Changing the Default

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

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NIH / NHLBI 1R01HL131512, Richter PI

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

ASSESS =1C	1 = Strong Recommendation: Benefits appear to outweigh risks and burdens	C = *Low Quality Evidence*---from observational studies, clinical experience, or flawed trials
ASSIST = 1A **Medications** **Supportive Counseling**	1 = Strong Recommendation: Benefits appear to outweigh risks and burdens	A = *High Quality Evidence*---from multiple well designed trials

"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

↓

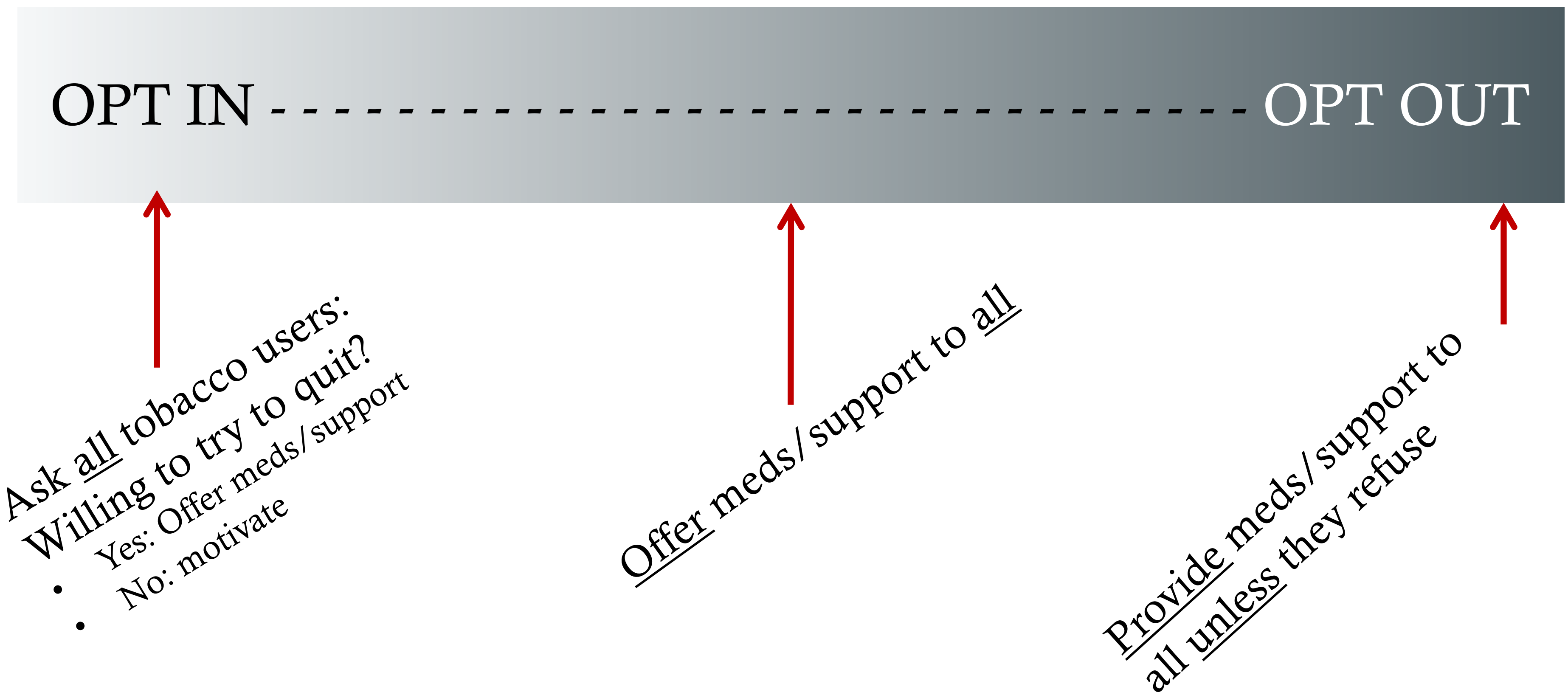
Provide:

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

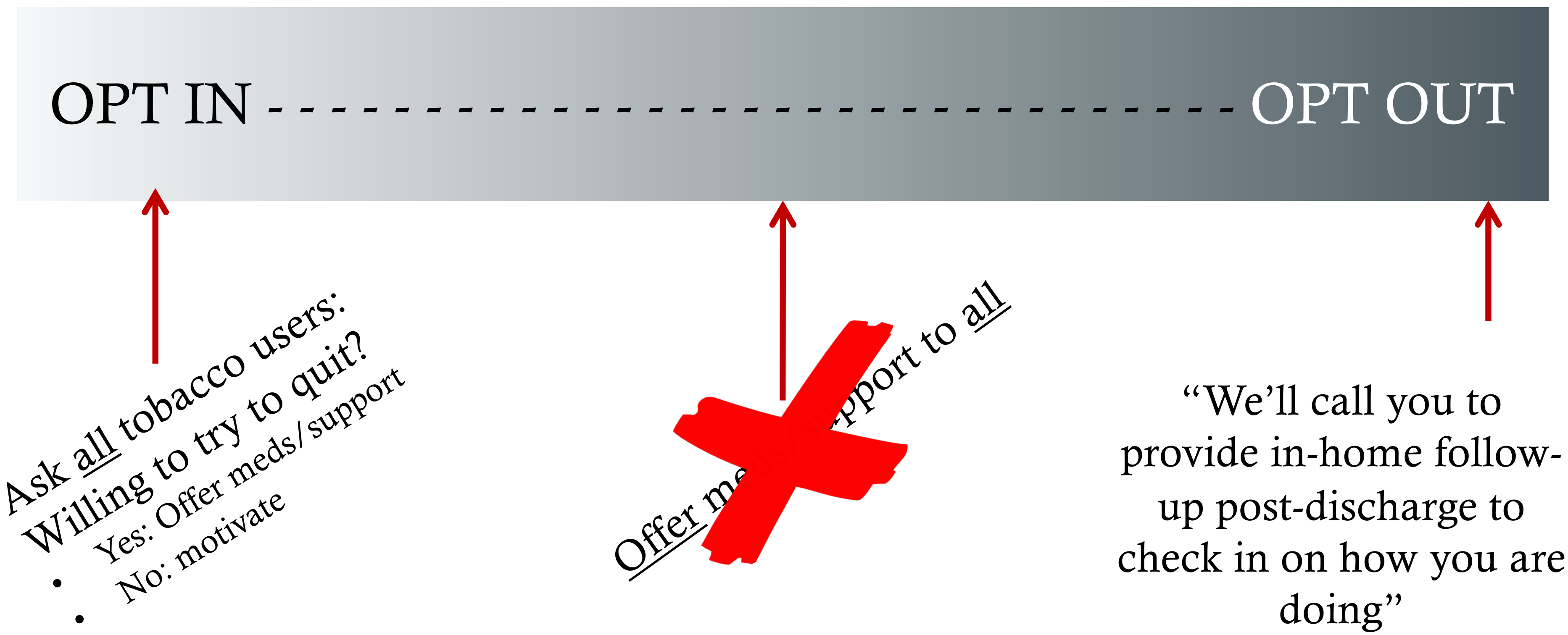
Richter & Ellerbeck, 2015; Faseru et al., 2017

Continuum of Intervention Directiveness/Intensity

Continuum of Intervention Directiveness/Intensity



Continuum of Intervention Directiveness/Intensity



Choice Architecture

Nudge, Thaler & Sunstein

Components	**OPT OUT**	**OPT IN**	
INTRODUCTION:	*"Because quitting is the best thing you can do for your health, KUMed provides tobacco treatment for everyone who smokes."*	*"Quitting is the best thing you can do for your health. Are you planning on staying quit once you leave the hospital?"*	
		yes	*no*
INPATIENT COUNSELING:	*"Let's create a brief treatment plan that outlines your thoughts, feelings, and plans to treat your tobacco use"*	*"If you'd like, we can create a brief treatment plan that outlines your thoughts, feelings, and plans about your tobacco use."*	Brief motivation: *'I'd like to talk with you about the risks of continuing to smoke and the roadblocks in trying to quit."*
INPATIENT MEDICATION:	*"I'm going to work with your medical team to get you inpatient medication to prevent withdrawal"*	*"Would you like inpatient nicotine replacement to prevent withdrawal?"*	*"Would you like inpatient nicotine replacement to prevent withdrawal?"*
OUTPT COUNSELING:	*"We provide in-home counseling post-discharge to help you with your plan."*	*"Would you like in-home counseling post-discharge to help you with your plan?."*	
OUTPT PRESCRIPTION/ STARTER PACK:	*"We send everyone who is medically eligible home with a prescription and 2 weeks of free NRT."*	*"If you are medically eligible, would you like a prescription and 2 weeks of free NRT?"*	

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.)

The University of Kansas Hospital

- 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

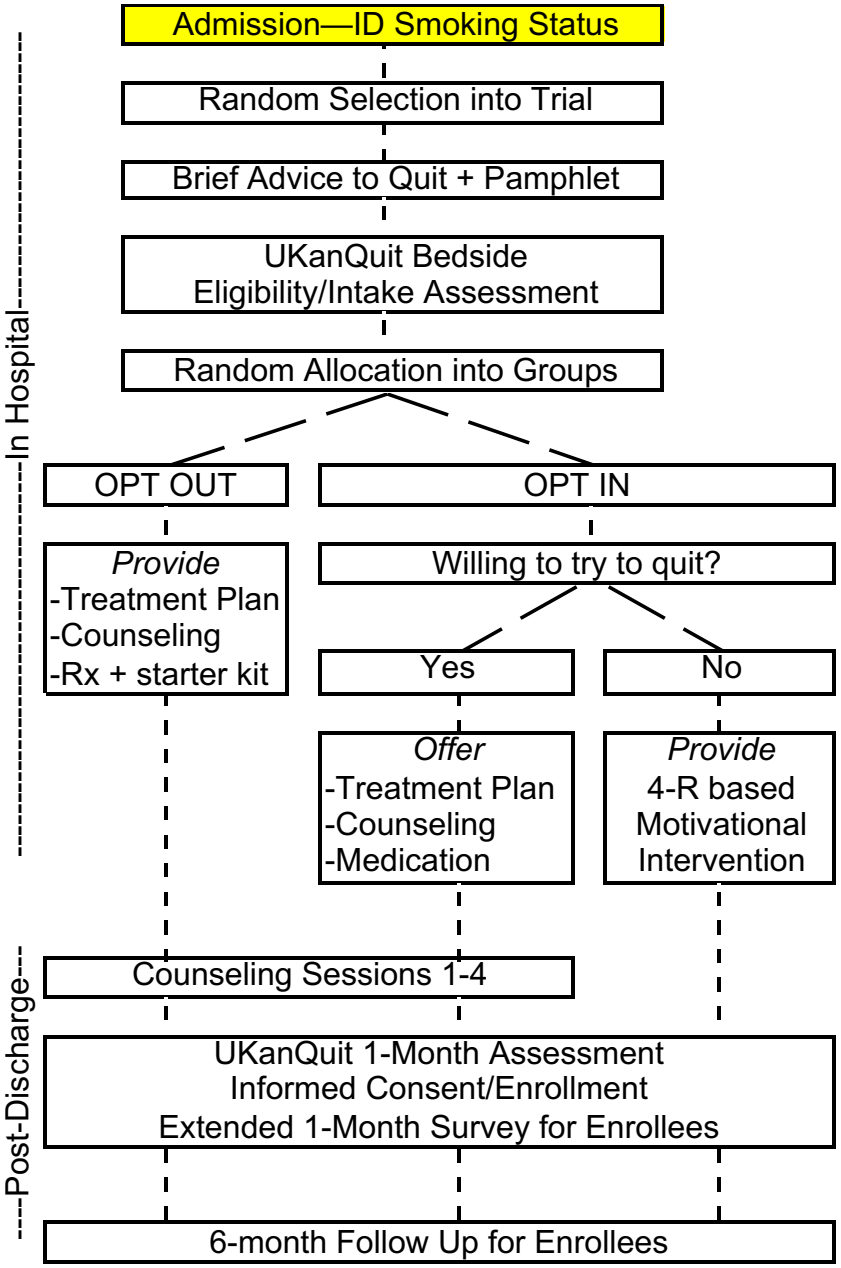
- Primary endpoint: rate of 7-day biochemically verified cigarette abstinence at 1 month after randomization in OPT IN arm versus OPT OUT arm.
  - Co-Endpoint: biochemically verified abstinence at 6 months

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=.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!!!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Eligibility/Intake Assessment
Random Allocation into Groups
In Hospital
OPT OUT
OPT IN
Provide
-Treatment Plan
-Counseling
-Rx + starter kit
Willing to try to quit?
Yes
No
Offer
-Treatment Plan
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-Medication
Provide
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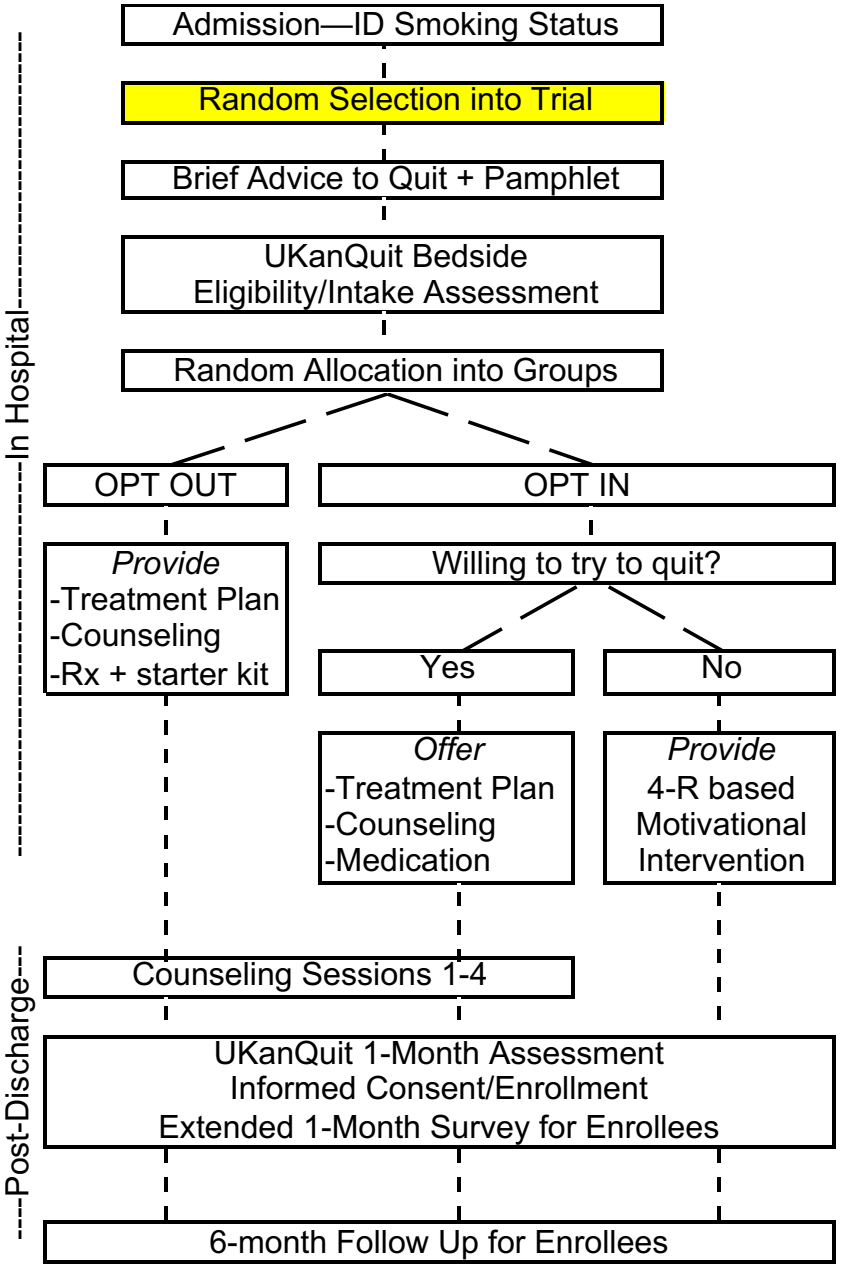
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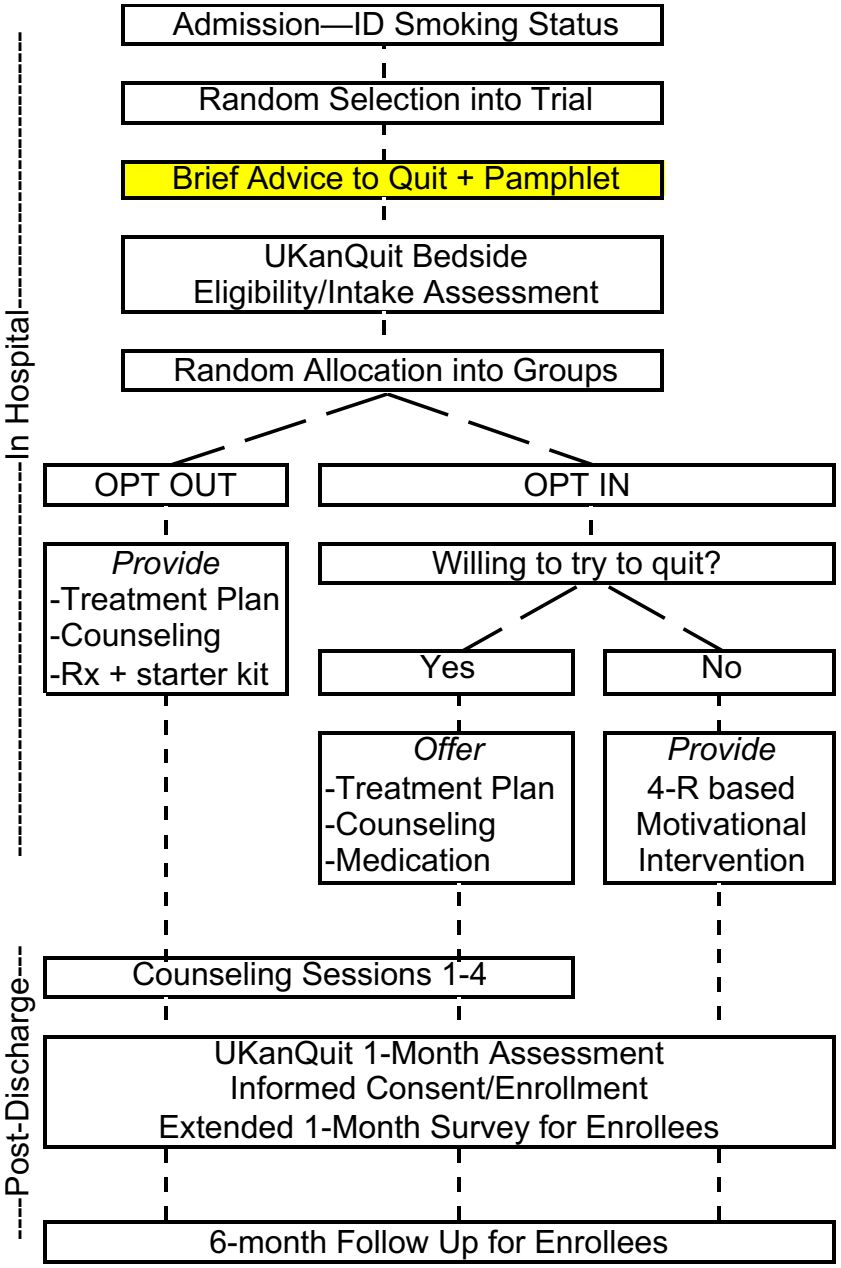
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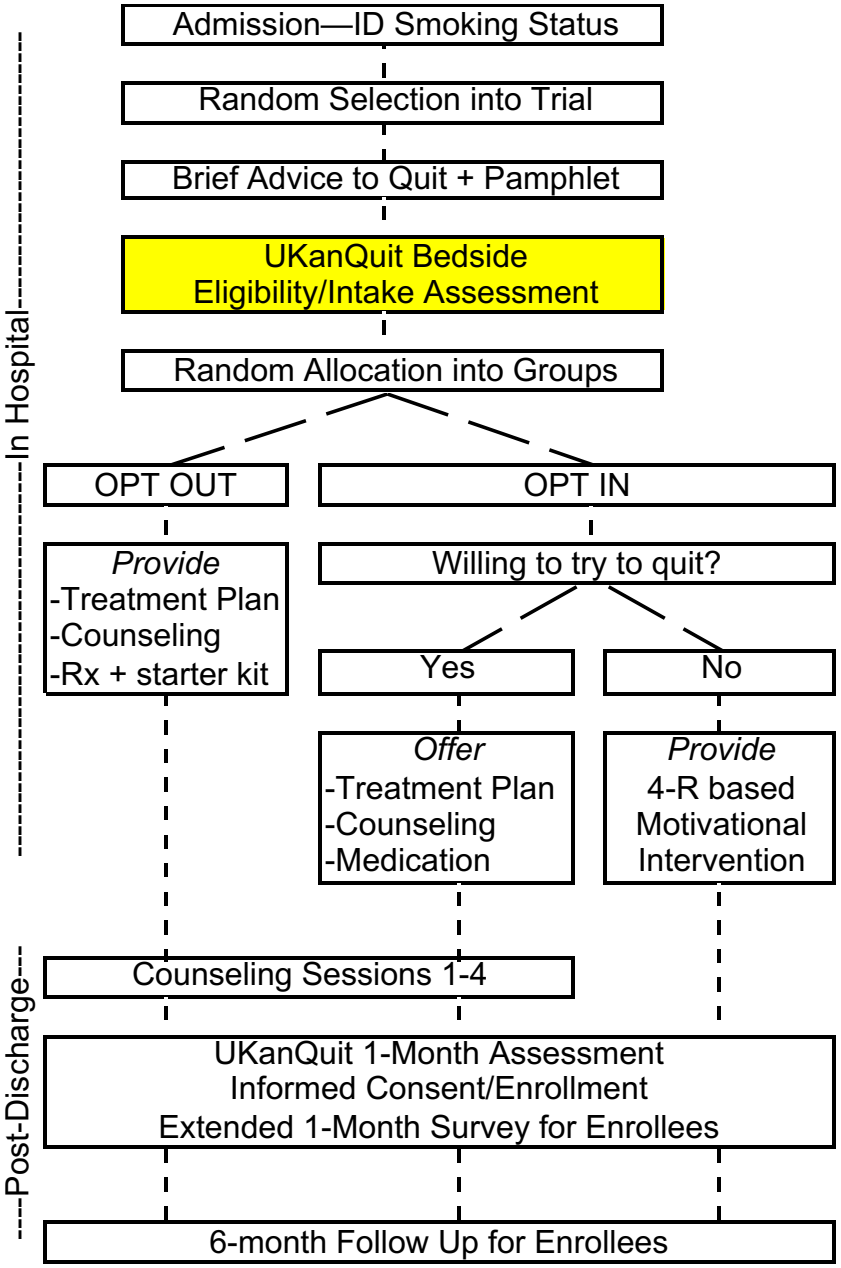
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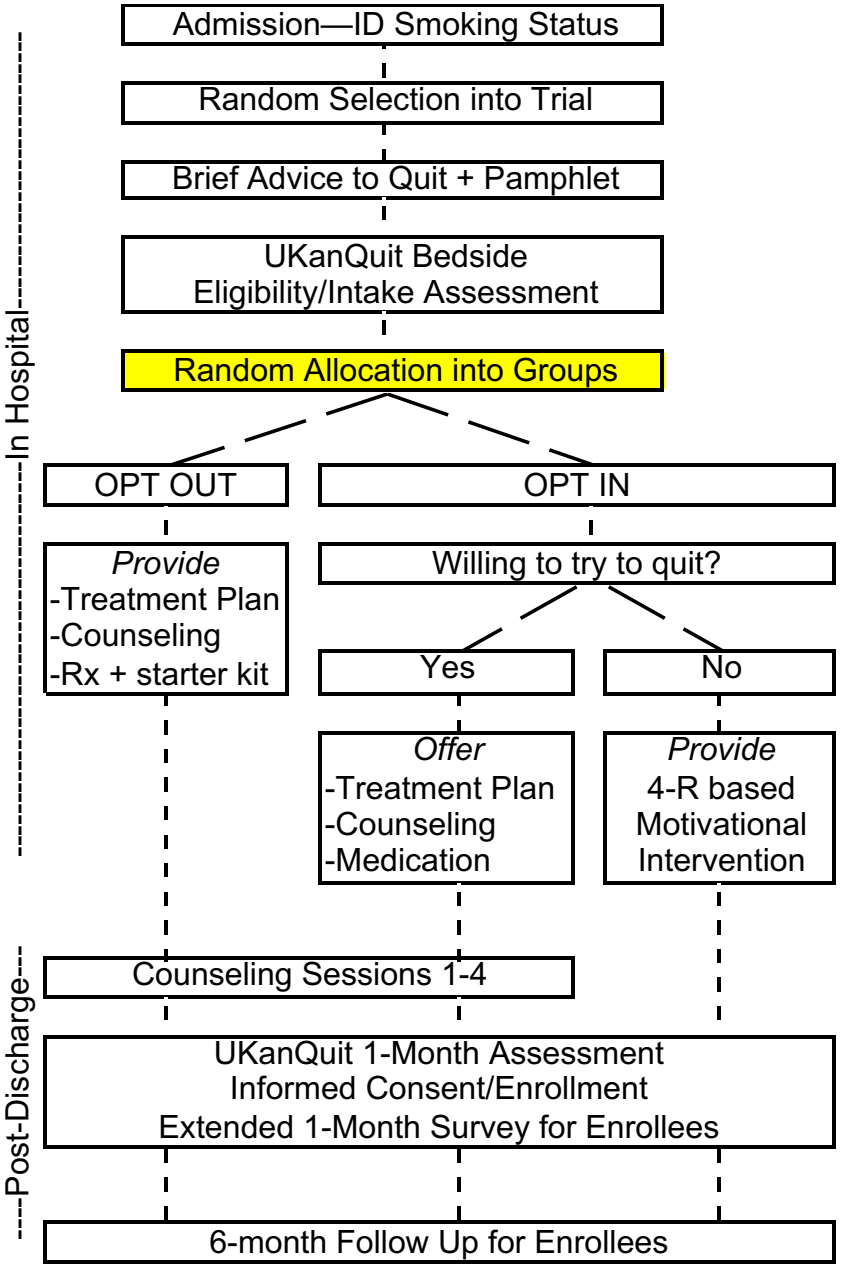
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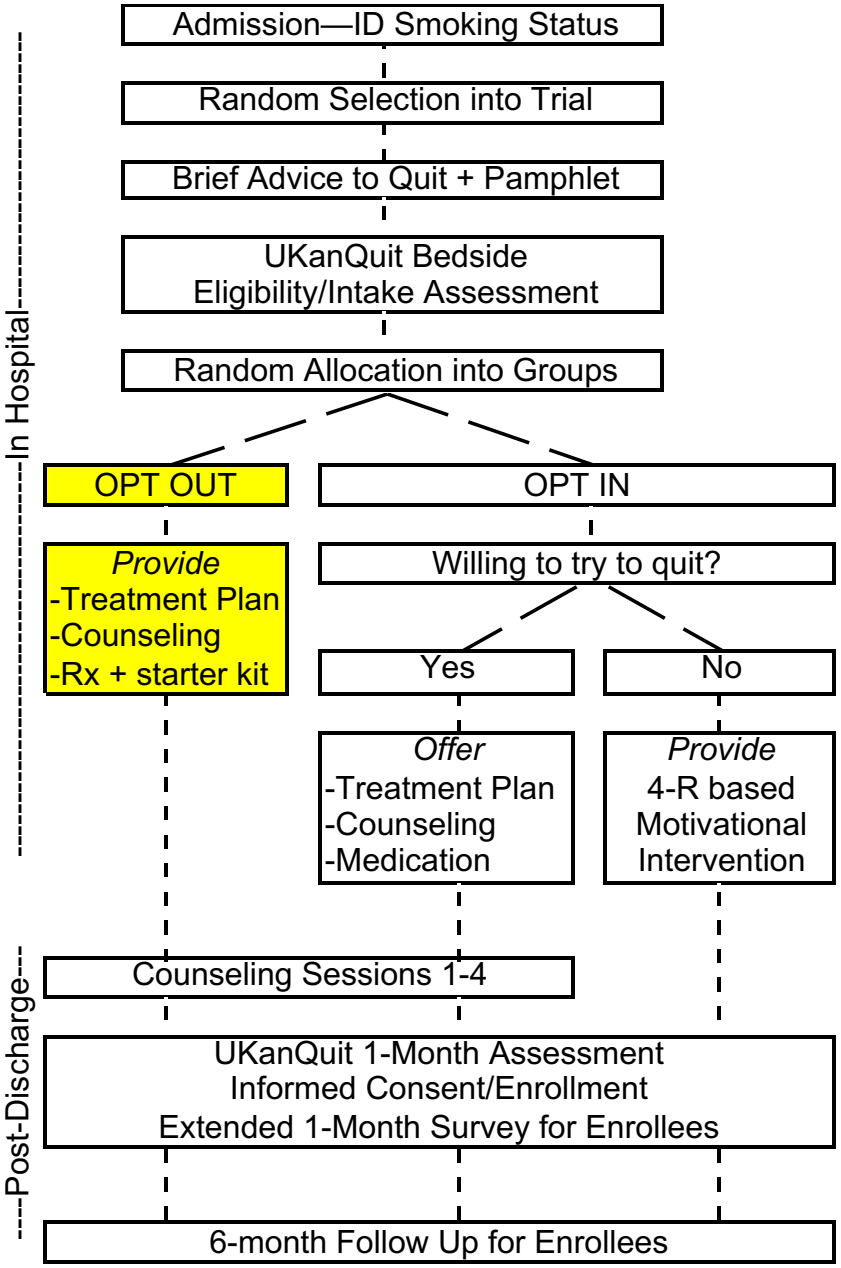
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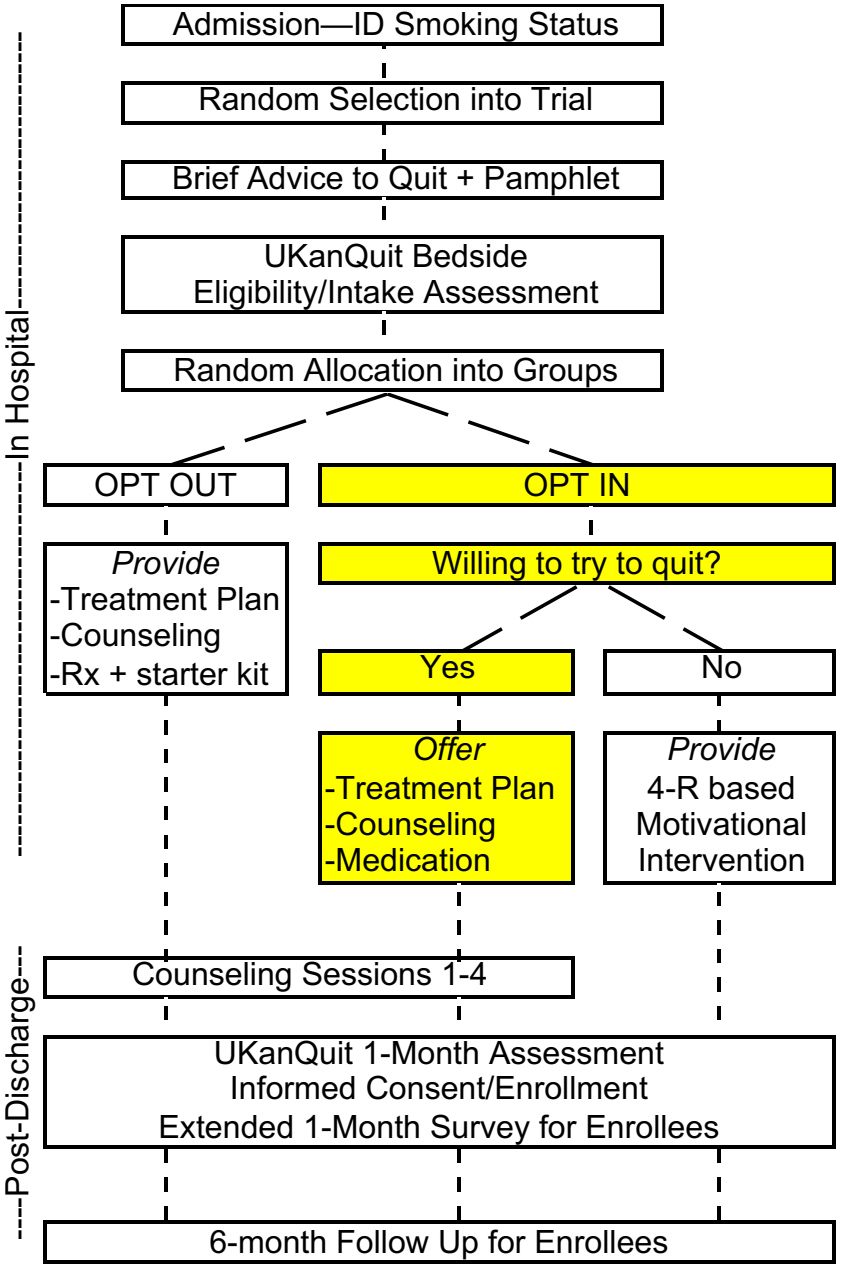
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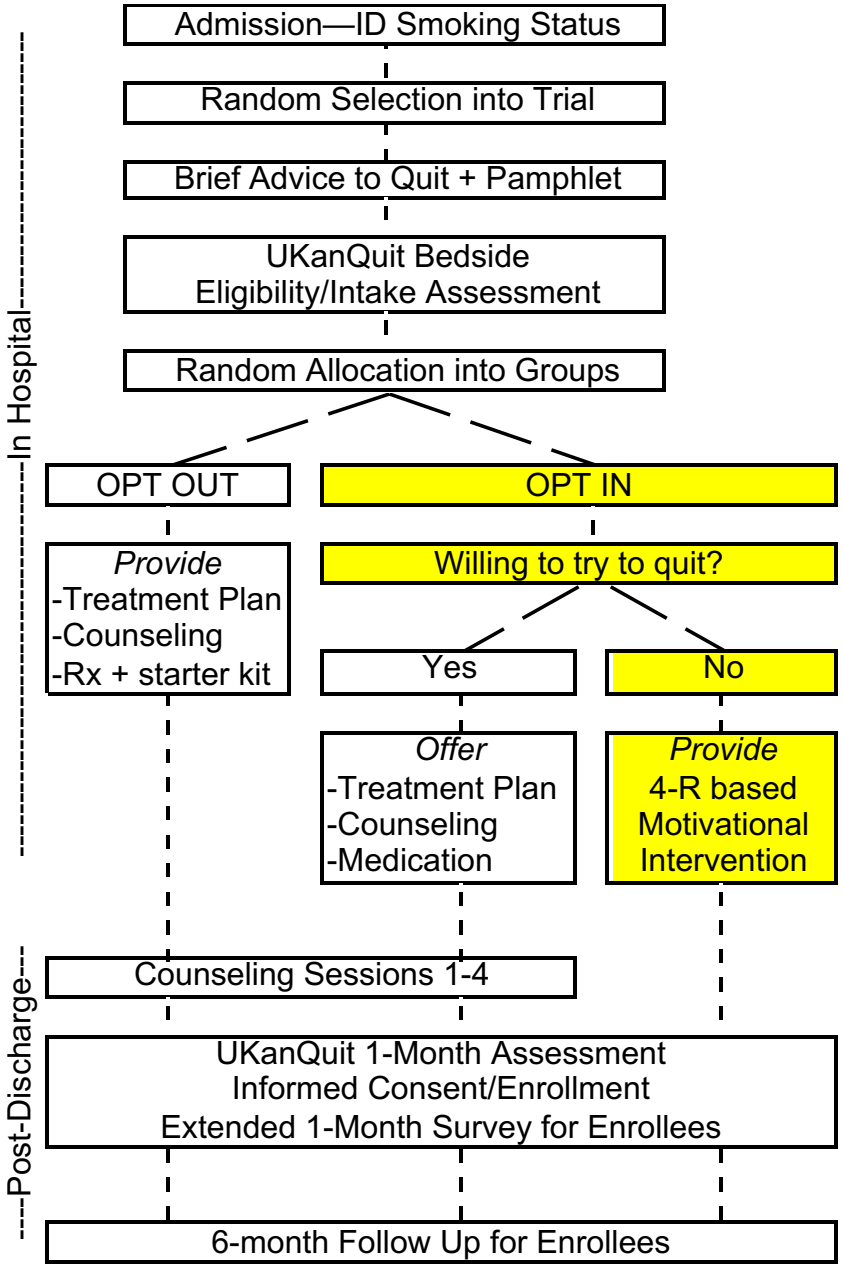
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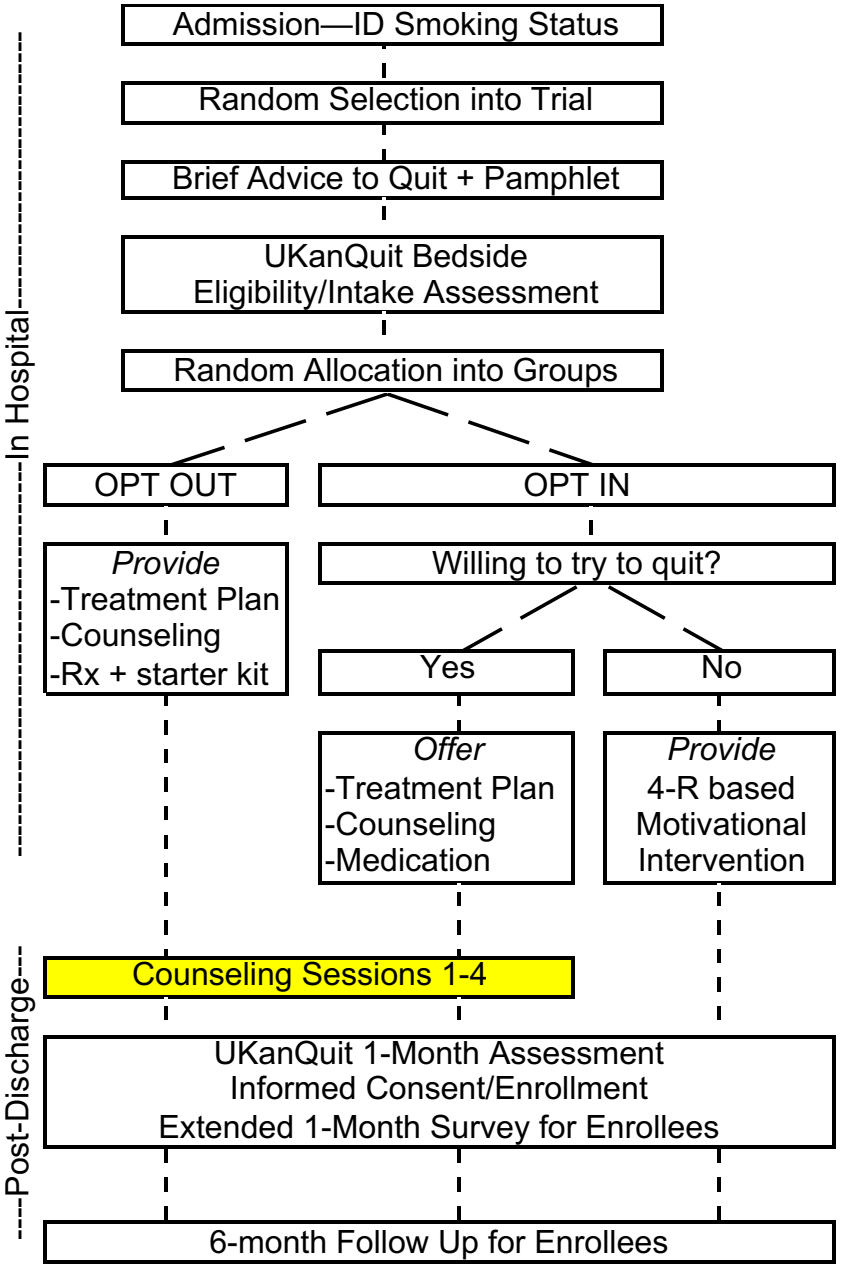
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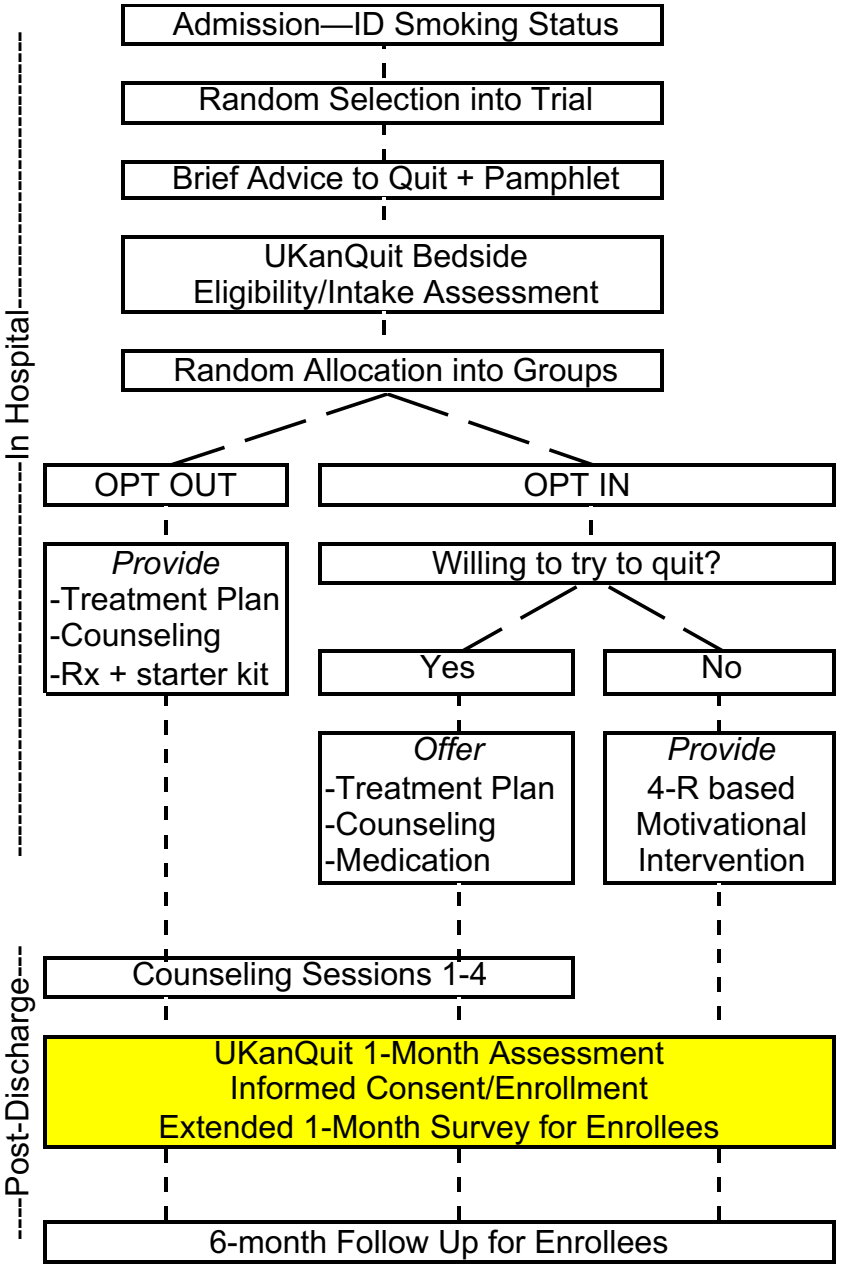
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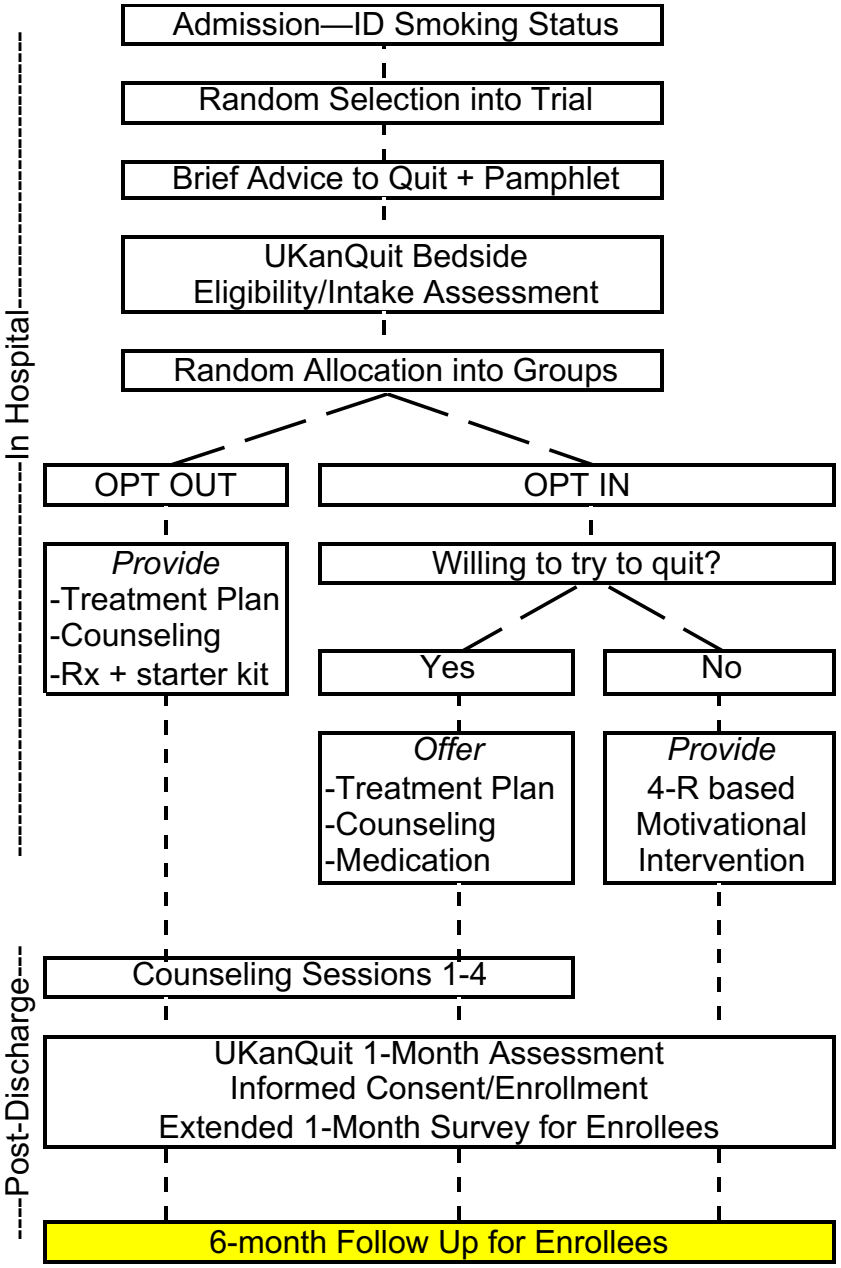
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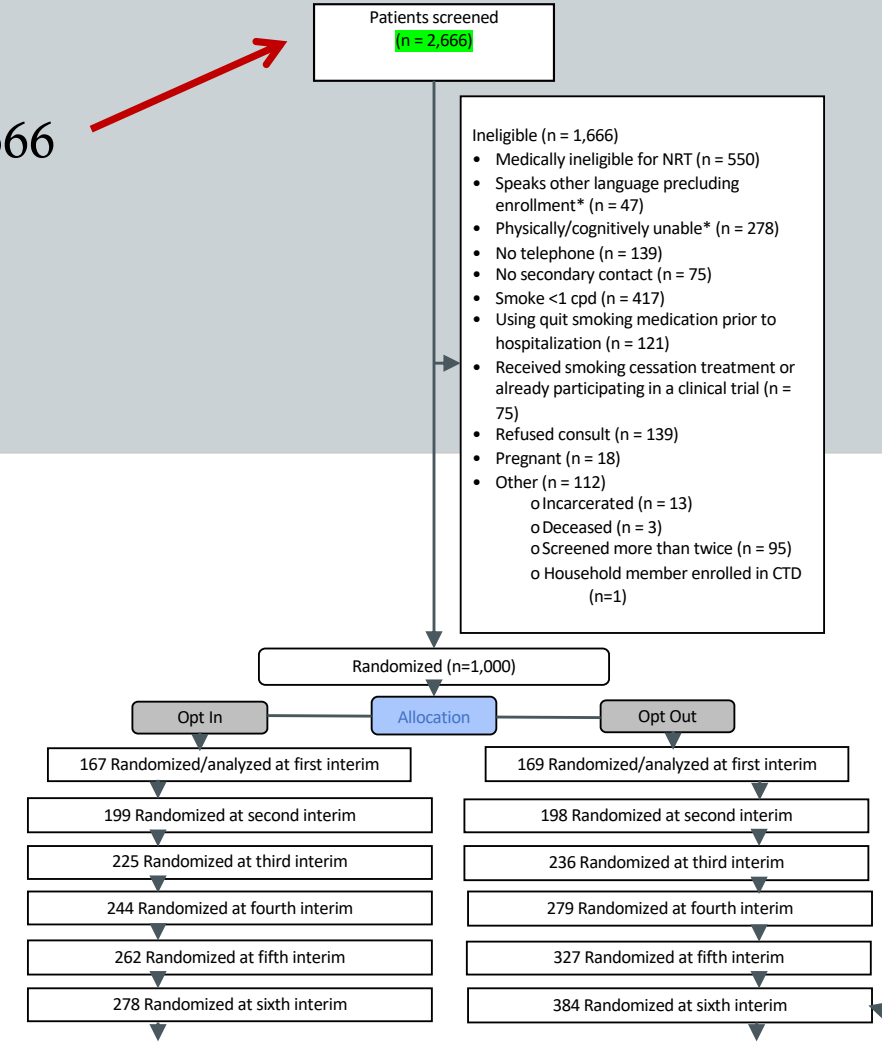
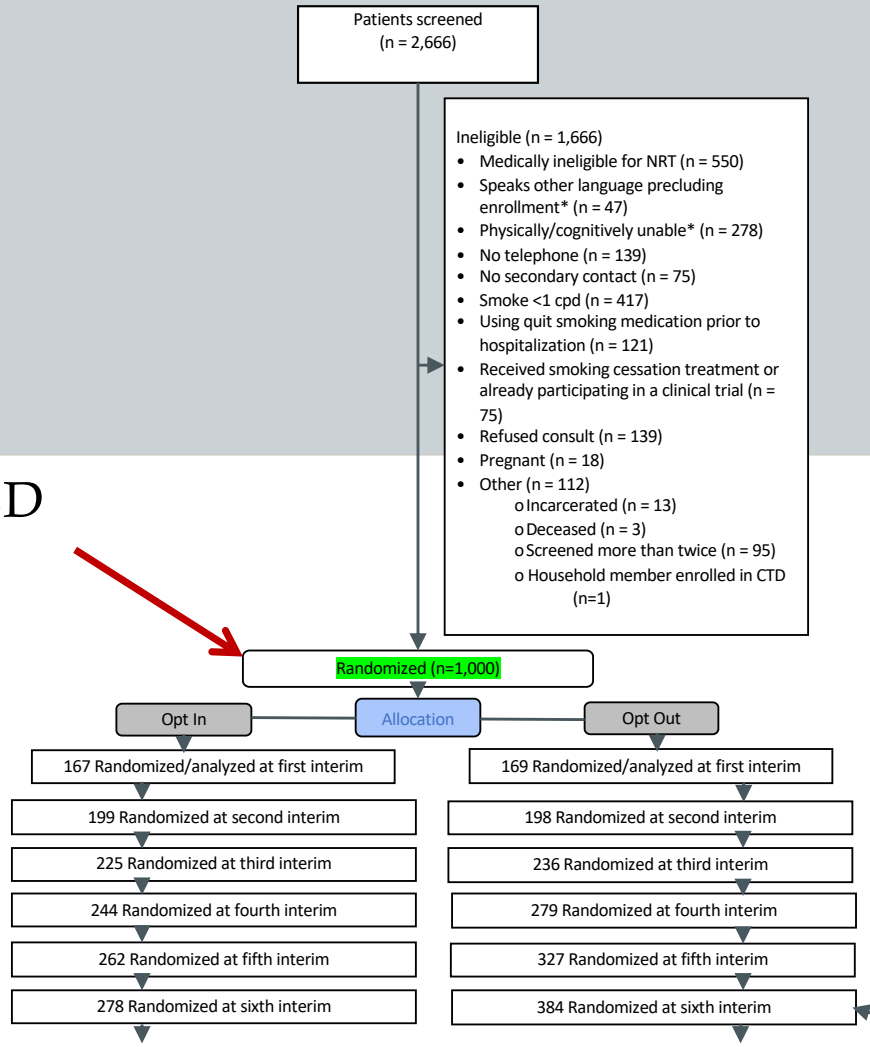
SCREENED 2,666



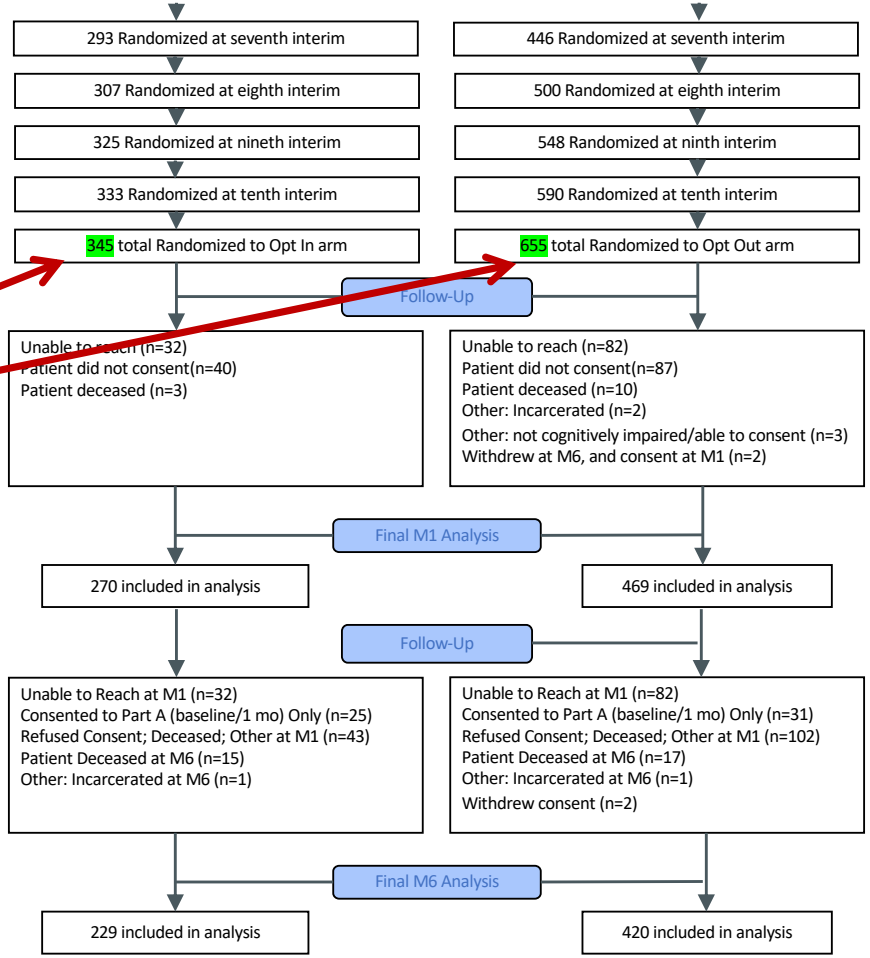
Protocol added 6-months co-primary outcome

RANDOMIZED
1,000



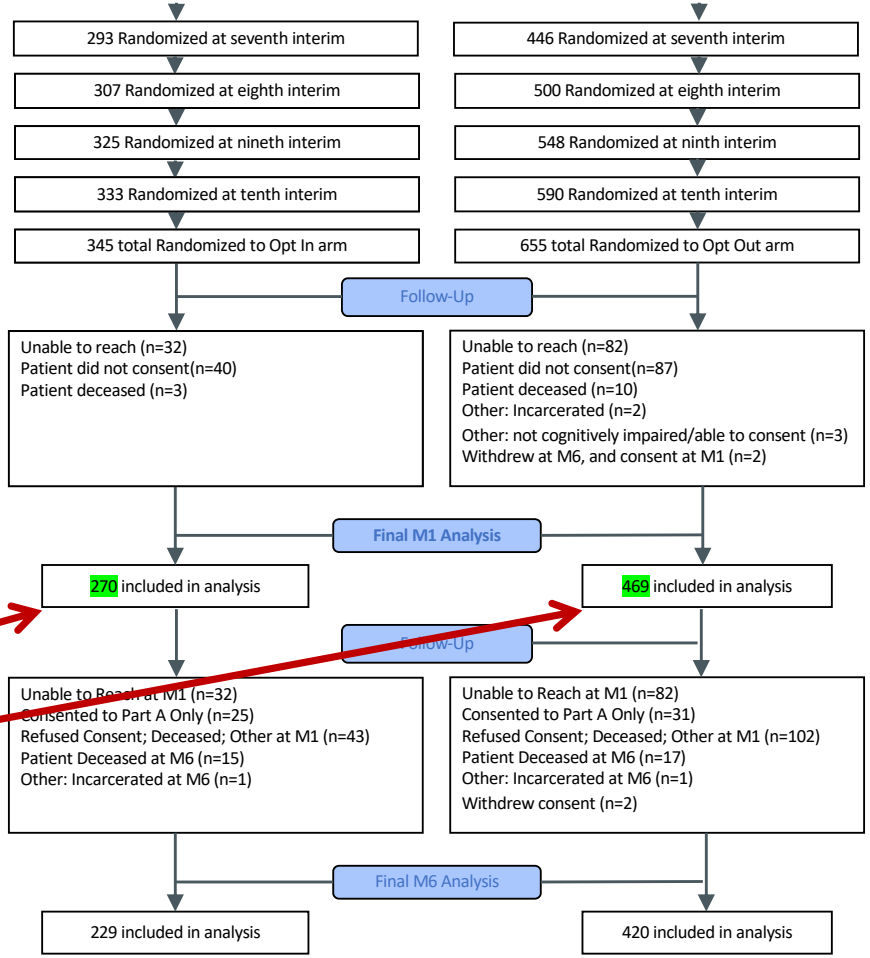
Protocol added 6-months co-primary outcome

345 OPT IN
655 OPT OUT

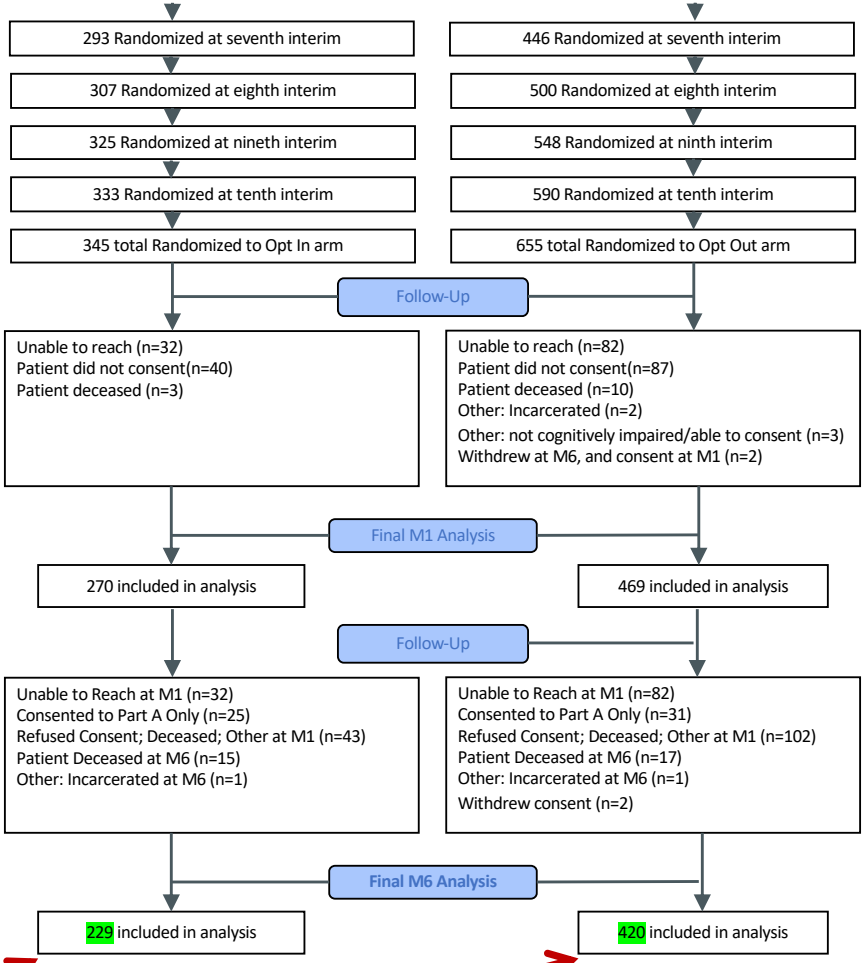


CONSENTED
&
ENROLLED

270 OPT IN
469 OPT OUT



739 = Study sample, main outcomes
74% of randomized included in trial



229 OPT IN
420 OPT OUT

649 = Study sample, 6 month outcomes

Table 1 (N=739)

	Opt In (270)	Opt Out (469)	d^
Demographics*			
Age (mean)	51.7	51.2	0.03
Female	45.6	48.2	0.06
Non-Hispanic White	58.5	57.6	0.02
Medicaid Primary insurance	18.9	21.1	0.08
Smoking Behavior			
HSI (heaviness of smoking index, mean)	2.5	2.2	0.17
Willing to stay quit post-discharge	64.1	66.3	0.05
Used e-cigs, past 30 days	4.8	8.1	0.31

*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

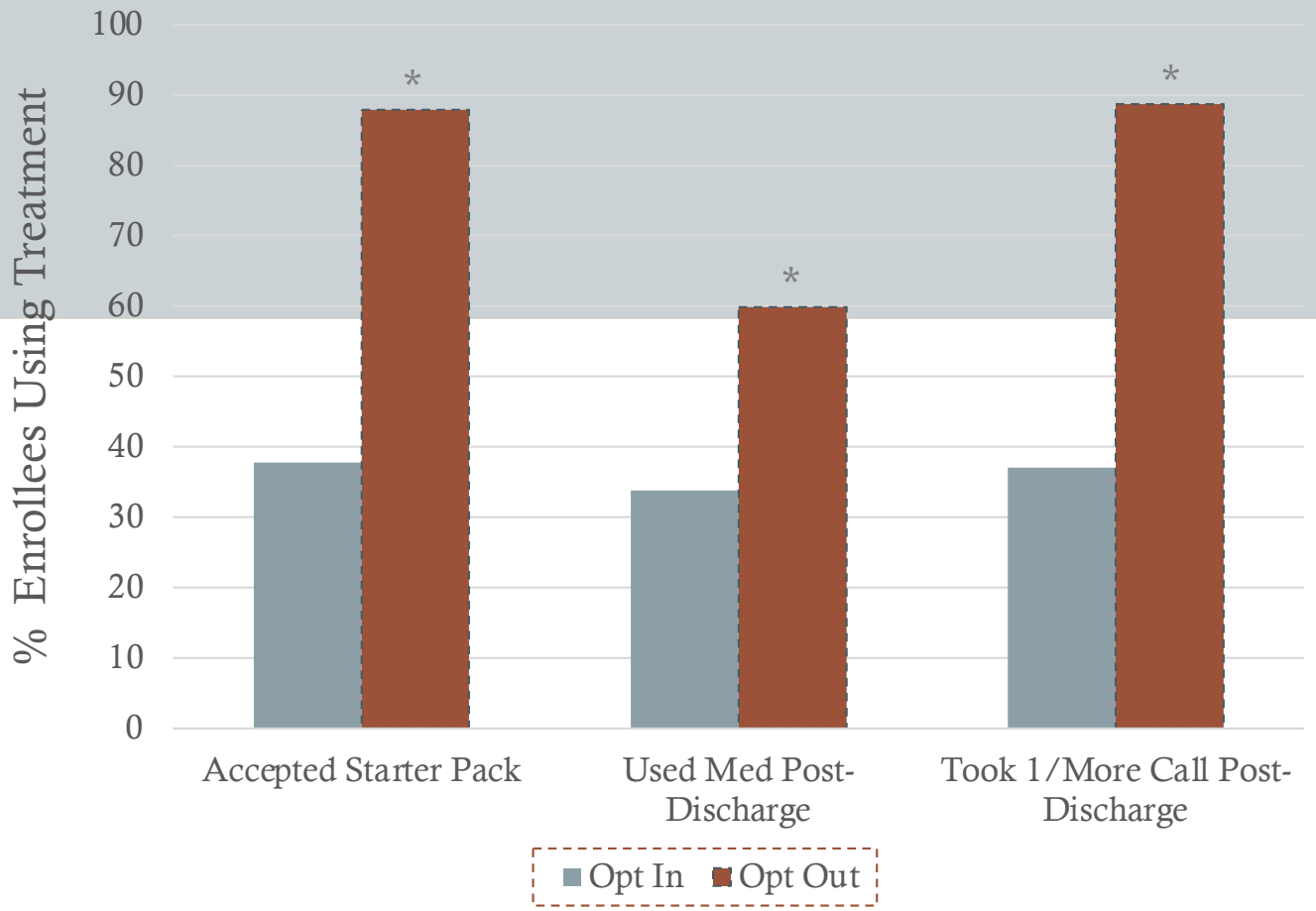
Abstinence Rates (95% Credible Interval)		Bayesian Posterior Probability Opt Out better than Opt In
Opt In	Opt Out	
15.8 (11.8, 20.5)	21.5 (17.9, 25.4)	**.971**

6 Month Outcomes (N=649)

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

Abstinence Rates (95% Credible Interval)		Bayesian Posterior Probability Opt Out better than Opt In
Opt In	Opt Out	
17.8 (13.2, 23.1)	18.5 (15.0, 22.4)	**.591**

Medication & Counseling Use (N=739)

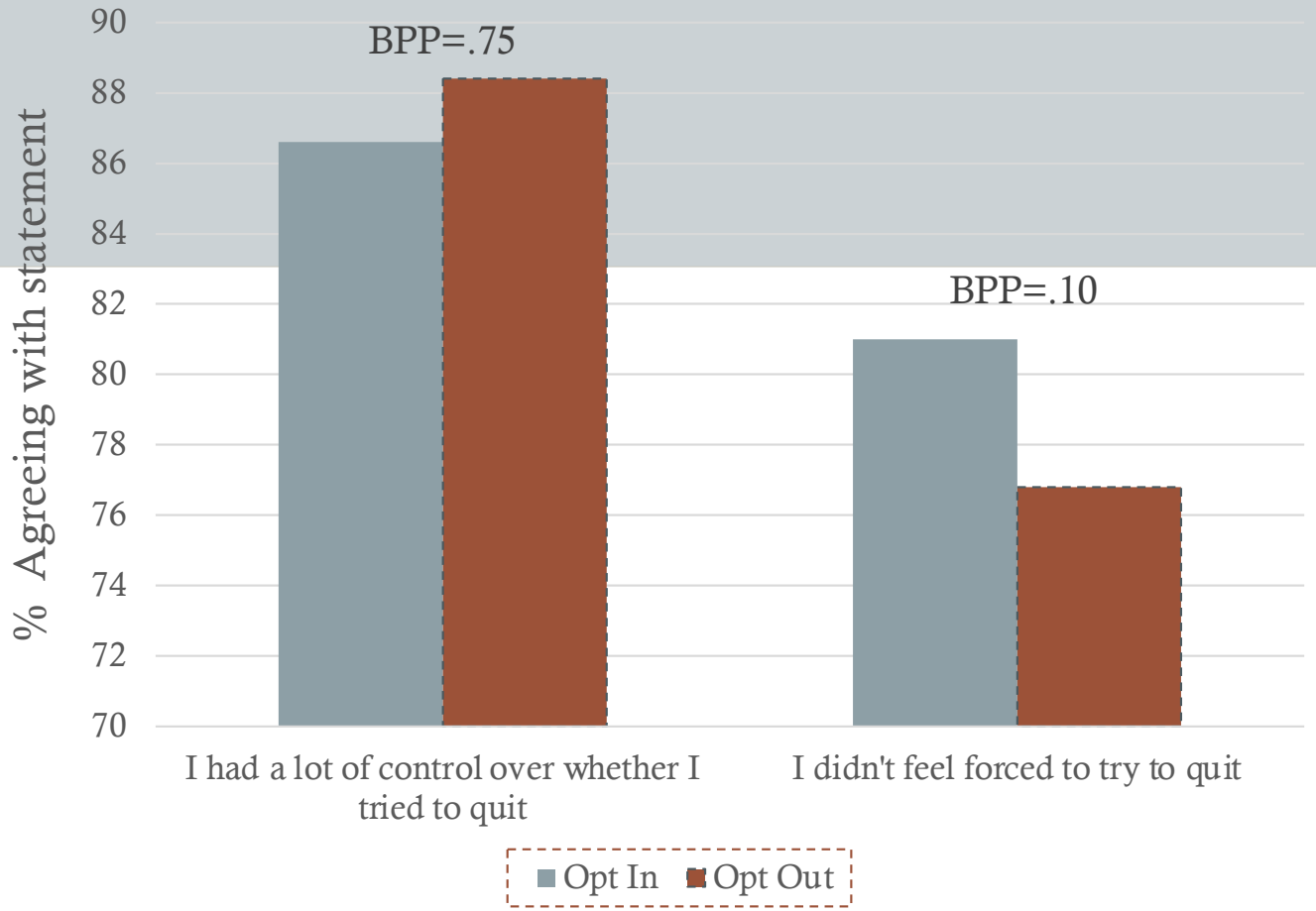


*Bayesian Posterior Probability 1.00

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)



Cost Effectiveness

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.

	Counseling (mean $ per/person)	Starter pack (mean $ per/person)	Sum (mean $ per/person)	Verified quit n (%)
Opt in (n=270)	15.35	21.46	36.81	43 (15.9%)
Opt out (n=469)	25.19	49.62	74.81	101 (21.5%)
Difference	9.84	28.16	38	5.6%
ICER				$678.6

ITT Quit Rates (N=1,000)

OPT OUT improves 1-month but not 6-month quit rate compared to OPT IN

	Abstinence Rates (95% CI)		Bayesian Posterior Probability Opt Out better than Opt In
	Opt In	Opt Out	
Month 1	12.4 (9.2, 16.1)	15.4 (12.8, 18.3)	**.902**
Month 6	11.8 (8.7, 15.5)	11.9 (9.5, 14.5)	**.512**

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

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Vivek Patel
Genevieve Casey
Alison Summers Hageman

Implementation Science & Equity

Center on Biomedical Research Excellence [Score 2.0]

Kimber Richter, PhD MPH
Christie Befort, PhD

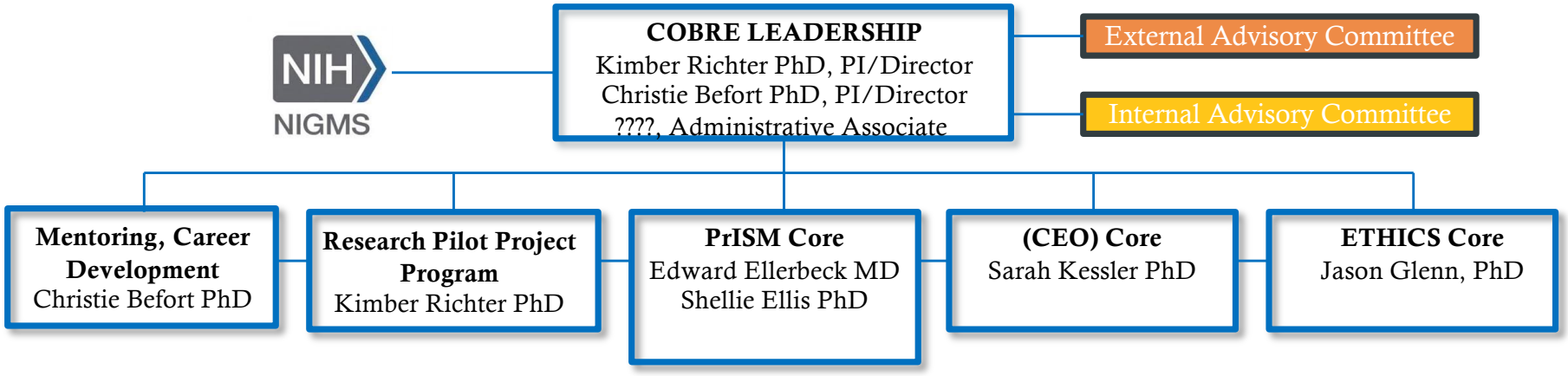
- Bench – bedside time lag: 17-years
  - 30–40% of patients fail to receive care consistent with current evidence
  - 20-25% of care that is provided is not needed or is potentially harmful

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

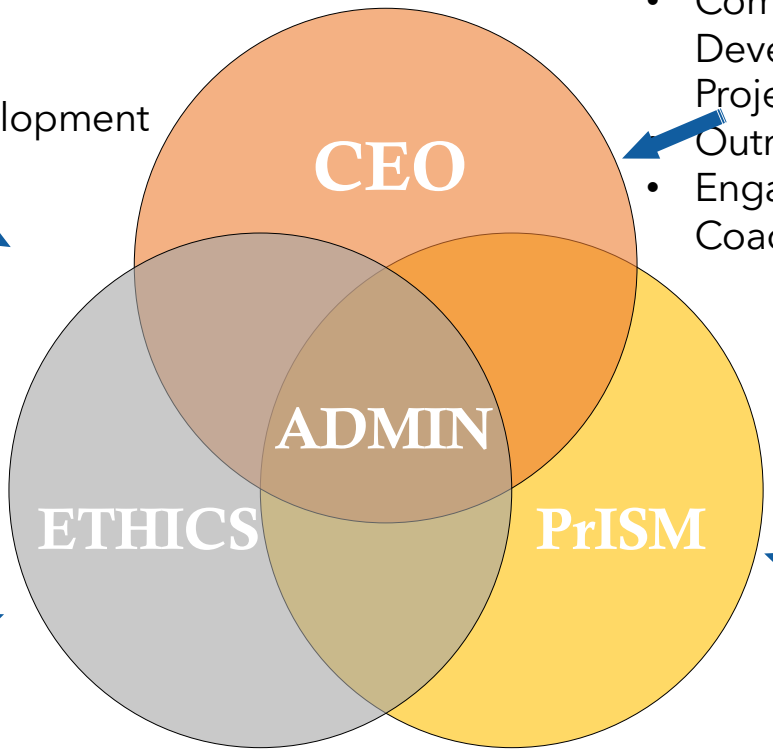
ISE COBRE Organizational Structure



Key Core Functions

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

Administrative Core
- Mentoring & Career Development Plans
- Evaluation



Pragmatic Implementation Science Methods
- Study Design
- Training Implementation
- Methods Support

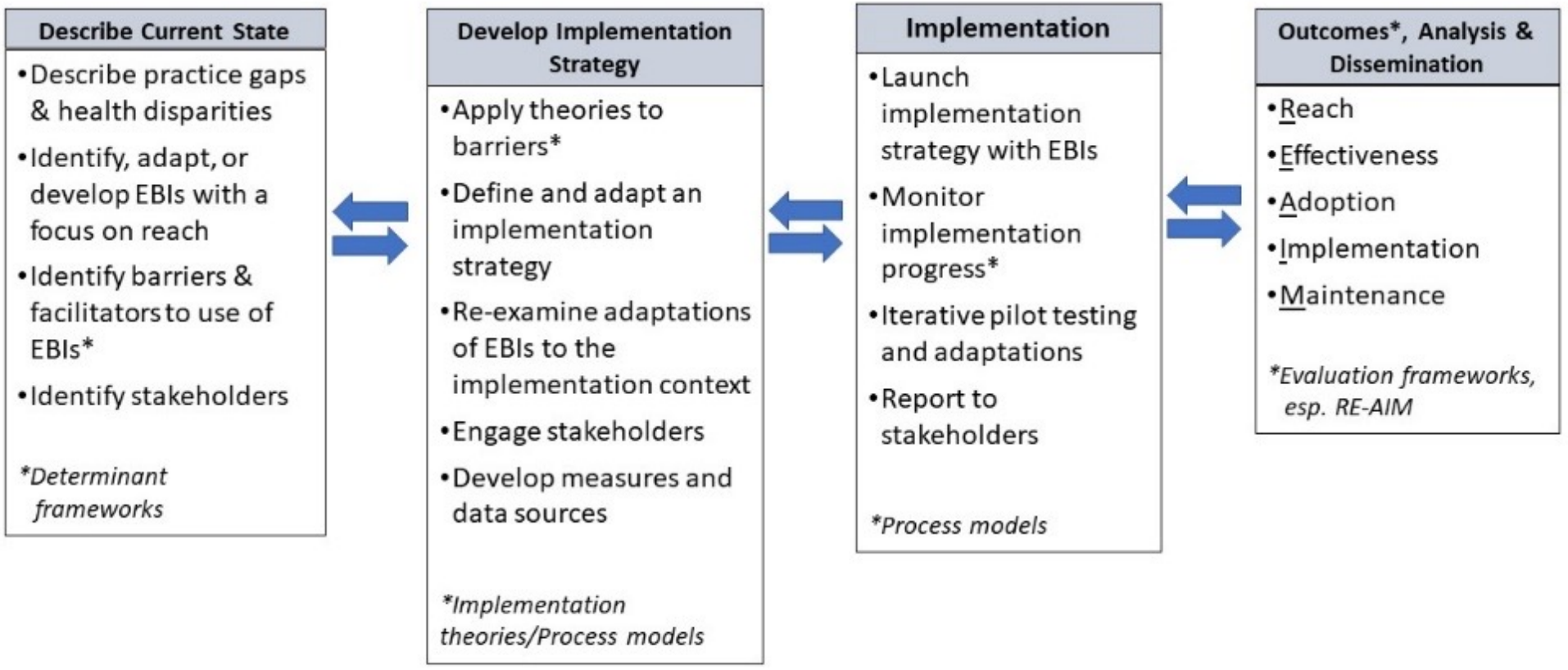
ETHICS, Human Subject & Regulatory
- Ethics Consultation
- Navigation
- Ethics/Compliance Training

ISE COBRE Pilot Projects 4 of 5

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

PrISM

Figure B. Stepped Approach to PrISM support of Implementation Research



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