

Creating a learning health system through randomization

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Grand rounds: Rethinking Clinical Research; March 6, 2020



Learning healthcare system

“A system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the delivery experience.”

– Institute of Medicine, 2012

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Why do we need randomized QI projects?

- Most health systems operational interventions have never been shown to be effective either in general or in particular
- We are often surprised...

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Health Care Hotspotting — A Randomized, Controlled Trial

Amy Finkelstein, Ph.D., Annetta Zhou, Ph.D., Sarah Taubman, Sc.D.,
and Joseph Doyle, Ph.D.

The scale of the problem

- In one year alone at my health system, we:
 - Fired millions of best practice alerts to prompt staff to provide evidence-based care or avoid adverse events
 - Made >19,000 telephone calls to patients after discharge from the hospital to improve continuity of care and satisfaction
 - Sent thousands of letters to remind patients they are overdue for preventive care testing
 - Hired half a dozen community health workers for the ED

Our program at a glance

At a glance



16

DEPARTMENTS



15

COMPLETED TRIALS



2

ONGOING TRIALS



9

TRIALS IN PLANNING

The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

**Creating a Learning Health System through Rapid-Cycle,
Randomized Testing**

Leora I. Horwitz, M.D., M.H.S., Masha Kuznetsova, M.P.H., and Simon A. Jones, Ph.D.

Ideal project characteristics

- Standard of care is already established
- High volume of cases
- Feasible randomization strategy
- Outcome of interest is relatively short-term
- Outcome of interest is already being collected
- Willing clinical/operational partner

Co-development with front-line

- We co-develop all projects with the end users
- Start with the problem, not the solution
 - What are challenges in daily work?
 - What are you doing that you think could be improved?
 - What are pain points in your work flow?
 - What outcomes are you dissatisfied with?
 - What do you not have capacity to do for all patients?

Randomization strategies

- Patient level
 - Epic can do this automatically
 - Good for patient-facing interventions like mailers, phone calls, MyChart prompts
- Practice level
 - Requires manual build in Epic
 - Good for provider-facing interventions like EHR alerts

Randomization strategies

- Any randomization strategy must be seamless and require no additional work by staff
- What if you can't do "true" randomization?
- Pseudo randomize by MRN (odd/even, 0-2,3-5,6-9)
 - Especially helpful for repeated interactions where patient must stay in same group over time
- Pseudo randomize by week (on/off/on/off)

IRB considerations



Institutional Review Board

Human Research Protection Program
1 Park Avenue | 6th Floor | New York, NY 10016
<http://med.nyu.edu/irb>

Self-Certification Form

Determining Whether Your Proposed Activity is Quality Improvement (QI)

Quality improvement vs research

Elements of QI Activity and Human Subjects Research: Key Differences		
Points to Consider	QI Activity	Human Subjects Research
Starting Point	To improve performance/care	To answer a question or test a hypothesis
Purpose	To assess a process/program/system as judged by established/accepted standards	To develop or contribute to generalizable knowledge
Design	Adaptive	Follows a fixed protocol throughout the duration of the proposed work
Benefits	Directly benefits a process/program/system; may or may not benefit patients	May or may not benefit current subjects; intended to benefit future patients
Risks	No anticipated increase in risk to patients, with the exception of possible privacy/confidentiality concerns	May put subjects at risk of harm
Participation Obligation	Responsibility to participate as component of care	No obligation for individuals to participate
Analysis	Compares a program/process/system to an established set of standards	To statistically prove or disprove a hypothesis
Adoption of Results	Promptly adopts results into local care delivery	Little urgency to disseminate results quickly
Publication	Clinicians are encouraged to share insights; results may be published	Investigators are obliged to share results

Quality improvement vs research

INSTRUCTIONS: Complete the following section to help you determine if your proposed activity falls in the realm of QI. If a statement is true, check off **YES**. If all of your responses to the below statements are positive (i.e., checked off **YES**), then your proposed activity constitutes QI that does not require IRB review or oversight.

QI Certification Statements		YES	NO
1	Your activity's primary objective is to produce an improvement in safety or care that <u>will be sustained</u> over time at the local institution or within a particular program at the local institution. NOTE: <i>If the intended outcome is simply to report on what happened at the local institution/program, it does not indicate research design or intent as it may not be generalizable outside of the local institution.</i>	<input type="checkbox"/>	<input type="checkbox"/>
2	Your activity does NOT use a fixed protocol for the duration of the proposed work. NOTE: <i>If frequent adjustments are needed, your answer should be "YES."</i>	<input type="checkbox"/>	<input type="checkbox"/>
3	Your activity does NOT involve an intervention that may pose risks greater than those presented by routine clinical <u>care</u> .	<input type="checkbox"/>	<input type="checkbox"/>
4	There will be minimal delays in implementing changes from results.	<input type="checkbox"/>	<input type="checkbox"/>
5	All individuals involved in key project roles have on-going commitment to the improvement of the local care situation.	<input type="checkbox"/>	<input type="checkbox"/>
6	Your activity is NOT funded by an outside organization with commercial interest in the use of the results. NOTE: <i>The purpose of this statement is to determine if the project has received funding to be conducted as a research study.</i>	<input type="checkbox"/>	<input type="checkbox"/>
7	Your activity is NOT part of a multi-center project that involves non-NYUL Health sites. NOTE: <i>If it is being conducted in a multi-site context with a common protocol across sites, then the results may be generalizable and thus constitute research.</i>	<input type="checkbox"/>	<input type="checkbox"/>

ClinicalTrials.gov

- We file all trials to ClinicalTrials.gov
- Had to get our institutional ClinicalTrials.gov person familiar with this type of project
- Forces us to develop a priori outcomes, though approach largely uncertain
- Allows us to publish later

Examples and lessons learned

Rapid cycle randomized trial lab: trials

- Flu vaccination best practice alert, NYULH inpatient, whole system
- **Post-discharge calls**, NYU Brooklyn inpatient
- **Community health workers**, NYU Brooklyn ED
- **Mailers for preventive care**, Clinically Integrated Network
- Posters for patient reported outcomes, Outpatient office
- **Tobacco cessation BPA**, NYULH outpatient
- **Preventive care phone calls**, Florida outreach center, clinically integrated network

Post-discharge phone calls

Post-discharge calls

- Two goals:
 - Reduce readmission rates
 - Increase patient experience ratings of hospital
- Expanded to new hospital; insufficient staff to call everyone
- Called only odd numbered MRNs

Post-discharge call results: readmission

Cohort	Total cohort	Reached	Readmission rate	Mean IP visits
Control - even MRN	1614	80 (5%)	178 (11%)	0.13 (0.38)

August 13, 2018-November 30, 2018

P=0.949

Post-discharge call results: HCAHPS

Cohort	Recommend hospital	Rate 10/10
Control	72%	64%

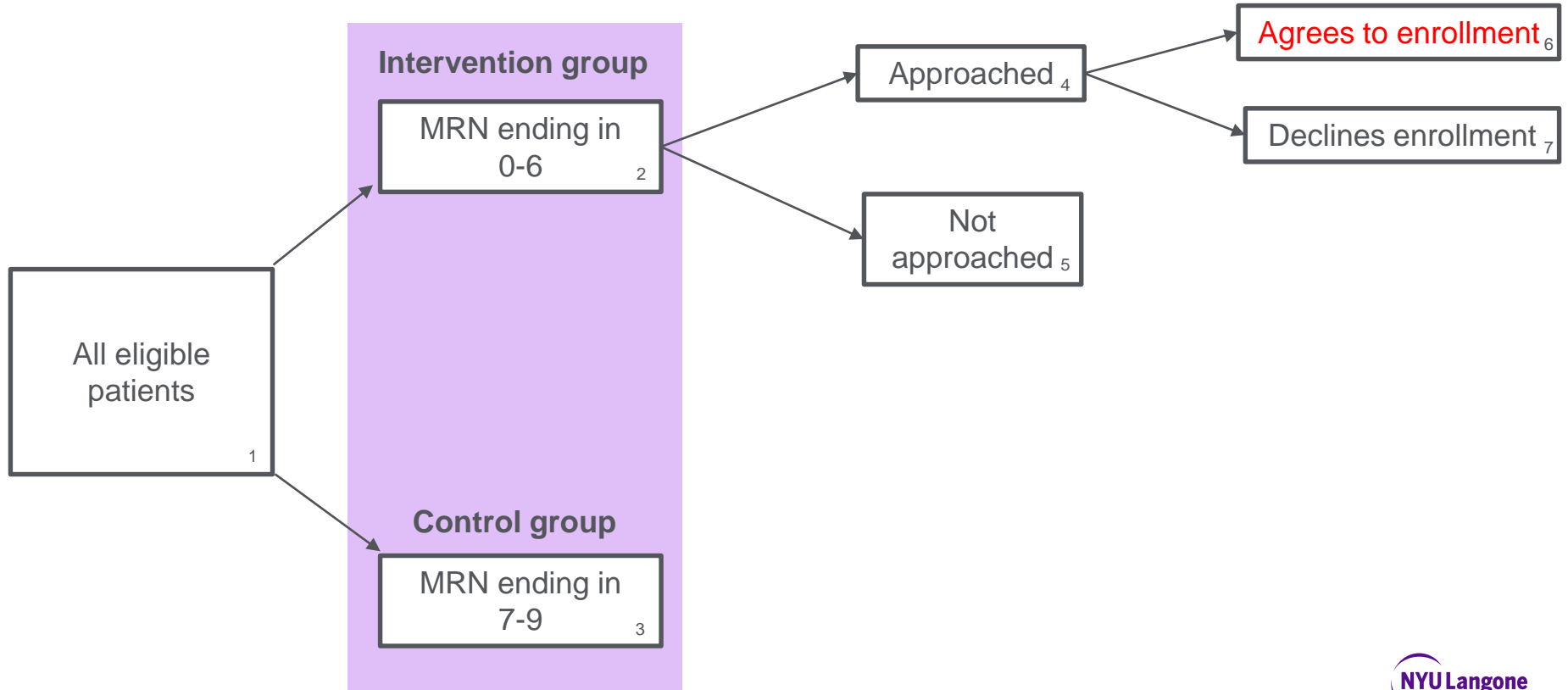
August 13, 2018-November 30, 2018

Community health workers in ED

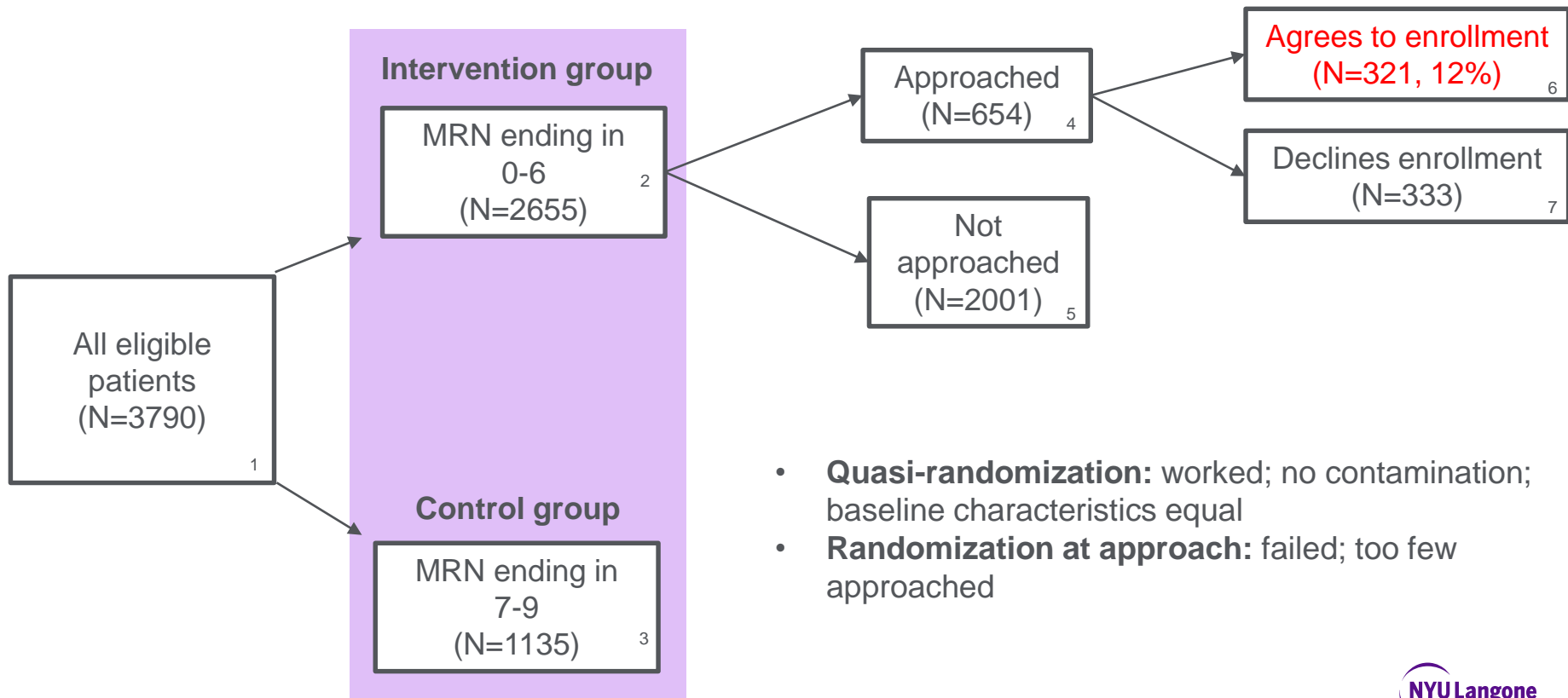
Community health workers in ED

- Focus on “high risk” patients as defined by prior utilization, social stressors or high risk diagnoses
- Goal: enroll in ED and follow for next 60 days
- Insufficient numbers of CHWs to offer to everyone; previously approaching on convenience basis

Quasi-randomization at approach



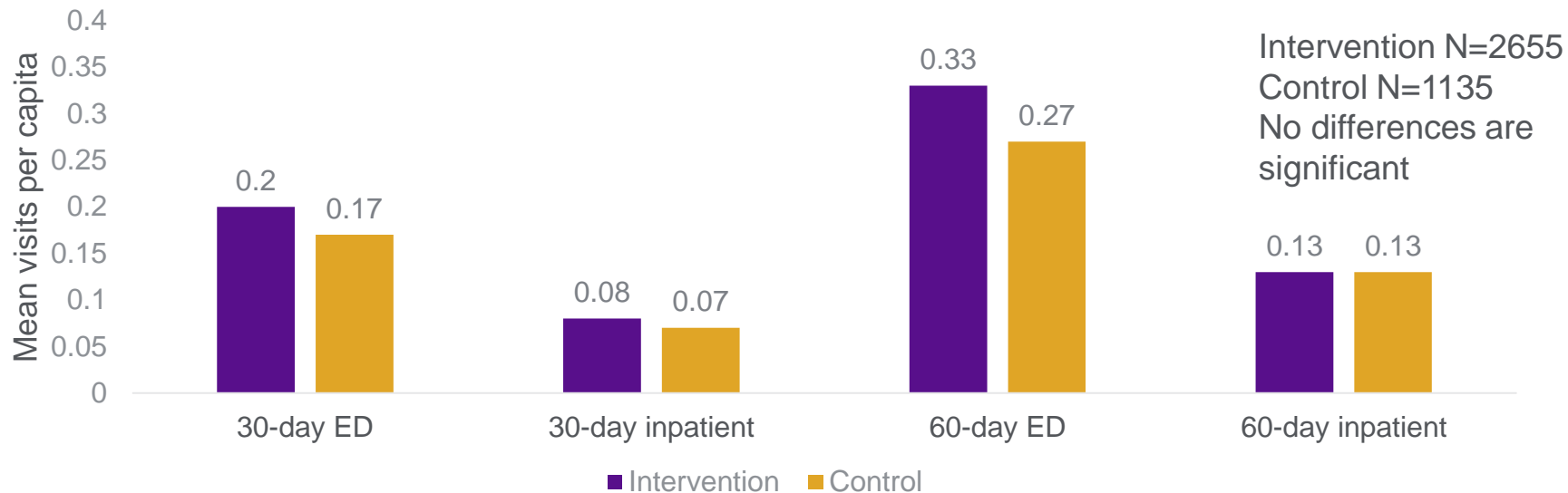
Quasi-randomization at approach



- **Quasi-randomization:** worked; no contamination; baseline characteristics equal
- **Randomization at approach:** failed; too few approached

RCT: Community health worker results

Community health worker intervention March 12-Aug 31, 2018



Mailers for care gaps

RCT: Mailers for care gaps



Practice Addr Line 1
Practice Addr Line 2
Practice City, Practice State Practice Zip Code

Member Name
Member Address Line 1
Member Address Line 2
Member City, Member State, Member Zip Code

Dear Member Name:

At NYU Langone Health, we care about your health. Our records indicate you are due for preventative health screenings: Gap 1, Gap 2, Gap 3, Gap 4

As a Healthfirst member, you are eligible to **receive a gift card** by completing health screenings. If you complete one or more screenings before December 31, 2018, you can get a gift card from Healthfirst by mailing in the enclosed form. For more information, see the Healthfirst reward form.

Do not miss this opportunity to earn a gift card from Healthfirst. Call us today at (718) 765-6512 to schedule an appointment for your health screenings.

We look forward to seeing you.

Provider Name

Practice Name

RCT: Mailers results

Table 1: Gaps status for people with complete follow up

Cohort	Control		Intervention		P Value
	Mean (SD)	N	Mean (SD)	N	
Gaps open at baseline	1.04 (1.04)	1591	1.04 (1.04)	1554	
Gaps closed at follow-up*	0.32 (0.32)	1591	0.35 (0.35)	1554	0.157
Gaps still open at follow-up	0.72 (0.72)	1591	0.69 (0.69)	1554	
Gaps closed at baseline	0.72		0.70		

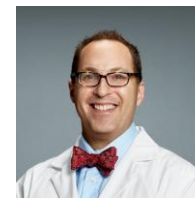
Tobacco cessation BPA

RCT: Tobacco cessation counseling

⚠️ TOBACCO CESSATION INTERVENTION NEEDED

Evidence shows that a brief counseling session reduces tobacco use.

Evidence-based



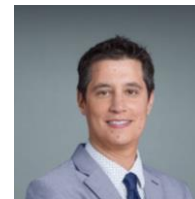
Adam Szerencsy, DO

VS.

⚠️ TOBACCO CESSATION INTERVENTION NEEDED

Tobacco cessation counseling is an NYULH priority clinical quality measure.

Institutional
priority



Devin Mann, MD

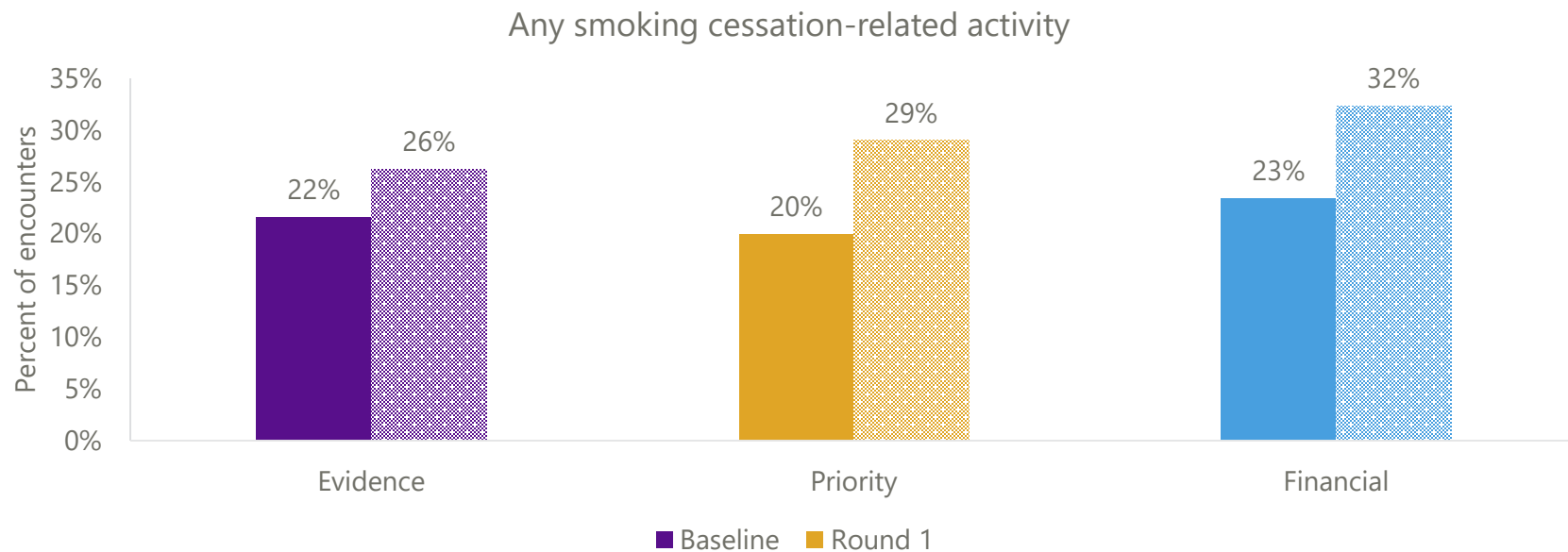
VS.

⚠️ TOBACCO CESSATION INTERVENTION NEEDED

Tobacco cessation counseling is a billable service (3-10 minutes: CPT 99406/0.38 RVU).
Charges are automatically filed using the SmartSet documentation.

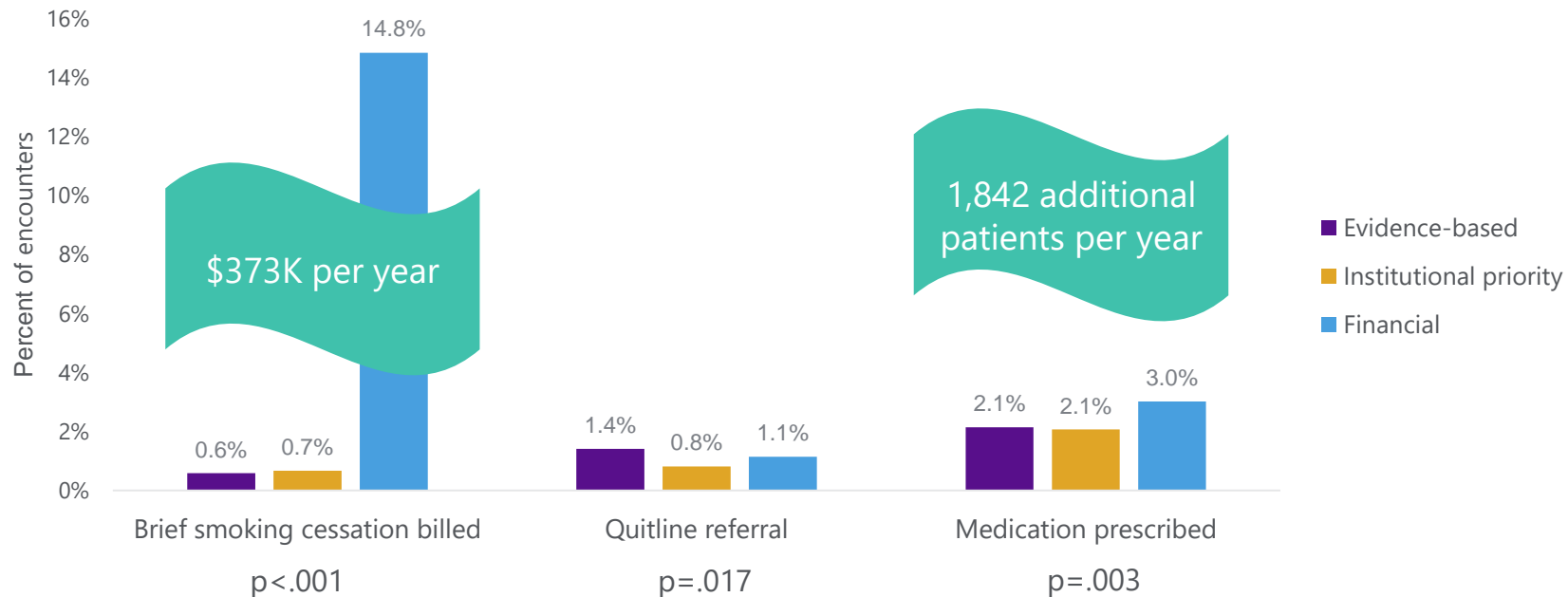
Financial

RCT: Tobacco cessation counseling



RCT: Tobacco cessation counseling

Cessation-related interventions



RCT Round 2: Tobacco cessation counseling

① TOBACCO CESSATION INTERVENTION

Tobacco cessation counseling
Charges are automatically filed

Open the SmartSet to:
• Perform counseling

① TOBACCO CESSATION INT

Evidence shows that brief cou

Open the SmartSet to:

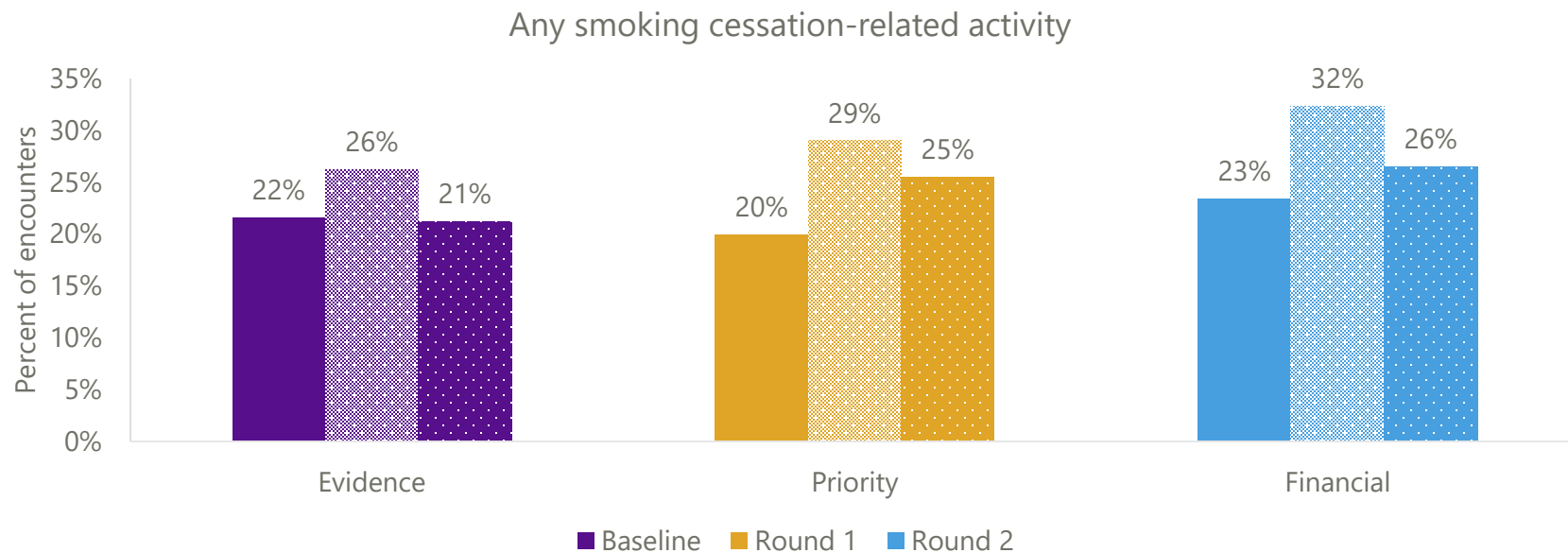
① TOBACCO CESSATION INT

Tobacco cessation counseling

Open the SmartSet to:

"I was seeing a patient today and I had the chart opened while in the room... so that I could take notes. In the Smart set box for tobacco cessation was an extremely large dollar bill sign... it was so large that I am sure my patient or her daughter saw it. I felt a little embarrassed and I couldn't wait to get out of the intake screen... Going forward, I am afraid... most of my patients are going to see the big fat dollar bill."

RCT: Tobacco cessation counseling



N baseline = 32,941 encounters; N round 1 = 14,738; N round 2 = 16,492

RCT Round 3: Tobacco cessation counseling

! TOBACCO CESSATION INTERVENTION NEEDED

Tobacco cessation counseling is a billable service (3-10 minutes: CPT 99406/0.38 RVU, > 10 minutes: CPT 99407/0.77 RVU). Charges are automatically filed using the SmartSet documentation.



Open the SmartSet to:

- Perform counseling

! TOBACCO CESSATION INTERVENTION NEEDED

Tobacco cessation counseling is a billable service (3-10 minutes: CPT 99406/0.38 RVU, > 10 minutes: CPT 99407/0.77 RVU). Charges are automatically filed using the SmartSet documentation.



Open the SmartSet to:

- Perform counseling

! TOBACCO CESSATION INTERVENTION NEEDED

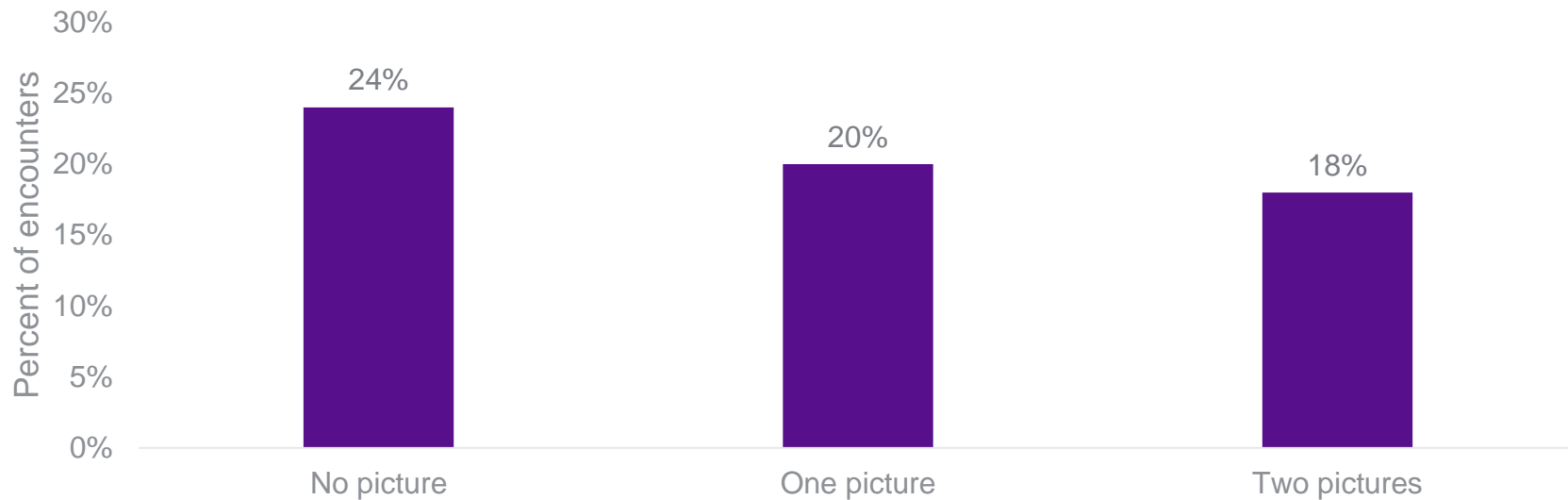
Tobacco cessation counseling is a billable service (3-10 minutes: CPT 99406/0.38 RVU, > 10 minutes: CPT 99407/0.77 RVU). Charges are automatically filed using the SmartSet documentation.

Open the SmartSet to:

- Perform counseling

RCT: Tobacco cessation counseling

Round 3: Financial message with/without pictures



Phone calls for care gaps

RCT: Preventive care outreach

Version	Selected key text changes
Original	My name is <<first name>> and I am calling on behalf of <<physician name>> at <<practice name>> to ensure your healthcare needs are being met, and that your health record is up-to-date. Is this a good time to talk? I only need a few moments of your time.



Ramsey Abdallah, MBA



Carrie Rooke, MPH



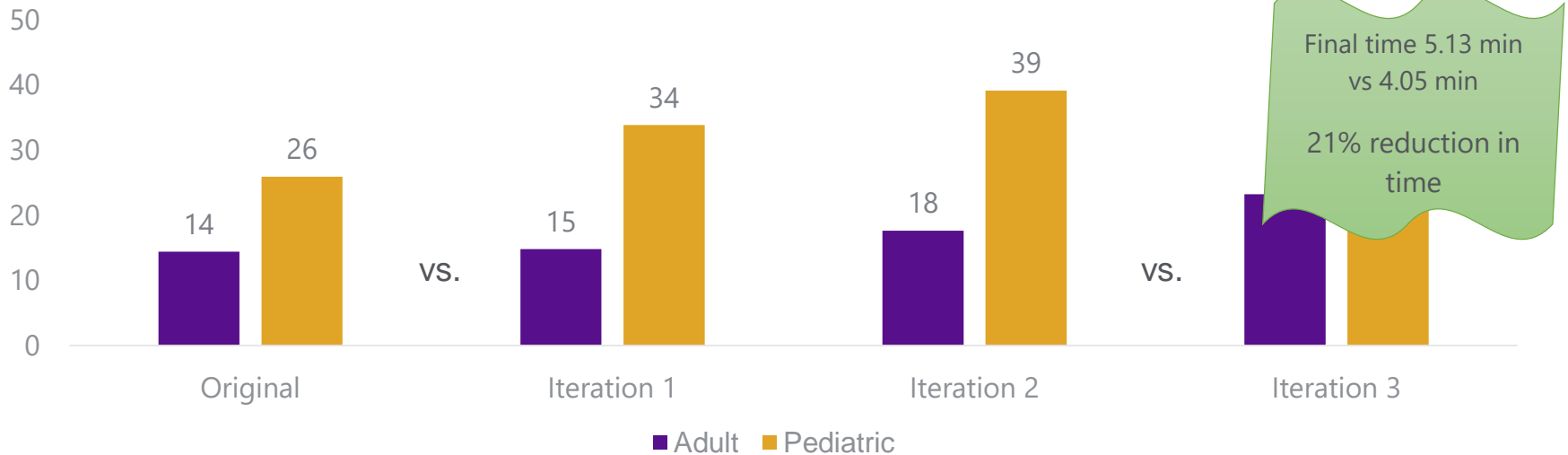
Matthew Penziner

RCT: Preventive care outreach

Version	Selected key text changes	Appointment rate	Mean call duration
Iteration 2	My name is <<first name>> and I am calling on behalf of <<physician name>> at <<practice name>> to help schedule your yearly checkup, and to ensure that your healthcare needs are being met. Is this a good time to talk? I only need a few moments of your time.	17.6%	3.33 min
Iteration 3	My name is <<first name>> and I am calling on behalf of <<physician name>> at <<practice name>> because we noticed that you have not been here this year and we would like you to come back for your yearly check-up. I can schedule it right away, it will only take a few minutes. Is this a good time to talk? I only need a few moments of your time.	23.2%	3.06 min
Both	[if hasn't had a visit and none scheduled] I can go ahead and help you schedule an appointment with <<physician name>> is that okay?		

RCT: Preventive care outreach

Annual visit call script appointment success rate



N roughly 200 per arm per round

Lessons learned

- Senior level administrative support is essential
- Trust of front-line is essential
- Statistical significance is not always the right threshold for decision-making

Lessons learned

- Collect complete set of baseline data first; invariably discover major differences in baseline outcomes from expected and challenges in data collection
- Must qualitatively debrief front-line users after the first run, not only before
- Randomization of approach not intervention makes efficacy eval difficult but represents system level benefit

THANK YOU

