Evaluating a Nurse Guideline for Bispecific Antibody Safe Step-Up Dosing in an Ambulatory Setting: A Continuous Quality Improvement Approach

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Proposal Presentation

July 9, 2024

DNP SCHOLARLY PROJECT TEAM

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Second Reader: Melissa Gomes Ph.D., APRN, PMHNP-BC, FNAP, FAAN
Associate Professor, Associate Dean for Diversity, Equity & Inclusion at UVA School of Nursing

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Assistant Professor of Nursing, UVA School of Nursing

Practice Mentor: Colleen Gerrity, DNP, RN, CPHON
Director Pediatric Nursing Dana Farber Cancer Institute

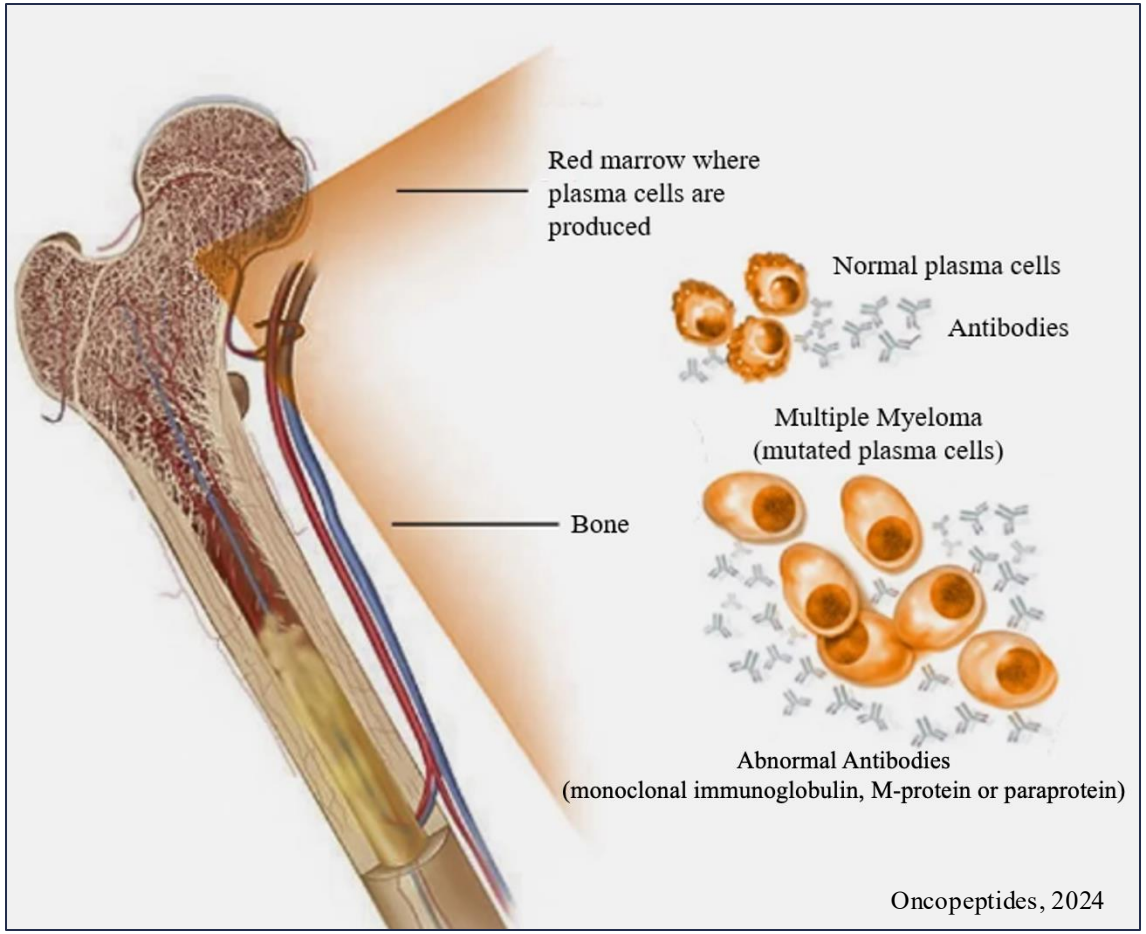
INTRODUCTION AND BACKGROUND

MULTIPLE MYELOMA

- Hematologic malignancy characterized by
  - Uncontrolled proliferation of plasma cells
  - Overproduction of monoclonal immunoglobulin
  - M-proteins or paraprotein

- 1.8% of all new cancer diagnosis in the U.S.
  - 2% of all cancer related deaths nationwide
  - Disproportionate high mortality burden

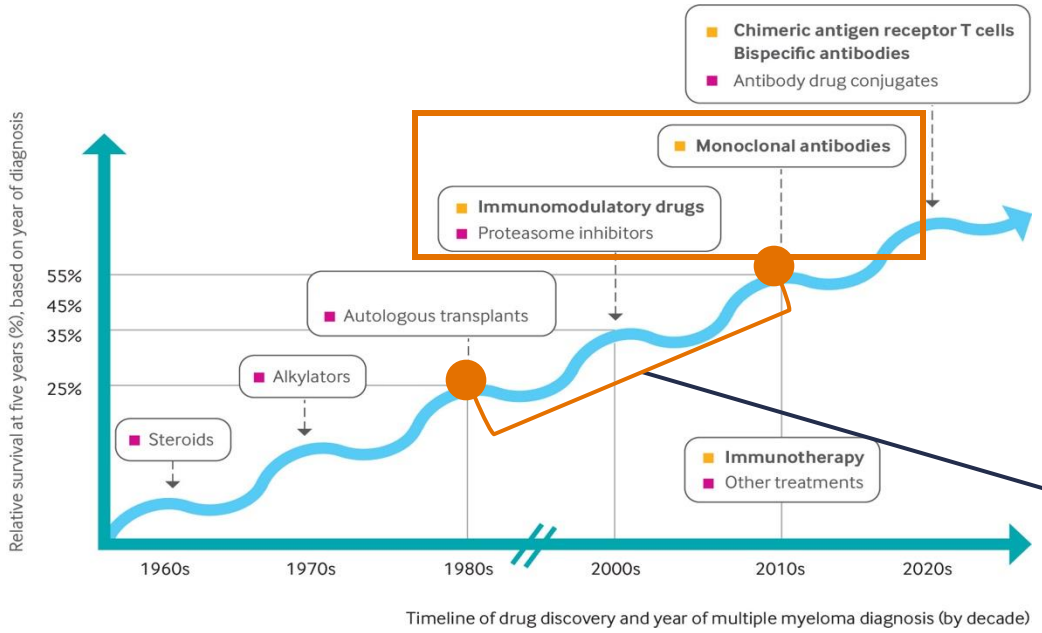
- Demographic Trends
  - Median age at diagnosis 69
  - Higher incidence in African Americans – two-fold increase compared to European Americans
  - Male predominance (M > F)



(National Cancer Institute, 2024)

TREATMENT CHALLENGES

- Substantial progress made in treatment
- Myeloma remains incurable, nearly all patients develop relapsed or refractory disease
- Prognosis poor with triple refractory disease



(Shah and Mailankody, 2020)

› Leukemia. 2019 Sep;33(9):2266-2275. doi: 10.1038/s41375-019-0435-7. Epub 2019 Mar 11.

Outcomes of patients with multiple myeloma refractory to CD38-targeted monoclonal antibody therapy

Ujjawal H Gandhi [1], Robert F Cornell [1], Arjun Lakshman [2], Zhubin J Gahvari [3], Elizabeth McGehee [4], Megan H Jagosky [5], Ridhi Gupta [6], William Varnado [7], Mark A Fiala [8], Saurabh Chhabra [9], Ehsan Malek [10], Joshua Mansour [11], Barry Paul [12], Alyssa Barnstead [13], Saranya Kodali [14], Amarendra Neppalli [11], Michaela Liedtke [6], Swapna Narayana [9], Kelly N Godby [7], Yubin Kang [12], Ankit Kansagra [4], Elvira Umyarova [14], Emma C Scott [13], Parameswaran Hari [9], Ravi Vij [8], Saad Z Usmani [5], Natalie S Callander [3], Shaji K Kumar [2], Luciano J Costa [15]

Affiliations + expand

PMID: 30858549 PMCID: PMC6820050 DOI: 10.1038/s41375-019-0435-7

Abstract

The introduction of CD38-targeting monoclonal antibodies (CD38 MoABs), daratumumab and isatuximab, has significantly impacted the management of patients with multiple myeloma (MM). Outcomes of patients with MM refractory to CD38 MoABs have not been described. We analyzed outcomes of 275 MM patients at 14 academic centers with disease refractory to CD38 MoABs. Median interval between MM diagnosis and refractoriness to CD38 MoAB (T_0) was 50.1 months. The median overall survival (OS) from T_0 for the entire cohort was 8.6 [95% C.I. 7.5-9.9] months, ranging from 11.2 months for patients not simultaneously refractory to an immunomodulatory (IMiD) agent and a proteasome inhibitor (PI) to 5.6 months for "penta-refractory" patients (refractory to CD38 MoAB, 2 PIs and 2 IMiDs). At least one subsequent treatment regimen was employed after T_0 in 249 (90%) patients. Overall response rate to first regimen after T_0 was 31% with median progression-free survival (PFS) and OS of 3.4 and 9.3 months, respectively. PFS was best achieved with combinations of carfilzomib and alkylator (median 5.7 months), and daratumumab and IMiD (median 4.5 months). Patients with MM refractory to CD38 MoAB have poor prognosis and this study provides benchmark for new therapies to be tested in this population.

BISPECIFIC ANTIBODIES

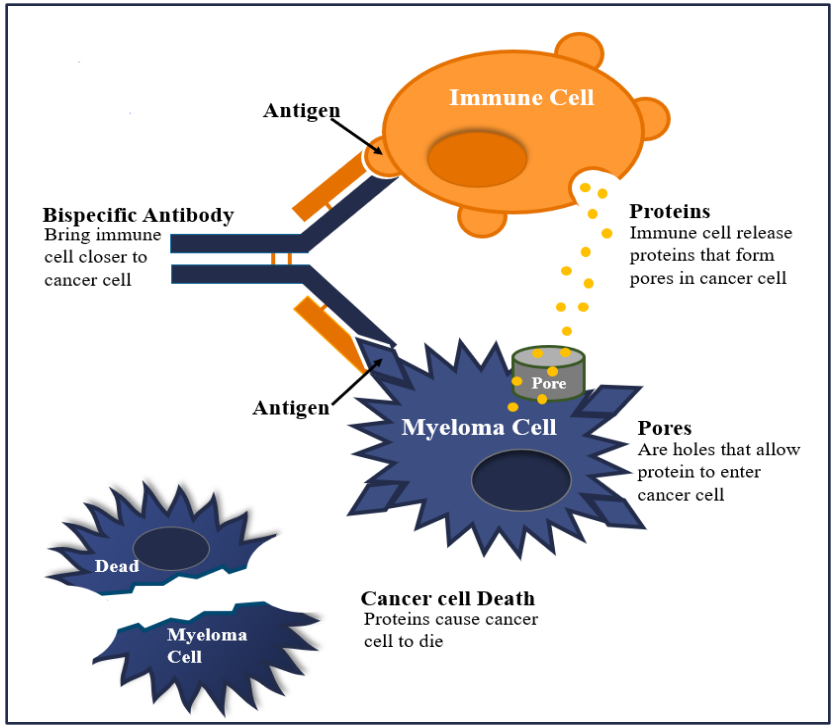
GROUNDBREAKING NEW TREATMENTS

Food and Drug Administration (FDA) approvals (2022–2023)

- Teclistamab – Target antigen B-cell maturation antigen (BCMA)
- Elranatamab – Target antigen BCMA
- Talquetamab – Target antigen GPRC5D

Mechanism of Action

- Bind CD3 on T cell and antigen on myeloma cell
- Forms immunological synapse
- Leads to T cell activation
- Targeted **RELEASE OF CYTOKINE** granules
- Results in apoptosis of myeloma cell



SIGNIFICANCE

BISPECIFIC ANTIBODIES EFFICACY

Benchmark Study for Evaluating the Impact of New Drug Treatment	ORR	Median PFS (months)	Median Overall Survival (OS) (months)
MAMMMOTH (Gandhi et al., 2019)	31%	3.4	8.6

Bispecific Antibody Clinical Trials	ORR	Median PFS (months)	Durable Response DOR (months)
MajesTEC-1 (Teclistamab) (Moreau et al., 2022)	63%	11.3	18.4
MagnetisMM-3 (Elranatamab) (Lesokhin et al., 2023)	61%	50.9% at 15	–
MonumenTAL-1(Talquetamab) (Chari et al., 2022)	67%	7.8 – 10.2	10.2

PROBLEM

Managing Treatment-Related Toxicities

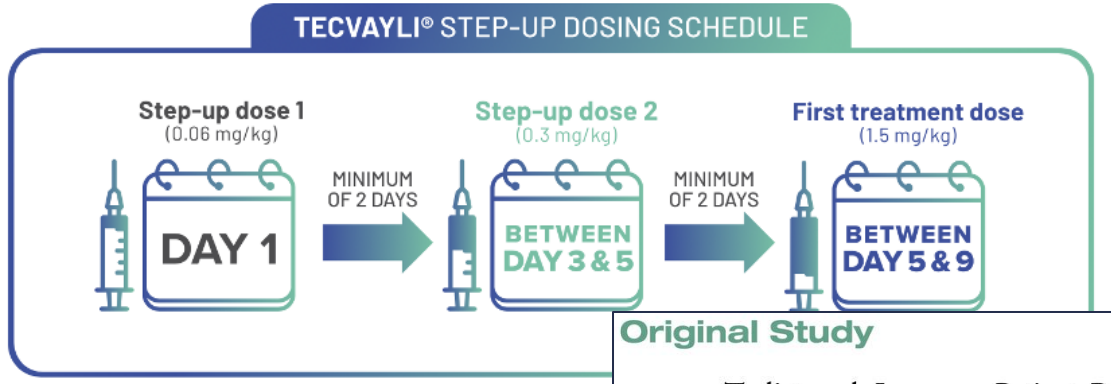
- Risk Evaluation and Mitigation Strategy
  - CRS
  - Neurotoxicity
- Step-up dosing requirement

Inpatient Resource Utilization

- Hospitalization requirement
- Average 10-days length of stay

Patient Quality of Life

- Impact of hospitalization
- Ambulatory administration benefits



Original Study

Teclistamab Improves Patient-Reported Symptoms and Health-Related Quality of Life in Relapsed or Refractory Multiple Myeloma: Results From the Phase II MajesTEC-1 Study

Thomas G. Martin,[1] Philippe Moreau,[2] Saad Z. Usmani,[3] Alfred Garfall,[4] María-Victoria Mateos,[5] Jesús F. San-Miguel,[6] Albert Oriol,[7] Ajay K. Nooka,[8] Laura Rosinol,[9] Ajai Chari,[10] Lionel Karlin,[11] Amrita Krishnan,[12] Nizar Bahlis,[13] Rakesh Popat,[14] Britta Besemer,[15] Joaquín Martínez-López,[16] Michel Delforge,[17] Danielle Trancucci,[18] Lixia Pei,[18] Rachel Kobos,[18] John Fastenau,[18] Katharine S. Gries,[18] Niels W.C.J. van de Donk[19]

Original Reports | Quality in Cancer Care

Real-World Safety and Health Care Resource Utilization of Teclistamab Under an Outpatient Model for Step-Up Dosing Administration

ABSTRACT

PURPOSE Teclistamab is initiated with a step-up dosing (SUD) schedule to mitigate the risk of cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity syndrome (ICANS). Early teclistamab users commonly received SUD in a hospital setting. This study aimed to evaluate safety and health care resource utilization (HRU) in real-world patients with multiple myeloma who initiated teclistamab SUD in an outpatient setting.

METHODS This was a retrospective study using Mayo Clinic's electronic medical records from October 26, 2022, to October 31, 2023. Patient characteristics were

PURPOSE STATEMENT

To evaluate the effectiveness a **nursing guideline** in detecting treatment-related toxicities, monitoring patient outcomes, and integrating telephone follow-up assessment within the infusion nurse workflow in an ambulatory setting.

AVAILABLE KNOWLEDGE

LITERATURE SEARCH and APPRAISAL

Literature Search

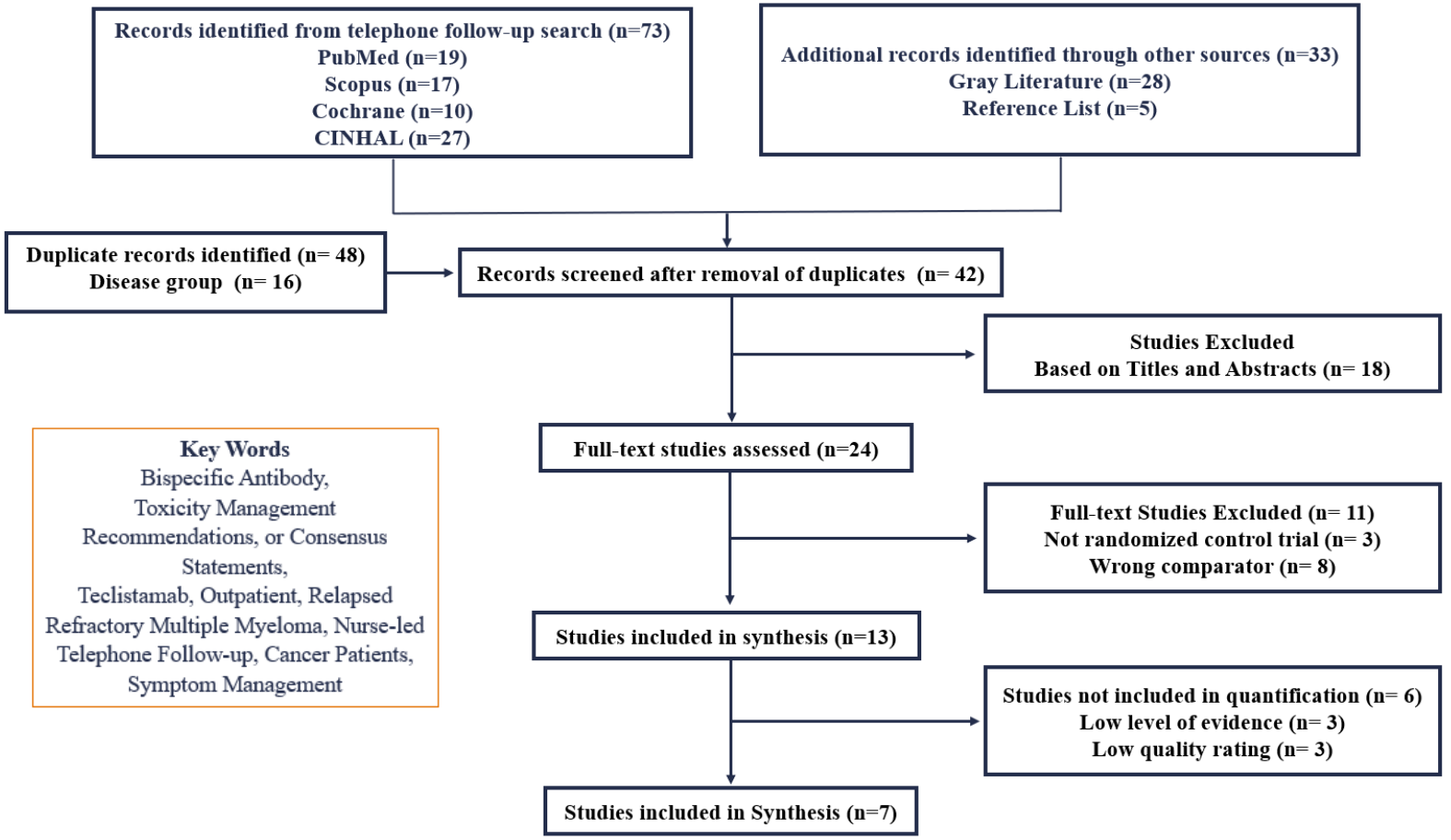
- 4 academic databases
- Gray literature
- Reference lists

PRISMA

- 106 articles
- 7 met criteria

Literature Appraisal

- JHEB Appraisal tool
- 2 consensus statements
- 3 observational studies
- 2 RCTs



LITERATURE THEMES

The following themes emerged from the literature review

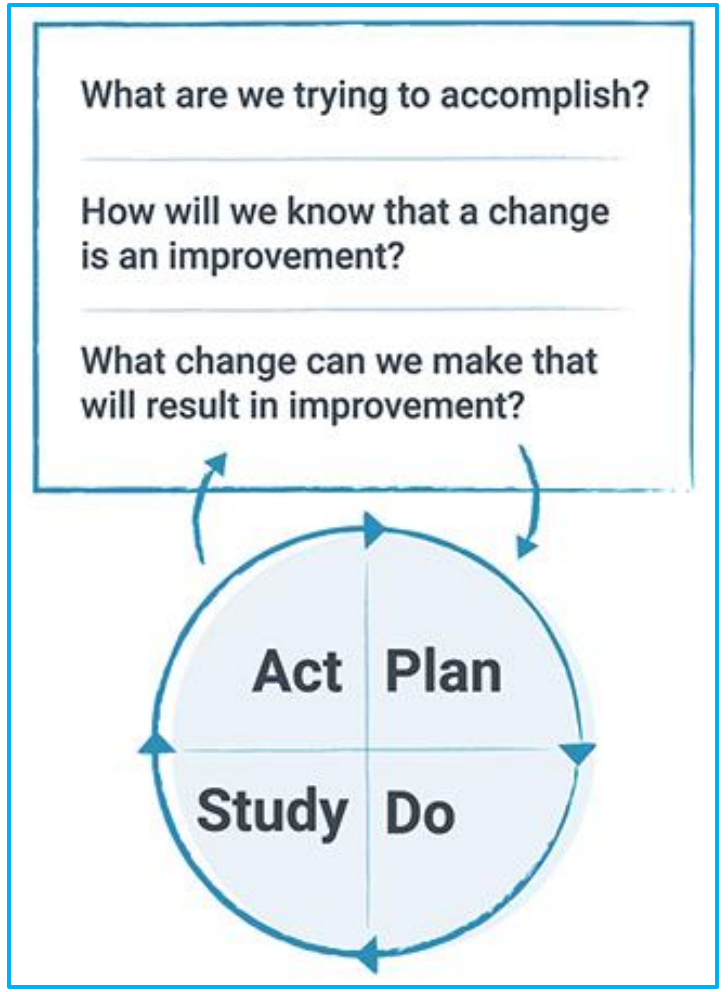
- Comprehensive education for patients and the health care team
- Standardized home monitoring procedures
- Robust interdisciplinary collaboration
- Evidence supported nurse-led telephone follow-up as a safe an effective approach for symptom detection and triage

METHODS

PROJECT DESIGN
Conceptual Framework

WHY CONTINUOUS QUALITY IMPROVEMENT (CQI) FRAMEWORK?

- Structured
- Iterative
- Data-driven
- Approach for evaluating and refining the NURSE GUIDELINE



CQI TEAM MEMBERS

PRIMARY STAKEHOLDERS

- **Janet Bagley** – Vice President Adult Nursing Services
- **Indy Robles** – Nurse Unit Director
- **Shonali Midha** – Myeloma Oncologist
- **Shahrier Hossian** – Myeloma Pharmacist
- **Anne Burgess** – Nursing Informatics
- **Nelle Fine** – Patient Education Specialist
- **Lauren McGovern** – Nursing Professional Development Educator

SETTING and INSTITUTIONAL REVIEW BOARD

Setting

- Location – Academic Ambulatory Cancer Center in urban northeast U.S.
- Unit – Hematology infusion specific for multiple myeloma

Institutional Review Board (IRB)

- Submitted to the IRB for review
- Determined to be a quality improvement initiative
- Implemented under organization's QI guidelines

ETHICAL and DIVERSITY, EQUITY, AND INCLUSION CONSIDERATIONS

Ethical Considerations: Nonmaleficence and Autonomy

- Nonmaleficence—through a nurse guideline designed to proactively prevent harm
- Autonomy—equipping patients and caregivers with tools to actively participate in their care and symptom monitoring

Diversity, Equity, and Inclusion (DEI)

- Risk-benefit analysis for outpatient eligibility
- Communication barriers were high risk with non-English-speaking patients
- Pilot phase exclusion to prevent harm
- Future initiatives for inclusivity

NURSE GUIDELINE DEVELOPMENT & IMPLEMENTATION

UNIVERSITY of VIRGINIA SCHOOL of NURSING

NURSE GUIDELINE

CORE COMPONENTS

Nurse and Patient Education	**Treatment Administration**	**Home Monitoring**
Supportive Care Process	**Urgent Care Process**	**Technology use in EMR**

RESOURCES AND INFRASTRUCTURE

NURSE and PATIENT EDUCATION

Nurse Education

- Complete required education (1-hour multimodal course)
- **Nurse Education included:**
  - Drug admin to SE monitoring
  - ASTCT grading criteria
  - Baseline VS and threshold limits
  - Telephone assessments + Triage
  - Simulation base-training with real-time assessments and triage scenarios
  - Supportive and Urgent workflow
  - Interdisciplinary team communication

Patient Education

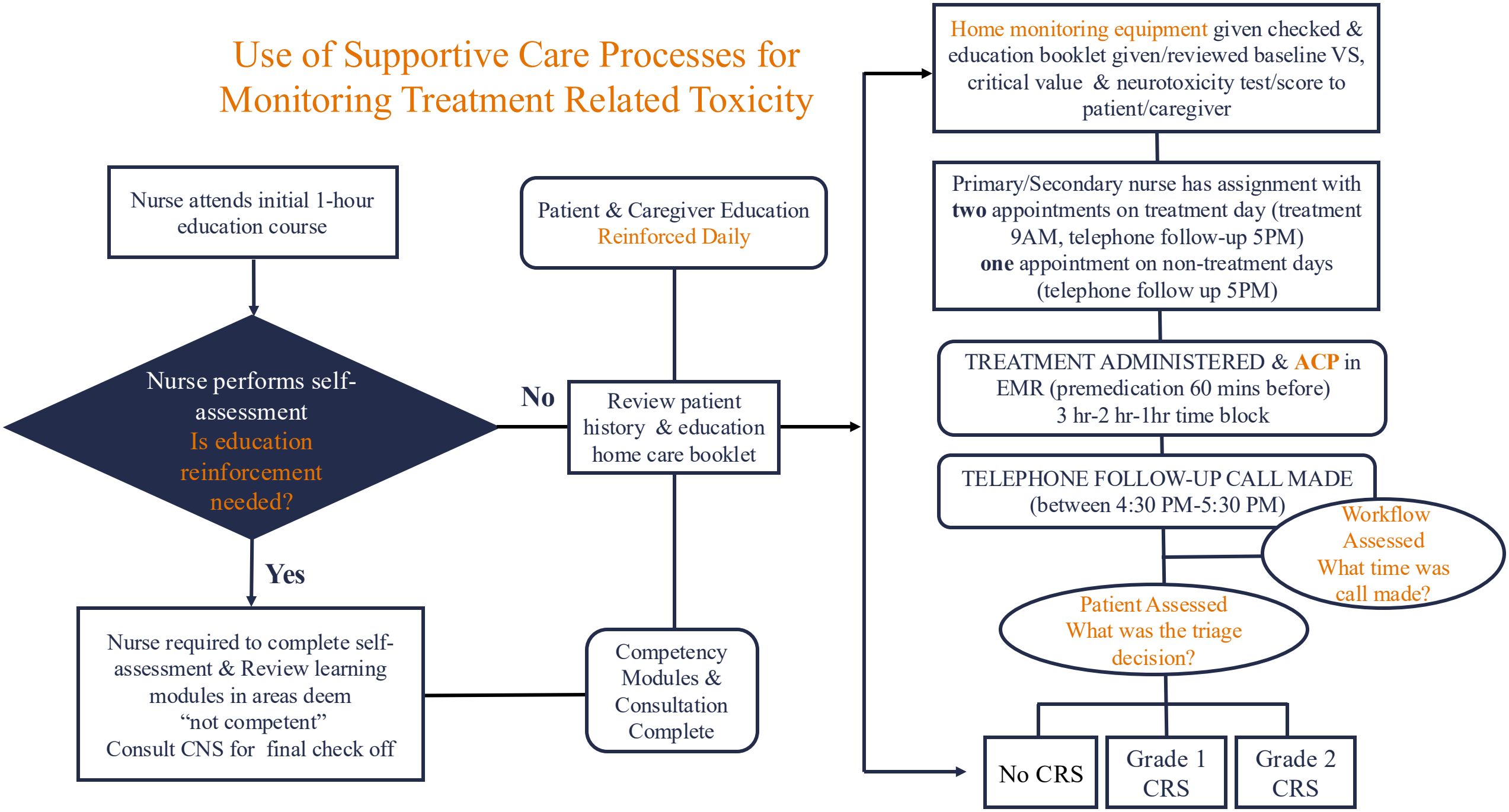
- Treatment and follow-up schedules
- Treatment Urgent and Non-urgent signs and symptoms
- How to perform and document VS and neurological assessments
- Communication with care team

TREATMENT ADMINISTRATION and HOME MONITORING

Treatment Administration	Home Monitoring
▪ 3 dose and 10-day follow-up calls ▪ 4 dose and 12-day follow-up calls ▪ Premedication ▪ Weekday (labs and provider visits)	▪ CRS Temperature, BP, HR, & pulse oximeter ▪ Neurological assessment ▪ Monitor 3 times daily ▪ Who to Call and When (during & after office hours)

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	Day 1 9AM 5PM	5PM	Day 3 9AM 5PM	5PM	5PM	
	Day 8 9AM 5PM	5PM	Day 10 9AM 5PM	5PM	Day 12 5PM	

Use of Supportive Care Processes for Monitoring Treatment Related Toxicity



Use of Supportive Care & Urgent Care Processes

Infusion Nurse Assess Adherence and Reinforce Nurse Guideline with patient and caregiver
Consult with Healthcare Team

Can patient and caregiver demonstrate adherence to Nurse Guideline?

Yes

Continue Assessments
Engagements
Consultations
throughout treatment

No

Evaluate Adherence of Clinical Pathway and Guidelines
Review content in booklet
Monitor workbook use
Reinforce items of concern
Use Teach Back Method
Consult with healthcare team on patient progress

Does Healthcare Team agree to continue treatment in ambulatory setting?

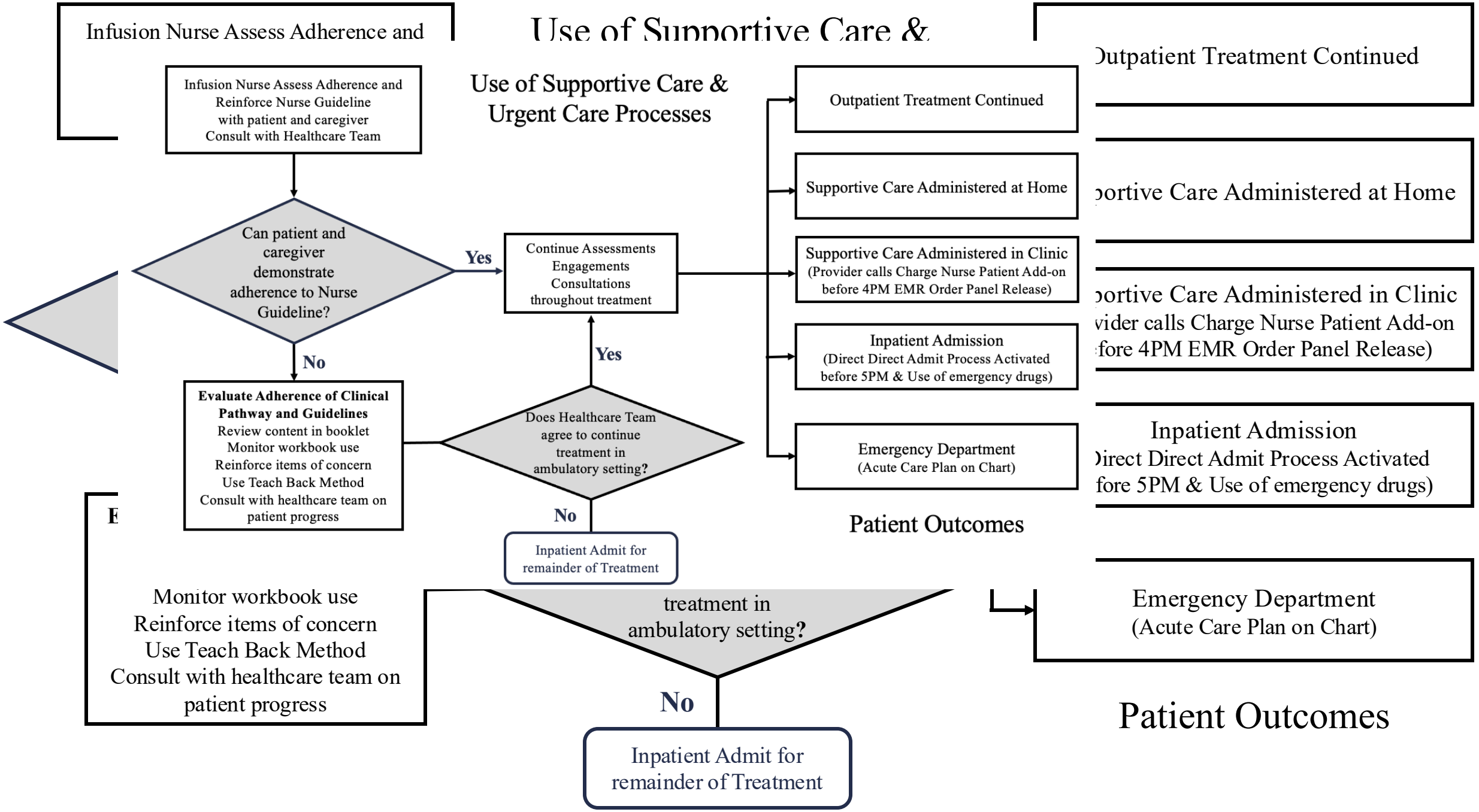
Yes

No

Inpatient Admit for remainder of Treatment

Patient Outcomes

- Outpatient Treatment Continued
- Supportive Care Administered at Home
- Supportive Care Administered in Clinic
  (Provider calls Charge Nurse Patient Add-on before 4PM EMR Order Panel Release)
- Inpatient Admission
  (Direct Direct Admit Process Activated before 5PM & Use of emergency drugs)
- Emergency Department
  (Acute Care Plan on Chart)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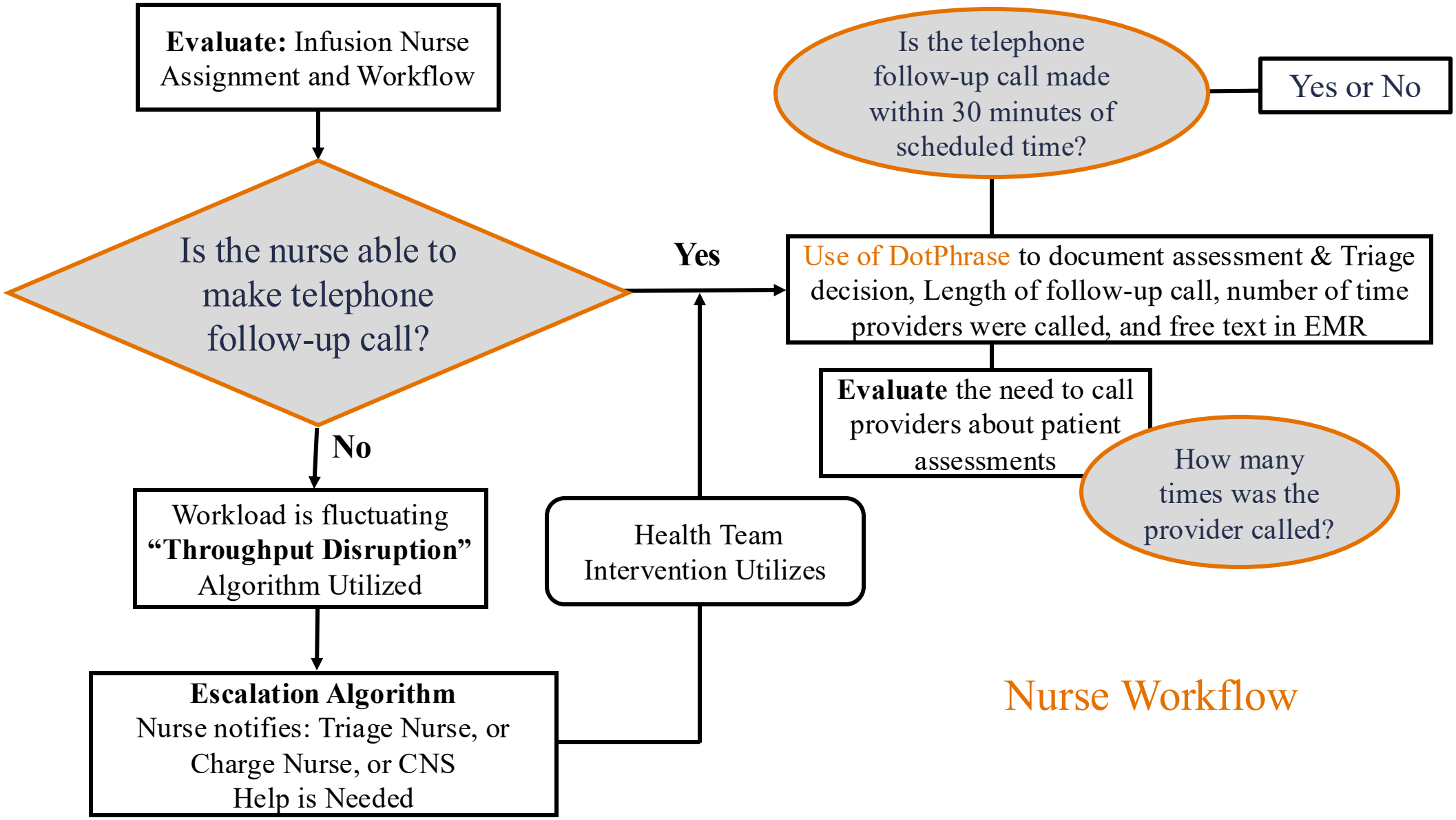
Inpatient Admission (Direct Direct Admit Process Activated before 5PM & Use of emergency drugs)
Emergency Department (Acute Care Plan on Chart)
Patient Outcomes

Procedure for Evaluating Use of Technology & Supportive Care Processes



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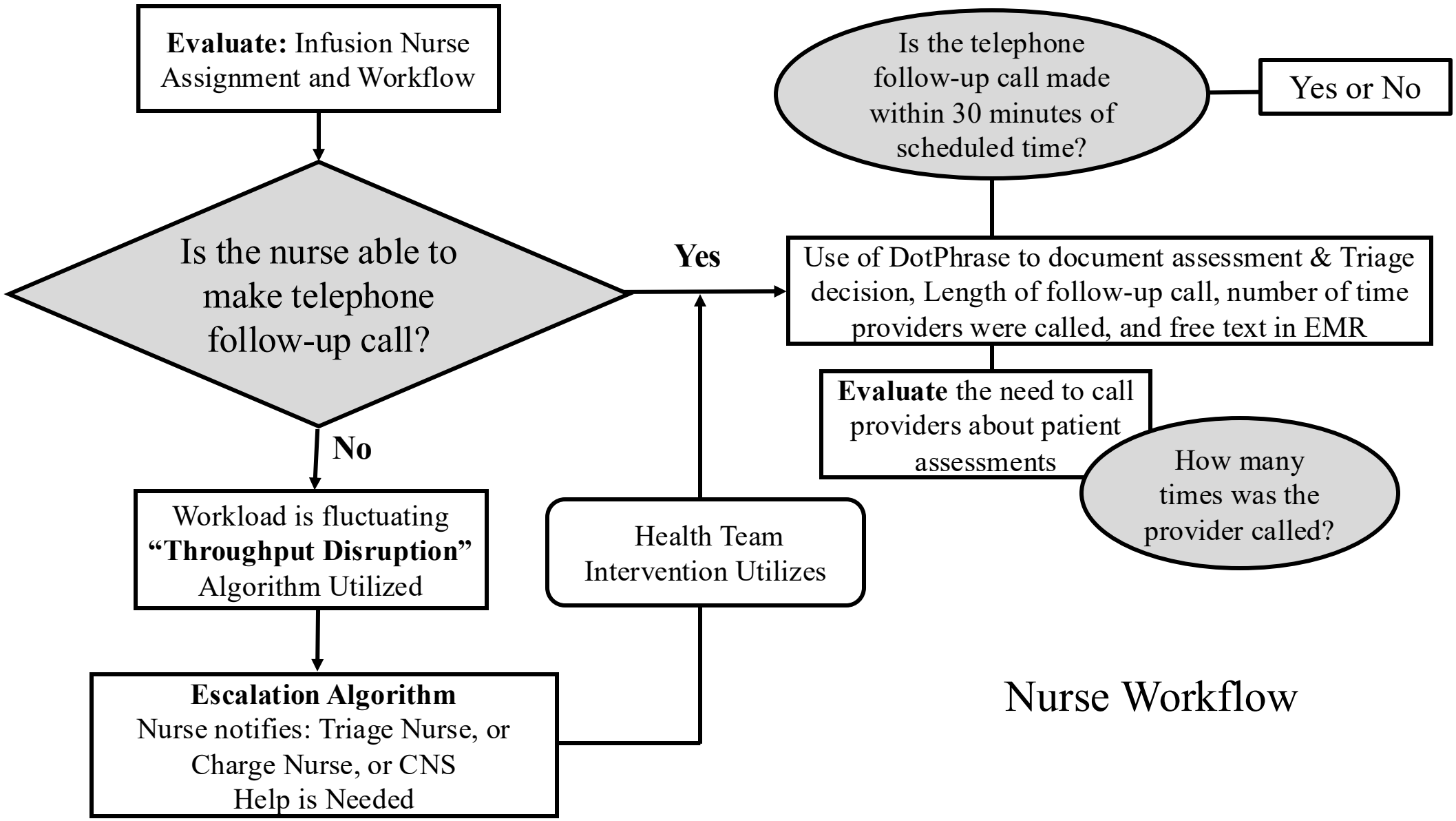


WHAT ARE WE TRYING TO ACCOMPLISH?

IMPLEMENTATION

Project Goal

- Transition bispecific antibody step-up dosing from an inpatient to ambulatory care without compromising safety

Strategy

- Implement a structured **NURSE GUIDELINE** integrated into existing infusion workflows

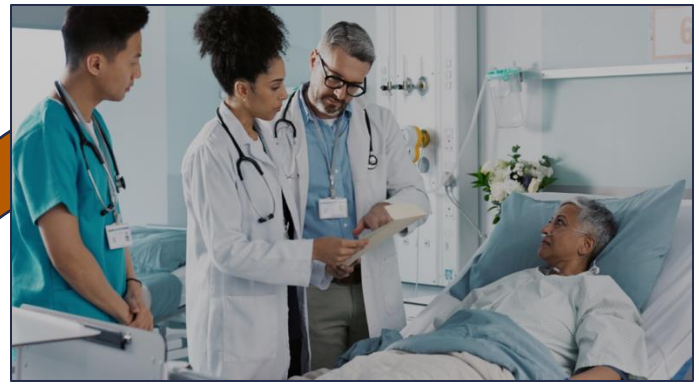
Support

- Leverage nurse-led telehealth follow-up management

Process

- Refine nurse guideline using 4 iterative PDSA cycles with 6 patients

Transition From Inpatient



To Ambulatory Care

CYCLE 1

PLAN
Reduce travel burden & Maintain safety

DO
Flexible scheduling

STUDY
Guideline adherence

ACT
Patient center scheduling

CYCLE 2

PLAN
Sustain nurse preparation for safe practice

DO
Coaching & support

STUDY
Accuracy of grading

ACT
Self-assessment tool

CYCLE 3

PLAN
Facilitate provider awareness

DO
Targeted education

STUDY
Patient Information

ACT
Communication

CYCLE 4

PLAN
Educate research team to promote integration

DO
Guideline reinforcement

STUDY
Adherence evaluation

ACT
Research integration

HOW WILL WE KNOW THAT A CHANGE IS AN IMPROVEMENT?

MIXED METHOD DATA COLLECTION

Data security

- All data recorded in a password-protected spreadsheet on the institution's encrypted server

Quantitative methods

- EMR documentation audits (dot phrase use, CRS/neurotoxicity grading accuracy)
- Systems audit of patient adherence (labs, provider, infusion, telehealth, education)
- Patient workbook audits: home monitoring vs. reported symptom timing
- Nurse education completion and self-assessment tool usage tracking

Qualitative methods

- Nurse debriefings and feedback sessions
- Stakeholder meeting notes
- Patient consultation notes

OUTCOME MEASURES

Toxicity Management

- Percent of nurses completing education, assessments, and competency reviews
- Percent of CRS and ICANS grading accuracy
- Percent of patients adhering to appointments
- Percent of patients reporting critical values at onset

Patient Outcomes

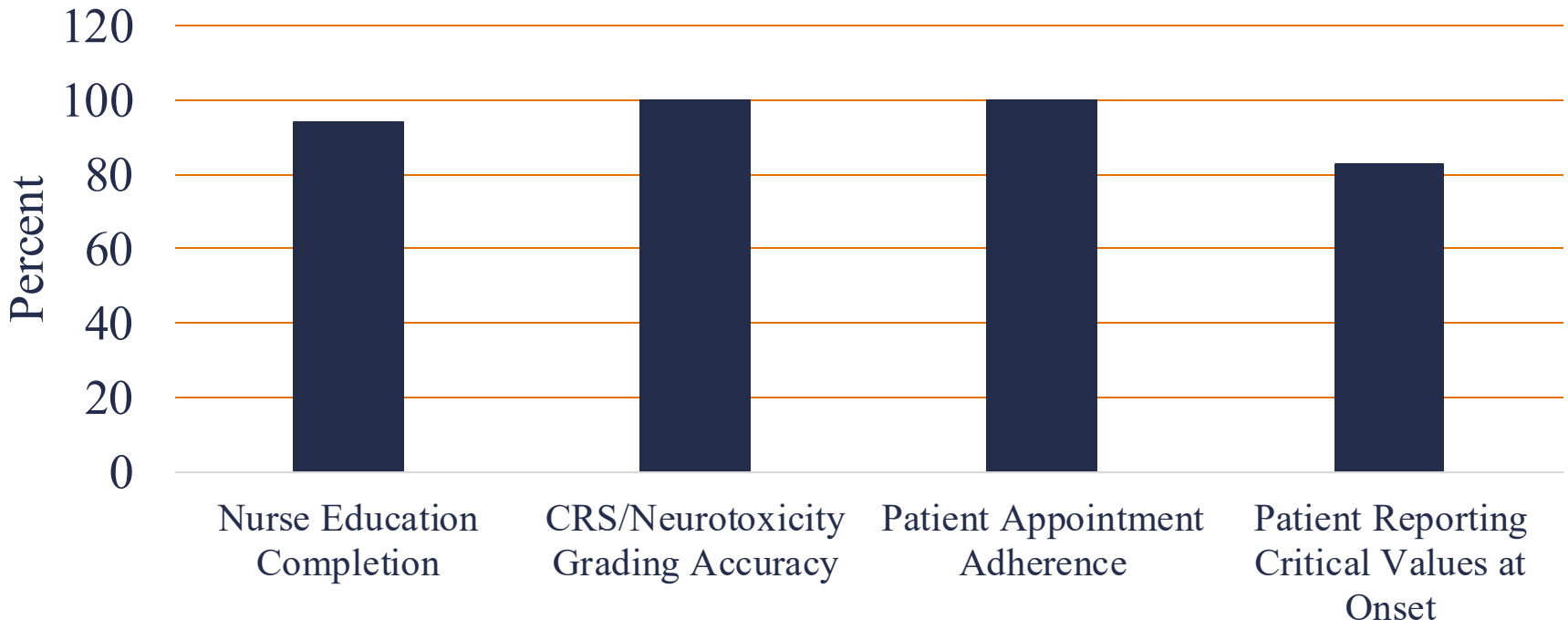
- Days spent outpatient versus inpatient for program-enrolled patients
- Disposition metrics for patients selected for the pilot

Infusion Nurse Workflow

- Percent of follow-up calls completed within the 30-minute targeted timeframe
- Percent of nurses using the workflow escalation algorithm
- Number of times the nurse needed to call the provider based on telephone assessment

RESULTS

TOXICITY MANAGEMENT OUTCOMES



Observed Patient (6 patients)

3 males and 3 females; age range: 50–79

3 commuted daily; 3 used local housing during step-up dosing

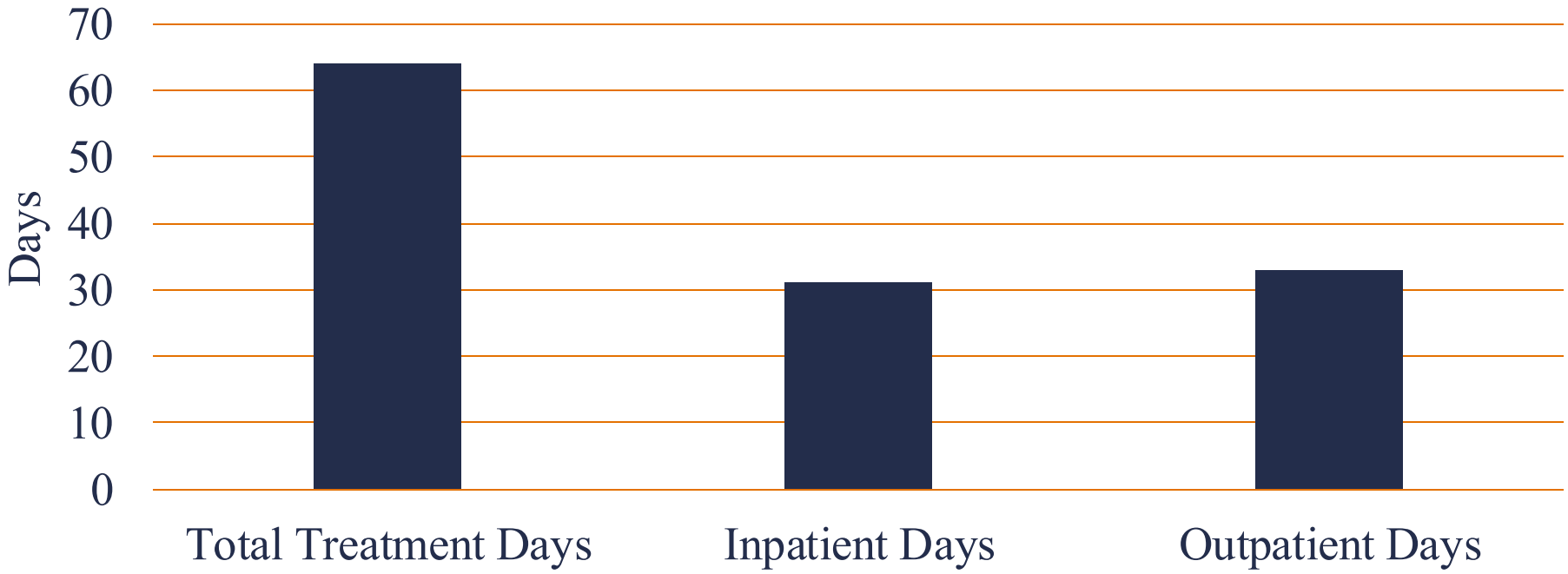
Even split: 3 standard-of-care and 3 research participants

PATIENTS OUTCOMES: DISPOSITION

Patient	Treatment Regimen	CRS Onset (time)	Time from Symptom Onset to Intervention	Patient Disposition		
				Emergency Department	Infusion Clinic Support	Hospital Admission
1	Talquetamab 10 days	NA	NA			
2	Talquetamab 12 days	After 2nd dose (31 hours)	10 minutes		Yes	Yes
3	Talquetamab 12 days	After 1st dose (32 hours)	13 hours		Yes	Yes
4	Teclistamab 10 days	After 1st dose (9 hours 45 minutes)	15 minutes	Yes		Yes*
5	Teclistamab 10 days	NA	NA			
6	Teclistamab 10 days	After 1st dose (30 hours)	30 minutes	Yes		Yes

*Discharged and completed treatment outpatient

TOTAL TREATMENT DAYS by SETTING



2 Patients with 12-day regimen
4 Patients with 10-day regimen
64 Total treatment days

INFUSION NURSE WORKFLOW: Telephone Follow-up

Patient	Nurse Calls /Patient (excludes weekends)	Percent Adherence to Scheduled Call Time (±30 minutes)	Average Length of Nurse Calls (minutes)	Number of Triage Calls to Provider	Use of Clinical Escalation Algorithm
1	8	100	4	0	0
2	4	100	5	0	0
3	3	100	11	0	0
4	4	100	7	0	0
5	8	100	6	1	0
6	1	100	5	0	0

WHAT CHANGE CAN WE MAKE THAT WILL RESULT IN IMPROVEMENT?

Change that will result in improvement

- Focus on changes that directly support frontline nursing practice

- Develop a structured, responsive model to:
  - Safely deliver complex therapies in the outpatient setting
  - Align with real-world workflows, patient needs, and interdisciplinary coordination

Looking Ahead: Ensuring Sustainability

- Requires institutional commitment to:
  - Appropriate nurse staffing
  - Protected time for education
  - Integration into existing operational systems

- Ongoing support needed through:
  - Strong leadership engagement
  - Continued workflow alignment
  - Mechanisms for real-time feedback and adaptation

DISCUSSION

FINANCIAL CONSIDERATIONS

- Project Goal: Deliver comparable care in the outpatient setting
  - Supports institutional efforts to reduce inpatient utilization

- Outpatient delivery may enhance access to care, especially in community settings

- Inpatient settings face financial constraints, including unreimbursed drug waste
  - Medicare DRG models limit reimbursement for high-cost therapies in hospitals
  - Outpatient care may offer greater cost flexibility and improved drug cost recovery

ESTIMATED DRUG COST PER 70kg PATIENT

Drug	GPO Pricing/mg	Step 1 dose/mg	Step 2 dose/mg	Step 3 dose/mg	Step 4 dose/mg
Teclistamab	$47.30	0.06	0.3	1.5	
Elranatamab	$181.10	12	32	76	
Talquetamab	$200.02	0.01	0.06	0.4	0.8

- Estimated cost of inpatient bed stay $4,155.00 per day (Massachusetts average-2022, Kaiser Family Foundation Inflation Calculator0

PRACTICE IMPLICATIONS

- Serves as a model for implementing novel therapies in the ambulatory setting
- Addresses key practice gaps in ambulatory bispecific step-up dosing administration
- Provides a structured, nurse-led approach to safe, scalable innovation

LIMITATIONS

A small number of patient participants

- Reflect early pilot phase implementation
- Provided valuable insight to inform future refinement

Staffing continuity

- Challenge with multiple days of treatment
- Overtime pay to ensure uninterrupted care

DISSEMINATION OF FINDINGS

- Submit a process-focused abstract to the Oncology Nursing Society Congress
- Prepare a manuscript to the Clinical Journal of Oncology Nursing
- Upload to Libra – poster, presentation, and manuscript

CONCLUSION

- Developed and implemented a nurse-led guideline
- support the safe outpatient administration
- Demonstrated feasibility, safety and strong nursing engagement

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