

ASCO's Quality Training Program

Project Title: Improving the Rate of patient counseling by the pharmacist prior to starting oral oncolytic therapy with capecitabine

Presenters: I. Alex Bowman, MD., Christine Hong, Pharm.D., Mary Gill, Eileen Marley, Pharm. D., BSN., Rebecca Yarborough, MD.

Institution: UT Southwestern Medical Center,
Simmons Comprehensive Cancer Center

Date: 4 October 2017

Institutional Overview: UTSW Simmons Comprehensive Cancer Center

- UT Southwestern Medical Center Hospital Based Clinics
- NCI-designated comprehensive cancer center
- 3 infusion centers: Dallas, Moncrief, Richardson

Problem Statement

Between January and May 2017, only 40.7% (n=11/27) of patients at the Simmons Cancer Center at UT Southwestern were counseled by a UT Southwestern pharmacist prior to the first dose of the oral chemotherapy drug capecitabine, exposing these patients to the risks of toxicity and non-adherence.

Team Members

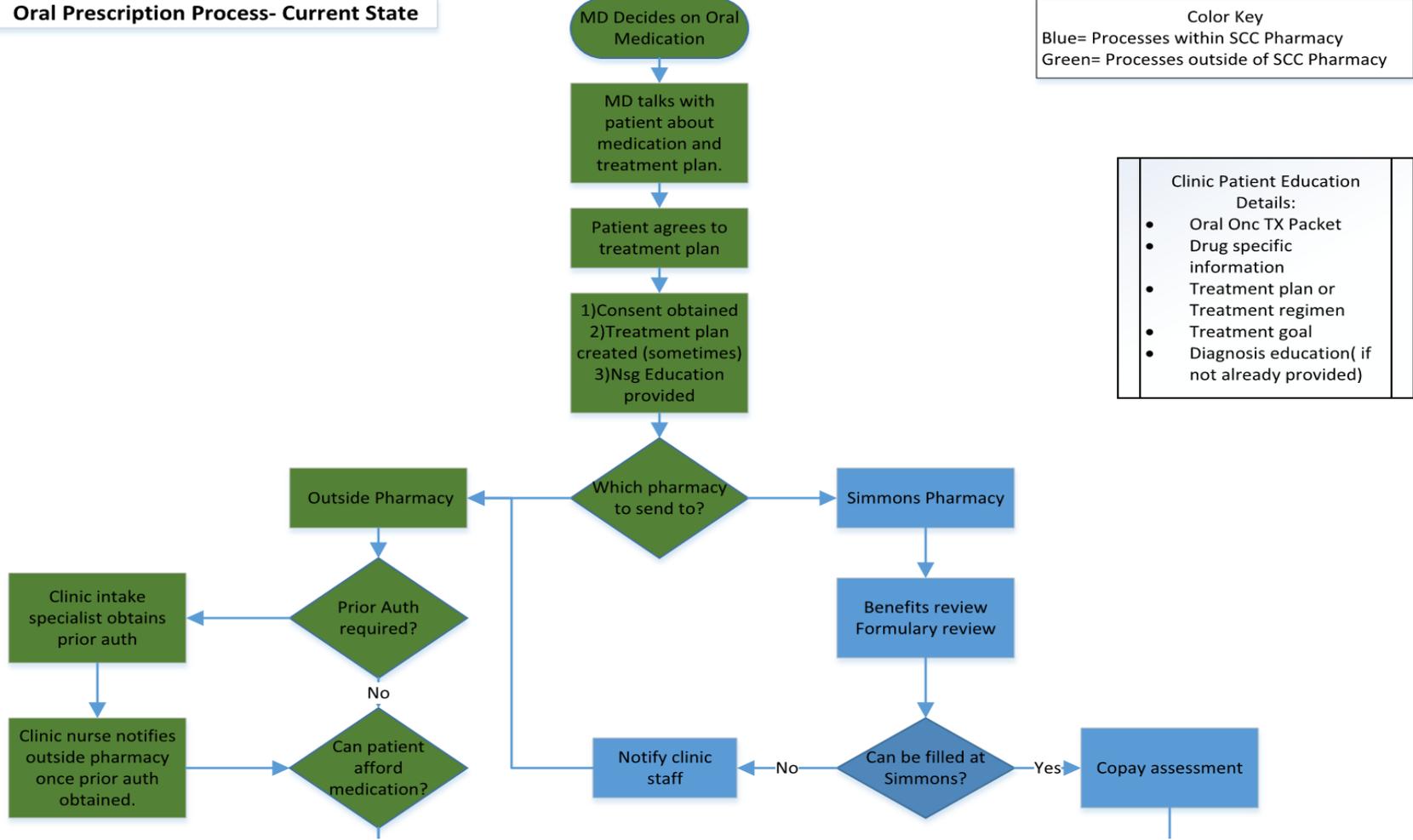
Project Team Members and Roles

Role	Name	Job Function
Project Sponsor [#]	John Cox, MD	Administrative and Resource Support, Project Guidance
Team Leader ⁺	I. Alex Bowman, MD	Project organization and leadership; MD input for workflow/process at PHHS and SCCC
Core Team Member [*]	Jieun Christine Hong, Pharm.D. MBA	SCC Pharmacy Input and organization, implementation of changes to pharmacy practices at PHHS
Core Team Member [*]	Eileen Marley, PharmD, BCOP	PMMH Pharmacy Input and organization, implementation of changes to pharmacy practices at PHHS
Facilitator	Amanda Shaughnessy	Team member who facilitates the team meetings to optimize group processes.
Core Team Member [*]	Rebecca Yarborough, MD	MD input for workflow/process at PHHS
Core Team Member [*]	Mary Gill, BSN	SCCC Clinic and RN Input
Other Team Member [^]	Donna Bryant, MSN, ANP-BC, OCN	SCCC Clinic and RN Input
Other Team Member [^]	Thanh Bui	SCCC Pharmacy Input
Core Team Member [*]	Susan Chacko, PharmD, BCOP	SCCC Pharmacy Input
Patient/ Family Member	Pending	
QTP Improvement Coach	Beverly Hardy-Decuir	Provides remote support to the team regarding the science of quality improvement and participation in the QTP.

Process Map

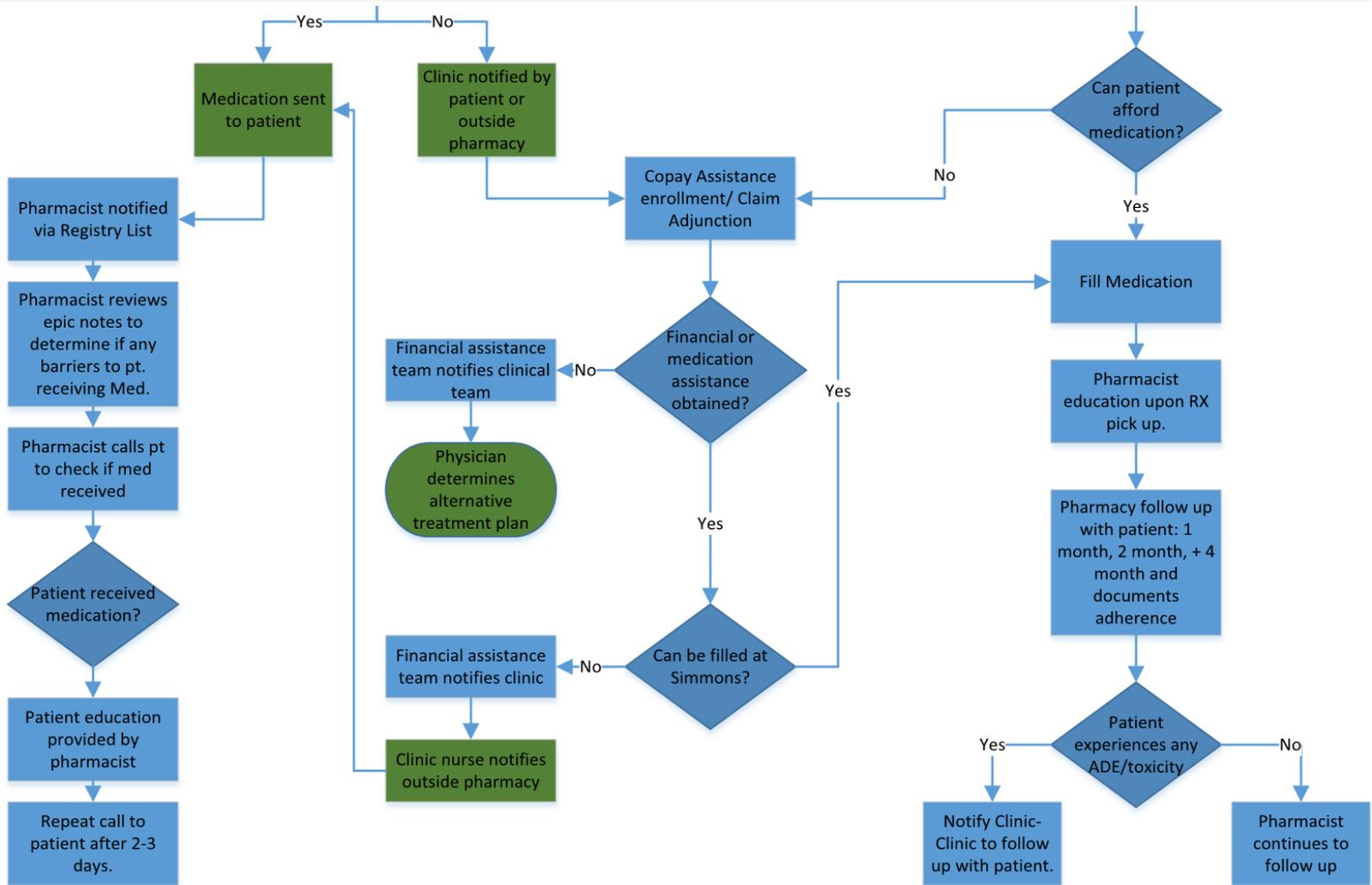
Oral Prescription Process- Current State

Color Key
 Blue= Processes within SCC Pharmacy
 Green= Processes outside of SCC Pharmacy



- Clinic Patient Education Details:
- Oral Onc TX Packet
 - Drug specific information
 - Treatment plan or Treatment regimen
 - Treatment goal
 - Diagnosis education(if not already provided)

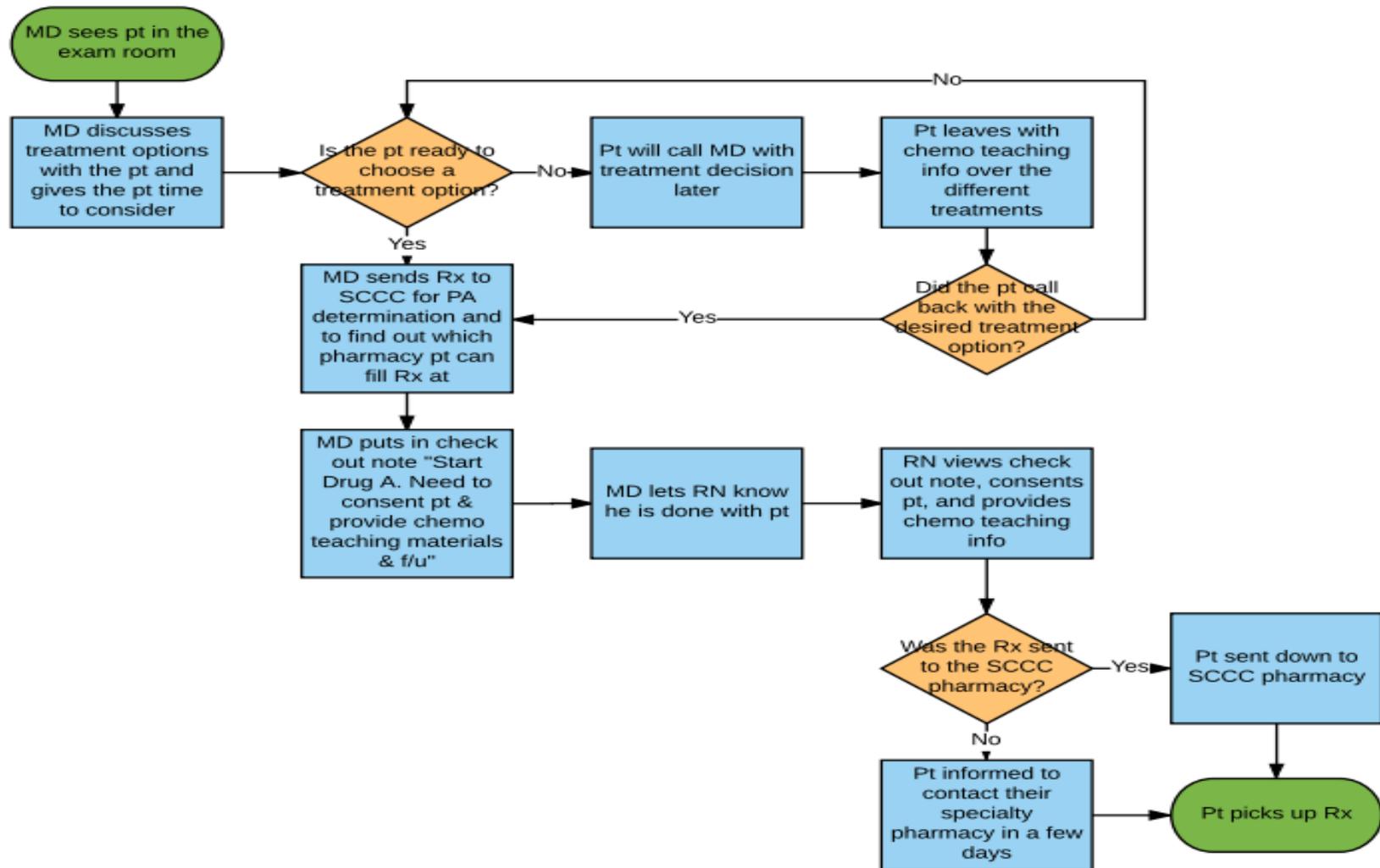
Process Map



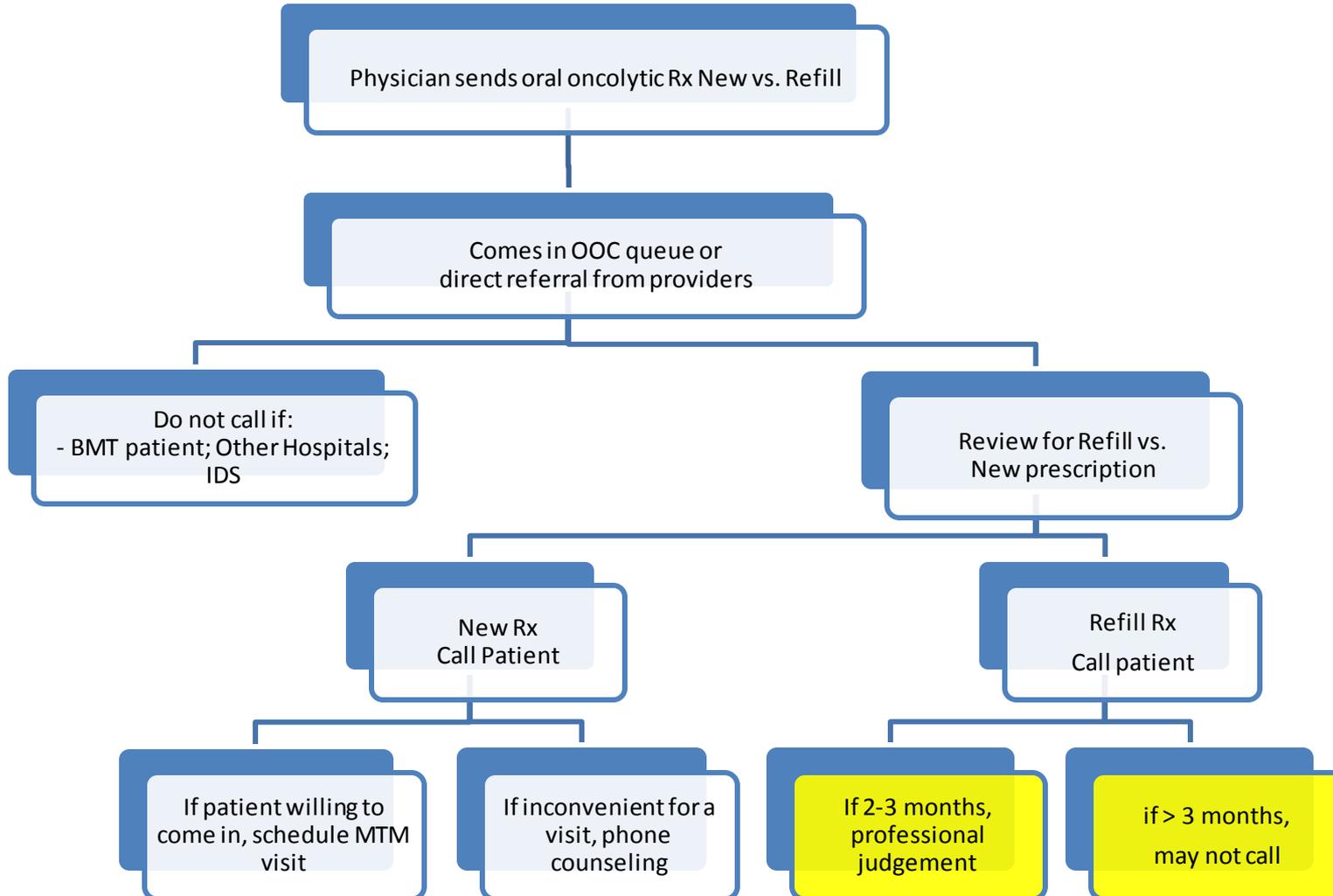
Diagnostic Data

- GI Clinic Observation
- Pharmacy-specific process mapping
- Workflow analysis of pharmacy process (pending)

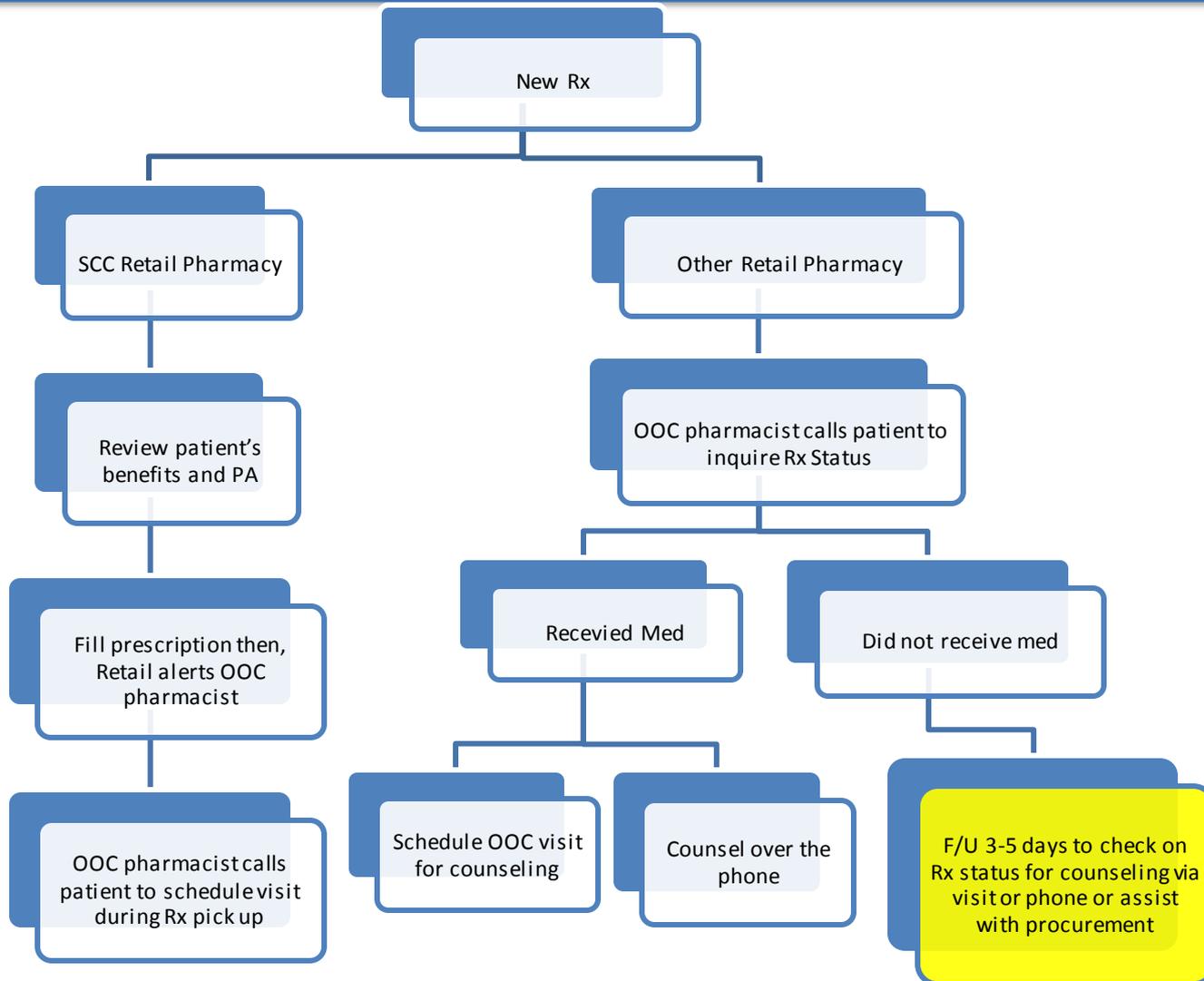
Process Map – GI Clinic



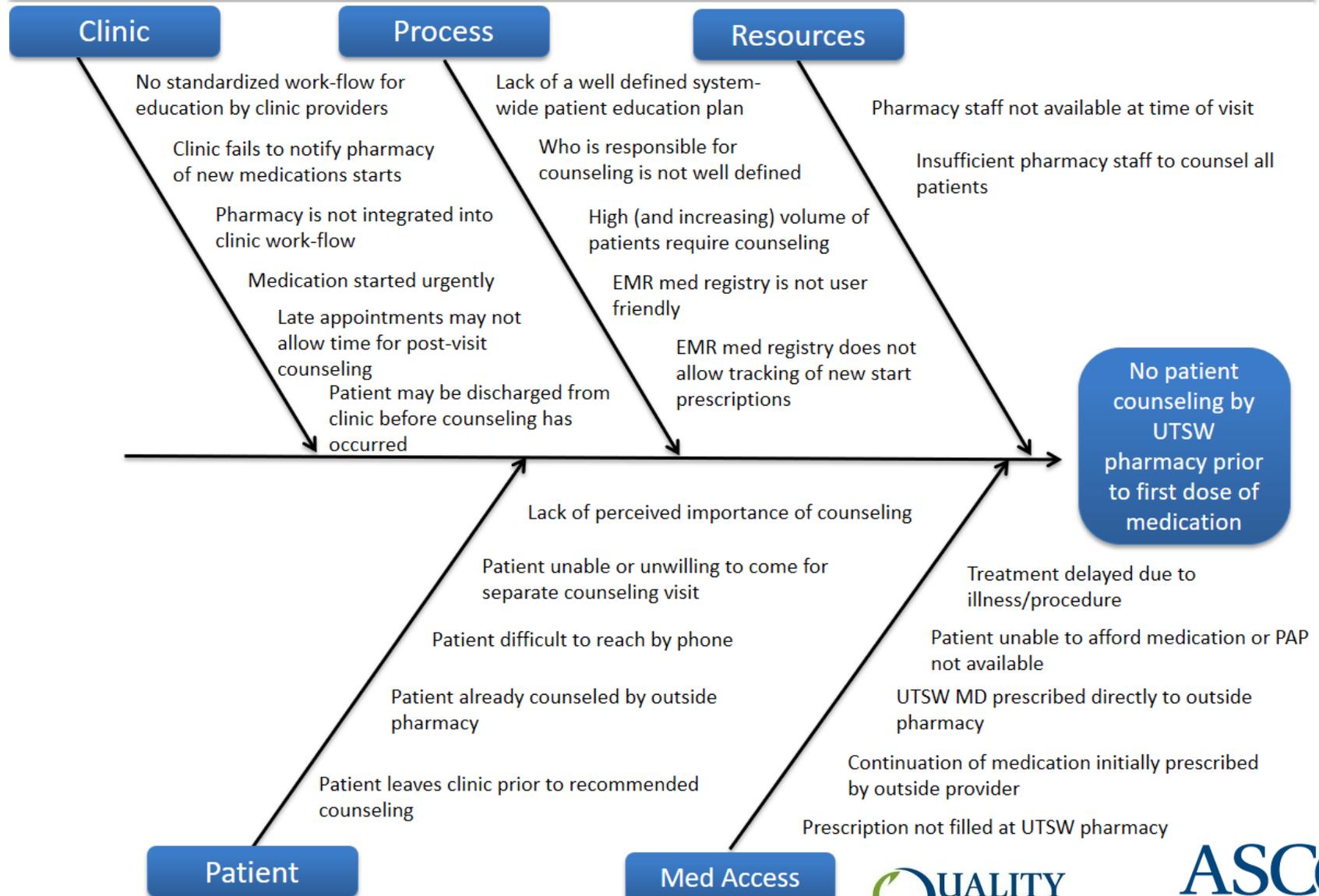
Process Map – Pharmacy



Process Map – Pharmacy



Cause & Effect Diagram



Aim Statement

From August 1st through September 30th, 90% of patients prescribed capecitabine for the treatment of oncology indication will be counseled by a UTSW pharmacist prior to taking the first dose of their medication.

Measures

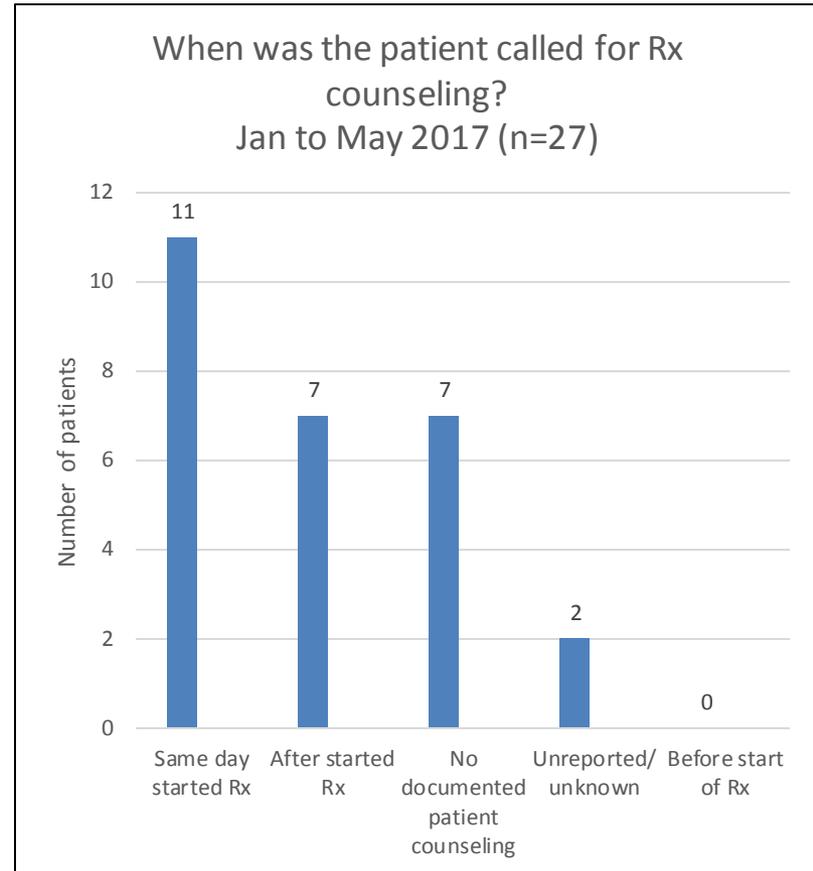
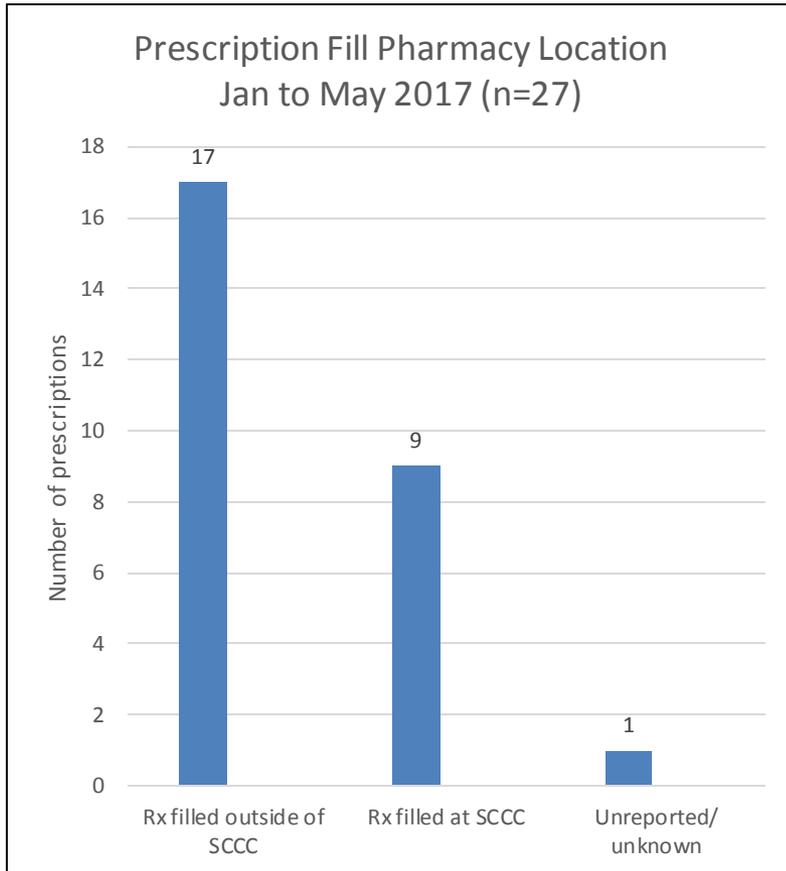
- Measure:
 - Number of new prescriptions for capecitabine during specified period
 - Number of prescription filled at UTSW vs. non-UTSW pharmacy location
 - Actual medication start date of administration
 - Method of counseling performed
 - Turnaround time to obtain prescription, counseling and start of medication by the patient
- Patient population:
 - All patients newly starting on capecitabine treatment
 - Exclusion: none
- Data source:
 - EPIC® HER, Pioneer®, documented patient reported data
- Data collection frequency: baseline and biweekly
- Data quality(any limitations):
 - patient reported data: date of first dose taken, prescription filled at non-UTSW pharmacy location

Baseline Data

Age	
1	age 30-39
6	age 40-49
6	age 50-59
8	age 60-69
5	age 70-79
1	age 80-89
Gender	
5	Male
22	Female
Diagnosis	
15	Breast cancer
11	GI
1	Other

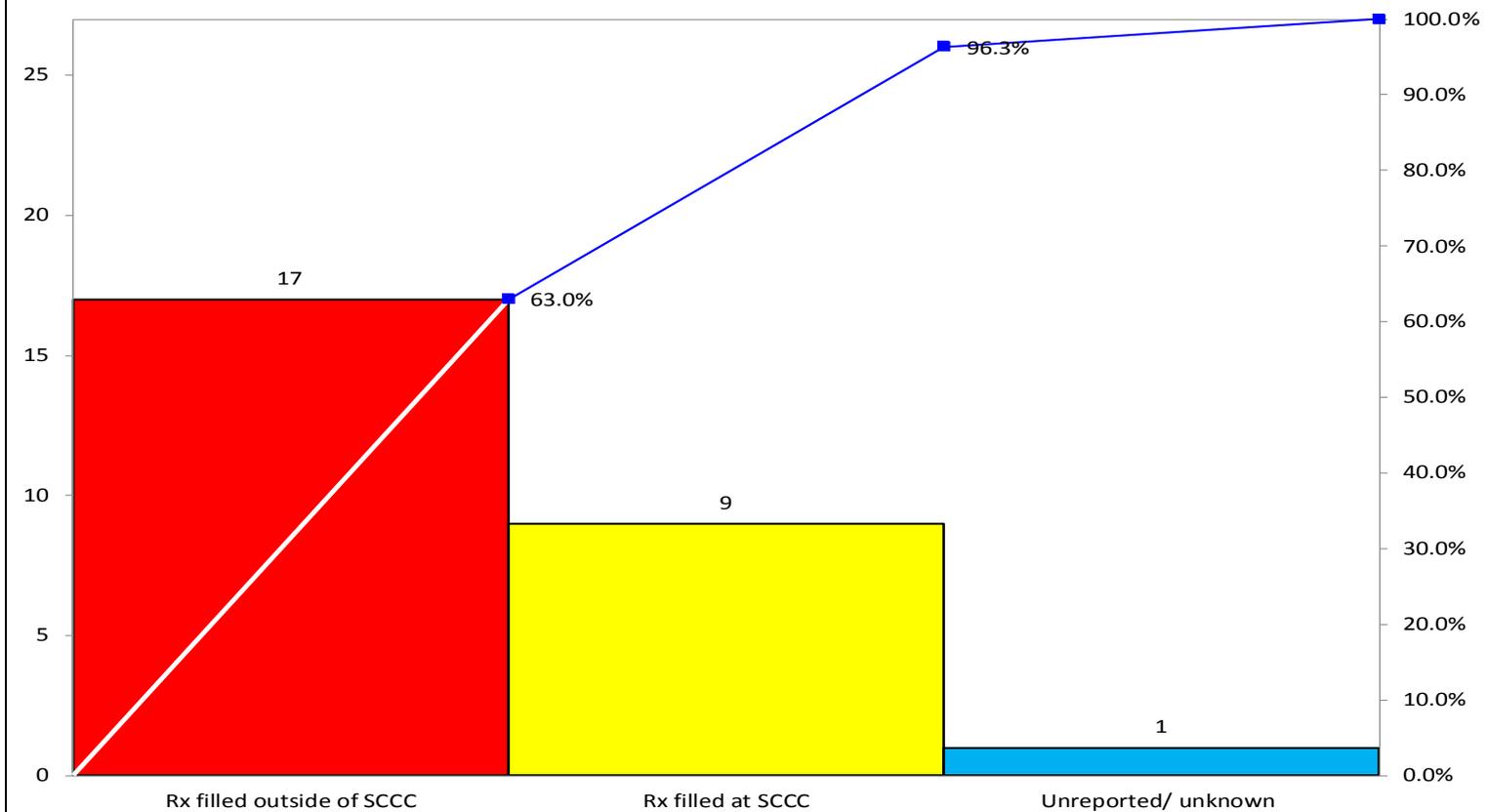
Race	
19	White
7	Black
1	Other
Ethnicity	
4	Hispanic
23	Non-Hispanic

Baseline Data



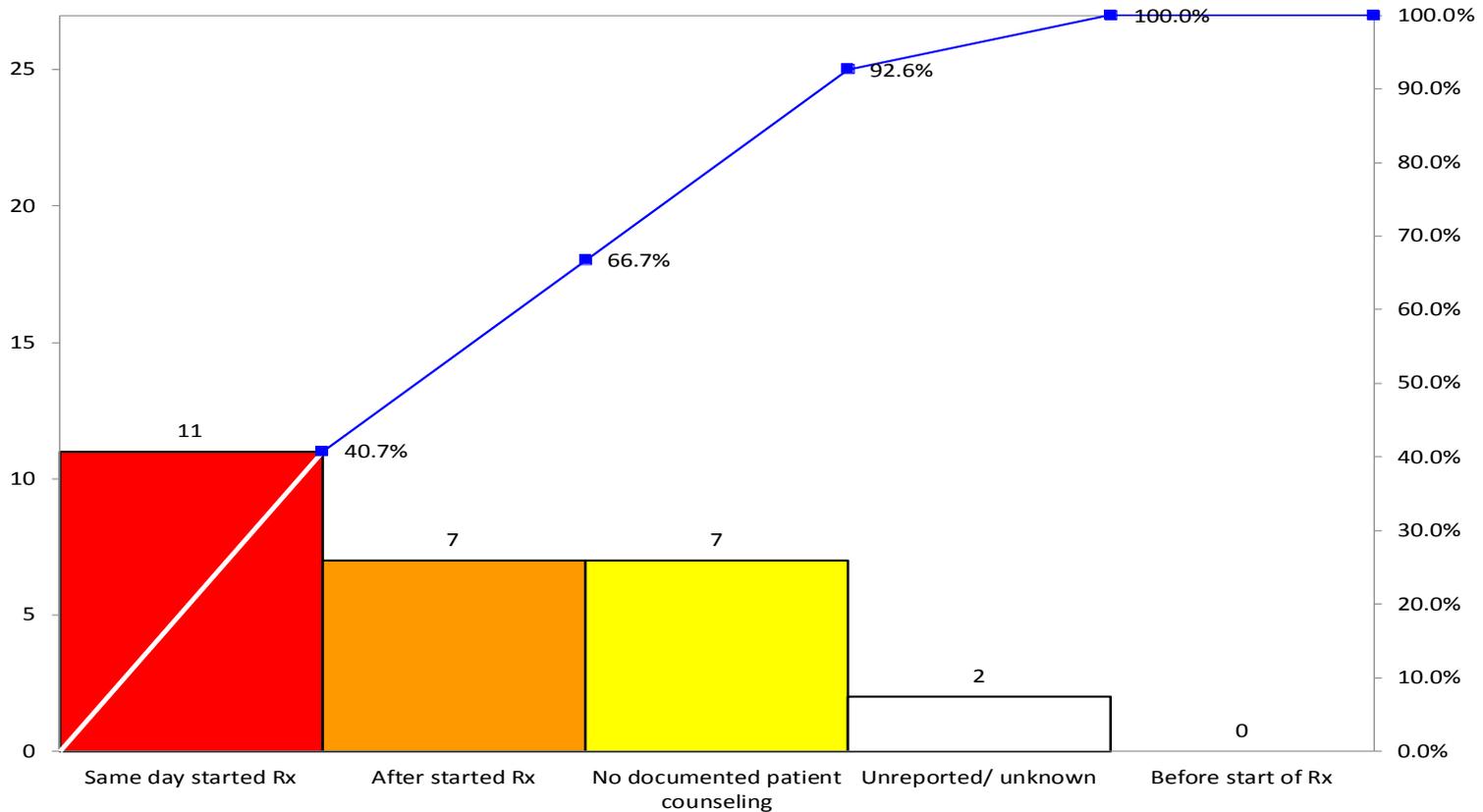
Baseline Data

Pareto Chart: Prescription Fill Pharmacy Location
Jan to May 2017 (n=27)



Baseline Data

Pareto Chart: When was the patient called for Rx counseling?
Jan to May 2017 (n=27)



Prioritized List of Changes (Priority/Pay –Off Matrix)

Impact	High	<ul style="list-style-type: none"> - Identify/Assign responsibilities for patient education - Develop standardized educational material - Educate providers on availability and importance of pharmacy education 	<ul style="list-style-type: none"> - Develop a pathway within the EMR to rapidly identify and prioritize patients requiring initial education - Dedicate pharmacy staff to early patient education (in person if possible) - Obtain dedicated clinical space for in-person counseling
	Low		<ul style="list-style-type: none"> - Standardize documentation for pharmacy education encounters - Coordinate release of Rx to outside pharmacy with plan for SCC pharmacist education
		Easy	Difficult

Ease of Implementation

PDSA Plan (Test of Change)

Date of PDSA Cycle	Description of Intervention	Results	Action Steps
8-17-17 – 8/29/17	Go-live date for EMR filtering	<ol style="list-style-type: none"> 1. (n) pts counseled, (n) rx written 2. Identified difficulties with use of EMR filtering 	<ol style="list-style-type: none"> 1. Routine engagement with IR (information resources)
8-30-17	Continued discussion with IR to optimize EMR	<ol style="list-style-type: none"> 1. (n) pts counseled, (n) rx written 2. Continued refinement of filtering process 	<ol style="list-style-type: none"> 1. Need for better ways to filter out inappropriate patients and manage completed work.
9-13-17	Continued discussion with IR to optimize EMR	<ol style="list-style-type: none"> 1. (n) pts counseled, (n) rx written 2. Continued refinement of filtering process 	<ol style="list-style-type: none"> 1. Pharmacy workflow observation planned 2. Pharmacy to document ideal workflow

Materials Developed

Patient instructions:

Administration: Take capecitabine _____ by mouth twice a day with meals approximately 12 hours apart, within 30 min of meals, for 14 days on, 7 days off. Patient to start on _____

Missed doses: If you miss a dose, take it as soon as you remember. If almost time for your next dose, skip the missed dose. Do not take extra medication to make up for the missed dose.

Medication adherence: Make sure to take capecitabine as instructed to get the maximum benefit out of the medication. As discussed you can use calendar and/or pill box to help with medication adherence.

Safe handling: Wear gloves when touching this medication or use medication cup to put the drug into and then take it. Wash your hands before & after.

Side effects and management:

- Diarrhea: Take Imodium A.D (loperamide)- 2 tablets at onset of diarrhea, then 1 tablet until diarrhea stops. May take up to 8 tablets in a 24 hour period if needed. Avoid milk products and cruciferous vegetables such as Brussel sprouts and broccoli. Try applesauce, toast) and clear liquid as a starting point. Eventually, pasta without sauce without skin, scrambled eggs and other easily digested foods can be added, as tolerated (water and/or Gatorade).
- Nausea and vomiting: Take your anti-nausea medicine. Take small sips of water during the day, instead of hard to drink a full glass at one time. Eat 5 or 6 small meals during the day, instead of 3 large meals.
- Mouth sores: Clean mouth gently, use soft-bristle tooth brush. Rinse mouth with solution (baking soda, 1/8 tsp salt and 1 cup warm water mix) three times daily after meals. Avoid crunchy foods. Don't drink orange, lemon, tomato, or grapefruit juice
- Fatigue: Perform mild activity regularly as tolerated & take frequent breaks in between activities.
- Hand-Foot Syndrome (HFS): Limit exposure of hands and feet to hot water when washing. Cool your hands and feet with ice packs or cool running water or compresses. Genie cream (eg. Udderly Smooth, Cetaphil cream) to keep your hands moist. Use soft slippers. Avoid unnecessary force or friction (rubbing) on the hands or feet

- Please call clinic right away for:

- Signs of an infection such as fever (over 100.4°F or 38°C by an oral thermometer); chills; cough; pain or burning when you pass urine.
- Signs of bleeding problems such as black tarry stools; blood in urine; pinpoint red spots on skin.
- Signs of heart or lung problems such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of ankles, or fainting.
- Signs of an allergic reaction (rare) soon after a treatment including dizziness, fast heart beat, face swelling, or breathing problems.
- Seizures or loss of consciousness with or without confusion, headache, or changes in eyesight.

- Please contact your clinic for painful hand-foot skin reaction, diarrhea > 4 stools per day than usual, nausea/vomiting, sores in mouth, yellowing of skin, unusual weakness or severe abdominal /stomach cramping/pain, or other bothersome side effects.

Medication reconciliation: If any new medications are added into your therapy or discontinued or dose changes, please inform the clinic/pharmacy. Please check with your doctor or pharmacist before taking any new medications including over-the-counter medications/herbal supplements.

Storage: Capecitabine tablets should be kept out of the reach of children, at room temperature, away from heat, light and moisture

Medication disposal: Return any unused medications or empty capecitabine bottles to pharmacy for safe disposal.

Refills: Please call your pharmacy at least one week before you run out of your medication for a refill, or if any side effects, please call physician's office first before ordering additional refills.

Appointments: Keep all appointments for lab work and physician/radiation visits as scheduled. Next MD appointment is on _____

Materials Developed: Patient Survey

Medication Therapy Management Clinic and Financial Assistance Program Patient Survey

I am aware of the pharmacist oral chemotherapy education program at the Simmons Comprehensive Cancer Center.	Y	N
I learned something new about my medication(s) by discussing with the pharmacist.	Y	N
I understand my medication better after discussing with the pharmacist.	Y	N
I am aware of the medication co-pay assistance program.	Y	N
I understand the benefits of applying for a co-pay assistance program.	Y	N
It is convenient to use Simmons Retail Pharmacy for my prescriptions.	Y	N
I feel safer and more confident taking my medication after discussing it with the pharmacy.	Y	N

Materials Developed: Registry List

Current oral oncolytic medication registry list

Age	Sex	Oral Rx Med	Last Ordered On	Admitted	Last Onc Visit	Next Onc Visit	Last MTM Visit	Last MTM Contact	Next M	Next MTM Outreach	Specialty Comments
48y/o	Male	capecitabine 500 mg oral tablet	09/19/2017		09/19/2017	10/05/2017				Not Specified	
90y/o	Male	capecitabine 500 mg oral tablet	07/19/2017		07/17/2017			07/27/2017		Not Specified	
67y/o	Male	thalidomide 50 mg oral capsule	09/25/2017		08/31/2017	10/05/2017				Not Specified	
73y/o	Male	cyclophosphamide 50 mg oral capsule	09/20/2017		09/25/2017	10/23/2017				Not Specified	
53y/o	Female	erlotinib (TARCEVA) 100 mg oral tablet	10/02/2017		10/02/2017	11/02/2017				Not Specified	
36y/o	Female	palbociclib 125 mg Cap	09/21/2017		09/21/2017	10/09/2017				Not Specified	
46y/o	Male	trifluridine-tipiracil 15-6.14 mg Tab	09/07/2017		08/29/2017	10/05/2017		09/20/2017		Not Specified	
41y/o	Male	temozolomide 140 mg oral capsule	09/19/2017		09/19/2017					Not Specified	
68y/o	Male	SUNItinib 50 mg oral capsule	08/29/2017		09/14/2017	10/05/2017				Not Specified	

Patient Name and MRN removed

Materials Developed: MTM Template

Drug Interactions

Drug Interactions Evaluated

yes no

Clinically Relevant Drug Interactions Identified

yes no

Provided the Patient With Educational Material Regarding Drug Interactions

yes not applicable

Adherence

Drug Name/Dose/Frequency

Medication picked up by patient (if no, skip to non-adherence reason)?

Yes No

Medication Dispensed Date

Pharmacy Benefits Plan

Medicare Part D Benefits Plan?

Yes No

Prior Auth Approved?

Yes No

Funding offered?

Yes No

Planned Start Date

Actual Start Date

Planned Stop Date (if applicable)

Actual Stop Date

Quantity Dispensed (RESEARCH ONLY)

Demonstrates Understanding of Importance of Adherence

yes no

Informant

caregiver

child/children

father

friend

mother

patient

significant other

spouse

other relative

Reliability of Informant

unreliable

fairly reliable

reliable

Doses expected to be taken since last adherence check?

Doses prescribed this cycle (RESEARCH ONLY)

Doses missed since last adherence check?

of Returned pulls (RESEARCH ONLY)

Materials Developed: MTM Template

Reasons for Non-Adherence

no problems identified	adverse effects
financial	instructed by provider to hold or take differently
lack of perceived benefit	language barrier
low health literacy	patient forgets
knowledge deficit	patient refuses
psychosocial	no transportation

Other Non-Adherence Reason

Adherence Tools Used

alarm	calendar
cell phone	directed education
keychain pill carrier	medication dosing chart or calculator
medication list	pill box
watch	

Other Adherence Tool

Support Network for Adherence

family member	healthcare provider	home health agency
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Other Support Network

Confirmed Plan for Next Medication Refill

delivery by pharmacy	pick-up at pharmacy	outside pharmacy	not applicable
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Refills Needed for Supportive Medications

yes, ordered or provider notified	not needed
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Patient Counseling

Counseled the Patient on the Following

adherence/missed doses	cost of medications/cost implications
doses and administration	lab monitoring/follow-up
pharmacy contact information	possible adverse effects and management
possible drug/OTC drug and food interactions	possible drug/Rx drug interactions
safe handling, storage, and disposal	therapeutic rationale
use of contraception	

Other Topic

Total Time Spent Counseling Patient

1-15 min	16-30 min	31-45 min	46 - 60 min	61 - 75 min	76 - 90 min	>90 min
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Materials Developed: Marketing

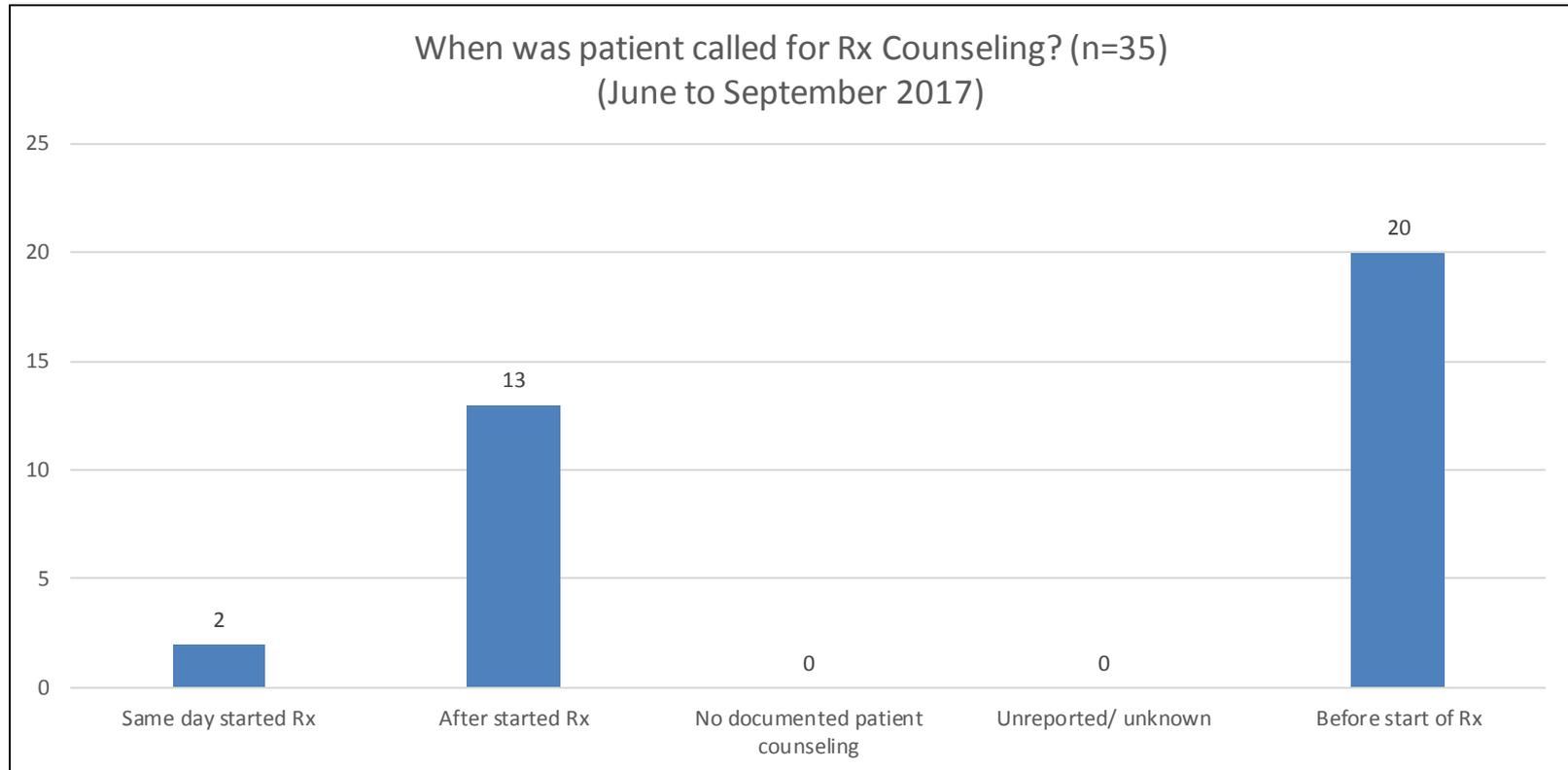
What is the Medication Management Clinic?

- Medication adherence and monitoring is very important while you are on treatment. We provide Adherence Management and patient monitoring for safety and efficacy.
- Pharmacist will meet with you to review your medications and offer education to answer your questions and help you to manage your medication treatment and potential side effects.
- Pharmacists will reach out to you monthly to check in on you and remind you to refill your medications. We work closely with your doctor to stay current about your medication therapy management though using same electronic medical record.

What does the Oncology Retail Pharmacy Services at UTSW Simmons Cancer Center Offer?

- Pharmacists work closely with your doctors and other caregivers to ensure your medication therapy is safe and effective
- Pharmacists can access your electronic medical record, including your medical history and medication records so that we can ensure your specialty drugs works well with your other medications. We can also communicate and follow up with your Doctor to help minimize any side-effects that you might be experiencing.

Change Data: Post Intervention



Conclusions

- The proportion of patients counseled by a UTSW pharmacist prior to starting capecitabine improved from 40.7% (Jan – May) to 62.8% (June – Sept 2017).
- 22.1% absolute improvement since project implementation
 - 37% reduction in patients not receiving counseling anytime prior to starting
 - 57% increase (0/27 -> 20/35) in patients receiving counseling before the first day on their medication
- Interventions:
 - EMR filter optimization discussion
 - Pharmacists awareness to focus on capecitabine patients
 - Verbal communication to insure patients are monitored
 - New education tools developed
- Require workflow analysis by the IR analyst to develop a tool that can be utilized by the pharmacist to triage daily workflow more efficiently

Next Steps/Plan for Sustainability

- Continue to refine EMR filtering process to rapidly and reliably identify patients appropriate for pharmacy counseling
 - Workflow analysis of pharmacy counseling process
 - Possible migration to a work-que or referral-based system for pharmacist notification
- Incorporation of specialty pharmacy medication
- Incorporation with an existing BMT pharmacy education program
- Analysis of resources required for Capecitabine MTM and make appropriate requests for additional staffing/funding/clinic space required for expansion
- Eventual expansion to all oral oncolytic medications