TRIO STUDIO: Facilitating Engagement Across Multi-Disciplines

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Attendees:
Quality Thinking Team: Denise Voskil-M, RUMC, Mary Harris U Chicago, Cynthia Tom-Klebb, 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.
The group first discussed the problem and its context yielding the following context diagram:

![Diagram showing the relationships between different disciplines such as Stem cell, Organ sponsor, Sponsor, Involving multiple disciplines, Radiology, eCmP, Aph, Donor (Injections)].

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

Day 0
- Transplant surgery
  - Transplant team

Day 4
- Total lymphoid IR radiation
  - Radiology

Day 4
- Arrival and storage of IP
  - Sponsor & Stem cell team

Day 11
- 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 is 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

- 01. Department Specific SOP / Department level Buyin via PI talks/presentations.  
What's different than SOC - Follow journey of living donor/Recipient.

- 02. Adding EMR note - communication pathway of living donor & Dept handoff.

- 03. Map each departments process and Visualise.

- 04. Finding multiple contacts in each department (to have backup for vacation & staff turnover)
- Incentive for study team to be involved - Continuing ED credits, Stem cell education, magnet status/research.

- 05. Present at other department internal meeting to educate/inform about organ transplantation.

- 06. Simulation/ mock-up trial protocols.

- 07. Invite participants to come and share their experiences (case studies from stanford/ Field trip to stanford/ video testimonials)

- 08. Approach PI's who are first point of contact to living donors.

Solutions are elaborated here as follows:

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
<End of Document. Thank you.>
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 educations 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.
Addendum 2 – 90 Day Follow up

Suggestions Proposed by the Studio Participants:

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.

**Implementation and Results:**

Since the 30-day follow-up on November 15, 2018, Lindsay is continuing to update the Standard Operating Procedures (SOP) to make them each department specific. Lindsay will include, on the SOP, a list of what is different than standard of care.

Lindsay sent the SOP to the TRIO Coordinator to help with organizing it by each department.

2. **Multiple contacts at 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 the 30-day follow-up, Lindsay is still attempting to establish multiple contacts for the Apheresis team. Lindsay’s contacts for the other departments have remained the same.

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.

**Implementation and Results:**

Lindsay looked into nursing contact hours as a form of incentive for study teams to be involved and continuing education (CE) for nursing staff. A contact hour is 50 to 60 minutes of instruction in a board-approved nursing continuing education class or activity.

Lindsay and the PI will not be pursing Continuing Medical Education (CME) for physicians.

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.
Implementation and Results:

The Organ Transplant team is using EMR notes in EPIC. Once patient signs consent, an EMR note will be created; it will include Lindsay’s contact information and will be specific to ensure department handoffs are done properly.

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.

Implementation and Results:

Lindsay has not created a visualized department map. She will create a new flow map, for each department, that will assist them in understanding their role in the study.

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.

Implementation and Results:

The Current Good Manufacturing Practice (cGMP) team performed a mock simulation. CGMP received a simulated study drug shipment, and Lindsay did a mock thaw and drug administration.

Lindsay stated that a mock simulation has not been performed for any other departments because what they need to do isn’t different from standard of care (SOC).

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

Implementation and Results:

Once a subject completes the study, the study team will create a video testimonial.

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.
Implementation and Results:

The PI has weekly meetings with the Organ Transplant department and monthly meetings with Human Leukocyte Antigens (HLA) lab to ensure that quality data is obtained. The PI is in constant communication with his department staff regarding their awareness of the study.

Lindsay stated that she has created a new flyer and has sent it to the IRB for approval. Once it’s approved, she will send it to TRIO for distribution.

Misc:

The donor, that signed consent, will not be on study as the recipient did not meet the inclusion/exclusion criteria.

Lindsay has reached out to the National Kidney Foundation (NKF) and the Living Donor Advocacy program at the University of Chicago to help with recruitment. They also have established a transplant liaison that goes out to different dialysis centers. The transplant liaison approaches patients who are interested in research and provides information about this study.
Addendum 3 – 1 Year Follow up
Suggestions Proposed by the Studio Participants:

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.

Implementation and Results:

Since the 90-day follow up, Lindsay is still updating the Standard Operating Procedures (SOP).

Lindsay will send the SOP to the TRIO coordinator who will then organize the SOP by each department.

2. **Multiple contacts at 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 the 90-day follow up, Lindsay periodically maintains contact with each department. Currently, there are no patients on study, however, everyone remains informed with any protocol updates.

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.

Implementation and Results:

A department staff member has learned the process to obtain continuing education credit for nurses. Whenever the need arises, the department is prepared to offer this as an incentive.

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.

Implementation and Results:

Lindsay has created a dot phrase for Epic. Her information is linked to this template for use when someone is enrolled on the study.
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.

**Implementation and Results:**

Once an SOP is created for each department involved in the study, Lindsay with create a process flow map. Once created, she will reach out to department contacts and review workflow feasibility.

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.

**Implementation and Results:**

Members from the Current Good Manufacturing Practice (cGMP) team all remain the same. From the mock trial that was performed, the various departments went on to write their own SOP.

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

**Implementation and Results:**

Lindsay reached out to her Chief Research Officer (CRO) to ask the sponsor for patient testimonials from other sites. Lindsay will follow up with the CRO to explore this possibility again.

9. **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.

**Implementation and Results:**

Lindsay will follow up on the new flyer and will send it over to TRIO for distribution.

**Misc.:**

Lindsay states that, in hindsight, she would have liked to review a list of potential candidates for this study from the previous calendar year to understand the number of patients that would have met the eligibility criteria, prior to committing to doing the study.
About the Institute for Translational Medicine (ITM)

The ITM is a partnership between the University of Chicago and Rush in collaboration with Advocate Health Care, the Illinois Institute of Technology (Illinois Tech), Loyola University Chicago, and NorthShore University HealthSystem that’s fueled by about $35 million in grants from the National Center for Advancing Translational Sciences at the National Institutes of Health through its Clinical and Translational Science Awards (CTSA) Program.

We’re part of a network of more than 55 CTSA Program-supported hubs across the country working to slash the time it takes to develop and share new treatments and health approaches. We work with you and for you to make participating in health research easy, so that together we improve health care for all.

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