MHIF FEATURED STUDY: AEGIS 2

DESCRIPTION:
CSL112 is being developed for use in patients with ACS (diagnosed with either STEMI or NSTEMI and exclusive of unstable angina) to reduce the risk of CV death, MI, and stroke upon delivery of CSL112.
Evidence from the Apo-I Event Reducing in Ischemic Syndromes-I (AEGIS-I) study has demonstrated that administration of apoA-I increases cholesterol efflux in MI patients.

CRITERIA LIST/QUALIFICATIONS:

Inclusion:
- Positive Troponin with at least 50% stenosis on > 1 epicardial artery or prior cath with at least 50% stenosis on > 1 epicardial artery or prior CABG
- Additional risk factor: DM, > 65 y.o., prior hx of MI or PAD

Exclusion:
- EF < 30%  Body weight < 50 kg
- ALT > 3 x ULN  Allergy to soy beans or peanuts
- GFR < 30  Plan for CABG

CONDITION: Acute Coronary Syndrome
PI: Thomas Knickelbine, MD
RESEARCH CONTACT: Stephanie Ebnet  Stephanie.ebnet@allina.com  612-863-6286
SPONSOR: CSL Behring

OPEN AND ENROLLING: Please Refer Patients to Steph!
Minneapolis Heart Institute Foundation® Cardiovascular Grand Rounds

Title: Pragmatic clinical research to improve patient health: Early lessons from PCORNet participation

Speaker(s): Steven M. Bradley, MD, MPH
Associate Director, Healthcare Delivery Innovation Center
Minneapolis Heart Institute® at Abbott Northwestern Hospital

Date: September 17, 2018
Time: 7:00 – 8:00 AM
Location: ANW Education Building, Watson Room

OBJECTIVES
At the completion of this activity, the participants should be able to:
1. Describe differences between traditional and pragmatic clinical trials.
2. Describe the infrastructure required to perform pragmatic clinical research.
3. List barriers to achieving the goals of pragmatic research.

ACCREDITATION
Physician - Allina Health is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. Allina Health designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Nurse - This activity has been designed to meet the Minnesota Board of Nursing continuing education requirements for 1.0 hours of credit. However, the nurse is responsible for determining whether this activity meets the requirements for acceptable continuing education.

DISCLOSURE POLICY & STATEMENTS
Allina Health, Learning & Development intends to provide balance, independence, objectivity and scientific rigor in all of its sponsored educational activities. All speakers and planning committee members participating in sponsored activities and their spouse/partner are required to disclose to the activity audience any real or apparent conflict(s) of interest related to the content of this conference.

The ACCME defines a commercial interest as “any entity” producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

Moderator(s)/Speaker(s)
Dr. Steven Bradley has disclosed that he DOES NOT have any real or apparent conflicts with any commercial interest as it relates to presenting his content in this activity/course.

Planning Committee
Dr. Alex Campbell, Jake Cohen, Jane Fox, Dr. Mario Gössl, Dr. Kevin Harris, Dr. Kasia Hryniewicz, Rebecca Lindberg, Amy McMeans, Dr. Michael Miedema, Dr. JoEllyn Moore, Pamela Morley, Dr. Scott Sharkey, and Jolene Bell Makowesky have disclosed that they DO NOT have any real or apparent conflicts with any commercial interest as it relates to the planning
of this activity/course. Dr. David Hurrell has disclosed the following relationship—Boston Scientific: Chair, Clinical Events Committee.

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| Novartis | Pfizer |

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When you request a transcript this serves as your personal tracking of activities attended. Most professional healthcare licensing/certification boards **will not accept** a Learning Management System (LMS) transcript as proof of credit; there are too many LMS’s across the country and their validity/reliability are always in question.

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**Maintaining these details are the responsibility of the individual.**

**PLEASE SAVE A COPY OF THIS FLIER AS YOUR CERTIFICATE OF ATTENDANCE.**

<table>
<thead>
<tr>
<th>Signature:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>My signature verifies that I have attended the above stated number of hours of the CME activity.</em></td>
<td></td>
</tr>
</tbody>
</table>

*Allina Health - Learning & Development - 2925 Chicago Ave - MR 10701 - Minneapolis MN 55407*
Pragmatic Clinical Research: Early Lessons from PCORNet

Steven M. Bradley, MD, MPH
Cardiology, Minneapolis Heart Institute (MHI)
Associate Director, MHI Center for Healthcare Delivery Innovation
Site Principal Investigator, LHSnet/PCORnet

WARNING

I am not a clinical trialist.

I did not design the studies we will discuss.

My interest in PCORNet relates to the underlying framework for clinical research.
Objectives

• **Why** PCORnet was created
• **What** PCORnet will do for research
• **How** it (is intended to) works
• **Lessons** learned along the way

[Image: Wong-Baker FACES® Pain Rating Scale]

Used with permission. Originally published in Wong & Wong’s Nursing Care of Infants and Children. ©Springer Inc.

Minneapolis Heart Institute
Center for Healthcare Delivery Innovation
Our national clinical research system is well-intentioned but flawed

- High percentage of decisions not supported by evidence*
- Current system is:
  - Too slow
  - Too expensive
  - Unreliable
  - Doesn’t answer questions that matter most to patients
  - Unattractive to clinicians & administrators


What if we could have at our fingertips **trustworthy, high-quality data** from health systems, people and partnerships to bring people the real-world answers they seek?

What if we could **decrease the time it takes to get clinical insights**?

What if we could achieve **significant cost savings** over a traditional clinical study?
Overall objectives of PCORnet: achieving a single functional research network

- **Create** a secure national research resource that will enable teams of health researchers, patients, and their partners to work together on researching questions of shared interest
- **Utilize** multiple rich data sources to support research, such as electronic health records, insurance claims data, and data reported directly by patients
- **Engage** patients, clinicians & health system leaders throughout the research cycle from idea generation to implementation
- **Support** observational and interventional research studies that compare how well different treatment options work for different people
- **Enable** external partners to collaborate with PCORI-funded networks
- **Sustain** PCORnet resources for a range of research activities supported by PCORI and other sponsors
Why is Traditional Clinical Research Slow and Costly?

Data is collected in care delivery
Not long ago, this data was only collected on paper.

Paper is OK, until....

...you want to start looking at many patients at once.

- Can’t find patterns, trends, outcomes
- Can’t make complex comparisons
- Can’t identify patients for important questions
What can we do with Electronic Health Records?

Using EHRs to find the right patients to answer a question

Developing a “computable phenotype”

Can you pull data from our EHR that will show me all patients between ages _____ and _____, who have been diagnosed with ________, with visits in the ____________ clinic over the past year?

I also need to know if they’re taking _______________ and have had any blood pressure readings over ___ or ___ lab values over ___ in the past year.
Now, what if you wanted to look at many patients at different health systems across the country?

But it can be hard...

- Data structure designed for local needs, not for collaboration
- Multi-site regulatory process is daunting and confusing
Objectives

- Why PCORnet was created
- What PCORnet will do for research
- How it (is intended to) works
- Lessons learned along the way

How Clinical Data Research Networks (CDRN) Work
CDMs allow data across sites to be compared.

- Allina’s data is optimized and coded for our organization. But what if we want to share it?
- If we just try to combine our data with the data from another care system, we’d have...

\[ \text{Apple} \neq \text{Orange} \]

CDMs allow data across sites to be compared.

- CDMs emphasize a common data structure...
- ...as a result, we now have data that’s sharable in a number of ways

\[ \text{Apple} = \text{Apple} \] (close enough)
CDMs allow data across sites to be compared.

### Types of Data

- **Biospecimen & Genomic Data**
- **Condition**
- **Encounters**
- **Lab Results**
- **Patient Satisfaction**
- **Procedures**
- **Claim**
- **Vital Status**
- **Demographic**
- **Prescribing**
Data federation allows for controlled data sharing

Data stored locally

Database 1

Database 2

Database 3

Database 4

Common data model

Data stored locally

Database 1

Database 2

Database 3

Database 4
Data federation allows for controlled data sharing.

Query for counts across sites

Common data model

Data stored locally

Federated Query Tool (Web-based)

Database 1

Database 2

Database 3

Database 4

CDRNs

ADVANCE
Accelerating Data Value Across a National Community Health Center Network (ADVANCE)
Oregon Community Health Information Network (OCHIN)

CRAP/CORN
Chicago Area Patient Centered Outcomes Research Network (CAP/CORN)
The Chicago Community Trust

PORTAL
Greater Plains Collaborative (GPC)
University of Kansas Medical Center

REACHnet
Kaiser Permanente & Strategic Partners Patient Outcomes Research To Advance Learning (PORTAL) Network
Kaiser Foundation Research Institute

Mid-South CDRN
Louisiana Public Health Institute (LPHI)

National PedsNet: A Pediatric Learning Health System
The Children’s Hospital of Philadelphia

New York City Clinical Data Research Network (NYC-CDRN)
Weill Medical College of Cornell University

OneFlorida Clinical Data Research Network
University of Florida

Patient-Centered Network of Learning Health Systems (LHSNet)
Mayo Clinic

Patient-oriented SCALable National Network for Effectiveness Research (pSCANNER)
University of California, San Diego (UCSD)

PaTH: Towards a Learning Health System
University of Pittsburgh

Scalable Collaborative Infrastructure for a Learning Healthcare System (SCILHS)
Harvard University

Minneapolis Heart Institute
Center for Healthcare Delivery Innovation

Allina Health
ABBOTT NORTHWESTERN HOSPITAL
This map depicts the number of PCORI-funded Patient-Powered or Clinical Data Research Networks that have coverage in each state.
### PCORnet Demographics

<table>
<thead>
<tr>
<th>Age</th>
<th>PCORnet*</th>
<th>2010 US Census</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20</td>
<td>34%</td>
<td>27%</td>
</tr>
<tr>
<td>21-44</td>
<td>27%</td>
<td>34%</td>
</tr>
<tr>
<td>45-64</td>
<td>24%</td>
<td>26%</td>
</tr>
<tr>
<td>65-74</td>
<td>9%</td>
<td>7%</td>
</tr>
<tr>
<td>75+</td>
<td>6%</td>
<td>6%</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Sex</th>
<th>PCORnet*</th>
<th>2010 US Census</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>55%</td>
<td>51%</td>
</tr>
<tr>
<td>Male</td>
<td>45%</td>
<td>49%</td>
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</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>PCORnet*</th>
<th>2010 US Census</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black/African American</td>
<td>14%</td>
<td>13%</td>
</tr>
<tr>
<td>White</td>
<td>54%</td>
<td>72%</td>
</tr>
<tr>
<td>Other/Missing</td>
<td>32%</td>
<td>15%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hispanic</th>
<th>PCORnet*</th>
<th>2010 US Census</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>19%</td>
<td>16%</td>
</tr>
<tr>
<td>No</td>
<td>52%</td>
<td>84%</td>
</tr>
<tr>
<td>Other/Missing</td>
<td>29%</td>
<td></td>
</tr>
</tbody>
</table>

*Number of patients with given characteristic with an encounter in any care setting divided by the total number of patients with an encounter in any care setting (2014).

### Selected Condition Counts: 23 Data Marts

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>530,000</td>
</tr>
<tr>
<td>Pulmonary Disease</td>
<td>1,900,000</td>
</tr>
<tr>
<td>Any Malignancy</td>
<td>740,000</td>
</tr>
<tr>
<td>MI</td>
<td>230,000</td>
</tr>
<tr>
<td>Stroke</td>
<td>230,000</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>139,000</td>
</tr>
<tr>
<td>Ulcerative Colitis</td>
<td>46,000</td>
</tr>
<tr>
<td>Hypertension</td>
<td>3,420,000</td>
</tr>
<tr>
<td>Renal Disease</td>
<td>671,000</td>
</tr>
<tr>
<td>Influenza/Pneumonia</td>
<td>578,000</td>
</tr>
</tbody>
</table>
Particularly Relevant for Clinical Trials

### Objectives

- **Why** PCORnet was created
- **What** PCORnet will do for research
- **How** it (is intended to) works
- **Lessons** learned along the way

---

**Randomized Clinical Trials (RCTs) in Cardiovascular Disease**

<table>
<thead>
<tr>
<th>Current challenges</th>
<th>Goals for future RCTs</th>
<th>A pragmatic solution: Registry-based trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific and operational complexity</td>
<td>Simplify operational approach</td>
<td>Identify sites and candidates using health registry data</td>
</tr>
<tr>
<td>Waning site and patient participation</td>
<td>Large sample sizes with representative populations</td>
<td>Informed consent, randomization and patient comprehension via internet portal</td>
</tr>
<tr>
<td>Regulatory issues</td>
<td>Fewer restrictions</td>
<td>Follow up: Outcomes ascertainment via patient report, electronic health records, and administrative claims</td>
</tr>
<tr>
<td>Inefficient and costly</td>
<td>Embed trials within routine clinical care processes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Leverage electronic records and data</td>
<td></td>
</tr>
</tbody>
</table>
I am not a clinical trialist.

I did not design the studies we will discuss.

My interest in PCORNet relates to the underlying framework for clinical research.

My Invitation to Participate in LHSNet

- Allina had successfully participated in CDM
- PI leaving Allina
- Asked to serve as PI “couple hours a week”
Demonstration Projects

• INVESTED
  – Influenza Vaccine to Effectively Stop Cardio Thoracic Events and Decompensated Heart Failure

• ADAPTABLE

INVESTED Trial

• More than 35,000 influenza-associated deaths each flu season

• Over 200,000 influenza-related excess hospitalizations

• Association between acute respiratory infections and cardiovascular events

Thompson et al JAMA. 2003;289:179-186
Thompson et al JAMA. 2004:292:1853-1840
Majid et al. Epi 2007(28):1205-1210
Association Between Respiratory Infections and MI or Stroke

Flu Vaccine Reduces CV Risk

Influenza Vaccine Placebo/Control

<table>
<thead>
<tr>
<th>Study</th>
<th>Events</th>
<th>Total</th>
<th>Events</th>
<th>Total</th>
<th>Risk Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Govart</td>
<td>7</td>
<td>927</td>
<td>5</td>
<td>911</td>
<td>1.38 (0.44 – 4.32)</td>
</tr>
<tr>
<td>FLUVACS</td>
<td>32</td>
<td>145</td>
<td>54</td>
<td>147</td>
<td>0.60 (0.41 – 0.87)</td>
</tr>
<tr>
<td>FLUCAD</td>
<td>16</td>
<td>325</td>
<td>30</td>
<td>333</td>
<td>0.55 (0.30 – 0.98)</td>
</tr>
<tr>
<td>DeVilliers</td>
<td>20</td>
<td>1620</td>
<td>20</td>
<td>1622</td>
<td>1.00 (0.54 – 1.85)</td>
</tr>
<tr>
<td>Phromninink</td>
<td>20</td>
<td>221</td>
<td>42</td>
<td>218</td>
<td>0.47 (0.29 – 0.77)</td>
</tr>
<tr>
<td>Total</td>
<td>95</td>
<td>3238</td>
<td>151</td>
<td>3231</td>
<td>0.64 (0.48 – 0.86)</td>
</tr>
</tbody>
</table>

Absolute Risk Difference: 1.74%
Number Needed to Treat: 58

Test for Heterogeneity P=2
Reduced Immune Response Among Patients with Heart Failure


INfluenza Vaccine to Effectively Stop CardioThoracic Events and Decompensated Heart Failure (INVESTED)

Post-MI or HF Hospitalization

N = 9300

RANDOMIZED 1:1 DOUBLE BLIND ANNUAL VACCINE STRATEGY

High Dose Trivalent Influenza Vaccine

Standard Dose Quadrivalent Influenza Vaccine

All other CV Rx per treating MD

Followed up to 4 times a year with annual re-vaccination to assigned strategy

Primary EP

Death or Cardiopulmonary Hospitalization

Duration

3 Influenza Seasons + Vanguard Season

INVESTED

Minneapolis Heart Institute
Center for Healthcare Delivery Innovation

Abbott Northwestern Hospital
What makes INVESTED “pragmatic”

• Strategy of high- vs low-dose vaccine (formulations could change)
• Straightforward inclusion criteria (large number of potential subjects)
• Recruitment leverages EHR
• Intervention a “one-shot” deal
• Endpoint ascertainment more simple and requires minimal adjudication

Leveraging the Common Data Model for Patient Enrollment

• Query on:
  – Enrollment criteria
  – Follow-up in Allina Health
  – Upcoming visits

• Targeted recruitment
  – Allina leading enroller for all of PCORnet!!
Allina’s Success

<table>
<thead>
<tr>
<th>PCORnet Site Name</th>
<th>Principal Investigator</th>
<th>Number Randomized</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Abbott Northwestern Hospital</td>
<td>Frank Blume</td>
<td>37</td>
</tr>
<tr>
<td>2. OneFlorida COIN</td>
<td>Carl Puglise</td>
<td>42</td>
</tr>
<tr>
<td>3. University of Iowa</td>
<td>Patricia Wisnauer</td>
<td>60</td>
</tr>
<tr>
<td>4. Northwestern University</td>
<td>Haji Muthambo</td>
<td>36</td>
</tr>
<tr>
<td>5. HealthPartners-Riverside Research</td>
<td>Karen Maggioni</td>
<td>32</td>
</tr>
<tr>
<td>6. Loyola University Medical Center</td>
<td>Matt Hoopes</td>
<td>30</td>
</tr>
<tr>
<td>7. Medical University of South Carolina</td>
<td>Sherwin Sumo</td>
<td>27</td>
</tr>
<tr>
<td>8. University of North Carolina Chapel Hill</td>
<td>Jo Ellen Rodgers</td>
<td>21</td>
</tr>
<tr>
<td>9. Mayo Clinic</td>
<td>Paul Kisse</td>
<td>17</td>
</tr>
<tr>
<td>10. Vanderbilt University</td>
<td>H. Keipp Talbot</td>
<td>13</td>
</tr>
</tbody>
</table>

Signs of Trouble

Wong-Baker FACES® Pain Rating Scale

0: No Hurt
1: Hurts Little Bit
2: Hurts Little More
3: Hurts Even More
4: Hurts Whole Lot
5: Hurts Worst
Demonstration Projects

• INVESTED
  – Influenza Vaccine to Effectively Stop Cardio Thoracic Events and Decompensated Heart Failure

• ADAPTABLE

What if an over-the-counter choice...
What if an over-the-counter choice...

19,000 Deaths/Heart Attacks
Or
Thousands of Bleeds Annually in the United States

The Role of Platelets in Acute Cardiovascular Events

Quiescent plaque

Lipid core

Vulnerable plaque

Inflammation

Inflammation → Thrombosis cascade

Collagen → platelet activation

Macrophages, Metalloproteinases

Plaque rupture

Platelet-thrombin micro-emboli

Heart Attack
Aspirin: A wonder drug

- Proven clinical benefit in reducing ischemic vascular events
- Cost effective
- Benefit with combination antiplatelet therapies
- But there are issues:
  - Emerging evidence for dose modifiers (ASA resistance, genetics, P2Y12 inhibitors)
  - Equal efficacy across patients?
  - Intolerance

Most effective dose uncertain

Clinical Equipoise

Distribution of aspirin dosing at discharge

High (25-fold) Variation Across Hospitals on Use of High Dose (325 mg) Aspirin

Hall et al. Circulation: Cardiovascular Quality and Outcomes 2019
The ADAPTABLE Aspirin Study

- To compare the effectiveness and safety of two doses of aspirin (81 mg and 325 mg) in high-risk patients with coronary artery disease:
  - **Primary Effectiveness Endpoint:** Composite of all-cause mortality, nonfatal MI, nonfatal stroke
  - **Primary Safety Endpoint:** Major bleeding complications

- To compare the effects of aspirin in subgroups of patients:
  - Women vs men
  - Older vs younger
  - Racial and ethnic minorities vs. whites
  - Diabetics vs. nondiabetics
  - Chronic kidney disease (CKD) vs. not
  - Internet users vs. not
  - P2Y12 inhibitor users vs. not

- To develop and refine the infrastructure for PCORnet to conduct multiple comparative effectiveness trials in the future

E-data Collection and Follow-up

- **N=20,000**
  - **ADAPTABLE enrollee**
  - **Baseline data**
  - **Web portal follow-up**
    - Randomized to 3 vs 6 mos contact
    - Patient-reported hospitalizations
    - Medication use
    - Health outcomes
  - **DCRI call center**
    - Patients who miss 2 contacts
    - Patient-reported hospitalizations
    - Medication use
    - Health outcomes

- **PCORnet Coordinating Center follow-up**
  - Via Common Data Model
  - Validated coding algorithms for endpoints

- **CMS and private health plans follow-up**
  - Longitudinal health outcomes
  - Validated coding algorithms for endpoints

- Death ascertainment
  - National Death Index (NDI) & Social Security Database
Cost Comparisons for Trial Design

ADAPTABLE: $850 per participant
- 20,000 participants
- $17M total cost (Directs + Indirects)

PROMISE* (pragmatic trial): $3,100 per participant
- 10,003 participants
- $27M total cost

BRIDGE**: $13,000 per participant
- 1,884 participants
- $23M total cost

*Outcomes of Anatomical versus Functional Testing for Coronary Artery Disease
**Perioperative Bridging Anticoagulation in Patients with Atrial Fibrillation

Signs of Trouble

Wong-Baker FACES® Pain Rating Scale

0 = No Hurt
2 = Hurts Little Bit
4 = Hurts Little More
6 = Hurts Even More
8 = Hurts Whole Lot
10 = Hurts Worst

01830 Wong-Baker FACIES Foundation. Visit us at www.wongbakerFACES.org
Used with permission. Originally published as Wong & Wong’s Nursing Drug and Dose Calculations, Gilotra Inc.
Vetting the Computable Phenotype

• Eligible Patients
  – Any ASCVD (prior MI, prior PCI or CABG, coronary angio with ≥75% stenosis, or h/o chronic ischemic heart dx, CAD, or ASCVD)
  – No ASA safety concerns (allergy, bleeding)
  – No anticoagulant or ticagrelor
  – Enrichment factor (>65 yo, creat >1.5, diabetes, CVD, PAD, 3V CAD, CHF, SBP>140, LDL>130)

• Any problems here?

Allina’s Recruitment Approach

<table>
<thead>
<tr>
<th>Week</th>
<th>Email/Letter and Phone Recruitment</th>
<th>Number of patients</th>
<th>Estimated Conversions</th>
<th>In-person Conversions</th>
<th>Weekly Conversions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>Initial email and letter – Group 1</td>
<td>100</td>
<td>2</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Week 2</td>
<td>Follow-up email – Group 1 Initial email and letter – Group 2</td>
<td>96 100</td>
<td>4 2</td>
<td>7 13</td>
<td></td>
</tr>
<tr>
<td>Week 3</td>
<td>Final email – Group 1 Follow-up email – Group 2 Initial email and letter – Group 3</td>
<td>90 96 100</td>
<td>4 4 2</td>
<td>7 17</td>
<td></td>
</tr>
<tr>
<td>Week 4</td>
<td>Final phone call – Group 1 Final email – Group 2 Follow-up email – Group 3 Initial email and letter – Group 4</td>
<td>85 90 96 100</td>
<td>8 4 4 2</td>
<td>7 25 (anticipated steady state)</td>
<td></td>
</tr>
</tbody>
</table>
Why Letters Won’t Work

• Familial Hyperlipidemia Project
  – QI project to identify and improve care of patients with FH
  – Patients identified using labs in EDW

• Letters to ~120 patients → 1 preventive clinic appointment

Future of PCORI Funding
More Trouble Brewing

The Power of MHI and MHIF

A Fresh Start
Just Ahead

Minneapolis Heart Institute
Center for Healthcare Delivery Innovation
Rethinking Our Approach

- Leverage new ways of patient identification (CDM)
- Leverage tried and true for patient enrollment

My View of Clinical Research
### Additional PCORNNet Studies in Early Stages

- Comparison of Oral Anticoagulants for extended VEnous Thromboembolism (COVET)

- Patient Reported Outcomes inVestigation following Initiation of Drug therapy with Entresto (Sacubitril/Valsartan) in Heart Failure (PROVIDE-HF)

### Observational Studies

- Trends and prevalence of PCSK9 inhibitor use

- Epidemiology of pre-diabetes

- Obesity and Heart Failure Survey Studies

- TVTR Linkage
PCORnet® for many kinds of research

Pre-research
- Feasibility queries
- Engagement
- Match-making

Interventional studies
- Clinical trials
- Pragmatic randomized clinical trials
  - e-Identification
  - e-Consent
  - e-Randomization
  - e-Follow-up
- Cluster randomization

Observational studies
- Cross-sectional
- Epidemiology
- Health services
- Comparative effectiveness or safety

Reengaged in a New Day

Wong-Baker FACES® Pain Rating Scale

0: No Hurts
2: Hurts Little Bit
4: Hurts Little More
6: Hurts Even More
8: Hurts Whole Lot
10: Hurts Worst
Conclusion

• PCORnet is a national network of networks to support pragmatic research

• Traditional approach to clinical trials can bridge to a refined pragmatic approach

• Important to participate in a changing research environment

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