In Action: Dissemination and Uptake of CER/PCOR

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Nilay Shah
In Action: Dissemination and Uptake of CER/PCOR Evidence

A Guiding Framework from Implementation Science and Case Study Application

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Associate Professor, Health Systems, Management and Policy

CER/PCOR Conference: Enhancing Uptake and Use by Patients, Clinicians and Payers
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Disclosure

- Colorado Clinical and Translational Sciences Institute (CCTSI) NIH/NCATS UL1TR001082
- CTSA Accrual to Clinical Trials NIH/NCATS UL1TR001857
- Innovation-Corps@CTSA NIH/NCATS UL1TR001417
- Center for American Indian and Alaska Native Diabetes Translational Research NIDDK P30 DK092923
- Problem-Solving Skills Training for Clinicians Providing Psychosocial Care in Pediatric Oncology NCI R25 CA183725
- FDA Special Government Employee, advises on issues of drug safety and risk management implementation.

The content is solely the responsibility of the presenter and does not necessarily represent the official views of the National Institutes of Health or the Food and Drug Administration.
Implementation Science (D/I)

**Dissemination (D)** is the targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to spread knowledge and the associated evidence-based interventions.

**Implementation (I)** is the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings. The intent is to promote adoption by an individual, organization or community to commit to, initiate, and sustain use of evidence-based practices.

Rabin in *Dissemination and Implementation Science in Health* (2012)
“Scientific knowledge about best care is not applied systematically or expeditiously to clinical practice. It … takes an average of 17 years for new knowledge generated by randomized controlled trials to be incorporated into practice, and even then application is highly uneven.”

-- Institute of Medicine (2001)
Implementation Challenge: a leaky pipeline

Transfer of Knowledge from Research to Practice and Policy

An implementation science framework: Diffusion of Innovation Theory

1. Innovation. Perceived value.
2. Communication Channels. Mass media vs. interpersonal channels.
3. Time and the Adoption Process. Early vs. late adopters.
4. Social System. Setting and group norms.

Developed by E.M. Rogers in 1962, is one of the oldest social science theories. It originated in communication to explain how, over time, an idea or product gains momentum and diffuses (or spreads) through a specific population or social system.
CER/PCOR case application

Uptake of metabolic screening and monitoring for patients taking antipsychotic medication

[derived from the landmark NIMH-funded Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) Study]
CATIE-Schizophrenia Trial: All-Cause Discontinuation

Proportion of patients without event

Time to discontinuation for any cause (mo)

Olanzapine (n=330)
Perphenazine (n=257)
Risperidone (n=333)
Quetiapine (n=329)
Ziprasidone (n=183)

CATIE Results: Metabolic Changes From Baseline

Glucose (mg/dL)

Glycosylated HB (%)

OLZ  13.7  0.4
QUET  7.5  0.04
RIS  6.6  0.07
PER  5.4  0.0
ZIP  2.9  0.11

NEJM 2005 353:1209-1223
CATIE Results: Metabolic Changes From Baseline

Cholesterol (mg/dL)

Triglycerides (mg/dL)

OLZ  QUET  RIS  PER  ZIP

NEJM 2005 353:1209-1223
Metabolic disorders are highly prevalent. Baseline rates of under-treatment are high.

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Prevalence</th>
<th>Non-treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>10.4%</td>
<td>30.2%</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>63.3%</td>
<td>88.0%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>33.2%</td>
<td>62.4%</td>
</tr>
</tbody>
</table>

1. Innovation

Faster adoption with....

- Greater perceived relative advantage
- Compatibility with existing systems & behaviors
- Lower complexity
- Trial use
- Observable behavior
## Case application: metabolic screening / antipsychotics

<table>
<thead>
<tr>
<th>D/I Strategy</th>
<th>D/I Tactics</th>
<th>Lessons Learned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demonstrate relative advantage.</td>
<td>Increased morbidity and mortality; years of life lost</td>
<td>Effective – raised awareness, but... trade-off with efficacy.</td>
</tr>
<tr>
<td></td>
<td>Dissemination of need-gap (scientific + pharma)</td>
<td>Focused primarily on patients with schizophrenia; CMHCs.</td>
</tr>
<tr>
<td></td>
<td>Synthesized literature (2005+)</td>
<td>Primarily targeted the psychiatric audience.</td>
</tr>
<tr>
<td></td>
<td>FDA class language (2008+)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Integrated care models. ‘Health Homes’ (ACA, 2012)</td>
<td>Fragmented - reliant on early adopter systems.</td>
</tr>
<tr>
<td>Promote trial use.</td>
<td>Screening fairs (pharma)</td>
<td>Fragmented – funding not coordinated.</td>
</tr>
<tr>
<td></td>
<td>NIMH funding for interventions. (2012+)</td>
<td></td>
</tr>
<tr>
<td>Make behavior observable.</td>
<td>Localized QI initiatives.</td>
<td>Fragmented - reliant on early adopter systems.</td>
</tr>
<tr>
<td></td>
<td>NCQA HEDIS measure (2014/2015)</td>
<td></td>
</tr>
</tbody>
</table>
2. Communication

• Knowledge transfer precedes behavior (necessary but not sufficient)

• Channels and media mix
  – Mass media channels offer rapid and efficient means of creating awareness & knowledge.
  – Interpersonal communication is more effective in persuading individuals to change behavior.

• Change agents
  – Transfer of ideas occurs faster among individuals with shared professions, education & social status
  – Increases the likelihood of information exchange and adoption.
## Case application: metabolic screening / antipsychotics

<table>
<thead>
<tr>
<th>D/I Strategy</th>
<th>D/I Tactics</th>
<th>Lessons Learned</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mass communication.</strong></td>
<td>FDA Warning</td>
<td>Framed as an issue for schizophrenia patients (‘on label’ usage)</td>
</tr>
<tr>
<td></td>
<td>Scientific literature</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pharma advertising (Pfizer, BMS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CME: on-line</td>
<td></td>
</tr>
<tr>
<td><strong>Interpersonal communication.</strong></td>
<td>CME: in-person</td>
<td>Primarily targeted individual ‘high’ prescribers (psychiatric) .... waned over time.</td>
</tr>
<tr>
<td></td>
<td>Pharma promotional activities (Pfizer, BMS).</td>
<td></td>
</tr>
<tr>
<td><strong>Support change agents to spread evidence.</strong></td>
<td>Medical liaisons: CME and speaker engagements (Pfizer, BMS).</td>
<td>Pharma-supported. Widespread use of this strategy has declined over time. ‘Academic Detailing’ focused more on reducing off-label use and polypharmacy.</td>
</tr>
</tbody>
</table>
3. Time and the adoption process

The adoption process involves several phases: (1) knowledge, (2) persuasion, (3) decision, (4) implementation and (5) confirmation. Individuals in a social system can be categorized based on their relative speed of adoption versus their peers.
Early adopters are:

- More highly interconnected through interpersonal networks
- Better able to cope with uncertainty
- Have greater knowledge and seek information more actively
- More likely to adopt a new behavior based on information from mass communication channels
Clinical research
  Clinical Studies
    Systematic reviews

Research synthesis

Health services research
  Clinical quality improvement
    Clinical care research
      Evidence-based medicine
        Clinical decision making

Glasziou and Haynes ACP JC 2005
Case application: metabolic screening / antipsychotics

Early adopters: Medicaid / state departments of mental health / and VA health systems where rates of serious mental illness are higher and antipsychotics usage greater.

Where there was an organizational champion.
Missouri MO HealthNet (Medicaid)

2015 APA Achievement
Gold Award for Community-Based Program

<table>
<thead>
<tr>
<th>Population Characteristics</th>
<th>U.S.</th>
<th>Missouri</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Health, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fair or poor health</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>Frequent mental distress</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Obesity</td>
<td>26</td>
<td>28</td>
</tr>
<tr>
<td>No exercise</td>
<td>23</td>
<td>26</td>
</tr>
<tr>
<td>Currently smoking</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Diabetes</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>High blood pressure</td>
<td>28</td>
<td>29</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>38</td>
<td>40</td>
</tr>
</tbody>
</table>

Medicaid Profile

Number of enrollees, million: 58.4, 1.1
Enrollees, % of population: 20, 21
Type of enrollees, %
  - Children: 50, 54
  - Adults: 26, 22
  - Elderly: 10, 8
  - Disabled: 14, 15

Sources: Centers for Disease Control, Kaiser Family Foundation

Dr. Joe Parks
Director, MO HealthNet
Formerly medical director for The MO Dept. of Mental Health
### Intention to screen for diabetes: MO HealthNet

<table>
<thead>
<tr>
<th>Would ‘Definitely’ Order a Blood Glucose Test, %</th>
<th>CMHC n=156</th>
<th>non-CMHC Psychiatry n=136</th>
<th>Primary Care n=499</th>
<th>Other n=133</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline visit (drug initiation)</td>
<td>56.6</td>
<td>45.6</td>
<td>39.1****</td>
<td>23.5****</td>
</tr>
<tr>
<td>One-year Follow-up (continuous use)</td>
<td>78.3</td>
<td>61.0***</td>
<td>60.2****</td>
<td>30.5****</td>
</tr>
<tr>
<td>Advocacy for Screening</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Promoters&lt;sup&gt;a&lt;/sup&gt;</td>
<td>76.2</td>
<td>61.8</td>
<td>49.4****</td>
<td>32.8****</td>
</tr>
</tbody>
</table>

Significance denotes differences between CMHC and each specialty tested by Pearson’s chi-square test of association and adjusted for multiple comparisons with the Bonferroni method ** p<0.05, *** p<0.01, **** p<0.001.

<sup>a</sup> Promoters are defined as providers who responded 9 or 10 (on a 10 point scale, with 10 being “Extremely Likely”) to “How likely are you to recommend glucose testing for adults taking antipsychotics to a colleague?”.
Who to target?

PCPs and Other providers -- greatest potential for population health impact

Lowest intention of screening and advocacy

Large segment

• 42% of patients
• 85% of prescribers

Net Promoter Score is defined as the percent of providers who responded 9 or 10 (on a 10 point scale, with 10 being “Extremely Likely”) to “How likely are you to recommend glucose testing for adults taking antipsychotics to a colleague?” less the percent who responded 6 or lower.
# Population-based metabolic testing rates: MO HealthNet

<table>
<thead>
<tr>
<th></th>
<th>Primary Cohort New Users</th>
<th>Secondary Cohort Survey Responder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual testing rates among new users of antipsychotics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose</td>
<td>79.6 (7413/9316)</td>
<td>79.0 (1433/1813)</td>
</tr>
<tr>
<td>Lipid</td>
<td>41.2 (3841/9316)</td>
<td>43.7 (793/1813)</td>
</tr>
</tbody>
</table>

| Annual glucose testing among new users of antipsychotics without diabetes |                          |                                  |
| No. of ascertainable type 2 diabetes risk factors |                          |                                  |
| None                           | 68.1 (2296/3373)         | 65.4 (467/714)                   |
| 1                              | 76.1 (1789/2350)         | 79.6 (354/445)                   |
| 2                              | 87.5 (997/1140)          | 87.8 (166/189)                   |
| 3 or more                      | 92.8 (779/839)           | 94.9 (129/136)                   |

**Data source:** Missouri Medicaid administrative claims data, 2010-2012.

Annual test period = Index +/- 180 days.

4. Social Setting

- Individuals are more likely to adopt an innovation if more members of their personal network have adopted.

- Opinion leaders within social systems tend to be early adopters, especially if the system norms favor change.

- Denser social systems generally reflect a cohesive normative environment and may facilitate diffusion.
Case application: metabolic screening / antipsychotics

• **Opinion Leader Professional Society.**
  National Association of State Mental Health Program Directors Director

• **Opinion Leader Health Systems.**
  • Kansas Medicaid
  • MO HealthNet (2015 APA Gold Award)
  • VA/VISNs

• **Denser Social Systems.** Community Mental Health Centers.
Behavioral Health

Primary Care

CMHC | VA

Glasziou and Haynes ACP JC 2005
Implications for CER/PCOR Dissemination

1. Is there sufficient evidence?
   • Is 1 rigorous RCT sufficient?
   • Is it a preponderance of evidence?
   • By whose authority? (FDA, professional societies, AHRQ, P&T committees, NCQA HEDIS, PCORI, etc.)

A model for consideration:
AHRQ | USPSTF recommendations (clinical preventive services) [+ increased stakeholder involvement]
Implications for CER/PCOR Dissemination

2. Who “owns” dissemination and implementation?
   • Single, national point of accountability?
   • Who should be the sustaining ‘convening’, ‘agenda setting’ authority?
   • Implement multi-stakeholder, public-private partnership, when possible

A model for consideration:
   • Pharma brand or product manager
   • U.S. Dept. of Health and Human Services.
Implications for CER/PCOR Dissemination

3. Approach as a sustained, dynamic series of D&I campaigns
   • Multi-level, multi-channel interventions.
   • Identify and target thought leaders and early adopters. Build a contagion effect.
   • Identify competing market and behavior forces. Strategize and intervene proactively. Adaptive D/I designs.
   • Ensure sustained (and sufficient) funding

A model for consideration:
   • Pharma promotion and marketing efforts for a product or therapeutic category
Implications for CER/PCOR Dissemination

4. Adopt time urgency
   • Design for dissemination. Broad stakeholder engagement. Anticipate barriers. Provide solutions-value (e.g., I-Corps).
   • Work dissemination efforts in parallel with evidence generation. “Soften the market.”
   • Use real-time data-based D/I surveillance – from Day 1
   • Faster-nimbler D/I funding. Eliminate/reduce funding gaps in stages of dissemination.

A model for consideration:
   • PCORI’s engagement pipeline approach (expand so more intentional in multi-stakeholder involvement)
   • A “Koo/R99-like” funding mechanism (A Pathway to Dissemination Award?)
Thank you.

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Dissemination and Uptake of Comparative Effectiveness Research

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Center for the Science of Health Care Delivery
Knowledge and Evaluation Research Unit
Mayo Clinic
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  – NIH:  R34 DK84009; R01HL131535
  – Patient Centered Outcomes Research Institute (PCORI)
  – Foundation for Informed Medical Decision Making (FIMDM)
  – American Diabetes Association (ADA)
  – Mayo Clinic Foundation for Medical Education and Research
  – Mayo Clinic CCaTS
EBM → KT

Glasziou and Haynes ACP JC 2005
Systematic Review: Comparative Effectiveness and Safety of Oral Medications for Type 2 Diabetes Mellitus

Background: As newer oral diabetes agents continue to emerge on the market, comparative evidence is urgently required to guide appropriate therapy.

LESS IS MORE

Initial Coronary Stent Implantation With Medical Therapy vs Medical Therapy Alone for Stable Coronary Artery Disease

Meta-analysis of Randomized Controlled Trials

Kathleen Stergiopoulou, MD, PhD; David L. Brown, MD
“There are now 75 trials and 11 systematic reviews of trials, per day…”

Bastian et. al, 2010

*PLoS Medicine*
ATP III Guidelines At-A-Glance
Quick Desk Reference

1. Step 1
Determine lipoprotein levels—obtain complete lipoprotein profile after 9- to 12-hour fast.

ATP III Classification of LDL, Total, and HDL Cholesterol (mg/dL)

<table>
<thead>
<tr>
<th>LDL Cholesterol – Primary Target of Therapy</th>
<th>Optimal</th>
<th>Near optimal/above optimal</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100-129</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

National Cholesterol Education Program
# Treatment of Low Grade Prostate Cancer

<table>
<thead>
<tr>
<th>Professional Group</th>
<th>Overused</th>
<th>Right Rate</th>
<th>Underused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncologists: AS*</td>
<td>9%</td>
<td>11.3%</td>
<td>79.7%</td>
</tr>
<tr>
<td>Urologists: RT*</td>
<td>48.2%</td>
<td>46.7%</td>
<td>3.5%</td>
</tr>
<tr>
<td>Radiation Oncologists: RT*</td>
<td>32.4%</td>
<td>45.4%</td>
<td>20.6%</td>
</tr>
<tr>
<td>Radiation Oncologists: AS*</td>
<td>5%</td>
<td>13.2%</td>
<td>80.0%</td>
</tr>
<tr>
<td>Radiation Oncologists: BT*</td>
<td>17.8%</td>
<td>36.3%</td>
<td>43.4%</td>
</tr>
<tr>
<td>Urologists: BT*</td>
<td>37.1%</td>
<td>42.1%</td>
<td>15.0%</td>
</tr>
<tr>
<td>Radiation Oncologists: RP</td>
<td>45.6%</td>
<td>48.8%</td>
<td>4.4%</td>
</tr>
<tr>
<td>Radiation Oncologists: RP</td>
<td>70.3%</td>
<td>23.5%</td>
<td>2.8%</td>
</tr>
</tbody>
</table>

Kim SP et al. Prostate Cancer Prostatic Dis 2014
The Translational Challenge

Uneven delivery of effective care well-documented

Only 50% of effective interventions are reliably delivered...and it takes a long time

If we only focus on **GENERATING** more information on comparative effectiveness, without attending to how to **IMPLEMENT** it, we will not improve quality or value or provide return on CER investment.
## CER Translation Gap

<table>
<thead>
<tr>
<th>Study</th>
<th>Results</th>
<th>Practice</th>
<th>Translation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALLHAT</td>
<td>Thiazide diuretics were superior in preventing cardiovascular disease events</td>
<td>ACE-inhibitors</td>
<td>No change</td>
</tr>
<tr>
<td>CATIE</td>
<td>Conventional antipsychotics were as effective as atypical antipsychotics for schizophrenia</td>
<td>Atypical Antipsychotics</td>
<td>No change</td>
</tr>
<tr>
<td>COMPANION</td>
<td>Compared to optimal medical therapy, both cardiac resynchronization therapy (CRT) and CRT plus defibrillator use improved survival, reduced hospitalization rates, and improved functional status in patients with moderate to severe heart failure</td>
<td>Medical therapy</td>
<td>Minimal change</td>
</tr>
<tr>
<td>COURAGE</td>
<td>Optimal medical therapy combined with percutaneous coronary intervention (PCI) had similar survival benefit and angina relief, compared to optimal medical therapy alone</td>
<td>PCI</td>
<td>Minimal/No change</td>
</tr>
<tr>
<td>SPORT</td>
<td>Surgery for lumbar spinal stenosis had better outcomes than nonsurgical treatment, according to the cohort study results</td>
<td>Surgical Treatment</td>
<td>No change</td>
</tr>
</tbody>
</table>

Source: Timbie 2012
Why?

- Misalignment of financial incentives
- Complexity of research
- Biases in interpretation of results
- Applicability of the evidence
- Limited use of decision support

Source: Timbie 2012; Morrato 2013
Surgical Decision Making
Challenging Dogma and Incorporating Patient Preferences

Three recently published randomized trials questioned the primacy of surgical management in 3 widely accepted operations: appendectomy for appendicitis, colectomy for diverticulitis, and knee replacement for osteoarthritis. What these studies had in common—setting them apart from others in the past—is that they, in randomized fashion, compared commonly used operations with significantly less aggressive or nonoperative alternatives. In all 3 trials, the less invasive treatment proved both safe and effective—not necessarily as definitive as a major operation but potentially more desirable in other important ways. All 3 of these trials challenge surgical dogma—shifting accepted treatment approaches away from long-established surgical gold-standard treatments. But when considered more broadly, these trials may begin reshaping how the routine appendectomy“ for uncomplicated appendicitis, whereas others concluded that “it was a negative trial that should not change practice.” So how should clinicians and patients interpret the findings of these trials when not even experts can agree? The answer should involve an appreciation of shared decision making in surgery, which has been conspicuously absent from these debates despite its importance in other specialties. Shared decision making is a collaboration in which the physician explains treatment options, elicits values from the patient, and, importantly, guides the conversation toward a decision consistent with the patient’s values and current evidence.

Shared decision making is particularly relevant because in all 3 studies neither treatment was superior across all outcomes. For one outcome, the traditional op
<table>
<thead>
<tr>
<th>Study Name and Patient Population</th>
<th>Standard Treatment vs Experimental Alternative</th>
<th>Absolute Differences (Standard vs Experimental)</th>
<th>Interpretation</th>
<th>Study Authors</th>
<th>Hypothetical Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPAC¹: Uncomplicated appendicitis in adults</td>
<td>Open appendectomy vs antibiotics (3 d IV, then 7 d PO)</td>
<td>Freedom from recurrence of appendicitis within 1 y; 100% vs 72.7% (95% CI, 67%-78%)</td>
<td>Overall surgical complications (20.5% vs 2.8%, ( P &lt; .001 )) Length of sick leave (19.0 d vs 7.0 d, ( P &lt; .001 ))</td>
<td>Relapse rate of 27% with antibiotics did not meet noninferiority threshold of 24%, thus favoring surgery over antibiotics</td>
<td>Antibiotics may allow me to avoid surgery entirely, or convert it to elective operation without increased risk of complications.</td>
</tr>
<tr>
<td>SCANDIV²: Perforated diverticulitis without feculent peritonitis</td>
<td>Colectomy (all types) vs laparoscopic lavage and interval colonoscopy</td>
<td>Severe complications within 90 d; 30.7% vs 26.0% (( P = .53 ))</td>
<td>Reoperation (5.7% vs 20.3%, ( P = .01 )) QOL score (0.73 vs 0.75, ( P = .32 )) Stoma at 90 d (69% vs 16%, ( P &lt; .001 ))</td>
<td>Colectomy preferable owing to lower reoperation rate</td>
<td>Lavage would leave me less likely to need stoma but more likely to need a reoperation.</td>
</tr>
<tr>
<td>&quot;A Randomized, Controlled Trial of Total Knee Replacement.&quot;³ Moderate-to-severe knee osteoarthritis eligible for unilateral knee replacement</td>
<td>Total knee replacement followed by 12 wk of nonsurgical treatment (exercise, education, diet, insoles, pain medications) vs nonsurgical treatment alone for 12 wk</td>
<td>Clinically significant (15%) improvement in symptom score: 85% vs 68%</td>
<td>Knee replacement within 1 y (98% vs 26%) Serious adverse events: (22% vs 4%, ( P = .05 ))</td>
<td>Knee replacement associated with greater symptom relief but more adverse events</td>
<td>Nonsurgical treatment can significantly improve my symptoms, without the risks of surgery.</td>
</tr>
</tbody>
</table>

Abbreviations: IV, intravenous; PO, by mouth; QOL, quality of life.
Clinical quality improvement

Evidence-based medicine

Clinical decision making

Clinical care research
Patient begins consultation with clinician.

Clinician and patient discuss medication options.

Patient leaves consultation with prescription.

Patient makes decision about medication.
Encounter Research

Research Evidence

decision aid

Patient values and preferences

within exam room
**User-centered Design meets CER**

- Evidence synthesis
- Observations clinical encounter
- Initial prototype
- Field testing
- Modified prototype
- Final Decision aid
- Evaluation

- Designers
- Study team
- Patients advisory groups
- Clinicians
Diabetes Cards

• Nature of diabetes medication discussions
• Summarizing the research evidence

Systematic Review: Comparative Effectiveness and Safety of Oral Medications for Type 2 Diabetes Mellitus

Background: As newer oral diabetes agents continue to emerge on the market, comparative evidence is urgently required to guide appropriate therapy.

had a beneficial effect on high-density lipoprotein cholesterol levels (mean relative increase, 0.08 to 0.13 mmol/L [3 to 5 mg/dl]) but a harmful effect on low-density lipoprotein (LDL) cholesterol levels (mean relative increase, 0.26 mmol/L [10 mg/dl]) compared with

• Iterative process – *Choice Architecture*
### Exenatide
- **Form**: Injectable medication
- **Used With**: Metformin or Sulfonylureas
- **Efficacy**: A1c by 0.5-1%
- **When Taken**: Twice (2) daily after meals

#### Side Effects
- Weight loss
- Gastrointestinal complaints

#### Monitoring Needs
- Monitor weight initially 1-3 times per week, less frequently thereafter

### Insulin
- **Form**: Injectable medication
- **Used With**: None or with Metformin and/or Sulfonylureas
- **Efficacy**: 0-0.5% A1c reduction
- **When Taken**: Once (1) or twice (2) daily

#### Side Effects
- Hypoglycemia

#### Monitoring Needs
- Monitor blood glucose daily, once (1) or twice (2) daily

### Glitazones
- **Form**: Oral medication
- **Used With**: None or with Metformin and/or Sulfonylureas
- **Efficacy**: 0.5-1% A1c reduction
- **When Taken**: Once (1) daily

#### Side Effects
- Weight gain
- Edema

#### Monitoring Needs
- Monitor weight initially 1-3 times per week, less frequently thereafter

### Sulfonylureas
- **Form**: Oral medication
- **Used With**: None alone or with Metformin
- **Efficacy**: A1c by 1-2%
- **When Taken**: Twice (2) daily

#### Side Effects
- Hypoglycemia

#### Monitoring Needs
- Frequent monitoring

### Metformin
- **Form**: Oral medication
- **Used With**: None alone or with Sulfonylureas
- **Efficacy**: A1c by 1-2%
- **When Taken**: Once (1) daily

#### Side Effects
- Constipation
- Volume-depletion symptoms

#### Monitoring Needs
- None when used alone

---

"Baseball Cards"
**Exenatide** (Jawara)

- **Form:** Oral medication
- **Typically used with:** Metformin or Sulfonylurea

**Efficacy:**
- May help lower A1C by 0.5-1%

**Weight Effects:**
- Can have a weight effect, the average weight gain is 2-4 pounds when combined with Sulfonylurea.
- If you have a weight effect, the combined average weight gain can be between 2-13 pounds.

**Hypoglycemia:**
- An uncommon side effect of Exenatide is decreased blood glucose. This may cause hypoglycemia. The risk of hypoglycemia increases with age, and it's important to be aware of this side effect.

**Other Side Effects:**
- Other rare side effects of Exenatide may include nausea and diarrhea of 100 people like you, 40 will experience nausea and 10 will experience diarrhea. As little as 2% of 100 people will have a severe form of diarrhea.

**Insulin**

- **Form:** Oral medication
- **Typically used with:** Metformin and/or Sulfonylurea

**Efficacy:**
- May help lower A1C by 1-2%

**Weight Effects:**
- Other side effects of Insulin may include nausea and diarrhea of 100 people like you, 40 will experience nausea and 10 will experience diarrhea. As little as 2% of 100 people will have a severe form of diarrhea.

**Hypoglycemia:**
- The risk of hypoglycemia with Insulin is less than 1% in people with a low risk.

**Other Side Effects:**
- Other rare side effects of Insulin include nausea, vomiting, and diarrhea. As little as 2% of 100 people will experience these symptoms within a year of use.

**Glitazones** (Lipid-lowering drugs like Rosiglitazone, Pioglitazone)

- **Form:** Oral medication
- **Typically used with:** Metformin

**Efficacy:**
- Insulin sensitivity improves in people with insulin resistance.

**Weight Effects:**
- A common side effect of Glitazones is weight gain. When combined with Metformin, which does not typically have a weight gain effect, the average weight gain is 2-4 pounds.

**Hypoglycemia:**
- It is important to be aware of this side effect.

**Other Side Effects:**
- Other side effects of Glitazones include nausea, vomiting, and diarrhea. As little as 2% of 100 people will experience these symptoms within a year of use.

**Metformin**

- **Form:** Oral medication
- **Typically used with:** Sulfonylurea

**Efficacy:**
- Metformin has shown an ability to lower A1C by 1-2%

**Weight Effects:**
- Metformin use has not been associated with significant changes in weight so you can expect minimal to no weight gain.

**Hypoglycemia:**
- Metformin causes no risk of severe hypoglycemia. The risk of severe hypoglycemia is less than 1% in people with diabetes.

**Other Side Effects:**
- Other side effects of Metformin include nausea, vomiting, and diarrhea. As little as 2% of 100 people will experience these symptoms within a year of use.

---

“Narrative Cards”
### Daily Routine

<table>
<thead>
<tr>
<th>Metformin</th>
<th>Insulin</th>
<th>Exenatide</th>
<th>Glitazones</th>
<th>Sulfonylureas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 2%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Daily Sugar Testing

<table>
<thead>
<tr>
<th>Metformin</th>
<th>Insulin</th>
<th>Exenatide</th>
<th>Glitazones</th>
<th>Sulfonylureas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 2%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Side Effects

<table>
<thead>
<tr>
<th>Metformin</th>
<th>Insulin</th>
<th>Glitazones</th>
<th>Sulfonylureas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 2%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Weight Change

<table>
<thead>
<tr>
<th>Metformin</th>
<th>Insulin</th>
<th>Exenatide</th>
<th>Glitazones</th>
<th>Sulfonylureas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 2%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Low Blood Sugar (Hypoglycemia)

<table>
<thead>
<tr>
<th>Metformin</th>
<th>Insulin</th>
<th>Exenatide</th>
<th>Glitazones</th>
<th>Sulfonylureas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 2%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Blood Sugar (A1C Reduction)

<table>
<thead>
<tr>
<th>Metformin</th>
<th>Insulin</th>
<th>Exenatide</th>
<th>Glitazones</th>
<th>Sulfonylureas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 2%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Incorporate patient preferences and context into clinical decisions
Incorporate research evidence and clinician’s expertise into patient decisions
Welcome to the Diabetes Medication Choice Decision Aid.

This guide provides information on medications to treat type-2 diabetes.

Let's get started

Caution: This application is for use exclusively during the clinical encounter with your clinician.
More helpful
Improved knowledge
Increased patient involvement
No difference in adherence (perfect adherence in control gr)
No significant impact on HbA1c levels

Mullan RJ et al. Archives of Internal Medicine 2009
Comparative effectiveness research

Patient centered translation into action

Decision aid

Patient-centered decision making
Effective Health Care Program
Comparative Effectiveness Review
Number 46

Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression: An Update of the 2007 Comparative Effectiveness Review

Effective Health Care Program
Medicines for Treating Depression
A Review of the Research for Adults
## Comparative Effectiveness Research

<table>
<thead>
<tr>
<th>BENEFITS</th>
<th>COSTS</th>
<th>SEXUAL PROBLEMS</th>
<th>SLEEP</th>
<th>WEIGHT CHANGE</th>
<th>DISCONTINUATION SYNDROME</th>
<th>GASTRO-INTESTINAL PROBLEMS</th>
<th>CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will this medicine work for me?</td>
<td>Citotriam</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td>The antidepressants presented in this decision aid at work the same for treating depression.</td>
<td>Esitalam</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td>These figures are estimates and are for comparative reference only. Adult out-of-pocket costs vary over time, by pharmacy, insurance plan coverage, presentation and dosage.</td>
<td>Fluoxetine</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td>6 out of 10 people will feel better with the first antidepressant they try.</td>
<td>Fluvoxamine</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td>4 out of 10 people will have to try other antidepressants before they find the one that is right for them.</td>
<td>Paroxetine</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td>How long before I feel better?</td>
<td>Sertraline</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td>SNRIs</td>
<td>Sertraline</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td>Most people need to take an antidepressant regularly for at least 6 weeks to begin to get the full effect.</td>
<td>Desvenlafaxine</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td>Most people taking antidepressants have at least one side effect.</td>
<td>Duloxetine</td>
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<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td>Understanding side effects</td>
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<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td></td>
<td>Other</td>
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<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td></td>
<td>Mirtazapine</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
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<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td></td>
<td>Nefazodone</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td></td>
<td>Trazadone</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td></td>
<td>TCAs</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
<tr>
<td></td>
<td>Amitriptyline or Nortriptyline</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
<td>Less Body</td>
<td>None</td>
<td>More Body</td>
</tr>
</tbody>
</table>

*All TCA are not included in the AHRQ report.*
Stakeholders meetings
24 participants / 12 organizations
(Health systems, patients, clinicians, buyers)

Clinical observations
2 primary care practices
(Patients, family physicians, care managers)

Focus groups/Discussion
Family physicians, care managers
Patients Advisory Groups
**Keep in Mind**

**Sexual Issues**

**Sleep**

**Cost**

**Weight Change**

**Stopping Approach**

**What You Should Know**

**Will this medicine work for me?**
- The antidepressants presented in this decision aid all work the same for treating depression.
- Most people with depression can find one that can make them feel better.
- 6 out of 10 people will feel better with the first antidepressant they try and the rest will have to try other antidepressants before they find the one that is right for them.

**How long before I feel better?**
- Most people need to take an antidepressant regularly for at least 6 weeks to begin to get the full effect.

**Understanding side effects**
- Most people taking antidepressants have at least one side effect.
- Many side effects go away after a few weeks, but some only go away after you stop the medicine.

**Weight Change**

Weight change is most likely to occur over a long period of time and depends on your actual weight.

<table>
<thead>
<tr>
<th>Weight loss</th>
<th>None</th>
<th>Weight gain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SSRIs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citalopram</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Escitalopram</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Fluvoxamine</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Paroxetine</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Sertraline</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Desvenlafaxine</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Duloxetine</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Venlafaxine</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Mirtazapine</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Bupropion</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Nefazodone</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Trazadone</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>SNRs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citalopram</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Escitalopram</td>
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<td>+</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Fluvoxamine</td>
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<tr>
<td>Sertraline</td>
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<td>+</td>
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<tr>
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<td>+</td>
</tr>
<tr>
<td>Mirtazapine</td>
<td>+</td>
<td>+</td>
</tr>
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</tr>
<tr>
<td>Trazadone</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>TCAs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amiptriptyline or Nortriptyline</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

**Stopping Approach**

Quitting your medicine all at once can make you feel sick, as if you had the flu (e.g. headache, dizziness, light-headedness, nausea or anxiety).

<table>
<thead>
<tr>
<th>None</th>
<th>More likely</th>
<th>Sick if you skip</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SSRIs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citalopram</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Escitalopram</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Fluvoxamine</td>
<td>+</td>
<td>+</td>
</tr>
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</tr>
<tr>
<td>Sertraline</td>
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<td>+</td>
</tr>
<tr>
<td>Desvenlafaxine</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Duloxetine</td>
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<td>+</td>
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<td>+</td>
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<tr>
<td><strong>SNRs</strong></td>
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<td>Citalopram</td>
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<td>Desvenlafaxine</td>
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<tr>
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<td>+</td>
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<tr>
<td>Venlafaxine</td>
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<tr>
<td>Mirtazapine</td>
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<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>TCAs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amiptriptyline or Nortriptyline</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
Comfortable
Knowledgeable
Satisfied
(feel better)

Free
Minimal resource needed

Engaged in decision making process

Comfortable
Satisfied
Use tool/like it
LESS IS MORE

Initial Coronary Stent Implantation With Medical Therapy vs Medical Therapy Alone for Stable Coronary Artery Disease

Meta-analysis of Randomized Controlled Trials

Kathleen Stergiopoulos, MD, PhD; David L. Brown, MD
Benefits

Improvement of symptoms in 100 people like you after treatment:

<table>
<thead>
<tr>
<th>Medicines alone</th>
<th>Medicines plus stents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td></td>
</tr>
<tr>
<td>One month</td>
<td>One month</td>
</tr>
<tr>
<td>Six months</td>
<td>Six months</td>
</tr>
<tr>
<td>One year</td>
<td>One year</td>
</tr>
</tbody>
</table>

- No improvement
- Feel better

Risks

During stent procedure

In 100 people like you:
- ONE will have a heart attack, stroke or other major complication, 99 will not.
- TWO will have bleeding or damage to a blood vessel, 98 will not.

Bleeding and clotting within one year

In 100 people like you:
- THREE will have a bleeding event from the additional blood thinner needed with a stent, 97 will not.
- TWO will develop a clot that forms in the stent leading to a heart attack, 98 will not.
Coronary artery disease is a CHRONIC disease.

If you don’t choose to have a stent placed now, it’s possible that you could still have one later.

**MEDICINES**

In 15 people like you: THREE will need a stent within one year, 12 will not.

**MEDICINES + STENTS**

In 15 people like you: ONE will need another stent within one year, 14 will not.

Based upon this shared information... What is most important to you?

**Did you know...**

Use of stents for stable coronary artery disease will NOT lower your risk of heart attack or death when compared to using medicines alone.
Direct-to-consumer advertisements continue to urge patients who take warfarin (Coumadin, and others) for atrial fibrillation to ask their doctors about the benefits of one or another of the newer oral anticoagulants.

**WARFARIN** — In patients with nonvalvular atrial fibrillation, warfarin reduces the risk of thromboembolic stroke by about 60%. If necessary, vitamin K, prothrombin complex concentrate, or fresh frozen plasma can reverse its anticoagulant effect. Drawbacks of warfarin include unpredictability and variability in dosage requirements, dietary restrictions, interactions with many other drugs, and the need for close monitoring to keep the international normalized ratio (INR) in the therapeutic range (2-3).
Welcome to the Anticoagulation Choice Decision Aid.

This tool will help you and your doctor discuss how to manage your Atrial Fibrillation.

Let's get started

Caution: This application is for use exclusively during the clinical encounter with your clinician.
To begin, let's review your medical situation

Gender
M F

Age

History of Hypertension
No

Congestive Heart Failure
No

Stroke / TIA / Thromboembolism
No

History of Vascular Disease
No

Diabetes Mellitus
No

Continue to consider your risk of stroke
Over the next 5 years

81 people will have no stroke

9 people will have a fatal or disabling stroke

10 people will have a non-disabling stroke

**Current Risk of Stroke without Anticoagulation**

In 100 people like you who are not taking an anticoagulant
Over the next 5 years:

Current Risk of Stroke without Anticoagulation:
- 81 people will have no stroke
- 9 people will have a fatal or disabling stroke
- 10 people will have a non-disabling stroke

In 100 people like you who are not taking an anticoagulant

Future Risk of Stroke with Anticoagulation:
- 93 people will have no stroke
- 3 people will have a fatal or disabling stroke
- 4 people will have a non-disabling stroke
- 12 people will avoid a stroke by taking anticoagulation
Anticoagulation Routine

Warfarin

- Once daily
- Regular blood tests

Direct Anticoagulants

- Apixaban (Eliquis)
  - AM
  - PM
- Dabigatran (Pradaxa)
  - AM
  - PM
- Edoxaban (Savaysa)
  - Once daily
- Rivaroxaban (Xarelto)
  - Once daily

Are you available to do the regular blood tests that Warfarin requires?
Lessons learnt

User-centered design happens in the field, takes multiple iterations and expertise

Challenges with evidence synthesis and changing evidence

Multipronged approaches to translating CER into practice may be necessary

Engaging the patients as part of the translation process critical
Uptake of CER into Practice

Diffusion of Innovations
Culture
Implementation matters – a bit...
Role of informatics
Perceived need – driven by users
Training and education
Contextualize to the practice
shah.nilay@mayo.edu

http://shareddecisions.mayoclinic.org
Addressing Barriers and Strategies to Enhance the use of CER/PCOR

A Look at Pre-Conference Survey Results

Ernest Law
Outline

• Survey Objectives

• Methods

• Results

• Limitations

• Discussion*
Survey objectives

• To identify the needs and gaps in the uptake and use of PCOR/CER evidence by patients, clinicians, payers

• To identify the best methods or approaches to enhance the uptake and use of PCOR/CER evidence by patients, clinicians, payers

• To stimulate discussion among attendees representing each perspective

• To assist in the development of a consensus document or other enduring material that provides benefit beyond the conference
Methods

• Survey development
  – Focused literature search for barriers and strategies to evidence implementation
  – Reviewed and refined by planning committee
  – Pre-tested with three non-invitees
Methods

• Survey instrument
  – Section 1: **perspective** and **work setting**
  – Section 2: Likert rating scale
    • 10 barriers: "…. extent that the barrier is an issue"
      – 1: None of the time → 4: All of the time
    • 6 strategies: "…effectiveness of the strategy"
      – 1: Not effective → 4: Extremely effective

– Section 3: Free-text
  • **Additional** barriers & strategies
Methods

• Survey administration
  – Web-based platform (Qualtrics)
  – Individual links emailed to registrants
  – Final cut-off for survey submission January 18th
    • 2-3 reminders to complete survey

• Respondents:
  – Conference invitees (selected by members of planning committee)
Methods

• Analysis
  – Descriptive statistics
  – Summary score with Likert responses to rank barriers and strategies
    • 1-None of the time/Not effective
    • 2-Some of the time/Somewhat effective
    • 3-Most of the time/Very effective
    • 4-All of the time/Extremely effective
  – Reported for all respondents & stratified by perspectives
Results

• 64 registrants (as of Jan 18th) emailed

• 46 surveys completed

• 73% response rate
## Primary Work Setting (n=46)

<table>
<thead>
<tr>
<th>Setting</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academia</td>
<td>25</td>
<td>(54%)</td>
</tr>
<tr>
<td>Industry</td>
<td>5</td>
<td>(11%)</td>
</tr>
<tr>
<td>Payer</td>
<td>4</td>
<td>(8%)</td>
</tr>
<tr>
<td>Patient advocacy</td>
<td>3</td>
<td>(7%)</td>
</tr>
<tr>
<td>Government</td>
<td>3</td>
<td>(7%)</td>
</tr>
<tr>
<td>Clinical practice</td>
<td>0</td>
<td>(0%)</td>
</tr>
<tr>
<td>Other*</td>
<td>6</td>
<td>(13%)</td>
</tr>
</tbody>
</table>

*non-profits, consultancy, professional organization, policy research, technology company
Please choose one of the following stakeholder perspectives you feel you can best represent.
## Barriers to CER/PCOR uptake: Ranking*

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Overall</th>
<th>Patient</th>
<th>Clinician</th>
<th>Payer</th>
</tr>
</thead>
<tbody>
<tr>
<td>CER evidence not applicable/lacks relevance.</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Access to CER studies difficult</td>
<td>9</td>
<td>3</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>CER poorly understood concept</td>
<td>8</td>
<td>5</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Lack of trust of CER methods &amp; results</td>
<td>7</td>
<td>8</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Uncertainty with regulations for unpublished data for public use</td>
<td>6</td>
<td>9</td>
<td>7</td>
<td>1</td>
</tr>
</tbody>
</table>

*10 = least encountered barrier; 1 = most extensively encountered barrier*
## Barriers to CER/PCOR uptake: Ranking*

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Overall</th>
<th>Patient</th>
<th>Clinician</th>
<th>Payer</th>
</tr>
</thead>
<tbody>
<tr>
<td>CER not applicable to patient subpopulations</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Lack of CER studies to support decision-making</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Insufficient education on how to interpret/apply CER results</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Lack of tools to incorporate CER into decision-making</td>
<td>2</td>
<td>7</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>There is not enough CER studies to support decision-making</td>
<td>1</td>
<td>6</td>
<td>1</td>
<td>7</td>
</tr>
</tbody>
</table>

*10 = least encountered barrier; 1 = most extensively encountered barrier
Selected additional barriers

• Patient perspective (9 responses):
  – *Peer reviewed manuscripts are intimidating to read, peer reviewed lay person summaries would help*
  – *It is difficult to know which sources of information to trust, e.g., NIH web sources vs. Industry web promotion*
  – *I am in a setting where access to publications is not a problem, but I know from anecdotal evidence that it is a big struggle for others.*
Selected additional barriers

• Clinician perspective (19 responses):
  – Difficulty delivering findings at the point of care in EHRs and clinical systems
  – Lack of an agreed upon systems perspective of the health condition that is being studied
  – Many clinicians who are implementers of CER do not understand the vagaries, biases, and limitations of CER when they have access to the results.
  – Time
Selected additional barriers

• Payer perspective (11 responses):
  – *Timeliness of evidence as it relates to when P&T decisions need to be made*
  – *Traditional marketing and social medial influence patients and clinicians, thereby undermining evidence-based approaches to care.*
  – *Changing the mindset that the RCT is the best way to evaluate a product*
## Strategies to CER/PCOR uptake: Ranking*

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Overall</th>
<th>Patient</th>
<th>Clinician</th>
<th>Payer</th>
</tr>
</thead>
<tbody>
<tr>
<td>More interactive workshops and conferences that explain CER</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Provision of direct-to-patient CER-based education materials</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Face-to-face academic detailing</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Creation of a registry/repository of CER evidence</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>High quality summaries with direct recommendations for decision-making</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Direct practice guideline incorporation</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

*6 = least effective strategy; 1 = most effective strategy
### Strategies to improve CER/PCOR uptake (overall, 46 responses)

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Not effective</th>
<th>Somewhat effective</th>
<th>Very effective</th>
<th>Extremely effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct practice guideline incorporation</td>
<td>21%</td>
<td>45%</td>
<td>34%</td>
<td></td>
</tr>
<tr>
<td>High quality summaries with direct recommendations for decision-making</td>
<td>2%</td>
<td>17%</td>
<td>62%</td>
<td>19%</td>
</tr>
<tr>
<td>Creation of a registry/repository of CER evidence</td>
<td>6%</td>
<td>34%</td>
<td>40%</td>
<td>19%</td>
</tr>
<tr>
<td>Face-to-face academic detailing</td>
<td>9%</td>
<td>51%</td>
<td>34%</td>
<td>6%</td>
</tr>
<tr>
<td>Provision of direct-to-patient CER-based education materials</td>
<td>11%</td>
<td>55%</td>
<td>28%</td>
<td>6%</td>
</tr>
<tr>
<td>More interactive workshops and conferences that explain the purpose,</td>
<td>9%</td>
<td>60%</td>
<td>26%</td>
<td>6%</td>
</tr>
<tr>
<td>scope, and application of CER</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Selected additional strategies

• Patient perspective (8 responses):
  – *In choosing among treatment options, my radiation oncologist sent me copies of recent journal articles.*
  – *Take data to clinician before decision on treatment*
  – *Provide plain language explanations underlying treatment decisions*
  – *"Research Club" for patients*
Selected additional strategies

• Clinician perspective (19 responses):
  – Keep away from new drugs for a period of time
  – Elicit patient goals; build patient relationship/trust
  – Dear Doctor letters with post-marketing updates
  – Enhanced methods regarding lining of different types of data (EMR, claims, PRO, social determinants)
Selected additional strategies

- Payer perspective (10 responses):
  - Outcomes researchers in P&T
  - Having mechanisms for payors to identify research questions that can be studied by CER investigators.
  - Offer CER certification course scholarships for payer representatives from small plans and/or Medicaid plans
  - Ability to sort through data and determine level of applicability, thus infer level of reproducibility in my patient population
Discussion

• Limitation to the survey:
  – Selection bias and generalizability
  – Small (unbalanced) stakeholders subgroups
  – Validity of perspective taken
To be continued in the breakout sessions!

DISCUSSION
What We’ve Learned: Overview of NPC Work on Stakeholder Views and Addressing Barriers to Use

Jennifer Graff
What We’ve Learned: NPC Research on Stakeholder Views and Barriers to Use

January 27, 2017
What PCOR and CER Can Be, It Must Be!

Are PCOR and CER fully developed research approaches? Where are we on the journey? What are the opportunities?

Maslow’s Hierarchy of needs
Insights Today Based On Research Portfolio on Generation, Use and Acceptance of CER

- Employers (Reynolds et al)
- Clinical Practice Guidelines (Wallace et al)
- Medicaid views (Weissman)
- Fit for Use (AcademyHealth)

- Journal Editors (Perfetto et al)

- NPC Annual CER Survey
- Employer, Insurer, Industry View (RAND)
- Employers (Reynolds et al)
- P&T use (Malone et al)
- Medical Policy (Chambers)
CER Remains Important but Impact Remains 3-5 Years Out

Importance of CER

Impact of CER

2016 Annual NPC CER Survey
Journal Editors Use the Same Criteria (ALMOST) for Reviewing Different Types of Studies

“Big data is more data. More bad ‘data’ cannot possibly make better data”

“We always get fewer RCTs than we want, so maybe we have a lower bar. But for RWE, we know we will get enough papers, so “was there an interesting question” becomes more important” - RT participant
Acceptance Varies by Clinical Practice Guideline Group

Rationale for using RWE data

- **When no RCT data is available**: 54%
- **To understand heterogeneity of tx options**: 46%
- **To identify adverse events**: 38%
- **As a supplement to RCT data**: 31%

Most, But Not All, Payers Use RWE For Some Decisions

- Best Available Evidence
- Use to Supplement RCT Findings
- Value of “My Patients”
- Do not Use

How often do you consider/value CER in Rx policies?

- Use
  - Almost never: 11%
  - Sometimes: 78%
  - Often/Almost Always: 11%

- Valuable
  - Almost never: 11%
  - Sometimes: 56%
  - Often/Almost Always: 33%

N=17
Hurwitz et al. Is There Evidence in the Real World that Real World Evidence is Used in P&T Monographs and Therapeutic Class Reviews? JMCP. In press.
Many Types of Evidence Cited in P&T Monographs; Findings Replicated in Medical Policy Review

Proportion of Reference Types by Review Type

<table>
<thead>
<tr>
<th>Published Studies</th>
<th>Therapeutic Class (n = 439)</th>
<th>Single Entity (n = 126)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Published clinical trials</td>
<td>35.3%</td>
<td>15.1%</td>
</tr>
<tr>
<td>Systematic Reviews/Meta-analyses</td>
<td>5.9%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Pharmacoeconomic</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Published RWE studies</td>
<td>4.8%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unpublished Studies</th>
<th>Therapeutic Class (n = 439)</th>
<th>Single Entity (n = 126)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal analyses</td>
<td>0.2%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Meeting abstracts (e.g., posters, symposia, presentations)</td>
<td>0.7%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Manufacturer info (e.g., product labels, data on file, &quot;daily med&quot;)</td>
<td>18.9%</td>
<td>42.1%</td>
</tr>
<tr>
<td>Expert/consensus statements</td>
<td>9.6%</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

N=17

Hurwitz et al. Is There Evidence in the Real World that Real World Evidence is Used in P&T Monographs and Therapeutic Class Reviews? JMCP. In press.
### Recommendations to Increase CER’s Impact

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Better translation of CER results into actionable recommendations</td>
<td>59%</td>
</tr>
<tr>
<td>Increased infrastructure and resources for decision-makers to use CER results</td>
<td>43%</td>
</tr>
<tr>
<td>Improving the relevance of CER questions</td>
<td>40%</td>
</tr>
<tr>
<td>Broader dissemination of CER results</td>
<td>37%</td>
</tr>
<tr>
<td>Improving the adequacy of databases used for CER</td>
<td>34%</td>
</tr>
<tr>
<td>Improving the quality of CER methods</td>
<td>31%</td>
</tr>
<tr>
<td>Greater input into CER from patients</td>
<td>20%</td>
</tr>
<tr>
<td>Greater input into CER from those who provide medical services</td>
<td>20%</td>
</tr>
</tbody>
</table>

N=137

2016 NPC Annual CER and the Environment for Health Care Decision-Making Survey
1. Ask An Important Question

- Question:
  - Delivery system reform, care coordination, wellness programs
- Endpoints
  - Long-term safety, impact on performance measures
- Comparators (usual care vs. optimal usual care)
- Population

Reynolds et al. 2010; Sabharwal RK, AJMC 2015;21(9); Malone et al
2. Understand Who CARES?

“Who’s the audience they’re trying to influence and what’s important to them? And so, if you want a payer to pay attention you have to have economic endpoints in the study.” - Payer

- Report break down of composite endpoints (Major CV event, total cost of care vs. individual endpoints or costs)
- Make the endpoints translatable to practice (post index costs vs. Per member/per month; return to work for stroke)
- Ability to apply to work force vs. retirees (Employers)
- Simplify the language
3. When? How Much?

• Timing Matters

• Evidence needed when uncertainty exists (changing patterns of use, clinical practice guidelines)

• More Impact — Not Just More Evidence

• Impact must justify the resources required to change practice (cost for administration etc.).
No Rosetta Stone Exists For Observational Studies
5. Lack of Standards Impacts All Stakeholders; Policies Are Needed to Gain Consensus

39% addressed by less than half of the best practices
61% addressed by most best practices
• 2 agree on how to do
• 12 disagree on how to do

Policies Needed:

1. Gain Alignment
   Perspectives may differ, but what items are included should not

2. Agree on Level of Consensus
   Minimum standards rather than best practices are most achievable

3. Garner Consensus
   Stakeholders should convene in an iterative process to gain consensus

4. Encourage Consensus
   Voluntary adoption is most likely for success

Morton SC. Journal of Clinical Epidemiology. 2015; online.
Barriers to Use – Payers
Mix of Systematic and Research Issues

Study not relevant
much effort to find/interpret
Methods too complex
Methods not transparent
No control for confounding
Not timely
Experience conducting
Experience interpreting

N=18; Barriers to use of observational studies in decision-making
6. Improve the Transparency of Methods

Share the population and generalizability

- Are they like my patients?
- Are the sites like my site?.

Be transparent in the study analysis and processes

- Methods are too complex (CPGs, Payers)
- Methods insufficiently explained (CPGs; Payers)
- Is it the first or the 12th analysis?
- Can this be recorded in a time box/lock registration?
Evaluate indirect treatment comparison studies and their usefulness in decision-making.

Assess the value of an observational study in CER by examining its relevance and credibility.

Use transparent methods to detect the presence of confounding in a case example.

Evaluate observational studies and their usefulness in decision-making.

Perfetto EM et al. JMCP 2016;22(6):609-16
8. Trust...in Data, Research, and Communication

• Trust the data?
  • Is it accurate, complete, and validate? (Kahn et al)
  • “I know where the holes (in the data) are” – Payer
  • “If they don’t know the datasets, can reviewers really evaluate those studies?” –Journal editor

• Trust the research type/validity?
  • Clinician acceptance?
  • Funding source/affiliation

• Trust and intermediary?
  • Employee health benefits consultant?
  • Clinical Practice Guidelines
  • Seal of approval on good studies?

Reynolds 2010.
9. Build Infrastructure to Make it Easy

- Easier to communicate results
- Easier to access data
- Easier to interpret data
  - More evidence = more time and resources
  - Expertise not typically on guideline development group
- Easier to understand impact to specific patients
10. CER should be collaborative... Not comparative between disciplines and stakeholders
What PCOR and CER Can Be, It Must Be!

Are PCOR and CER fully developed research approaches? Where are we on the journey? What are the opportunities?

Maslow’s Hierarchy of needs
Break
A Deeper Dive: Small Group Discussions
Observations: Reports from Small Group Discussions and Overall Consensus
Lunch and Presentation: A Learning Network - Improving the Dissemination of PCOR-Based Clinical Decision Support

Barry Blumenfeld, RTI International
The Patient Centered Outcomes Research Clinical Decision Support Learning Network (PCOR CDS-LN)

Transforming Patient Centered Research into Action

Barry Blumenfeld, MD, MS
bhb@rti.org
Learning Objectives for Today

– What is the PCOR CDS Learning Network?
– Some Key Concepts
– What We Have Learned So Far?
– What We are Doing Next
Translating knowledge gained from Patient-Centered Outcomes Research (PCOR) into clinical practice is key to healthcare quality improvement. A promising way to ensure that PCOR informs clinical care is through clinical decision support (CDS), which uses technical and non-technical approaches to make it easier for care teams – including patients – to make decisions and take actions known to enhance outcomes.
Definitions we are Using

PCOR IS...
The ACA defines PCOR as, “comparative clinical effectiveness research on the impact of patient health outcomes of two or more preventive, diagnostic, treatment, or health care delivery approaches.”

CDS is...
Clinical Decision Support (CDS) is a process for enhancing health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery. Information recipients can include patients, clinicians and others involved in patient care delivery; information delivered can include general clinical knowledge and guidance, intelligently processed patient data, or a mixture of both; and information delivery formats can be drawn from a rich palette of options that includes data and order entry facilitators, filtered data displays, reference information, alerts and others.*

A Short Story - Patient-Centered CDS
What is the evidence for self-measured BP monitoring?
A Short Story - Patient Centered CDS

The Clinician:

1. Has difficulty finding specific evidence among multiple sources
2. Questions which evidence is most reliable
3. Needs to know about evidence that is actionable both for her and the patient
4. Wonders what the evidence says around what is measurable
The Clinician Wants:

1. One or more repositories with PCOR-enabled CDS tools

2. Embedded clinical care and patient engagement that generate secure and reliable data

3. Confidence that any CDS tool fits into the EHR and workflow

4. Clinically meaningful results for her care and reimbursement
The Patient:

1. Has concerns with the side effects of her meds
2. Knows that her pen and paper logs are inconsistently used
3. Is open to the idea of sharing data with her MD “in theory”
4. Agrees technology could be helpful but “not good with computers”
The Patient Wants:

1. To learn how she can mitigate side effects
2. Support to improve how she tracks her data from the convenience of home
3. Her safety, privacy, and reliability concerns to be addressed
4. Usable tools and data that help her self-measure her BP for improved decision-making
A Short Story - Patient Centered CDS

Delivering evidence through CDS...
to promote patient-centered care...
Requires collaboration among multiple stakeholders.

The PCOR CDS Learning Network

Our Mission
To create a learning network that allows stakeholders to turn knowledge from patient-centered evidence and practices* into clinical decision support (CDS) that improves care and outcomes.

Inform         Connect         Advance

• 4 year Cooperative agreement awarded by AHRQ
• Period of performance: 4/2016 – 1/31/2020
• PI: Barry Blumenfeld, MD, MS, (bhb@rti.org)
• Senior Investigators: Blackford Middleton, MD, MPH, MSc and Jerome Osheroff, MD, Robert Greenes, MD, PhD, and Kensaku Kawamoto, MD, PhD, MHS

*Includes CER and PCOR
PCOR CDS Learning Network Strategies

- **Inform**
  - Provide Stakeholders with a broad array of up-to-date information germane to Patient-Centered CDS

- **Connect**
  - Provide information and services that allow stakeholder to connect and collaborate

- **Advance**
  - Foster the collaborative development of concepts, frameworks, policies and standards for Patient-Centered CDS
What We’ve Learned so far...
Key Concepts

PCOR
Findings

CDS
Key Concepts: PCOR-Enabled CDS
*This is a new term and is still being defined
Patient Centered CDS is a broader concept and subsumes PCOR-Enabled CDS.

Patient Centered CDS is both a channel for PCOR findings and a source of data for research.
One of the first activities of the PCOR CDS-LN was to identify barriers and facilitators to the dissemination of PCOR-Based CDS. A critical artifact that grew out of this effort is the Analytic Framework for Action (AFA).

The AFA provides a means by which we can organize the findings and recommendations of the PCOR CDS-LN. It represents the lifecycle of activities that must occur to disseminate POCR through CDS, measure impact, and create a learning system.
Step 1: Applying objective measures of evidence for identifying and prioritizing PCOR findings that are to be transformed and disseminated via Patient–Centered CDS, assessing or defining their implementability, and defining stewardship and governance requirements.
Step 2: Applying consensus-based data and knowledge standards for translating PCOR findings into CDS interventions that support comparative and/or patient-centered decision-making (i.e. risk calculators, cognitive aides).
Step 3: Applying standardized methods and architectures for operationalizing CDS interventions into clinical workflows, which deliver the right information to the right people in the right formats through the right channels at the right times ("CDS Five Rights").
Step 4: Ensuring that CDS interventions measurably improve clinician and patient decision-making, care processes, and outcomes.
Step 5: Aggregating local CDS-related outcomes and effectiveness measures to facilitate patient-centered, system level learning from identified gaps in PCOR knowledge, clinical practice, and patient outcomes.
Throughout the Process: Recognize and manage external factors including the marketplace, policy, legal, and governance factors that impact development, dissemination, and implementation processes for patient-centered CDS.
The Environmental Scan: A “Springboard for Action”

- Purpose: Examine the barriers and facilitators to the use of CDS as a vehicle for putting PCOR findings into practice to improve outcomes.

- Goal: Give the PCOR CDS-LN a comprehensive review of the current state of the field to include: technologies and architectures; user needs; policy; and more.
Online Bibliography

- 316 citations
- PubMed, PCORI, Executive Committee recommendations
- Organized by Analytical Framework for Action
- Collection to be curated and disseminated
- Citations to be appended to the Environmental Scan

https://www.zotero.org/groups/pcor_cds-ln_envscan/items
## Some Barriers and Facilitators

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Facilitator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defining PCOR</td>
<td>Refine definition of PCOR</td>
</tr>
<tr>
<td>Defining and Describing Patient-Centered CDS</td>
<td>Generate a use cases</td>
</tr>
<tr>
<td>Access to Literature Around Patient-Centered CDS</td>
<td>Online bibliography</td>
</tr>
<tr>
<td>Costs and Competing Priorities for development and implementation</td>
<td>Estimate development and implementation costs in use case</td>
</tr>
<tr>
<td>Identifying PCOR to be disseminated via CDS</td>
<td>Build and/or extend partnerships with AHRQ and PCOR</td>
</tr>
<tr>
<td>Means for Evaluating PCOR for Patient-Centered CDS</td>
<td>Develop a resource with evaluation tools</td>
</tr>
<tr>
<td>Access to PCOR for Patient Centered CDS</td>
<td>Plan with AHRQ for development and dissemination of a repository</td>
</tr>
<tr>
<td>Patient-Centered CDS Not Aligned with Payer Priorities</td>
<td>Involve payers to insure payer perspectives</td>
</tr>
</tbody>
</table>

Full report available at: [http://www.pcorcds-ln.org](http://www.pcorcds-ln.org)
The Barriers and Facilitators Workgroup

- Propose criteria for selecting PCOR findings to be used as use cases
- Determine PCOR findings to be applied in use cases
- Populate a use case matrix (see below), which is organized by the Analytic Framework for Action
- Disseminate findings
Million Hearts Initiative: SMBP Monitoring

http://millionhearts.hhs.gov/tools-protocols/smbp.html
<table>
<thead>
<tr>
<th>Current State</th>
<th>Barriers</th>
<th>Facilitators</th>
<th>Recommendations</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Addressing External Factors</strong> (Marketplace, Policy, Legal, Governance)</td>
<td>Uncertain marketplace</td>
<td>Marketplace has been and remains challenging in that vendors don’t implement CDS in any standardized way</td>
<td>MITRE Corp developing repository and PCOR CDS artifact</td>
<td>Build personalized patient medical/pharmacy coverage into CDS (antihypertensive tiering/preferred Rx etc.)</td>
</tr>
<tr>
<td><strong>Prioritizing PCOR</strong> (What findings are appropriate given level of evidence, priorities, available data, etc.)</td>
<td>PCOR has a new dissemination group to potentially prioritize PCOR</td>
<td>Differences between the inclusion criteria and methodology of clinical trials/observational data and “real-life” application</td>
<td>“High quality” and “scientifically sound” PCOR evidence</td>
<td>Publicly available criteria for prioritizing PCOR</td>
</tr>
<tr>
<td><strong>Authoring CDS</strong> (Intervention Types, Knowledge issues, Data issues)</td>
<td>A host of API-based services and approaches increasingly available</td>
<td>Access to Reliable PCOR Measures When Authoring PCOR-Based CDS</td>
<td>NA</td>
<td>Publish a library of approved patient-reported data sets and measures</td>
</tr>
<tr>
<td><strong>Implementing CDS Interventions</strong> (Localization issues, architecture/methods, workflow integration,)</td>
<td>Variable degrees of monitoring the status of implementation and maintenance</td>
<td>Providers not trained to integrate PCOR into workflow</td>
<td>Leadership commitment to CDS as an intervention</td>
<td>Identify known implementation strategies and tools for improving care delivery that are transferable to PCOR-based CDS</td>
</tr>
<tr>
<td><strong>Measuring Decisions and Actions</strong> (Measuring CDS efficacy and impact as well as value delivered and ROI/cost-benefit)</td>
<td>Ad hoc recording between home and clinic settings muddies measurement</td>
<td>Uncertainty as to how the patient’s role in the intervention captured</td>
<td>Providers already reporting BP control for a number of measures and so there is momentum for expanding to this guideline</td>
<td>Publish a use case that identifies barriers and opportunities for measuring the effects of PCOR-based CDS</td>
</tr>
<tr>
<td><strong>Learning from PCOR-based CDS Experience</strong> (Feeding results back to broadly enhance care/ outcomes/guidance faster)</td>
<td>CDS monitored within HCOs</td>
<td>Unknown how to integrate PCOR-Based CDS into a Learning Health System</td>
<td>Hardwired CQI process at team, department, organization, insurer, gov levels</td>
<td>Evaluate whether specific patient subgroups respond to different CDS approaches</td>
</tr>
</tbody>
</table>
Finding: There is a need to help both patients and clinicians navigate to PCOR findings suitable for CDS implementation.

Our Experience:
- Current resources (e.g. guidelines.gov) didn’t help to narrow
- The BFWG arrived at SMBP Monitoring through our network of experts rather than a particular source

Recommendation: Invent or build on a repository with vetted PCOR by levels of implementability.
Finding: PCOR-based patient-centered information is not offered in any type of machine-readable format

Our Experience:
– The SMBP Monitoring guideline is a narrative handout geared to clinicians and patients
– The SMBP Monitoring guideline and others elsewhere don’t provide machine-readable logic

Recommendation: Work with CDC to plan and develop its SMBP Monitoring guideline as CDS
Takeaway 3...

Finding: Unclear how SMBP monitoring data will be accurately and consistently reported in the patient record

Our experience:

- What, if any, PCOR evidence is there around reminders for patients at home to self measure BP?
- How do data in SMBP reflect factors such as device type (ambulatory BP monitor vs home BP monitor), patient position (supine vs sitting), etc.?

Recommendation: Collaborate with researchers and vendors around ways to structure and capture SMBP monitoring data
Where We Are Going...
Welcome to the Patient-Centered Outcomes Research (PCOR) Clinical Decision Support (CDS) Learning Network

Creating an ecosystem which allows all stakeholders to reduce the friction of turning knowledge from PCOR findings into CDS-enabled actions to produce better care and outcomes.
Activities in 2017

- **Key Topic Workgroups**
  - Barriers and Facilitators (in progress)
  - Dissemination
  - Technical Standards
  - Evaluation
  - Sustainability
- **Enhancing the Collaboration Hub** [www.pcorcds-ln.org](http://www.pcorcds-ln.org)

- **Annual Meeting**
  - 2nd Annual Meeting in September 2017, Washington DC (open attendance)

- **Planning E-Journal** focused on Patient-Centered CDS in 2017
- **Developing consensus recommendations and reports**
- **Promoting Patient-Centered CDS research**

Engaging and Collaborating with You!
Questions?

- Contact Information
  - Barry Blumenfeld, MD, MS (bhb@rti.org)
  - Collaboration Hub: http://www.pcorcds-ln.org
What Is the Future of CER and CER Education? How Will CER Be Integrated Into Practice?

Diana Brixner, University of Utah & President-Elect, Academy of Managed Care Pharmacy (AMCP)
Bill Galanter, University of Illinois at Chicago
Lou Garrison, University of Washington & President, International Society of Pharmacoeconomics and Outcomes Research (ISPOR)
Perspectives on the Future of Comparative Effectiveness in Research, Education and Practice

Diana Brixner, RPh, PhD
Professor, Department of Pharmacotherapy
Executive Director of Pharmacotherapy Outcomes Research Center
Director of Outcomes, Program in Personalized Health
Academy of Managed Care Pharmacy President Elect
The opportunity for CER has never been brighter

• CER is being considered for regulatory decisions for medical devices
• Data sources available to conduct CER is growing
• Research methods for CER are rapidly improving
• CER education is being integrated into medical/pharmacy schools and for health care decision makers
• Health plans and systems are increasingly using CER evidence in decision making
• Significant efforts to increase information exchange between manufacturers and health care decision makers are ongoing
• Value based care in infiltrating health care practice

What more could we want???
CER and Medical Devices

• The Center for Biologics Evaluation and Research (CBER) has recognized the following in evaluation of medical devices for regulatory decisions
  – There is limited clinical trial evidence
  – Evidence for medical devices often exists in the HER
  – Such data may be supportive in evaluating benefit-risk

• Could such evidence also support regulatory decisions for Drugs? Time will tell..

• We are currently conducting an observational study within a health plan to evaluate the cost-effectiveness of a MBDA test in RA to better target use of biologics

CER and Big Data

- PCORnet, the National Patient-Centered Clinical Research Network, is designed for faster, easier, and less costly clinical research. Visit [http://www.pcornet.org](http://www.pcornet.org)

- Clinical and Translational Science Awards (CTSA) program is incorporating emerging data and technology into its vision statement. Find more at [https://www.ncbi.nlm.nih.gov/books/NBK169207/](https://www.ncbi.nlm.nih.gov/books/NBK169207/)

- Biologics and Biosimilars Collective Intelligence Consortium is a managed care organizational infrastructure to enable active surveillance of biosimilars in distributed research networks (DRNs). Explore more at [http://www.amcp.org/BBCIC/](http://www.amcp.org/BBCIC/)

- CancerLinQ, HMO Network, Vizient (UHC) and others.

But there are challenges!
Improving CER Methods

• ISPOR Good Practice Guidelines\(^1\)
  – Comparative effectiveness research methods
  – Observational study methods
  – Economic evaluations and modeling
  – Clinical Outcomes Assessment
  – Use of Outcomes Research in Health Care Decision Making

• More sophisticated methodologies in CER
  – Indirect treatment comparisons
  – Multi criteria decision analysis
  – Causal inference
  – Predictive analytics
  – Dynamic Treatment Regimes

\(^1\) https://www.ispor.org/workpaper/practices_index.asp
Addressing CER Educational Needs

• AMCP-NPC-ISPOR CER Certificate Program

• PhRMA Foundation CER Education Grants

• CER Study checklists
  – STROBE
  – GRACE Principles

• The perspective of the learner is very important
  – Students/Fellows
  – Researchers
  – HCDMS
  – HCPs

• ISPOR and AMCP working together on education and expertise exchange between researchers and payers

Increasing the Exchange of Health Care Economic Information (HCEI) between Manufacturers and Health Care Decision Makers (HCDMs)

• The AMCP Partnership Forums
  – Improving the Exchange of Pharmacoeconomic Data, to clarify and update FDAMA section 114¹
  – Enabling the Exchange of Clinical and Economic Data Pre-FDA Approval, to more easily share information on products awaiting FDA approval for forecasting, benefit design and efficient formulary decision making²

• AMCP Format 4.0³
  – Value Framework for the evaluation of new products
  – Continuous adaptation to accommodate information exchange

• All this work has led to draft guidance on drug and device communications⁴

Getting CER Imbedded into Practice

• Going from Volume to Value Driven Health Care\(^1\)

TRUE REFORMS
• Adequate payment for high-value services by specialists as well as primary care
• Condition-based payments to support the best outcomes, not just lower procedure costs
• Accountability for costs and quality that providers can control, not shifting “full risk”
• Accessible data on the utilization and prices for all services in every community
• Support for community-based, multi-stakeholder solutions to high-value delivery & payment

A SUSTAINABLE FUTURE
• Collaboration to develop innovative solutions for better quality and lower costs
• Competition to achieve the most effective implementation of solutions
• Savings from eliminating avoidable services, not denying access to needed care
• Rewards for providers based on cost and quality outcomes, not their size or structure
• Patients able to access affordable care that enables them to be healthy and productive

Value Based Insurance Design\(^2\)
  – encourages the use of services when the clinical benefits exceed the cost and likewise discourages the use of services when the benefits do not justify the cost

\(^1\)http://www.chqpr.org/goals.html
\(^2\)http://content.healthaffairs.org/content/26/2/w195.abstract
Getting CER Imbedded into Practice

• Bring researchers and HCDMs closer together
  – Outcomes researchers on P&T committees
  – Joint positions between academia and health plans to support relevant research
  – CER conducted in health plans and systems
    • Validate models with health plan data
    • Conduct observational studies within health plans

• Value Driven Outcomes in Health Systems
  – Understanding costs and related outcomes across system
  – Identify High Variability in Clinical Costs and Outcomes and Association With Reduced Cost and Improved Quality

http://jamanetwork.com/journals/jama/article-abstract/2552208
The opportunity for CER has never been brighter 🌞🌞

Thank you!

My daughter

ME

Thank you!
How Will CER Be Integrated Into Practice?
-Use of Clinical Decision Support and EHR’s to promote use of CER by clinicians, past & future

Bill Galanter, PhD, MD, MS
Chair, P & T Committee
Associate Chief Health Information Officer
Faculty, Colleges of Medicine & Pharmacy
Associate Professor of Medicine
University of Illinois at Chicago

January 27, 2017
Disclosure of Conflicts

None

Funding

AHRQ: U19HS021093, U18HS016967, U18HS016973

Attorney General Consumer and Prescriber Education Grant Program

NPSF
Goal is the best treatment for the particular patient at the specific time

CDS can assist in many area’s of medication use;

- Therapeutic decisions
- Prompting Use
- Shared decision making
- Dosing
- Patient education
- Monitoring
Targets for medication use CDS

- **Patient** beliefs, genotypes, insurance, preferences
- **Rx** Drug name similarity
- **Lab**
- **Dx**

CDS for Clinician: EHR → CDS
Evidence/CER Based Guidelines

Anticoagulation Committee

P&T/Pharmacy

MSEC

*GUIDELINE*

IS

EHR/CDS

Venous Thromboembolism (VTE) Prophylaxis
June 2015

Key Content Expert: Mathew Thambi, PharmD, MPH and Bill Galanter, MD/PhD, UIH Anticoagulation QI Committee

Approved By: Medical Staff Executive Committee
# Evidence/CER Based Order Set

## Anticoagulation Committee

### P&T/Pharmacy

### MSEC

### *GUIDELINE*

### IS

### EHR/CDS (Order Set)

---

<table>
<thead>
<tr>
<th>Component</th>
<th>Order Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SECTION 4: Pharmacological Prophylaxis (Must-Select One)</strong></td>
<td></td>
</tr>
<tr>
<td>✔ Patient on Therapeutic Anticoagulation</td>
<td></td>
</tr>
<tr>
<td>✔ Pharmacological Prophylaxis Contraindication (transient)</td>
<td></td>
</tr>
<tr>
<td>✔ Pharmacological Prophylaxis Contraindication Permanent</td>
<td></td>
</tr>
<tr>
<td>✔ Patient Ambulating, No Pharmacologic Prophylaxis Indicated</td>
<td></td>
</tr>
<tr>
<td><strong>Low Risk Prophylaxis Medications</strong></td>
<td></td>
</tr>
<tr>
<td>✔ heparin</td>
<td>5,000 units, INJECTION, SC, Q12H</td>
</tr>
<tr>
<td>✔ enoxaparin (enoxaparin for prophylaxis)</td>
<td>30 mg, INJECTION, SC, Q12H</td>
</tr>
<tr>
<td>✔ enoxaparin (enoxaparin for prophylaxis)</td>
<td>40 mg, INJECTION, SC, Q24HR - non-std time</td>
</tr>
<tr>
<td>✔ fondaparinux</td>
<td>2.5 mg, INJECTION, SC, DAILY</td>
</tr>
<tr>
<td><strong>High Risk Prophylaxis Medications excluding THA/THA</strong></td>
<td></td>
</tr>
<tr>
<td>✔ heparin for BMI ≤ 50 kg/m2</td>
<td>5,000 units, INJECTION, SC, Q12H</td>
</tr>
<tr>
<td>✔ heparin for BMI ≥ 50 kg/m2</td>
<td>7,500 units, INJECTION, SC, Q12H</td>
</tr>
<tr>
<td>✔ enoxaparin (enoxaparin for prophylaxis)</td>
<td>30 mg, INJECTION, SC, Q12H</td>
</tr>
<tr>
<td>✔ enoxaparin (enoxaparin for prophylaxis)</td>
<td>40 mg, INJECTION, SC, Q24HR - non-std time</td>
</tr>
<tr>
<td>✔ fondaparinux</td>
<td>2.5 mg, INJECTION, SC, DAILY</td>
</tr>
<tr>
<td><strong>Total Hip Medications</strong></td>
<td></td>
</tr>
<tr>
<td>✔ warfarin (warfarin*)</td>
<td>mg, TABLET, PO, QHS</td>
</tr>
<tr>
<td>✔ aspirin</td>
<td>325 mg, EC TABLET, PO, BID</td>
</tr>
<tr>
<td>✔ enoxaparin (enoxaparin for prophylaxis)</td>
<td>30 mg, INJECTION, SC, Q12H</td>
</tr>
<tr>
<td>✔ enoxaparin (enoxaparin for prophylaxis)</td>
<td>40 mg, INJECTION, SC, Q12H</td>
</tr>
<tr>
<td>✔ enoxaparin (enoxaparin for prophylaxis)</td>
<td>40 mg, INJECTION, SC, Q24HR - non-std time</td>
</tr>
<tr>
<td>✔ fondaparinux</td>
<td>2.5 mg, INJECTION, SC, DAILY</td>
</tr>
<tr>
<td>✔ rivaroxaban is contraindicated in CrCl ≥30ml/min</td>
<td></td>
</tr>
<tr>
<td>✔ rivaroxaban</td>
<td>10 mg, TABLET, PO, Q24HR - non-std time</td>
</tr>
<tr>
<td><strong>Total Knee Medications</strong></td>
<td></td>
</tr>
<tr>
<td>✔ aspirin</td>
<td>325 mg, EC TABLET, PO, BID</td>
</tr>
<tr>
<td>✔ fondaparinux is contraindicated in CrCl ≥30ml/min</td>
<td></td>
</tr>
<tr>
<td>✔ fondaparinux</td>
<td>2.5 mg, INJECTION, SC, DAILY</td>
</tr>
<tr>
<td>✔ rivaroxaban is contraindicated in CrCl ≥30ml/min</td>
<td></td>
</tr>
<tr>
<td>✔ rivaroxaban</td>
<td>10 mg, TABLET, PO, Q24HR - non-std time</td>
</tr>
</tbody>
</table>

CDS for Metformin Contraindication
(Can you change behavior with pop-up’s?)

- **SEVERE**
  - CrCl <30

- **MODERATE**
  - CrCl 30-50

- **MILD**
  - CrCl 50-60

- **ALL**

Proportion receiving Med

- Pre-Alert
  - *P=<=0.001

- Post-Alert
  - SEVERE
  - MODERATE
  - MILD

*Can you change behavior with pop-up’s?*
Individualized dosing of warfarin

Initial dose of warfarin
CDS Directed Education

Pharmacogenomics Alert

Genetic testing to determine warfarin metabolism and sensitivity is now routine for patients newly starting warfarin at UI-Health. Warfarin has a narrow therapeutic index, and inappropriate dosing can increase hospital length of stay and risk for bleeding. Genetic information can assist in more effective warfarin dosing. If the patient was taking warfarin as an outpatient, warfarin should be dosed accordingly.

If this patient is new to warfarin, and the goal INR is 2-3, an initial warfarin dose of 3.6 mg is recommended, which should be rounded to the nearest 0.5 mg and considered in the context of clinical factors.

If the INR goal is not 2-3, please talk to your service pharmacist or page #4361. A consult with the pharmacogenomics service will automatically be provided to assist you with interpreting genotype results and dosing warfarin. If you would like to learn more about the pharmacogenetics of warfarin or the UI-Health warfarin dosing guidelines hit the evidence link below. Please page the pharmacogenetics service at #4361 with any questions.
Pharmacogenetics Service

The Pharmacogenetics Service is supported by the Office of the Vice President for Health Affairs and serves as a consult service with Clinical Directorship provided by PharmDs experienced in warfarin pharmacogenetics and anticoagulation, Medical Directorship provided by physicians from Cardiology and Medicine, and Laboratory support provided by the CLIA and CAP accredited Molecular Pathology Laboratory.

The service is responsible for validating and reporting pharmacogenetic test results, providing patient assessment and warfarin dose estimations, serving as a source within the medical center for education and information on warfarin pharmacogenetics, and providing quality assurance assessment of warfarin–pharmacogenetic testing.

<table>
<thead>
<tr>
<th>Warfarin Genetics</th>
<th>Clinical Utility of Warfarin Pharmacogenetics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidelines for Warfarin Dosing based on Genotype</td>
<td>Genetic Information in the Warfarin Labeling</td>
</tr>
<tr>
<td>Pharmacogenetics Service Team</td>
<td>For More Information about Warfarin Genetics</td>
</tr>
</tbody>
</table>

UI-HEALTH Warfarin Use Guideline G-13.23
Dosing Procedure

College of Pharmacy Seminar 7/25/12 (Video)
CDS Directed Education

Statin Alert

TENTH FLOOR, TEST DUAL MRN has an active order for atorvastatin.

Gemfibrozil **should not** be ordered as these two drugs when used together increases the risk of rhabdomyolysis twelve-fold.

There is no compelling inpatient use for this combination.

For more information regarding the risks of using these two drugs together, click on the 'Article' button below.

For clinical questions related to this alert, please contact the PharmD covering your unit or page the PharmD on call (#4958).
Context Lipid-lowering agents are widely prescribed in the United States. Reliable estimates of rhabdomyolysis risk with various lipid-lowering agents are not available.

Objective To estimate the incidence of rhabdomyolysis in patients treated with different statins and fibrates, alone and in combination, in the ambulatory setting.

Design, Setting, and Patients Drug-specific inception cohorts of statin and fibrate users were established using claims data from 11 managed care health plans across the United States. Patients with at least 180 days of prior health plan enrollment were entered into the cohorts between January 1, 1998, and June 30, 2001. Person-time was classified as monotherapy or combined statin-fibrate therapy.

Main Outcome Measure Incidence rates of rhabdomyolysis per 10 000 person-years of treatment, number needed to treat, and relative risk of rhabdomyolysis.

Results In 252 460 patients treated with lipid-lowering agents, 24 cases of hospitalized rhabdomyolysis occurred during treatment. Average incidence per 10 000 person-years for monotherapy with atorvastatin, pravastatin, or simvastatin was 0.44 (95% confidence interval [CI], 0.20-0.84); for cerivastatin, 3.34 (95% CI, 1.46-13.68); and for fibrate, 2.82 (95% CI, 0.38-8.24). By comparison, the incidence during unexposed person-time was 0 (95% CI, 0-0.48; P = .056). The incidence increased to 5.98 (95% CI, 0.72-216.0) for combined therapy of atorvastatin, pravastatin, or simvastatin with a fibrate, and to 1035 (95% CI, 389-2117) for combined cerivastatin-fibrate use. Per year of therapy, the number needed to treat to observe 1 case of rhabdomyolysis was 22 727 for statin monotherapy, 484 for older patients with diabetes mellitus who were treated with both a statin and fibrate, and ranged from 9.7 to 12.7 for patients who were treated with cerivastatin plus fibrate.

Conclusions Rhabdomyolysis risk was similar and low for monotherapy with atorvastatin, pravastatin, and simvastatin; combined statin-fibrate use increased risk, especially in older patients with diabetes mellitus. Cerivastatin combined with fibrate conferred a risk of approximately 1 in 10 treated patients per year.

Conclusions Published online November 22, 2004 (doi:10.1001/jama.292.21.2585).

Disorders of muscle, ranging in severity from asymptomatic creatine kinase elevation to rhabdomyolysis, are among the most discussed adverse effects associated with use of lipid-lowering agents, especially 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors (statins).1,2,5 Fibrates also have been associated with primary muscle injury, especially when used in combination with a statin.5,6,11

The epidemiology of statin-associated and fibrate-associated myopathy is poorly described, with most attention focused on rhabdomyolysis. Based on review of case reports, older age, female sex, low body mass index, hypothyroidism, diabetes mellitus, and impaired renal or hepatic function have been cited as potential risk factors for rhabdomyolysis,10,11 but these have not been confirmed by clinical trials or observational studies. Myopathy, defined as a serum creatine kinase level of more than 10 times the upper limit of normal, has been estimated to occur in 0.1% to 0.5% of patients treated with statins during randomized controlled trials.10 However, the incidence of rhabdomyolysis has not been reliably estimated. The product labeling for some statins presents incidence estimates for myopathy and rhabdomyolysis combined, although in labeling for other statins the occurrence of rhabdomyolysis is described separately.14,15 One epidemiologic study estimated the incidence of myopathy associated with lipid-lowering drugs at 2.3 per 10 000 person-years of treatment and suggested that fibrate use as monotherapy conferred a 5.5-fold increased risk compared with statin use.15 Another study reported 1 case of rhabdomyolysis among 2935 patients treated concurrently with a statin and fibrate.16 Two separate analyses, based on case reports submitted to the US Food and Drug Administration, found that reporting of rhabdomyolysis was greater for cerivastatin and cerivastatin than for other statins,18 and that reporting of fatal rhabdomyolysis was 17- to 79-fold greater for cerivastatin than for other statins.18

Following the withdrawal of cerivastatin from the US market in August 2001 because of high reporting of rhabdomyolysis in association with its use,18 we conducted this study to estimate the incidence of rhabdomyolysis in patients treated with statins and fibrates, alone and in combination, in the ambulatory setting.
CDS (Reminders/Order Set) effect on VTE Prophylaxis rates

% of patients receiving pharmacologic Prophylaxis

Months pre- & post-intervention

-12 -10 -8 -6 -4 -2 0 2 4 6 8 10 12
CDS effect on VTE event rates

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. Events/ No. Admissions (%)</th>
<th>No. Events/ No. Admissions (%)</th>
<th>Relative Changea %</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Control Group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total VTE</td>
<td>94/18,317 (0.51)</td>
<td>87/20,330 (0.43)</td>
<td>−15.7</td>
<td>0.22</td>
</tr>
<tr>
<td>VTE by discharge service type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>47/8,516 (0.55)</td>
<td>33/9,981 (0.33)</td>
<td>−40.0</td>
<td>0.02</td>
</tr>
<tr>
<td>Neurology</td>
<td>3/690 (0.43)</td>
<td>7/706 (0.99)</td>
<td>NAb</td>
<td>0.34</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>29/1,533 (1.89)</td>
<td>27/1,731 (1.56)</td>
<td>NA</td>
<td>0.47</td>
</tr>
<tr>
<td>Obstetrics/gynecology</td>
<td>1/2,844 (0.04)</td>
<td>3/3,011 (0.10)</td>
<td>NA</td>
<td>0.63</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>4/487 (0.82)</td>
<td>6/456 (1.32)</td>
<td>NA</td>
<td>0.54</td>
</tr>
<tr>
<td>Surgical</td>
<td>10/4,247 (0.24)</td>
<td>11/4,445 (0.25)</td>
<td>NA</td>
<td>0.91</td>
</tr>
<tr>
<td>Total major bleeding</td>
<td>232/18,317 (1.27)</td>
<td>266/20,330 (1.31)</td>
<td>3.15</td>
<td>0.72</td>
</tr>
<tr>
<td>Medical service</td>
<td>103/8,516 (1.21)</td>
<td>133/9,981 (1.33)</td>
<td>9.92</td>
<td>0.46</td>
</tr>
<tr>
<td>Total minor bleeding</td>
<td>320/18,317 (1.75)</td>
<td>326/20,330 (1.60)</td>
<td>−8.57</td>
<td>0.27</td>
</tr>
<tr>
<td>Medical service</td>
<td>203/8,516 (2.38)</td>
<td>221/9,981 (2.21)</td>
<td>−7.14</td>
<td>0.44</td>
</tr>
</tbody>
</table>

60 y/o with DM, Obesity, HTN, Sickle Cell Disease...
## EHR Embedded Disease Management

### Chronic Disease Summary

#### DIABETES

<table>
<thead>
<tr>
<th>This Patient</th>
<th>Measure</th>
<th>Last Data Point</th>
<th>Trend</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diabetes Control</td>
<td>HbA1c = 7.5% &lt;br&gt;~ 25 hrs ago</td>
<td></td>
<td>Order HbA1c &lt;br&gt;Refer to treatment guidelines &lt;br&gt;Patient education &lt;br&gt;Change goal to 8% &lt;br&gt;Order endocrinology consult</td>
</tr>
<tr>
<td></td>
<td>Medical attention for nephropathy</td>
<td>Not recorded</td>
<td></td>
<td>Order microalbumin &lt;br&gt;Order urine protein &lt;br&gt;Order ACEI/ARB &lt;br&gt;Order nephrology consult &lt;br&gt;Document patient on dialysis</td>
</tr>
</tbody>
</table>

#### HYPERTENSION

<table>
<thead>
<tr>
<th>This Patient</th>
<th>Measure</th>
<th>Last Data Point</th>
<th>Trend</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood Pressure Control</td>
<td>BP = 136/78 &lt;br&gt;~ 25 hrs ago</td>
<td></td>
<td>Refer to treatment guidelines &lt;br&gt;Patient education &lt;br&gt;Enter avg. home BP</td>
</tr>
</tbody>
</table>
EHR Embedded Disease Management

Diabetes Mellitus Type II ≥ 18 yrs old

GLYCEMIC CONTROL
- A1c: 7.5% (~1 yr ago)
- Weight control: BMI =
- Education: Not recorded

ANNUAL EXAMS/EVALUATIONS
- Dilated eye: ~<1 yr ago
- Foot: Not recorded
- Nephropathy: Not recorded

MONOTHERAPY

METFORMIN

If A1c target not achieved after ~3 months of monotherapy, proceed to 2-drug combination.
- Choice dependent on patient and disease-specific factors

EFFICACY | HYPO RISK | WEIGHT | SIDE EFFECT | COST
--- | --- | --- | --- | ---
METFORMIN | highest | low risk | neutral/loss | GI/lactic acidosis | low

MONITOR A1c q 3 mos
- A1c ≥ 7%
- A1c target not achieved ≥ 3 mos
- Treatment change

MONITOR A1c q 6 mos
- A1c < 7%
- A1c target achieved longer than 3 mos
**History of Present Illness:** 60 yr old, metformin is not working well enough.

**Problem list:**
- DIABETES MELLITUS
- HTN
- Sickle Cell Dz

**Home Medications:**
- metformin 1000 extended release PO twice a day

**Results review:** HGB A1C 8.8%

**Impression and Plan**

**Diagnosis**
- Diabetes mellitus E11.9

**Course:** not well treated.

**Orders**

Pharmacy:

- **glipizide** 10 mg oral tablet  **OR**  insulin glargine 100 units/mL subcutaneous solution
Diabetes Mellitus 2nd Med Conundrum

![Diagram showing treatment options for diabetes]

<table>
<thead>
<tr>
<th>Monotherapy</th>
<th>Metformin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>high</td>
</tr>
<tr>
<td>Hypo risk</td>
<td>low</td>
</tr>
<tr>
<td>Weight</td>
<td>neutral/loss</td>
</tr>
<tr>
<td>Side effects</td>
<td>GI/ lactic acidosis</td>
</tr>
<tr>
<td>Costs</td>
<td>low</td>
</tr>
</tbody>
</table>

If A1C target not achieved after ~3 months of monotherapy, proceed to 2-drug combination (order not meant to denote any specific preference—choice dependent on a variety of patient- and disease-specific factors):

<table>
<thead>
<tr>
<th>Dual therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfonylurea</td>
</tr>
<tr>
<td>DPP-4 inhibitor</td>
</tr>
<tr>
<td>SGLT2 inhibitor</td>
</tr>
<tr>
<td>GLP-1 receptor agonist</td>
</tr>
<tr>
<td>Insulin (basal)</td>
</tr>
</tbody>
</table>

Efficacy: high, moderate risk, low risk, neutral, low risk, intermediate, low risk, intermediate, high.

Hypo risk: gain, loss, neutral, GI.

Weight: edema, HF, xfs, gain, loss, gain, GI, hypoglycemia.

Side effects: hypoglycemia, high, low, variable.

Costs: low, high, low, high, high, variable.

If A1C target not achieved after ~3 months of dual therapy, proceed to 3-drug combination (order not meant to denote any specific preference—choice dependent on a variety of patient- and disease-specific factors):

History of Present Illness: 60 yr old, metformin is not working well enough.

Problem list:
  DIABETES MELLITUS
  HTN
  Sickle Cell Dz

Home Medications:
- metformin 1000 extended release PO twice a day

Results review: HGB A1C 8.8%

Impression and Plan
Diagnosis
  Diabetes mellitus E11.9
Course: not well treated.
Orders

Pharmacy:
  glipizide 10 mg oral tablet  OR  insulin glargine 100 units/mL subcutaneous solution

When to Use Retrospective Aggregate Data

Using your institutions own data to help make decisions

My Patient
- 60 year old, HTN, HL, Sickle Cell
- A1C 8.8%, Sex, Race, no CVD, no CVA

Intervention
- Insulin vs. Sulfonylurea

Patient Satisfaction
- 85% I
- 92% S

A1C
- 7.4% I
- 7.6% S

10yr Life Expectancy
- N too small

Summary

-CER can/should be used to develop the clinical guidelines that inform care and CDS design

-CDS can increase appropriate drug use through alerts, order sets and reminders

-CDS can provide clinician and patient education to promote better decisions and outcomes

-Future EHR and CDS design should be able to provide data on important clinical questions that need CER

-Future EHR and CDS design should be able to help clinicians to leverage their own institutions data for therapeutic decisions and to become “learning healthcare systems”
Comparative Effectiveness and Patient-Centered Outcomes Research:
Enhancing Uptake and Use by Patients, Clinicians and Payers

Session: What is the Future of CER and CER Education? How Will CER Be Integrated Into Practice?

January 26, 2017
Lou Garrison, PhD.
Professor Emeritus, University of Washington
On the other hand . . .

- Cost pressures continue: high and growing share of GDP
- Worsening life expectancy in some groups, e.g., opioid addiction epidemic.
- Repeal of ACA—Cadillac tax; PCORI, etc.
- Inability to move quickly to value-based payment systems for the entire system.
- System inertia: 17-year diffusion curve
An Economic Perspective

• **Generation:** CER is a “public good” will be undersupplied by a “free market”, implying that we will need to subsidize or incentivize it some way to approach the optimal amount.

• **Value of Information:** More CER information is needed and desirable, but it is costly to produce and we need to weigh the costs and benefits.

• **Uptake and Use:** Incentives to use CER information appropriately are critical.
Three Questions

1. What is the future of CER?
2. What is the future of CER education?
3. How will CER be integrated into practice?
1. What is the future of CER?

- **CER:**
  - Intervention compared to SoC
  - Real-world outcomes (effectiveness); not efficacy
  - Patient-focused

- **It is undersupplied:** there will be excess demand for it.
  - Can we regulate it? FDA can, e.g., by requiring longer or additional studies.
  - Can we reward its production: e.g., performance-based risk-sharing agreements.
  - “Endogenous” vs. “Exogenous”/Learning health care system.

- **If we can reduce the costs of producing it** (e.g., via big data, etc.), we will get more.
2. What is the future of CER education?

• Demand is rising as a part of HTA
  – ISPOR has over 20,000 members in 115 countries.

• Methodological advances: value of information, network meta-analysis, patient engagement; implementation science [these need to be taught]

• Need for more than CER/clinical evidence base: we need it for benefit-risk analysis and for CEA/CUA.
3. How will CER be integrated into practice?

• It depends on incentives (intrinsic vs. extrinsic) to use the information
  – Kavita Patel cited challenges of FFS medicine
  – Choosing Wisely has had limited success
• Rise of dissemination/implementation science: guidelines not sufficient
  – Incentives: “greater perceived relative advantage” (Morrato)
  – “Misalignment of financial incentives” (Shah)
• Incorporation into clinical guidelines and pathway development is key.
• How can delivery systems and providers signal that they are providing higher-quality care based on the use of CER?
• Challenge: Why do EU health systems outperform US—with the same CER information?
Frameworks use different attributes of value: Where Does CER Fit In?

<table>
<thead>
<tr>
<th>Context/Perspective</th>
<th>ACA/AHA</th>
<th>ASCO</th>
<th>ICER</th>
<th>Sloan Kettering</th>
<th>NCCN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical benefit</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Toxicity / safety</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Treatment novelty</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Condition rarity and condition burden</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Affordability</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Cost effectiveness</td>
<td>X</td>
<td></td>
<td></td>
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</tbody>
</table>

Source: Adapted from P. Neumann, May 25, 2016
Thank you!

lgarrisn@uw.edu
Conference Summary and Next Steps?

Glen Schumock, University of Illinois at Chicago
THANK YOU FOR ATTENDING!