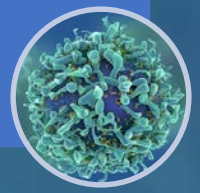
A Community Pathologist-Driven Approach to the Implementation of Best Practices in Immuno-Oncology (IO) Across the Multidisciplinary Cancer Care Team

- Pfizer grant: 34604349
- Program/project collaborators:
  - American Society for Clinical Pathology
  - Q Synthesis LLC
- Dates: Jan 1, 2018 – Dec 31, 2019

Educational activities blending online and live education

- Online modules to increase core IO knowledge/skills among pathologists and laboratory professionals

IO Scientific Core Online Modules



- Live panel discussions at ASCP 2018 Annual Meeting and ASCP 2019 Annual Meeting with enduring (online) recordings

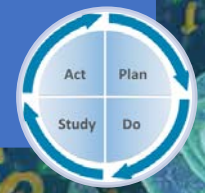
IO Implementation Panel Discussions

- Live, virtual group discussions to empower community pathologists, senior laboratory professionals, and laboratory administrators to guide IO delivery

IO ChangeMakers: Virtual Leadership Discussions

- Intensive quality improvement (QI) initiatives at 3 accredited community cancer centers to help design and implement improvements in IO delivery

Multidisciplinary Live QI Initiatives



IO Practice Survey

- Online survey to assess the state of IO-related practices (baseline and follow-up)

Educational Impact: Increased Knowledge and Confidence

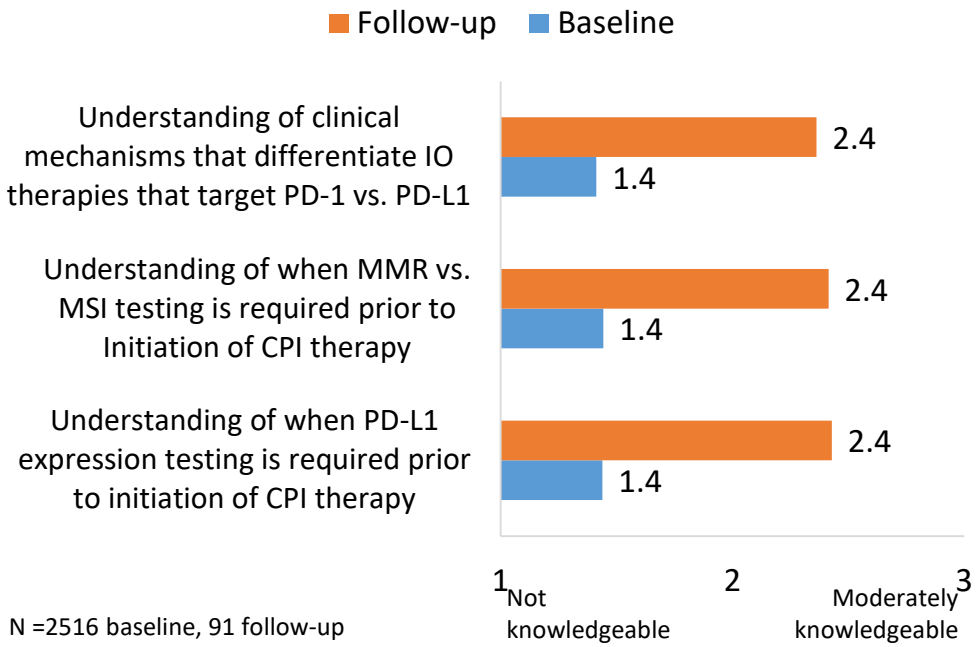
3,678 unique learners in the education*

Pretest and posttest scores showed a significant increase in overall knowledge of IO science among participants in the online education: 28.8% gain, t(4,954) = 90.3, p < .01

Mean pretest score: 46 → Mean posttest score: 75

Follow-up respondents rated their knowledge in several areas of IO significantly higher than respondents did in the baseline IO practice survey, including their understanding of PD-L1 testing, MMR vs. MSI testing, and PD-L1 vs. PD-1.

Mean Level of Understanding of IO Science



N =2516 baseline, 91 follow-up

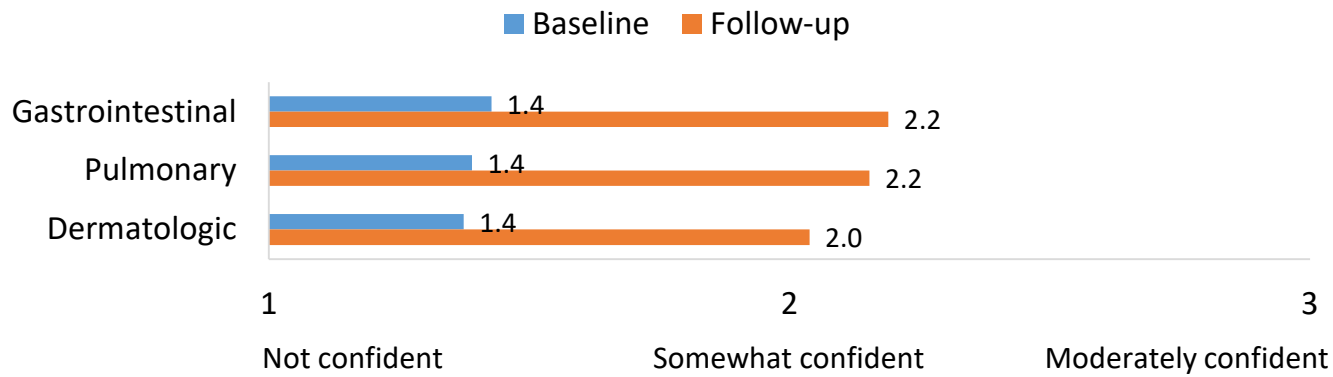
The learning objectives where the most follow-up respondents indicated that the education had increased their confidence or ability included:

- Describing basic concepts of IO
- Describing concepts in biomarkers and PD-L1
- Explaining the advantages/implications of immune-checkpoint therapy

Follow-up respondents rated their confidence in their ability to suggest an IO treatment based on pathology testing and patient history significantly higher than respondents did in the baseline practice survey, t(1,987) = 8.9, p < .01.

Follow-up respondents rated their confidence in their ability to recognize various types of immune-related adverse events (irAEs) significantly higher than respondents did in the baseline IO practice survey.

Mean Level of Confidence in Ability to Recognize the Clinicopathologic Features of Gastrointestinal, Pulmonary, and Dermatologic irAEs



QI Initiatives: Plan-Do-Study-Act (PDSA) Cycles

	Reflex Biomarker Testing Protocols (Cancer Center 1)	Biomarker Tracking Dashboard (Cancer Center 1)	PD-L1 Ordering Reference Card (Cancer Center 2)
Problem/ Aim	Biomarker testing for PD-L1 and MMR/MSI testing inconsistent or delayed; missed opportunities for IO therapy Need to standardize reflex IO biomarker testing protocols for various cancer types	PD-L1 test results for patients with advanced NSCLC often not available when medical oncologists develop a treatment plan, delaying planning decisions Need PD-L1 test results available at patient's second outpatient appointment	Clinicians not ordering the correct type of PD-L1 test based on cancer type and intended IO therapy; repeat testing may be required, delaying treatment planning Need a tool to help cancer clinicians select and order the correct type of PD-L1 test.
Plan/ Do	Pathology worked with medical oncology to develop reflex biomarker testing protocols for specific cancers. • The cancer team established criteria around when the tests should be ordered, which labs will perform the testing, and how the results will be communicated. • The protocols were updated every 3 months to incorporate significant updates.	IT developed a dashboard to allow navigators to track and coordinate PD-L1 testing and improve the communication of results. • Dashboard allows nurse navigators to track biomarker test ordering and helps ensure that patients receive appropriate testing, timely results, and timely treatment plans. • Nurses used it daily to track biomarker orders, coordinate with pathology, and notify clinicians when results became available.	Developed a PD-L1 reference card to indicate which PD-L1 test should be ordered, providing it to cancer clinicians • Card outlined the different PD-L1 antibody types and highlighted when PD-L1 testing is a companion vs. complementary diagnostic test. • For 22C3, the card outlined when the test results would require specific scoring methods.
Study/ Act	6 months after initiating the reflex testing protocols, pathology reviewed how testing rates had improved from baseline testing rates.	Navigators utilized the dashboard to minimize testing delays and coordinate with pathology and 9 different reference labs. 4 months after the dashboard launched, 83% of PD-L1 test results were in the chart at the second outpatient appointment for advanced NSCLC Navigators expanded the dashboard to track PD-L1 testing for breast cancer and bladder cancer.	PD-L1 test forms were filled out by different people in the clinic. They were all made aware of the reference card. 3 months after the reference cards were provided to cancer clinicians, 100% of the initial PD-L1 tests were being ordered correctly.

QI Initiatives: Plan-Do-Study-Act (PDSA) Cycles (cont.)

	Proactive Symptom Management (Cancer Center 2)	Extended Oncology Clinic Hours (Cancer Center 3)	IO Journal Clubs (Cancer Center 3)
Problem/ Aim	Patients treated with checkpoint inhibitors (CPIs) receiving timely diagnosis and treatment when they develop immune-related adverse events (irAEs). Proactively assess patients for symptoms, and identify and manage irAEs earlier.	Patients who develop certain irAEs not having access to the oncology clinic outside of regular business hours. Expand access to the oncology clinic for the management of certain non-emergent irAE symptoms by extending hours.	Cancer clinicians having difficult keeping up with the rapid changes in IO biomarker testing and FDA-approved treatments. Providing regularly scheduled, ongoing education highlighting key advances in IO biomarker testing and recent FDA approvals.
Plan/ Do	Pilot an electronic patient-reported outcome (ePRO) tool to improve the identification and management of irAEs. • The cancer centered selected an ePRO with a mobile application, and IT integrated it with the hospital EHR system. • Patients asked to use the ePRO, and nurses assigned to review the information. When symptoms trigged an alert, nurses called the patient to discuss. Patients also notified to call the cancer center if they reported alarming symptoms.	Established a symptom management service at the oncology clinic that ran during the extended hours. • Oncology clinic formed a symptom management team that included an advanced practice provider and an oncology nurse. This team staffed the clinic and treated patients who presented with non-emergent symptoms, • The expanded hours included weeknights and weekends.	Hold a monthly IO journal club where cancer clinicians may discuss how the latest clinical advances in IO may impact patient care. • A nurse navigator was assigned to coordinate and lead the monthly IO journal club meetings. • At each meeting, cancer clinicians reviewed updates in IO biomarker testing and the latest FDA approvals with IO therapies.
Study/ Act	Prior to the ePRO, the cancer center did not have a reliable way of tracking irAEs. 3 months after launching the ePRO, the cancer center identified 27 patients treated with CPIs who reported irAE symptoms. Nurses contacted patients and intervened with supportive care treatments.	3 months after launching the extended hours clinic, the oncology clinic saw a 23% reduction in ER utilization among their patients receiving chemotherapy and IO therapy. Patients treated with IO therapy were seen at the extended hours for possible irAE symptoms.	During the first 3 months, discussions focused on new or expanded indications approved by the FDA. Starting in the 4th month, nurses presented real cases of irAEs and discussed management strategies. Pathologists discussed emerging biomarkers (e.g., tumor mutation burden [TMB]).

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Impact Summary

- COMPATH IO reached the target audiences (including pathologists, laboratory professionals, and other members of multidisciplinary care teams)
- Significant knowledge gain among participants in the online education (29% increase in overall IO knowledge of IO science)

Mean pretest score: 46 → Mean posttest score: 75

- Follow-up survey showed gains in knowledge and confidence around the clinical gaps addressed by the project, including:
  - Awareness of the core science of IO
  - Awareness of current guidelines for IO testing and reporting
  - Understanding of clinical indications and analytical processes related to biomarker and pathway testing
  - Ability to inform the selection of appropriate IO cancer treatment

- Topics in IO ChangeMakers discussions focused around key challenges and barriers to biomarker testing, including:
  - Ensuring that clinicians understand test results and communicating results to inform clinical action
  - Navigating disagreements about testing policies/procedures
- Summary of improvements from the QI program:
  - Increased the use of PD-L1 and MMR/MSI testing in patients with advanced NSCLC, colorectal, gastric, cervical, urothelial, and triple negative breast cancer
  - Increased the likelihood that the correct PD-L1 test would be ordered based on the type of cancer and the intended therapy
  - More timely and proactive detection and management of irAEs
  - Increased patient access to cancer clinicians by extending clinic hours to manage irAEs
  - Held ongoing education meetings as “IO journal clubs” to review the latest advances in IO biomarker testing and therapy

- “…This was a great introduction to some of the newer choices our clinicians are exposed to and have to decide on for research for the future, and treatment of current patients.”
- "I appreciated the challenge to think of the value of ancillary testing and how best to approach testing requests.“
- “Reinforced the need for oncologists and pathologists to communicate about the patient when ordering tests.”