Practical Implementation of Nursing Science

A Refined Approach to Onboarding CAR-T and Cellular Therapy Products: A Learned Experience

PUBLISHED ABSTRACT

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Background: Chimeric antigen receptor T-cell therapy (CAR-T) is a groundbreaking commercially available therapeutic option for advanced lymphoma, leukemia and, most recently, multiple myeloma. Since 2017, our institution has onboarded six Food and Drug Administration (FDA) approved CAR-T products with varying requirements for administrative and training milestones. The process for onboarding CAR-T therapies was not well defined and presented challenges with regard to learning program requirements in real time, onboarding multiple therapies simultaneously, depending on external agencies and manufacturers for guidance, synchronizing program resources, and communicating with stakeholders and staff.

Intervention: Driven by the Plan Do Check Act (PDCA) change model, between 2019 and 2021 we reviewed current process, performed a key stakeholder analysis, a crosswalk analysis with vendor and regulatory body requirements, and identified key program implementation milestones.

Findings: We developed a framework that leads with a kickoff meeting, then company portal training, apheresis and cellular therapy lab training, product review and product administration, dry run, activation meeting, authorized representative training for Risk Evaluation Mitigation Strategy (REMS), and hospital REMS launch. Each milestone has a recommended initiation period relative to FDA approval, estimated duration, description of content and resources, and required program participants. With this framework, we have reduced our center's time from FDA approval to activation from 1,090 days to 8 days (99%).

Implications: Our methodical approach resulted in a standardized blueprint for future cellular therapy products by defining our center's timeline and resources to external vendors. This has also lessened wasted resources and unexpected delays prior to FDA approval (e.g., meetings, document management, and refresher trainings), allowing the program to focus more on patient care. Most importantly, our initiative has achieved quicker site activation, which allows patients to gain more expeditious access to groundbreaking curative products.

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COMPETING INTERESTS

The authors have no competing interests to declare.

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