TRIO STUDIO: Facilitating Engagement Across Multi-Disciplines
by Lindsay Basto, MSN, RN
Clinical Research Manager, Transplant Institute
University of Chicago

At IIT Institute of Design
Authors: Santosh Basapur, MS, Raj C. Shah, MD, Prof. Keiichi Sato, and Sherry Robison
Email for questions: basapur@iit.edu, raj_c_shah@rush.edu, and/or srobison@bsduchicago.edu
# TABLE OF CONTENT

- Topic of Studio: Study Approval Process Optimization
- TRIO STUDIO: Facilitating Engagement Across Multi-Disciplines
- Attendees
- Summary
- Top 3 Actions Proposed by the Studio Participants to Lindsay Basto
- TRIO Studio Problem Description
- Main problem for the studio participants to solve
- Studio Methodology
- Quality Science Method
- Quality Science Based Solutions
- Problems Analysed to Identify and Define Issues
- Analysis of Issues and Causes
- Solutions Generated by Quality Science Approach Team
- Appendix 1
- Appendix 2
- Appendix 3
- Addendum 1 – 30-Day Follow-up
TRIO STUDIO: Facilitating Engagement Across Multi-Disciplines
by Lindsay Basto
Clinical Research Manager, Transplant Institute
University of Chicago

Facilitators: Sherry Robison, TRIO ITM and Santosh Basapur, IIT Institute of Design

Research Assistants: Sai Abhignan (MDes Students)

Attendees:
Quality Thinking Team: Denise Voskil-M, RUMC, Mary Harris U Chicago, Cynthia Tom-Klebba, Loyola, Tharani Jeyaram, U Chicago, Laurencia Perea, U Chicago, Drew Simon ITM RUMC, Nurie Dervishi ITM UChicago, Sherry Robison, ITM UChicago, and Raj Shah, ITM RUMC.

Summary
Lindsay Basto, University of Chicago, introduced the transplant study and facilitating engagement across disciplines in this complex multi-disciplinary study and the challenges her team is experiencing. She gave background information and introduced the challenges to the studio.

Quality Thinking approach was used to solve the problems faced by Lindsay and her research team at UChicago Transplant Institute. Many suggestions, based on experiences at different institutions, were made.

Top 3 Actions Proposed by the Studio Participants to Lindsay Basto:

1. **Department specific SOP:** The SOP should be department specific and list what is different than standard of care.

2. **Multiple contacts in each department:** Request multiple contacts for each department that will provide coverage for time-off and staff turnover. Contacts should include research coordinators and research teams, not just PIs.

3. **Incentive for study teams to be involved:** Continuing education credits or stem cell knowledge should be used as incentives for the departments. Magnet status for nursing involves research; this study would be an ideal study to help with the Magnet status designation.
TRIO Studio Problem Description:

The goal is to engage multiple disciplines in continued involvement across study activities.

Lindsay Basto from U Chicago introduced the problem. Multiple disciplines within U Chicago need to interact smoothly in order conduct their portion of the research within an acute period of time and in a specific order. The multiple disciplines involved in this study include the organ transplant team, stem cell transplant team, cGMP, radiology, apheresis and the sponsor.

Lindsay explained that patients who undergo organ transplant must take immunosuppression medication every day for the life of the transplanted organ. Immunosuppression medications are vital to prevent rejection of the transplanted organ. Immunosuppression medications have many side effects. The goal of the study is to find a safe and tolerable means of inducing donor specific immune tolerance, in contrast to non-specific (immunosuppression) in order to achieve durable survival of well-functioning allogenic solid organ transplants. Subjects on the study will be weaned off immunosuppression medications.

Six weeks surrounding kidney transplant, the consent process takes place which involves the living donor and recipient. The solid organ and stem cell transplant teams are both involved in the consent process. The donor and recipient are evaluated by multiple different teams:

- Donor has G-CSF mobilization and apheresis (stem cell)
- G-CSF is shipped to the sponsor for processing (stem cell and sponsor)
- Transplant surgery occurs (transplant team)
- Total Lymphoid Irradiation (10 fractions by radiology)
- Study drug is shipped from the sponsor and arrives for storage (sponsor and stem cell)
- Study drug infusion in outpatient BMT suite (stem cell)
- Follow up by solid organ and stem cell transplant teams

Current efforts include a very detailed 10 page single space SOP which is used by all departments when subjects are enrolled. Emails are sent to the different departments with updated flyers which include study details. Mock runs and in-services have been completed in appropriate areas.
Lessons learned so far by Lindsay and her research team:

- Many staff need to be involved
- High turnover without clear communication as to who is replacing them
- Takes a personal connection
- Disciplines are un-familiar to study coordinator
- Sub-Is are busy with normal clinical schedule and this is not a priority

Lindsay’s call to action: “Do you have suggestions to best engage study staff in continued education and protocol updates to allow for such a complex study to run smoothly once a subject is enrolled?”
Main problem for the studio participants to solve:
Does the TRIO studio audience have suggestions for facilitating engagement across multiple disciplines in a complex multi-disciplinary study?

**Studio Methodology**
Quality Science approach was used to solve this problem.

**Quality Science Method**
The Six Sigma Quality Science approach was used which consisted of five steps:

1. Problem definition and mapping of actual structure of the process
2. Identify issues and analyze causality using Fishbone analysis
3. Generated ideas to address to issues – Brainstormed using SCAMPER method
4. Merged smaller ideas and scale ideas to create bigger solutions
5. Actionable insights and solutions were proposed and solutions were rated by the team on implement-ability (0-4 scale)
Quality Science Based Solutions:

Problems Analysed to Identify and Define Issues.

Define the problem

Problems:
Multiple disciplines need to interact to smoothly conduct their portion of the research in an acute period of time in a specific order.
- What are the competing studios? Context helps - Stem cell studies are many.
- Define a patient pool - kidney transplant waiting list, living donor list.
- Scheduling multiple teams at same visit for patient.
- 10 page single space SOP - not dept specific, not simplified.
- Teams doing familiar things but don't know what is different with this study.
- Fear that everything is different.
- Rare event study.
- If EMR connection - causes max billing problems.

Analysis of Issues and Causes
Causes for the issues found in step one were discussed as a group.
Map the process

- Consent process
  - Solid organ team
  - Stem cell team
- Donor & Recipient evaluation
  - Evaluation by multiple teams
- Donor G-CSF mobilisation
  - Stem cell
- Ship for cell processing
  - Stem cell sponsor
- Transplant surgery
  - Transplant team
- Total lymphoid IR radiation
  - Radiology
- Arrival and storage of IP
  - Sponsor & Stem cell team
- IP infusion in out-patient
- Follow up by both solid organ and stem cell donor team
Here is the summary of that discussion:

1. **Competing Studies**: Stem cell has many studies and may be too overwhelmed with their studies to spend much time on this study. They may need more assistance with what to do and when for the study.

2. **Potential Patient Pool**: Use a cold approach of approaching potential patients. Review the kidney transplant waiting list and the living donor list.

3. **Standard Operating Procedure (SOP)**: A ten page, single-space SOP is not department specific. It seems cumbersome and is not simplified.

4. **Various Teams Research**: The multiple departments involved in this study are doing research that is familiar to them. They don’t know what is different with this study. They fear everything involved in an organ transplant, living donor or stem cell transplant is different.

5. **Electronic Medical Record (EMR)**: Electronic medical records are updated but someone reviewing needs to dig deep into the record to see if a patient is on a study or what is involved with the study.

6. **Communication**: Coordinators turnover and there no clear communication as to who is taking their place. There’s no personal connection with several of the departments.
Solutions Generated by Quality Science Approach Team:
Multiple solutions were discussed and then aggregated before recommending them to study team.

Solutions

1. **Department specific SOP**: The Standard Operating Procedure should be department specific and list what is different than standard of care. Even department level simulation runs of study can or should be conducted to know preparedness.

2. **Multiple contacts in each department**: Request multiple contacts for each department that will provide coverage for time-off and staff turnover. Contacts should include research coordinators and research teams, not just PIs.
3. **Incentive for study teams to be involved:** Continuing education credits or stem cell knowledge seminars should be used as incentives to engage with the departments. Magnet status for nursing involves research; this study would be an ideal study to help with the continuance of Magnet status designation.

4. **Add EMR note:** An EMR note for the living donor and recipient will ensure department handoffs are done properly. The EMR note should also be in the snapshot of EPIC that way it’s easily visible to anyone accessing the EMR.

5. **Map each departments process and visualize.** Map each departments process and visualize what needs to be done with help the departments understand their role in the study. Create a new flow map that will assist the visualization of the process.
6. Simulations/Mock: Conduct simulations or mock runs with each department so they can see what is involved and how to avoid any bottlenecks in the study.

7. Participant Testimonials: Invite participants to give a short video testimonial that can be shown to other possible participants and donors during recruitment. Standford has been successful with the study and possibly their study participants can provide testimonials.

8. PI – PI Contact: PI is frontline for the study. They can provide a warm handoff to coordinators or their research teams so the transplant study team can work closely with them on the study. Brochures can be left in the waiting area to assist with patient knowledge of research and the study.
Appendix 1.
Slides used by Lindsay Basto, MSN, RN, Clinical Research Manager, Transplant Institute, UChicago Medicine.

Appendix 2.
Quality Thinking Team Pictures
Appendix 3.
Actual pictures of white board from the studio session
Addendum 1 – 30-Day Follow-up

Top 3 Actions Proposed by the Studio Participants:

1. **Department specific SOP:** The SOP should be department specific and list what is different than standard of care.

   Implementation and Results:

   Since Design Studio on October 10, 2018, Lindsay is working on creating department specific Standard Operating Procedures (SOP) for the following teams: Organ Transplant, Stem Cell Transplant, Current Good Manufacturing Practice (cGMP), Radiology, and Apheresis. Lindsay stated that she would include, on the SOP, a list of what it is different than standard of care.

2. **Multiple contacts in each department:** Request multiple contacts for each department that will provide coverage for time-off and staff turnover. Contacts should include research coordinators and research teams, not just PIs.

   Implementation and Results:

   Since Design Studio, Lindsay is establishing multiple contacts in each department.

   From the Radiology team, she has the names of two physicians, advanced practice nurses, and one research coordinator.

   The cGMP team contacts she has established are the Technical Director and Assistant Director.

   Stem cell contacts include the inpatient manager, a nurse educator and two study coordinators.

   Lindsay has researched out to the Apheresis team but has not established any contacts outside of the manager yet.

   Lindsay and a research nurse are on the Organ Transplant team.

   Lindsay is also working with another transplant physician and his study coordinator to possibly cross-enroll or if a potential participant doesn’t want to participate in their study they’ll refer them to each other.

3. **Incentive for study teams to be involved:** Continuing education credits or stem cell knowledge should be used as incentives for the department. Magnet status for nursing involves research; this study would be an ideal study to help with the Magnet status designation.
Implementation and Results:

Lindsay has looked into the process of Continuing Medical Education (CME). CMEs are difficult and very time consuming to establish.

In the future, she is planning to set up nursing Grand Rounds to educate nurses on the study.

Lindsay will also give SOCRA continuing education credits for anyone SOCRA certified.

Misc:

At the time of Design Studio, the research team was following 3 potential participants. As of November 15, 2018, 1 potential participant decided they weren’t interested in the study, 1 currently doesn’t qualify as their GFR is not low enough for a transplant and 1 subject has consented. The kidney recipient consent of the current consented subject is pending.

The 90-day follow up is scheduled for January 10, 2019.