

Real World Data from Real World Patients

Piyush Srivastava MD, Kaiser Permanente July 12, 2019



Kaiser Permanente Health System Representative of a Real World Population

- Largest Integrated System in the USA
 - Providing both care and coverage in one system
 - Aligned Incentives
 - Coordinated Care along the Continuum
 - 21 Accredited Cancer Centers in Northern California
- Kaiser Permanente Health Connect: Robust EMR
 - Patient information housed in one, easily retrievable place
 - Facilitates coordinated care for >8 million patients in California
 - Patients able to manage own health
 - Appointments, refills, securely email physician



Kaiser Permanente and the FDA A Natural Collaboration

- OHOP-interest in better understanding various types of clinical data which can be generated in a real world setting
- KP-interest in operationalizing the 'patient's voice' (PROs) in clinical workflows

Only made sense to.....

- 1. combine expertise to study the integration of PRO measures in a large healthcare delivery system
- 2. study the natural history of patient reported physical function in an advanced real world pancreatic cancer population



Pancreatic Cancer Patient Reported Outcomes using the electronic medical record



PanPROE Goals

- Assess feasibility and logistical challenges associated with incorporating an electronic PRO into an EMR
- Characterize natural history of Physical Function in real world Pancreatic Cancer using PROs and ClinRO
- Examine Score Change that would reflect a clinically meaningful difference in PF in both the PROMIS and ECOG measures
- Describe relationship between PF change and clinical events captured on the EMR
 - New therapy, dose modifications, hospitalizations, Palliative Care Conversations, Hospice Referral

Establish an intimate working relationship between the FDA and KP



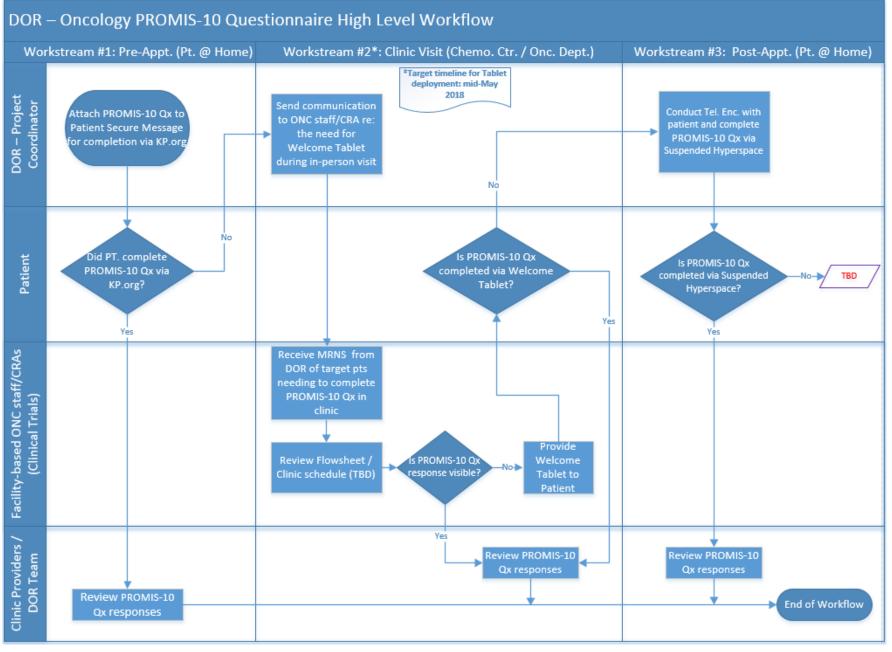
PanPROE Tools

- PROMIS 10a (Short Form, Physical Function)
 - Every Outpatient Oncology Visit; at least monthly
- PGIS Anchor Questions (at baseline and each follow up)
 - "In general, how would you rate your current Physical Function?"
 - "Choose the option that best describes your current Physical Function compared to the last Doctor's visit (at this office)?"
- ClinRo-ECOG score at every visit, at least monthly



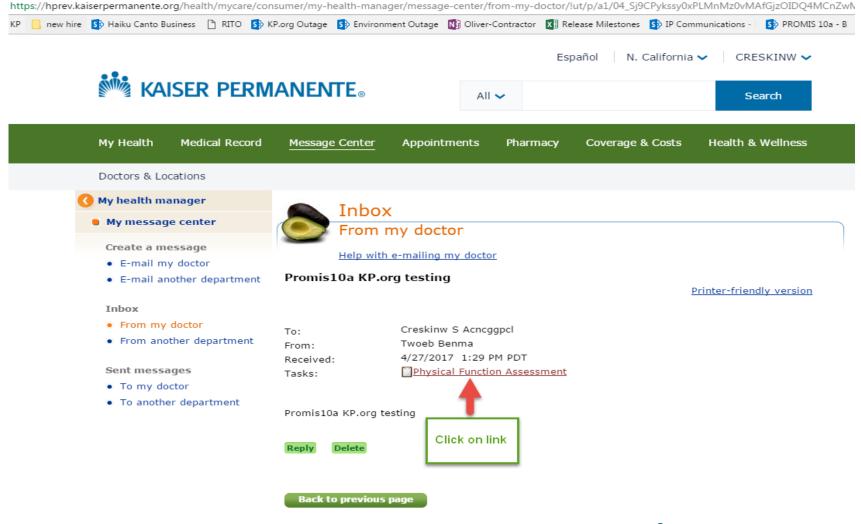
PanPROE Workflow



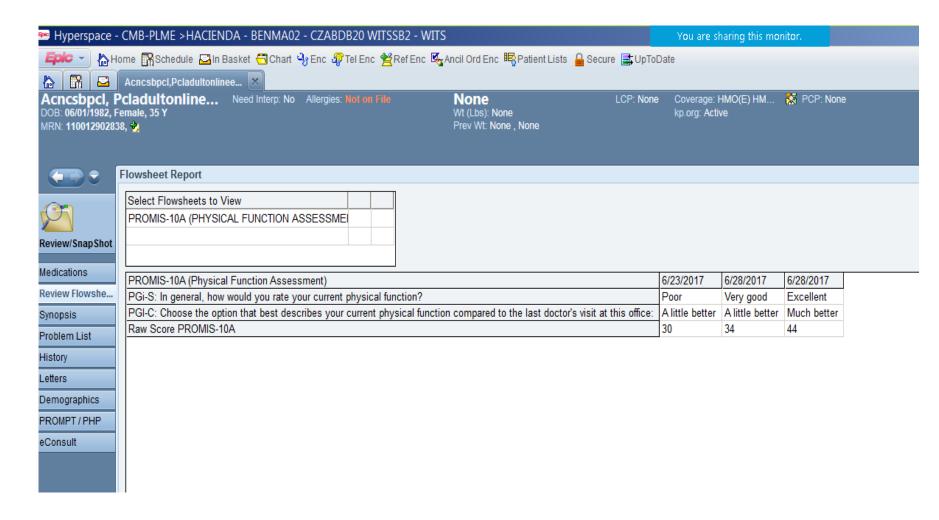


PanPROE Sending patient questionnaire via secure message

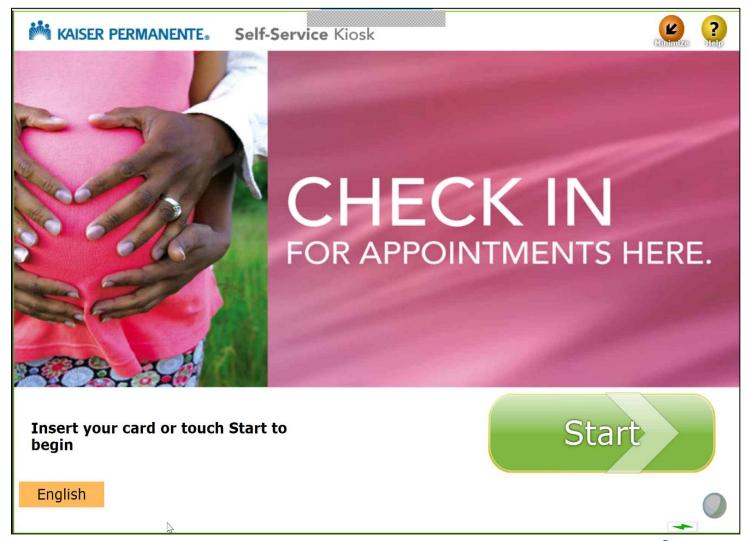
What the patient sees when logging on...

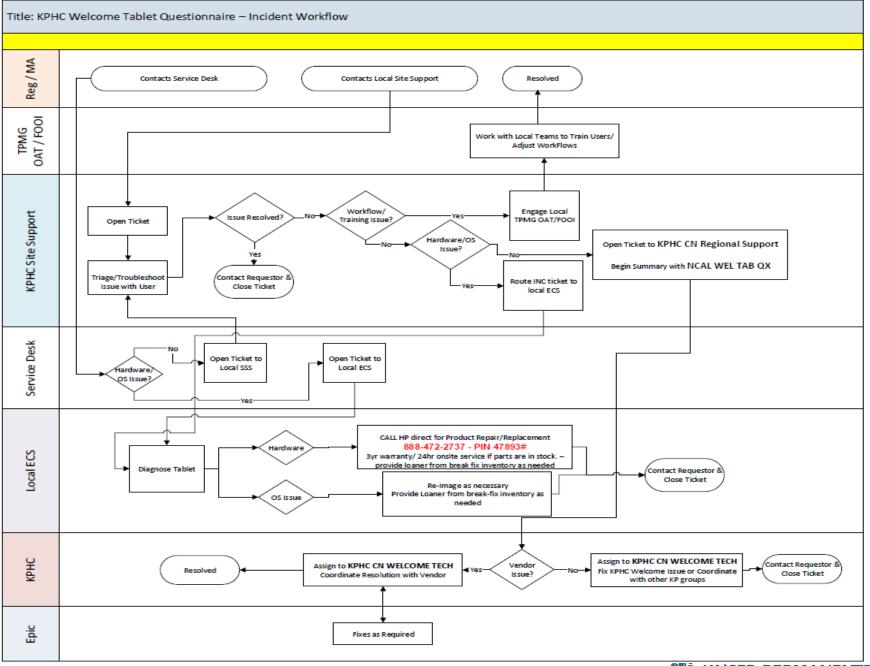


Integration into our electronic medical record...



Oncology clinic staff starts the process...





Operational Insights

- Outreach to patient too rapid and thus, overwhelming
 - Practice to reach out to patient within 1 week of initial Oncology Visit
 - "Too quick"; "Need more time to process diagnosis"
- Patient preference for 'live person'
 - Increased Response Rate with phone call
 - Emotional nature of diagnosis?
- Incorporation as routine part of Oncologic care
 - Every patient, every time
 - Workflow for Oncology Providers/Staff
- Tangible benefit needed for patients
 - Symptom management, care decisions



In Gratitude...

NIH/NCI

Ashley Wilder Smith, PhD, MPH

Roxanne Jensen, PhD

US FDA

Paul Kluetz, MD

Laura Lee Johnson, PhD

Michelle Campbell, PhD

Elektra Papadopoulos, MD, MPH

Richard Pazdur, MD

KPNC Division of Research

KP/TPMG Technology/QOS

KP Clinical Trials

KP Oncology Clinics

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