

Structuring and strategic planning for the NIH transplant and cell therapy (TCT) clinical program

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Background: The intramural research program of the National Institutes of Health (NIH) spans basic, translational, and clinical research across 27 Institutes/Centers. All clinical research is conducted at the Clinical Center, a research hospital with 200 inpatient beds, 93 day hospital stations, and many outpatient clinics. All patients are enrolled on research protocols and are not billed for care. Protocols developed by principal investigators (PIs) are scientifically reviewed, resourced, and staffed by the Institute, with the support of Clinical Center staff. Blood and marrow transplant and cell therapy (TCT) research is distinct in that PIs across multiple Institutes (NCI, NHLBI, NIAID) have TCT protocols, staffed by multiple institute or branch-specific inpatient ward services. The lack of a consolidated program led to inefficiency, missed opportunities for quality improvement, inconsistent depth of scientific review, mismatch between the number of trials open and floor capacity, and lack of unified scientific vision or direction. I embarked on a project to complete the restructuring and consolidation of the TCT program, laying the groundwork for future strategic planning. Specific objectives were to develop and implement 1) program-wide scientific review, 2) program-wide morbidity and mortality, 3) a process for real-time monitoring of program metrics.

Methods/Approach: 1) create a leadership team, 2) complete merging of the clinical services, 3) stakeholder interviews, 4) data-gathering on past trends, 5) develop processes for program-wide activities, communicate, get buy-in, 6) measure process metrics of scientific review and morbidity and mortality conferences before and after new process implementation, 7) define metrics for a program dashboard.

Results: The leadership team was established by creating a Medical Director role which I took on in December 2021, creating a new role, Chief of Donor Services and Quality, filled in May 2022, and expanding the role of the Chief of Operations. The clinical services were fully merged into 2 adult clinical services each with a disease-based focus and a consolidated pediatric service. A new process of scientific review of TCT protocols that aimed to capture PIs previously outside the program was implemented September 2022 and now captures 100% of new protocol and significant amendment reviews. A new process for joint morbidity and mortality was instituted January 2023; 3/13 deaths in 2022 meeting criteria for review not previously captured have been reviewed to date. I established a mechanism for program leadership to be alerted of new deaths via notification by the IRB. We have identified critical metrics for the dashboard, both extractable directly from the EMR and by other means.

Future directions/impact: Having established program-wide activities supporting scientific and safety review, I plan to develop further then implement the dashboard, use it to conduct periodic assessments of trial volumes, and match to floor capacity. As the program matures, we will plan a scientific retreat to discuss the scientific direction of the program and opportunities for synergy and collaboration. This cross-institute, NIH-wide program is unique at the Clinical Center and can serve as a model for other research areas whose efficiency and impact would benefit from similar consolidation.