Moffitt’s ICE-T fuels CAR-T Infrastructure Execution for Commercial Launch

Ramona Repaczki-Jones, MS, Performance Improvement Director;
Fred Locke, MD, Vice Chair/Interim Chair,
Taiga Nishihori, MD, Associate Member;
Scott Eldredge, MBA, MHA, Division Administrator
Claudio Anasetti, MD Senior Member

Moffitt Cancer Center
Blood and Marrow Transplant and Cellular Immunotherapy
ICE-T: Immune Cell Therapy Medical Service

Initial State:
- Borrowed resources from BMT to start ICE-T
- Projected the need for commercial CARs
- Moffitt’s support

Growth in Blood and Marrow Transplant and Cellular Immunotherapy Program

Current State:
- ICE-T: separate service from BMT
- Team: Inpatient/Outpatient Attending Physicians, APPs, RNs, Pharmacists and other support services dedicated to ICE-T
  - Physicians: 46% BMT CI / 46% Malignant Heme / 8% Medical Oncology

Growth:
- Physicians: + 5 / APPs + 10 / PharmD + 1
- BMT CI Treatment Center spaces + 6 / Apheresis spaces + 3

Physician Leadership:
- Dr. Anasetti and Dr. Locke: Journal for Immunotherapy of Cancer: Transplanters drive CARs to the clinic by brewing ICE-T: the Moffitt roadmap
Moffitt’s Blood and Marrow Transplant and Cellular Immunotherapy Program

BMT Service: ~430 transplants/year

- 17 physicians representing ~ 11CFTE / 26 APPs / 8 Pharmacists
- Clinic and Treatment Center:
  - 18 transplant nurse coordinators; 20 treatment center RNs; 8 medical assistants; 3 clinic RNs; 2 medical office assistants
- Apheresis unit: 5 apheresis practitioners
- Inpatient unit: 36 beds; 100+ RNs

Accreditation

- Compliance with the FACT standards for hematopoietic cellular therapy (HCT) and immune effector cells
- Integrated the CAR-T needs into our BMT standard operating procedures (SOPs) and guidelines when possible, as well as created new ones to address specific CAR-T needs:
  - Management of CRS and Neurotoxicities
  - Patient Selection for CAR-T
  - Evaluation and testing for CAR-T Therapy
  - Commercial CAR-T Overall Process
  - Documenting CAR-T therapy and placing orders
  - Adherence to REMS for commercial CAR-T
Axicabtagene ciloleucel (Yescarta™) and Tisagenlecleucel (Kymriah™) Preparation

- Matrix team approach
  - Clinical, quality, data management, information technology, project management, scheduling, financial, revenue integrity, legal, corporate compliance, cybersecurity

- Built on BMT experience
  - Workflow, documentation, and electronic ordering approach

- Site readiness
  - Great synergy between cellular therapy laboratory, apheresis, and clinical domains
ICE-T New Documentation

- Consult Note
- Outpatient Progress Note
- Re-Evaluation Note
- Inpatient Progress Note
- Discharge Summary
- Cell Toxicity Note
- Apheresis procedure note to support BMT and ICE-T
Goals of ICE-T Documentation

- Discrete documentation of key data elements to facilitate CIBMTR reporting, operation analyses, regulatory reporting
  - type of therapy, detailed chemo by day, CRS, neurotoxicities
  - collection data in the apheresis documentation

- Use of smart templates to import known data elements from other areas in the EHR
  - Infusion date, consent date

- Strategies to reduce physician time
  - imbedded algorithm calculations: parts of CRS and neurotoxicities grades driven by symptom selection
  - accessible grading references in the note, one click away
  - display of previous CRS and Neurotoxicity grades
REMS: Risk Evaluation and Management Strategy

- Unexpected requirement brought by commercial CAR-Ts
- Clinician driven consensus on creating SOPs to drive reportable adverse events
- Reporting to CAR-T vendors
  - Harnessed the power of ICE-T documentation and EHR
Electronic Orders in Cerner™

- Workup power plan
- Admission power plan
- Transitioning from Inpatient to Outpatient power plan
- Chemo plans for Yescarta vs. Kymriah
- Outpatient follow up power plan
Design Strength of Electronic Orders

- Multi phase power plans to support multi-disciplinary approach
  - Many of the power plans have 3 phases
  - Separation of scheduling appointment orders, MD decisions, nursing orders

- Development of a quality infrastructure to empower clinical teams to work at the top of their license
  - MD to initiate power plans and allowing the nursing staff to place orders ‘by protocol’ per standard operating procedures

- Matrix approach to achieve a solid scheduling infrastructure to support:
  - Accurate scheduling of BMT and ICE-T appointments when sharing similar location and provider resources
  - Creating an environment to seamlessly update physician templates to reflect appointments from separate services

- Sustain discrete data elements for future interfaces
Workflow Optimization

- Modeled after the BMT approach, to standardize the commercial CAR T process for Yescarta and Kymriah

- Involvement of Moffitt wide teams to secure handoff of processes
  - Clinical teams
  - Financial authorization/Reimbursement/Revenue Cycle
  - Schedulers
  - Risk Management
  - Information Technology
  - Data Management

- Standard operating procedures and algorithm development to maintain consensus on the process which contains many moving parts
Data Management

- Information technology resources: mapping, analysis, development of the 4000 forms [4000; 4100; 4006]
  ∞ 1807.9 hours

- Data management resources: mapping, testing, analysis
  ∞ 195 hours

- Status: 4000 r2, 4100 r1, 4006 r1 mapped in the database, not agnis-ready yet
  ∞ Ongoing preparation to update with the latest revision from CIBMTR
Data Management Challenges

- CIBMTR forms maintenance
  - Projections of upcoming form changes

- Multi-functional resources
  - Recruiting staff who understands the BMT and Cellular Immunotherapy domain information plus information technology

- Culture shift
  - Expand beyond maintaining CIBMTR data needs, to embracing the operations, quality, and research data needs
Next Steps

- Interface development
  - Harness the discrete data elements available in the electronic health record, completed by providers, into the data repository which submits to CIBMTR, and provides reporting for operations, quality, and research needs

- Adaptability to embrace change management
  - Develop data strategies to fluidly embrace upcoming changes in BMT and cellular immunotherapies
    - IT roadmap
    - Execution of interoperability initiatives
      - Visibility of successful deployments
      - Vendor expectations

- Reporting and analysis
  - Data reporting professionals skill set, to be added to the data management team
Thank you

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It took a large village to accomplish the launch of Axicabtagene ciloleucel (Yescarta™) and Tisagenlecleucel (Kymriah™).

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