Improving Value Through Evidence Development

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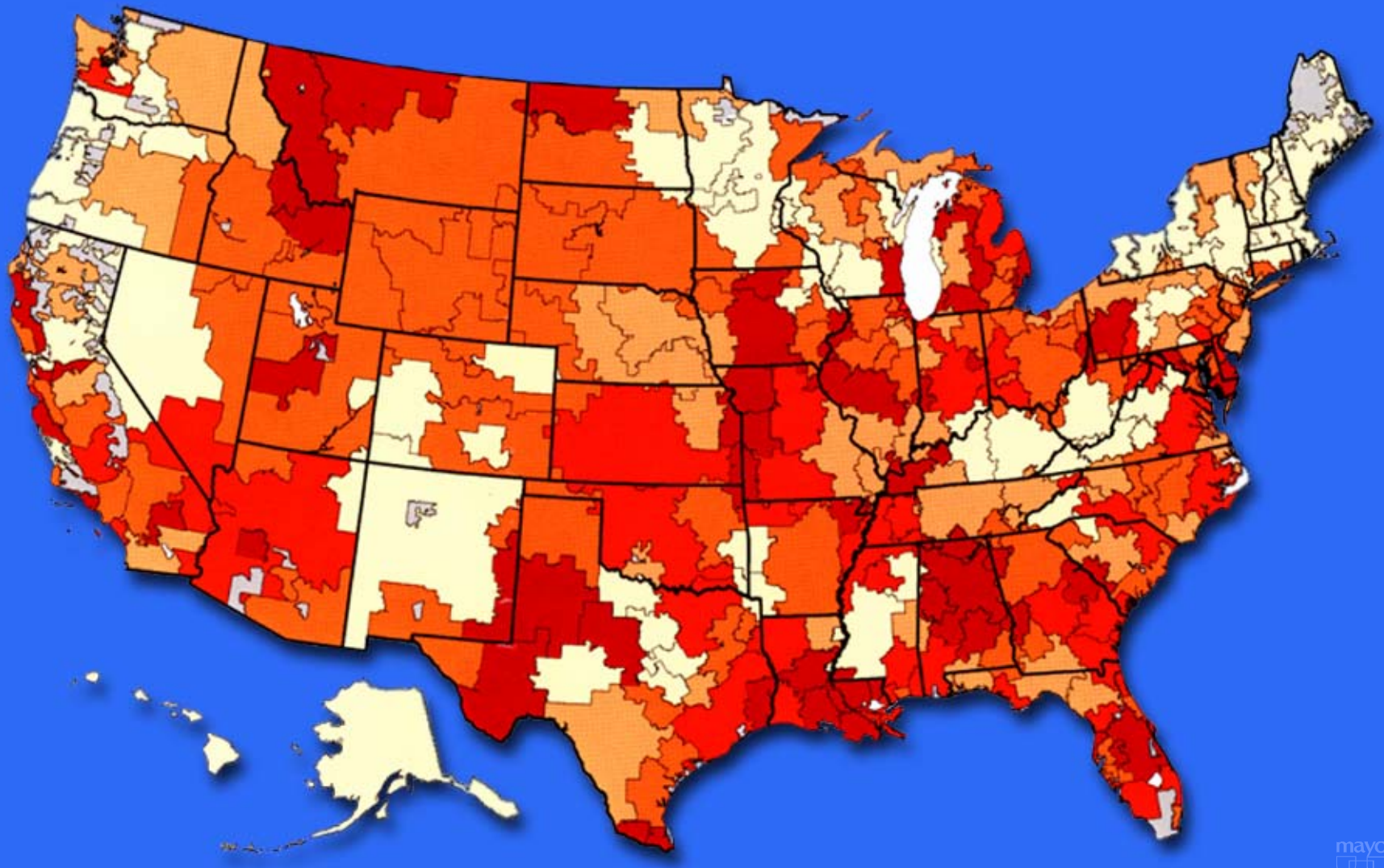
Percutaneous Coronary Interventions



Chronic Wound Therapy

- $20 billion spent in US on care of chronic wounds
- NPWT in top 20 list for DME spending
- Is it better than standard wound care?
- HTA excludes all observational studies
- 6 RCTs, all low quality, 5 with N<25
- Same situation with HBO, e-stim, etc.

Why we know so little…

- Evidence producers
  - NIH: discovery and proof of concept
  - Industry: FDA and market focus
  - AHRQ: modest budget, broad portfolio
  - DERP / /BCBSA / Cochrane: reviews
- Decision makers have no significant influence in what evidence is created

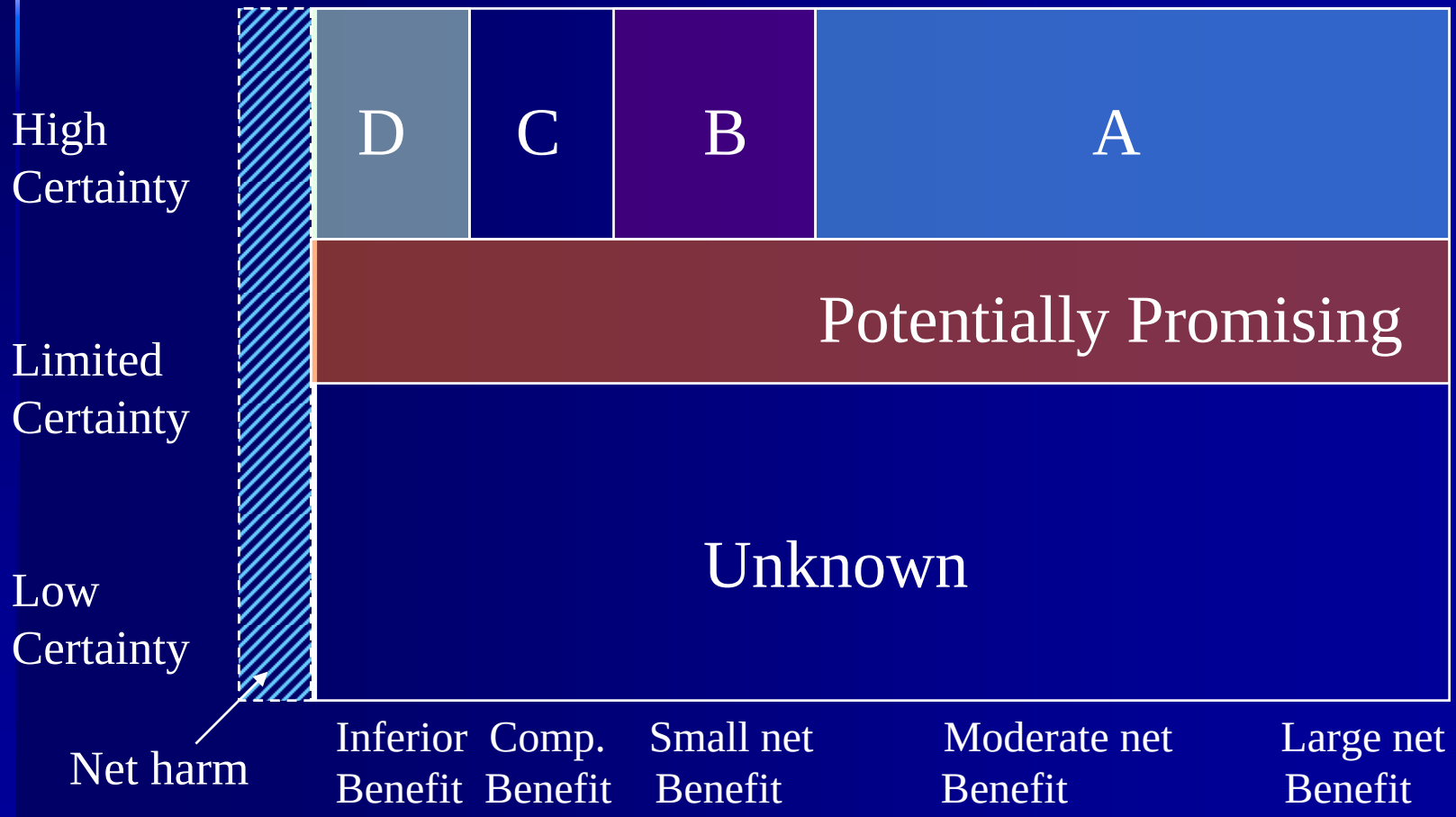
Policy Pearl

- In evidence-based decision making, whoever controls the evidence controls the decisions

Medical Necessity

- Adequate evidence to conclude that the item or service
  - improves net health outcomes
  - generalizable to the Medicare population
  - as good or better than current covered alternatives

Comparative Clinical Effectiveness



Use of “CED” by CMS

- National Emphysema Treatment Trial
- PET for suspected dementia pragmatic trial
- ICD registry
- National Oncologic PET registry

Center for Medical Technology Policy (CMTP)

- Non-profit funded by CHCF, BSCF
- Create better evidence for decisions
- Replicate CED with private payers
- Pilot projects
  - CT angiography for coronary disease
  - Radiation therapy for prostate cancer
  - Gene expression profiling for breast cancer

Medicare CCTA Coverage

- EPC report / MCAC mtg 3/2006
- No national coverage policy
- LCDs based on ACC appropriateness
  - CCTA can “reliably rule out CAD” in low/intermediate risk patients
  - CCTA can reliably replace angiography
  - Indications will be revised “as higher level evidence-based studies become available”
- No trials ongoing or planned for low/intermediate risk pts

CMTP CCTA pilot project

- Workgroup
  - GE, Phillips, Siemens, Toshiba
  - Aetna, Kaiser, United, (CMS)
  - ACC, ACR, AHA
  - FDA, AHRQ
- Draft protocol under development
  - low/intermediate risk pts
  - CCTA or usual care
  - Outcomes are utilization and MI / cardiac death
- Possible CED funding mechanism

Prospective studies: ROI

- NETT ($30M, 7 years)
- Swedish joint replacement registry
- CATIE ($42M, 6 years)
- Avastin – Lucentis NEI trial
- COURAGE ($33M, 8 years)
- CCTA pilot project

VBID Implications

- VBID depends on reliable evidence about comparative effectiveness
- Many innovative plan designs also depend on informed clinicians/patients
- Benefit design can be a potent lever in creating better evidence

More Information

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