Project Title: Assessment of operational structures, workload and role groups in a research clinic. **Name and Institution**: Irini Sereti, MD, MHS, National Institute of Allergy and Infectious Diseases (NAIID), National Institutes of Health (NIH).

Collaborators and Mentors: Beth Grace, Contractor and Dr H. Clifford Lane, Clinical Director NIAID. **Topic Category**: Research.

Background and significance: The HIV research clinic (OP-8) was established at the dawn of the AIDS epidemic to support cutting edge clinical, translational and basic HIV research conducted by the Laboratory of Immunoregulation (LIR) and Critical Care Medicine Department (CCMD) at the NIH. Over the past decade, the research scope of LIR/CCMD has expanded beyond HIV and three additional groups started operating through the same clinic. Principal investigators (PIs), trainees and research nurses are under NIAID and CCMD leadership; case managers and treatment room nurses are under the Clinical Center Nursing department (CCND). The addition of new groups increased regulatory requirements and an expanded scope of research into parasitic diseases, influenza, Ebola and COVID-19 increased nursing staff workload and required steep learning from clinic staff. These changes impacted the overall identity of the clinic with added challenges due to different operational styles of research protocols and groups and a post-pandemic nursing staff shortage. Nursing management capped case managers workload which in turn led to shifting of tasks, role confusion and a higher workload for other role groups including the study coordinators (NIAID/CCMD research nurses with protocol-specific responsibilities). Staff shortages and COVID-19 initiatives have also resulted in uneven work distribution. Combined with a post-COVID desire for more telework and a new hospital scheduling process, this has led to lower job satisfaction for many, including PIs, and higher staff turnover.

<u>Objectives:</u> Assess operational structures, workload and role definitions in OP-8.

Methods:

- 1. Communication/meetings with main stakeholders: leadership of various labs/groups, PIs, study nurses, case managers, CCND management.
- 2. Assembly of task force with representation of all role groups to assess current operational structures, role definitions (swim lanes), existing workload and distribution.
- 3. Involvement of outside consultant to facilitate processes, meetings of task force and survey preparation.
- 4. Surveys to probe areas of job dissatisfaction, what "success" looks like, what metrics can be used now and moving forward, to measure success.

Results: Clinical leadership of LIR/CCMD met in 2022 and agreed on the need for operational assessment, research prioritization and redefinition/optimization of staff roles. A task force was assembled representing all role groups. A critical case manager shortage in January 2023 necessitated establishment of a "tiger team" that met over a month's period and delivered recommendations for immediate implementation to provide additional support to the areas of scheduling of complicated research visits (shifting task to trainees) and documentation (shifting task to licensed providers), to avoid decreasing research activities.

The taskforce of OP-8 (TACL) has so far met 7 times and will continue to meet while a survey, that is currently being prepared, will be distributed to the wider clinical group.

<u>Conclusions:</u> An expanded research focus, changes in leadership, complexity of new systems, and post-pandemic fatigue have created challenges that require reassessment of the vision and identity of our research clinic as well as the operational paradigms and role definitions. Staff turnover, job satisfaction and productivity (new protocols, number of visits) will be important metrics to follow. A need for strategic planning is emerging.