Mon 2/4/2019 10:43 AM

IRB Quality Initiative <PROVOST-IRB-QUALITY@pobox.upenn.edu>

RE: Mehta 827461 QI Letter

To Hemmons, Jessica; 'qiirb@upenn.edu'

Cc Spencer, Evan; Agarwal, Anish

You forwarded this message on 5/30/2019 2:09 PM.

Hi Jessie,

The proposed changes do not change the QI determination. The original letter still applies.

Institutional Review Board
University of Pennsylvania
Office of Regulatory Affairs
Old Vet Quad, Suite 151E
3800 Spruce Street
Philadelphia, PA 19104
www.upenn.edu/IRB

From: Hemmons, Jessica <jhemmons@pennmedicine.upenn.edu>
Sent: Thursday, January 31, 2019 9:50 AM
To: 'qiirb@upenn.edu' <qiirb@upenn.edu>
Cc: Spencer, Evan <Evan.Spencer@uphs.upenn.edu>; Agarwal, Anish <Anish.Agarwal@uphs.upenn.edu>
Subject: RE: Mehta 827461 QI Letter

Hi,

I'm writing in reference to our QI Project 827461.

Our project began by collecting information about post-op medication use by telephone, and our current program engages patients after their procedure through a text message conversation to learn about their pain and use of prescribed medications.

We would like to understand the most efficient approach in gathering this data. Currently, patients receive a set of text message questions and our team awaits responses. As an alternative we have learned that we can send patients a single text message with a link to a web-based survey which would ask the same question set, but allow for patients to click through the questions rather than the text message exchange.

We would like to include this survey link as a method to collect information for this project. We would compare the methods to see which are the most efficient. This may be completed as two groups – one receiving text conversations and one receiving the text link to an online survey containing the questions. The results of the comparison could possibly lead to a publication.

Please let me know if this still qualifies as QI.

Thank you so much,
Jessie

University of Pennsylvania ◆ Institutional Review Board
Quality Assurance/Quality Improvement Project Determination Form

This worksheet is a guide to help the submitter and the IRB to determine if an activity is quality assurance/quality improvement or is human research as defined by the Health and Human Services (HHS) or Food and Drug Administration (FDA). Once completed, please email the form to qiirb@upenn.edu. The IRB will contact you with the results of their review and may request additional information to assist with their determination.

Activities that meet the definition of human research will require submission to the IRB via HS-ERA (https://medley.isc-seo.upenn.edu/hsProtocol/jsp/fast.do). QA/QI activities that do not meet the definition of human research will be reviewed and granted a letter of QA/QI review and acknowledgement from the IRB. If there is interest in disseminating or publishing the results of the QA/QI activity, this correspondence can be submitted to a peer-reviewed journal or other publication as evidence of IRB review. Please see the IRB's guidance document on QA/QI projects for additional information that may be helpful while completing this form: [http://www.upenn.edu/IRB/mission-institutional-review-board-irb/guidance]

Project Title:	An evaluation of the pain experience and use of systemic opioids after discharge following knee arthroscopy				
Funding Source:	None				
Project Leader		☐ Ed.D. ☐ J.D. ☒ M.D. ☐ Ph.D.			
Name:	Dr. Samir Mehta	☐ Pharm.D. ☐ R.N. ☐ Other (specify):			
Job Title:	Interim Medical Director, Orthopaedic Clinical Research UPHS	Phone:	215-662-2982	Email:	Samir.Mehta@uphs.upenn.edu
Department:	Orthopaedic Surgery Emergency Medicine	**Primary Contact** (If different from Project Leader): Jessie Hemmons			
		Phone:	215-746-8255	Email:	jhemmons@pennmedicine.upenn.edu

Key Personnel

Name and Degree:	Department (Affiliation if other than University of Pennsylvania)	Email
Kit Delgado, MD MS FACEP	EM & Epidemiology	kit.delgado@uphs.upenn.edu
Jessie Hemmons, MS	Emergency Medicine	jhemmons@pennmedicine.upenn.edu

QI/QA Assessment Process

In order for the IRB to assess whether your project meets the definition of human subjects research requiring IRB review or may qualify as a quality improvement/assurance activity, please provide the following information:

1. Provide a summary of the purpose and procedures of the proposed project. In your summary, please address:
   - the project question or hypothesis that you are planning to evaluate
   - the project design

- any interaction or intervention with humans
- a description of the methods that will be used and whether they are standard or untested
- whether identifiable data from individuals will be used (if so, identify the source of the data and how the data will be obtained or accessed).
- a description of how the collected data will be used- (example, prepare a report for operational leaders, publish the findings, etc).

At UPHS, patients who are treated for acute fractures and/or undergo orthopedic surgical procedures and have no contraindications to narcotics are routinely prescribed opioids following the procedure and given a prescription for oral opioids prior to discharge home. The number of pills prescribed upon discharge varies from provider to provider, ranging from 30-90 pills. This project would address if this number of pills is in accordance with the number of pills that patients require, and how patients are storing or disposing of unused pills. The purpose of the research would be to better understand the amount of opioid pain medication actually required by patients following different orthopedic procedures, with an aim to better meet post-treatment pain requirements and reduce the risk for opioid diversion in the West Philadelphia community. An additional aim of this project is to see if texting patients can be an efficient and effective method for collecting this information as part of clinical standard of care.

This project will be conducted with Dr. Kit Delgado in the Emergency Medicine Department, who as part of the Nudge Unit, "aims to leverage insights from behavioral sciences, principally behavioral economics, to design and test interventions that steer providers and patients toward better decisions to improve health care delivery and outcomes."

This project would include all Orthopedic patients or ED patients treated for acute fracture discharged from the University of Pennsylvania Health System with an opioid prescription. Patients will contacted via phone call, text message, or text to an online survey and they will consent to receive text message communications as part of their general surgical consent process.

Patients would be contacted via phone or text message 3-8 days following their orthopedic procedure. The following template would be used for telephone calls:

Hi, my name is [investigator's name] and I am calling from the University of Pennsylvania. I am calling to check in with you to see how you are doing after your recent orthopedic procedure. It looks like you had your knee arthroscopy on (date) with Dr XXX, so we just wanted to call and see how you are feeling in terms of pain levels and ask if you are having any concerns that you would like to make your doctor aware of. Do you have a few minutes to go over some questions about how you are feeling?

1. How are you feeling?
2. How many days after your procedure did your pain substantially improve (i.e. wisdom tooth removal- pain lasted for 2 weeks, but the most intense pain lasted 3 days)?
3. Since you have been home, on a scale of 1-10, with 1 being not at all able and 10 being extremely able, how have you been able to manage your pain at home?
4. What types of things have you been doing to manage your pain?
5. Have you used any methods such as ice or NSAIDS like Tylenol or Motrin to help with your pain?
6. It looks like you were prescribed (RX) for your pain. Have you been using this medication?
7. Are you still using it?
8. How many pills do you have remaining?
9. Do you plan on using the remainder of the medication?
10. Do you plan on using any other methods of pain relief, such as (ice, NSAIDS like Tylenol or Motrin, or any different method provided above if given)?
11. Have you had any concerns after your procedure?
12. Did the physician/medical team educate you about your medications and go over the directions for using them?

13. Is there anything you would to relay to the medical team about how you are feeling?

After completing the interview, the investigator will provide information to the patients about methods for safely disposing any unused medication, including: (b) finding a local "buy back" program, or (c) flushing the unused medication down the toilet (per FDA recommendations).

For text messages, the introductory statement will be modified to fit with texting standards. The introductory message will be:

"Hi we are contacting you on behalf of Penn Medicine. We would like to check in to see how you've been managing your pain at home since your recent procedure."

Then we will text the questions in the above script.

If patients reported continued opioid usage at the first time of outreach, a second contact will be made 5-8 days following the first. At the second outreach attempt will include the same questions as above.

Responses would be collected in a Redcap database and/or electronic texting platform, using qualitative and quantitative metrics. Patient demographics including age, parity, procedural complications, and opioid use prior to discharge would be included in the database. This data would be collected from the hospital record in Epic.

We will tabulate the total number of tablets left at 1 week and 2 weeks (if still reporting any pain at 1 week call). We will compare the demographic and clinical characteristics of those who had no pills left over using t-tests for continuous variables and Chi-square tests for categorical variables. We will also use these data to determine proportions of patients who have their pain needs met by alternative proposed default opioid order dispense amounts (20, 30, 40, 50, and 60). These data will be used to implement a new opioid discharge order and also inform the impact of New Jersey's new law mandating more than a 5 day supply for new opioid prescriptions on UPHS orthopedics practices in NJ.

Publishable findings may be submitted to a peer-reviewed journal.

2. If the primary purpose of your project is for quality assurance or improvement/operations, have you obtained approval from the operational leader within your department or health system [Please refer to FAQ item 1 of the QI Project Guidance Document]?

   ☒ Yes – Please specify whom: Dr. Samir Mehta, Interim Medical Director, Orthopaedic Clinical Research UPHS

   ☐ No [Contact the appropriate operational leader for approval]

   [Examples of operational leaders include a medical director of a unit or clinical area, division/department chief, nurse manager, Dean, other health system or institutional leader that can approve the implementation of a quality assurance/improvement project].

Please Note: By submitting your proposed project for a QA/QI determination you are certifying that if the project is established to qualify as QA/QI, you and your Department would be comfortable with the following statement in any publications regarding this project: "This project was reviewed and determined to qualify as quality improvement by the University of Pennsylvania's Institutional Review Board."