NYU Grossman School of Medicine

Rapid Randomized Controlled Quality Improvement Program Toolkit

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Introduction: What is a rapid randomized controlled quality improvement project?

This toolkit provides practical guidance on how to implement a rapid RCQI project

This toolkit will assist clinicians, research staff and hospitals in developing, implementing, sustaining and standardizing randomized controlled quality improvement (RCQI) projects.

It is designed to support practical implementation, and provides guidance on how to establish an RCQI program, and how to run individual projects; it contains numerous templates and documents to facilitate project design and implementation.

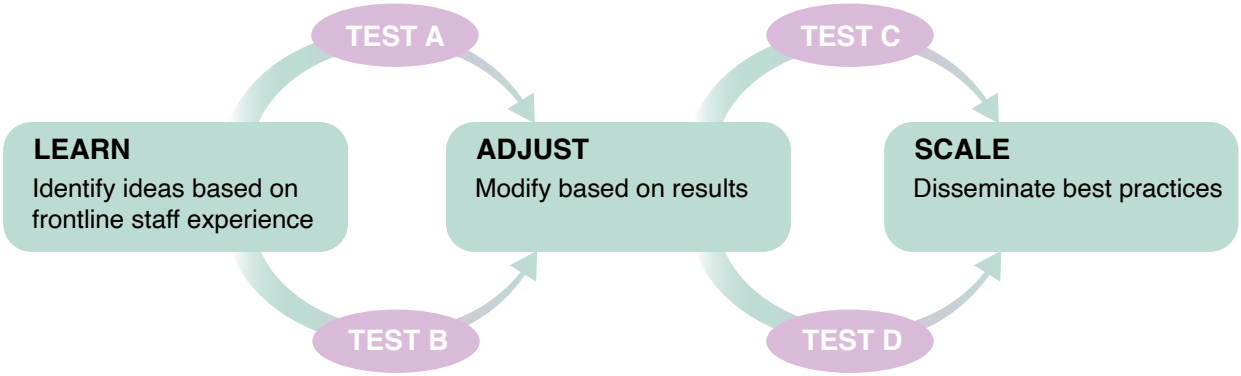
A randomized controlled quality improvement project is a quick way to produce robust evidence on whether interventions do – or do not - work

An RCQI project is a type of intervention in which participants are randomly assigned to the treatment or control group. The different groups allow researchers to determine the effects of the intervention while keeping other variables constant and reducing bias. In clinical medicine, the randomized controlled trial is considered the gold standard of hypothesis testing. This same rigor also makes it an invaluable tool for quality improvement work.

At NYU, we apply the randomized, controlled method to test ideas in a cycle of rapidly iterated quality improvement projects, which allows us to fine tune each intervention based on data. As *Figure 1* shows, this means we do not just do one trial; we test, adjust, test again, and then scale.

Our goal is to transform our healthcare institution into a learning healthcare system by using rapid cycle, randomized quality improvement projects to test simple and pragmatic ideas that can quickly change practice and have the potential for scalability nationally.

Figure 1



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To be successful, rapid RCQI projects must meet three criteria

There are three core criteria that must be met to run a successful rapid RCT. These criteria ensure that the project is robust, but also feasible, easy and quick to implement.

1. To keep the project rapid, **the frequency of the event needs to be high.** Statistical power often requires at least hundreds of events in a short-term period. Hundreds of texts sent to parents to remind them of childhood vaccine appointments will work; targeting rarer interventions like ER opioid overdoses will not.

2. **The outcomes from your study should be routinely captured** and not increase the workload of frontline workers. For example, the number of no shows at outpatient appointments. If possible, the project should run completely in the background.

3. **The randomization scheme should not require clinicians or staff to allocate subjects** nor impact their normal workflow. For example, the RCT can be embedded in the electronic health record (EHR) and health care delivery system such that it is invisible to clinicians.

To learn more about our project criteria, read Creating a Learning Health System through Rapid-Cycle, Randomized Testing.

Getting your program started: What we've learned about how to set up an RCQI program at your institution

A successful learning healthcare system is one that doesn't just run one-off RCQI projects, but builds a program and a culture of rapid quality improvement. This takes time and effort. This section outlines what – for us – were the building blocks of developing a successful program. It talks about how to engage wider leadership and staff within your institution; the importance of defining your projects as 'quality improvement' (not research); and how to work with IT departments.

Staff engagement: without engagement and participation from staff throughout your institution your program will not be effective

All of our projects are run in close collaboration with teams and leadership throughout the hospital. They bring us projects and priorities; work with us to develop and iterate the ideas we test; and do the bulk of the work to ensure our trials run smoothly and effectively. For us, we've found four strategies effective in engaging staff:

Identify champions – Champions are stakeholders who are actively involved in the project and are influential among their colleagues (i.e. nurse leaders, their staff, staff members from IT, C-suite senior leadership, and clinicians). These champions can help with project staff planning, using their experience to promote project continuation and sustainability, and managing other stakeholders' expectations.

Develop strong relationships – Stakeholder engagement during the planning, designing, implementation, and evaluation stages of a project is crucial. Developing these relationships builds trust. And trust leads people to work together more easily and effectively.

Communicate regularly – Regular communication is critical to secure and maintain stakeholder support. By maintaining regular communication with stakeholders, project staff can establish themselves as the key source for information about the project. Once the project is implemented, communicating regularly with stakeholders regarding project successes, failures, and new initiatives will help manage expectations and build support for the project.

Manage expectations – Sharing project outcomes early on and often is vital. Also, consider what types of outcomes stakeholders will find most meaningful. Identify early outcomes that key stakeholders would consider a "success" to demonstrate and communicate results. Most importantly, be sure to set reasonable expectations early. Most tests of change find no significant difference. Make sure your full team knows this going in. It is often helpful to frame null results as opportunities: a license to be more creative, to test new ideas, to iterate further.

Quality improvement not research: identifying where you need IRB approval and where you do not

Institutional Review Boards (IRB) distinguish between QI projects and human subjects research projects. This distinction is important; where a project is research, and involves human subjects, it is subject to IRB review under federal regulations. However, although QI projects may (indeed, often) involve human participants, most do not require IRB review. You should therefore work closely with your IRB to clarify which types of projects require their review, and which do not.

The approach taken by NYU's IRB is summarized in *Figure 2* and a table summarizing the differences between human subjects research and QI projects is below. The appendix contains an IRB-created checklist for you to work through when deciding if your project qualifies as a QI project.

Figure 2: Defining human subjects research

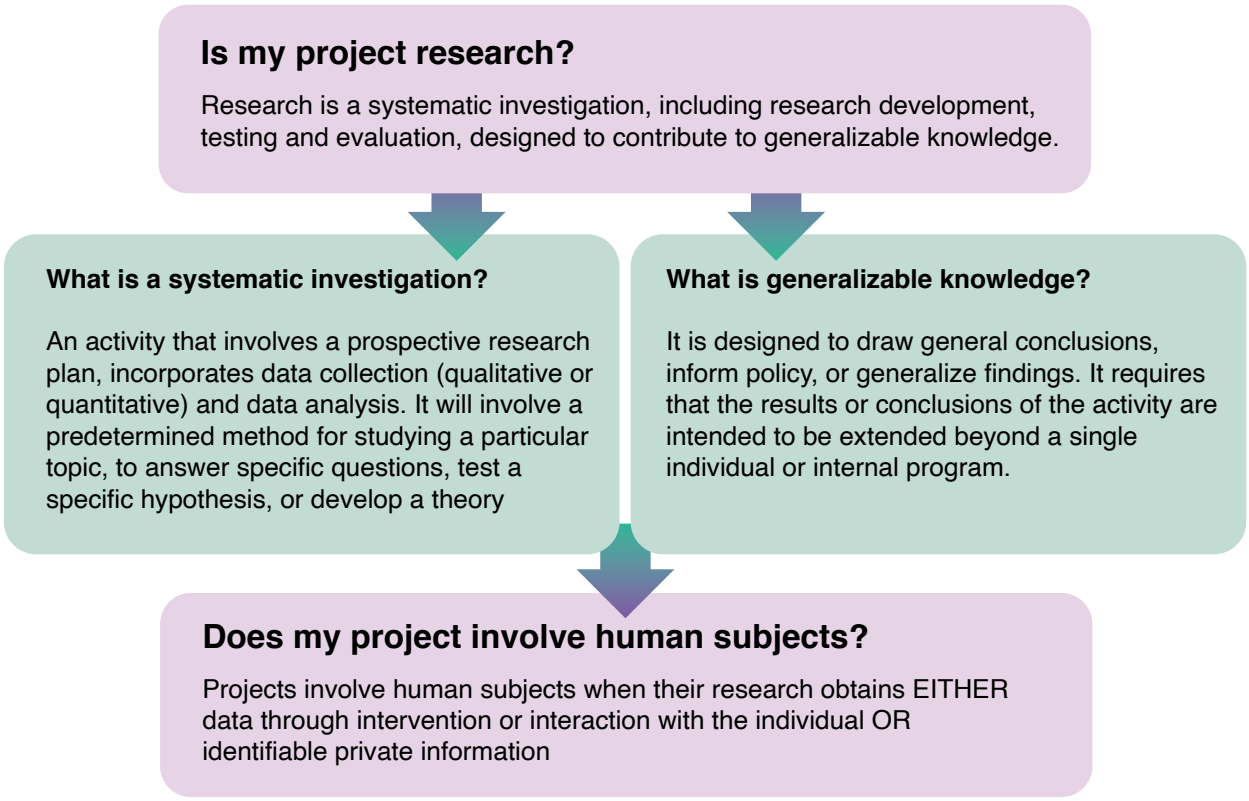

Table 1: The differences between human subjects research and QI

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

IT is essential: What you need from your information technology department

Almost all projects will need active support from your IT department. Some projects, such as those involving decision support, are wholly embedded in the electronic health record (EHR) and require substantive IT resources. Others may need IT support only to help with randomization (for instance, creating a randomized patient list or set of practices) or to extract data from the EHR to track outcomes.

It is thus crucial to engage the support and participation of the IT department early on while developing your program. If possible, meet directly with the Chief Information Officer or equivalent senior role to explain the nature of and value of the program and to set expectations for the type of IT support that will be needed and available over time.

These projects differ from usual IT requests in that they are iterative, often in rapid succession. If necessary, work with IT to develop a process for approval, prioritization, and resource allocation for each project. Build in the anticipated need for multiple iterations.

Finally, work with IT to maximize the capability of the EHR to help with your projects. Many EHR systems have the capability to automatically randomize patients or clinicians to different messages, views, workflows, order sets or other tools. Some systems can only randomize patients; others only providers. Find out early what the capability of your local system is and keep it in mind for project planning.

Whenever possible, include an IT employee (manager, analyst, etc.) as part of the project team, engaged from the start in development.

Once established, an ongoing system should have a process for onboarding new projects. This typically requires presenting the following information to the IT department:

- Project title
- Department stakeholder and IT stakeholder
- Problem you are trying to solve and what's required from an IT perspective
- Potential solutions to problem
- Funding for request

For NYU internal IT project requests, access the form here.

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Running a successful project: How to set up and run an RCQI project

Once the building blocks of your program are in place, you also need to develop processes to run successful, rapid, projects – and to do so repeatedly. In this section we outline what we have found important in delivering a successful RCQI project. It covers: project planning; clinicaltrials.gov registration; data requests; randomization; statistical analyses and results.

1. Develop and fill in a project plan

We collect a consistent set of information for each project we run, and use this to guide the planning and delivery of our projects, referring to it throughout the project. Our template is located at our website here. You can also find it in the appendix below.

Ideally, the bulk of the information (describing the project, the outcomes, etc) should be filled out by the clinical or operational team who are running the project.

2. Clinicaltrials.gov registration

ClinicalTrials.gov is a clinical trials database run by the United States National Library of Medicine (NLM) at the National Institutes of Health (NIH). Randomized controlled quality improvement (RCQI) projects should be registered on the database.

Registering RCQI projects or clinical trials at start-up provides a transparent record of study updates, timeline and results. To start, registration allows researchers to see where there is need for new trials and where there are gaps in research, thereby avoiding unnecessary duplication of similar trials. Furthermore, registration allows participants and researchers to search for key areas of interest. From there, researchers can identify potential collaborators within and outside their institution.

On the regulatory side, registration helps IRBs determine the adequacy and appropriateness of the study results. Many journals require IRB or Clinicaltrials.gov trial registration as a condition of the publication of research.

Moreover, when publishing, it is important to report trials with positive and negative findings to increase the transparency of results.

3. Get data

You will need data at both the start and end of your project. During the planning stages of your project, pull data to understand the problem you are trying to address, obtain accurate baseline information, determine actual data availability, and establish an extraction code that can be used for subsequent analyses. Often reviewing your initial data report reveals refinements that are needed to the data structure to ensure that the correct population and measures are being captured. Do not wait until the end of the project to discover this need! Validating data with your team at the start of the project will reduce issues in later analyses.

It is useful to have a dedicated data analyst on your team to help with any data requests for your projects. Clearly communicate with your analyst the project summary, scope of the work, and the necessary data elements at the outset of every request. Additionally, it is helpful to have a standardized process for extracting such data such as an online data request portal or template. The following can be included in the data request template:

- QI/IRB approval status
- Funding for request
- Project title
- Project summary: objectives, research question and hypothesis, research strategy, and experimental approach
- Request specification: services required for the project (e.g., frequency of data pulls)

For NYU internal data requests, access the form here.

4. Randomize

Randomization is at the core of the RCQI approach. However, there are many potential approaches to randomization – you need to find the one that works best for your project.

Firstly, decide what level of randomization is best. That is, who is being randomized? Most often, the unit of randomization should be the same as the intervention target. An intervention directed at patients should randomize at the patient level. An intervention directed at clinicians should randomize at the clinician level. So, first determine who your intervention is aimed at.

Then determine whether it is feasible to randomize at that level. Can patients be randomized for a patient-facing intervention? If not, is there a way to emulate patient-level randomization? For instance, if patients cannot be randomized directly, sometimes randomizing clinic or hospital unit approximates patient-level randomization. When using pseudo randomization schemes be sure to think about how it approximates the desired scheme and what types of contaminations or problems might arise from it. For example, randomization by clinician is not likely to work for a patient-facing intervention if multiple different clinicians take care of the same patient. Use the table below to help determine which randomization level is right for your project.

Table 2: Randomization level options

Randomization level	When to use	Limitations
Patient/Subject	• To determine the effectiveness of a patient-focused intervention (e.g., care coordination, patient engagement) • Most granular level, high statistical power	• If the intervention is clinician-facing, there may be contamination among clinicians who will see both versions • May be difficult to randomize at patient level; pseudo-randomization strategies may be needed
Clinician	• To determine the effectiveness of a clinician-focused intervention • To ensure that a clinician will only see 1 version of an intervention (e.g., best practice alert in the electronic health record (EHR))	• Clinicians are regularly hired, so adding them to a pre-specified randomization list may be cumbersome and infeasible • IT functionalities at this level may be unavailable
Unit/office	• To determine the effectiveness of a unit/office-focused intervention • To ensure that a unit/office of clinicians/patients will only see 1 version of the intervention • Useful to use in a multidisciplinary setting	• Least granular level; fewer randomization units may limit power • System operations may change over time • Contamination is possible if clinicians work in multiple units • Baseline differences among and within units/offices are likely so must account for these differences • IT functionalities at this level may be limited; may need to create a pre-specified randomization list

Next, choose a randomization scheme. To work, it is crucial for the randomization scheme to be seamless and invisible to the end users. This will help reduce user bias and will maximize engagement with the project. Frontline workers do not have time to be responsible for randomization or keeping track of study group allocations. **Therefore, never plan to have frontline workers randomize participants or update records of randomization allocation.**

Options for randomization schemes are shown in *Table 1*. They can be formal randomization or pseudo-randomization. It is sometimes necessary to use a pseudo-randomization scheme, such as assigning subjects to groups by characteristics of the medical record number, or having clinics alternate weeks between intervention and control activities. Pseudo-randomization can be a powerful tool and make otherwise impossible randomizations possible.

We always recommend working with a statistician to weigh the pros and cons of all the options to find what works best for your specific project.

Table 3: Randomization scheme options

Randomization scheme	Characteristics	Intervention level applications
Simple randomization	Subjects are assigned a group purely randomly	Can be applied to any intervention level, but is most commonly used when randomizing individuals
Block randomization	Randomize subjects into blocks/ groups to ensure equal sample size and then the blocks are assigned randomly assigned to the experimental or control arm	Can be applied to any intervention level. Useful with small sample sizes to ensure equal numbers between intervention arms.
Stratified randomization	Subjects are assigned to blocks/ groups based on covariates then simple randomization is done within each block to assign subjects into study arms	Most applicable for interventions at the individual level
Cluster Randomization	Units (or clusters) of subjects are randomly allocated to study arms	Ideal when there are clear groups among individuals, such as zip-codes, hospital department, or social economic status

Pseudo-randomization	A method which emulates randomness, but ultimately is systematic selection	Used when other standard randomizations are not possible Still needs to be effective at reducing sampling biases You will need to be able to defend your choice of using this method instead of a standard randomization scheme. It can be as simple as allocating based on odd vs even medical record numbers

5. Develop an analytical plan

Consider what types of statistical analysis will be needed to analyze your results. If the randomization is done well, it is often possible to use very simple analyses to detect differences between control and intervention groups – such as a t or z test, a chi-square test, or survival analysis. A direct comparison between control and intervention groups greatly improves the readability and accessibility of your findings. Randomization should eliminate any baseline differences between your control and intervention groups – but it is good practice to double check. If you find that there are statistical differences between your groups consult with your statistician to find the right analysis for your project and goals.

6. Analyze results

Once your project is complete, analyze your results. Do your results meet the pre-discussed success threshold? If yes, implement the best intervention into practice and disseminate where applicable. If no, it is opportunity to redefine the intervention and iterate. See our negative results section below for additional guidance.

Communicate your findings to the team. Include a participant flow diagram, baseline characteristics (demographic and baseline measures), pre-specified primary and secondary outcome measures by arm and statistical analyses, and any adverse events in your report; these components are conceptually similar to preparing a manuscript. Wherever possible, use graphs, tables, and other data visualization tools to make your data easier to understand for your audience.

7. Deal with negative, or null, results

Negative results can lead to numerous positive changes. One of the great strengths of our model is that all results are informative. Negative results in particular are important opportunities to reflect on current practices and methodologies. If an intervention tested current practices, a negative result is a great time to reflect on current practices and methodologies and to ask the question "how can we do better?"

While working with a novel intervention, a negative result can be frustrating and disheartening, but it doesn't have to be the end of the project. Negative results are a great learning opportunity and should be used to better understand the population, site, or healthcare system; it is an opportunity to determine what happened and to understand why the intervention didn't have the desired result. After any negative result you should be able to answer: what were the pitfalls of the intervention, what had success, and is there any room for improvement? Once these questions are answered you can get back to the drawing board and work towards your desired results – ideally by running an RCQI on a 'tweaked' intervention.

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Appendix 1: IRB checklist to determine if project is human subjects research

INSTRUCTIONS: Complete the following section to help you ascertain 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 only 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. **NOTE:** 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.		
2	Your activity does **NOT** use a fixed protocol for the duration of the proposed work. **NOTE:** If frequent adjustments are needed, your answer should be **YES.**		
3	Your activity does **NOT** involve an intervention that may pose risks greater than those presented by routine clinical care.		
4	There will be minimal delays in implementing changes from results.		
5	All individuals involved in key project roles have on-going commitment to the improvement of the local care situation.		
6	Your activity is **NOT** funded by an outside organization with commercial interest in the use of the results. **NOTE:** The purpose of this statement is to determine if the project has received funding to be conducted as a research study.		
7	Your activity is **NOT** part of a multi-center project that involves non-NYULMC sites. **NOTE:** 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.		

Appendix 2: Rapid RCT Lab project template

Rapid RCT Lab: Project name

CLINIC	• Clinicaltrials.gov status • Approval number, if assigned
INTRODUCTION	• Background Problem analysis • Baseline data Observations • Objective(s) Project location • Planned end study date • Key stakeholders Project lead Team members
INTERVENTIONS	• Intervention A vs. Intervention B description • Intervention C vs. Intervention D description
OUTCOMES	• Primary outcome • Rationale • Is this outcome currently routinely captured in clinical care • Minimum clinically important effect size • Secondary outcome(s) • Balancing outcome(s) • Subanalyses • Demographic characteristics Other cohorts, if any • Unintentional consequences • Conditions for continuing/terminating the project • Specify factors to consider if no significant difference found for the primary outcome (e.g., any improvement in primary outcome, secondary outcomes).

PARTICIPATION	• Study population definition • Exclusion criteria • Expect N/week • N required to reach desired effect size with 80% power
RANDOMIZATION	• Unit of randomization (patient, provider, hospital-level) Allocation ratio • Sequence generation • Method for generating the random allocation sequence • Type of randomization, details of any restriction (e.g., blocking & blocking size) **Allocation concealment mechanism** • Mechanism for implementing random allocation sequence **Implementation** • Who will generate random allocation sequence • Who will enroll participants • Who will assign participants to interventions **Blinding** • Patient? Provider? Investigator? Y/N • Data Analyst? Y/N
DATA ANALYSIS	• Analytical approach • Rationale

*Template based on 2017 CONSORT Checklist of Information to Include When Reporting Randomized Trials Assessing NPTS.

Randomized QI Improvement Project Application Form

Please review the summary below and complete your application.

Thank you!

OVERVIEW
CHIDS Randomized Quality Improvement Projects will support evaluation through randomization of existing or new interventions that are designed to increase adoption of best practice. Often we implement interventions for quality improvement that "seem like a good idea" without a clear sense of whether they are working or whether they could be made more effective. Randomization of patients, clinicians or practices to an intervention or different versions of an intervention enables rapid assessment of outcomes with minimal bias. In this program, CHIDS faculty and staff will work with you to develop pragmatic trials embedded in usual practice that will help to rapidly improve clinical care or operations.

Examples of randomized QI projects conducted to date include testing of:
• versions of telephone scripts to encourage patients to come for routine annual physicals
• mailers to encourage patients to obtain routine preventive care
• poster messaging to encourage patients to complete patient-reported outcome surveys
• electronic health record alerts to encourage smoking cessation counseling
• post-discharge telephone calls to reduce readmissions and improve patient satisfaction
• an emergency department-based community health worker program

PROPOSED PROJECTS SHOULD:
• have a high volume of events (>100/month) to facilitate rapid testing and iteration
• be intended to encourage best practice; studies to determine clinical efficacy of new treatments are not eligible
• involve outcomes that are already captured in routine practice

SUPPORT
Applicants should be prepared to co-design a trial with the CHIDS team, and should expect to run multiple iterations of the intervention over the course of the year. Funding is in the form of CHIDS staff support. CHIDS will provide study design expertise, project management, IT support, data extraction and cleaning, statistical analysis, regulatory reporting and manuscript support.

Areas of interest include, but are not limited to:
• Reducing EHR burden and improving functionality
• Improving patient experience, MyChart use and engagement
• Zero Harm - avoiding preventable adverse events
• Novel approaches to providing clinical care such as group visits, telehealth, e-consultation, peer coaching, patient-centered decision-making tools
• Identifying and mitigating patient safety risks in ambulatory settings
• Reducing overutilization of unnecessary treatments, tests and services
• Improving medication management
• Improving clinical utility, timeliness and effectiveness of consultation and ancillary services
• Standardizing care for common conditions

ELIGIBILITY
Full-time employees of NYU Langone Health, Family Health Centers at NYU Langone, NYU Winthrop Hospital, NYU College of Nursing, or NYUPN practices, including non-physicians, students and trainees. A student or trainee applicant must also have identified an experienced mentor who commits to the project. Projects that span multiple settings are welcome; however, projects conducted solely at Bellevue or the VA are ineligible.
APPLICATION FORM
The application is due by _____
DEADLINES
Application form: _____
Final decision: _____
Anticipated project start date: _____
Project duration: maximum one year
DIRECT QUESTIONS TO: _____

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Application	
Title of Project	
Project Lead (Name of Project Lead, Degree, and Affiliation)	
Project Lead NYU Email	
Describe the problem you are trying to solve, including what is currently being done and what the baseline outcome rate is. (500 word maximum)	
What is the primary outcome you seek to improve?	
Is this outcome currently routinely captured in clinical care?	◯ Yes ◯ No
How would you measure this outcome?	
List intervention ideas we could test in a rapid cycle experiment (1-5 ideas)	
Where will this project take place (e.g., Tisch, Medicine, 17 East)?	
Approximately how many patients/events would be targeted by the intervention each month?	
Are there any special logistical considerations (e.g., project will be affected by an upcoming workflow change)?	

IRB Checklist to determine QI vs human subjects:

Certification for the Project Leader	
Date	
Print Name	
Signature	
	I certify that the information provided above is accurate.
NOTE: If the results of this form indicate your proposed activity is considered QI and not research involving human subjects, consistent with the federal regulations governing human subject research, IRB review or oversight is not required.	

References

1. https://www.ahrq.gov/patient-safety/settings/long-term-care/resource/hcbs/medicaidmgmt/mm2.html
2. https://www.hii.iu.edu/stakeholder-buy-in-and-engagement/
3. Simple, block, stratified https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3136079/
4. Simple, block, stratified, minimization https://www.sciencedirect.com/science/article/pii/S1551714415300471
5. Simple, block, Stratified https://www.lexjansen.com/pharmasug/2006/Posters/PO06.pdf
6. Simple https://online.stat.psu.edu/stat509/node/65/
7. Minimization https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3317766/
8. Cluster https://catalyst.harvard.edu/docs/biostatsseminar/Donner%20slides.pdf
9. Anova https://www.sciencedirect.com/topics/computer-science/analysis-of-variance
10. Regression https://www.sciencedirect.com/topics/medicine-and-dentistry/regression-analysis
11. glm https://online.stat.psu.edu/stat504/node/216/
12. Multilevel https://www.youtube.com/watch?v=m4fx_mzlBQI
13. Kaplin Meirer https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3932959/
14. t/z test https://researchbasics.education.uconn.edu/t-test/#
15. cox prop https://www.jstor.org/stable/1402659?seq=1
16. Log rank https://www.statsdirect.com/help/survival_analysis/logrank.htm
17. Chi-square https://libguides.library.kent.edu/SPSS/ChiSquare
18. https://clinicaltrials.gov/ct2/about-studies/glossary
19. https://prsinfo.clinicaltrials.gov/definitions.html
20. https://clinicaltrials.gov/ct2/manage-recs/how-report
21. https://clinicaltrials.gov/ct2/manage-recs/background