PUTTING POSITIVE QUALITY INTERVENTIONS INTO ACTION: CONSISTENT CLINICAL STANDARDS FOR MEDICALLY INTEGRATED TEAMS

Kirollos Hanna, PharmD, BCPS, BCOP
University of Minnesota Medical Center and Mayo Clinic

Stacey McCollough, PharmD and Jared Crumb, PharmD
Tennessee Oncology

Raquel Rhone, PharmD and Donnell Hale, BSN, RN, OCN
Texas Oncology

FACULTY DISCLOSURES

Kirollos Hanna

- Receives speaking fees from: Seattle Genetics; Astellas; Abbvie
- Receives consultancy fees from: Seattle Genetics; Abbvie
- Receives advisory board fees from: Abbvie; Astellas•

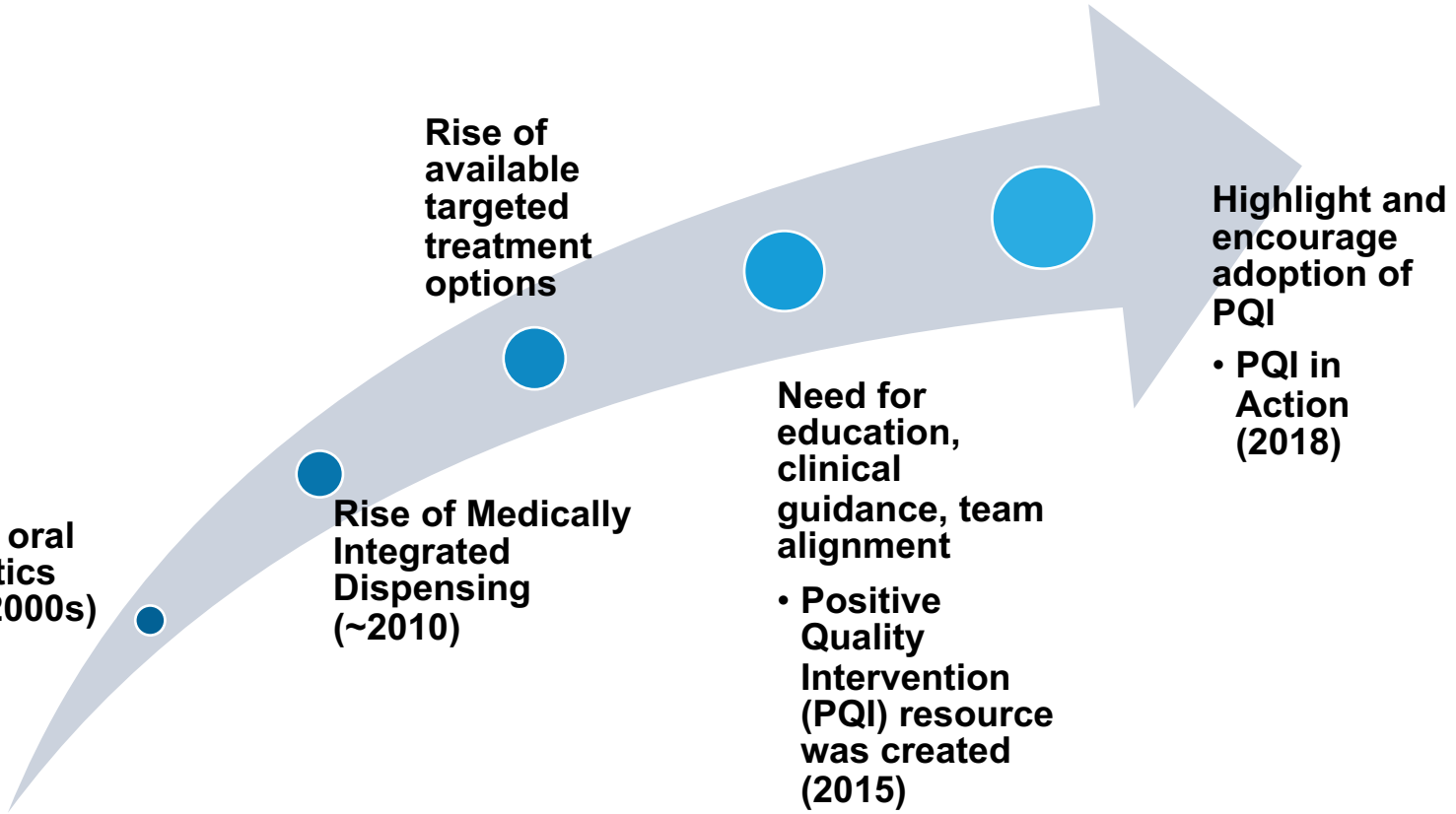
Stacey McCullough

- Receives advisory board fees from: Abbvie; Atara; DSI; Exelixis; BeiGene; Verastem; Genetec

Nothing to disclose:

- Donnell Hale
- Raquel Rhone
- Matthew Schulz

INTRODUCTION – HOW DID WE GET HERE?



KNOWLEDGE ASSESSMENT:

- Throughout this presentation
- Be prepared to answer questions
- Polling results will *not* display for Pre-Assessment Questions

PRE-ASSESSMENT QUESTION #1

- Are you a :
  a) Physician
  b) Nurse
  c) Pharmacist
  d) Pharmacy Technician
  e) Other

PRE-ASSESSMENT QUESTION #2

The PQI in Action article accomplishes which of the following:

a) Highlights a cancer center/medical practice as a world leader in oncology
b) Identifies procedural gaps in care and discusses the benefits within a Medically Integrated Pharmacy (MIP) model
c) Shares effective practices and examples of PQI implementation including review of a specific drug therapy that improved patient outcomes
d) Furthers the mission to improve the current model and keep patients and the dispensing of their drugs at the site of care with the provider
e) All of the Above

PRE-ASSESSMENT QUESTION #3

Which of the following practices were involved with the PQI in Action article for regorafenib that was presented today?

a) Texas Oncology
b) Georgia Cancer Specialists
c) GHOSH Center
d) Tennessee Oncology
e) A and C
f) B and D
g) A and D
h) All of the above

LEARNING OBJECTIVES

- Define a PQI and its purpose
- Describe examples of how PQIs increased multidisciplinary team interaction and improved patient care
- List the benefits of incorporating consistent clinical principles contained within the PQI into regular practice

EXPERT PANEL

Yesterday's Challenges = Today's Opportunities

EXPERT PANEL

When did you establish medically integrated dispensing services at your practice?

Describe the general workflow

EXPERT PANEL

What challenges are you facing in your day to day operation?

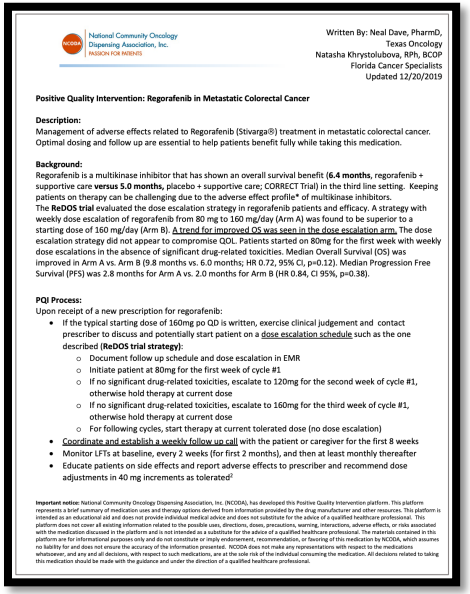
MEETING THE NEED: PQI

Problem:

- New drug therapies
  - Frequency
  - Complexity
- Information Overload
- Lack of standards for:
  - Drug therapy protocols
  - Staff Education
  - Patient Education
  - Follow-up
  - Management

Solution:

- PQI



National Community Oncology Dispensing Association, Inc.
MISSION FOR PATIENTS

Written By: Neal Dave, PharmD, Texas Oncology
Natasha Khrystolubova, RPh, BCOP Florida Cancer Specialists
Updated 12/20/2019

Positive Quality Intervention: Regorafenib in Metastatic Colorectal Cancer

Description:
Management of adverse effects related to Regorafenib (Stivarga®) treatment in metastatic colorectal cancer. Optimal dosing and follow up are essential to help patients benefit fully while taking this medication.

Background:
Regorafenib is a multikinase inhibitor that has shown an overall survival benefit (**6.4 months**, regorafenib + supportive care **versus 5.0 months,** placebo + supportive care; CORRECT Trial) in the third line setting. Keeping patients on therapy can be challenging due to the adverse effect profile* of multikinase inhibitors.
The **ReDOS trial** evaluated the dose escalation strategy in regorafenib patients and efficacy. A strategy with weekly dose escalation of regorafenib from 80 mg to 160 mg/day (Arm A) was found to be superior to a starting dose of 160 mg/day (Arm B). A trend for improved OS was seen in the dose escalation arm. The dose escalation strategy did not appear to compromise QOL. Patients started on 80mg for the first week with weekly dose escalations in the absence of significant drug-related toxicities. Median Overall Survival (OS) was improved in Arm A vs. Arm B (9.8 months vs. 6.0 months; HR 0.72, 95% CI, p=0.12). Median Progression Free Survival (PFS) was 2.8 months for Arm A vs. 2.0 months for Arm B (HR 0.84, CI 95%, p=0.38).

PQI Process:
Upon receipt of a new prescription for regorafenib:

- If the typical starting dose of 160mg po QD is written, exercise clinical judgement and contact prescriber to discuss and potentially start patient on a dose escalation schedule such as the one described (**ReDOS trial strategy**):
  - Document follow up schedule and dose escalation in EMR
  - Initiate patient at 80mg for the first week of cycle #1
  - If no significant drug-related toxicities, escalate to 120mg for the second week of cycle #1, otherwise hold therapy at current dose
  - If no significant drug-related toxicities, escalate to 160mg for the third week of cycle #1, otherwise hold therapy at current dose
  - For following cycles, start therapy at current tolerated dose (no dose escalation)
- Coordinate and establish a weekly follow up call with the patient or caregiver for the first 8 weeks
- Monitor LFTs at baseline, every 2 weeks (for first 2 months), and then at least monthly thereafter
- Educate patients on side effects and report adverse effects to prescriber and recommend dose adjustments in 40 mg increments as tolerated[2]

Important notice: National Community Oncology Dispensing Association, Inc. (NCODA), has developed this Positive Quality Intervention platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

POSITIVE QUALITY INTERVENTIONS (PQI)

- Explanation and Purpose of PQIs
- Current Process
- Examples of concise interventions (PQIs)

EXPLANATION AND PURPOSE OF PQIS

Provide peer-reviewed, clinical guidance documents

Promote higher quality patient care

Operationalize and standardize best practices to achieve positive clinical outcomes

Authored by clinical practitioners and based on real-world practice experience and data

PQI PROCESS

Identify Topic Need and Identify Topic Experts

(Peer recommendations, volunteers, committee members)

Pre-writing Conference

(Identify the Intervention)

Document Creation and Revisions

(PQI Committee)

Send to MD for Medical Review

Publish on NCODA Website

(updated twice-yearly)

EXPERT PANEL

Kirollos Hanna: Discuss your role in the PQI process.

What do you look for during your review?

PQI FORMAT - BY SECTIONS (PART ONE)

Description

- 1-2 sentences
- “The purpose of this PQI is to…”
- What the intervention is doing/helping

Background

- 1 paragraph
- Pertinent historical data and information
- Drug, mechanism of action, clinical trial experience
- The main focus of the intervention (the “why”)

PQI FORMAT - BY SECTIONS (PART TWO)

The PQI Process

- The intervention in step by step points
- Clinician-directed guidance
- “Upon receiving a prescription for….”
- Critical clinical criteria that may be missed/overlooked (specific intervention)

Patient Centered Activities

- Patient-directed guidance
- Key counseling points
- Administration, drug-drug interactions, dose modifications

Supplemental Information

- Additional tables, graphs, background or other drug information not critical to intervention

References

- AMA Format

PQI EXAMPLE

Regorafenib in mCRC

REGORAFENIB PQI – COLORECTAL CANCER

National Community Oncology Dispensing Association, Inc.
PASSION FOR PATIENTS

Written By: Neal Dave, PharmD,
Texas Oncology
Natasha Khrystolubova, RPh, BCOP
Florida Cancer Specialists
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REGORAFENIB PQI – COLORECTAL CANCER

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REGORAFENIB PQI – COLORECTAL CANCER

Patient Centered Activities:

- Provide Oncology Chemotherapy Education (OCE) sheet
- Provide patient starter kit
- Ensure patient knows dosing schedule (once daily for 3 weeks on and 1 week off)
- Ensure patient knows to take dose with a low-fat meal (<600 calories and 30% fat)
- Only open 1 bottle of Regorafenib at a time. **Medication expires 7 weeks after bottle is opened**
- Ensure patient or caregiver is able to take and record blood pressure at home weekly
- Consider Anti Diarrheals and Moisturizing cream i.e Urea 20%

Copay Assistance:

- Commercial patients can enroll in a $0 copay card assistance program (online enrollment- www.zerocopaysupport.com)

Supplemental Information:

*Dose limiting side effects include (percentage refers to all grades)[1]:
Skin and subcutaneous tissue adverse events, including palmar-plantar erythrodysesthesia (Hand and Foot syndrome) 72%, diarrhea 43%, hypertension 30%, fatigue 64%, increased LFTs (AST-65%, ALT-45%, Bilirubin-45%). The median time to first adverse event was 2 weeks with worst incidences occurring at 3 weeks. The worst severity of diarrhea occurred at 4 weeks. Increases in LFTs usually occur within the first 8 weeks of therapy.

REGORAFENIB PQI – COLORECTAL CANCER

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EXPERT PANEL

What do you find most valuable about the PQI format?

KNOWLEDGE ASSESSMENT

Live Polling Questions

ASSESSMENT QUESTION #4

PQI stands for:

a) Personal Quality Interview
b) Professional Question Intervention
c) Positive Quality Intervention
d) Performance Quality Improvement

ASSESSMENT QUESTION #5

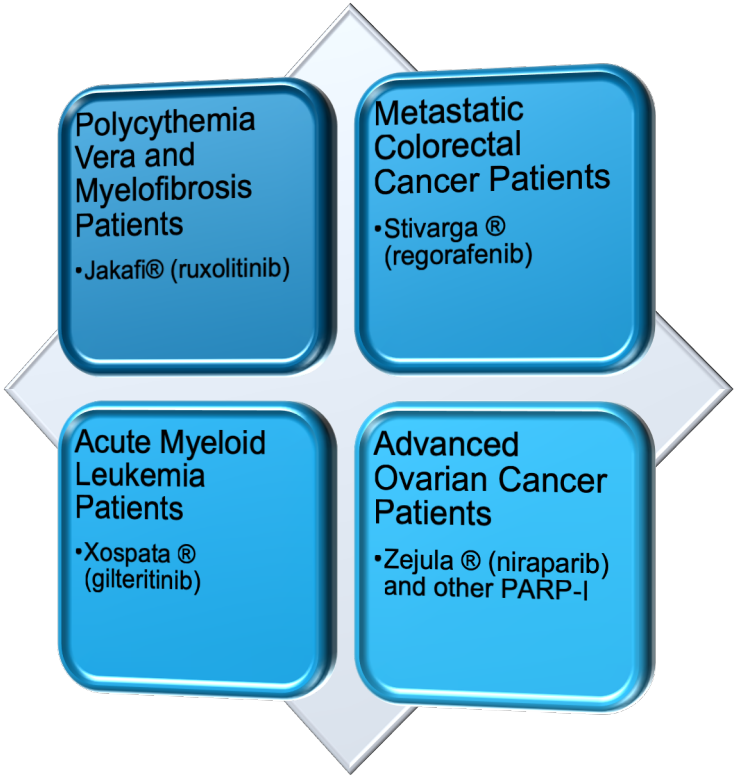
The purpose of a PQI is to:

a) Provide guidance on a specific aspect of patient care
b) Present a concise review and stepwise process around a key clinical area that may be overlooked
c) Improve the quality and frequency of clinical communication across the multidisciplinary team
d) All of the above

PQI IN ACTION

Practical Experience and Positive Outcomes

FOUR COMPLETED PROJECTS & ARTICLES



FOUR COMPLETED PROJECTS & ARTICLES

UTAH CANCER SPECIALISTS

PRESCRIPTION SERVICES COORDINATOR
DANIELLE ERCANBRACK, CPHT
Utah Cancer Specialists | Salt Lake City, Utah

NURSE MANAGER
TINA MCCALLUM, RN
Utah Cancer Specialists | Salt Lake City, Utah

DIRECTOR, PHARMACEUTICAL SERVICES
NEIL NEBUGHR, RPH
Utah Cancer Specialists | Salt Lake City, Utah

HEMATOLOGIST/ONCOLOGIST
WAYNE ORMSBY, MD
Utah Cancer Specialists | Salt Lake City, Utah

NEW ENGLAND CANCER SPECIALISTS

PHARMACIST
JEFF AUDET, RPH
New England Cancer Specialists | Scarborough, Maine

PHARMACY MANAGER
ERIC DALLARA, RPH
New England Cancer Specialists | Scarborough, Maine

EXECUTIVE DIRECTOR
STEVEN D'AMATO, BSPHARM
New England Cancer Specialists | Scarborough, Maine

FINANCIAL ADVOCATE SUPERVISOR
TORIE LAVOIE
New England Cancer Specialists | Scarborough, Maine

NURSE SUPERVISOR
DAWN WHITTEN, RN, BSN, OCN, CBCN
New England Cancer Specialists | Scarborough, Maine

HEMATOLOGIST/ONCOLOGIST
JOHN PAUL WINTERS III, MD
New England Cancer Specialists | Scarborough, Maine

ALABAMA ONCOLOGY

MEDICAL ONCOLOGIST/PRACTICE PRESIDENT
BRIAN ADLER, MD
Alabama Oncology | Birmingham, Alabama

ONCOLOGY NURSE
KARLA LANGNER, RN, BSN
Alabama Oncology | Birmingham, Alabama

PHARMACY MANAGER
AUSTIN COX, PHARMD
Alabama Oncology | Birmingham, Alabama

PATIENT ADVOCATE
BRANDI GUDWIEN, CPHT
Alabama Oncology | Birmingham, Alabama

NEBRASKA CANCER SPECIALISTS

MEDICAL ONCOLOGIST
TIMOTHY HUYCK, MD
Nebraska Cancer Specialists | Omaha, Nebraska

ADVANCED PRACTICE PROVIDER
KATIE RUCH, MSN, APRN-NP, AOCNP
Nebraska Cancer Specialists | Omaha, Nebraska

OUTPATIENT PHARMACY MANAGER
MICHAEL BRODERSEN, PHARMD, BCOP
Nebraska Cancer Specialists | Omaha, Nebraska

REGISTERED PHARMACY TECHNICIAN
ANDREA NELSON
Nebraska Cancer Specialists | Omaha, Nebraska

UNIVERSITY OF MINNESOTA HEALTH

ASSISTANT PROFESSOR OF MEDICINE
ARMIN RASHIDI, MD, PHD
University of Minnesota Health | Minneapolis, Minnesota

HEMATOLOGY/ONCOLOGY CLINICAL PHARMACIST
JEFF ENGLE, PHARMD ,MS
University of Minnesota Health | Minneapolis, Minnesota

ONCOLOGY NURSE CARE COORDINATOR
JUDI BUTLER, MSN, RN, OCN
University of Minnesota Health | Minneapolis, Minnesota

ONCOLOGY CLINIC PHARMACY LIAISON
DOMINIQUE CLOUTIER, CPHT
University of Minnesota Health | Minneapolis, Minnesota

ROCKY MOUNTAIN CANCER CENTERS

ASSOCIATE CHAIR, USO HEMATOLOGY RESEARCH PROGRAM
JOHN M. BURKE, MD
Rocky Mountain Cancer Centers | Aurora, CO

PHARMACY MANAGER
DEREK BURNS, PHARMD, DCPS, DPLA
Rocky Mountain Cancer Centers | Aurora, CO

NURSE CLINICIAN
ERIC BLAKELY, RN
Rocky Mountain Cancer Centers | Aurora, CO

LEAD PHARMACY TECHNICIAN
JESSICA RUSH, CPHT
Rocky Mountain Cancer Centers | Denver, CO

FOUR COMPLETED PROJECTS & ARTICLES

TEXAS ONCOLOGY

MEDICAL ONCOLOGIST
SUDHA TEERDHALA, MD
Texas Oncology | Mesquite, Texas

PHARMACY MANAGER
LESLIE GIANG, PHARMD
Texas Oncology | Mesquite, Texas

PRACTICE ADMINISTRATOR
TERRI WELLS
Texas Oncology | Mesquite, Texas

NORTHWEST ONCOLOGY & HEMATOLOGY

MEDICAL ONCOLOGIST
STEVEN KANTER, MD
Northwest Oncology & Hematology | Rolling Meadows, Illinois

CLINICAL PHARMACY MANAGER
LISA RAFF, PHARMD, BCPS, BCOP
Northwest Oncology & Hematology | Rolling Meadows, Illinois

SIMMONS CANCER INSTITUTE (SOUTHERN ILLINOIS UNIVERSITY)

PROFESSOR AND CHIEF
LAURENT BRARD, MD, PHD
Simmons Cancer Institute | Springfield, Illinois

CERTIFIED NURSE PRACTITIONER
LORIE SPORRER, FNP-BC
Simmons Cancer Institute | Springfield, Illinois

SWEDISH AMERICAN (UNIVERSITY OF WISCONSIN HEALTH)

MEDICAL ONCOLOGIST
WILLIAM C. SCHULZ, MD
Swedish American | Rockford, Illinois

ONCOLOGY CLINICAL PHARMACIST
RALITZA ANGUELOVA, PHARMD
Swedish American | Rockford, Illinois

ONCOLOGY CLINICAL PHARMACIST
ELIZABETH LINDQUIST, PHARMD
Swedish American | Rockford, Illinois

MEDICATION ACCESS SPECIALIST
HEATHER MAYNARD, CPHT
Swedish American | Rockford, Illinois

JOLIET ONCOLOGY & HEMATOLOGY ASSOCIATES (AMITA)

ONCOLOGY CLINICAL PHARMACIST
FLORENCE OSISANYA, PHARMD
Joliet Oncology & Hematology Associates | Morris, Illinois

DIRECTOR OF PHARMACY
JENNIFER CHIRILLO, PHARMD
Joliet Oncology & Hematology Associates | Morris, Illinois

ONCOLOGY NURSE
TANYA HIBLER, RN
Joliet Oncology & Hematology Associates | Morris, Illinois

ST. LUKE'S HEALTH SYSTEM (MOUNTAIN STATES TUMOR INSTITUTE)

ONCOLOGY CLINICAL PHARMACIST
STEPHANIE MATTA, PHARMD, BCOP
St. Luke's Health System | Boise, Idaho

ORAL ONCOLOGY PHARMACIST
JULIA KERR, PHARMD
St. Luke's Health System | Boise, Idaho

GENETIC COUNSELOR
EMILY FASSI, MS, LCGC
St. Luke's Health System | Boise, Idaho

2020 NCODA Spring Forum

UNIVERSITY OF MINNESOTA HEALTH MASONIC CANCER CLINIC AND FAIRVIEW SPECIALTY PHARMACY

Minneapolis Location

Jeff Engle, PharmD

Counsels a patient

2020 NCODA Spring Forum

TENNESSEE ONCOLOGY

Nashville Location

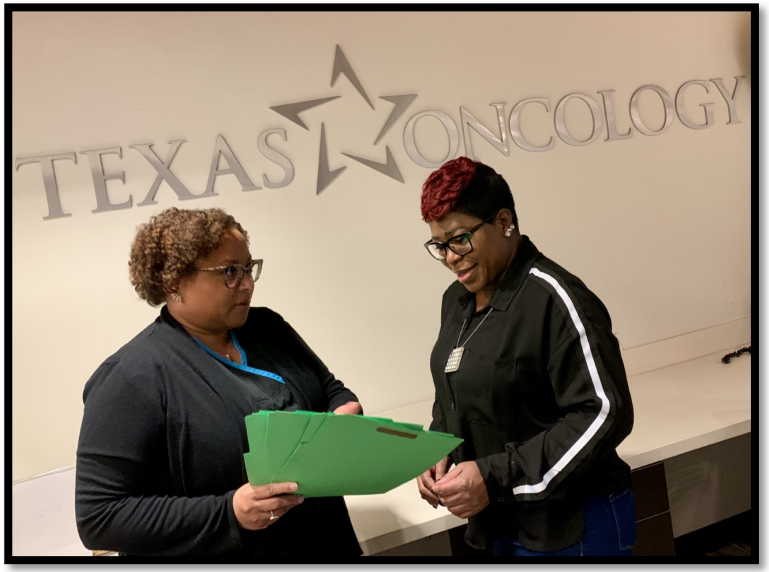
Edward Arrowsmith, MD

Discussing patient case with colleague

TEXAS ONCOLOGY

Baylor Charles A. Sammons Cancer Center
Dallas Location

Raquel Rhone, PharmD
Discussing patient case with colleague



PQI IN ACTION - REGORAFENIB

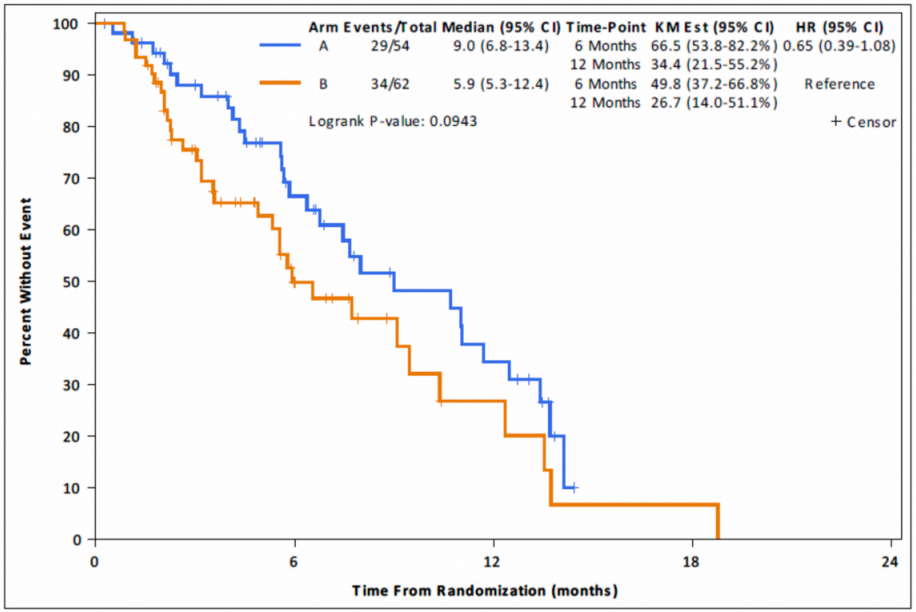
How two leading oncology organizations are improving outcomes for metastatic colorectal cancer patients via the PQI

REGORAFENIB PQI PRINCIPLES:

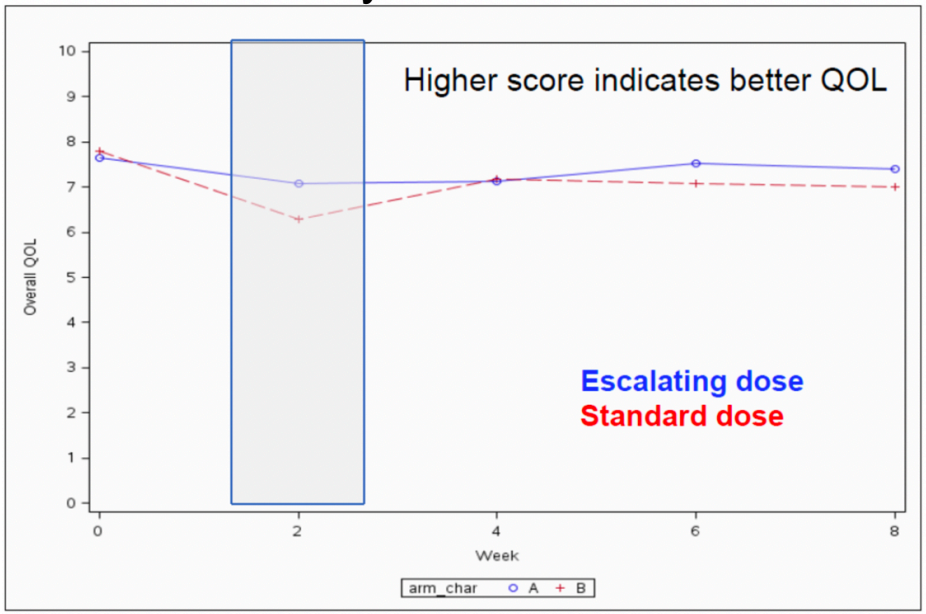
1. Dose escalation
2. Weekly follow-up for eight weeks
3. Urea-based cream

REDOS TRIAL

Overall Survival



Quality of Life



REGORAFENIB DOSE ESCALATION

Week	Dose
1	80mg
2	120mg
3+	160mg

UREA-BASED CREAM

Include with initial dispensing of regorafenib

Recommended for patient to have on hand

WEEKLY FOLLOW-UP

For the first eight weeks of therapy

WHEN AND WHERE DO YOU USE THIS PQI?

- Built into the EMR regimens
- Initial Staff education on drug therapy
- Ongoing department meetings and huddles
- Seeing the therapy for the first time in a while
- Review upon refills
- Especially important during dose escalation to review adverse event management and appropriate dosing upon refill dispense

SUMMARY

Although the current landscape is becoming increasingly complex, the PQI offers a solution

Closing Suggestions from the Expert Panel

LOOKING AHEAD:
FUTURE PARTNERSHIP OPPORTUNITIES

Challenge yourselves to do more for your patients!
The PQI provides the clinical foundation.

Improve workflow processes at your organization.
Improve the clinical outcomes for your patients.

POST-ASSESSMENT QUESTION #1

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CE ACCREDITATION

Putting Positive Quality Interventions into Action: Consistent Clinical Standards for Medically Integrated Teams

Credit Hours: 1.0

Pharmacist Credit Code: V5Es

Technician Credit Code: 3yan

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https://doi.org/10.1016/S1470-2045(19)30272-4

Questions?

#NCODAForum20