Industry Insights - Growing Opportunities for Physicians and Researchers in Health Systems Research

John Hornberger, MD, MS

Cedar Associates LLC
Menlo Park, CA
President and CEO
Where am I going? Where should I go?
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Finding: Marked improvement in life expectancies
- Were far apart in ’55-’60
- All increased
- Less variance in ’05-’10
- No indication that trend is leveling off

Question: What are ‘determinants’ of these increases?
- Less poverty, more education, less pollution, better nutrition, more effective health care, societal shocks (e.g., war), ????

Source: Data.UN.org; published in Science, 2010
Meaningful and interesting issues

Questions for health systems researchers

- Finding: Marked reductions in age-adjusted mortality rates for stroke (also ischemic heart disease), but similar effects not seen for cancers

- Questions:
  - What are the ‘determinants’ of the decline for mortality in cardiovascular disease but not cancer?
  - Are the findings here related to those shown in the prior slide? Is cardiovascular mortality declining across all countries and populations?
  - How might a government-funded health insurance fund apply these findings in organizing its system?


What is health systems research?

• Scientific and multidisciplinary
  – Physicians/nurses/pharmacists, decision analyses, economics, statistics, epidemiology, anthropology, psychology, business/finance, sociology

• Studies effect of
  – Social factors, financing systems, organizational structures and processes, health technologies, personal behaviors on
  – Outcomes (life expectancy, mortality, quality of life) and the quality/cost of health care

• Scope includes individuals, families, organizations, communities, governments, populations

Lohr K, Steinwachs D, 2002
Where do we work?

- Research and teaching organizations
  - Academic universities (e.g., Stanford)
  - Non-academic profit and not-for-profit (e.g., Cedar)
- Government agencies – (e.g., Medicare, AHRQ, FDA)
- Health insurance companies (Aetna, Cigna, United Health)
- Non-profit foundations (Rockefeller, Packard Foundation)
- Non-government organizations (AIDS relief organizations)
- Provider organizations (e.g., Kaiser, Sutter, Express Scripts)
- Innovation companies (pharmaceuticals, devices, diagnostics)
My own journey

Source: *Eyewitness: Anish Kapoor at Kensington Gardens*  
Photographs from the Guardian Eyewitness series
The past

- Residency training at Stanford (Internal Medicine)
- Post-doc fellowship(s)
  - General Internal Medicine, Nephrology, Health Services Research (incl. Master Degree)
  - Funded by Agency for Health Care Policy and Research – now AHRQ
  - Research mentor(s) – Alan Garber, Bill Brown, Victor Fuchs, Tom MaCurdy, Mark Hlatky, Philip Lavori, co-fellows (Doug Owens, Mark Helfand, Bradford Middleton)
  - Focused on health technology assessment of dialysis interventions
- Incredible pace of learning and exploration
  - Limitless possibilities (“solve the healthcare mess”)

Career Center
The past

• First ‘real’ job - Assistant Professor of Health Services Research (courtesy in Dept of Medicine)

• Even more learning - Unparalleled access to the best and the brightest
The past

• First ‘real’ job - Assistant Professor of Health Services Research (courtesy in Dept of Medicine)
• Even more learning - Unparalleled access to the best and the brightest
• Difficult funding environment
  – NIH funding at historic lows
  – Concerns raised about opportunities for MD investigators

"If we didn’t do so well in the easy box, they wouldn’t have given us this complicated box."
The past

- Working on really cool stuff!
  - Language and cultural barriers in health care delivery
  - Renal services: What works, what doesn’t, is it worth it?
  - Bayesian analysis and design of research studies
- Personal questions arose about “fit” with academics (“focus, focus, focus”)
- No Career Center at that time, but ...
- Met talented, likeable people who attended department research seminars but worked in other settings. Asked me to collaborate with them – first as consultant, then job offers.
The past

• Hired by Roche (Director of Health Economics)
  – Management realized there was something going on in this area, but not sure what
  – Hired a group of inquisitive, hard-working people to figure it out

• Even more learning
  – The R&D process – being there at the inception
  – The commercialization process – the good, the bad, and the ugly
  – Genomics! Joined as the Human Genome Project was winding down; because of Roche’s investment in this field, was way ahead of where I would have been if remained at Stanford

• Continued as part of the Stanford community
  – Adjunct Professor of Medicine
  – Co-founded two community based clinics (Willow and Ravenswood) – still attend at Willow supervising Stanford residents

• More explorations about my personal fit with ‘corporate’ culture
The past

• Set out on “my own” – sort of
  – Senior Partner of what was then a small research firm (Acumen, LLC – now one of FDA and Medicare’s main research firms; e.g., published recent paper in JAMA on comparative effectiveness of Rosiglitazone versus pioglitazone)
  – More cool projects
    • New product development and technology assessments
    • Study outreach programs for immigrants with HIV – how to overcome stigma and get access to regular source of care
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• Time to set up new shop – Cedar Associates is “planted“(2006)
The present – Cedar Associates

• Specialize in providing scientifically reliable and credible evidence on clinical outcomes and economics of services and technologies (www.cedarecon.com)
  – Research implementation
    • Technology assessment - Cost-effectiveness research/Budget impact model
    • Comparative effectiveness (registries, clinical utility studies, surveys)
    • Econometric and statistical analysis
  – Research planning and strategy

• Funding
  – Industry (pharmaceutical, devices, diagnostics)
  – Non-profit foundations (Rockefeller) - assessing how coverage decisions are being made by government programs in low-income countries (e.g., Rwanda, Indian states, Thailand)

• 12 full-time employees – virtual partners in academia and other research firms
Projects we have worked on

A sample

• Health technology assessment
  – Personalized medicine and genomics - Predict response to chemotherapy, diagnose ovarian cancer, determine the cause of cancer if diagnosis remains uncertain, predict response to psychiatric drugs, prenatal aneuploidy testing, preventing ICU-related pneumonias
  – Biotech drugs - involved in most of newest and most influential products, e.g., Herceptin, Rituxan, Velcade, Febuxostat, Victoza

• International projects
  – How to allocate resources to increase access to anti-retroviral drugs for HIV in low-income countries?
  – How agencies in low-income countries decide on what conditions and treatments should be covered in their health insurance plans?
What is in an HTA?

- What is the **disease**?
  - Who is affected and how many people?
  - What is the burden to them? (Clinical, quality of life, and economic)

- How is it **currently managed**?
  - What are the limitation(s) of current management?

- What’s **new**?
  - How does it work? (mechanism of action, biological processes)
  - What’s its validation? (clinical trials or related)
  - How should it be used? (place in therapy)

- What **difference** does it make?
  - Clinical and economically (value proposition)

- **Is it worth it?** (cost-effective, budget models)
HTA
Readiness for a new technology

- What is the **unmet medical need**?
- What factors affect **adoption** of the new technologies?
  - Cognitive
  - Cultural
  - Political
  - Legal
  - Financial / economic
• **Magnitude** of effect relative to existing approaches?
• **Generalizability** to real world practice?
• **How much** more will it cost patients, clinicians, hospitals, third-party payers?
• Is the product a **cost-effective use of resources**?

*Specifics vary for drugs, devices, and diagnostics*
What are the channels for market access?
  • KOLs that influence clinical guidelines
  • Strategic use of comparative effectiveness

How is a fair market value determined for a product?

Who decides? What is the payment stream? Who pays? To whom? Effect of price?

What techniques are used to negotiate value?

Which stakeholders have the most influence in these negotiations?

What are other non-financial incentives – i.e., cognitive, cultural, ethical, legal, political – to adopting new technology?
THE HTA ARSENAL

- **Mock Health Technology Assessment (HTA)**
  - How might professional societies review the technology?

- **Provider financial analyses**
  - How do physician practice payment incentives influence the potential to adopt a new technology? (also hospitals)

- **Economic analyses**
  - What is the cost-effectiveness and budget impact to payers of a new technology? (for dossiers in many countries, incl. USA)

- **Pricing analyses**
  - What is the best analytical approach to determine and defend a ‘value-based price’

- **Communications**
  - Dossiers, manuscripts and abstracts, presentations
Why HTA?

- Worries about cost of health/medical care in the USA and lack of “bending of the cost curve”

Source: Estimates from Chief Actuary of CMS, October 2009
Why HTA?

*Depends on stakeholder*

- **Patients and advocacy organizations**
  - Can it provide a framework to highlight why it’s important for more funding for research and technologies for their disease/condition?

- **Clinicians**
  - Should they adopt a new technology? In whom? How to use? Effect on their practice economics?

- **Payers**
  - Should it be covered? Is it affordable? Prior authorization useful?

- **Innovators/Investors**
  - What evidence is required for adoption, coverage, and payment?
  - What level of investment is required?
The future
What will not change

- Not much difference in way payers evaluate technologies
  - Hard to imagine NICE-like activities adopted in USA soon (e.g., experience with mammography screening)

*NICE – National Institute of Health and Clinical Excellence (UK)*
The future
What will not change

- Coverage and reimbursement decisions that upset and, at times, confuse industry, patients, physicians, etc.
  - Mammography
  - Computed Tomographic Colonography
  - Coverage for ESAs
  - Warfarin molecular diagnostic
The future
What will not change

- Finger pointing
  - Cycles through physicians, hospital organizations, industry, patient advocacy groups, politicians, etc.

Agenda

10:00-10:30: Tedium
10:30-11:00: Finger Pointing
11:00-11:30: Important-looking button pushing on various mobile devices
11:30: Lunch

"Okay if that's all the finger pointing we have today, we can move on!"
Even more skepticism about ‘independent’ claims of researchers

Section 6002 (Sunshine Rule) of the Patient Protection and Affordable Care Act of 2010 is a very important step in the right direction - designed to create more transparency about funding sources.
The future
What will change

- Increased funding to academic medical centers for comparative effectiveness research ($0.4 Bn in the Fiscal Stimulus Package)

- New institutions (e.g., Personalized Medicine, Patient-Centered Outcomes Research Institute)
  - Effectiveness may be undermined by vague objectives/goals, bureaucratic hurdles, political challenges
The future

What will change

- More consumer involvement in decision making (clinical and financial)
  - Higher deductibles
  - Health savings accounts
  - Information download/exchange

... but progress is likely to be slow because of threats to stakeholders’ control over payment streams and hard-to-implement business models.
The future
Uncertain effects

• What are the real determinants of increasing life expectancy?
• How to bend the cost curve?
• The evolving role of academic medical centers? Do we need a new Flexner report for the 21\textsuperscript{st} Century?
• Who will be in control of “decisions at the bedside”? 
How to bend the cost curve

- Why health care is unlike any other market? (K Arrow, 1956)
  - Asymmetry of information
  - Uncertainty

- The solution
  - More signaling and screening (Akerlof’s The Market for Lemons, 1970)
    - Reduced smoking by requiring labeling information on risk → required government intervention
    - More transparent labeling of clinical outcomes and costs
  - More evolution of principal-agent relationships
    - As confidence in others erodes (government, industry, insurers, clinicians, etc.), patients take more responsibility for decision making (room for market solutions)
How might your experience matter?

- The high demand for **high quality** researchers in health systems research
- What we look for ...
  - Technically proficient
  - Scientific “temperament”
  - Communication skills
  - Life-long learners (humility)
  - Respectful of others and other perspectives
Questions?
Cedar Associates LLC specializes in health technology assessments to inform decision making about the health and financial implications of adopting new technologies. Most funded by industry, but also have funding from foundations (e.g., how are coverage decisions made in low-income countries?)
WHO IS CEDAR?

- Analysis considers diverse perspective – patients, payers, physicians, hospitals, government agencies
- Clients who fund us are interested in best quality - unbiased - science that informs decision makers about their technology. We help inform strategy and conduct clinical and economic research.
- Mix of work:
  - High-end diagnostics (50%), drugs (30%), devices (20%)
  - International in scope – multiple submissions to NICE, Canadian CDR, CMS, VA, managed care markets, Israel, Singapore, Japan, etc.
- Many other firms - large and small. Large firms’ core business is usually product based (e.g., data) and they have internal groups that do analyses. Many cottage and solo firms.
- While we focus on HTA, there are related firms that use our analyses, often referring to themselves as reimbursement or market access firms
  - These are less clinically science based
  - Do market research on CPT codes, physician incentives, where procedures and/or drugs are most used, payment streams, lobby congress or payers, etc.
Cedar Associates LLC
Clinical Effectiveness Decision Analytical Research

http://www.cedarecon.com

275 Middlefield Road, Suite 200
Menlo Park, CA 94025

Tel: 650.327.2085
Fax: 650.327.1506
Toll-free: 877.571.3779
Email: jhornberger@cedarecon.com