The agency is requiring the addition of a **Boxed Warning** and **Contraindication** to the terbutaline tablet label to warn against this use.

Terbutaline is approved to prevent and treat bronchospasm (narrowing of airways) associated with asthma, bronchitis, and emphysema. The drug is sometimes used off-label (an unapproved use) for acute obstetric uses, including treating preterm labor and treating uterine hyperstimulation. Terbutaline has also been used off-label over longer periods of time in an attempt to prevent recurrent preterm labor.

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Lessons Learned

- State sponsored and governed projects can produce best available evidence
- Evidence informs not dictates policy
- Structure of industry interface important
 - Need evidence not lobbying (independence)
 - Must be formal
 - Must be transparent
- Cost must be considered (policy process)
- Big gaps in evidence need filling

An Evolving Policy Construct (Eddy)

- Resources are limited
- Cost of services must be considered
- Priorities must be set
- Some beneficial services won't be provided
- Objective is to maximize population health
- All patients should be treated equitably
- Determine priority on benefit, harm, and cost

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Evolving Policy Construct (continued)

- Empirical evidence should trump subjective
- Criteria for treatment use
 - Evidence that it is better than nothing for population
 - That benefit outweighs harms in improving health
 - Comparatively better than other treatment at improving population health
 - When determining whether the treatment satisfies the three criteria above, the burden of proof must lie with people advocating the use of a service
- Outcomes should reflect preference of patients

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Politics

- Rationing
- Governance
- Racial and ethnic disparities
 - More thorough the evidence the more policy can account for differences
 - Identifies gaps that need to be filled
 - Helps address cost which disproportionately affects minorities
- Knowledge is the foundation for honest debate
- Resource limits dictate value purchasing

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23



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24

