The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) conducts over 460 clinical trials. These trials are conducted by 101 individual research staff in 13 programs across 3 campuses.

The HDFCCC previously estimated workload based on patient accrual and/or the average percentage of data that was completed each month by Clinical Research Coordinators (CRCs). These estimates did not account for the complexity of a clinical trial.

This project aims to develop and implement the Ontario Protocol Assessment Level (OPAL) Tool originally developed by Smuck, et al., (2011) to address inadequate staffing in the Hematologic Malignancy Research Program (HMRP) at UCSF’s HDFCCC.

The HMRP was selected to pilot this project as the program struggled to meet and maintain HDFCCC’s goal of 85% monthly data completion due to the fluctuations in patient accruals onto their complex clinical trials.

Goals

The goal of this project was to:

- Develop and implement a workload assessment tool referencing the OPAL model developed by Smuck, et al., (2011).
- Provide each Clinical Research Manager (CRM) with a monthly cumulative HDFCCC OPAL score for their staff. This would allow the CRM to determine a minimum and maximum workload that can be assigned to a CRC and proactively identify staffing needs.

Results

The HMRP’s cumulative HDFCCC OPAL score ranged from 847-1091. The average monthly HDFCCC OPAL score per CRC ranged from 107-150.

After implementation of the HDFCCC OPAL Tool in February 2018, the HMRP effectively used the HDFCCC OPAL scores to assign CRCs a workload that allowed the program to consistently maintain their data completion percentage of 85% or more from March 2018 through December 2018.

Conclusions

This pilot project demonstrates that the OPAL tool can be developed and implemented to evaluate the varying complexities inherent to staffing clinical trials. The application of the HDFCCC OPAL tool allows CRMs to identify the workload required for a clinical trial and make staffing adjustments proactively in order to ensure all trials are audit-ready.

Reference