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## A PBRN Case Example:

# NIMH Mental Health Research Network

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Group Health Cooperative Behavioral Health Service  
NIMH Mental Health Research Network

## Outline

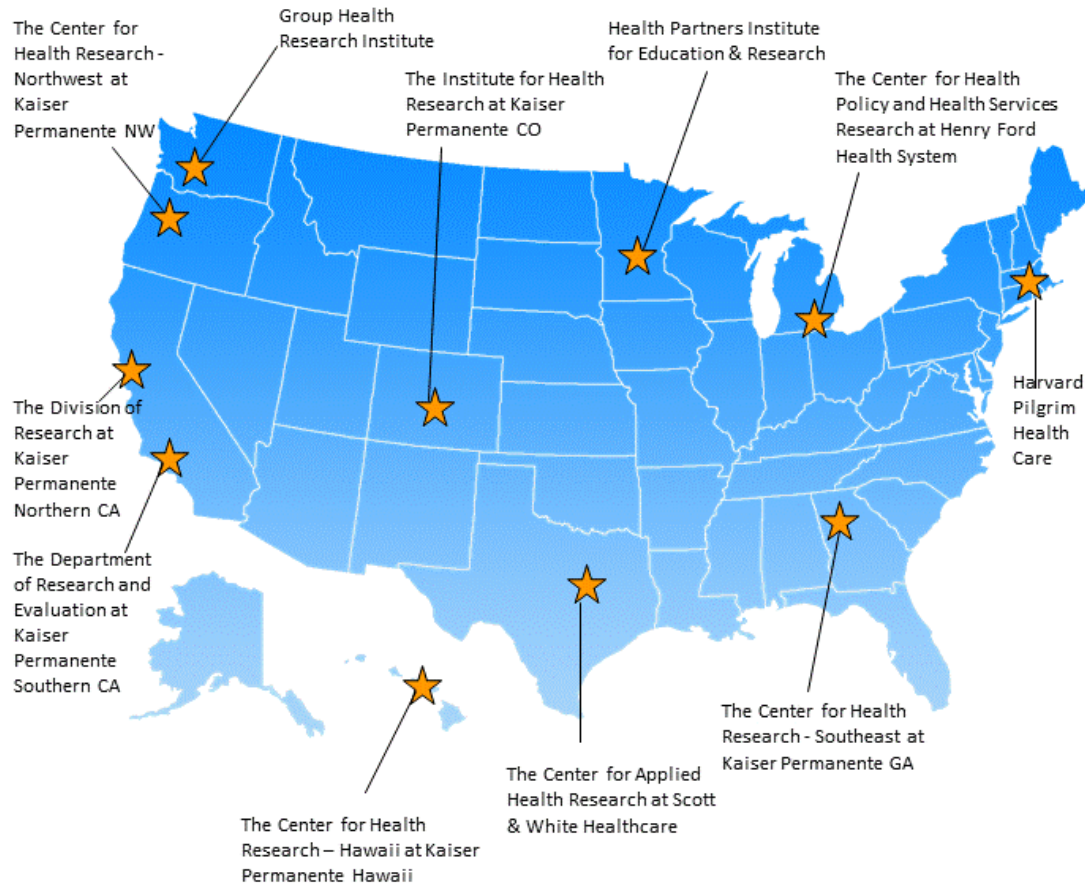
- Description of Mental Health Research Network
  - MHRN Data regarding antidepressant treatment
  - MHRN clinical trials experience
  - Pharmacotherapy trials in real-world practice:
    - What's easy
    - What's hard
    - Where might we need to compromise
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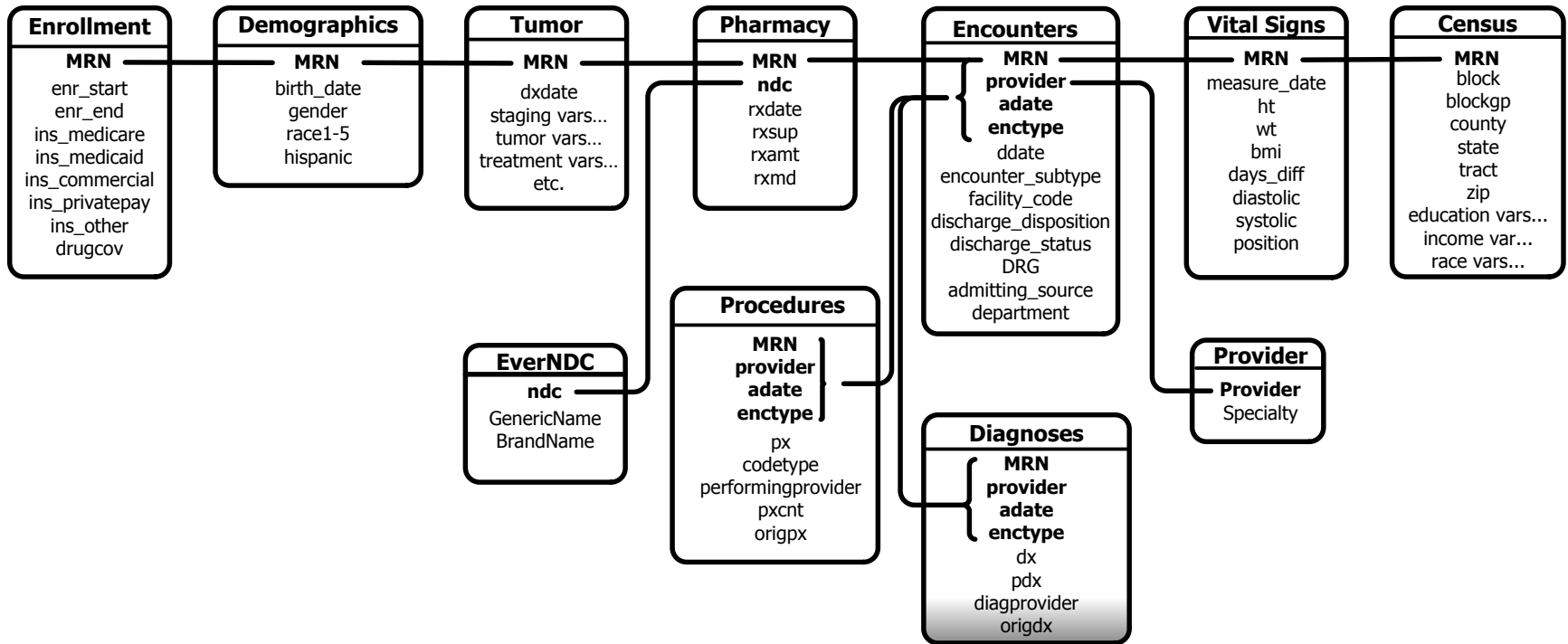
## Mental Health Research Network

- 11 research centers affiliated with large health systems
  - Combined population of 12 million in 13 states
  - Longitudinal data from electronic medical records and insurance claims
  - Harmonized procedures for data extraction & processing, IRB review, data sharing, outcome assessment
  - Supported by NIMH cooperative agreement (i.e. intended to be a public resource)
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# Mental Health Research Network



# Virtual Data Warehouse structure

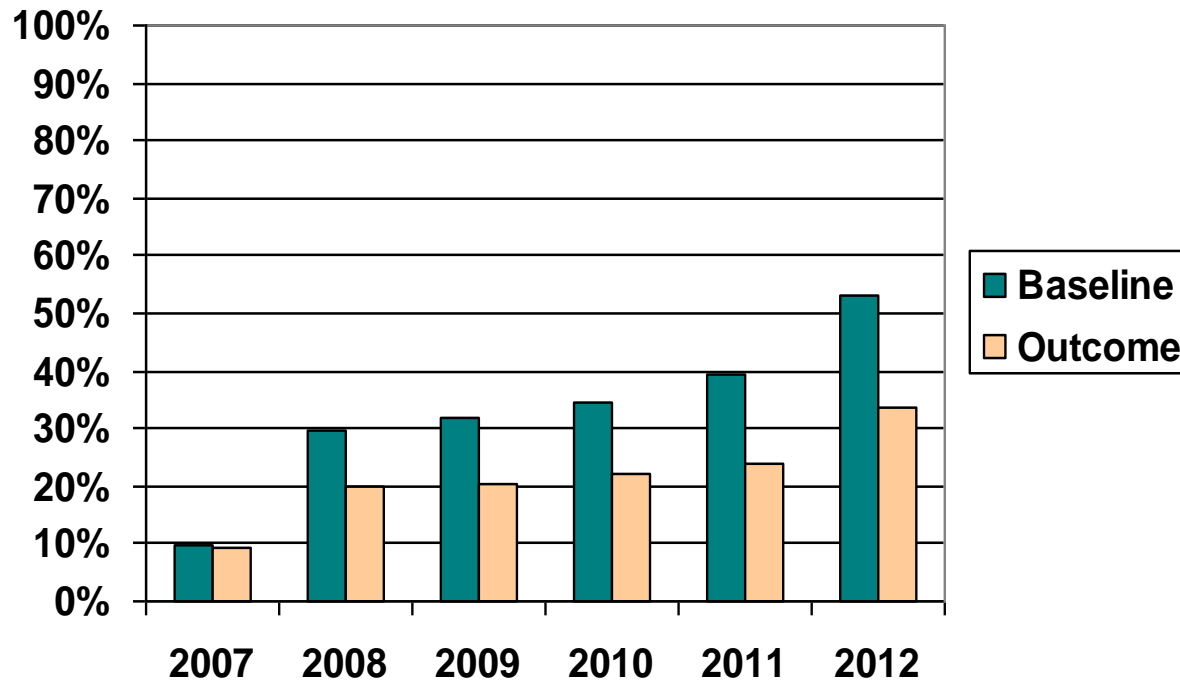


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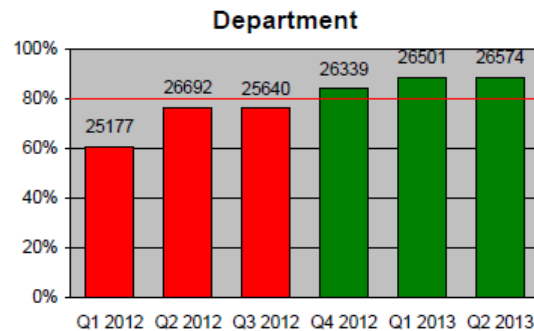
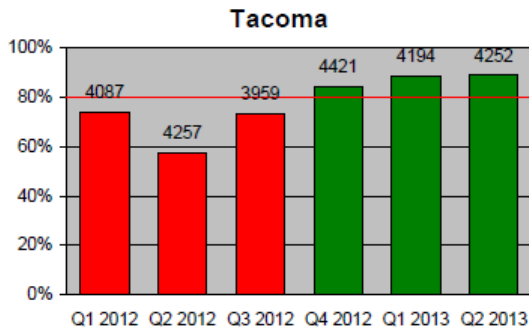
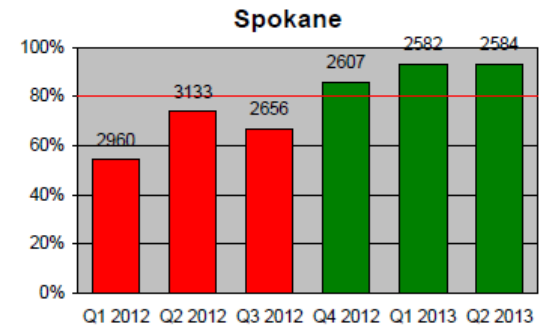
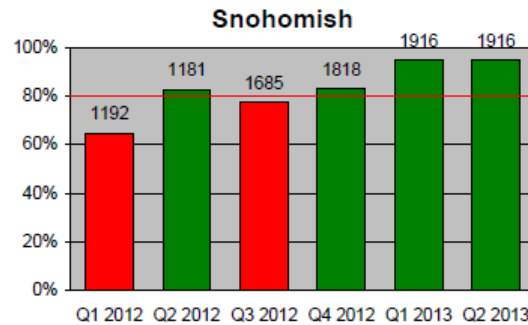
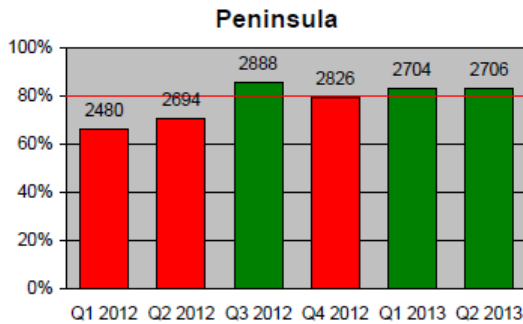
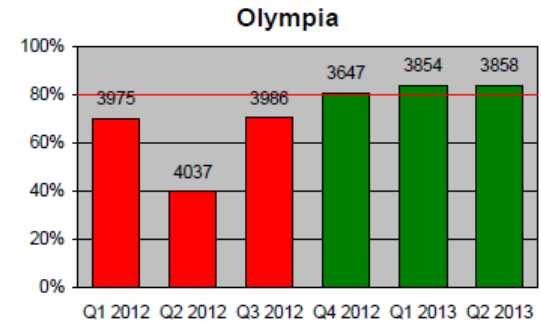
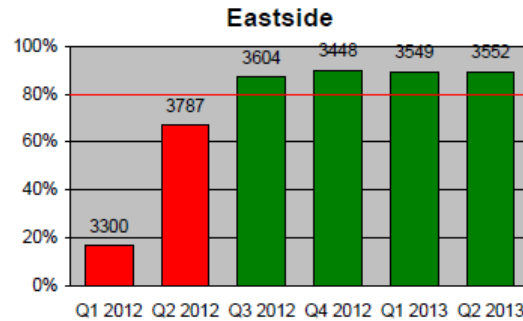
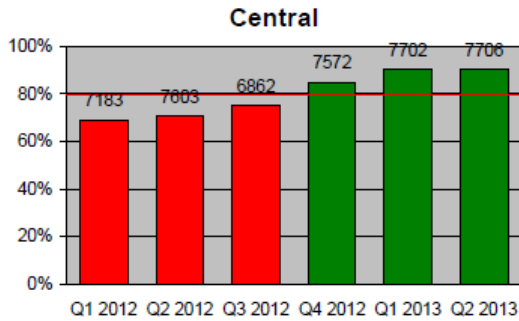
## Antidepressant initiation cohort (2007-2011):

- 327,000 antidepressant treatment episodes
  - Longitudinal data on
    - Treatment(s) received (including switch/augmentation)
    - Adherence
    - Concomitant psychotherapy
    - Co-occurring conditions
    - Prior mental health treatments
  - AND - standard assessments of baseline severity and outcome
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## Proportion of primary care antidepressant treatment episodes with PHQ9 recorded in EMR



## Compliance Rate of PHQ9 Documentation by Quarter

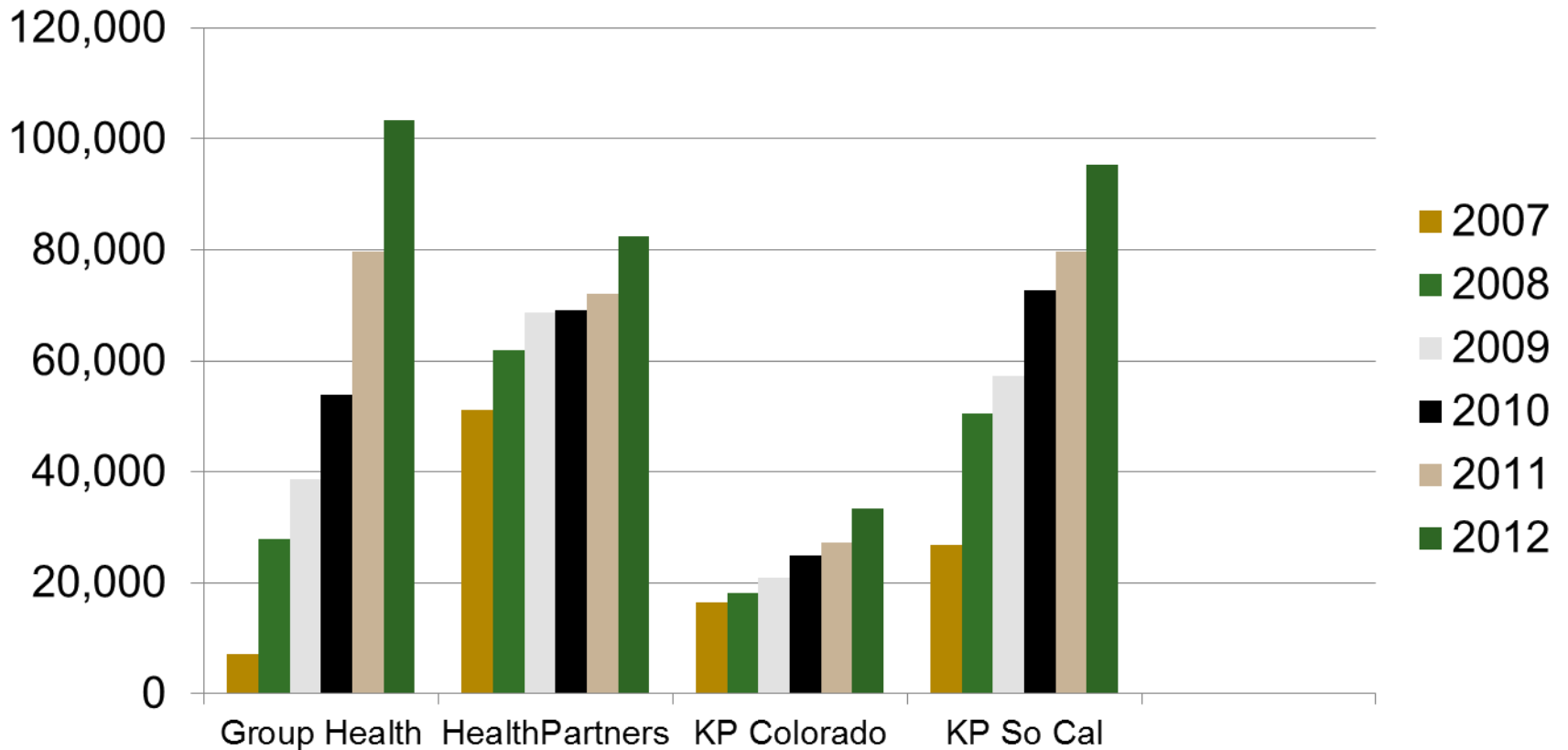


**Target = 80%**

- All visits, including group, count toward this measure.
- Patients >= 12 years old.



## Use of PHQ9 across four health systems



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## Example: Replicating STAR\*D sample:

At five of the 11 MHRN sites over one year:

- 75,000 new episodes of antidepressant treatment
- 27,000 with Citalopram

Compared to 2800 enrolled in STAR\*D phase one.

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## MHRN Multi-site clinical trials:

- Behavioral activation psychotherapy vs. usual care for depression in pregnancy (completed)
- Low-intensity outreach interventions to prevent suicide attempt (in progress)
- Decision support and nurse care management to reduce CV risk in people with SMI (proposed)

Q: What do these trials have in common?

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Q: What do these trials have in common?

A: All are psychosocial / organizational interventions

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## Steps in treatment development / evaluation:

- Phase 2
  - Phase 3 (placebo control)
  - Phase 3 (active control)
  - Phase 4 / Comparative effectiveness
  - New use or “re-purposing”
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## Components of clinical trials

- Sampling / Screening
  - Baseline assessment
  - Treatment assignment
  - Treatment delivery
  - Outcome assessment
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## Stages of efficacy / effectiveness research

	Phase 2	Phase 3 (Placebo)	Phase 3 (Active)	Phase 4 (CER)	New Use
Sampling / Screening	Easy	Easy	Easy	Done	Easy
Baseline Assessment	Easy	Easy	Easy	Done	Easy
Treatment Assignment	Hard	Hard	Easy	Done	Easy
Treatment Delivery	Hard	Hard	Needs Work	Done	Needs Work
Outcome Assessment	Hard	Needs Work	Needs Work	Done	Needs Work

## Need to compromise a bit:

- Outcome assessment:
    - Telehealth (or fully automated) assessments
    - Distinguishing tolerability and safety
  - Treatment delivery:
    - Fully operationalized treatment protocols
    - Separation of assessment and treatment functions
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## The hard things:

- Assessments done solely for research
- Placebo in the face of an effective alternative
- Blinding in real-world practice
- Distinct clinical and research records

All are customary, but are they always necessary?

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## How will RDoC and Experimental Medicine change all of this?

- More portable assessments
  - Blinding may be less important
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## Is blinding essential?

- Assessors: Absolutely – no change there.
  - Clinicians: Maybe – but there are pros and cons
  - Patients: Probably - but does introduce distortion
  - Analysts: Probably – but we don't usually
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## The goal: a real learning healthcare system:

“Each patient care experience naturally reflects the best available evidence, and, in turn, adds seamlessly to learning what works best in different circumstances.”

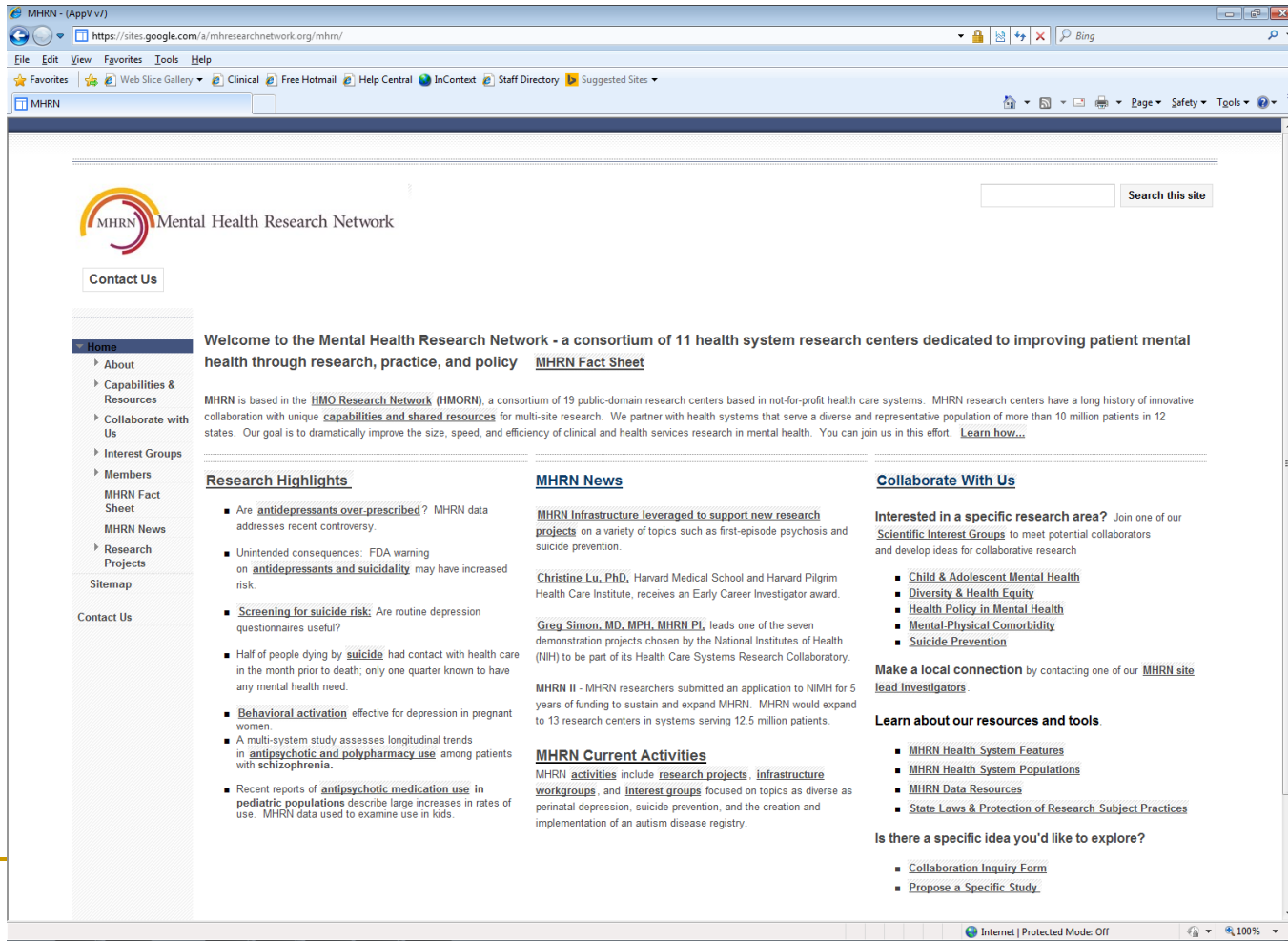
IOM Roundtable on Evidence-Based Medicine, 2008

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## A learning healthcare system means:

- All experience contributes to evidence
  - Evidence is truly based in experience
  - It all happens continuously, in real time
  - Clinical data = research data
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Visit us at: [mhresearchnetwork.org](https://mhresearchnetwork.org)



The screenshot shows the MHRN website homepage in a browser window. The page features a navigation menu on the left, a search bar at the top right, and several main content sections. The main heading reads: "Welcome to the Mental Health Research Network - a consortium of 11 health system research centers dedicated to improving patient mental health through research, practice, and policy". Below this, there is a "Research Highlights" section with several bullet points, a "MHRN News" section with two news items, and a "Collaborate With Us" section with a list of research areas and a call to action to contact lead investigators. The footer of the page includes a link to "Learn about our resources and tools" and a section for "Is there a specific idea you'd like to explore?" with links to a collaboration inquiry form and a proposal for a specific study.

**MHRN - (AppV v7)**  
<https://sites.google.com/a/mhresearchnetwork.org/mhnr/>  
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 MHRN

**MHRN Mental Health Research Network**  
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 Capabilities & Resources  
 Collaborate with Us  
 Interest Groups  
 Members  
 MHRN Fact Sheet  
 MHRN News  
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 Contact Us

**Welcome to the Mental Health Research Network - a consortium of 11 health system research centers dedicated to improving patient mental health through research, practice, and policy** [MHRN Fact Sheet](#)

MHRN is based in the **HMO Research Network (HMORN)**, a consortium of 19 public-domain research centers based in not-for-profit health care systems. MHRN research centers have a long history of innovative collaboration with unique **capabilities and shared resources** for multi-site research. We partner with health systems that serve a diverse and representative population of more than 10 million patients in 12 states. Our goal is to dramatically improve the size, speed, and efficiency of clinical and health services research in mental health. You can join us in this effort. [Learn how...](#)

**Research Highlights**

- Are **antidepressants over-prescribed**? MHRN data addresses recent controversy.
- Unintended consequences: FDA warning on **antidepressants and suicidality** may have increased risk.
- Screening for suicide risk**: Are routine depression questionnaires useful?
- Half of people dying by **suicide** had contact with health care in the month prior to death; only one quarter known to have any mental health need.
- Behavioral activation** effective for depression in pregnant women.
- A multi-system study assesses longitudinal trends in **antipsychotic and polypharmacy use** among patients with schizophrenia.
- Recent reports of **antipsychotic medication use** in pediatric populations describe large increases in rates of use. MHRN data used to examine use in kids.

**MHRN News**

**MHRN Infrastructure leveraged to support new research projects** on a variety of topics such as first-episode psychosis and suicide prevention.

**Christine Lu, PhD**, Harvard Medical School and Harvard Pilgrim Health Care Institute, receives an Early Career Investigator award.

**Greg Simon, MD, MPH, MHRN PI**, leads one of the seven demonstration projects chosen by the National Institutes of Health (NIH) to be part of its Health Care Systems Research Collaboratory.

MHRN II - MHRN researchers submitted an application to NIMH for 5 years of funding to sustain and expand MHRN. MHRN would expand to 13 research centers in systems serving 12.5 million patients.

**MHRN Current Activities**  
 MHRN activities include **research projects**, **infrastructure workgroups**, and **interest groups** focused on topics as diverse as perinatal depression, suicide prevention, and the creation and implementation of an autism disease registry.

**Collaborate With Us**

**Interested in a specific research area?** Join one of our **Scientific Interest Groups** to meet potential collaborators and develop ideas for collaborative research

- Child & Adolescent Mental Health**
- Diversity & Health Equity**
- Health Policy in Mental Health**
- Mental-Physical Comorbidity**
- Suicide Prevention**

**Make a local connection** by contacting one of our **MHRN site lead investigators**.

**Learn about our resources and tools**

- MHRN Health System Features**
- MHRN Health System Populations**
- MHRN Data Resources**
- State Laws & Protection of Research Subject Practices**

**Is there a specific idea you'd like to explore?**

- Collaboration Inquiry Form**
- Propose a Specific Study**

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