

The Role of the Clinical Pharmacist in an Academic Hematology/Oncology Practice: “The Carolina Experience”

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Speakers

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 - Thoracic and Sarcoma
- **Kaitlyn Buhlinger, PharmD, BCOP, CPP**
 - Leukemia



- **No relevant disclosures**



- **Oncology workforce challenges**
- **Role of Clinical Pharmacist (CP)**
- **Integration of CP into clinic workflow**
- **UNC program**
- **Impact of CP care**



Cancer care volume is increasing

- **1.76M expected to receive a cancer diagnosis in 2019; predicted rise to 2.3M by 2035**
- **15.5M estimated cancer survivors in 2016; predicted rise to 20.3M by 2026**
- **Number of oncology clinicians increasing at a slower rate**
 - **First generation of oncologists and oncology RNs trained in the 1970s are retiring**



AACR Cancer Progress Report. <https://www.cancerprogressreport.org/Pages/default.aspx>.

CDC. Expected new cancer cases and deaths in 2020. https://www.cdc.gov/cancer/dcpc/research/articles/cancer_2020.html

Yang W, et al. J Oncol Pract. 2014



Improved cancer outcomes brings more visits

- **Treatment advances include a growing number of new therapies and biomarker tests**
- **Management of new and sometimes poorly understood toxic effects**
- **Improved survival = longer duration of therapy**



Innovative practice models are needed

- **Team based practice can improve patient experience and practice efficiency**
- **In addition to NPs and PAs, Clinical Pharmacists can co-manage patients**
 - Symptom management
 - Treatment toxicity
 - Long term survivorship



CPs can make a meaningful impact on workforce capacity

- **At just 25% of their work capacity, oncology pharmacists could provide 2.5 million to 3.5 million 30-minute oncology patient visits by 2020**
- **Value of oncology pharmacists**
 - **Systematic review 66 peer-reviewed studies validated positive outcomes:**
 - Clinical care
 - Patient education
 - Informatics
 - Cost savings



Health System Pharmacists

Pharmacist Titles*	Pharmacist Roles
Outpatient Staff Pharmacist	Check prescriptions for accuracy, drug interactions with other known prescriptions, communicate questions/concerns with prescribers, educate patients upon dispensation, process claims with insurance companies.
Inpatient Staff Pharmacist	Check prepared IV and oral products being distributed to inpatients for safety and accuracy, communicate with medical teams, manage inventory and other operations of medication prep and delivery.
Clinical Pharmacy Generalist	Verify orders, may or may not round with medical team, and serves as a resource for medication & dosing questions, therapeutic drug monitoring, and patient education. Commonly work with surgery, general medicine, and hospitalist services, or cover a variety of disease states; generally has 0-2 years of residency training.
Clinical Pharmacist Specialist	Works closely with the medical team (rounding or seeing patients in clinic). May verify orders, may prescribe under a collaborative practice, performs patient education, large academic component (e.g. research and teaching) Focused on a specific disease state; generally have at least 1 year but commonly 2 years of residency training & board certification.



*These are not official terms or definitions, and often tasks overlap depending on the model of their health system. Pharmacists in all of the above may have a range of experience and training.

Advanced Practice Pharmacists



Collaborative Care Agreements

- 48 states and Washington DC
- Order and interpret laboratory & other tests
- Initiate/modify/discontinue medication therapies
- Additional credentialing available in select states



Clinical Pharmacist Practitioner (CPP)

- Specialized pharmacist credential
- Approved by NC Board of Pharmacy & Board of Medicine
- Manages patients under collaborative care agreements
- Limited billing opportunities

Frost TP & Adams AJ, *Res Social Adm Pharm*. 2018;14(5):501-504



Education Requirements

- **CPP Eligibility**

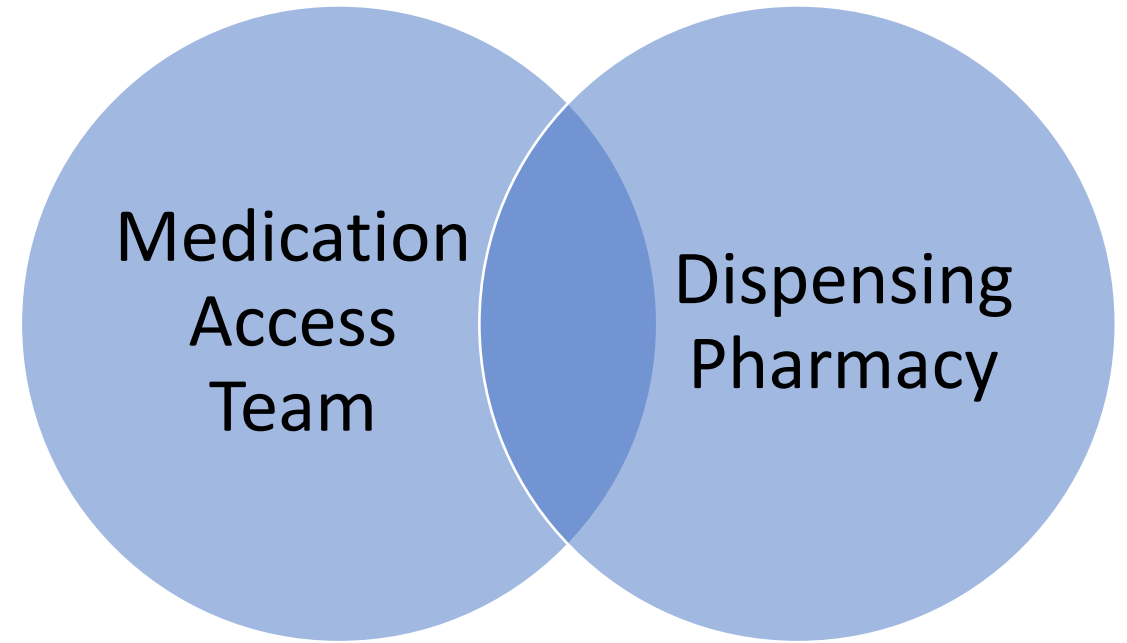
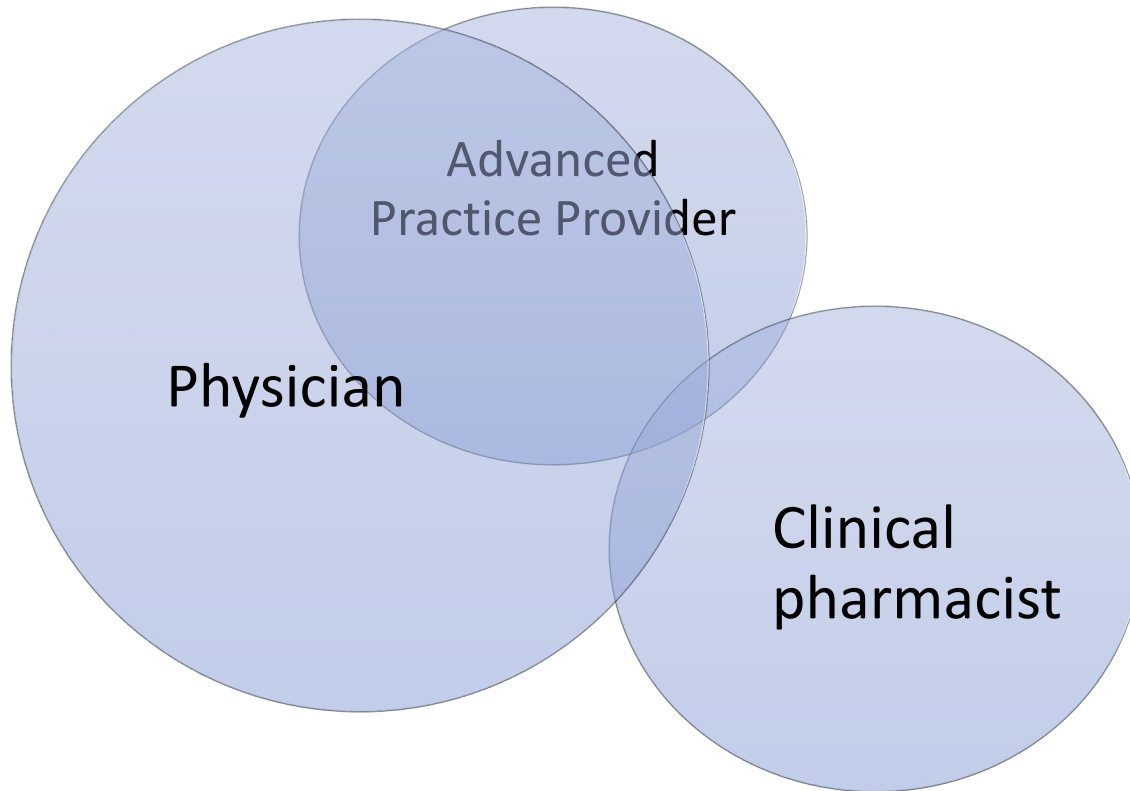
- Board of Pharmacy Specialties Certification
- Completed pharmacy residency with 2 years experience
- Doctor of pharmacy with 3 years experience and completion of approved certificate program
- Bachelor of pharmacy with 5 years experience and completion of 2 approved certificate programs

- **CPP Renewal**

- Annual renewal process
- Additional continuing education requirements
- Regular meetings with supervising physician



The Clinical Pharmacist Specialist in the Outpatient Setting



Models of Clinical Pharmacist Practice

- **Billing (the North Carolina Experience)**
 - Even in North Carolina, pharmacists are **NOT** providers! (APP is somewhat of a misnomer).
 - We cannot bill for our pharmacist services
 - We have *shared or independent* visits, billable under the facility or administrative fees
 - Physician vs hospital based clinics
 - Cannot bill for telemedicine visits
 - As patients are not physically at the facility

PROVIDER STATUS?



Models of Clinical Pharmacist Practice in Clinic

Non-templated	Templated
<p>WHAT IS IT</p> <ul style="list-style-type: none">• Sees patients off <u>provider's template</u> as indicated<ul style="list-style-type: none">• “Bills”/documents within these encounters• The more traditional/historical model for outpatient clinical pharmacists	<p>WHAT IS IT</p> <ul style="list-style-type: none">• Sees patients off their <u>own defined template</u><ul style="list-style-type: none">• “Bills”/documents within these encounters• Somewhat of a more novel and advanced model of pharmacist care
<p>PROS</p> <ul style="list-style-type: none">• Time to do non-templated tasks• Provides some flexibility to complete, does not require dependence on scheduling/rooming procedures	<p>PROS</p> <ul style="list-style-type: none">• Easier to organize patient care and also provides a format to focus learners<ul style="list-style-type: none">• Opportunity to create pharmacist-led programs surrounding complex patients and regimens
<p>CONS</p> <ul style="list-style-type: none">• Can be challenging to organize time and provide tasks for learners• Limits the ability to build CPP-centered programs	<p>CONS</p> <ul style="list-style-type: none">• Still responsible for other non-templated tasks; challenging to manage time in between templated visits• Dependent on clinic workflows, requiring resources and space for rooming and scheduling
<p>Perhaps a hybrid approach provides advantages of both models (ie. some days/parts of days template and others non-template)</p>	



Consultative Model: Case of Ms. VV

27 y/o pregnant female
(26wks) with newly
diagnosed metastatic NSCLC
with significant disease
burden, pending NGS results

- What is the safest chemotherapy to administer during pregnancy?

Next-generation
sequencing detects
EML4-ALK fusion

- Is it safe to initiate an ALK inhibitor during pregnancy?



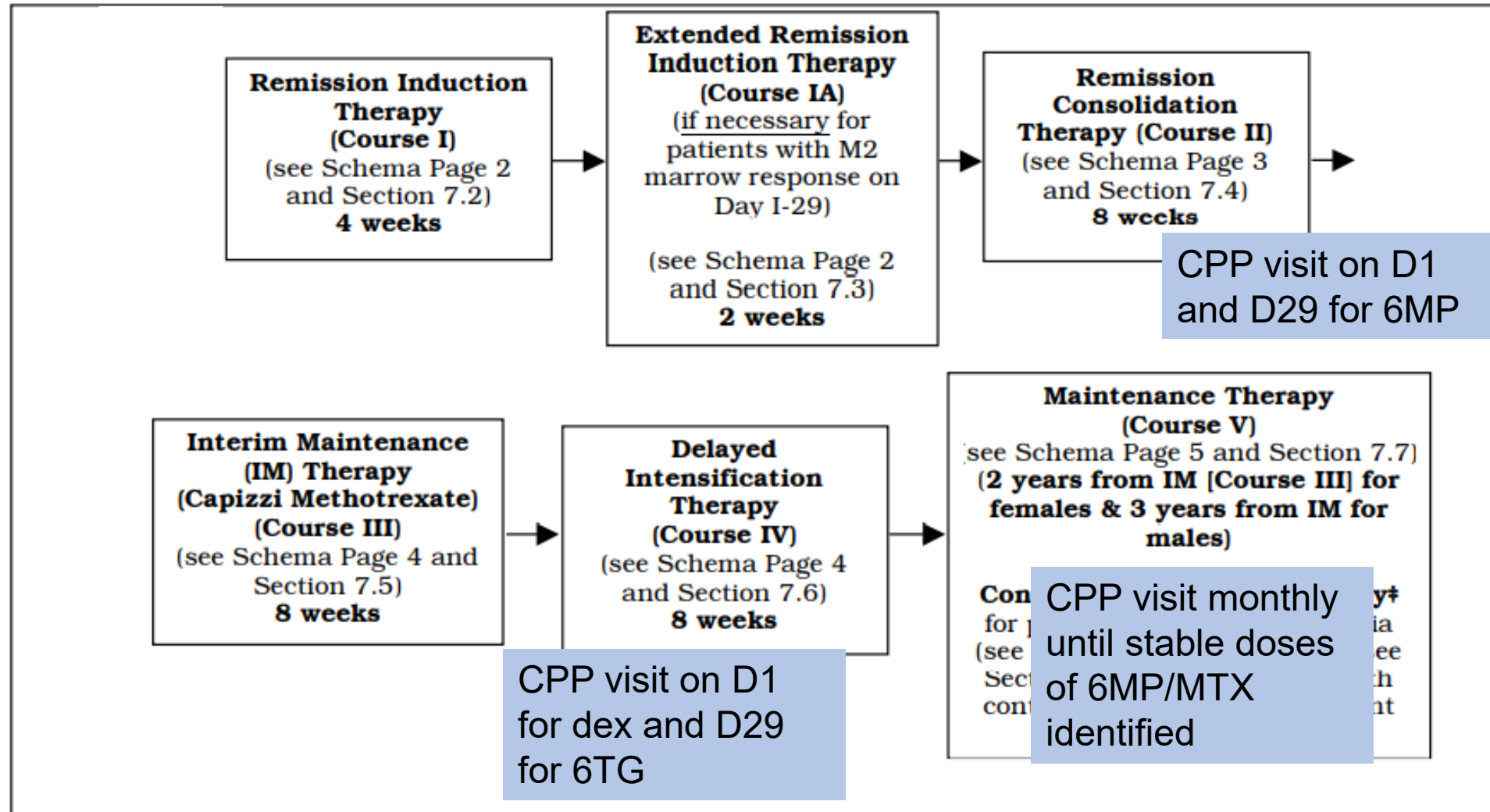
Co-Management Model: Case of Ms. PD

78 y/o F with newly diagnosed metastatic NSCLC, starting on capmatinib for MET exon 14 skipping mutation



CPP Role in Young Adult ALL

- CPP sees patient templated whenever oral chemotherapy is introduced



CPP-led CLL Venetoclax Program

- Risk of TLS and very specific/intense monitoring requirements
- IMPACT!
 - From May 2016 to April 2020, 39 patients using this protocol were assessed with an average number pharmacist visits for ramp-up = 5.3 visits
 - Previously reported real world TLS rates with this regimen = 13.4%; and TLS on study = 4.6%
 - No episodes of laboratory or clinical TLS were identified during study period with CPP led protocol

Prior to initiation

- Venetoclax prescription sent to specialty pharmacy for access investigation
- Confirm that computed tomography (CT) scans and labs allow for stratification of low/medium or high risk for TLS
- Confirm hepatitis B serologies have been ordered, or if previously drawn, do not support previous infection
- Allopurinol prescription sent—instruct to initiate at least 72 hours prior to venetoclax initiation
- Assess need for prophylactic antimicrobials and prescribe as appropriate
- Drug interactions assessed, medications switched or washed-out as indicated
- Overview and education of chemotherapy regimen and logistical implications
- Infusion orders entered (i.e., obinutuzumab and embedded TLS labs)
- Patient provided calendar—calendar also used to assist in scheduling full ramp-up

Venetoclax Week 1

- Once medication access achieved, proceed with scheduled plan including visit with clinic pharmacist
- Confirm taking allopurinol for at least 72 hours—review other medications for potential interactions
- If week 1 labs within limits, initiate therapy with week 1 dose pack
- Patient instructed to return to infusion center for lab draw and read +/- IV fluids in 6 hours, as well as the following morning for labs prior to taking next dose

Venetoclax Week 2

- Confirm taking allopurinol—review other medications for potential interactions
- Assess for toxicity and provide supportive care medication prescriptions if needed
- If week 2 labs within limits, initiate therapy with week 2 dose pack
- Patient instructed to return to infusion center for lab draw and read +/- IV fluids in 6 hours, as well as the following morning for labs prior to taking next dose

Venetoclax Week 3

- Confirm taking allopurinol—review other medications for potential interactions
- Assess for toxicity and provide supportive care medication prescriptions if needed
- If week 3 labs within limits, initiate therapy with week 3 dose pack
- If labs show dehydration or TLS, will go to infusion for IV fluids or other supportive medications
- Send prescription for week 5 venetoclax to allow specialty pharmacy delivery prior to week 5

Venetoclax Week 4

- Assess for toxicity and provide supportive care medication prescriptions if needed
- If week 4 labs within limits, initiate therapy with week 4 dose pack
- If labs show dehydration or TLS, will go to infusion for IV fluids or other supportive medications
- Remind patient that they will be receiving shipment of bottle of venetoclax 100 mg daily tablets (400 mg daily) required to start week 5
- Provide pharmacy contact to ensure this is coordinated—patient should not take 400 mg daily until instructed to do so

Venetoclax Week 5

- Confirm patient has bottle of venetoclax 400 mg daily supply
- Assess for toxicity and provide supportive care medication prescriptions if needed
- If week 5 labs within limits, initiate therapy with venetoclax 400 mg daily
- If labs show dehydration or TLS, will go to infusion for IV fluids or other supportive medications
- Consider week 6 clinic visit/labs if concern related to TLS, adherence, or tolerability
- Confirm follow-up appointments related to infusion of anti-CD20 mAbs are scheduled as well as next provider visit

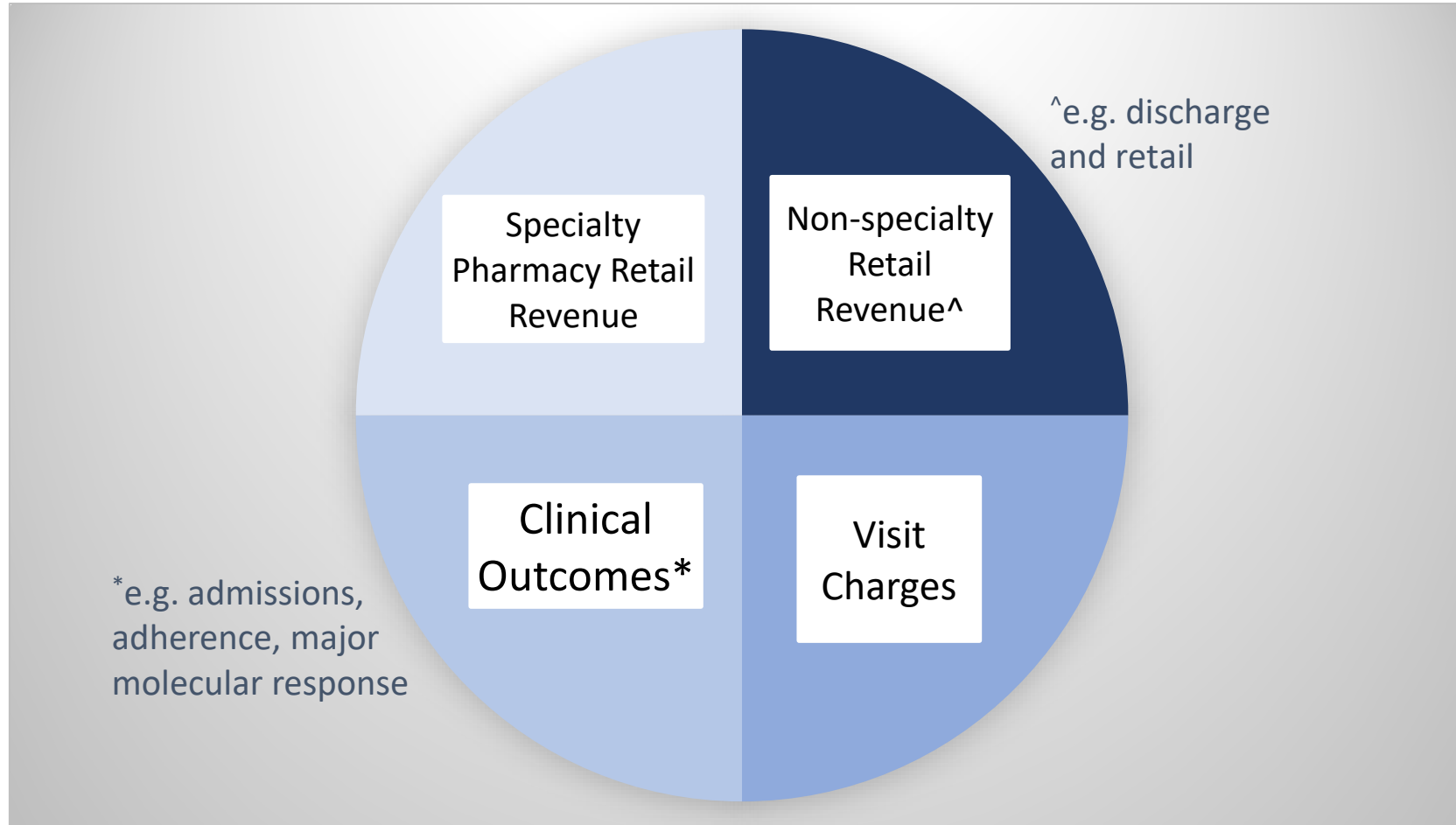


Oncology CPP Representation: Current State

Oncology CPP Positions
Oncology Supportive Care
Bone Marrow Transplant and Cellular Therapy (2)
Oncology Infusion
Leukemia (2)
Breast Oncology
Pediatric Hematology/Oncology
Thoracic/Sarcoma
Head & Neck Oncology/Melanoma
Genitourinary/Neurologic Oncology
Hillsborough General Oncology
Myeloma / Lymphoma
Gynecologic Oncology
Gastrointestinal Oncology
Benign Hematology
Hematology/Oncology Float
McCreary General Oncology



CPP Funding Mechanisms



CPP Growth

Facility Charge Revenue Model	
Year	Site
2009	Oncology Supportive Care
2010	Bone Marrow Transplant
2011	Oncology Infusion

Specialty Retail Pharmacy Revenue Model	
Year	Site
2012	Leukemia / Myeloma / Lymphoma
2014	Gastrointestinal / Breast Oncology
	Pediatric Hematology / Oncology
2015	Thoracic / Head & Neck Oncology / Sarcoma / Melanoma
	Genitourinary / Neurologic Oncology
	Hillsborough Oncology
	Myeloma / Lymphoma
2017	Gynecologic Oncology Sarcoma / Melanoma
2019	Gastrointestinal Oncology Benign Hematology
2021	McCreary Oncology Leukemia (2 nd FTE)



CPP Clinic Revenue

Clinic	% of Total Revenue (FY21)	% Specialty eScripts @UNCHCS
BMT	6.6%	73.3%
CNS Oncology	1.6%	79.8%
GI/Breast Oncology	16.0%	46.8%
GU Oncology	14.9%	61.0%
Gyn Oncology	5.6%	45.5%
Lymphoma/Myeloma	4.7%	10.5%
Leukemia	25.5%	56.5%
Melanoma/Head and Neck	6.0%	72.7%
General Oncology (Hillsborough)	2.0%	17.2%
Peds Heme/Onc	6.9%	43.1%
Thoracic Oncology	10.1%	73.4%

Goal for Specialty CPP positions = 10:1 ROI



Justifying the Role: Understand the Treatment Landscape

Oral chemotherapy growth in leukemia

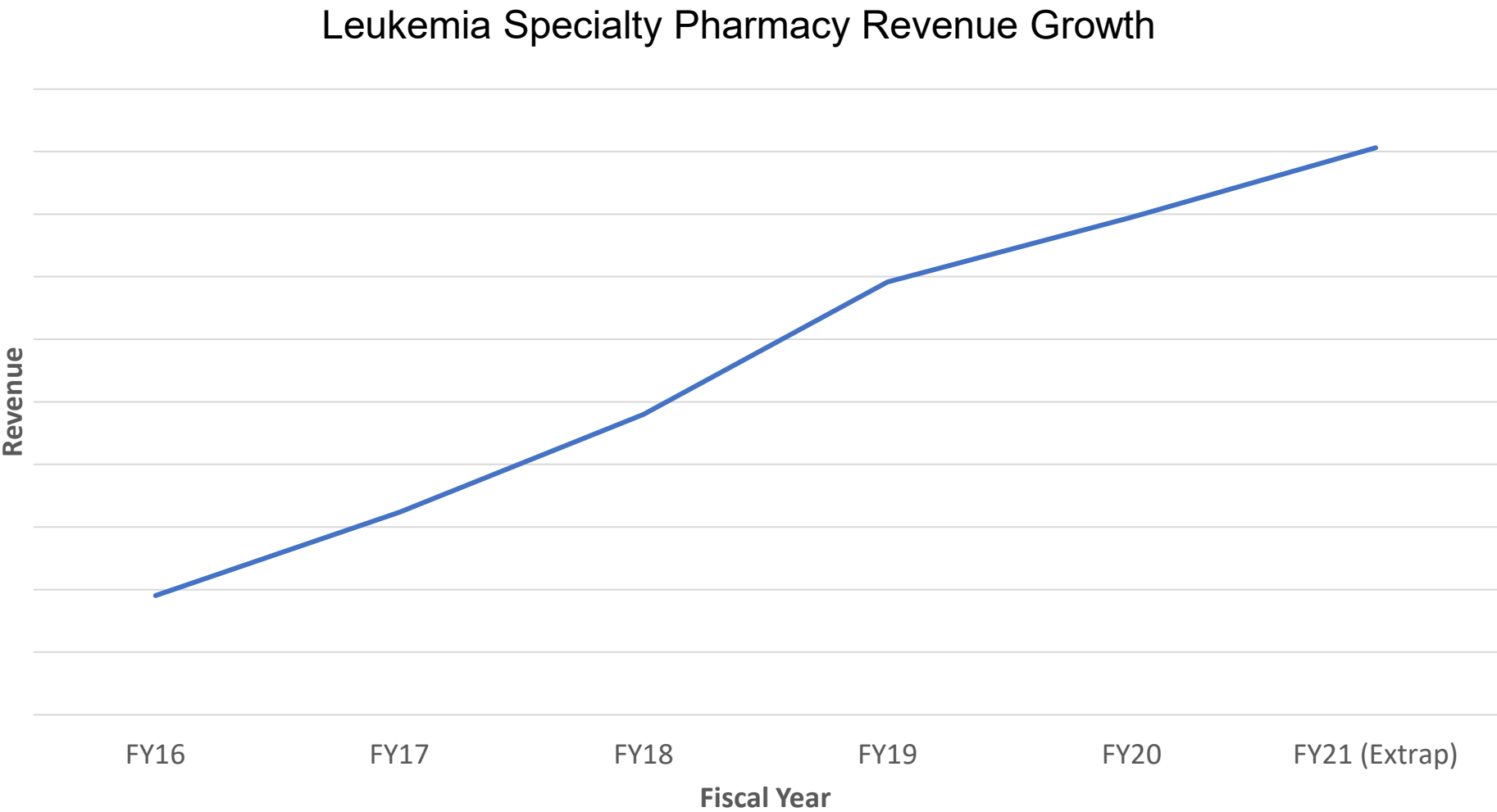
	2015	2020
Acute Myeloid Leukemia (AML)	Sorafenib	Sorafenib, Midostaurin, Gilteritinib, Glasdegib, Ivosidenib, Enasidenib, Azacitidine, Venetoclax
Acute Lymphoblastic Leukemia (ALL)	Methotrexate, 6-Mercaptopurine	Methotrexate, 6-Mercaptopurine
Chronic Lymphocytic Leukemia (CLL)	Ibrutinib, Idelalisib	Ibrutinib, Idelalisib, Duvelasib, Acalabrutinib, Venetoclax
Chronic Myeloid Leukemia (CML)	Imatinib, Nilotinib, Dasatinib, Bosutinib, Ponatinib	Imatinib, Nilotinib, Dasatinib, Bosutinib, Ponatinib
Myelodysplastic Syndrome (MDS)	Lenalidomide	Lenalidomide, Decitabine

Venetoclax approval activity

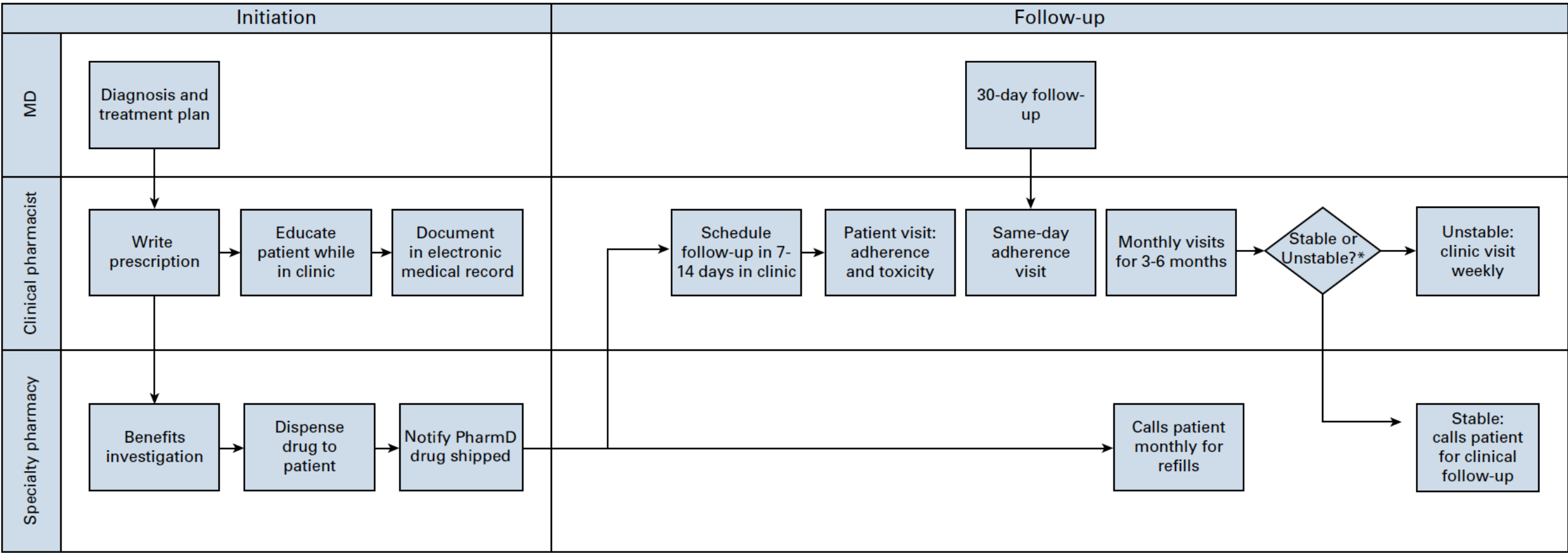
Date	Indication	Approval Type
April 2016	Relapsed/refractory CLL with 17p deletion	Accelerated approval
June 2018	Relapsed/refractory CLL in combination with Rituximab	Regular approval
November 2018	Newly diagnosed AML age ≥ 75 yrs or unfit for intensive induction chemotherapy (combination with azacitidine, decitabine, or low-dose cytarabine)	Accelerated approval
May 2019	All adults with CLL/SLL (regardless of prior treatment or mutation status)	Accelerated approval
October 2020	Newly diagnosed AML age ≥ 75 yrs or unfit for intensive induction chemotherapy (combination with azacitidine, decitabine, or low-dose cytarabine)	Regular approval



Justifying the Role: Financial Impact



Oral Chemotherapy Program Model



Patient Outcomes: Improved Molecular Response Rates in CML

Adherence and Response Rates Pre- and Post-Intervention in CML

Response	Clinical Trial (%)	Pre-intervention	Post-intervention	P-value
100% adherence	41	48	60	0.253 ^a /0.104 ^b
> 90% adherence	74	NA	95	0.029 ^b
EMR (PCR < 10%)	66	54.8	88.9	0.0138 ^a
MMR at 12 months (PCR < 0.1%)	60	57.6	83.3	0.0575 ^a

a. pre- vs. post-intervention

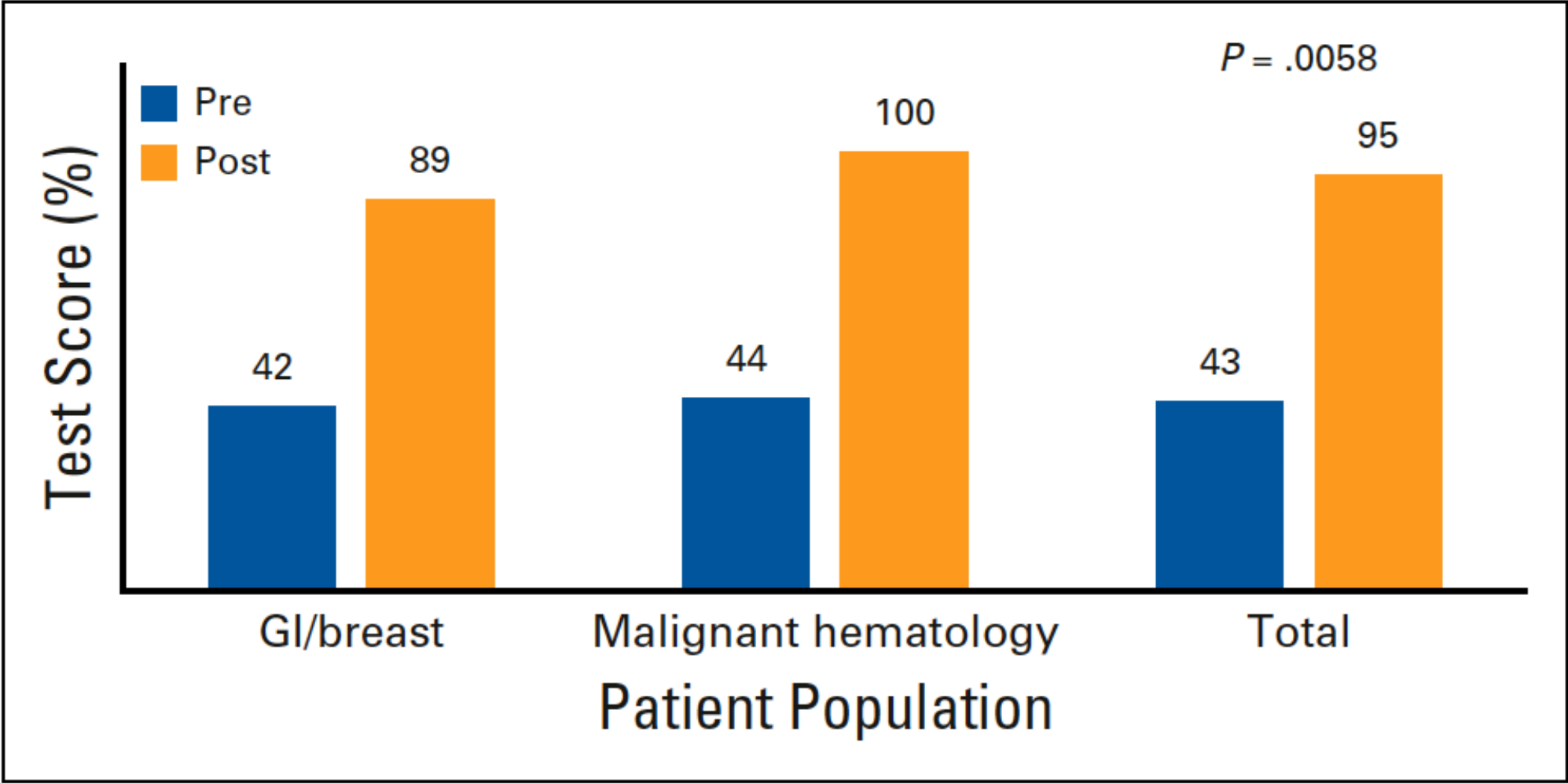
b. Versus clinical trial benchmark

CML: chronic myeloid leukemia; EMR: early molecular response; MMR: major molecular response; PCR: polymerase chain reaction



Improved Patient Understanding

Patient Understanding Pre and Post Pharmacist Education



Bone Marrow Transplant and Cellular Therapy: Patient and Provider Perceptions

Patient and Provider Expectations and Experiences

Question About the Role of Pharmacists	Patients			Providers (N = 50)	
	Expectation		Experience Post (n = 83)	Expectation	Experience
	Pre (n = 27)	Post (n = 83)			
Educate about safe and appropriate use of medications related to bone marrow transplantation	88.9	98.8	100	100	98.0
Educate about safe and appropriate use of medications not related to bone marrow transplantation	77.8	90.1	87.9	88.0	92.0
Be a reliable source of general drug information	88.9	98.8	96.4	100	100
Be a reliable source of clinical drug information.	92.6	100	98.8	100	96.0
Assist doctors in designing a medication regimen	92.6	97.5	98.8	94.0	98.0
Monitor response to medications, including adverse effects	88.9	96.3	93.9	86.0	88.0
Work with the patient and physician to help manage medications	88.9	96.3	95.2	94.0	94.0
Take personal responsibility for drug-related problems	80.8	96.3	92.8	90.0	90.0
Update medication profile at each point in care	92.6	96.2	89.2	90.0	87.8
Educate patients about their bone marrow transplantation	69.2	71.6	73.5	62.0	79.6

NOTE. Data are presented as percentage of positive responses ($\geq 80\%$ indicates successful service delivery).



Inpatient Clinical Pharmacists

Inpatient Clinical Pharmacists
Malignant Hematology (2)
Medical Oncology
Benign Hematology
Bone Marrow Transplant and Cellular Therapy (2)
Oncology Float
Evening Clinical Oncology Pharmacist

Benign Hematology Factor Stewardship Program

- Led by Department of Pharmacy in collaboration with UNC Hematologists
- Key elements to program development and implementation
 - Selection of one formulary factor product within each clotting factor class
 - Establishment of guidelines on blood factor prescribing, order review, compounding, and administration
 - Initial and ongoing education of pharmacy, nursing, and medical staff
- Dedicated benign hematology clinical pharmacist
 - Rounds with hematology consult team daily
 - Manages therapeutic drug monitoring
 - Recommends treatment plan modifications and dose adjustments as appropriate
- Outcomes
 - In year 3: blood factor doses decreased by 45% despite 22% in volume of patients compared to year prior
 - Decrease in re-admissions for bleeding episodes in hemophilia A patients
 - Through year 4: > \$4 million in annual cost savings



Thank you



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