Texas Tech University Health Sciences Center
Office of Research Integrity

Quality Improvement
And
Human Subjects Research

EXAMPLES

PLEASE NOTE:

The distinction between Quality Improvement (QI) and Human Subjects Research can often be difficult to make. The following examples have been provided for the purpose of guidance for project teams and study authors. Both examples address the same general concept, in order to better illustrate the differences between QI and Research.

The following are examples only, and have intentionally been kept brief. They do not represent the full level of detail that should be written in actual project submissions.

THIS IS AN EXAMPLE OF A RESEARCH PROTOCOL

Comments have been added in order to highlight particular characteristics that set research and QI apart.

Protocol for Research Entitled:

Transitional Care Management: Does it Work?

Commented [DT1]: The research team is trying to determine if an intervention works or not. This is a hint that the work is research. This is a research question, not a QI aim.

Principal Investigator:

Dr. Richard Smith, M.D., Associate Professor, Family Medicine, Texas Tech University Health Sciences Center, 3601 4th St., Lubbock, TX 79430, Phone (806) 743-1234

Co-Investigators:

Michael Jones, M.D., Resident, Family Medicine, TTUHSC Amarillo, 1400 S. Coulter St., Suite 5100. Amarillo, TX 79106

Cindy Morgan, M.D., Resident, Family Medicine, TTUHSC Permian Basin, 800 W. 4th St., Odessa, TX 79763

Hypothesis:

Transitional Care Management will reduce 30-day readmission rates in a Family Medicine clinic.

Background:

Patients often leave the inpatient setting with new diagnoses, new medications, change in therapy and new specialists to follow up with. The risk for medical error following discharge is high and is reflected in the rate of readmission to the hospital within 30 days. Transitional Care Management is one method that can be used to address this problem, however, there is currently little to no data demonstrating its effectiveness.

Commented [DT2]: Research may use interventions that are not evidence based.

Procedure:

In order to test the hypothesis of this study, the following steps outlined below will be conducted in the following order. This will be implemented in the Family Medicine clinics.

Commented [DT3]: Terminology is also important in making the QI vs. Research determination. A "study" is usually research, while QI is usually referred to as a "project".

(1) Patients will be divided into two groups: Those who are discharged on a Monday/Wednesday/Friday, and those who are discharged on a Tuesday/Thursday/Saturday. Those discharged on Sundays will be put in one group or the other on alternating Sundays.

Commented [DT4]: Control groups are a sign of research. A QI projects generally do not have a control groups; rather, interventions are applied to everyone.

(2) We will implement the Transitional Care Management Protocol for the M/W/F/altSu group, and make no changes to the T/Th/Sa/altSu group. We will obtain informed consent for all participants.

Commented [DT5]: Informed consent is a requirement for most human research studies. QI projects do not require informed consent.

(3) The Transitional Care Management protocol consists of:
    a. Prior to discharge, a resident will conduct a medication reconciliation reflecting any changes made during admission, and collect up to date contact information from the patient which will be updated in the EMR.

b. 1-2 business days after discharge a resident will call to check in on the patient. During the phone call the resident will review changes to medication, answer questions, and review the hospital follow up appointment date.
c. At the hospital follow up visit 7-14 days after discharge, the provider will review the information from the phone call and address any issues such as new medications, follow up labs, or imaging.

(4) Rates of 30-day readmission for each group will be monitored and recorded.
(5) This will continue for a period of 3 months, after which the data will be analyzed.

Data Analysis:

Data will be recorded in an Excel Spreadsheet as it is collected. At the end of the three month period we will use bivariate statistical methods to compare the rate of 30-day readmission in the experimental group to the control group. In this way we will evaluate the effectiveness of Transitional Care Management in reducing readmission rates.

Commented [DT6]: Research studies typically examine data after a set end point. QI projects continually monitor data over time, and respond to the data as the project moves forward.

Commented [DT7]: This type of data analysis is a sign of research, because QI project data analysis does not look for statistical significance between two treatment groups. Rather, QI projects look for clinical significance to determine if the change being tested has resulted in improvement.

THIS IS AN EXAMPLE QUALITY IMPROVEMENT APPLICATION

TTUHSC OP 73.18 Attachment A

Quality Improvement Review Board Application

1. Project leader: (a TTUHSC faculty member with >50% appointment at TTUHSC)

Name	Dr. Richard Smith
Title	Associate Professor
Department	Family Medicine
Campus	TTUHSC Lubbock
Phone number	806-743-1234
E-mail	Professor@ttuhsc.edu

2 Project team: (list all involved with the project)

Name	Title	Department	E-mail address	Role on the project
Michael Jones	Resident	Family Medicine	Michael.Jones@ttuhsc.edu	Training providers, collecting data
Cindy Morgan	Resident	Family Medicine	Cinthia.morgan@ttuhsc.edu	Interpreting data

3. Project Title:

Implementing Transitional Care Management at TTUHSC Family Medicine Clinic

4. Provide a brief (2-4 sentence) summary of your project.

The purpose of this project is to improve the transition of care from the inpatient setting to the outpatient setting by implementing Transitional Care Management, which is considered the standard of care. This involves a medication reconciliation at the time of discharge, a phone call within 1-2 days of discharge, and a follow up visit to the hospital 7-14 days from discharge. We expect that this will improve outcomes for our patients.

Commented [DT8]: Terminology is important in making the determination between QI and Research. If you are doing QI, be careful not to call your project team "researchers", or refer to your project as research or as a "study".

Commented [DT9]: QI projects use evidence based interventions, therefore there is a reasonable expectation of improvement. QI works to bring a clinic up to the current standard of care. By comparison, research works to determine the efficacy of interventions, thus to define a new standard of care.

5. State the project goal(s). Include information about who will benefit from the project. Note that QI project goals are intended to bring about immediate improvements in a specific population.

Our goal is to decrease re-admission rates for Family Medicine Clinic patients by 10% compared to baseline over the course of 3 months. Our target population are the patients cared for by the Family Medicine resident service team, and we expect the patients to immediately benefit from this project.

Commented [DT10]: This is a QI goal; an evidence based intervention will be applied with the expectation to immediately improve care for the patient population.

6. Provide background information and significance of the project. What is the problem that your project addresses?

Patients often leave the inpatient setting with new diagnoses, new medications, change in therapy and new specialists to follow up with. The risk for medical error following discharge is high and is reflected in the rate of readmission to the hospital within 30 days. For instance, the 30 – day readmission rate for Medicare patients was 16% in 2010. Transitional Care Management was created to address this 30 –day period following discharge. It consists of making contact with the patient 1-2 business days following discharge, followed by a hospital follow up visit 7-14 days later. The phone call will help to address issues or questions regarding changes to management prior to the hospital follow up visit. We expect that the phone call will also serve as a reminder of the hospital follow up visit and therefore will decrease rate of no-shows. Hospital follow up visits will be set up 7-14 days from discharge with the primary provider or resident. Through implementing Transitional Care Management, we hope to improve the transition of care for patients from the inpatient setting to the outpatient setting and reduce the rate of 30 day readmission. .

7. Describe your plan of improvement intervention. What procedures will you follow?

Our initial planned interventions are:
1) Prior to discharge, residents will reconcile medications, reflecting any medication changes made during admission and collect up to date contact information from the patient which will be updated in the electronic medical record.
2) 1-2 business days from discharge a resident will call to check in on the patient. During the phone call the resident will review changes to medication and review the hospital follow up appointment date. Notes from the call will be recorded in a template in the electronic medical record.
3) At the hospital follow-up visit 7-14 days after discharge, the provider will review the information from the phone call and address issues such as new medications, follow up labs or imaging.
4) As we monitor ongoing data we will make adjustments in the plan. Additional improvement cycles will be developed iteratively in response to the data.

Commented [DT11]: QI projects are designed such that they can respond to the data. Plans for improvement change as learning occurs through each PDSA cycle.

8. What is the relationship between the project team and the project participants (patients/students)? Is the project team in a position to effect change in the setting?

The Family Medicine residents are providers for the project participants. Yes, we are in a position to effect permanent change in this setting.

Commented [DT12]: QI projects should not involve patients/students or ask for access to medical records for a population whom the project team have no influence. A QI team will be in a position to make changes and impact long term improvement.

9. Where and how will you obtain data? Describe what will be collected and the source of data. Do you routinely access these data (medical records, student scores, etc.) in your normal scope of work?

We will access the hospital re-admission report generated by the hospital quality department on a weekly basis.

10. How will you analyze your data? How will you measure if the intervention was successful?

Data will be plotted on a control chart to evaluate change over time and identify special cause variation attributable to intervention cycles.

Commented [DT13]: Evaluating change over time is a standard QI data analysis method. This is done to determine if the change that was made resulted in an improvement.

11. Describe any ethical considerations (data confidentiality, possible coercion, subject selection, risk/benefit ratio, etc.) and explain what you are doing to address these concerns.

Patient data will be de-identified. Only members of the project team will access project data. Any patient lists will be shredded at the end of each day. All electronic project data will be kept secure in accordance with TTUHSC Information Technology security policies.

Commented [DT14]: Typically, the only risk to participants in a QI project is to confidentiality. Therefore measures must be in place to protect participant confidentiality.

12. Who is providing the necessary funding and resources for this project? If the project is conducted outside of TTUHSC and/or requires information or project participants that are not controlled by TTUHSC, please provide an appropriate letter of support.

There is no funding for this project, and all resources needed are supplied by the TTUHSC Family Medicine department.

13. What are your plans for dissemination of project results?

Results will be disseminated to relevant inpatient unit leadership as well as within the Family Medicine Clinic. In addition we plan to present a poster at a national conference.

Submit completed application to the TTUHSC Quality Improvement Review Board at QIRB@ttuhsc.edu. Additional pertinent information may be submitted as attachments. Questions may be directed to the Director of Quality Improvement Review at the above email address or by phone at 806-743-4276.

Please sign electronically and attach to an email – OR - print, hand-sign, then scan and send via email.

Project leader Signature:

_____

Date: _____