The Current Comparative Effectiveness Landscape: NIH Activities

Michael S Lauer, MD, FACC, FAHA
Director, Division of Cardiovascular Sciences
National Heart, Lung, and Blood Institute

Comparative Effectiveness Summit
Grand Hyatt, Washington DC

Disclosures: None

November 5, 2012
An NIH Success Story

Thanks to Gary Gibbons
“Yeah, But …?”

“I recalled how I had helped get an access road built to his farm, how I had visited him in a military hospital, how I had…, how I had…”

Matthews C. Hardball. 1988
Telling a Landscape Story
A “Credible” Science Landscape Story

The Ecology of Biomedical Research

Growth from 1994 to 2003: 7.8%
Growth from 2003 to 2008: 3.4%

Percent of total health costs: 4.5%
Percent on health services research: 0.1%

Major sources:

Industry: 58%
Federal: 33%

Dorsey ER et al. JAMA 2010;303:137-43
Research Project Grants Applications, Awards, and Success Rates

![Graph showing research project grants applications, awards, and success rates from 1995 to 2010. The graph indicates an increase in applications and awards from 1995 to 2010, with a corresponding decrease in success rate.](image-url)
The NIH Landscape (Map)

https://nihmaps.ninds.nih.gov/ninds
The NIH Landscape (Map)

[Image: NIH Landscape Map]

https://nihmaps.ninds.nih.gov/ninds
NIH CER in 2012 ($490 Million, 592 Projects)

https://nihmaps.ninds.nih.gov/ninds
Zoom in for a Closer Look

https://nihmaps.ninds.nih.gov/ninds
https://nihmaps.ninds.nih.gov/ninds
3U10HD055944-03S1 (Supplement, 2009)
PI: CASSON, PETER R
Metformin Use During in Vitro Fertilization in Polycystic Ovary Syndrome

Abstract:
established, continued metformin use will reduce the rate of embryonic loss, as well as adverse obstetric outcomes later in gestation. To address this issue, this application proposes a 500 subject multicenter, three arm, and randomized, blinded clinical trial, giving metformin both for 3 months prior and during the IVF cycle, and assessing oocyte and embryo quality. Further, the proposal continues the metformin or placebo through the first 12 weeks of gestation to assess the potential beneficial effect reducing embryonic loss. If this hypothesis is proven true, metformin administration at IVF would represent a novel and promising strategy for improving IVF outcomes.

Topics:
- embryos, oocyte, oocytes, egg, embryo, sperm, maturation, fertilization, mo
- network, recruitment, consortium, center, clinical, research, multicenter, cEN
- design, optimal, re, limitations, overcome, optimization, optimize, optimize

https://nihmaps.ninds.nih.gov/ninds
Output So Far

http://projectreporter.nih.gov/reporter.cfm
A “Credible” Science Landscape Story

Cycle of Credibility

Data

Use of Diagnostic Imaging Studies and Associated Radiation Exposure for Patients Enrolled in Large Integrated Health Care Systems, 1996-2010

Rebecca Smith-Bindman, MD
Diana L. Miglioretti, PhD
Eric Johnson, MS

Context: Use of diagnostic imaging has increased significantly within fee-for-service models of care. Little is known about patterns of imaging among fee-for-service models of care among patients enrolled in integrated health care systems.

Carboplatin and Paclitaxel With vs Without Bevacizumab in Older Patients With Advanced Non–Small Cell Lung Cancer

Junya Zhu, MS, MA
Dhruv B. Sharma, PhD
Stacy W. Gray, MD, AM
Aileen B. Chen, MD, MPP

Context: A previous randomized trial demonstrated that adding bevacizumab to carboplatin and paclitaxel improved survival in advanced non–small cell lung cancer (NSCLC). However, longer survival was not observed in the subgroup of patients aged 65 years or older.

Objective: To evaluate the relationship between bevacizumab use and survival in patients aged 65 years or older.
Data on Diagnostics (HMO RN)

Smith-Bindman R et al. JAMA 2012;307:2400-2409
Data on Therapeutics (SEER-CMS)

Zhu J et al. JAMA 2012;307:1593-1601
A “Credible” Science Landscape Story

Control of Urinary Incontinence

Anticholinergic Therapy vs. OnabotulinumtoxinA for Urgency Urinary Incontinence

Funding:
NICHD
NIH-ORWH

Revascularization (NCDR, STS, CMS)

Funding: NHLBI ARRA-CER

Strategies for Multivessel Revascularization in Patients with Diabetes

Funding:
NHLBI
Cordis
J and J
Boston Scientific
Eli Lilly
Sanofi-Aventis
BMS

Weight-Loss In Primary Care

Funding: NHLBI

Treatment of Localized Prostate Cancer

Funding:
VA
NCI
AHRQ

Effects of Clopidogrel Added to Aspirin in Patients with Recent Lacunar Stroke

Funding: NINDS, Sanofi-Aventis, Bristol-Meyers Squibb
A “Credible” Science Landscape Story

New Investigator-Initiated CER Applications

Number of Projects by FY

- **Awarded**
- **Unawarded**

<table>
<thead>
<tr>
<th>Year</th>
<th>Awarded</th>
<th>Unawarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>100</td>
<td>150</td>
</tr>
<tr>
<td>2008</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>2009</td>
<td>1000</td>
<td>1500</td>
</tr>
<tr>
<td>2010</td>
<td>200</td>
<td>300</td>
</tr>
<tr>
<td>2011</td>
<td>150</td>
<td>200</td>
</tr>
</tbody>
</table>
Newly announced awards

Coordinating (Duke with others)
Health-care associated infections
Colon cancer screening
Suicide prevention
Lumbar imaging
Night-time antihypertensives
Chronic pain
Maintenance hemodialysis
Final Thoughts

- NIH CER activity “all over the map”
- Big data sources yield fruit
  - HMORN, CTSAs, SEER, CMS, registries
- Productivity: “Done a lot lately”
- Direction:
  - Digital data, integrated systems
  - Links (AHRQ, VA, CMS, FDA, PCORI, industry)
  - Practical trials, much lower costs
“If all the seas were black ink, and the marshes were quills, and the heavens were parchments, and all the people were scribes…

…They would not suffice to record the depth of the government…”

-- Babylonian Talmud
(~1500 years ago)
Question Assumptions, Disrupt, Innovate