Creating a learning health system through randomization

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Grand rounds: Rethinking Clinical Research; March 6, 2020
“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
“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
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...
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**

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)
Self-Certification Form
Determining Whether Your Proposed Activity is Quality Improvement (QI)
## Quality improvement vs research

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

<table>
<thead>
<tr>
<th>QI Certification Statements</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Your activity’s primary objective is to produce an improvement in safety or care that will be sustained over time at the local institution or within a particular program at the local institution. <strong>NOTE:</strong> 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Your activity does <strong>NOT</strong> use a fixed protocol for the duration of the proposed work. <strong>NOTE:</strong> If frequent adjustments are needed, your answer should be &quot;YES.&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Your activity does <strong>NOT</strong> involve an intervention that may pose risks greater than those presented by routine clinical care.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. There will be minimal delays in implementing changes from results.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. All individuals involved in key project roles have on-going commitment to the improvement of the local care situation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Your activity is <strong>NOT</strong> funded by an outside organization with commercial interest in the use of the results. <strong>NOTE:</strong> The purpose of this statement is to determine if the project has received funding to be conducted as a research study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Your activity is <strong>NOT</strong> part of a multi-center project that involves non-NYUL Health sites. <strong>NOTE:</strong> 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.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Total cohort</th>
<th>Reached</th>
<th>Readmission rate</th>
<th>Mean IP visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control - even MRN</td>
<td>1614</td>
<td>80 (5%)</td>
<td>178 (11%)</td>
<td>0.13 (0.38)</td>
</tr>
</tbody>
</table>

August 13, 2018- November 30, 2018

P=0.949
Post-discharge call results: HCAHPS

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Recommend hospital</th>
<th>Rate 10/10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>72%</td>
<td>64%</td>
</tr>
</tbody>
</table>

August 13, 2018-November 30, 2018
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

All eligible patients

<table>
<thead>
<tr>
<th>Intervetion group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRN ending in 0-6</td>
<td>MRN ending in 7-9</td>
</tr>
</tbody>
</table>

- Approached
  - Agrees to enrollment
  - Declines enrollment
- Not approached
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

Mean visits per capita

30-day ED
- Intervention: 0.2
- Control: 0.17

30-day inpatient
- Intervention: 0.08
- Control: 0.07

60-day ED
- Intervention: 0.33
- Control: 0.27

60-day inpatient
- Intervention: 0.13
- Control: 0.13

Intervention N=2655
Control N=1135
No differences are significant
Mailers for care gaps
RCT: Mailers for care gaps

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) 785-6512 to schedule an appointment for your health screenings.

We look forward to seeing you.

Provider Name

Practice Name
## Table 1: Gaps status for people with complete follow up

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Control</th>
<th>Intervention</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gaps open at baseline</td>
<td>1.04 (1.04)</td>
<td>1.04 (1.04)</td>
<td></td>
</tr>
<tr>
<td>Gaps closed at follow-up*</td>
<td>0.32 (0.32)</td>
<td>0.35 (0.35)</td>
<td>0.157</td>
</tr>
<tr>
<td>Gaps still open at follow-up</td>
<td>0.72 (0.72)</td>
<td>0.69 (0.69)</td>
<td></td>
</tr>
<tr>
<td>Gaps closed at baseline</td>
<td>0.72</td>
<td>0.70</td>
<td></td>
</tr>
</tbody>
</table>
Tobacco cessation BPA
RCT: Tobacco cessation counseling

Evidence-based

- Evidence shows that a brief counseling session reduces tobacco use.

VS.

Institutional priority

- Tobacco cessation counseling is an NYULH priority clinical quality measure.

VS.

Financial

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

Any smoking cessation-related activity

Percent of encounters

- Evidence: Baseline - 22%, Round 1 - 26%
- Priority: Baseline - 20%, Round 1 - 29%
- Financial: Baseline - 23%, Round 1 - 32%
RCT: Tobacco cessation counseling

Cessation-related interventions

- Brief smoking cessation billed: 14.8% (Evidence-based) with p < .001
- Quitline referral: 1.4% (Evidence-based) with p = .017
- Medication prescribed: 3.0% (Financial) with p = .003

$373K per year

1,842 additional patients per year
“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

Evidence

- Baseline: 22%
- Round 1: 26%
- Round 2: 21%

Priority

- Baseline: 20%
- Round 1: 29%
- Round 2: 25%

Financial

- Baseline: 23%
- Round 1: 32%
- Round 2: 26%

N baseline = 32,941 encounters; N round 1 = 14,738; N round 2 = 16,492
RCT Round 3: Tobacco cessation counseling

1. TOBACCO CESSION INTERVENTION NEEDED

Tobacco cessation counseling is a billable service (3-10 minutes: CPT 99405/0.38 RVU, > 10 minutes: CPT 99407/0.77 RVU). Charges are automatically filed using the SmartSet documentation.

Open the SmartSet to:
• Perform counseling

2. TOBACCO CESSION INTERVENTION NEEDED

Tobacco cessation counseling is a billable service (3-10 minutes: CPT 99405/0.38 RVU, > 10 minutes: CPT 99407/0.77 RVU). Charges are automatically filed using the SmartSet documentation.

Open the SmartSet to:
• Perform counseling

3. TOBACCO CESSION INTERVENTION NEEDED

Tobacco cessation counseling is a billable service (3-10 minutes: CPT 99405/0.38 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

- No picture: 24%
- One picture: 20%
- Two pictures: 18%
Phone calls for care gaps
## RCT: Preventive care outreach

<table>
<thead>
<tr>
<th>Version</th>
<th>Selected key text changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original</td>
<td>My name is &lt;&lt;first name&gt;&gt; and I am calling on behalf of &lt;&lt;physician name&gt;&gt; at &lt;&lt;practice name&gt;&gt; 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.</td>
</tr>
</tbody>
</table>

Ramsey Abdallah, MBA

Carrie Rooke, MPH

Matthew Penziner
## RCT: Preventive care outreach

<table>
<thead>
<tr>
<th>Version</th>
<th>Selected key text changes</th>
<th>Appointment rate</th>
<th>Mean call duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iteration 2</td>
<td>My name is &lt;&lt;first name&gt;&gt; and I am calling on behalf of &lt;&lt;physician name&gt;&gt; at &lt;&lt;practice name&gt;&gt; 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.</td>
<td>17.6%</td>
<td>3.33 min</td>
</tr>
<tr>
<td>Iteration 3</td>
<td>My name is &lt;&lt;first name&gt;&gt; and I am calling on behalf of &lt;&lt;physician name&gt;&gt; at &lt;&lt;practice name&gt;&gt;  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.</td>
<td>23.2%</td>
<td>3.06 min</td>
</tr>
<tr>
<td>Both</td>
<td>[if hasn’t had a visit and none scheduled] I can go ahead and help you schedule an appointment with &lt;&lt;physician name&gt;&gt; is that okay?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
RCT: Preventive care outreach

Annual visit call script appointment success rate

<table>
<thead>
<tr>
<th></th>
<th>Adult</th>
<th>Pediatric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original</td>
<td>14</td>
<td>26</td>
</tr>
<tr>
<td>Iteration 1</td>
<td>15</td>
<td>34</td>
</tr>
<tr>
<td>Iteration 2</td>
<td>18</td>
<td>39</td>
</tr>
<tr>
<td>Iteration 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Final time 5.13 min vs 4.05 min
21% reduction in time

N roughly 200 per arm per round

Center for Healthcare Innovation and Delivery Science
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