Why participate in a PCORnet study?

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What is a PCORnet study?

- Address research questions that may need large patient populations – to find participants or to answer a research question with a well powered study.

- Questions are often pragmatic and real life practice focused.

- Data collection can be partially automated from EMR.

- Often we are one site among many.
Studies that I am involved in

- **PREVENTABLE**: Studies effects of statins in individuals over 75 years of age including effects on dementia and disability (site PI)

- **PCOG90**: Seeks to identify individuals over 90 years of age without dementia to identify protective factors (project co-I and site PI) (Scored 3 points from payline)
Pluses to PCORnet studies

- Often working with a team of established investigators
  - Great for less experienced researchers
  - Faculty with more experience in bench, health services, or other research

- Typically single IRB

- Study design is fairly sophisticated and detailed

- Often greater research infrastructure involved

- Funding application easier or already funded
Pluses to PCORnet studies (cont)

- Might use a computable phenotype
  - Inverts typical process (patient relationship -> study to study -> some patient relationship)
  - Allows recruitment from across Neb Medicine
  - Does require chart review to be sure that patient is a good fit
  - Do not require individual clinicians to find and refer patients (I even recruited patients from my clinic that I wasn’t thinking about)
How does this benefit individual faculty?

• Way to build a track record in clinical research and be invited for subsequent studies

• Typically single IRB

• Can learn about clinical research in structured environment

• Can build connections with other investigators – particularly for promotion

• Potential for publications
How can this benefit a department or division?

- Great way for getting a foothold into clinical research
- Attractive for generalists or to study common diseases
- Great for specialties without much industry sponsored research
- Offer access to research for patients
Downsides to PCORnet studies

• Need to review budget to be sure that it will cover costs or have help in this regard

• Unlikely to be able to pay for full-time staff like a study coordinator

• Faculty effort can add up

• You have often little relationship with the participants
Our Experience with PREVENTABLE

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<th>Total reached out to at least 1x</th>
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<tbody>
<tr>
<td>Declined:</td>
</tr>
<tr>
<td>Ineligible:</td>
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</table>

Total # touches to patients to date
4389 (does not include total attempts)

note: with early statin filter issues, est 400 marked ineligible

<table>
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<th>Total emails sent out on 1st contact</th>
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<table>
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Our Experience with PREVENTABLE

- Good number of patients are ineligible – take statin, have CAD/stroke history, etc.

- Need to contact many folks to enroll a patient – concerns about being in research, concerns about statin, etc.
Lessons Learned

• Want to work with IRB early on
  
  • Study had single IRB but local policies can be in conflict
  
  • Needed to get an ethical access waiver to expand beyond Geriatrics clinic
  
  • Needed to get permission to have physician consent be confirmatory and done via phone
Lessons Learned (cont)

• Be sure the sites know about your project

  • We needed to get explicit consent due to COVID protocols – ended up being very positive
  
  • Presented to clinic medical directors or even at clinic staff meeting
  
  • Found that they wanted to participate, and that potential subjects would often contact PCP for advice
Lessons Learned (cont)

• Run queries to find your best sites
  • Initially excluded Bellevue and Grand Island
  • Later found that these were sites with the most patients

• Try to avoid bottlenecks
  • This is typically me – so need to dedicate time and prioritize messages from team
Summary

• Working with PCORnet can be a great way to get involved in research and network with researchers

• PCORnet team is a great resource in the process

• Do need to be mindful of budget before committing to project

• Be sure to engage IRB and clinical sites in the process
Acknowledgements

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