

Thrombosis and Hemostasis Societies of North America

Travel to a Mentor Award

Awardee: Arash Mahajerin, CHOC Children's Specialists (CHOC)

Mentor: Neil A. Goldenberg, Johns Hopkins All Children's Hospital (JHACH)

Travel Period: 4/22/18 – 4/28/18

Summary

I have been working with Dr. Goldenberg since 2012 on various pediatric thrombosis-related endeavors. He has been an excellent mentor and has successfully guided my primary research project, The Children's Hospital-Acquired Thrombosis (CHAT) Registry. In brief, the CHAT project has three key phases:

Phase 1: A retrospective case/non-case cohort to identify independent risk factors for pediatric hospital-acquired thromboses and develop a risk-prediction algorithm

Phase 2: A prospective cohort study to validate the Phase 1 risk-prediction algorithm with a bio-banking pilot (see below)

Phase 3: A randomized, controlled trial of prophylaxis measures for those identified as "high risk" from our validated risk-prediction algorithm

During my week at JHACH, we focused three key objectives:

1. Discuss establishment of a bio-repository aspect to the CHAT project Phase 2
2. Learn the building blocks of setting up an investigator-initiated clinical trial (Phase 3)
3. Explore new research and collaborative ideas

In addition, I spent a half-day in clinic with Dr. Goldenberg, gave a case presentation on a challenging thrombosis patient of mine, and gave an hour-long presentation on the CHAT project to the entire JHACH research division.

Details regarding the three key objectives below:

1. Discuss establishment of a bio-repository aspect to the CHAT project

While at JHACH, I spent time touring the biorepository and spent two separate one-hour sessions with the manager of the bio-repository in which we reviewed: working study design and goals for the biorepository aspect, sample requirements, shipping requirements, costs associated with shipping and storing samples (including the yearly storage costs) as well as costs associated with running the assays. We formulated a temporary budget which we plan to continue working on through teleconferences over the next several months with Dr. Goldenberg to finalize a plan and budget.

In addition, I met with representatives from the research lab to discuss a new assay for assessing thrombotic risk, i.e. CloFAL, and how we may incorporate this assay into our bio-repository project.

2. Learn the building blocks of setting up an investigator-initiated clinical trial

Dr. Goldenberg arranged several meetings with all of the key stake-holders in the research department so I may learn the keys to setting up an investigator-initiated clinical trial (as this is the long-term goal of CHAT). I met with the following teams/people/persons:

A. Clinical Database Nurses: They reviewed the process of setting up a clinical database

B. Database design manager: This session built on the previous session and we explored the specifics of REDCap – a database software for research

C. Research Compliance Manager: This was a two-hour session of the JHACH modules for investigator responsibilities and Food and Drug Administration (FDA) requirements for initiating a clinical trial

D. Epidemiology/Statistics: I met with Dr. Amankwah, the head biostatistician at JHACH and we explored statistical aspects of risk-prediction validation – particularly the differences between discrimination and calibration in a risk-prediction algorithm

E. Dr. Ghazarian, Director of Health Informatics: We met to review the proposed research for CHAT and she provided critical feedback on how to optimize the electronic health record for data retrieval

F. Grants Administration: I met with the people in the grants administration office to review successful qualities for a grant application relevant to CHAT

G. Investigational Drug Pharmacist: I met with Dr. Napolitano who reviewed the requirements for using an investigational drug in a clinical trial

H. Dr. Ahumada, Director of Predictive Analytics: We met to discuss future endeavors in machine learning and how it may apply to clinical research

I. Clinical Research Coordinators: I had several one-hour sessions with various clinical research coordinators to discuss tips/tricks for improving efficiency in clinical trials

3. Explore new research and collaborative ideas

In addition to reviewing the CHAT project, Dr. Goldenberg and I discussed potential new endeavors for thrombosis-related research.

I met with Dr. Shimony, a neuro-surgery fellow with a vested interest in cerebral sinovenous thrombosis (CSVT), and we discussed a potential collaboration to review the risk factors pertinent to CSVT.

I met with Dr. Jacobs, cardiovascular surgeon, and we discussed a potential collaboration to review anti-platelet agent dosing in pediatric patients with congenital heart disease.

It was an excellent week at JHACH and with Dr. Goldenberg and in addition to learning a great deal of research organization (in general and specific to CHAT), I came away with two new possibilities for research that will lead to further collaboration. All of our original goals for the week were accomplished and new endeavors came to light.