

An Overview of the Evidence Landscape

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Organization



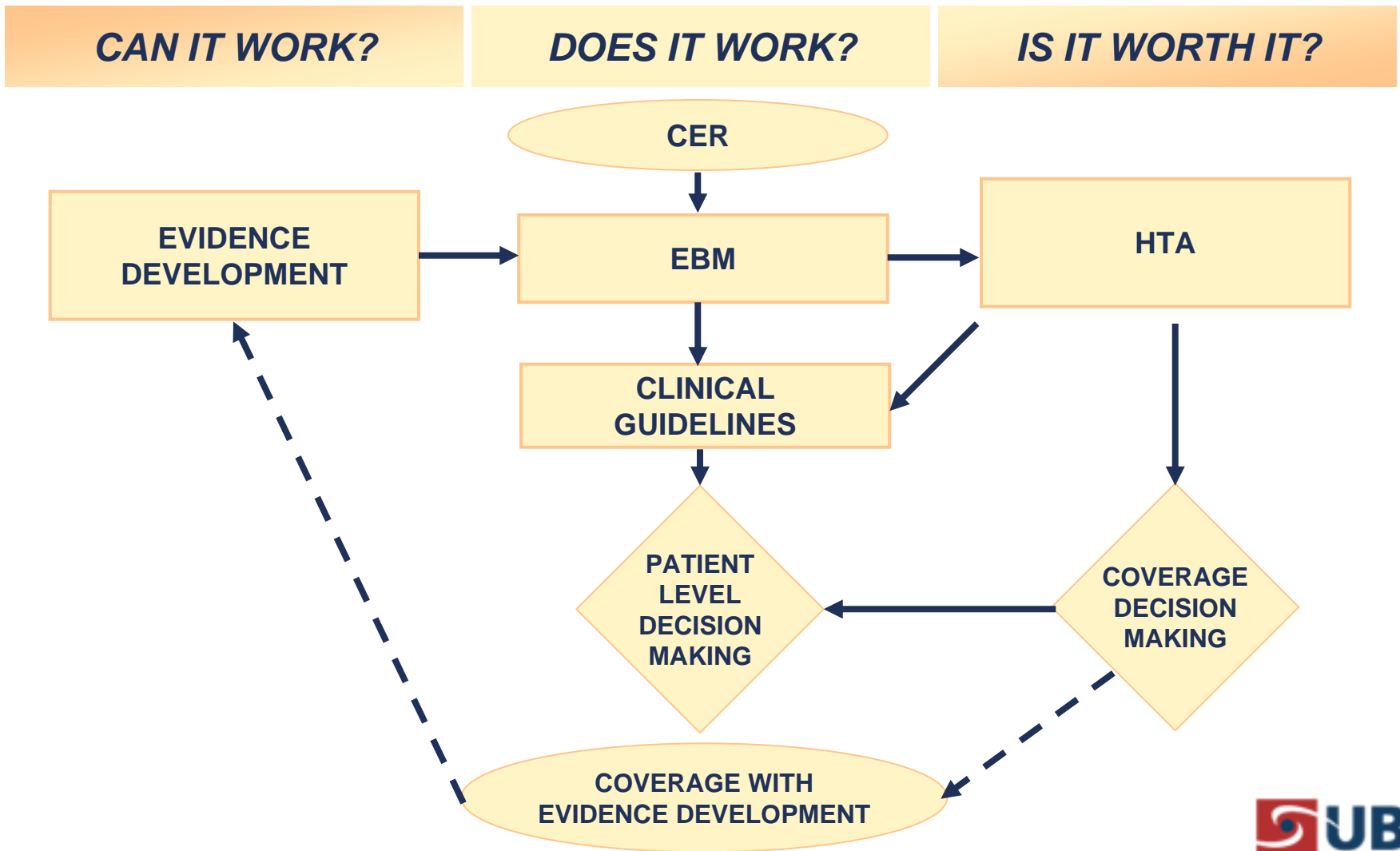
- Historical Backdrop
- The 2006-2008 Evidence Landscape “Wave”
- Why Now?
- Summary and Take Home Points

Evidence Eras in the US

- 1970's: Health Technology Assessment (HTA)
- 1980's: Effectiveness Research
- 1990's: Outcomes Research
- 2000's: Evidence-Based Medicine
- Of Late: “*Comparative Effectiveness Research*”
- Coming?: “Payment for Outcomes”

EBM-CER-HTA Relationships

Source: Drummond et al., *IJTAHC*, June, 2008



Failure of Early Federal Efforts

- Congress' Office of Technology Assessment
- National Center for Health Tech Assessment
- IOM's Council Health Care Technology
- Agency Health Care Policy & Research Clinical Guidelines
- Medicare's Cost-Effectiveness Coverage Rule

Why Did Early Federal Efforts Fail? Were Seen as Threatening to...

- Innovation
- Medical autonomy
- Market access

Thus, these efforts lost political support.

Meanwhile, US Private Sector Activities Succeeded

- BCBSA's Technology Evaluation Center
 - AMA's Diagnostic & Therapeutic Tech Assessment
 - American Academy of Physicians' Clinical Efficacy Assessment Project
 - ECRI
 - Hayes
 - AMCP's Format for Formulary Submissions
 - Oregon's Drug Effectiveness Review Project
 - Many others (e.g. Kaiser)
- ...and continue to succeed

Why Did Private Sector Activities Succeed?

- Perceived as useful by the market
 - Clinical decision making
 - Purchasing
 - Coverage, formulary placement
 - Cost containment
- Politically insulated

Also.....

...Many International Public Sector Activities Succeeded

- UK (NICE)
- Australia (PBAC)
- Canada (CADTH)
- Other EU Countries

...because...

...perceived to be useful in...

- Coverage
- Pricing
- Cost containment
- Clinical decision-making

Now, Since Late 90's in US, Deepening Federal Commitment

- Agency HC Research & Quality
 - Medicare Modernization Act (2003)
 - 41 EBM-related Centers!

- Medicare:
 - Medicare Evidence Development & Coverage Advisory Committee (MedCAC)
 - “Coverage with Evidence Development” (CED) Policy
 - » “Conditional Coverage”

Why Do New Federal Evidence Efforts Seem to be Succeeding?

Feds learned a political lesson!

- Developing evidence at arms length from policy use
- Not including cost-related analyses
- Perceived to be useful and not so threatening
- Medicare's "Coverage with Evidence Development" policy billed as a *positive* way to cover new technology
- Perceived "Success" of NIH Comparative Trials (e.g., WHI, ALLHAT, CATIE)

The 2006-2008 Evidence Landscape “Wave”



Four Major Themes/Orientations

1. Broad EBM-related review/overhaul
2. Enhancement of evidence base
3. Conditional coverage; Paying for Outcomes (P4O)
4. Renewed interest in Health Technology Assessment (HTA)

Theme 1: Broad EBM Overhaul



IOM Roundtable on EBM

- Vision: “Learning Health Care System”
- Goal: By 2030, 90% of all health care decisions be patient-specific, best evidence-based
- Process: Engage all stakeholders, craft an integrated, comprehensive national solution via broad consensus

**Theme 2:
Enhance Evidence Base:
The “Comparative Effectiveness
Research” (CER) Initiative**

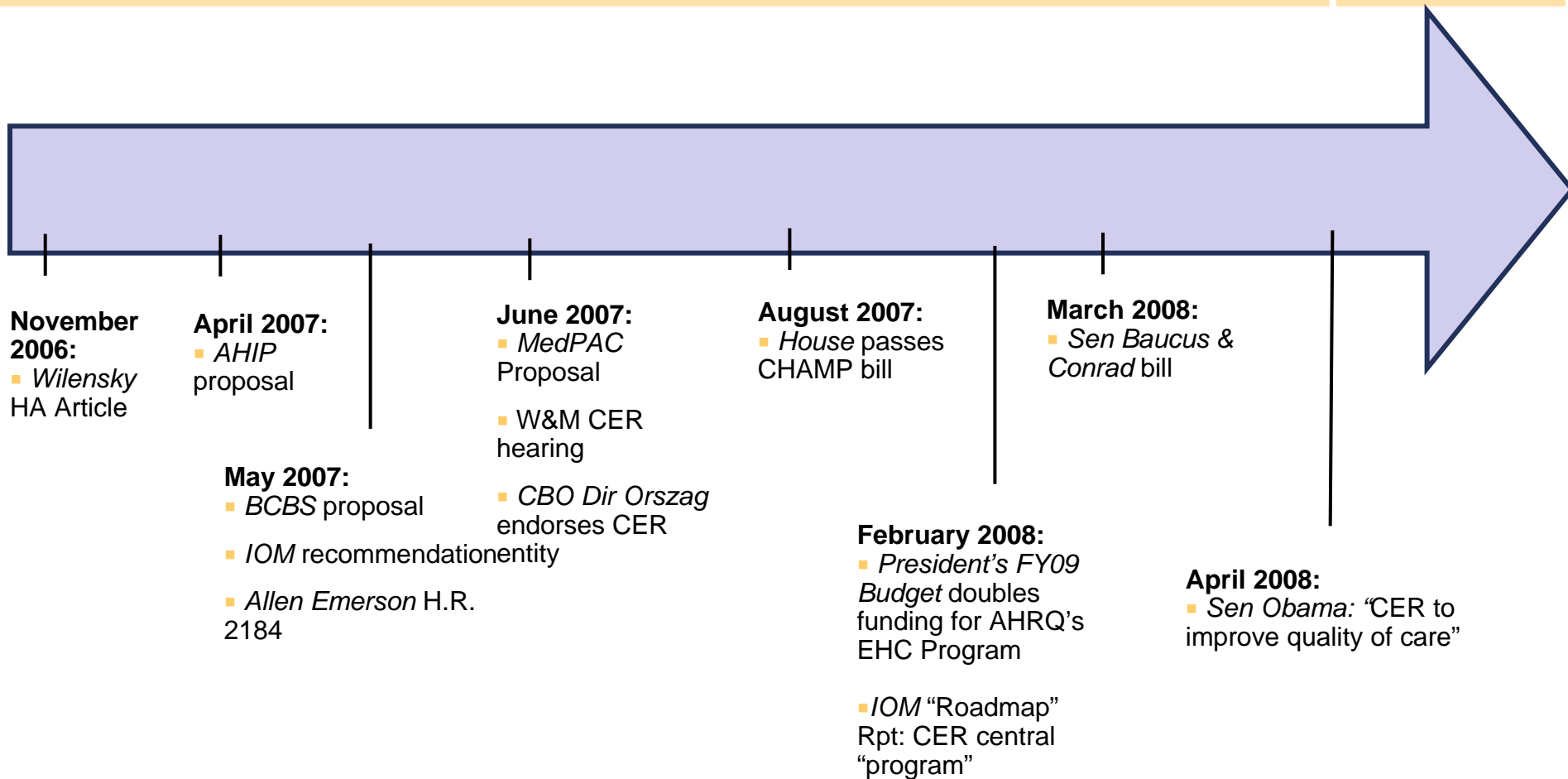


Proposed National Institute/ Center for CER

- Major new investment (i.e. \$100s of Millions!) in “comparative effectiveness research”*
- 3 Legislative Bills (2 House, 1 Senate)
- 4+ private sector proposals

* Now at jeopardy due to Wall Street Bailout?

Stakeholders, Especially Health Plans, Call for a Centralized CER Entity



3 Tracks for Improving Opportunity for Comparative Effectiveness Trials

- Collaborative stakeholder movement
 - Center for Medical Technology & Policy (CMTP)
- Streamlining operations & logistics & regulatory inefficiencies
 - Clinical Trial Transformation Initiative (CTTI)
- Streamlining analytical methods
 - Pragmatic Approaches to Comparative Effectiveness (PACE) Initiative

Theme 3:

Conditional Coverage & Paying for Outcomes (P40)



Conditional Coverage/(P4O)

Conditional
Reimbursement

Coverage linked to production of further evidence (e.g. CMS' "coverage with evidence development")

P4O

Coverage/price depending on patient outcomes (e.g., treatment response, treatment outcome)

Theme 4:

Renewed Interest in Enhancing Health Technology Assessment (HTA)



Renewed Interest in Enhancing Health Technology Assessment (HTA)

- Enhanced funding for assessments (e.g. MMA 2003)
- Enhanced methods development (e.g. systematic reviews)
- Enhanced data systems (e.g. data warehouses; EMR)
- Increased private sector stakeholder interest in HTA
- Proposed HTA principles

Key Principles for Improved Conduct of HTAs for Resource Allocation Decisions

The International Working Group for HTA Advancement*

- Michael Drummond, UK (co-chair)
- J. Sanford Schwartz, US (co-chair)
- Bengt Jonsson, Sweden
- Bryan Luce, US
- Peter Neumann, US
- Uwe Siebert, Austria
- Sean Sullivan, US

IJTAHC, 24:3 (2008)

*Established with seed money from Schering-Plough.

www.ihe.ca/ijtahc.html

HTA Working Group's Motivation



“To stimulate discussion of HTA program goals and procedures to enhance the rigor, validity and usefulness of HTA”

The Principles

1. The **goal and scope** of the HTA should be **explicit** and **relevant** to its use
2. HTA should be an **unbiased** and **transparent** exercise
3. HTA should include **all relevant technologies**
4. A clear **system for setting priorities** for HTA should exist
5. HTA should incorporate **appropriate methods** for assessing **costs and benefits**

The Principles (cont.)

6. HTAs should consider a **wide range of evidence** and **outcomes**
7. A full **societal perspective** should be considered when undertaking HTAs
8. HTAs should explicitly characterize **uncertainty** surrounding estimates
9. HTAs should consider and address issues of **generalizability** and transferability
10. Those conducting HTAs should actively engage **all key stakeholder** groups

The Principles (cont.)

11. Those undertaking HTAs should actively seek all available data
12. The implementation of HTA findings needs to be monitored
13. HTA should be **timely**
14. HTA findings need to be **communicated** appropriately to different **decision makers**
15. The link between HTA **findings** and **decision making processes** needs to be **transparent** and clearly defined

Why This Evidence Wave Now?

- Past initiatives viewed as useful, getting better, *not* sufficient
- In US, federal activity focused on improved evidence, *not* cost
- Increased realization: all stakeholders be included
- Realization: alternative is blunt cost control measures, thus...
- Much less political opposition

But mainly....

...it is the....

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- Public and policy realization that the evidence base for clinical and payer decision-making is inadequate

and....

- Concern about the enormous and unrelenting increase in cost of health care

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THANK YOU!