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Management of Oral Chemotherapy Services: A Pharmacist-Led Model

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Faculty Disclosures

- Nothing to disclose.

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Objectives

- Summarize the current challenges and opportunities facing the pharmacy profession with regard to oral chemotherapy agents
- Demonstrate the establishment of a successful pharmacy-led oral chemotherapy program in light of today's challenges

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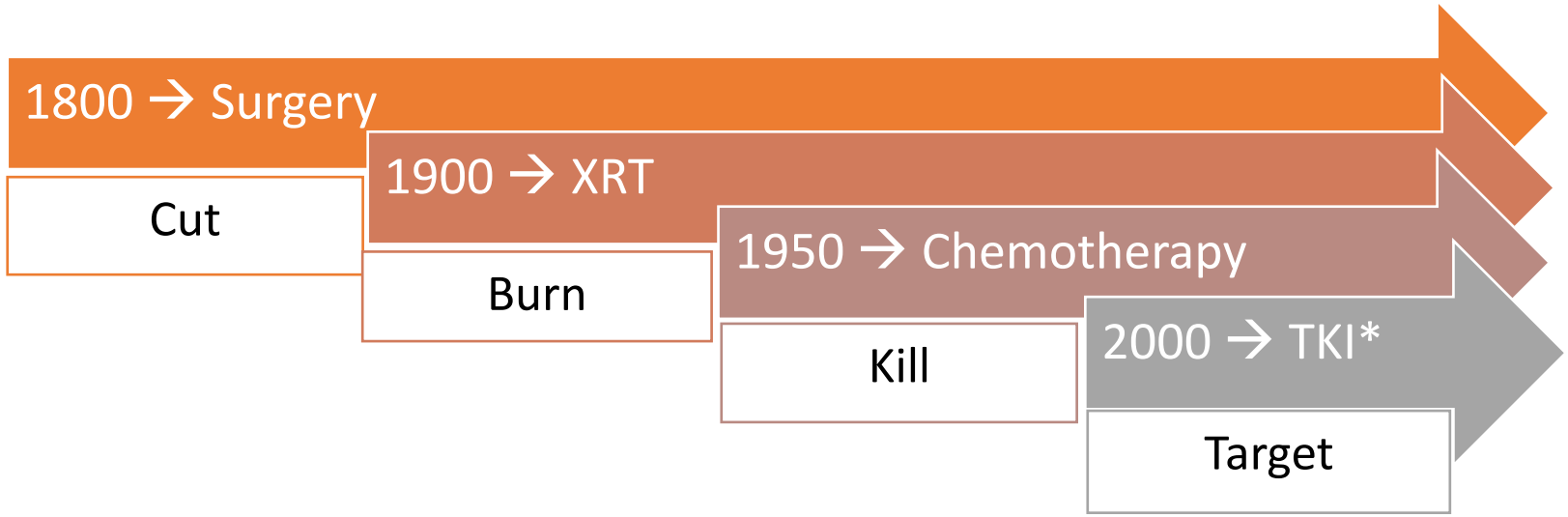
How We Treat Cancer



***TKI = Tyrosine Kinase Inhibitors**

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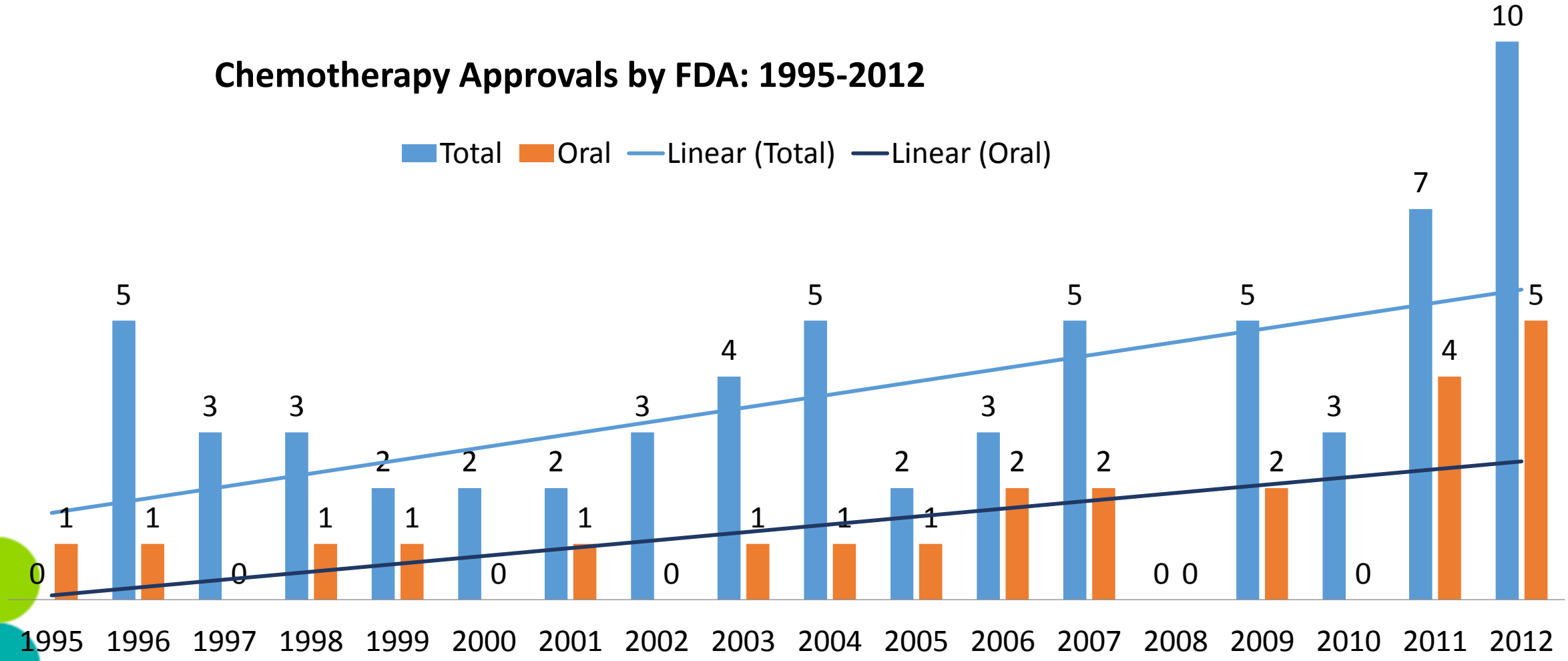
Shift Towards Oral Chemotherapy



Food and Drug Administration. New Drug Approvals. http://www.fda.gov/Drugs/NewsEvents/ucm130961.htm

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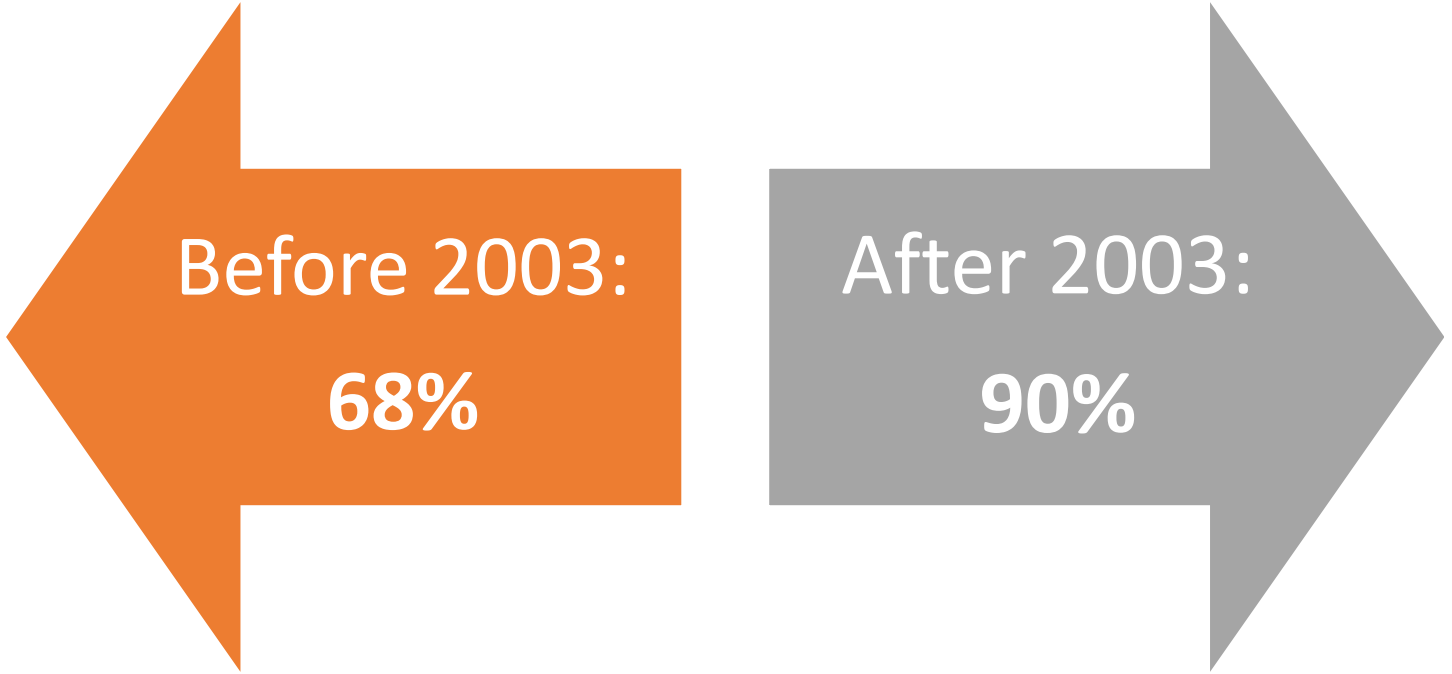
Prognosis: 5-yr Survival in CML



Druker BJ, et al. *N Engl J Med.* 2006;355:2408-17.

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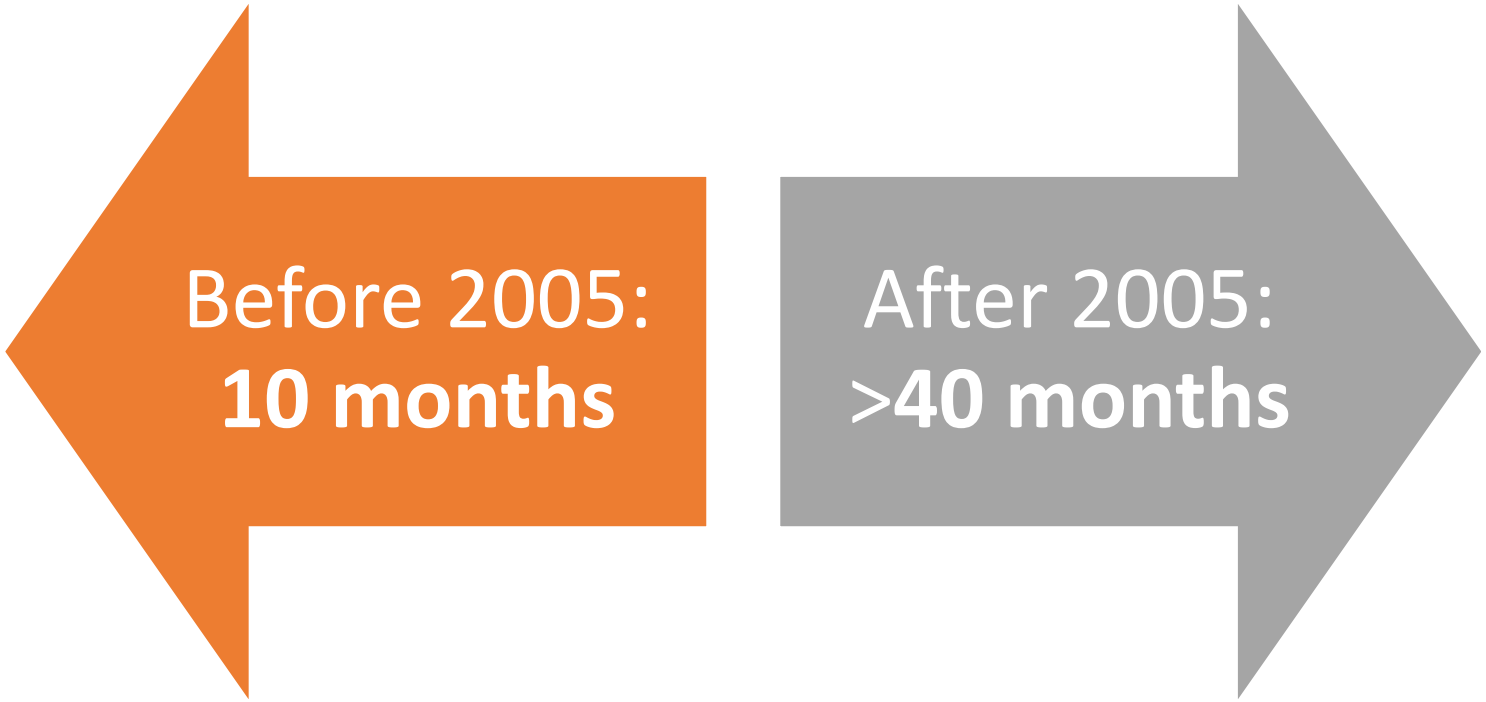
Prognosis: Median Survival for Stage IV RCC



Thuret R et al. *Prog Urol*. 2011 Apr;21(4):223-224

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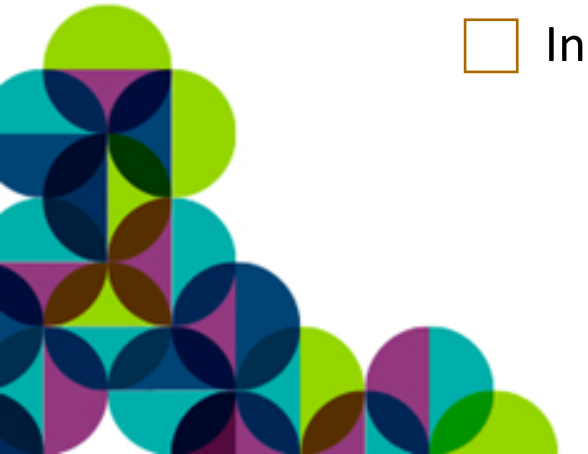
Oral Chemotherapy: Pros and Cons

Benefits	Concerns
Convenient	Adherence
Patient Empowerment	Cost
Decreased toxicity (?)	Storage/handling
Increased efficacy (?)	Therapy monitoring



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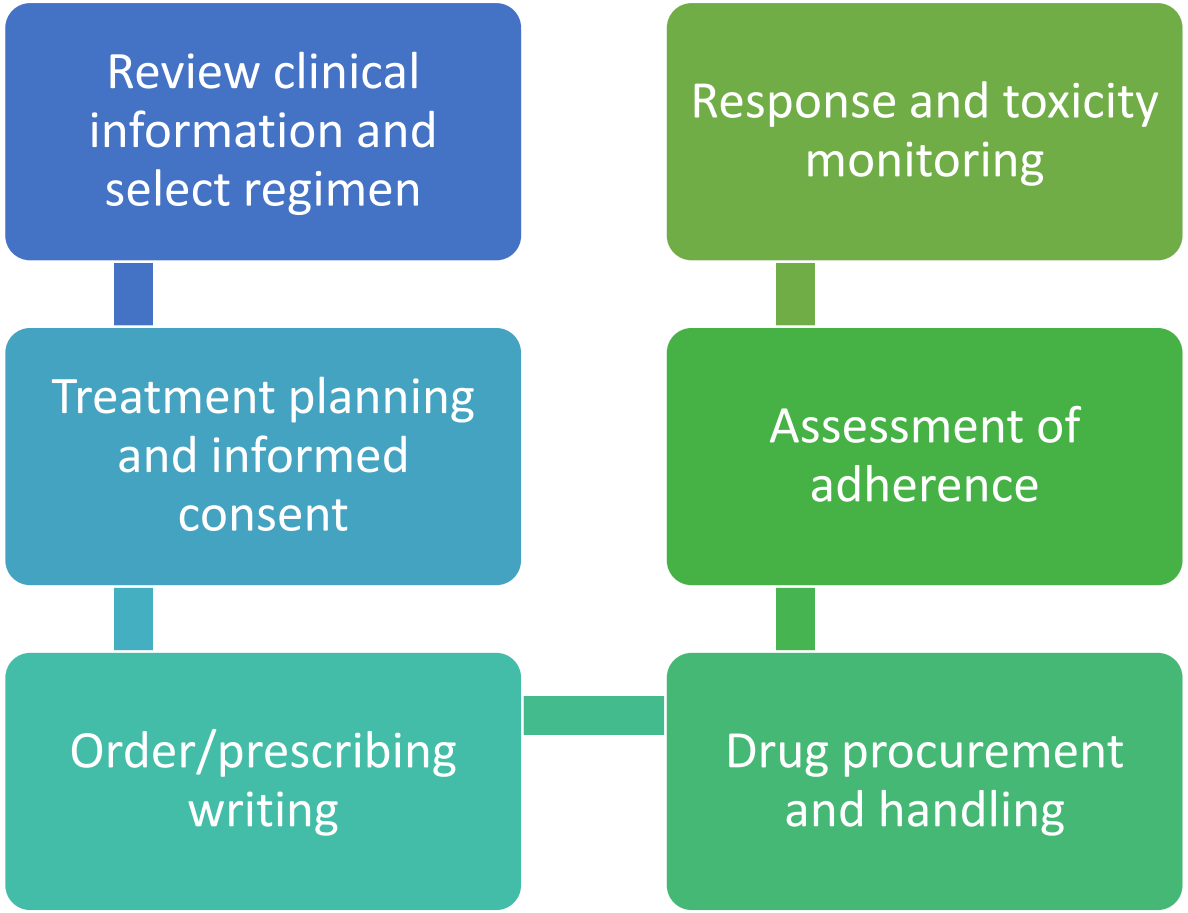
2013 ASCO/ONS Recommendations: Oral Chemotherapy Considerations



Neuss MN, et al. *J Oncol Pract.* 2013; 9(2 Suppl):5s-13s.

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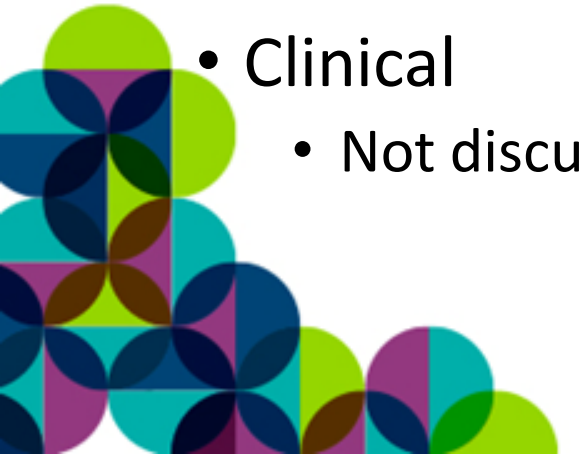
2013 ASCO/ONS Recommendations: The Role of the Pharmacist

- Operational
  - Chemotherapy drugs (oral or parenteral) are **prepared by a pharmacist, pharmacy technician, or nurse** determined to be qualified according to the practice's policies, procedures, and/or guidelines
  - If practice/institution manages **its own pharmacy, the practice/institution has a policy regarding the storage of chemotherapy** (including separation of look-alike products, sound-alike products, and agents available in multiple strengths)
- Clinical
  - Not discussed



Neuss MN, et al. *J Oncol Pract.* 2013; 9(2 Suppl):5s-13s.

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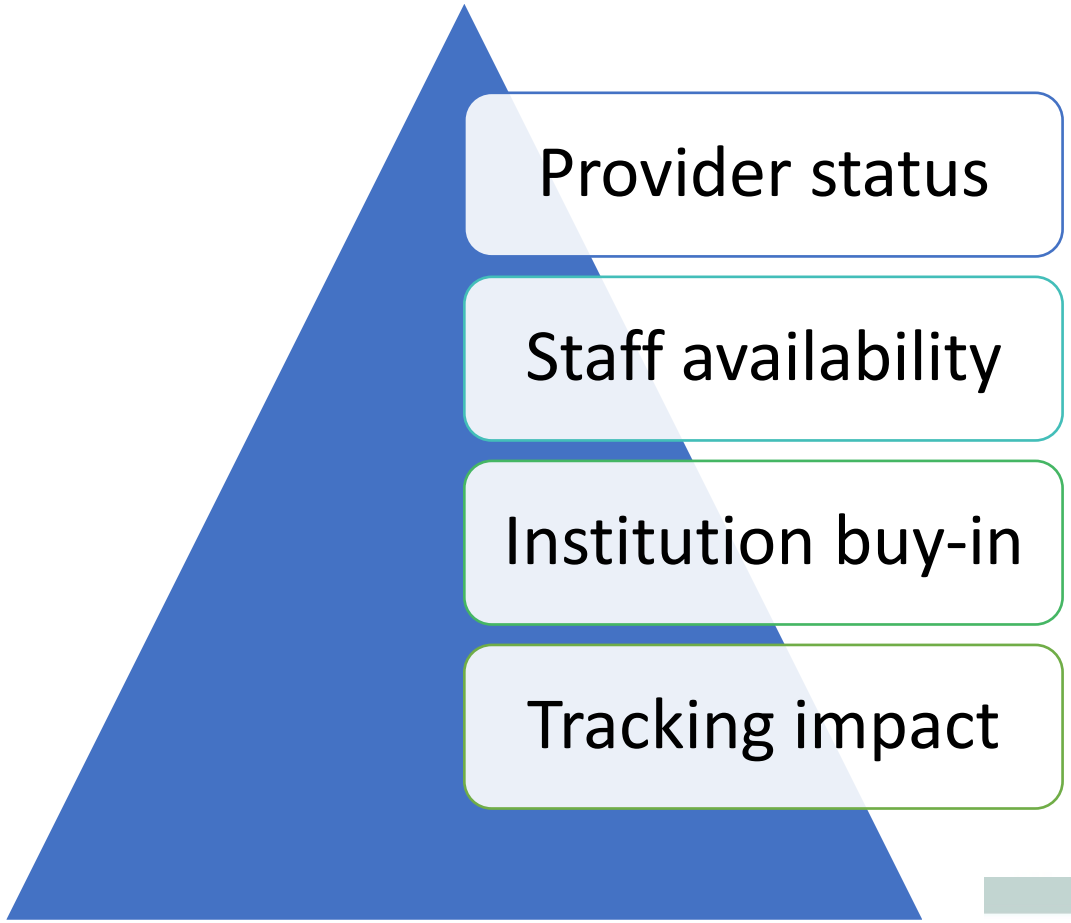
Challenges for a Pharmacy-Led Oral Chemotherapy Program



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Question: What is the primary challenge for oncology pharmacists in managing patients on oral chemotherapy?

A. Lack of standard credentialing for pharmacists
B. Lack of resources (space, staff, etc.)
C. Lack of recognition for our roles in ASCO/ONS guidelines
D. Lack of an easy tracking mechanism for impact

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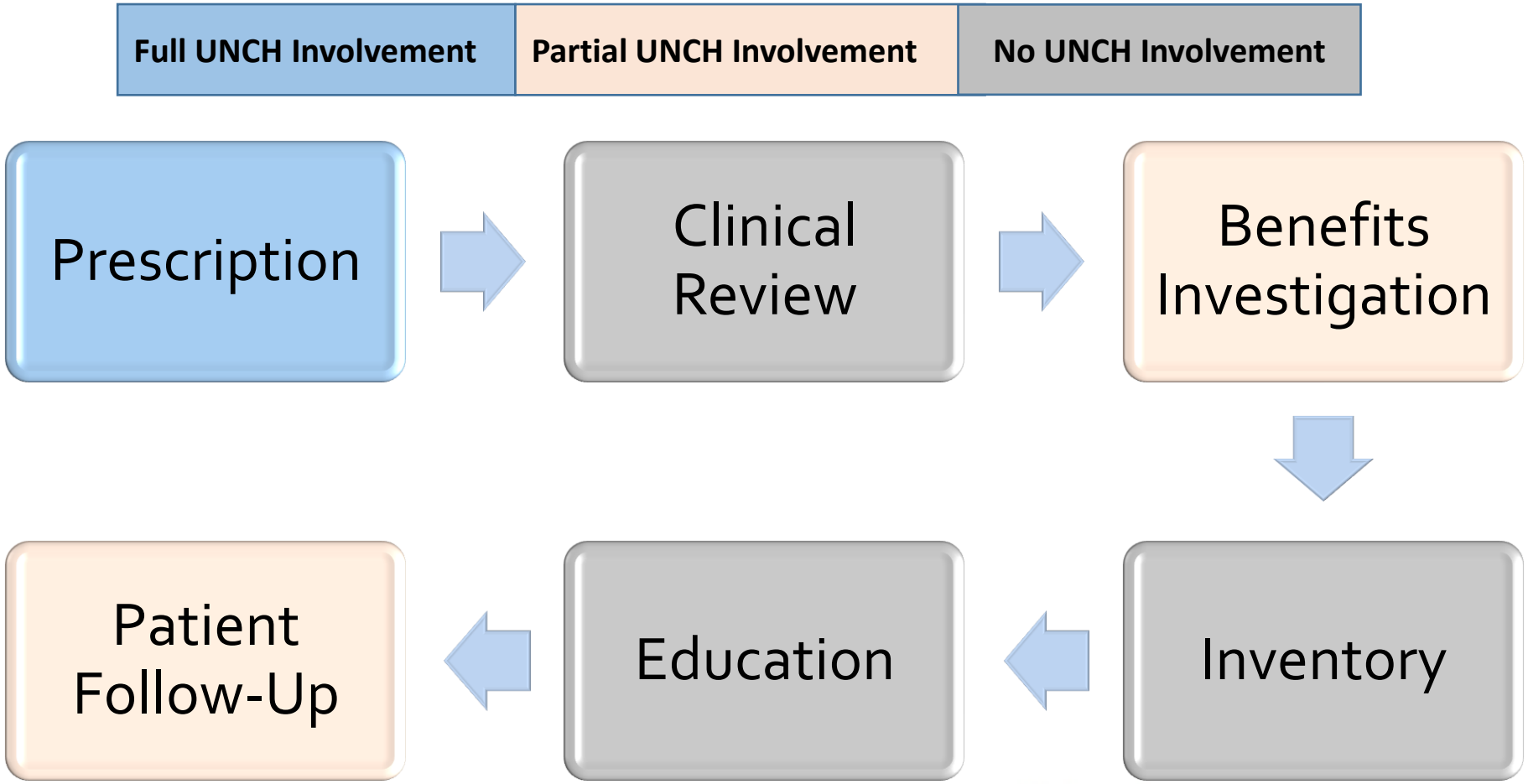
Our Experience



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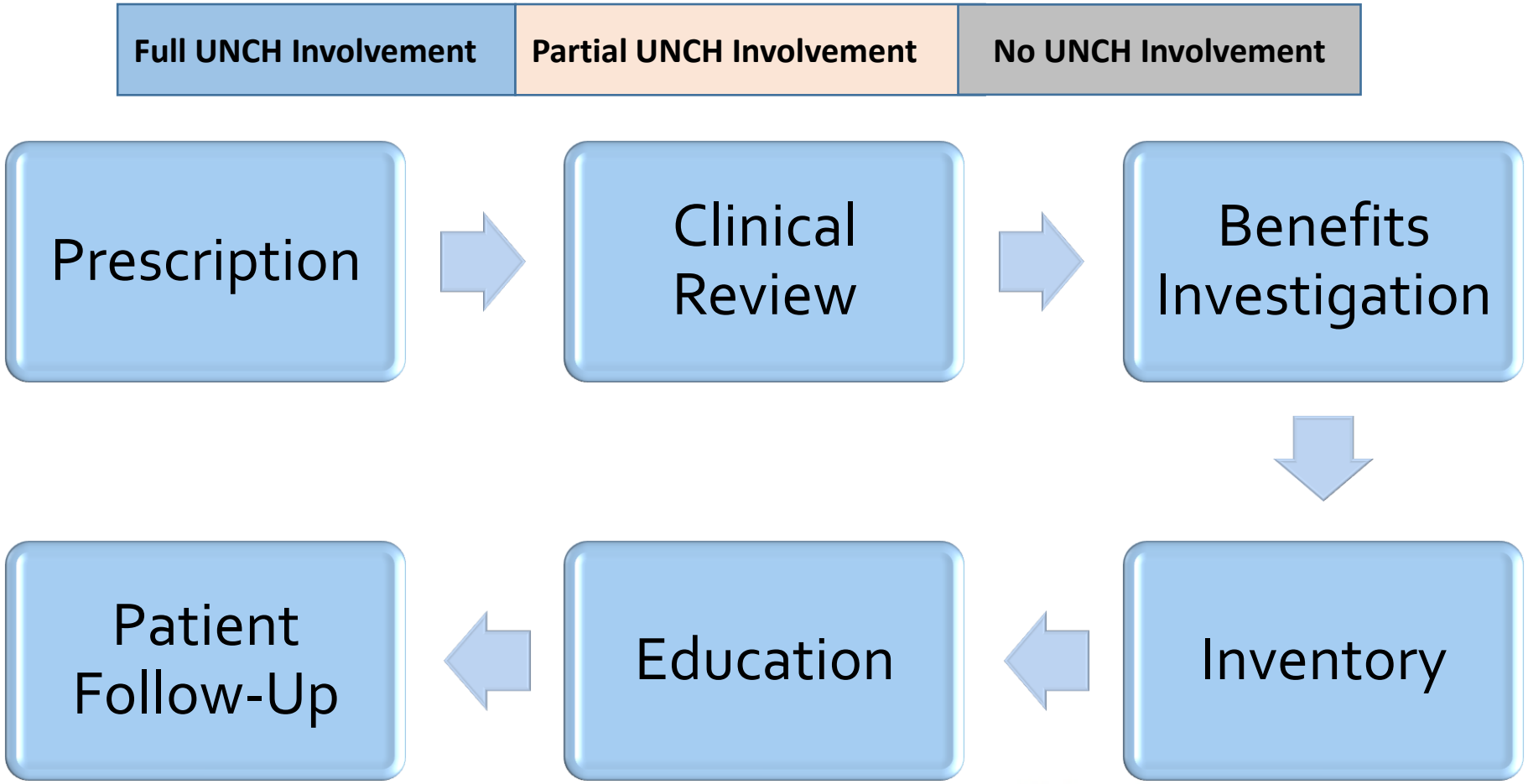
Our Experience – Our Goal



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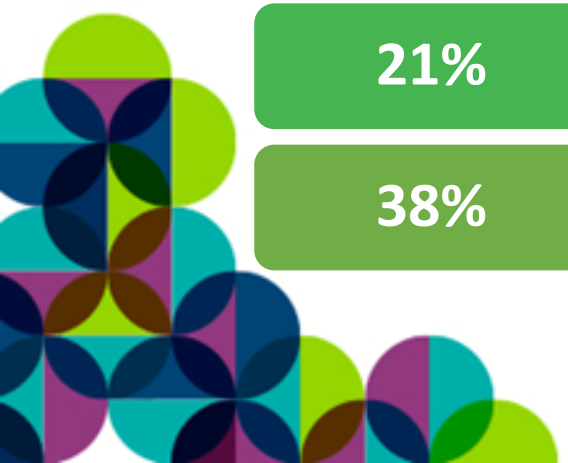
Oral Chemotherapy Program: Needs Assessment

- A survey of 95 oncology patients on oral chemotherapy was conducted at UNC's Cancer Hospital
- Here are the major findings and gaps:

44%	• Don't always think about the last time they ate • Taking oral chemo agents with significant food-drug interactions
14%	• Taking their oral chemotherapy agents incorrectly with regard to food
30%	• Sometimes forget to take their oral chemotherapy
21%	• Sometimes deliberately cut back on their oral chemotherapy because of side effects
38%	• From the patients who cut back, 38% don't tell their MD



Muluneh et al. *J Clin Oncol. 2012*;30 (suppl;abstr 6042)

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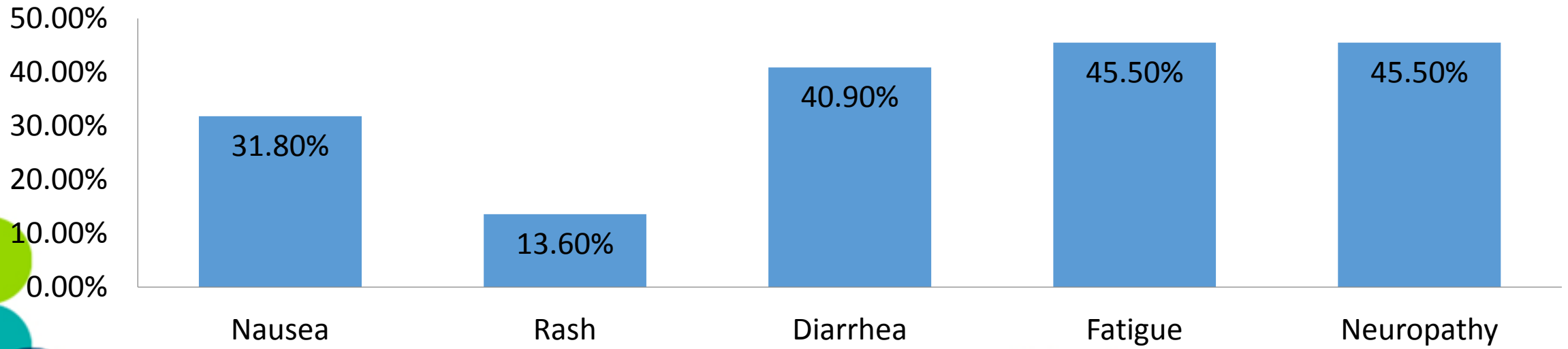
Barriers to Adherence

Reasons for Intentionally Cutting Back	Frequency
Adverse Effects	41%
MD Instructions	45.5%
Delay in Refill	16.9%
Other: Out-of-pocket cost (n=3), vacation (n=2), emotional (n=1), don't remember (n=1), misc. (n=2)	



Muluneh et al. *J Clin Oncol. 2012*;30 (suppl;abstr 6042)

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Gap Analysis: Operational Needs

Quality Standard	Quality Standard ID	Quality Standard Criteria	Weight	Our Institution	
				Compliance	Recommended Action Plan
Organizational Structure	PHARM Core 1	The organization has a clearly defined organizational structure outlining direct and indirect oversight responsibility throughout the organization.	2	NONE	Create organizational structure document that shows oversight responsibility. Show reports that demonstrate oversight (e.g. meeting minutes)
Organizational Documents	PHARM Core 2	Organization's documents address:	No Weight		Produce program description with mission statement.
	PHARM Core 2 (a)	Mission statement	2	NONE	
	PHARM Core 2 (b)	Organizational framework for program	2	NONE	
	PHARM Core 2 (c)	The population served	2	NONE	
	PHARM Core 2 (d)	Organizational oversight and reporting requirements of the program	2	NONE	
Review and Approval	PHARM Core 3	The organization:	No Weight		
	PHARM Core 3 (a)	Reviews written policies and documented procedures no less than annually and revises as necessary	3	FULL	
		Maintains and complies			

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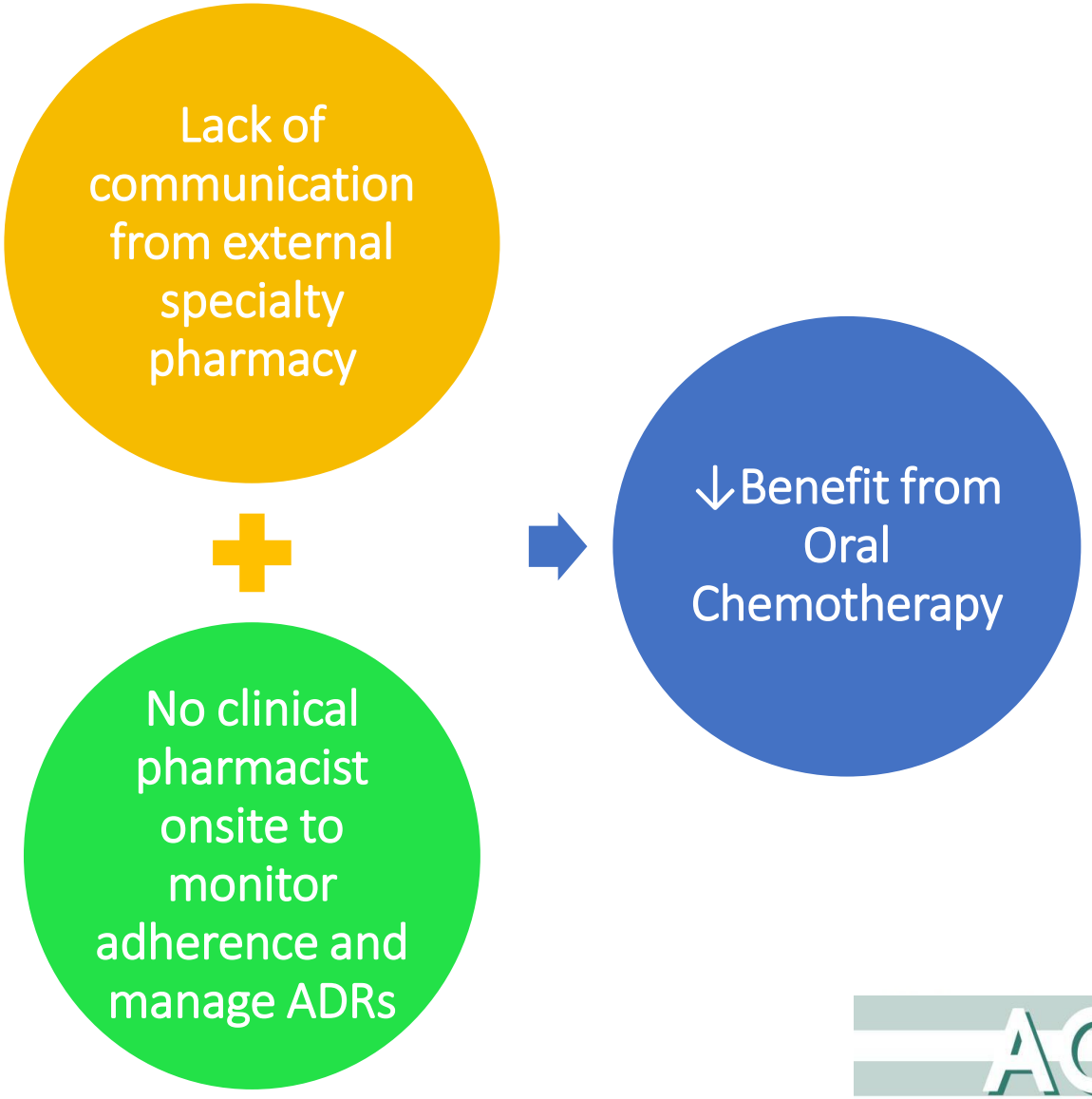
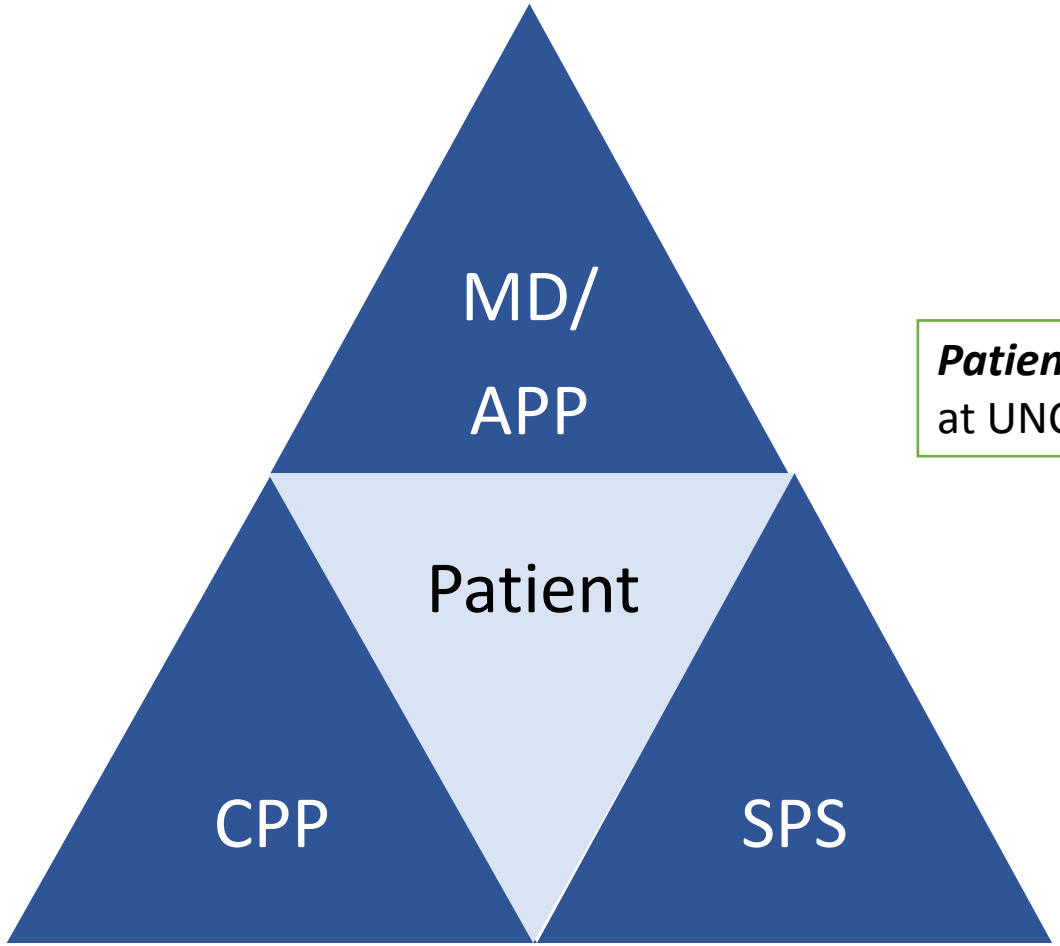
The Gaps


Lack of communication from external specialty pharmacy
No clinical pharmacist onsite to monitor adherence and manage ADRs
↓Benefit from Oral Chemotherapy

Intervention:
UNC's Comprehensive Oral Chemotherapy Program



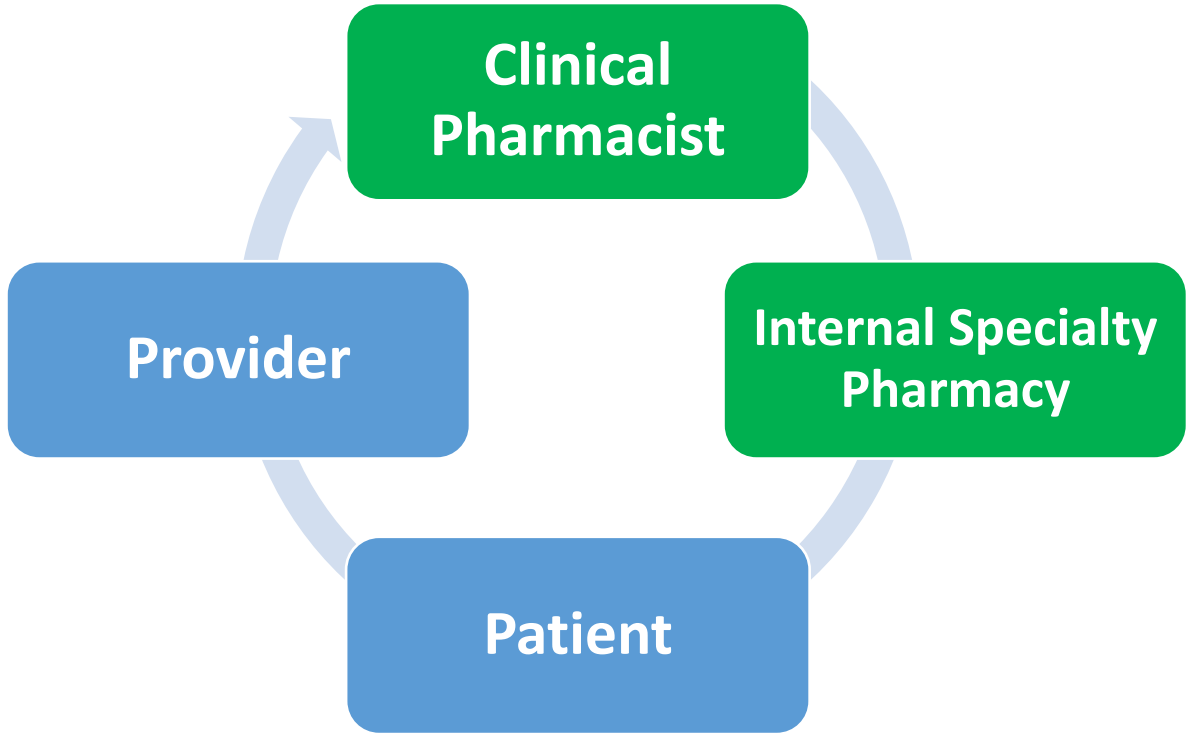
Patient-Centered Model: Three connected pieces at UNC for Maximal Benefit of Oral Chemotherapy

CPP = Clinical Pharmacist Practitioner; SPS = Specialty Pharmacy Services; MD = Medical Doctor

Oral Chemotherapy Workflow Overview

Before

After



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Clinical Pharmacist Practitioners (CPP): Scope of Practice

- Patient Assessment
- Initiate, adjust, discontinue drug therapy
- Order, interpret, monitor labs
- Formulate clinical assessments
- Develop therapeutic plans
- Coordinate care for wellness and prevention of disease
- Conduct patient education

Hammond et al. *Pharmacotherapy*. 2003; 23:1210–1225

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Clinical Pharmacist Practitioner

- Clinical pharmacists who work under a collaborative practice agreement
- In North Carolina, this designation (CPP) allows licensed pharmacists with supervision from a licensed physician to provide medication therapy management, including controlled substances
- Licensure is issued by the Board of Pharmacy and Medicine

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Question: Which one of the following components is critical for a successful oral chemotherapy program?

A. An oncology clinical pharmacist
B. An oncology-trained nurse
C. An internal specialty pharmacy
D. All of the above

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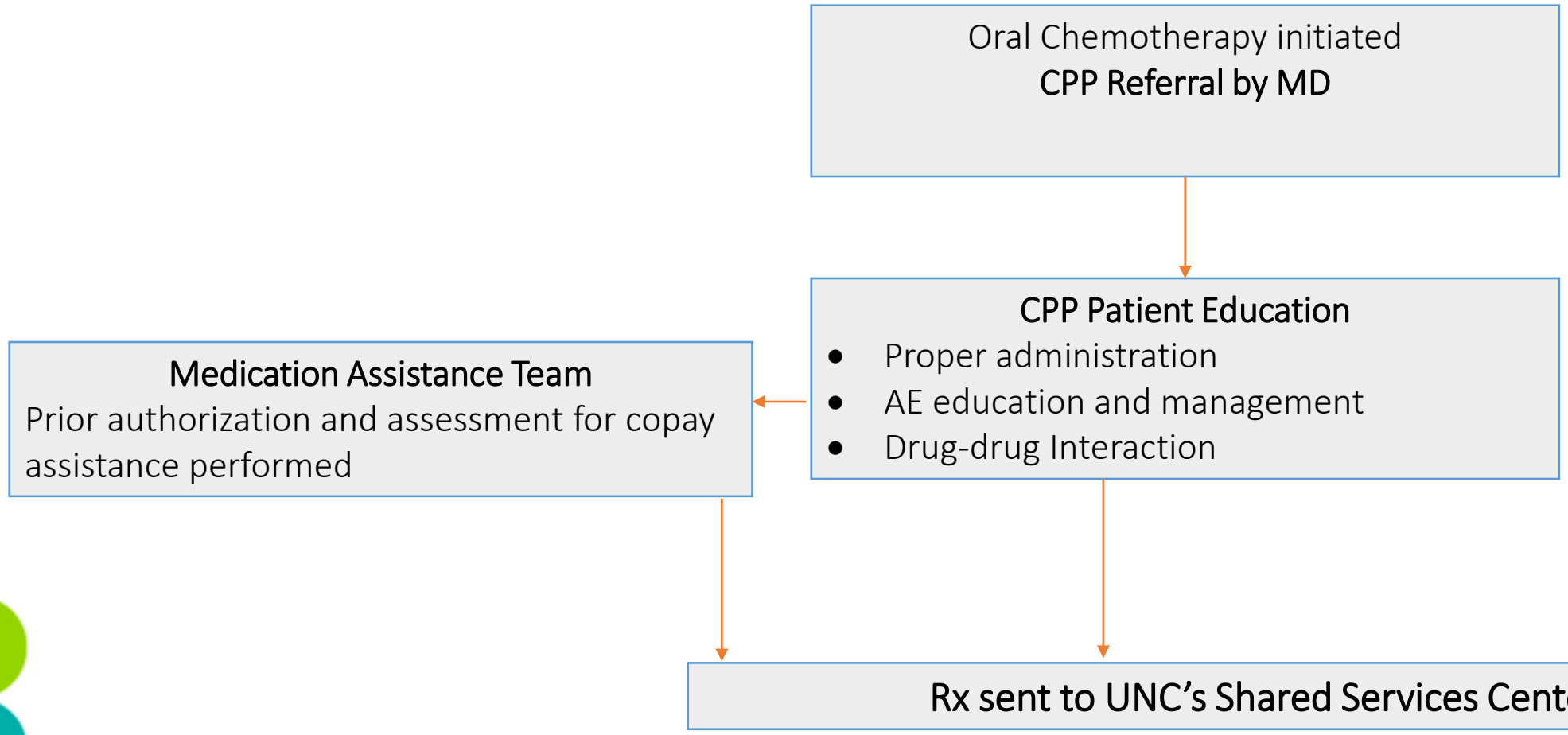
Oral Chemotherapy Program Workflow



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Rx sent to UNC's Shared Services Center

Patient receives medication

CPP first follow-up (1-2 weeks)
Emphasize educational points, management of early-onset toxicities, laboratory evaluation

CPP second follow-up (4-6 weeks)
Assessment of adherence and management of toxicities

Continued follow-up
(3 months post-initiation)
Assessment of adherence, management of toxicities, evaluation for drug-drug interactions

[MD Follow up]

MD Visit (4-6 weeks)
CPP to see patient prior to MD

MD Visit
(3 months post-initiation)
CPP to see patient prior to MD

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Patient condition at 3 mo. assessment by CPP:

- Increased risk of non-adherence (MPR< 85%)?
- Adverse drug reactions?
- Abnormal lab values and need for dose adjustment?
- Request of physician for additional f/u?

No

Stable

Q3-6 month appt with MD

Q3 month phone call with CPP Q6month visit with CPP

Yes

Unstable

Visits will be individualized

Q2-4 weeks prn

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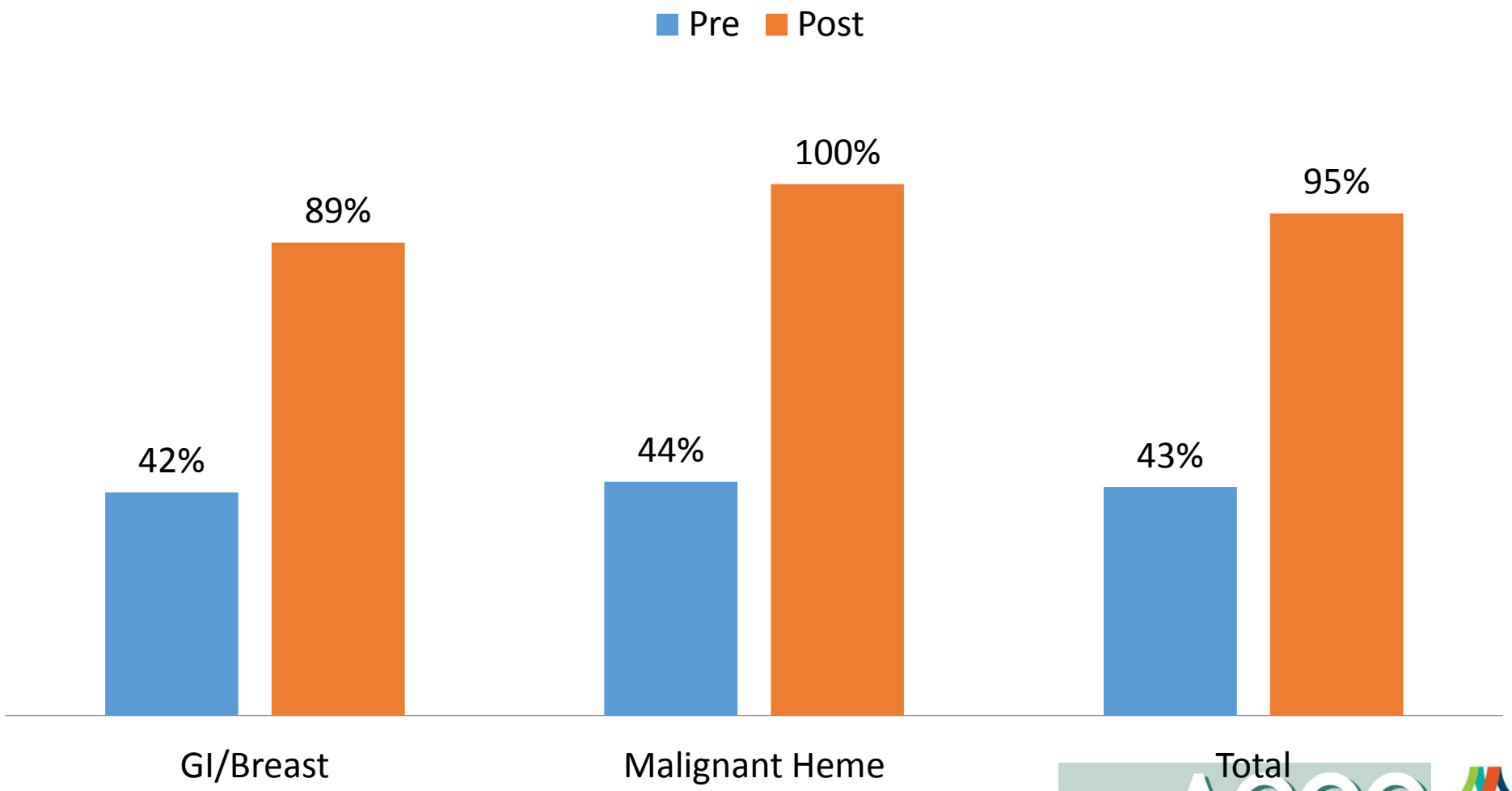
Results: Improved Education of Patients



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Oral Chemotherapy Agents

- Solid Tumor (GI and Breast)
  - Everolimus (Afinitor), N=19
  - Imatinib (Gleevec), N=12
  - Sorafenib (Nexavar), N=15
  - Regorafenib (Stivarga), N=7
  - Temozolomide (Temodar), N=2
  - Lapatinib (Tykerb), N=2
  - Capecitabine (Xeloda), N=38
  - Trametinib (Mekinist), N=2
- Malignant Hematology (CML, CLL, AML, ALL)
  - Bosutinib (Bosulif), N=5
  - Imatinib (Gleevec), N=8
  - Nilotinib (Tasigna), N=6
  - Dasatinib (Sprycel), N=
  - Ibrutinib (Imbruvica), N=16
  - Idelalisib (Zydelig), N=12
  - Bexarotene (Targretin), N=2
  - Sorafenib (Nexavar), N=1

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Adherence Rates

- Malignant Hematology Patients: Goal = >90%
  - Extrapolated from the CML literature by Marin et al.[1]
  - Found that MMR (major molecular response) rates in CML patients who were adherent <90% of time were 13.9%, whereas the probability of MMR in patients who were adherent >=90% was 93.7%.
- Breast/GI Cancer Patients: Goal = >80%
  - This goal was based on breast cancer literature which defined greater than 80% as optimal adherence.[2]
- Data was collected from September 2014 until May 2015 and adherence was assessed at every patient encounter.

1. Marin D, et al. *J Clin Oncol*. 2010;28:2381-8.
2. Partridge A, et al. *J Clin Oncol*. 2010;28:2418-22.

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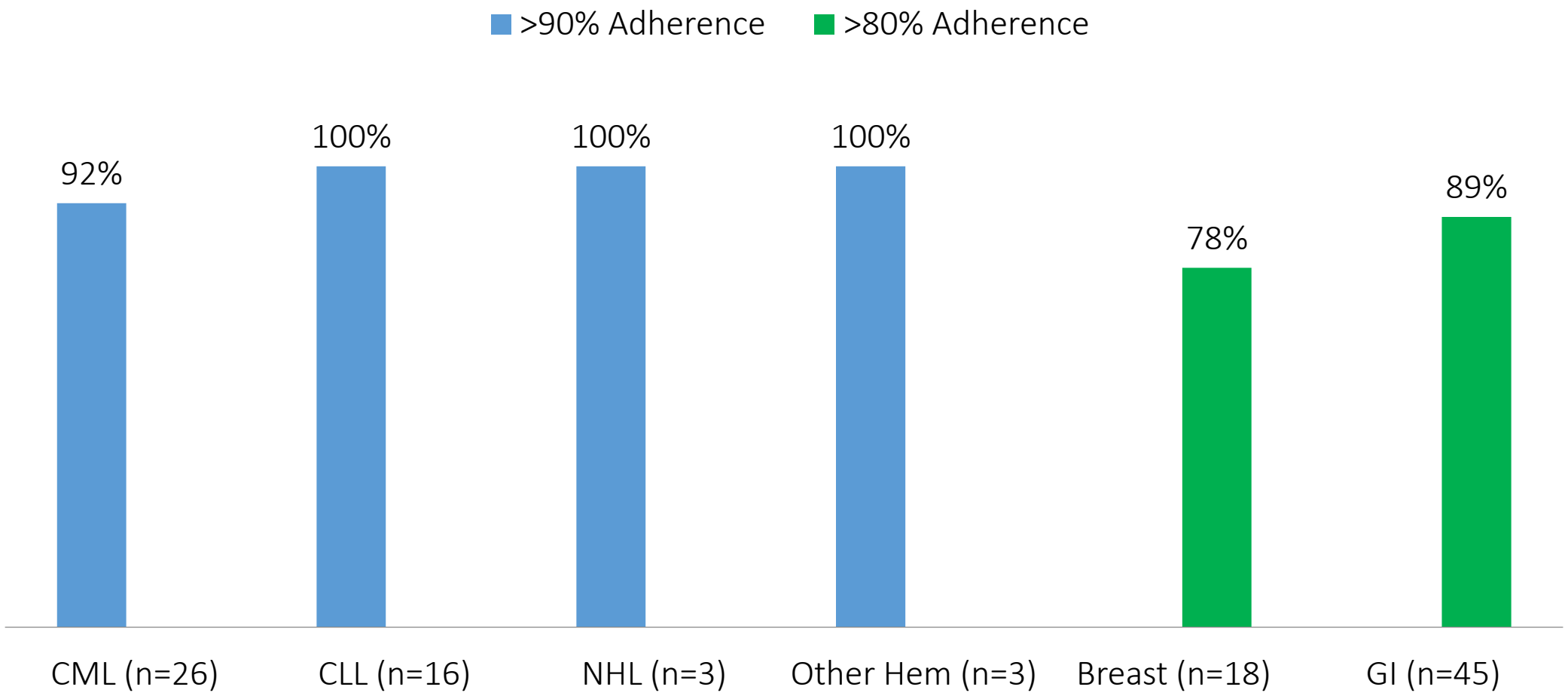
Results: Improved Adherence Rates



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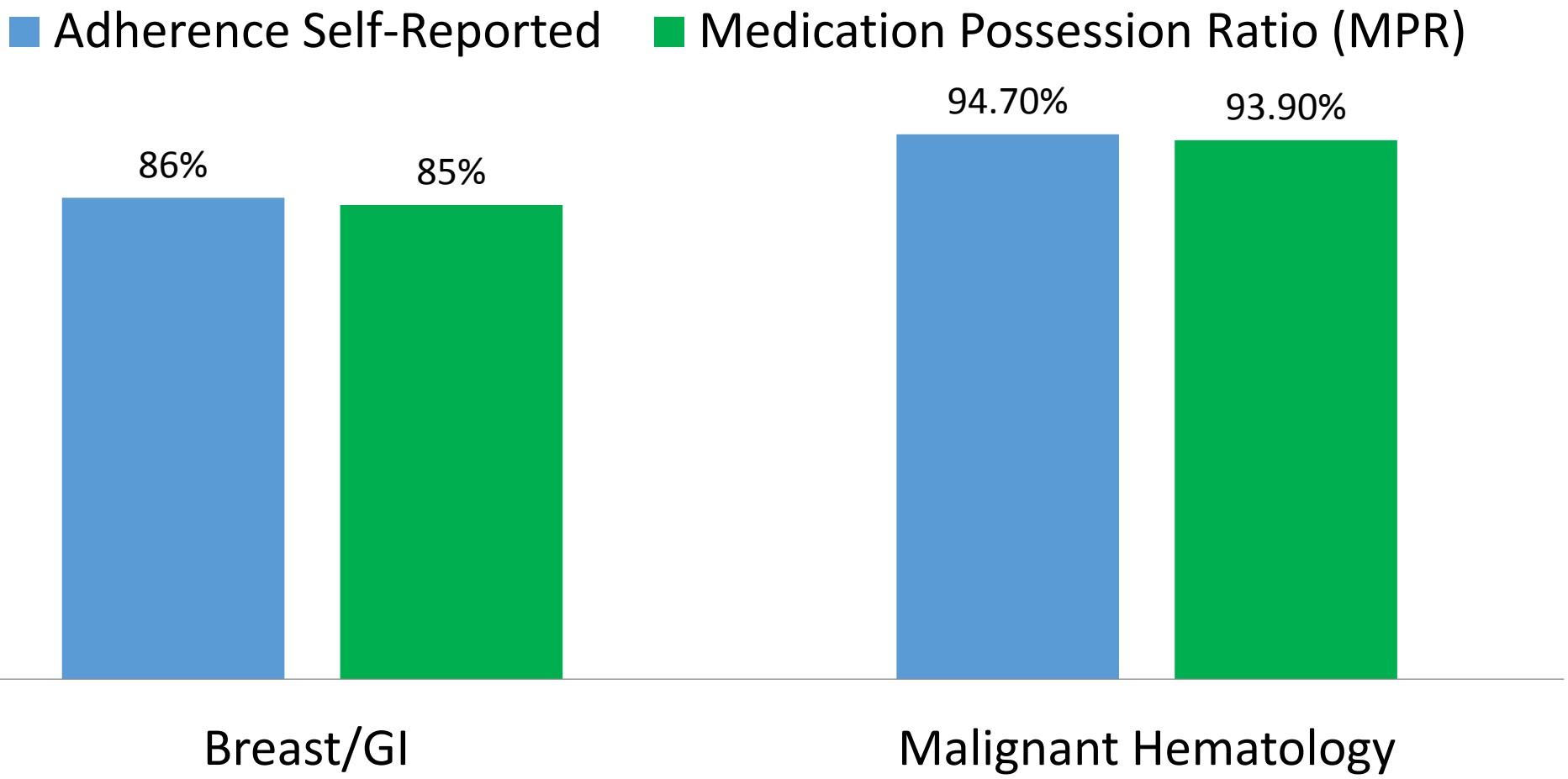
Results: Improved Adherence Rates



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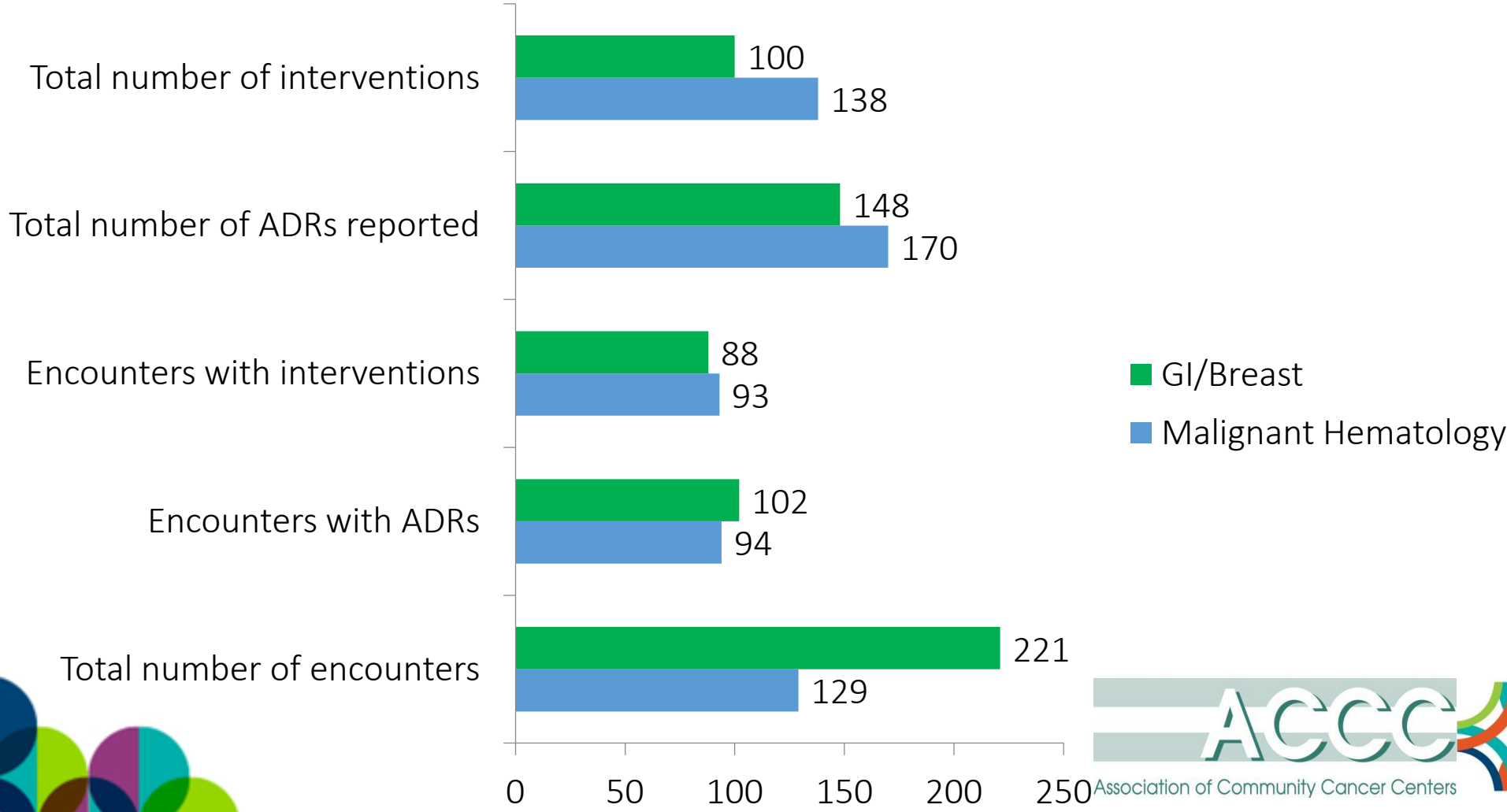
Increased Frequency of Clinical Assessments and Management of Toxicity



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Improved Molecular Response Rates in CML Patients

	Pre-Intervention	Post-Intervention
100% Adherence	52%	74%
>90% Adherence	N/A	92%
	Clinical Trials	**Our Data**
EMR (PCR <10%)	66%[1,2]	93%
MMR (PCR <0.1%)	60%[3,4,5,6]	79%

- **Achieving EMR (Early Molecular Response) by 3-6 months after starting therapy is associated with increased overall survival in CML patients.[1]**

1. Hughes TP, et al. *Blood*. 2014;123:1353-60.
2. Marin D, et al. *Blood*. 2012;120:291-4.
3. O'Brien SG, et al. *N Engl J Med*. 2003;348:994-1004.
4. Saglio G, et al. *N Engl J Med*. 2010;362:2251-9.
5. Kantarjian H, et al. *N Engl J Med*. 2010;362:2260-70.
6. Brümmendorf TH, et al. *Br J Haematol*. 2015;168:69-81.

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Improved Financial Outcomes

- Estimated annual potential revenue $4 million for July 1, 2014 – June 30, 2015
- Actual revenue earned exceeded expectation this fiscal year
- Physical expansion at an off-site location with new automation
- Sustainable financial model which allowed for expansion of clinical pharmacist practitioners in the ambulatory clinics

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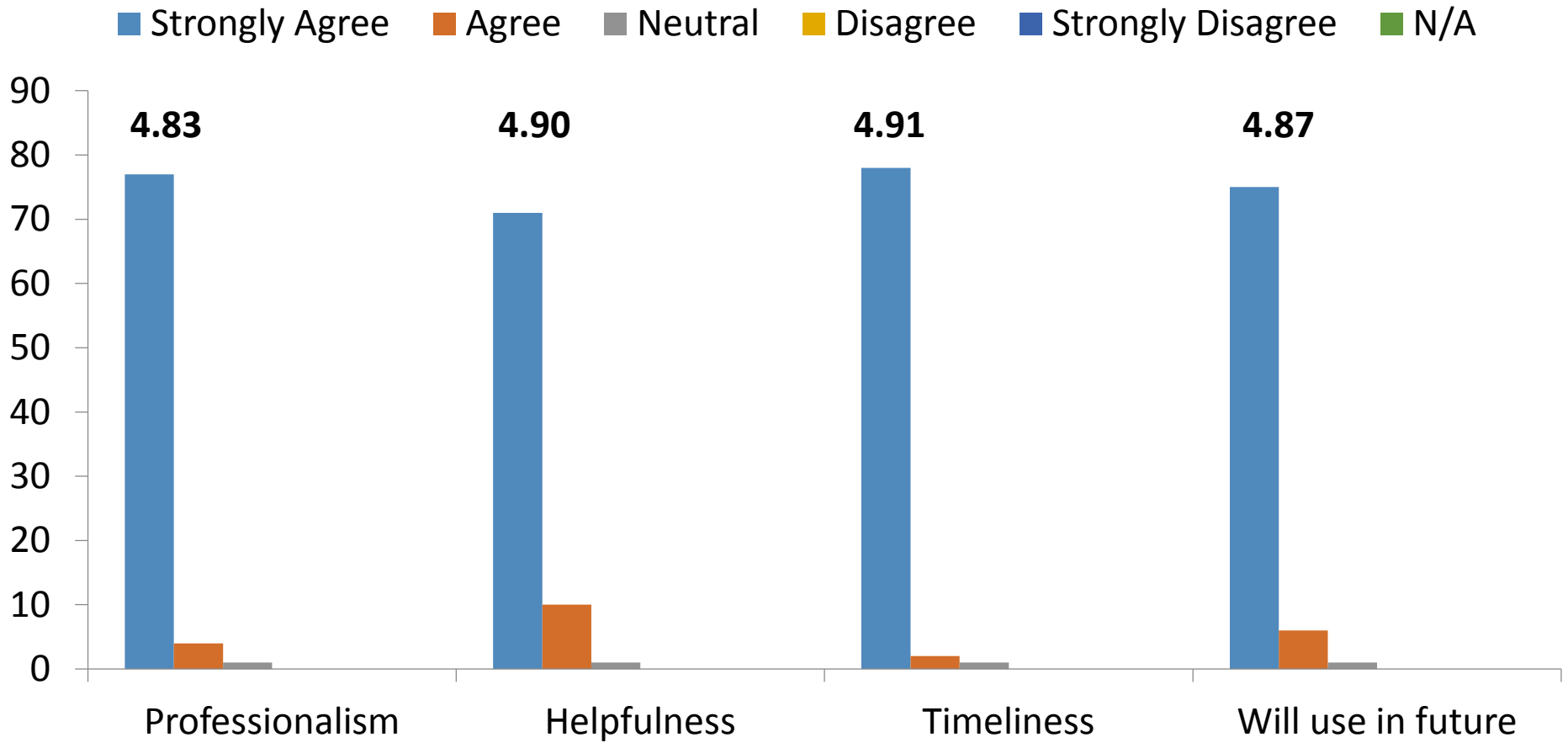
Patient Satisfaction



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Next Steps – Opportunities and Challenges

- Short Term
  - Continue to expand clinical pharmacy services in areas that have an unmet need (i.e. GU clinic, CNS tumors)
  - Conduct a Lean Six Sigma-based intervention to improve workflow among the clinic, specialty pharmacy, and medication assistance program
- Long Term
  - Standardize clinical tracking tools across disease groups in order to easily measure impact
  - Figure out better reimbursement strategies for clinical pharmacist services
  - Navigate the challenging world of restricted distribution by PBMs and drug manufacturers

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