PRACTICAL IMPLEMENTATION OF THE CARTOX APPLICATION USING SIMULATION IN THE CLINICAL ENVIRONMENT

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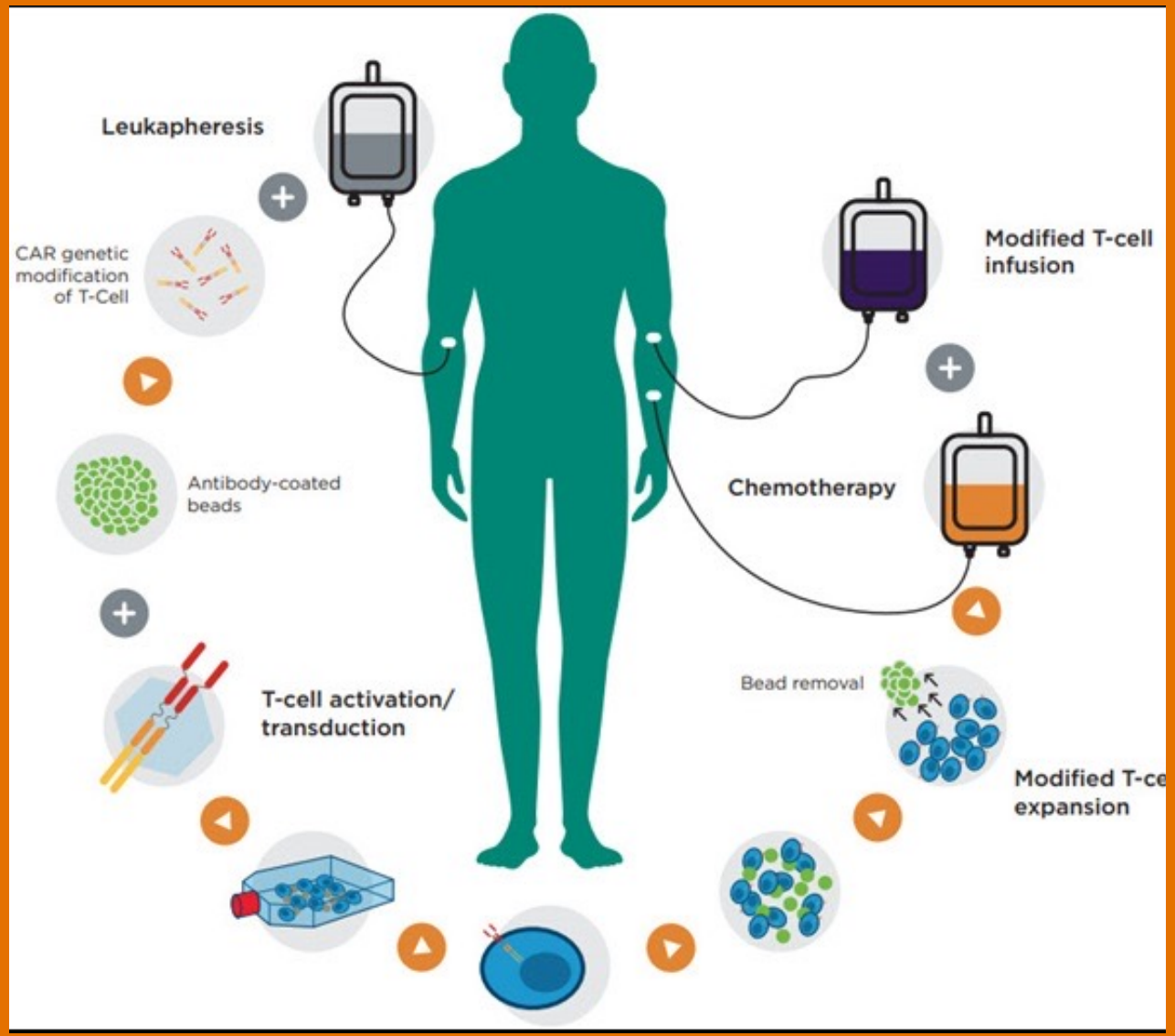
BACKGROUND

- Immunotherapy as a treatment modality have restored hope across multiple medical specialties of chronic, progressive, and even terminal medical conditions.
- Chimeric antigen receptor T cells (CAR-T) is no exception; while lifesaving, this comes with the potential for severe symptoms that could be lethal and can add to significant cost to patients and institutions.

(Lee et al., 2019).

HOW CAR-T WORKS



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BACKGROUND CONTINUED

Cytokine release Syndrome (CRS)

- Systemic inflammatory response caused by the release of inflammatory cytokines.
- Spectrum of clinical features from fevers to multiorgan failure.
- Presents similarly to sepsis; Where sepsis may have clinical manifestations of CRS, it does not require the same first line treatment.

Immune Effector Cell Associated Neurotoxicity (ICANS)

- Encephalopathic state with a presentation that can range from mild tremors to seizures and loss of consciousness (LOC).
- Early subtle signs are diminished attention, mild aphasia, and/or handwriting changes.
- Delayed ICANS

PROBLEM DESCRIPTION

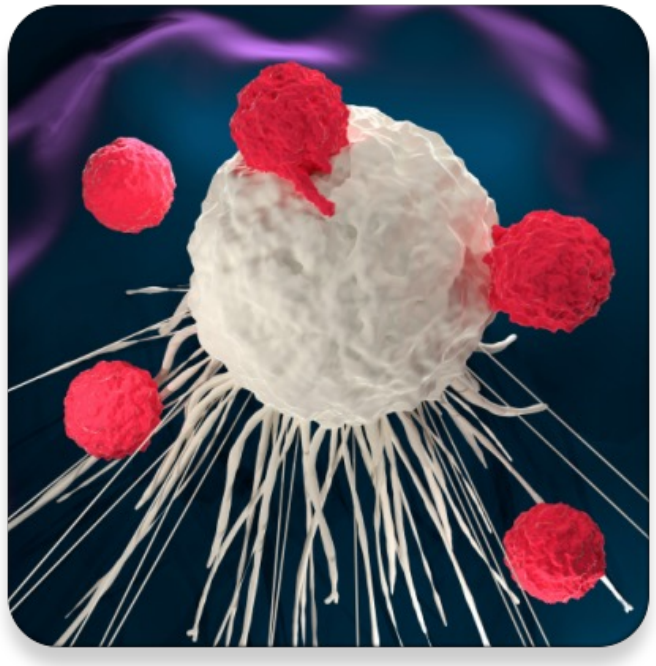
Global: Toxicity

- CRS can occur up to 70.0% patients
  - 18.0% CRS grade 3-4
    - IL6 blockers and/or IV Steroids
  - The median time to CRS onset is ~ 5 days (range, 1-12 days).
  - Neurotoxicity typically occurs ~20.0% patients
  - Neurotoxicity is also associated with high-grade CRS and high-disease burden.

(Shah, et al., 2021)

PROBLEM CONTINUED

- Early recognition and intervention systems are key components in preventing adverse outcomes (Lee et al., 2019).
- One such system designed to aid with toxicities is the CARTOX™ mobile application.



CLINICAL PROBLEM

Patients receiving CAR-T therapy are at heightened risk for the development of potential lethal toxicities. Variation in identification, grading and treatment of these toxicities, amongst healthcare providers, can impact overall severity of these complications. In addition to potential lethal toxicities, cultural barriers exist within the healthcare environment which further dissuade the use of clinical decision assistive devices such as the CARTOX™ app.

REVIEW OF LITERATURE THEMES

- Healthcare culture
- Availability and useability

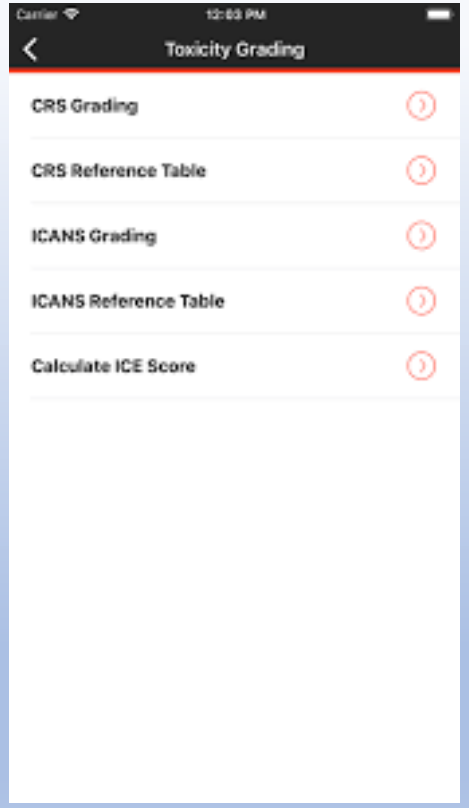
ROL SUMMARY

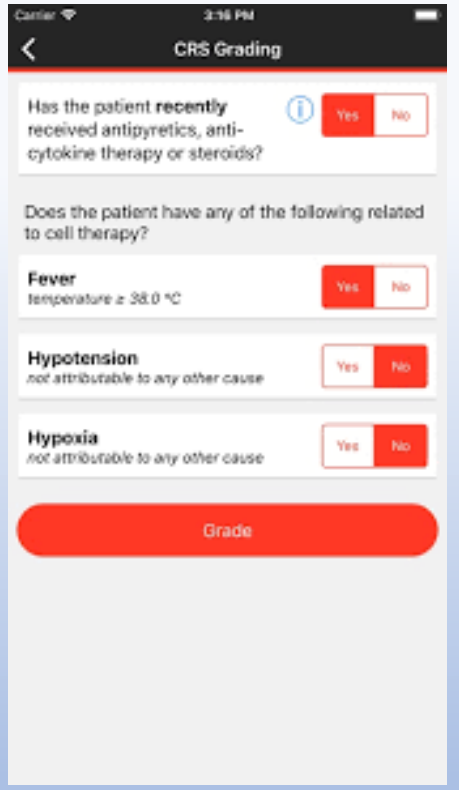
- Most applications are geared towards education versus assistive decision tools
- Clinicians tend to avoid adoption and utilization of APPs due to healthcare culture
  - One way to combat this to improve user friendliness "usability"
- Simulation proven effective educational tool

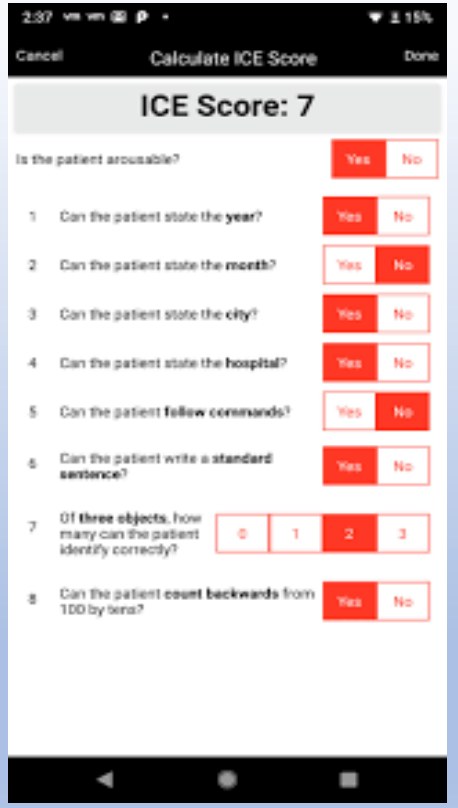
INSTITUTIONAL REVIEW BOARD DETERMINATION AND ETHICAL CONSIDERATIONS

- IRB process
- Multidisciplinary – all HCP that care for IEC patients are invited to participate
- Include all IEC patients
  - Maintain patient confidentiality
- Beneficence: Benefits the patient by providing providers with the tools to effectively and safely care for patients
- Bias: reducing bias by standardizing the process.

CARTOX APP





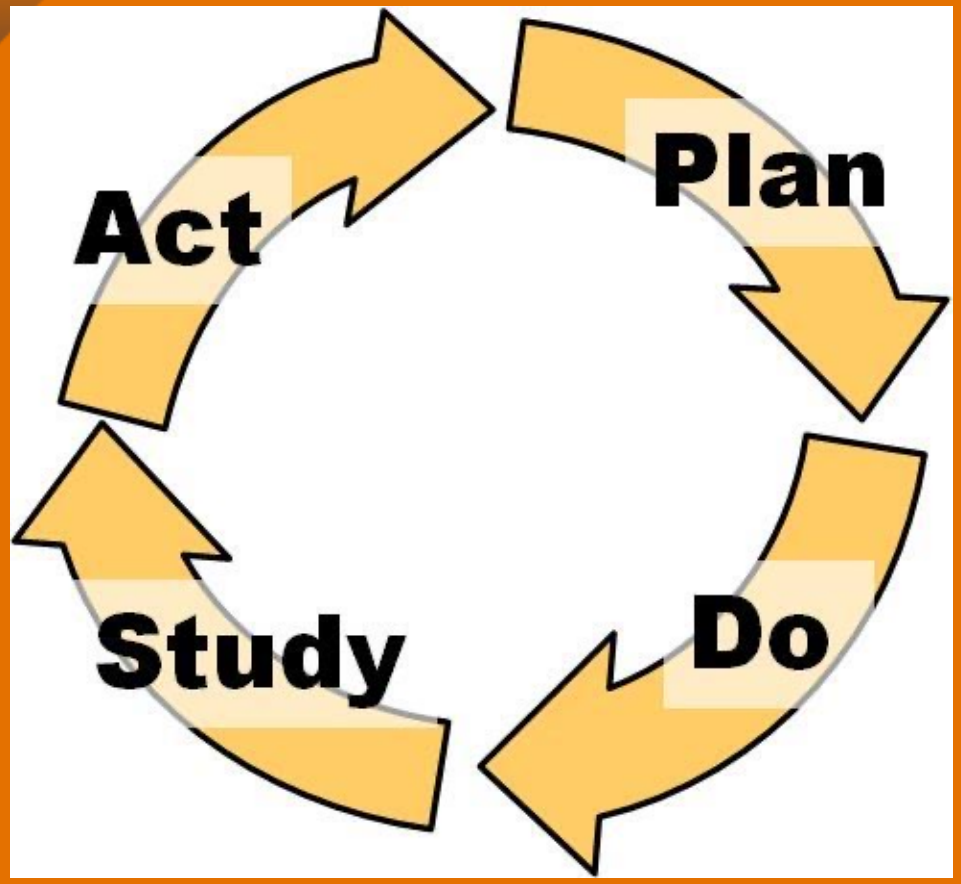


- Developed by Sherry Adkins, RN, MSN, ANP-C

PROJECT PURPOSE

To determine if the use of the CARTOX™ mobile application within a simulation environment improves recognition, grading and intervention compared to current/standard practice for Health Care Professionals caring for patients receiving CAR-T therapy.

QI PDSA CYCLE



- **Plan:** Describe the problem, the objective of the test and a description of:
  - Who, what, when and where changes are involved.
- **Do:** Carry out the test, document results and any problems.
- **Study:** Analyze the results, compare them to the objectives and decide on next steps.
- **Act:** Modify or refine the change and plan for the next cycle.

Repeat this cycle as necessary

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Belson, 2016.

PLAN

- **WHO:** Health Care Professionals (HCP) caring for IEC patients.
- **WHAT:** Recognition, accuracy of grading and timeliness of intervention
- **WHEN:** Simulation completed October 2022 with EMR review January 1, 2022, through January 30th, 2023
- **WHERE:** NCI Designated Cancer Center within an academic medical center in the Southeastern United States

DO

- **Consider clinical question**
- **Intervention**
  - 6 simulations were conducted in the clinical environment with CARTOX™ application demonstration/in-service.
    - 3 simulations in the infusion center
    - 3 simulations in the inpatient unit
  - Medical Record (EMR) review of IEC patients between January 2022-January 2023 pre and post simulation
  - EMR note template created to use in documentation for trained HCP on CARTOX™ app.
- Emailed all participants following simulation

STUDY

- **Analyze and compare results:** Conducted pre (n=17) and post (n=6) simulation EMR review examining timeliness of recognition, accuracy of grading and timeliness of intervention.
- EMR note template was created to use in documentation for trained HCP on CARTOX™ app.

STUDY: RECOGNITION

- Based on the data captured fever was the primary presenting symptom to indicate possible toxicity. In both pre (n=17) and post (n=6) EMR review 100% of cases that presented with fever, a neutropenic fever work up was initiated along with supportive care.

Presenting symptom	Pre-Sim % (n=17)	Post-Sim % (n=6)
Fever (CRS)	76% (n=13)	83% (n=5)
AMS (ICANS)	12% (n=2)	0% (n=0)
None (no toxicity)	12% (n=2)	17% (n=1)

STUDY: GRADING

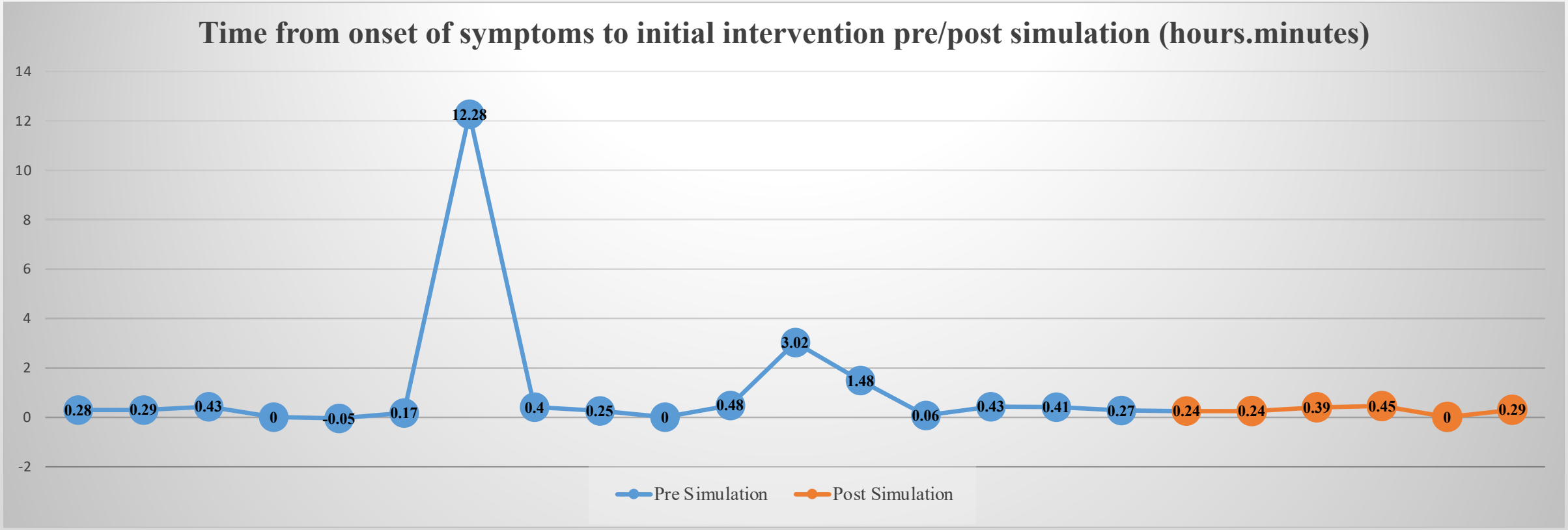
- Grading was accurate throughout both the pre and post EMR review. The toxicity grading was validated and verified by the Primary Investigator (PI) using the ASTCT consensus grading and the CARTOX™ app.

Grading	Pre-Sim % (n=17)	Post-Sim % (n=6)
Grade 1→2	38% (n=5)	83% (n=5)
Grade 1-2→3-4	8% (n=1)	20% (n=1)
CRS→ICANS	65% (n=11)	80% (n=4)

STUDY: TIMELINESS TO INTERVENTION

- When evaluating the timeliness to intervention, the PI examined how much time elapsed between recognition (onset) of symptoms to time of first intervention (medication administration, supportive care, consults and imaging).
- Typical medications utilized include acetaminophen, intravenous fluid bolus (IVF), IL6 blocker and/or IV steroids.

STUDY: TIMELINESS TO INTERVENTION



	Pre Simulation	Post Simulation
Average	1.35	0.32
Median	0.40	0.29
Min	0.00	0.24
Max	12.28	0.45

TRAINED HCP POST EMR

Patient	Attending / MD	Principal Investigator	APPs (NP/PA)	Nurses (RN)
Patient 1	X	X	X	X
Patient 2	X	X	X	X
Patient 3	X	X	X	X
Patient 4	X		X	X
Patient 5		X	X	X
Patient 6				X

ACT: STRENGTHS & LIMITATIONS

Strengths

- Decreased facility cost
- Improved patient outcomes
  - Decreased length of stay (LOS)
- Usability/accessibility

Limitations

- Organizational change
  - Vocera® paging system
  - Personal cellphone
  - Staffing shortage
- Availability (unavailability) of HCPs to attend simulations
- Healthcare culture

CONCLUSION/IMPLICATIONS FOR PRACTICE

- Simulation in combination with app is effective
- Sustainability: Continue simulation sessions and education on the use of the CARTOX™ app.
  - Integrate into the onboarding process for all new HCP hires.
- Ambulatory CAR-T Program:
  - Template for the patient caregiver educational program
- Data gathering
  - Validate through improved patient outcomes.
- Adds to the body of evidence

COST ANALYSIS

- CAR-T infusions for the first half of FY22 resulted in a small loss of ~$50K. This loss was driven primarily by a noncommercial insurance payers.
- Enhancement of early recognition, accurate grading of toxicity and timeliness of intervention will ultimately reduce complications length of stay (LOS) and admissions.
- CARTOX™ app is free to download and use; managed by MD Anderson.

DNP SCHOLARLY PROJECT TEAM

- **Advisor:** Dr. Regina DeGennaro, DNP, RN, CNS, AOCN, CNL
- **Second Reader:** Dr. Beth Quatrara, DNP, RN, CMSRN, ACNS-BC
- **Practice Mentor:** Dr. Indumathy Varadarajan, MD
- **DNP Mentor:** Dr. Elizabeth Lester, DNP, RN, MSN, AGACNP
- **RN Coordinator:** Glenda Royael, RN
- **RN Coordinator:** Jessica Brandt, RN

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  UVA Health, UVA School of Nursing
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  UVA Health

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