Changing the Default

Moving to an Opt-Out Approach for Treating Tobacco Use Disorders

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Department of Health Services, Policy & Practice (Brown)
Happened to you/a family member?

Health care provider, after intake, tells you

- Your blood pressure is well above normal…
  - She asks you if you are ready to change it within the next 30 days

- You have shortness of breath due to asthma…
  - He asks you if you are willing to address it at this time
Guidelines

• 5 “A”s of tobacco dependence treatment
  • US – 3rd “A” – “Is the tobacco user willing to try to make a quit attempt at this time?”

U.S. PHS Clinical Practice Guideline
# Strength of Evidence

<table>
<thead>
<tr>
<th>ASSESS = 1C</th>
<th>1 = Strong Recommendation: Benefits appear to outweigh risks and burdens</th>
<th>C = Low Quality Evidence---from observational studies, clinical experience, or flawed trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSIST = 1A Medications Supportive Counseling</td>
<td>1 = Strong Recommendation: Benefits appear to outweigh risks and burdens</td>
<td>A = High Quality Evidence---from multiple well designed trials</td>
</tr>
</tbody>
</table>
“Unwilling” Smokers Benefit from Cessation-Oriented Care

- Smokers not ready to quit actually quit at the same rates as those who are ready to quit (Ellerbeck, 2009)

- Inter99 Study - smokers not planning on quitting will accept treatment and quit (Pisinger, 2005)
  - Only 11% planning to quit in next month
  - 27% enrolled in groups
  - 35% of enrollees quit
    - Only half of those who ultimately quit, initially said they were planning to quit

- Harm??? No data (smokers, providers, systems)
Screen vs Proactively Treat?

**Screen!**

- Guideline recommended
- ???

**Proactively Treat!**

- Some will quit who say they’re not ready
- Smokers, even those not planning to quit, more satisfied with providers who offer tobacco treatment
- If we don’t we’ll miss treating 80% of smokers

Conroy et al., 2005
Defaults Affect Behavior

• For any choice point, there’s a default – what you get if you do nothing

• Making an option the default increases the chances that it will occur

• Organ donation—
  • Germany – no one is a donor, have to “opt in” – 12%
  • Austria – everyone is a donor, have to “opt out” – 99%

• HIV screening – screening rates increased when it was changed to opt-out

Johnson et al, 2005; Van De Veer, 1986; Klein, 2014
Opt-In vs Opt-Out Tobacco Treatment in Hospital

*Changing the Default*

**Opt In**

Offer: in-patient medication

Offer: Brief Advice to quit

Ask: Willing to try to quit?

Yes

Offer:

1. Treatment plan
2. Post discharge Meds
3. Post discharge Support

No

Motivational Intervention

**Opt Out**

Provide: in-patient medication

Provide: Brief Advice to quit

Provide:

1. Treatment plan
2. Post discharge Medication
3. Post discharge Support

Richter & Ellerbeck, 2015; Faseru et al., 2017
Continuum of Intervention Directiveness/Intensity

OPT IN

Ask all tobacco users: Willing to try to quit?
- Yes: Offer meds/support
- No: motivate

Provide meds/support to all unless they refuse

OPT OUT
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- Yes: Offer meds/support
- No: motivate

Offer meds/support to all

Provide meds/support to all unless they refuse
Continuum of Intervention Directiveness/Intensity

OPT IN

- ---------------

OPT OUT

Ask all tobacco users: Willing to try to quit?
- Yes: Offer meds/support
- No: motivate

“We’ll call you to provide in-home follow-up post-discharge to check in on how you are doing”
### Choice Architecture

*Nudge, Thaler & Sunstein*

<table>
<thead>
<tr>
<th>Components</th>
<th>OPT OUT</th>
<th>OPT IN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTRODUCTION:</strong></td>
<td>“Because quitting is the best thing you can do for your health, KUMed provides tobacco treatment for everyone who smokes.”</td>
<td>“Quitting is the best thing you can do for your health. Are you planning on staying quit once you leave the hospital?”</td>
</tr>
<tr>
<td><strong>INPATIENT COUNSELING:</strong></td>
<td>“Let’s create a brief treatment plan that outlines your thoughts, feelings, and plans to treat your tobacco use.”</td>
<td>“If you’d like, we can create a brief treatment plan that outlines your thoughts, feelings, and plans about your tobacco use.”</td>
</tr>
<tr>
<td><strong>INPATIENT MEDICATION:</strong></td>
<td>“I’m going to work with your medical team to get you inpatient medication to prevent withdrawal.”</td>
<td>“Would you like inpatient nicotine replacement to prevent withdrawal?”</td>
</tr>
<tr>
<td><strong>OUTPT COUNSELING:</strong></td>
<td>“We provide in-home counseling post-discharge to help you with your plan.”</td>
<td>“Would you like in-home counseling post-discharge to help you with your plan?”</td>
</tr>
<tr>
<td><strong>OUTPT PRESCRIPTION/STARTER PACK:</strong></td>
<td>“We send everyone who is medically eligible home with a prescription and 2 weeks of free NRT.”</td>
<td>“If you are medically eligible, would you like a prescription and 2 weeks of free NRT?”</td>
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</table>
Innovations Demanded by Research Question

• Delayed consent – population based study, want all smokers, not just willing study participants

• Adaptive trial – interim analyses every 13 weeks, reweight randomization to favor stronger arm
  • More ethical – get more power for 3+ arm studies

• Bayesian design

NIH R01 HL131512 (Richter, P.I.)
• Randomized clinical trial
• 1,000 smokers
• Integrated into hospital service
Changing The Default For Tobacco Treatment

Aim 1: To determine the population impact of changing the default for tobacco cessation treatment

• **Hypothesis**: More enrolled in **OPT OUT** will utilize counseling, medications, and be abstinent from smoking at 1 month post randomization compared to **OPT IN**

Other Aims: To identify 6-month abstinence, treatment reach, patient response, costs

R01 HL131512 (Richter, P.I.)
Adaptive Trials

- Definition (FDA): “…an adaptive design is defined as a clinical trial design that allows for prospectively planned modifications to one or more aspects of the design based on accumulating data from subjects in the trial.”
  - Planned
  - Clearly-defined
  - Valid (e.g. 5% Type I error rate, etc.)

https://www.fda.gov/media/78495/download
CTD Design

• Initially randomize participants equally to the two arms until 400 participants randomized.

• After that, do an interim analysis that changes the allocation to weigh more towards the better performing arm (using 1-month endpoint).

• Interim analyses occur every 13 weeks until success or 1000 max participants enrolled.
  • Success occurs if the posterior probability of one arm being better than the other is bigger than .9925 for both 1-month & 6-month endpoints.
  • The type I error of this design is 5% and the power is more than 80%.
  • The details of these calculations uses simulation and we will not go into these details today
CTD Main Outcomes

• Primary endpoint: rate of 7-day biochemically verified cigarette abstinence at 1 month after randomization in OPT IN arm versus OPT OUT arm.
  • Co-Endpoint: biochemically verified abstinence at 6 months
What Will be Missing from the Results of this Trial?

- p-value!!!
  - For example, some trial results can say the comparison between drugs A and B is statistically significant (e.g. p=0.0137).
  - What does this mean?
  - It means that “the probability of being more extreme than the test statistic summarizing the differences between drugs A and B, under the null hypothesis of drug A is the same as drug B, is 0.0137.”
  - Awkward! Can’t we just calculate the probability drug A is best?
What Will be Missing from the Results of this Trial?

- Can’t we just calculate the probability drug A is best?
- Bayesian posterior probabilities
  - **OPT OUT** has a .XX probability of being the best @ 1-month.
  - **OPT OUT** has a .XX probability of being the best @ 6-months.
  - Much clearer!!!
In Hospital

**Admission—ID Smoking Status**
- Random Selection into Trial
- Brief Advice to Quit + Pamphlet
- UKanQuit Bedside Eligibility/Intake Assessment
- Random Allocation into Groups

**OPT OUT**
- Provide -Treatment Plan -Counseling -Rx + starter kit

**OPT IN**
- Willing to try to quit?
  - Yes
    - Offer -Treatment Plan -Counseling -Medication
  - No
    - Provide 4-R based Motivational Intervention

**Counseling Sessions 1-4**

**Post-Discharge**

UKanQuit 1-Month Assessment
Informed Consent/Enrollment
Extended 1-Month Survey for Enrollees

6-month Follow Up for Enrollees
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6-month Follow Up for Enrollees
Patients screened 
(n = 2,666)

Ineligible (n = 1,666)
• Medically ineligible for NRT (n = 550)
• Speaks other language precluding enrollment* (n = 47)
• Physically/cognitively unable* (n = 278)
• No telephone (n = 139)
• No secondary contact (n = 75)
• Smoke <1 cpd (n = 417)
• Using quit smoking medication prior to hospitalization (n = 121)
• Received smoking cessation treatment or already participating in a clinical trial (n = 75)
• Refused consult (n = 139)
• Pregnant (n = 18)
• Other (n = 112)
  • Incarcerated (n = 13)
  • Deceased (n = 3)
  • Screened more than twice (n = 95)
  • Household member enrolled in CTD (n=1)

Randomized (n=1,000)

Protocol added 6-months co-primary outcome

SCREENED 2,666
Patients screened (n = 2,666)

Ineligible (n = 1,666)
- Medically ineligible for NRT (n = 550)
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Randomized (n=1,000)

Protocol added 6-months co-primary outcome
Unable to reach (n=82)
Patient did not consent (n=87)
Patient deceased (n=10)
Other: Incarcerated (n=2)
Other: not cognitively impaired/able to consent (n=3)
Withdrew at M6, and consent at M1 (n=2)

Unable to reach (n=32)
Patient did not consent (n=40)
Patient deceased (n=3)

293 Randomized at seventh interim
307 Randomized at eighth interim
325 Randomized at ninth interim
333 Randomized at tenth interim

469 included in analysis
Final M1 Analysis

Consented to Part A (baseline/1 mo) Only (n=25)
Refused Consent; Deceased; Other at M1 (n=83)
Patient Deceased at M6 (n=15)
Other: Incarcerated at M6 (n=1)

Unable to reach (n=82)
Patient did not consent (n=87)
Patient deceased (n=10)
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Refused Consent; Deceased; Other at M1 (n=83)
Patient Deceased at M6 (n=15)
Other: Incarcerated at M6 (n=1)

420 included in analysis
Final M6 Analysis

Consented to Part A (baseline/1 mo) Only (n=31)
Refused Consent; Deceased; Other at M1 (n=103)
Patient Deceased at M6 (n=17)
Other: Incarcerated at M6 (n=1)
Withdrew consent (n=2)

Final M6 Analysis

229 included in analysis

OPT IN
345

OPT OUT
655
**CONSENTED & ENROLLED**

270 OPT IN

469 OPT OUT

739 = Study sample, main outcomes

74% of randomized included in trial
Unable to reach (n=32)
Patient did not consent (n=40)
Patient deceased (n=3)

Unable to reach (n=82)
Patient did not consent (n=87)
Patient deceased (n=10)
Other: Incarcerated (n=2)
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Withdrawed at M6, and consent at M1 (n=2)

293 Randomized at seventh interim
307 Randomized at eighth interim
325 Randomized at ninth interim
333 Randomized at tenth interim
345 total Randomized to Opt In arm

446 Randomized at seventh interim
500 Randomized at eighth interim
548 Randomized at ninth interim
590 Randomized at tenth interim
655 total Randomized to Opt Out arm

Unable to reach (n=82)
Patient did not consent (n=31)
Refused Consent; Deceased; Other at M1 (n=102)
Patient deceased at M6 (n=17)
Other: Incarcerated at M6 (n=1)
Withdrew consent (n=2)

Final M1 Analysis
270 included in analysis

Final M6 Analysis
12 included in analysis

Follow-Up
420 included in analysis

Final M1 Analysis
469 included in analysis

Follow-Up
229 included in analysis

229 OPT IN
420 OPT OUT
649 = Study sample, 6 month outcomes
Table 1 \((N=739)\)

<table>
<thead>
<tr>
<th>Demographics*</th>
<th>Opt In (270)</th>
<th>Opt Out (469)</th>
<th>d^</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean)</td>
<td>51.7</td>
<td>51.2</td>
<td>0.03</td>
</tr>
<tr>
<td>Female</td>
<td>45.6</td>
<td>48.2</td>
<td>0.06</td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>58.5</td>
<td>57.6</td>
<td>0.02</td>
</tr>
<tr>
<td>Medicaid Primary insurance</td>
<td>18.9</td>
<td>21.1</td>
<td>0.08</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Smoking Behavior</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>HSI (heaviness of smoking index, mean)</td>
<td>2.5</td>
<td>2.2</td>
<td>0.17</td>
</tr>
<tr>
<td>Willing to stay quit post-discharge</td>
<td>64.1</td>
<td>66.3</td>
<td>0.05</td>
</tr>
<tr>
<td>Used e-cigs, past 30 days</td>
<td>4.8</td>
<td>8.1</td>
<td>0.31</td>
</tr>
</tbody>
</table>

*Percentages/n=739 unless otherwise noted
Cohen’s d effect size: <0.2 negligible, 0.2-0.5 small, >0.5-0.8 medium, >0.8 =large
1 Month Main Outcomes (N=739)

OPT OUT improves 1-month quit rate compared to OPT IN

<table>
<thead>
<tr>
<th>Abstinence Rates (95% Credible Interval)</th>
<th>Bayesian Posterior Probability</th>
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<tbody>
<tr>
<td>Opt In 15.8 (11.8, 20.5)</td>
<td>Opt Out 21.5 (17.9, 25.4)</td>
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## 6 Month Outcomes (N=649)

OPT OUT improves 6-month quit rate compared to OPT IN

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<td>Opt Out</td>
<td>18.5 (15.0, 22.4)</td>
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</table>
Medication & Counseling Use (N=739)

- Accepted Starter Pack
- Used Med Post-Discharge
- Took 1/More Call Post-Discharge

*Bayesian Posterior Probability 1.00
Perceived Coercion

• Perceived coercion items from the MacArthur Admission Experience Survey

• Did patients feel forced to quit in the opt-out arm, and if this affects treatment response

• At 1 month, we ask:
  • I had more influence than anyone else about whether I tried to quit
  • I had a lot of control over whether I tried to quit smoking
  • I chose to try to quit smoking
  • I felt forced to try to quit smoking
  • It was my idea to try to quit smoking
Control, Feeling Forced to Quit (N=739)

<table>
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<tr>
<th>Statement</th>
<th>% Agreeing with statement</th>
<th>BPP</th>
</tr>
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<tr>
<td>I had a lot of control over whether I tried to quit</td>
<td>BPP=.75</td>
<td></td>
</tr>
<tr>
<td>I didn't feel forced to try to quit</td>
<td></td>
<td>BPP=.10</td>
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Opt In
Opt Out
The incremental cost effectiveness ratio (ICER) was $678.6, which represents the cost of getting one more person to quit in the opt out condition.

<table>
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<tr>
<th></th>
<th>Counseling (mean $ per/person)</th>
<th>Starter pack (mean $ per/person)</th>
<th>Sum (mean $ per/person)</th>
<th>Verified quit n (%)</th>
</tr>
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<tbody>
<tr>
<td>Opt in (n=270)</td>
<td>15.35</td>
<td>21.46</td>
<td>36.81</td>
<td>43 (15.9%)</td>
</tr>
<tr>
<td>Opt out (n=469)</td>
<td>25.19</td>
<td>49.62</td>
<td>74.81</td>
<td>101 (21.5%)</td>
</tr>
<tr>
<td>Difference</td>
<td><strong>9.84</strong></td>
<td><strong>28.16</strong></td>
<td><strong>38</strong></td>
<td><strong>5.6%</strong></td>
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<tr>
<td><strong>ICER</strong></td>
<td></td>
<td></td>
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OPT OUT improves 1-month but not 6-month quit rate compared to OPT IN

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<tr>
<td>Month 1</td>
<td>Opt In: 12.4 (9.2, 16.1)</td>
<td>15.4 (12.8, 18.3)</td>
</tr>
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<td>Month 6</td>
<td>Opt In: 11.8 (8.7, 15.5)</td>
<td>11.9 (9.5, 14.5)</td>
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Ethics of Opt-Out Care

- Default treatment is coercive and/or paternalistic
- Which is more paternalistic?
  - Asking if they’re ready and only offering meds/counseling if they say they are “ready”
  - Giving meds/counseling, letting patient decide if they want/not
    - What happens in most medical care
- Where there is strong evidence that support a given therapy, the default should be set to that therapy
- Defaults should be options that make the choosers better off, as judged by themselves
  - 70% of smokers want to quit, even if they’re not ready/willing now

Johnson et al, 2005; Van De Veer, 1986
Stand to Gain

If Opt-Out proves more effective:

• Free to deliver care to 3x-5x as many smokers (20%-100%)

• Simplify treatment algorithm – don’t have to ask/judge if patient is ready or willing

• No excuses for not treating
  • 2836 European physicians – 2 top barriers to treating:
    • patients’ lack of willpower and low interest in quitting

• Reduce tobacco use rates, illnesses, deaths, costs

Pipe et al, 2009
Population Impact
Selective vs Universal Treatment

• In a population 100 people – which is better?
  • 50% quit rate among 20% of people?
  • 20% quit rate among 100% of people?

• Even if a lower percentage quits, if you spread effective treatment across a broader population, you can get greater numbers of quits
The Single Biggest Barrier to Providing Treatment
Conclusions

• Compared to OPT IN, OPT OUT
  • High probability of improving the quit rate at 1-month
  • Low probability of improving the quit rate at 6 months

• OPT OUT outperformed OPT IN:
  • medication utilization
  • counseling utilization
  • sense of control over quitting

• At a much lower cost than cancer treatments, and comparable cost to other cessation interventions
Discussion

- OPT OUT approach did not result in better rates of long-term abstinence
  - Ditch this approach?
  - What would trials of other treatments, in other health areas (asthma?) conclude?
- Population-based trials, and trials of brief interventions, might benefit from delayed consent
- Adaptive trials can get more patients the effective treatment and yield results faster
- Bayesian analysis is new, simpler, and unknown to researchers/reviewers…
# The Team

<table>
<thead>
<tr>
<th>Edward F. Ellerbeck</th>
<th>Laura Mussulman</th>
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<tbody>
<tr>
<td>Babalola Faseru</td>
<td>Niaman Nazir</td>
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<td>Delwyn Catley</td>
<td>Elena Shergina</td>
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<td>Byron Gajewski</td>
<td>Andrea Elyachar</td>
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<td>Tresza Hutcheson</td>
<td>Marjorie Cooper</td>
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<tr>
<td>Taneisha Scheuermann</td>
<td>Lety Sarmiento</td>
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<td>Theresa I. Shireman</td>
<td>Craig Warlick</td>
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<td>Chuanwu Zhang</td>
<td>Vivek Patel</td>
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<tr>
<td>Laura Martin</td>
<td>Genevieve Casey</td>
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<tr>
<td>Jinxian Hu</td>
<td>Alison Summers Hageman</td>
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Implementation Science & Equity
Center on Biomedical Research Excellence  [Score 2.0]

Kimber Richter, PhD MPH
Christie Befort, PhD

- Bench – bedside time lag: 17-years
  - 30–40% of patients fail to receive care consistent with current evidence
  - 20-25% of care that is provided is not needed or is potentially harmful
ISE COBRE

Overall

- Provide scientific mentoring and institutional support for implementation science and equity
- Provide core infrastructure in methodology, engagement and ethical issues in human subjects’ research
- Select and train outstanding, multi-disciplinary senior and early-career faculty
ISE COBRE Organizational Structure

NIH
NIGMS

COBRE LEADERSHIP
Kimber Richter PhD, PI/Director
Christie Befort PhD, PI/Director
????, Administrative Associate

External Advisory Committee
Internal Advisory Committee

Mentoring, Career Development
Christie Befort PhD

Research Pilot Project Program
Kimber Richter PhD

PrlSM Core
Edward Ellerbeck MD
Shellie Ellis PhD

(CEO) Core
Sarah Kessler PhD

ETHICS Core
Jason Glenn, PhD
Key Core Functions

**Administrative Core**
- Mentoring & Career Development Plans
- Evaluation

**ETHICS, Human Subject & Regulatory**
- Ethics Consultation
- Navigation
- Ethics/Compliance Training

**Community Engagement & Outreach**
- Community Advisory Board Development for Research Projects
- Outreach Services
- Engagement & Outreach Coaching

**Pragmatic Implementation Science Methods**
- Study Design
- Training Implementation
- Methods Support
## ISE COBRE Pilot Projects 4 of 5

<table>
<thead>
<tr>
<th>Project</th>
<th>Lead (Department)</th>
<th>Mentors</th>
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</thead>
<tbody>
<tr>
<td>Nutricity: A mHealth nutrition intervention to improve diet quality among Latino children</td>
<td>Heather Gibbs, PhD RD LD (Dietetics &amp; Nutrition, SHP)</td>
<td>Debra Sullivan, PhD RD Jamie Zoellner, PhD RD (UVA)</td>
</tr>
<tr>
<td>Implementing Advance Care Planning as a Healthy Aging Activity in Rural Primary Care</td>
<td>Heather Nelson-Brantley, PhD RN NEA-BC CCRN-K (SON)</td>
<td>Christie Befort, PhD Barb Polivak, PhD RN FAAN Terri Fried, MD (Yale)</td>
</tr>
<tr>
<td>Preliminary Studies on Implementation of Smoking Cessation Interventions for Low-Income Women</td>
<td>Taneisha Scheuermann, PhD (Population Health, SOM)</td>
<td>Kim Richter, PhD MPH Ross Brownson, PHD (Wash U)</td>
</tr>
<tr>
<td>Improving the Quality of Prenatal Care for Low-Income, Black Women</td>
<td>Sharla Smith, PHD MPH (Population Health, SOM)</td>
<td>Megha Ramaswamy, PhD MPH Kevin Ault, MD FACOG, FIDSA</td>
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</tbody>
</table>
**PrISM**

**Figure B. Stepped Approach to PrISM support of Implementation Research**

<table>
<thead>
<tr>
<th>Describe Current State</th>
<th>Develop Implementation Strategy</th>
<th>Implementation</th>
<th>Outcomes*, Analysis &amp; Dissemination</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Describe practice gaps &amp; health disparities</td>
<td>- Apply theories to barriers*</td>
<td>- Launch implementation strategy with EBIs</td>
<td>- Reach</td>
</tr>
<tr>
<td>- Identify, adapt, or develop EBIs with a focus on reach</td>
<td>- Define and adapt an implementation strategy</td>
<td>- Monitor implementation progress*</td>
<td>- Effectiveness</td>
</tr>
<tr>
<td>- Identify barriers &amp; facilitators to use of EBIs*</td>
<td>- Re-examine adaptations of EBIs to the implementation context</td>
<td>- Iterative pilot testing and adaptations</td>
<td>- Adoption</td>
</tr>
<tr>
<td>- Identify stakeholders</td>
<td>- Engage stakeholders</td>
<td>- Report to stakeholders</td>
<td>- Implementation</td>
</tr>
<tr>
<td></td>
<td>- Develop measures and data sources</td>
<td></td>
<td>- Maintenance</td>
</tr>
<tr>
<td>*Determinant frameworks</td>
<td></td>
<td></td>
<td>*Evaluation frameworks, esp. RE-AIM</td>
</tr>
</tbody>
</table>

*Implementation theories/Process models*
PrISM Core—Tools & Resources

- Equity focused frameworks
  - PRECIS-2 Tool
- Clinical informatics
  - HERON
  - Greater Plains Collaborative
- Biostatistics and data analysis
  - REDCap
  - Velos eResearch
- Qualitative methods, instrument development and mixed methods
  - Nvivo
  - Atlas Ti
  - Dedoose