

### Conducting a Pilot Project?



As Researchers, we have access to:

- ✓ Ethics Guidance
- ✓ Methodology Guidance

BUT...

- ❑ Implementation relies on prior experience & word of mouth
- ❑ MAJOR Lack of Support/Guidance for Implementing Pilot Projects

### Context

Up to 70% of patients on dialysis experience symptom burden. These symptoms are often underreported and undermanaged.



SUPPORT Dialysis Pilot Project launched at Toronto General Hospital to address these needs using electronic Patient-Reported Outcome Measures (ePROMs) for systematic symptom assessment and management.

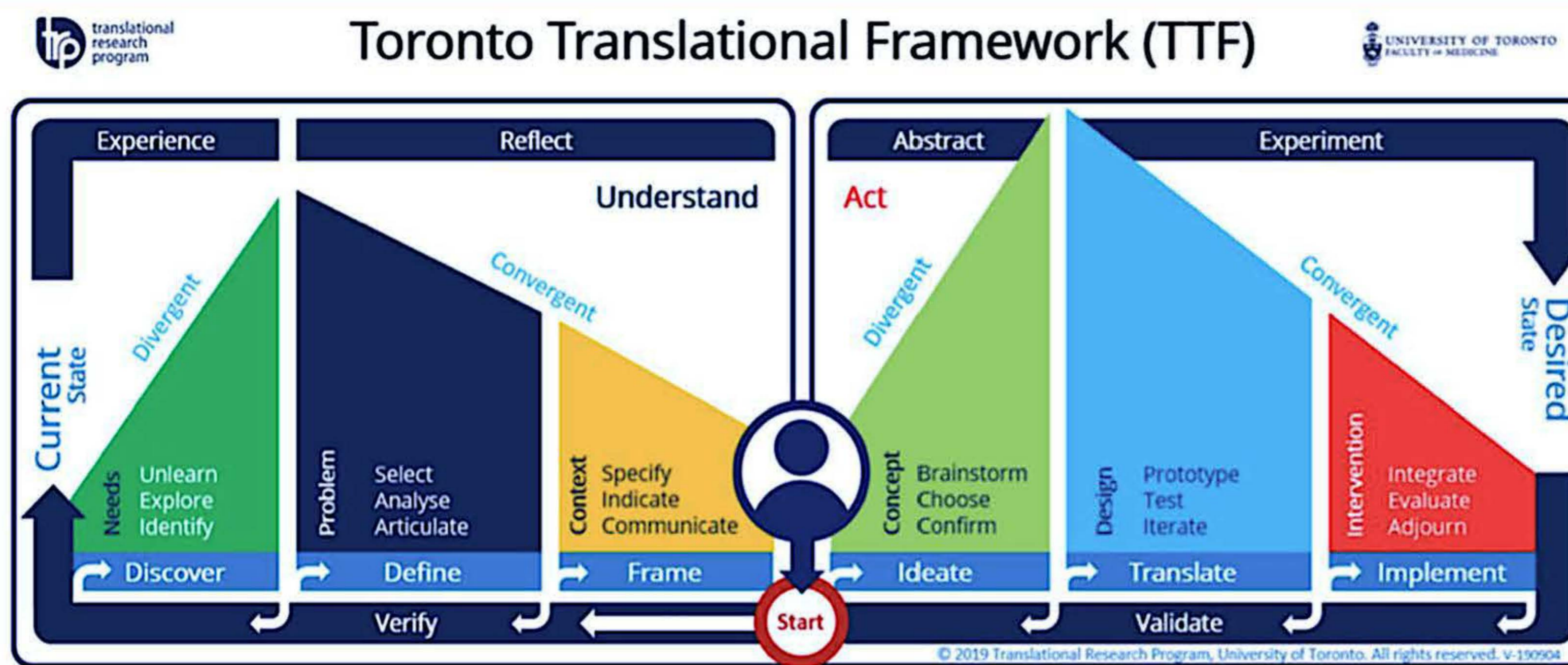
One month after the pilot launch, patients flagged with high symptom severity weren't being referred by the physicians.

How did the study stakeholders at the Toronto General Hospital dialysis unit experience the implementation and delivery of the SUPPORT-Dialysis pilot study?

### References

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\*Dainschroder, L.J., Reardon, C.M., Widerquist, M.A.O. et al. The updated Consolidated Framework for Implementation Research based on user feedback. *Implementation Sci* 17, 75 (2022). <https://doi.org/10.1186/s13012-022-01245-0>  
\*Wong, D., Cao, S., Ford, H., Richardson, C., Belenko, D., Tang, E., Ugenti, L., Warsmann, E., Sissons, A., Kulandavelu, Y., Edwards, N., Novak, M., Li, M., & Mucsi, I. (2017). Exploring the use of tablet computer-based electronic data capture system to assess patient reported measures among patients with chronic kidney disease: A pilot study. *BMC Nephrology*, 18(1), 356. <https://doi.org/10.1186/s12882-017-0771-7>

### Research Design and Methods



### Understand

Aims

Using the SUPPORT-Dialysis pilot as a case study, we aimed to identify the core challenges associated with implementing pilot studies in complex care systems

Methods

- #### Data Collection
- Purposive sampling through circle-of-care
  - Semi-structured interviews with patient participants, research team, and health care providers (n=21)
  - Document review for additional environmental context

- #### Qualitative Data Analysis
- Framework analysis through data familiarization, inductive and deductive code generation, and construction of themes guided by the **Consolidated Framework for Implementation Science (CFIR)**

### Act

Based on the qualitative results, we developed a **Pilot Project Checklist** to support researchers/clinicians in the successful implementation of pilot programs within complex care environments.

- #### Pilot Project Checklist Development
- Conceptualized and designed a checklist of recommendations based on qualitative results guided by the Toronto Translational Thinking Framework and CFIR
- Extracted key takeaways from the qualitative findings
  - Created a guide in a concise and user-preferred format
  - Preliminary feedback on the conceptual guide from the Kidney Health and Education Research Group was positive

### Pilot Project Checklist

Key Considerations For Successful Implementation Of Your Pilot Project



#### PURPOSE

Interventions that are found to be effective on an individual scale or within a specific context often encounter difficulties when implemented in new contexts. While investigators have access to ethics and methodology guidance, there is limited support regarding the best approaches implementing pilot projects within complex care systems.

#### METHODS

Using the SUPPORT Dialysis Pilot Project as a Case Study, we determined key barriers and facilitators to pilot project implementation. We conducted 1-on-1 interviews with 21 key stakeholders at the patient, healthcare provider and research team level. After performing a qualitative framework analysis to identify the most relevant factors, we extracted the corresponding key takeaways. See QR code for report containing a full outline of our methodology.

#### CHECKLIST RECOMMENDATIONS

- Consult Target User Base**  
When designing a new intervention or adapting an intervention from another context, consult with your target population and user base early on. Ensure a human-centered approach by verifying that your intervention is addressing a real need faced by your target populations (both patients and clinicians). Be careful not to rely on one perspective.
- Clarify Pilot Study Goals with Stakeholders**  
In establishing the pilot project goals, clarify the differences between pilot and clinical trial design with both the research team and participants. Pilot projects assess feasibility, refine interventions, and test implementation strategies on a small scale, informing larger studies. They are not rigorous evaluations providing definitive evidence for clinical adoption.
- Create Formal Site Preparation Plan**  
Establish a formal plan for site preparation, clinician and patient engagement. Building from previous plans may be used as a starting point, but understanding what resources were available for the previous plan are essential to gain a realistic depiction of what is feasible. Adapt to your site & setting. After site preparation, conduct readiness assessment.
- Model Information Flows**  
To better predict how your intervention will fit in a designated system, model typical clinical information flows related to the intervention in question (i.e., referral processes, sharing clinically relevant information between multidisciplinary teams, etc.) Ensure that relevant information is shared through channels preferred by stakeholders
- Promote Ownership for Stakeholder Engagement**  
Onboard members from each pilot stakeholder group into the research team to promote ownership (i.e. not just a passive participant, but an active project driver). Liaison from in-group members to stakeholders promotes buy-in and commitment to essential pilot tasks.
- Identify Opportunities for Communication with Large Groups**  
When beginning site preparation, identify opportunities for communication with large groups of key stakeholders that doesn't cause undue burden or disrupt workflows in a significant way (i.e. rounds, team meetings, etc.)
- Emphasize Expectations of Involvement**  
For providers that are participating in your pilot, it is important to emphasize expectations of involvement, clearly defining assigned tasks and instructions for engaging with the intervention.
- Consider Training for Project Agents**  
With new interventions, pilot participants may require training to familiarize themselves with the process. Consider additional involvement of specific care providers when training is not feasible.
- Create Opportunities for Feedback and Clarification**  
Share progress & key updates throughout the study, providing stakeholders with opportunities for clarification and avenues for feedback (both direct and anonymous).
- Use Clear Operational Definitions**  
Use consistent & clear definitions of terms throughout the project, recognizing that different stakeholders (patients/care providers) may have different understandings which can lead to miscommunication and differences in expectations.
- Establish Common Ground with Stakeholders**  
Differences in patient participant expectations vs. what healthcare teams/interventions can provide can be a large point of participation frustration, risking dropout or poor engagement. Consider focus groups to establish common ground.
- Understand Best-Suited Methods of Communication for Stakeholders**  
Keys to effective communication with patient participants includes active listening to their concerns, understanding the methods of communication that best suit them, using appropriate language, and maintaining a warm demeanor.
- Remain Open to Project Adaptation**  
Maintain flexibility and openness to adapting the intervention to better fit the needs of the user population, when appropriate. Remembering; the goal of a pilot project is not to produce a bias free and statistically significant effect size, rather to assess feasibility and determine if and how this intervention can provide value to its users.
- Shared Monitoring of Key Success Indicators**  
Harness data management systems to coordinate shared monitoring of key project success indicators and assign task priority.
- Consider Available Resources for Implementation**  
In a research setting, pilot project success may be dependent on resources that are not available in the clinical setting. Consider: are research coordinators, recruiters or assistants filling crucial roles in the intervention delivery? Consider how a larger scale will impact the delivery of the intervention? (Logistical, operational, resource barriers).
- Consider Systemic Factors in Project Implementation**  
Understand what systemic factors (billing codes, clinical scope) may impact roles or responsibilities on a larger scale. Consultation with relevant stakeholders including healthcare administrators, and policy makers when appropriate.

### Anticipated Impact

Through developing a **Pilot Project Checklist**, we hope to support researchers and clinicians in designing Pilot Projects and provide a systematic means of implementing them. This will increase our sensitivity during the evaluation of pilot feasibility and acceptability and reduce the burdens of implementation inefficiencies.