



**ASPIRE Workshop 1:
Conceiving the Research Idea**

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What to Expect from this program

- Just-in-time structured instruction on research principles
- Professional and peer feedback on your project
- Accountability assistance

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What is Expected of you?

- Come to workshops prepared
- Participate in the large & small group workshops
- Post-class meeting with local preceptor(s)
- IRB training +/- IRB attendance

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What to Expect Today

- Large Group Workshop
- Small Group Workshop
- Session Evaluation

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Resources

- ASPIRE website ASPIREKPCO.weebly.com
- Small Group Mentor
- Local Research Preceptor

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<http://WWW.ASPIREKPCO.WEEBLY.COM>

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Conceiving a Research Question

Background:

- Current ACC/AHA Guidelines recommend statin therapy in patients with T2DM over 40 years of age and an ASCVD risk score $\geq 7.5\%$
- There are hundreds, maybe thousands of DM patients in our system who meet this criteria and are NOT on a statin

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Conceiving a Research Question

Can letters to patients serve as a population management strategy to get eligible T2DM patients onto statin therapy?

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PICO

Population
Intervention
Comparison
Outcome(s)

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Population*

- T2DM
- ASCVD \geq 7.5%
- No statin therapy in past year

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Intervention*

- Send eligible patients a letter explaining benefits of statin therapy
- Ask patient to pick up Rx for a statin (already ordered)
- Include a phone number to ask a pharmacist any questions

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Comparison*

- Patients not receiving this intervention

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Outcome*

- Purchase of a statin Rx within 3 months of letter mail date

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Refined study question

Among T2DM patients likely to benefit from statin therapy, will an intervention involving a letter, a pre-ordered statin prescription, and pharmacist counseling significantly increase statin initiation compared to no intervention?

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FINER

- Feasibility
- Interesting
- Novel
- Ethical
- Relevant

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Objectives

Primary:

Quantify the effect of the intervention on the rate of “statin starts” within 3 months of letter mail date (=index date)

Secondary:

- (1) Among statin-starters, compare persistence at 1 year
- (2) Among statin-starters, compare proportion with an elevated CK or ALT during the 6-mo post-index

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Primary Objective Compare short-term efficacy...

Outcome: number of statin starts (Defined as: purchase of a statin Rx within 3 months of index date)

Hypothesis: More patients in the intervention group will start statins compared to those in the no intervention group

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Secondary Objectives Compare longer term efficacy...

Outcome: Statin persistence (Defined as: statin purchase at one year post-index date \pm 45 days)

Hypothesis: There will be similar rates of statin persistence at one year among statin-starters in each group

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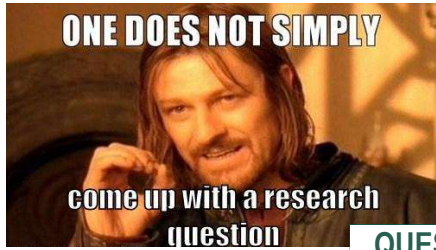
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Secondary Objectives
Compare safety...

Outcome: Number of individuals with CK > 600 IU/L or ALT > 200 IU/L during 6 months post-index date in each group

Hypothesis: The incidence of abnormal CK or ALT levels will be similar between the two groups

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QUESTIONS?

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