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Expectations for Patient Centered Outcomes Research: Implications of Electronic Clinical Data

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Expectations for Patient Centered Outcomes Research: Implications of Electronic Clinical Data

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October 19, 2011

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Improving Health and Health Care
As the professional society for health services researchers and health policy analysts, our mission is three-fold:

1. Support the development of health services research
2. Facilitate the use of the best available research and information
3. Assist health policy and practice leaders in addressing major health challenges

We work to both “push” the production of research and promote the “pull” by decision makers
Faculty

Molly Coye, M.D., M.P.H., M.A.,
Chief Innovation Officer
UCLA Health System
Faculty

David Lansky, Ph.D.,
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Pacific Business Group on Health (PBGH)
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Faculty

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Advocate
AdvancedBC.org
Expectations for Patient-Centered Outcomes Research: Implications of Electronic Data

Setting the Context

October 19, 2011
Molly Joel Coye, MD, MPH
Chief Innovation Officer
UCLA Health System
Health reform offers...

accountability
research data

a new emphasis on the voice of the patient

new data streams - changed to integrate consumer concepts like ‘time to resolution’

support for patient decision making

PCORI - consumers want research linking clinical outcomes to utilization patterns and cost
A changing world

PatientsLikeMe R&D Director Paul Wicks, presenting at TEDx Berkshires, walks through the medical decision process faced by patients and clinicians trying to manage their illness in a world lacking in data.

http://www.youtube.com/watch?v=adwHhBRghzM
consumers, patients find their way to new technologies...
new technologies
that support engagement

activation, not just satisfaction.

and some portion of patients – maybe most of them – want data.
that challenge our ideas of who does research..

**ALS Lithium Study - The Results**

In 2008, a small Italian study was published suggesting that the drug Lithium could slow the progression of ALS. In response, hundreds of members of PatientsLikeMe began taking the drug and using a new tool and a matching algorithm to conduct a patient-lead observational study. The results of that study, published in Nature Biotechnology, show that we were unable to replicate the promising findings of the Italian group, but that PatientsLikeMe may provide a useful way of conducting observational studies faster and cheaper than existing trial methods.
and who pays for research..

The $3 million dollar prize is approximately double that of the Nobel Prize in Medicine.
introduce new tools
new ways to change behavior
Our health management programs are designed to enable complete flexibility to care team parameters. Our applications work across the entire healthcare spectrum.
the good news...
the greatest leverage is exactly where this action is...
A purchaser perspective on Comparative Effectiveness Research

Expectations for Patient Centered Outcomes Research: Implications of Electronic Clinical Data

David Lansky, PhD
October 19, 2011
The Pacific Business Group on Health

- The Pacific Business Group on Health helps purchasers to improve the quality and availability of health care while moderating costs.

- Our 50 members spend 12 billion dollars annually to provide health care coverage to more than three million employees, retirees and dependents in California alone.
Generally, what are purchasers looking for?

- **Improved health outcomes at sustainable costs**
  - Accountability for outcomes & costs
  - Transparent outcomes & costs
- **Infrastructure that supports continuous improvement**
  - Coordinated care
  - Evidence-based medicine
  - Reduced errors
  - Increased diagnostic and treatment appropriateness
- **Engaged patients and consumers**
- **Consumer and provider incentives aligned to support value**
Policy mechanisms to drive transformation

- EHR incentive program
- Accountable care organizations - 2012
- Health insurance exchanges - 2014
- PQRS and Physician Compare - 2013
- Hospital value-based purchasing
- Physician value-based purchasing
- Episode payment
- Medical homes & “hotspotting”
- Shared decision-making
Purchaser mechanisms to drive transformation

• Identify higher value specialists and encourage their use through payment & benefit design:
  ➤ pay for performance (outcomes, appropriateness, patient experience)
  ➤ episode payment (outcomes, appropriateness, patient experience)
  ➤ global payment (budget or capitation)
  ➤ reference pricing
  ➤ tiered networks
  ➤ value based benefit design

• Increase selection of cost-effective technology (drugs and devices, diagnostics…)

• Increase patient engagement in cost-conscious decisions – choice of hospital, surgeon, treatment
Purchaser expectations of health IT

Information infrastructure that:

• supports purchaser evaluation of care providers: quality, resource use, and cost measures
• drives efficiencies in medical care
• permits innovation in medical care
• engages individuals as actors in their care – as patients and as consumers
Constraints on purchaser action

Purchasers would like to see providers voluntarily use the most cost effective resources, but that only seems to happen when they bear financial risk.

So purchasers are looking for other means to implement CER findings.
Constraints on purchaser action

Need to understand mindset and constraints on program designs:

• Unwilling to limit patient’s ability to choose providers or interfere in physician’s treatment choices

• Unable to implement widespread payment policy changes, right now

• Feel overwhelmed by marketing, detailing, distribution of expensive technologies that drive up costs with uncertain benefit

• Have had good experience with a benefit design approach (medication formularies, reference pricing) - doesn’t require contract changes, leaves ultimate choice up to consumer – but critical that consumer be fully engaged in importance of his/her decision

• Need to address compelling evidence that consumers believe more expensive care is better
“How do consumers respond to comparative cost and resource use information?” Presentation of AHRQ-sponsored research by Shoshanna Sofaer, DrPH. October 6, 2011
How can purchasers use CER results to alter health care decisions?

- How to recognize (measure) and reward providers who use cost-effective services
- Provider payment
- Coverage decisions
- Shared decision-making
- Benefit design
Alliance to Advance Affordable Healthcare
Guiding Principles

• To avoid the creation of perverse incentives in the initial payment rates for new tests and treatments by not paying more for new interventions until adequate evidence exists to demonstrate improved patient outcomes or health system efficiency.

• To reduce incentives for over-utilization of established test and treatment options when they are more expensive than equally effective alternative options.

• To produce overall savings for the health care community that will lower the costs of insurance coverage borne by purchasers and patients.
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ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization


Table 2. Patients Without Prior Bypass Surgery

<table>
<thead>
<tr>
<th>Indication</th>
<th>CCS Angina Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. One- or 2-vessel CAD without involvement of proximal LAD</td>
<td>Asymptomatic</td>
</tr>
<tr>
<td>* Low-risk findings on noninvasive testing</td>
<td>I (4)</td>
</tr>
<tr>
<td>* Receiving no or minimal anti-ischemic medical therapy</td>
<td>I (2)</td>
</tr>
<tr>
<td>13. One- or 2-vessel CAD without involvement of proximal LAD</td>
<td>III or IV</td>
</tr>
<tr>
<td>* Low-risk findings on noninvasive testing</td>
<td>U (5)</td>
</tr>
<tr>
<td>14. One- or 2-vessel CAD without involvement of proximal LAD</td>
<td>II</td>
</tr>
<tr>
<td>* Intermediate-risk findings</td>
<td>U (3)</td>
</tr>
<tr>
<td>* Receiving no or minimal anti-ischemic medical therapy</td>
<td>U (5)</td>
</tr>
<tr>
<td>15. One- or 2-vessel CAD with high-risk findings on noninvasive testing</td>
<td>II</td>
</tr>
<tr>
<td>* Intermediate-risk findings</td>
<td>U (4)</td>
</tr>
<tr>
<td>* Receiving a course of maximal anti-ischemic medical therapy</td>
<td>A (7)</td>
</tr>
<tr>
<td>16. One- or 2-vessel CAD with high-risk findings on noninvasive testing</td>
<td>II</td>
</tr>
<tr>
<td>* High-risk findings on noninvasive testing</td>
<td>U (6)</td>
</tr>
<tr>
<td>* Receiving no or minimal anti-ischemic medical therapy</td>
<td>A (7)</td>
</tr>
</tbody>
</table>

Abov

ities and payers may choose to use these criteria either prospectively in the design of protocols or pre-authorization procedures, or retrospectively for quality reports. It is hoped that payers would use these criteria as the basis for the development of rational payment management strategies to ensure that their members receive necessary, beneficial, and cost-effective cardiovascular care, rather than for other purposes.

It is expected that services performed for appropriate indications will receive reimbursement. In contrast, services performed for inappropriate indications will likely require additional documentation to justify payment because of the unique circumstances or the clinical profile that must exist in such a patient. It is critical to emphasize that the writing group, technical panel, Appropriateness Task Force, and clinical community do not believe an uncertain rating is grounds to deny reimbursement for revascularization.

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The Comparative Clinical Effectiveness of CT colonography for colorectal cancer screening vs. OPTICAL COLONOSCOPY is rated as:

- C --- Comparable

The Comparative Value of CT colonography for colorectal cancer screening vs. optical colonoscopy screening is rated as:

- c, b, or a --- low, comparable, or high, depending on reimbursed price ratio*

The Integrated Evidence Rating = Cc, Cb, or Ca*

*If reimbursed price of CTC = same price as optical colonoscopy, comparative value = c
If reimbursed price of CTC = half the price of optical colonoscopy, comparative value = b
If reimbursed price of CTC = one-third that of optical colonoscopy, comparative value = a

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**Health Technology Clinical Committee**

**Findings and Coverage Decision**

**Topic:** Computed Tomographic Colonography (CTC)
**Meeting Date:** February 15, 2008
**Final Adoption:** August 15, 2008

**Number and Coverage Topic**

20080215B – Computed Tomographic Colonography (CTC)

**HTCC Coverage Determination**

Computed Tomographic Colonography (CTC) for routine colorectal cancer screening is **not a covered benefit.** This decision does not apply to use of CTC for other diagnostic purposes.

**HTCC Reimbursement Determination**

<table>
<thead>
<tr>
<th>Comparative Value</th>
<th>a</th>
<th>b</th>
<th>c</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reasonable/Comparable</td>
<td>I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>I</td>
<td>I</td>
<td></td>
</tr>
</tbody>
</table>

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Shared decision making
applications of CER
UnitedHealth Premium Physician Designation Program Summary Methodology

Dr. Pratt’s Patients
- Mrs. Jones
  Claim 1, 2, 3...
- Ms. Parker
  Claim 1, 2, 3...
- Mr. Smith
  Claim 1, 2, 3...

Assess Quality of Care
- Evidence-based Medicine Measures
- Evidence-based Procedure-related Measures
- Meets Criteria for Quality Designation

Dr. Pratt is Board Certified in His Primary Specialty

Dr. Pratt Receives Quality Designation

Eligible for Cost Efficiency Designation
- Total Resources and Total Costs: Episodes of Care
  - Medical Conditions (ETGs)
  - Procedure Related Episodes (PEGs)
- Adjusted for:
  Case-mix and severity of patients to account for differences in practice, patient type and illness burden

Dr. Pratt Receives Quality AND Cost Efficiency Designation

Compare Resources Used and Costs to the Market Median
- Same Geographic Area
- Same Specialty

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EHR Data Requirements

- Indications for treatment (appropriateness)
- Patient reported outcomes (health status, functioning, patient experience)
- Procedural data
- Resource use data
- Coordination of care measures
- Longitudinal measurement (readmissions, costs, complications, change in function)
Health IT System Requirements

• Standardized data set
• Standard data interfaces from hospital systems
• Interfaces to health plan and CMS data
• Access to cost and resource use data
• Common computational algorithms
• Flexible EHR platforms (or consider EHR as data capture platform, distinct from CER and quality reporting function)
• Network of registries (possibly federated for common queries)
Health IT Requirements for Purchaser CER Adoption

• Continuous acquisition of clinical data aligned with evidence
• Clinical decision support to implement evidence at point of care
• Shared decision making to engage patients with evidence at point of care
• EHR algorithms to evaluate conformity – for both continuous feedback and evaluation
• Data infrastructure to integrate, compute, report results
• Packaging information in usable ways for consumers, purchasers, policymakers
• Teachable moments to engage consumers
• Incentives to engage consumers
Consumer Hopes and Expectations for PCOR and PCORI

Alice Leiter
Director, Health IT Policy
Nonprofit organization with nearly 40 years of experience working on issues important to women and families

Work primarily on national level, with grass-roots presence in several states

Priorities:

~ Improve access to quality, affordable health care
~ Promote fairness in the workplace
~ Advance policies that help women and men meet the dual demands of work and family
~ NPWF leads several coalitions, including the Consumer Partnership for eHealth (CPeH)

VP Christine Bechtel sits on Health IT Policy Committee
Background and Context

PCOR is being defined as “research that is informed by the perspectives, interests and values of patients throughout the research process, from the selection of research questions to the dissemination of research results. [It] is intended to be practically relevant. Its real-world impact on patients is known and included in decisions about prevention, diagnosis and treatment.”
Historically, consumer advocates have felt that the word “patient,” or, more recently, the phrase “patient-centered,” can be slapped on anything, but rarely does that actually mean anything. As a result, consumers tend to be skeptical. Patients themselves are often involved too late, if at all, and tend to feel like window-dressing, rather than meaningful participants in decision-making. With respect to research, patient participation has primarily involved being the objects. Not as involved in the development of questions, selection of measures, analysis, interpretation or dissemination of research.
Now, however, there is real money on the table to implement patient-centered outcomes research, as well as an entity that will have some clout. PCOR and PCORI truly could signal a sea-change. But in order for it to be a meaningful change, there are certain approaches that must be taken. From the perspective of the consumer community, the question is how hard the research community is willing to push to make consumer engagement and participation a reality – now is the time that consumer support and involvement can be made or broken.
Consumer Asks

1. Embrace consumer participation on all levels and across all aspects of PCOR
   ~ Consumers should be part of informing the research question and relevant measures and supported throughout
   ~ Patient-contributed data should be included where appropriate

2. Design should be transparent

3. Ensuing results must be used in ways that are meaningful to patients
» The shared goal is to make use of research-generated information in a way that is meaningful to patients

» With respect to obtaining information, patients want information that is useful to them

» That is not information that one typically gets out of a randomized controlled trial
  ~ For example, women and minorities are generally under-represented
  ~ Consumers want information that can be stratified by various groups and therefore more narrowly and strategically applicable

» Most clinical or quality measurements involve content that matter to doctors. (e.g. patient survival)
Consumer Asks

» There can be a fundamental disconnect for patients with respect to research, whereby they don’t necessarily feel that research is about or for them

» Patients want information on how a particular treatment approach or procedure might have an impact on them (e.g. quality of life and experience of care)
How to Make This Happen

» As the consumer community says again and again, if you want consumers involved in something, you must involve them on the front-end – both early and often

» Thus PCOR must engage patients from step one of the research process, and step one is developing the question

» Meaningful inclusion requires an infrastructure to identify, prepare and support patients research activities for which they haven’t been prepared

» Preparation must involve a basic understanding of the scientific process but also emphasize the unique contributions of patients to the endeavor and prepare them to effectively represent and communicate their perspective
How to Make This Happen

» Patients can also be involved in generating the actual evidence by reporting their own data, such as functional status

~ This is information that only patients could report or know, and that a doctor either could not or would not ask, or be able to report

~ An electronic format makes this easier to do, as there is the potential for bi-directional exchange of data, patient reporting directly to physicians, etc
How Can Consumers Help?

» Participate in discussions like this!
» Think of proactive asks and solutions, rather than playing passive and/or cranky role
» When given the opportunity to participate, do so willingly and actively
» Contribute data when asked
Questions?

aleiter@nationalpartnership.org
202-238-4845

Thank you!
“I am not a statistic!”
Patient perspectives on electronic data collection and research

Musa Mayer, MS, MFA
Ambivalence, and yet...

- Patients understand that experiences and outcomes vary, and
- They want to be treated as individuals.
- They know that collective data forms the basis for medical knowledge, and is
- Used to guide treatment choices.
- Patients are often motivated to help others and to share their own experiences.
Metastatic breast cancer (MBC)

• Unique population?
• Patients and families affected look for help in
  – Making treatment decisions
  – Dealing with side-effects and symptoms
• Disease is progressive, ultimately fatal
• Median survival 2 ½ to 3 years, yet highly variable, depending on multiple factors
• Responsible for >40,000 US breast cancer deaths each year
PCORI patient-focused questions

1. “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
2. “What are my options and what are the benefits and harms of those options?”
3. “What can I do to improve the outcomes that are most important to me?”
4. “How can the health care system improve my chances of achieving the outcomes I prefer?”

www.pcori.org/patient-centered-outcomes-research
Patients reaching out

- Online community > 11 years, currently 1,700 patients and family members sharing stories, info, research, advice
- “Silent Voices” survey
  - Living Beyond Breast Cancer
  - 618 MBC patients
  - Online
  - Complex
  - Internet user demographic
Health-related information is critical

618 LBBC survey responders said they:

• Highly valued information
• Three-quarters sought information daily or weekly
• Found support through information; it helped them to cope, to feel in control
• Looked to different members of their healthcare team to provide information in different ways.
• One third felt they lacked knowledge about availability of educational programs and materials
• Used varied sources of printed patient information; government websites and articles targeted to medical professionals

Mayer, Seminars in Oncology Nursing, Vol 26, No 3 (August), 2010
The BRIDGE Global MBC Survey

• 1,342 patients from 13 low- and high-resource countries
  – Physician referrals
  – Face-to-face/telephone interviews in own language
• Three-quarters sought information on their own
• Nearly half felt their information needs were not met
Clinical trial participation and attitudes

Fact Sheet: Bridging Gaps, Expanding Outreach – Metastatic Breast Cancer Patient Survey
Patient registries

• Genentech sponsored

• Goals:
  – Characterize treatment patterns
  – Describe natural history of disease

• registHER followed 1,023 HER2+ MBC patients

• VIRGO is following 1,037 MBC with other forms of the disease

• Rapid accrual, few refusals

Patient Reported Outcomes (PROs)

- Poor adherence and completion rates
- Inherent bias, especially in controlled trials
- Not integrated into medical care
- Adds additional burden to an already overburdened system, perceived as lower priority
- But….real potential exists for integrating patient-reported data into medical practice as well as using it for research
Patients appreciate being asked

• Want and expect their data to be noted, tracked and used to improve their care and the care of others
• But, they are rarely asked...
• Patients are often shocked that no one learns from their experiences, especially if atypical
• “Why aren’t they studying us long-term survivors?”
Reasons for optimism, if...

• The healthcare system cares about patients enough to ask them how they are doing
• Patients may appreciate being treated as more than body parts with a disease entity
• Information-gathering could be integrated fully with medical care, and can improve that care
• Safety could be dramatically improved.
• Beyond clinical trials:
  – Real world populations
  – Long term toxicity and efficacy data
The challenge

• How can gathering electronic data about and from patients serve to *humanize* the medical experience, rather than introducing another layer of technology that consumes precious time and resources? How can it be made to engage and enrich physician-patient communication?
2011 Papers In Progress

→ Assessing site-level data variability in multi-site CER
→ Using distributed data networks to construct diabetes and asthma cohorts for CER and public health surveillance
→ Using mobile technologies for primary research data collection
→ A survey of informatics platforms that enable distributed CER
→ Data model considerations for clinical effectiveness researchers
→ Strategies for de-identification and anonymization of EHR data in multicenter research studies
→ Approaches to IRB approval of multi-site CER and QI studies
→ Building the Informatics Infrastructure for CER: A Review of the Literature
→ The EDM Forum: A Network for Research Networks on CER
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