Health Care That Works:

Evidence-Based Medicaid

A HCA grading system, reference pricing and variable cost sharing
Principles of Evidence Based Coverage

- Consistency of decisions
- Transparency of decisions
- Processes that highlights the evidence
- Lead with safety

- Ensuring Fairness in Health Care Coverage Decisions
Evidence Based Benefits are medically necessary benefits that offer access to affordable quality health care for the population served.

Evidence Based Benefits use the best evidence of proven value to the population while respecting the appropriateness of services and the authority of the treating provider.
WA’s Evidence Based Purchasing – The Journey

- HB 1299 directed agencies providing state purchased health care to use evidence-based medicine
- SB 6088 (2003) Prescription Drug Program
- HB 1088 (2007) – Children’s mental health -- ADHD and antipsychotic quality/cost initiatives (e.g. 2\textsuperscript{nd} Opinion)
- Evidence-Based Practice Center in Oregon Reviews Drug Classes (Working with 13 other states in DURP)
- Independent P&T Committee selects the most or equally effective drug(s) in class
- Cost considered only when comparing equally effective drugs in developing PDL
- SB 5892 (2009) -- Engaging the community to Improve Generic Drug Use
Results of Our Efforts to Date

Bending the cost curve!

Prescription drug costs dropped by 23%, thanks to a series of evidence-based initiatives.
Results of Our Efforts to Date

- Medicaid generic utilization rate
  - Gone from 68% to 81%

- Safer prescribing
  - Set safety standards of too much too many and too young (all trends have reduced)
    - Stimulants and antipsychotics
  - Effectively moved several thousand clients to lower cost equally effective drugs
    - PPI, Second generation antidepressant

- Worked with the community on Feedback reports
  - Mental health Rxing, OB Outcomes and generic utilization
Moving Beyond Prescription Drugs: Determining Medicaid “medical necessity”

- Administrative rule defines the process for determining “medical necessity” (2005)
- Negotiated with stakeholders over 18 month period
- Establishes a transparent, evidence-based process to determine medical necessity for services subject to prior authorization.
- Treating provider has opportunity to submit evidence for review.

Medicaid’s Grading System for Service Authorizations (WAC 388-501-0165)

A = Randomized controlled clinical trials
   (cannot be based on Type III or Type IV evidence alone)

B = Consistent and well done observational studies
   (cannot be based on Type IV evidence alone)

DSHS generally approves above the line

Below the line, provider needs to show the evidence or DSHS will disapprove via Prior Authorization

C = Inconsistent studies

D = Studies show no evidence, raise safety issues, or no support by expert opinion
GRADE A: Solid evidence that this technology has good value

EXAMPLE: Cardiac rehabilitation

- Gets an “A” by helping patients recover faster than those who don't receive exercise programs.
- Helps avoid further surgery, hospitalization and another heart attack.
- Under Hayes criteria, status has now changed to “Covered”
GRADE B: Reasonable evidence and data points in direction of value

EXAMPLE: Bariatric surgery in 2003 got a “D” but in 2004 it gets a “B”

Surgery gets a “B” for diabetics who are obese (BMI >35) and a “D” for other co-morbid conditions (WAC 388-551-1600 Aug 2004)

- Approval rates dropped (95% to 67%)
- Costs are down ($36,000 to $17,000 per case)
- Mortality and serious complications are reduced (0% in 2005)
- Expected annual savings and clinical outcomes are better
GRADE C: Questionable evidence and data points in different of values

**Example:** PET Scans for Cancer 2009 gets a “C”

**Example:** The use of PET–CT for preoperative staging of NSCLC reduced both the total number of thoracotomies and the number of futile thoracotomies but did not affect overall mortality.


**Example:** The use of PET-CT in Lymphoma should be limited to one


**Example:** All other cancers must have a non-diagnostic conventional scan
GRADE D EXAMPLE: Disabling idiopathic generalized dystonia
Grade D: No evidence, evidence of unsafe, or off-label

Example: Deep brain stimulators

- Stimulating the brain with an electrode can reduce muscle spasms but treatment in dystonia gets a “D” for no studies

- Deep brain stimulation is rated “D”, but has a humanitarian device exemption

- HRSA allows these children to access this technology at UCSF

Provider and vendor have opportunity to demonstrate improved outcomes by:

- FDA humanitarian device exemption
- Institutional Review Board approval
Cadillac's vs. Chevy's: What is the Grade?
Grading system for health care service: Reference Pricing

- Generic Drugs
- Glasses
- Std Wheel chairs
- Older Codes (CPT/HCPCS with evidence)

Approves above the line or pay the rate above the line

Below the line the benefit is non-covered or has a higher co-payment or is paid at the existing rate

- Brand Drugs
- Contacts
- Customized Wheel chairs
- New Codes (CPT/HCPCS without evidence)
Grading system for health care service: Cost Sharing Model

Zero co-payments
- Vaccines
- Generic Drugs
- Low cost existing technology

Higher Co-payments
- Brand Drugs
- New technology without evidence
Grade ?: Drugs and other Technology

Example: Anti-psychotics & ADHD Drugs
- RED Flags were developed for too much, too many, too young and drug adherence
- Prescribing above the RED Flags requires a second opinion

Example: New Technology and New Codes
- A new HCPC Codes get an MSRP
- A new CPT typically gets a higher RVU
- Evidence and costs are not allowed to be considered

Example: Narcotics
- Working with the community to establish an Evidence Based Maximal narcotic dose (120 mg of morphine equivalent/day)
Evidence Based Benefits and Law: Keys to the path

- Legislative and executive branch partnership
- Be Transparent
- Engage the provider community
- Find Common Values
- Make Consistent Coverage Decisions
- Make Bias Free zones
Questions?

The Current Principle in Health Care
“Facito aliquid operis ….”
Always do something

VERSUS

An Evidence Based Principle
"Primum non nocere"
"Declare the past, diagnose the present, foretell the future; practice these acts. As to diseases, make a habit of two things — to help, or at least to do no harm."
Evidence-Informed Health Policy:

*Increasing Health Value for Dollar*

National Association of Medicaid Directors
November 8, 2011

Mark Gibson, Director
*Center for Evidence-based Policy*
Oregon Health & Science University
The State Dilemma

States in political vise:

- Advocates & industry want maximum service
- Taxpayers want to limit expenditures
- Highest demand during economic downturn
- Safety net for low income persons
- Unlimited demand & limited resources
State Response to Tightening Vise

Generally:
- Reduce eligibility for state medical assistance
- Cut provider payments
- Cut categories of care

Some:
- Use evidence to inform policy
- Demand higher standard of evidence for payment
- Seek pragmatic, high-quality, independent, CER
Why Do We Need Evidence to Inform Policy?

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

– Iain Chalmers
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.
Telling Parents That Babies Should Sleep on Their Stomachs

**Table: Comparison of Prone vs Non-prone Sleeping Position**

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment n</th>
<th>Control n</th>
<th>OR (95% CI Random)</th>
<th>OR (95% CI Random)</th>
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<td>59/110</td>
<td>33/218</td>
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<td>10/146</td>
<td>5/146</td>
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<td>Torkkan 1986</td>
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**Test for heterogeneity chi-square 193.52, df = 24, p < 0.00001**

**Test for overall effect: z = 8.05, p < 0.00001**

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*Center for Evidence-based Policy*

*Addressing policy challenges with evidence and collaboration*

*Oregon Health & Science University*
## Estrogen + Progestin for Prevention After WHI & HERS

<table>
<thead>
<tr>
<th>Condition</th>
<th>1992</th>
<th>2002</th>
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<tr>
<td>CHD</td>
<td>Suspected benefit ⊗⊗⊗⊗⊗</td>
<td>Confirmed harm ⊕⊕⊕⊕⊕</td>
</tr>
<tr>
<td>Hip Fracture</td>
<td>Suspected benefit ⊗⊗⊗⊗⊗</td>
<td>Confirmed benefit ⊕⊕⊕⊕⊕</td>
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<tr>
<td>Colorectal Cancer</td>
<td>Suspected benefit ⊗⊗⊗⊗⊗</td>
<td>Confirmed benefit ⊕⊕⊕⊕⊕</td>
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<tr>
<td>Breast Cancer</td>
<td>Suspected harm ⊗⊕⊕⊕⊕</td>
<td>Confirmed harm ⊕⊕⊕⊕⊕</td>
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<tr>
<td>Stroke</td>
<td>Suspected harm ⊗⊕⊕⊕⊕</td>
<td>Confirmed harm ⊕⊕⊕⊕⊕</td>
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<tr>
<td>Thrombosis</td>
<td>Suspected harm ⊗⊕⊕⊕⊕</td>
<td>Confirmed harm ⊕⊕⊕⊕⊕</td>
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<tr>
<td>Gall Bladder Disease</td>
<td>Suspected harm ⊗⊕⊕⊕⊕</td>
<td>Confirmed harm ⊕⊕⊕⊕⊕</td>
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</table>
“The administration of corticosteroids to brain-injured patients has seemingly caused more than 10,000 deaths during the 1980s and earlier.”
State Experience Using Evidence-Informed Policy

- Vendor supplied research
- US Preventative Services Task Force
  - Results, methods & example
- AHRQ Effective Health Care Program
- Drug Effectiveness Review Project (DERP)
  - States’ own motion, direct application
- Medicaid Evidence-based Decisions (MED)
DERP

- Established 2003
- Self-governing collaboration
- 10 states & CADTH
- Administered by Center
- Research conducted by federally designated EPCs
DERP

- Comparative systematic reviews
- 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
Completed DERP Reports

- 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 (Opiod Analgesics)
- Good evidence, marginal differences (Triptans)
- Good evidence, significant clinical differences (glitazones)
- Even classes with good evidence often have significant gaps (subpopulations)
MED Project

Evolved to meet policy needs

- Intervention focus
  - Diagnostics
  - Devices
  - Procedures
  - Programs

Range of research products

- Systematic reviews
- Limited time & resources
- Poor evidence-base
- Existing high quality SR available
Sample MED Reports

- 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
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
Terbutaline for Preterm Labor

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

Safety Announcement

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.
Lessons Learned

- State sponsored & government projects can produce best available evidence
- Evidence *informs*, not dictates, policy
- Structure of industry interface important
  - Need evidence, not lobbying
  - Must be formal
  - Must be transparent
- Cost must be considered (policy process)
- Big gaps in evidence need filling
An Evolving Policy Construct

- Resources are limited
- Cost of services must be considered
- Priorities must be set
- Some beneficial services will not be provided
- Objective is to maximize population health
- All patients should be treated equitably
- Determine priority on benefit, harm, and cost
An Evolving Policy Construct

- Empirical evidence should trump subjective
- Criteria for treatment use
  - Evidence that is better than nothing for population
  - Benefit outweighs harms
  - Comparative benefits
  - Burden of proof with advocates
- Outcomes should reflect preference of patients
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