TRIO STUDIO: Recruitment and Study Design for Kidney Transplantation Microbiome Study

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TRIO STUDIO: Recruitment and Study Design for Kidney Transplantation Microbiome Study

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Facilitator: Santosh Basapur, IIT Institute of Design

Attendees:
Tharani Jeyaram, UChicago; Pratik Shah, M.D., UChicago; Jyotsna Soundararajan, UChicago; Cynthia Tom Klebba, Loyola; Drew Simon, RUMC; Raj C. Shah, RUMC; Keiichi Sato, IIT; Nurie Dervishi ITM, UChicago; and Sherry Robison, ITM UChicago.

Summary
Pratik Shah, M.D., Section of Nephrology, University of Chicago Medicine, introduced his study as a single-center, prospective, observational cohort study. Subjects who will be asked to participate in the study are adult kidney transplant recipients with no diagnosis of irritable bowel disease or on probiotics. Dr. Shah and his team plan to enroll 40 subjects on the study in a year. Dr. Shah requested the studio audience to ideate solutions for two questions:

1. How do we get pre-transplant time-matched stool samples from our subjects?

2. How do we recruit from other ITM institutions for this study?

Design Thinking approach was used to solve the problems faced by Dr. Shah and his team.

Top 3 Actions Proposed by the Studio Participants to Dr. Shah:

1. Expand Collaboration to Other Physicians: Attend weekly meetings for gastroenterology, nephrology, microbiome physicians, infectious disease, etc. to tell them about the study, gain some interest from other departments and recruit their patients.

2. Patient Awareness Engagement: Explain to patients what they are contributing, educate on microbiome, what is their quality of life and 30% of people face diarrhea post kidney transplant.

3. Home Visits to Collect Samples: Establishing a relationship with patients by going to their home or dialysis center to collect the samples would build trust and relationships. Shipping samples by Federal Express to the Clinical Research Center would assist the patients that live far away.
TRIO Studio Problem Description:

Pratik Shah, M.D., Section of Nephrology, University of Chicago Medicine, introduced his study. He explained the hypothesis of genetic markers in gut microbial populations before transplantation, and/or changes in microbial community structures soon after transplantation could predict which patients are at risk for developing diarrhea. Dr. Shah’s study is currently a single-center, prospective, observational cohort study. Subjects that will be asked to participate in the study are adult kidney transplant recipients with no diagnosis of irritable bowel disease or on probiotics. Dr. Shah and his team plan to enroll 40 subjects on the study in a year. The study is funded through a one year grant and the funding will end at the end of 2019.

Subjects who receive a transplant from a deceased donor will be asked to provide a stool sample when they enroll, 24-hours immediately prior to transplant, and post-transplant at 1 week, 1 month, 3 months, 6 months and at each episode of diarrhea. Deceased donor kidney transplants are difficult to predict which makes it hard to collect the stool samples, especially pre-transplant. Living donor kidney transplants are scheduled in advance and are easier to collect the samples. Kidney transplantation is the treatment of choice for patients with end-stage renal disease. Post-transplant diarrhea is a common debilitating complication after kidney transplantation (approximately 30%). A significant portion of post-transplantation diarrhea remains unexplained.
Subjects who receive a transplant from a living donor will be asked to provide a stool sample 1 month prior to transplant, 1 week prior and post-transplant at 1 week, 1 month, 3 months, 6 months and at each episode of diarrhea.

Subjects will self-collect their stool sample in the kits provided by the research team. They will then bring the stool samples to their clinic visits. They also will have blood drawn and give urine at their visits. The stool samples, blood and urine will be stored in the Clinical Research Center at University of Chicago. Once samples from 6 subjects are received, they will be sent to Marine Biological Lab for 16S and shotgun sequencing.

Current efforts include generating a list of patients with highest probability of kidney transplant but this is difficult to predict. Collaboration with other kidney transplant medical centers with higher percentage of living donor kidney transplants has been unsuccessful as they are not interested in this research or they do not have the research teams in place.

Dr. Shah requested the studio audience to ideate solutions for two questions:

1. How do we get pre-transplant time-matched stool samples from our subjects?
2. How do we recruit from other ITM institutions for this study?
Figure 1. Dr Shah presenting his kidney transplant study
Main problem for the studio participants to solve:
The goal is to collect time matched stool samples from kidney transplant recipients at serial time points before and after transplantation and analyze the diversity, composition and functional capacity of the microbiota over time. Dr. Shah and his team are doing this to help better understand post-transplantation diarrhea.

Dr. Shah’s call to action: “How do we get pre-transplant time-matched stool samples from kidney transplant patients (specifically deceased donor kidney transplant recipients)? How do we recruit from other ITM institutions for this study?”

Studio Methodology
Design Thinking approach used as part of the studio to solve this problem.

Design Thinking Method
We used the Design thinking approach with five steps:

1. Created a free form mind map of the problem and identification of issues – Mind Mapping technique
2. Actionable insights were identified
3. Generated ideas to address issues
4. Synthesized solutions from the smaller ideas – Creative integration of smaller ideas led by Design Thinking Expert facilitator was done using white boards.
5. Solutions were proposed and were rated by the team on implement-ability (0-4 scale)
Design Thinking Based Solutions:

Problem visualized with Insights
The group first discussed the problem and its context yielding the following context diagram as well as the stakeholder map:

Figure 2 Mind Map of Issues
Figure 3 Stakeholder Map
High level insights:
Following the context discussions, insights were generated as follows:

Ideas:

Smaller sample size is alright (Not necessary to get 40 people)

Move collaboration call from Nephrology to G.I -
they might have more research + Ideas

Participatory design of trial

Engage patient advocacy group

Co-ordinator collects samples at subjects home

Testimonials of Transplanted patients
- Chicago police cheif’s testimonial

Handouts/ Brochures

Collect only stool sample
- Easier to explain to study
- Dialysis centre

Figure 4 Ideas as listed during discussion
Solutions Generated by Design Thinking Approach Team:
Five relatively implementable solutions were created to solve the issues of recruitment. They are as follows:

1. **Expand Collaboration to Other Physicians**: Attend weekly meetings for gastroenterology, nephrology, microbiome physicians, infectious disease, etc. to tell them about the study, gain some interest from other departments and recruit their patients.

2. **Patient Awareness Engagement**: Explain to patients what they are contributing, educate on microbiome, what is their quality of life and 30% of people face diarrhea post kidney transplant.

3. **Home Visits to Collect Samples**: Establishing a relationship with patients by going to their home or dialysis center to collect the samples would build trust and relationships. Shipping samples by Federal Express to the Clinical Research Center would assist the patients that live far away.

4. **Website**: Add to the website patient oriented information about kidney transplants, give information about research and have patient testimonials.

5. **Patient Voice in Trial Design**: Ask the patients about the study, what they would like happen, and how it can occur (bringing samples to clinic, sending samples, etc.). Have patients participate in quality of life after transplant sessions to help educate the physicians and study team.
<table>
<thead>
<tr>
<th>Solutions:</th>
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<tbody>
<tr>
<td>Patient voice in Trial design (Participatory design)</td>
<td>5.</td>
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<td>Patient awareness management</td>
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<td>- Quality of life</td>
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<td>- 3-% people face</td>
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<td>- what am I conditioning</td>
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<td>- microbiom education</td>
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<td>- citizen scientists</td>
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<td>- Sharing analysis results to individuals who gave samples</td>
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<tr>
<td>Website</td>
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<td>- Patient oriented information</td>
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<td>- Research Information</td>
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<td>- Testimonials</td>
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<td>Expand collaboration call to other physicians</td>
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<tr>
<td>- attend weekly meetings</td>
<td>1.</td>
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<td>- Gastroentrology</td>
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<td>- Nephrology</td>
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<td>- Microbiome researchers</td>
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<td>Success stories of stool collection in complicated studies might help</td>
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<td>Home Visits for samples</td>
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<tr>
<td>Shipped by Fedex packages/ Collect at dialysis appointment, Funding application for sampling study</td>
<td>3.</td>
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*Figure 5 Solutions as visualized on whiteboards*

*<End of Document. Thank you.>*
Appendix 1.
Slides used by Pratik Shah, M.D., University of Chicago Medicine.

Appendix 2.
Session Pictures
Appendix 3.
Actual pictures of white board from the studio session.
TRIO STUDIO: Recruitment and Study Design for Kidney Transplantation Microbiome Study

- JD GAS
  Smaller sample size is OK (not necessarily)
  More collaboration with
  NEPHI-PEDS GROUP
  GI - may need
  Nephrologists
  Including Stool and Blood

- Participating Design of Trial
- Engage Patient Advocacy Group
  Coordination of samples @
  Stool/Pediatric
  Stool/Blood
  Collect only Stool Sample
  - Easier to explain to Subj.
  - Diagnosis ETA

- 90 Ped Sample
  - Bonus is give all samples

- Results to Participants
  - Stool
  - Individual Results
  - Preliminary Data Analysis
  (6 samples so far)

- Implementation
  - Stool/Pediatric
  - Blood/Pediatric
  - Diagnostics
SOLUTIONS

1. Patient voice in trial design (Participatory)
   - Quality of life after analysis
   - 30% of new cases
   - Patient engagement
   - what patients are doing
   - Microbiome education
   - Citizen Scientists

2. Activation
   - Sharing analysis results
   - do individual who gave samples

3. Website
   - Patient oriented information
   - Research info
   - Testimonials

4. Expand collaboration call to other
   - Attend weekly meetings
   - Physicians
   - Nephrology
   - Microbiome researchers
   - Other...
   - 4a. Success stories of stool collection in complicated studies might help.

5. Home visits for samples
   - Shipped by Fedex packages
   - Collect at dialysis app
   - Funding application for "sampling" study