TRIO STUDIO: How to Cope and Manage End of Life for Clinical Trials Patients?

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TRIO STUDIO: How to Cope and Manage End of Life for Clinical Trials Patients?

By Lauren Wall, Ellaine Hoekstra, Morgan Whipkey and Aurelie Desgardin, University of Chicago, Department of Medicine, Section of Hematology/Oncology

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Attendees: Jacqueline Ansted, UChicago; Jenny Mitchell, UChicago; Raj Shah, RUMC; Lainie Ross, M.D., UChicago; Julian Solway, M.D., UChicago; Laura Magda, UChicago; Drew Simon, RUMC; Andrea Flores, UChicago; Jessica Shore, Loyola; Tharani Jeyaram, UChicago; Charlene Gamboa, RUMC and Ashley Lopez, ITM

Summary
Lauren Wall, Elaine Hoekstra, Morgan Whipkey, and Aurelie Desgardin from the University of Chicago (UChicago) gave background information and introduced the problem to the participants.

Lauren and her team are looking to educate and develop standard processes for clinical research staff on how to handle clinical trial patients who enter hospice/end of life.

Design Science Methodology and Quality Science Methodology were both used to solve the problem faced by Lauren and her team. Many suggestions, based on experiences within different departments, were made.

Top 3 Actions Proposed by the Design Science Participants to Lauren and her team:

1. Empower Clinical Research Coordinator to communicate with PI about the needs of the team
   a. Better training for coordinators when they join the team
   b. Ability to deal with situations without (or by) taking things personally
   c. Define priorities so that the team has similar understanding of issues and priorities
   d. Allocate roles and responsibilities to appropriate team members

2. Review the Protocol for scientific and operational details. This will help prepare the team for execution of protocol via development of good standard operating procedures.

3. Take this issue of handling grief to the national level – NCATS. This is an important issue and it could be ideal to get funding for research to explore solutions at a national level.
Top 3 Actions Proposed by the Quality Science Participants to Lauren and her team:

1. **Training**: Create scripts to answer questions. Do initial training then follow-up training. Pair nurses with non-clinical team to assist with processes.

2. **Surveys**: Have non-clinical team do surveys quarterly and at time of exit interview.

3. **Debriefing Sessions**: Have debriefing sessions quarterly or as needed. Create a non-clinical team self-care process and have team based meetings with scenario based FAQs.
TRIO Studio Problem Description:

Lauren and her team explained the goal is to educate and develop standard processes for clinical research staff on how to handle clinical trial patients who enter hospice/end of life. Currently there is no training or education for Clinical Research Coordinators on how to cope with this problem. There are no policies for follow-up procedures during the end of life process for clinical trial patients. There is also a lack of support in dealing with the end of life process for clinical trial patients.

Lauren and her teams’ current efforts include reaching out the Employee Assistance Program (EAP) through the University of Chicago to do a seminar. They have encouraged non-clinical staff to reach out to clinical staff on how to approach end of life patients. They have also asked their peer institutions of they have any standard operating procedures (SOPs) on how to handle end of life patients enrolled in clinical trials.

Lauren and her team is asking the TRIO Studio participants how they should educate and develop standard processes for the clinical research staff on how to effectively and appropriately communicate with and manage end of life for clinical trial patients.

Image: Lauren and her team presenting to the TRIO Studio.
Main problem for the studio participants to solve:
How to educate and develop standard processes for the clinical research staff on how to effectively and appropriately communicate with and manage end of life for clinical trial patients?

Studio Methodology
Design Science approach as well as Quality Science approach were used as part of the studio to solve the 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)

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)
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 1. Mind map of Issues with context
Figure 2. Stakeholder Map
High level insights:
Following the context discussions, insights were generated as follows:

- Design of trials with solution - consortium
- Need of solve problem
  Not just oncology but with all diseases and all phases of study
- Scripts
- Home hospital communication? or text message communication?
- Discussing scenarios as a team
- Solve problem with input from all stakeholders
  - Including family, physician, MDS, nurses and non-clinical staff
- Is survivor follow up needed?
- Reframe - Clinical Staff is not only the protector of protocol
  - Not only the protector of protocol, get PI involved
- CRO
  - Previous is sponsor to PI, now is sponsor to CRO
Solutions Generated by Design Thinking Approach Team:

Five implementable solutions were created to solve the issues. The ideas were discussed to be of importance and deeper impact and hence made into these solutions.

The solutions are as follows:

1. Empower Clinical Research Coordinator to communicate with PI about the needs of the team
   a. Define priorities so that the team has similar understanding of issues and priorities
   b. Ability to deal with situations without (or by) taking things personally
   c. Better training for coordinators when they join the team
   d. Allocate roles and responsibilities to appropriate team members
2. Review the Protocol for scientific and operational details. This will help prepare the team for execution of protocol via development of good standard operating procedures.
3. Take this issue of handling grief to the national level – NCATS. This is an important issue and it could be ideal to get funding for research to explore solutions at a national level.
4. A simple immediate solution could be to have condolence cards ready so that the team can send them to families when the death occurs. This sets up a mechanism for team members to express their feelings.

5. Create a discussion group to discuss traumatic scenarios. This will enable sharing, finding of common ground among the team as well as a platform to ideate and create solution(s) as a team to different situations faced.

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Figure 4. Design Science solutions discussed.
Quality Science Based Solutions:

Problems Analysed to Identify and Define Issues.
Lauren and her teams’ problem were analyzed and classified into the following table sections. Problems identified include non-clinical research staff not having training on coping with end of life with their research participants. Non-clinical research staff need emotional support when their research participants enter Hospice/end of life care. There’s also disconnect between the sponsors and non-clinical staff as far as follow-up procedures during Hospice/end of life care.

![Figure 5. Problem Definition](image)
Figure 6. Understanding the process

Fish Bone Analysis

Figure 7. Fish Bone Analysis to figure out causality of problems
Solutions Generated by Quality Science Approach Team:

Five solutions were created to solve the issue of innovative ways to educate non-clinical research staff on Hospice/end of life coping mechanisms for their research participants. They are as follows in the list below and the diagram digitized from whiteboard:

1. **Training:** Create scripts to answer questions. Do initial training then follow-up training. Pair nurses with non-clinical team to assist with processes.

2. **Surveys:** Have non-clinical team do surveys quarterly and at time of exit interview.

3. **Debriefing Sessions:** Have debriefing sessions quarterly or as needed. Create a non-clinical team self-care process and have team-based meetings with scenario-based FAQs.

4. **SOP for the Sponsor:** Create an SOP so the sponsor understands the procedures when a research participant enters end of life care.

5. **Institutional Support:** Talk with the hospital Pastors to see if there is any Pastoral care available for the non-clinical staff and check with OCR to see if they have any available resources.
Solutions_Science Approach

01 Training Language
- Initial training
- Follow-up training
- PI training (who does what?)

02 Surveys to Coordinators during & exist interview
Not just oncology but with all diseases and all phases of study.

03 Debriefing Sessions Questions
Coordinator Self-care (role play)
Scenario Based FAQ
Team Based Meetings

04 Institutional Support (OCR, Pastoral)

05 Nurse Paired with Clinical Team

06 SOP for Sponsor

<End of Document. Thank you.>
Appendix 1.
Slides used by Lauren Wall, Elaine Hoekstra, Morgan Whipkey, and Aurelie Desgardin

Appendix 2.
Actual pictures of white board from the studio session.

Design Science
TRIO STUDIO: How to Cope and Manage End of Life for Clinical Trials Patients?

- Design of Trials w/ EoL -Consortium
- Need of SOP - Not just Oncology but w/ all diseases & all phases of Study
  - Less recovery is needed & Scripts & ensuing of State
  - How comm? or Text msg commmedia?
- Discussing Scenarios as a team
- SOP w/ input from all stakeholders including family, patient, MDs, nurses, non-clinical
  - Survivor followup needed?
- Redefine - Clinical Staff is not only the protector of Protocol
  - Get PI involved - Do No Harm
- Prev. Sponsor → PI
  Now Sponsor → CRD
IDEAS

15. Protocol Review
   - Scientific
   - Operational

1. Research Subject Advocate
2. Trial design w/ Stakeholder ideas
3. Involuntary/Voluntary stop of Participation
4. Scripts for calling for visit to hospital for deceased pts.
5. CTSA + NCATS Consultation (How) participant
6. PI calling pt's family (Stating appreciation)
7. Oncology Psychology support (Grief counseling)
8. Discussion group to address traumatic scenarios
9. SOP w/ stakeholders and pt/pts family
10. Involve family in consent; build better relationships
11. Define high priority, low priority data points
12. Empower CRC Communication with PI
13. TRIO w/ Sponsor
14. GSD
15. Home Visits
SOLUTIONS

1. Empower CRC communication with P.I.
   - Define 1-1 priority
   - Facilitating personally or not
   - Scripts
   - Better Onboarding process
   - Involuntary/voluntary stop of participation
   - Responsibility allocation for staff

2. Protocol Review
   - Scientific
   - Operational

3. Take it National (NCATS)

4. Condolences card from Study team

5. Discussion group to address traumatic scenarios
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Quality Science

Diagram:
- Define the Problem
  - Current State
    - Research protocol usually conducted on a life line
    - Emotions of removing to life
    - Discouraged from viewing each other
  - Goal State
    - 
- Who is experiencing the problem
  - Senior (non-clinical, PI, nurses)
  - Study Subject
  - Families
  - Labs
- What is the scale of the problem
  - Subject Care
  - Burn out
  - Sponsor/Coop Group/Institution
  - PI, Burden
  - Recruitment
- Why does this problem exist
  - Tough topic
  - Balance
  - Data Center
    - Communication of SOPs
    - Restructure
      - Roles
    - Social Resonance
      - Refuge Training
Understanding the Process of Subject Participation:

- New Employee
  - Basic: Consent
  - (Physicians, Nurses, Coordinators)

- Consent Pt.
  - On Study
  - Following Subjects
  - Subjects Ask Questions
    - "Will this hurt me?"

- Subject Dues
  - Coordinators
  - Graces Bored

Why-Why Analysis

- No Training
  - On-Becoming (SOPs, Protocols, Training)

- Time
  - (Busy Coordinators)

- No Information Sessions

- Point of Cause
  - FAQ

- Intl. Support (Occ. Part)
  - No FAQ
Solutions

1. Training (scripts to answer questions)
   - Initial training
   - Follow up training
   - Nurse paired w/ Clinical team

2. Institutional Support (OCR, Pathway)
   - Debriefing sessions QUEST
   - Surveys to Coordinators (During & End)
     - QUALITY
     - Coordinator Self-Care (Role play)
   - SOP for Sponsor

3. Team based meetings

4. Experience based focus
Addendum 1 – 30 Day Follow Up

Top 3 Solutions Generated by Design Science Team:

1. **Empower Clinical Research Coordinator to communicate with PI about the needs of the team**
   a. Better training for coordinators when they join the team
   b. Ability to deal with situations without (or by) taking things personally
   c. Define priorities so that the team has similar understanding of issues and priorities
   d. Allocate roles and responsibilities to appropriate team members

Implementation and results:

At the 30 day follow up, the team held information sessions at staff meetings, clarifying roles of the team members. They reviewed who the coordinators can go to for support, such as senior staff members, nurses and supervisors, when faced with a difficult situation. The team is working on revamping their staff training and will incorporate these topics.

Lauren plans to speak with faculty team members to coordinate an End of Life training for her team.

2. **Review the Protocol for scientific and operational details.** - This will help prepare the team for execution of protocol via development of good standard operating procedures.

Implementation and results:

They team has not yet reviewed the protocol but it is on their list of actions items.

3. **Take this issue of handling grief to the national level – NCATS.** - This is an important issue and it could be ideal to get funding for research to explore solutions at a national level.

Implementation and results:

At this moment, Lauren and her team are not able to move forward with taking this issue to NCATS. They may revisit this suggestion in the future.
Top 3 Solutions Generated by Quality Approach Team:

1. **Training** - Create scripts to answer questions. Do initial training then follow-up training. Pair nurses with non-clinical team to assist with processes.

   **Implementation and results:**
   
   At the 30 day follow up, the team has created a thank you card for patients when they transition off of the study. Prior to implementing this, they will present the card to their section chief for approval and then submit to IRB for approval. They plan to create training scripts in the future.

2. **Surveys** - Have non-clinical team do surveys quarterly and at time of exit interview.

   **Implementation and results:**
   
   The team has not yet created surveys but it is something they plan to do.

3. **Debriefing Sessions** - Have debriefing sessions quarterly or as needed. Create a non-clinical team self-care process and have team based meetings with scenario based FAQs.

   **Implementation and results:**
   
   The team has not begun these debriefing sessions.

**Misc.:** Lauren and her team stated there have been short term schedule changes that have put a hold on implementing suggestions given. They are creating a plan to start implementing other items and hope to have more information in future follow ups.
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.

Join the movement and learn more about how we help researchers, physicians, community members, industry, government organizations, and others. Visit us at chicagoitm.org and connect with us on Facebook, Twitter, Instagram, YouTube, and LinkedIn @ChicagoITM.

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