**TPMG Delivery Science Research Project -- Final Report**

Project Title: **Pilot Study of the Ascertainment of Physical Function (PF) in Pancreatic Cancer Patients using Patient Reported Outcome (PRO) and Clinician Reported Outcome (ClinRO) Measures within a Health System with an Electronic Health Record (EHR)**

Principal investigator: Stephen K. Van Den Eeden, PhD

Primary clinical collaborator(s): Piyush Srivastava, MD

Start and end dates (month and year): 10/24/2017-10/1/2022

Overview

1. Please describe the problem your project was designed to address. (50 words or less)

Our primary effort was to develop and evaluate the process of implementing a quality-of-life (QoL) measure in pancreatic cancer in the KPNC EHR system. Our second effort was to evaluate the tool used – the PROMIS Physical Function (PF10a) short form against two standard patient reported questions (the Patient Global Impression Change scale (PGI-C) - and the Patient Global Impression Severity scale (PGI-S)), and the ECOG PF clinical rating.

1. What did your project find? (50 words or less)

With regard to implementation, we determined that it was feasible to enable HealthConnect host a patient-facing QoL questionnaire. We also determined that this was a difficult process with high costs and time demands. The PROMIS-PF10a – was highly predictive of adverse clinical markers (emergency room and hospitalization visits, referral to hospice and death).

1. What was your project’s primary or most important product? (50 words or less)

# There are two primary ‘products’ that arise from the study. The first is our team’s working relationship with leadership at the Food and Drug Administration. Specifically, the project has had direct involvement with/by Paul Kluetz, MD, Deputy Director, Oncology Center of Excellence at the FDA and leads their Patient-Focused Drug Development program. A second outcome will be our experience with the process as represented in a manuscript we are currently working on.

1. In carrying out this project, what problems or barriers did you encounter? (50 words or less)

There were two primary issues that we both anticipated and subsequently encountered. These were 1) the often debilitating health and functional status pancreatic cancer patients have at diagnosis making participation less likely, and 2) issues related to integration of the QoL measure into the clinical workflow.

1. In your experience with this project, what was the most positive or constructive aspect? (50 words or less)

We would say our working relationship with Dr. Paul Kluetz and the FDA was the most significant positive outcome. The FDA is in a significant effort to consider QoL measures in the approval process in new drug (or indication) applications to better inform that process, as well as patients. This project enhanced KP relationship with the FDA.

Measures of impact

Note: It’s okay to say “no” to any of the below questions. We want your honest appraisal of what you and others learned.

1. Did your project lead to a change in clinical practice?

No, please describe any barriers experienced.

Yes, please describe the changes and successes.

1. Did your project help clinicians or other program leaders better understand the problem you were addressing?

No, please describe any barriers experienced.

Yes, please describe activities, tools, methods or other approaches that supported their understanding the problem.

With cancer care, the patient’s voice is increasingly viewed as an important determinant in influencing the clinician stated performance status. The PROMIS PF-10a was tested as a valuable tool to help the patient take an active role in helping to determine well-being, and response to chemotherapy in a manner objective to the clinician in helping to determine physical function or status. This project transitioned the PROMIS 10a survey into an electronic version able to be answered by patient on own electronic devise or tablet (at the start of visit). The form was then automatically incorporated into the EMR and part of the patient’s record.

1. Dissemination -- did your project lead to a presentation, report or publication?

No, please describe barriers, if any.

Yes, please list.

We have presented the results to the Food and Drug Administration (who were partners on the study). We anticipate preparing a manuscript and making presentations at national oncology meetings in the future.

1. Did you or others learn something else from your project?

Formed a new relationship

Learned that the right data aren’t currently available

Identified unanticipated barriers to improving clinical practice

Other learnings

If yes to any of the above, please describe.

The project served as one of the catalysts to solidify a relationship with TPMG NCAL Oncology and the FDA. With this relationship, FDA continues to see TPMG/KP as a partner in providing ‘real world’ patient experiences to clinical trial enrollment. Dr. Srivastava was asked to join the FDA OCC ECC Initiative: Pancreas Cancer (an initiative to expand clinical trial enrollment parameters for pancreatic cancer) out of this relationship.

1. Did your project address a TPMG Total Performance priority?

Operational Excellence (quality and safety, efficiency and effectiveness, consistent excellence)

Exceptional Care Experience (including care coordination)

Joy and Meaning in Medicine (physician practice)

Affordability

6. What next steps, if any, are needed so that the findings of your project can be implemented to improve clinical practice or operations?

Work with others within KPNC to continue to develop and implement Patient Reported Outcomes where feasible and there is patient and clinical value. We have provided our insights and, where appropriate, recommendations to Drs. Jed Katzel and Ray Liu in work they are doing on Patient Reported Outcomes to enhance their efforts.

Comments

Please feel free to add other observations. All comments are welcome. We are particularly interested in observations that could help us better use TPMG’s resources to support research, and/or use research to better support TPMG.

**Thank you!**