Improving Evidence for Decisions

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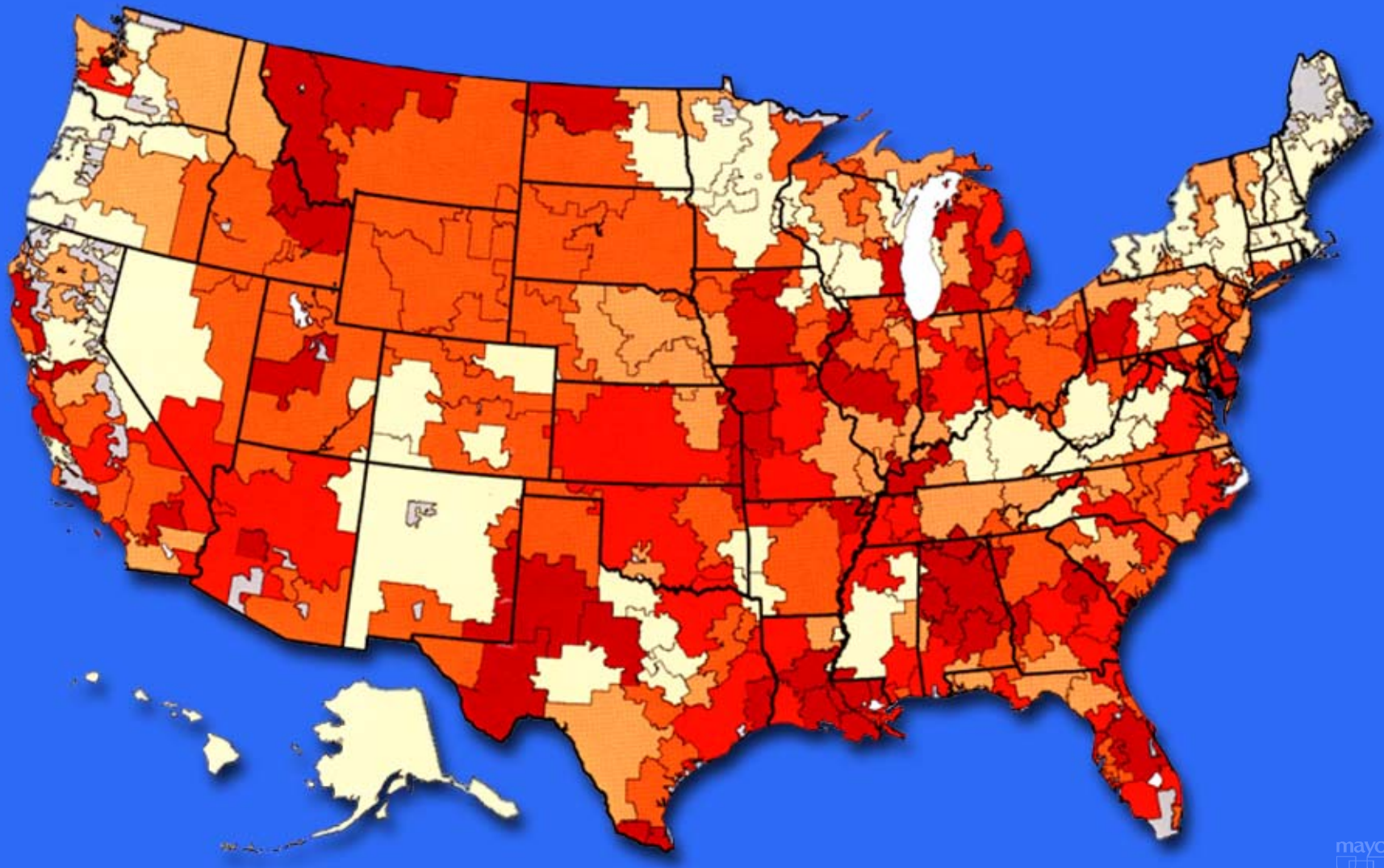
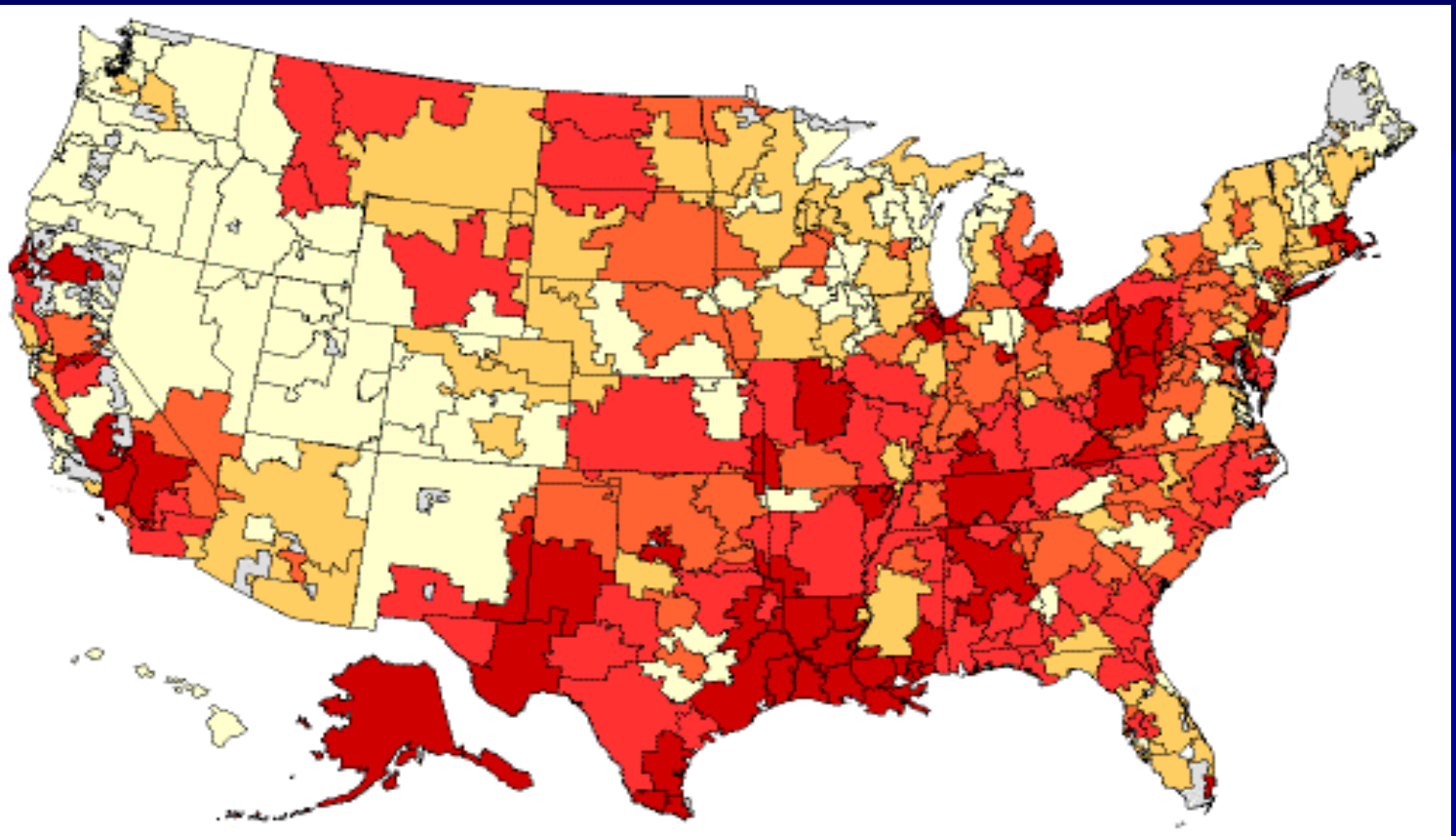
CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Percutaneous Coronary Interventions



Inpatient Spending



Map 2.5. Inpatient Hospital Services per Medicare Enrollee
by Hospital Referral Region (1995)

- $2516 to 3723 (61)
- 2321 to < 2516 (60)
- 2117 to < 2321 (61)
- 1893 to < 2117 (62)
- 1483 to < 1893 (62)
- Not Populated

Contributors to Variation

- Inconsistent use of good evidence
- Lack of high quality evidence from studies selected and designed to inform clinical decisions
  - Evidence gaps are systematic and widespread
  - Existing clinical research enterprise will not correct the problem

CMS Evidence Objectives

- Provide more and better information for health care decision makers
  - In context of where patients and physicians have stronger incentives for better decisions
- Support innovation while ensuring systematic learning about optimal use
- Expand capacity of clinical research enterprise to produce information oriented to decision makers
  - pts, clinicians, payers, policymakers
- Move toward system in which care delivery and evaluation become a single process
  - Move from LP to MP3 technology

Coverage with Evidence Development

- Links coverage with prospective data collection
- Based on reasonable and necessary
  - Adequate evidence of benefit
  - Adequate evidence of potential value and provided in appropriately designed study
- i.e. “promising, important, potentially high value, and under careful investigation”
- Retains EBM as conceptual framework for coverage and payment

Categories of questions

- Safety concerns, side effects
- Off-label uses or new combinations of approved uses
- Risks and benefits in subgroups
- Generalizability - patient and provider types excluded from trials
- Comparative effectiveness
- Outcomes not measured in trials
- Surgery, non-regulated or limited regulatory review technologies

LVRS – NETT trial

- Procedure billed as “bullectomy” with rapid increase in 1995
- AHRQ TA showed high mortality and no comparative trials
- NHLBI funded NETT trial in 1996
- CMS covered pts at centers following the trial protocol
  - Similar legal basis to coverage of transplants
- High mortality subgroup found in 2000
- Final results in 2003

PET for suspected AD

- Evidence supports clinical utility in limited context, but not broadly
- Non-coverage difficult to sustain
- covers for sx progressive for 6 months; diagnostic uncertainty (AD vs FTD)
- Broader coverage for use in a large, community-based, practical clinical trial
  - established precedent for R&N in trials
- CMS, AHRQ, Alz Ass, industry, academics have developed protocols

Prophylactic ICD policy

- Medicare expanded ICD coverage to most pts with EF<35%
- Linked to submission of data to national ICD “starter” registry though QNet
- Range of questions may be addressed, though data is observational
- Robust registry will have follow up data on clinical outcomes, device firing
- ICD registry workgroup expanded

Off-label use of cancer drugs

- Medicare law requires on label+compendia
- CMS reviewed Camptosar, Eloxatin, Avastin and Erbitux
- Mandatory coverage of off-label use in NCI-sponsored clinical trials
- Other off-label use remains at discretion of contractors
- Intent is to move toward coverage of trials identified by patients and clinical oncologist

Key conceptual issues

- How to evolve from ad hoc to systematic policy approach
- Priority setting: criteria, participants, process
- Roles and governance: what organizations oversee and implement various functions of the initiative
- Funding
  - How much can be accomplished by PCE
  - What are other sustainable sources and mechanisms of funding
  - What is the business case for each potential funder?

Implementation Issues

- Methods: When to use registries, practical trials, registries, outcomes studies, etc
- Infrastructure: what exists, what needs to be created, how can this be done most efficiently
- Legal and ethical: private payer contractual issues, HIPAA, human subjects, conflicts of interest

Next Steps

- Guidance on coverage with evidence development
  - Open door forum 2/14
  - Comments received 3/15
  - Initial draft nearing completion
- ICD registry workgroup and CMS-NCI collaboration moving forward
- IOM/AHRQ/CMS discussions
  - Larger stakeholder mtg 3/1
  - Initial focus on registries to “break trail”
  - Focus of effort to broaden dialog and develop additional pilot evaluations