UTOPIAN Primary Care Trials Group – Session 1 *draft*

Wednesday, January 29, 2020 from 4:00 p.m. to 5:00 p.m., Room 552

Attendance:
Andrew Pinto (AP) – Chair
Aashka Bhatt (AB)
Ann Burchell (AB)
Noah Crampton (NC)
Michele Greiver (MG)
Sumeet Kalia (SK)
Olga Klenova (OK)
Aisha Lofters (AL)
Christopher Meaney (CM)
Marjan Moeinedin (MM)
Rahim Moineddin (RM)
Donatus Mutasingwa (DM)
Braden Gregory O'Neill (BGO)
Jennifer Rayner (JR)
Carolyn Steele Gray (CSG)
Abhimanyu Sud (AS)
Ross Upshur (RU)
Pinky – St. Michael's Hospital research staff

Regrets:
Payal Agarwal (PA)
Sheila Dunn (SD)
Noah Ivers (NI)
Peter Selby (PS)

Item	Topic	Minutes	Action	Responsible
1	Introductions and objectives of Primary Care Trials Group (Andrew Pinto)	The agenda for the day's meeting was reviewed; no items were added. A Dropbox would be created with resources relating to primary trials, such as reference articles. The resources will also be updated on the DFCM website in due course. The objective of the Primary Care Trials Group was suggested as follows: that first and foremost, the group support its members and their work, whether that be learning how to conduct clinical trials, helping members connect and possibly find co-investigators, and/or helping them interact with research sites for the purposes of study recruitment. In addition, this group can be a supportive space for learners, such as graduate students being mentored. Ultimately, UTOPIAN hopes to become a world-class platform for clinical trials.		
2	Learning topic: Recruitment to Primary Care Trials			
2.a.	Building research connections and culture	Recruitment is difficult and time-consuming and is becoming more difficult over time in key aspects such as mobilizing enthusiasm, having control of patient lists, and understanding the	Andrew Pinto, Michelle Greiver, Aashka Bhatt and Rabiya Siddiqui would be visiting the 14 U of T	AP, MG, AB, RS

		nature of different practices. Creating an enabling, supportive research culture, working with site chiefs and respecting organizational dimensions will be important for researchers going forward. With nuances in study design and timing, researchers need to rely on strong relationships at the site-level and hopes that group members will be able to share best practices and pitfalls when recruiting from different sites and for different study methods. Researcher flexibility is also key, as inclusion criteria may change due to contextual factors of a study.	affiliated sites to introduce them to UTOPIAN and inviting them to contribute to its development	
2.b.	Bespoke recruitment using EMR data	Recruitment depends on relationships built over time. The hope is that each project, once value is demonstrated, can help build recruitment for the next project. Ongoing recruitment, with permission to contact potential subjects, will be very helpful. EMR data, with permission, could be used to identify sites who have many potential subjects and may not be sites that traditionally participate in research. Andrew Pinto's comment: [The IGNITE RCT is currently at 80% recruitment. The IGNITE team used EMR to identify patients living in poverty by markers in their charts (postal code, ODSP, OW codes, etc.). They verified lists of patients with physicians and sent letters under the physicians' covers to patients to invite them to participate in trials.] Braden O'Neill's comment: ["Bespoke" recruitment is necessary to get community-based practices involved in research. The BedMed study, first, recruits family doctors from non-traditional sites (taking advantage of CME days to generate interest); second, have Research Assistants (RAs) travel to practices and generate a list of potentially eligible study participants. Finally, site family doctors review these lists and the RA, having patient contact information, sends patients a letter inviting them to participate in the study.] Aashka Bhatt's comment: The SARTAN-AD study run by Dr. Sandra Black followed a similar process: a) a preliminary search in the UTOPIAN database to identify sites who have potentially eligible patients, b) visit to the top 5 sites, c) re-identification of patients by the RA, d) access for the RA to the site's EMR to do chart reviews, e) list vetting by the physician, f) invitation letter mailed to patients, and g)		

		phone follow-up in 1 to 2 weeks if patients do not respond.		
2.c.	Involving RAs in the circle of care	There is little clarity on who can be included in a patient's circle of care, specifically RAs who are calling patients to invite them to studies. **Idea:** A portion of grant funding could be used to pay for a nurse or another member of the team within the circle of care to call potential trial recruits from a doctor's office. Aashka Bhatt and Michelle Greiver's comments: RAs are considered part of the circle of care with REB approval; a physician would sign an agreement to assign the U of T employee as part of the circle of care. Physicians would then give the RA access to their EMR to re-identify the patients. A Privacy Officer at U of T. reviews this standard agreement. The SARTAN-AD and PICORI OPTIMUM projects have been done in this way. There is an issue of consistency across sites for REBs regarding flexibility with the circle of care.		
2.d.	Organising resources	**Idea:** Group members could standardise recruitment wording from protocols of its members, as well as provide templates that can assist in recruitment (posters, for example). At the site level, UTOPIAN staff look to where posters are put up to increase visibility and work with the sites to reposition them.		
3	Support for clinical trials across UTOPIAN and expansion to include non-academic sites (Aashka Bhatt)	Aashka Bhatt showed members a list of sites and corresponding Research Officers (herself or Rabiya Siddiqui) that site chiefs can distribute to doctors interested in collaborating with UTOPIAN. She added that the UTOPIAN Research Administrator (position to be filled) could also be contacted to assess the feasibility of studies. The table illustrates the following about each site: who is at the site (clinicians and/or researchers and/or researcher-clinicians); what research topics they are interested in; how REB works at each site; site staff to talk to before submitting a study for REB approval; contracts and data sharing agreements required. Same information could be expanded to community health centres. Ultimately, the research readiness of each site needs to be assessed and known. Research involvement and readiness can be championed by the UTOPIAN and DFCM executive.		

4	Discussion of trial proposals and ongoing work			
4.a.	BedMed Study (Braden O'Neill)	**P:** adults with hypertension **I:** taking BP medication at night **C:** taking BP medication in the morning **O:** composite of all-cause death and hospital admission or emergency department visit for acute coronary syndrome/MI, heart failure, or stroke Braden O'Neill will update the group once the U of T REB has approved the study. The study has not recruited sites within UTOPIAN yet.		
4.b.	Meditation intervention for opioid use disorder (Abhimanyu Sud)	**P:** people on opioid agonist therapy in primary care settings **I:** meditation intervention; pre/post feasibility study **C:** no control group **O:** changes in anxiety and depression scores (PHQ-9) Currently leading a feasibility study on a meditation intervention for individuals who have opioid use disorder who are on opioid agonist therapy medication, including Buprenorphine or Methadone. There is high comorbidity of opioid use disorder with depression, anxiety, and PTSD, and mental health has a great impact on agonist therapy treatment adherence. There has not been a lot of knowledge generated in primary care settings on opioid use disorder. His goal is to submit the study for consideration for an NIH grant (Behavioral and Integrative Treatment Development Program – R34 Planning Grant) in March 2020. The UTOPIAN staff were able to identify 800 patients in the UTOPIAN database who were being treated for opioid use disorder and inquired whether approval from the REB is required to identify those individuals. Group members discussed the difference in re-identifying physicians with a large proportion of patients and re-identifying patients themselves. **Clarification post-meeting from UTOPIAN staff:** Cannot re-identify to individual physician until the researcher agrees to use UTOPIAN services and resources, and relevant REB is sought. Only site-level re-identification can be provided to non-UTOPIAN members.		

4.c.	ePRO Tool Project (Carolyn Steele Gray)	The project begins in a hospital setting and reaches out to primary care practices, introducing a new technology. This technology, which will be launched in January 2021, will enable better communication between patients and primary care practitioners regarding patient symptoms and self-management of complex health issues and disabilities. Currently, the study is focused on co-design.		
4.d.	BETTER WISE Project (Aisha Lofters)	**P**: patients aged 40-65 years **I:** a BETTER visit with a prevention practitioner, focused on chronic disease prevention and screening **C:** wait list (same intervention after 6 months) **O**: score on a composite index looking at evidence-based measures for which that person is eligible This funded study engaged Markham Stouffville Hospital and other sites throughout Ontario (not part of UTOPIAN; one in Oakville and two in Northern Ontario). She mentioned that, for recruitment, the study team budgeted for clerical staff time of nurses and health promoters to contact patients. This feature of the study was an advantage for some sites. For other sites, this led to them declining to participate. Academic sites felt their staff did not have time to participate in recruitment, even if there was budget.		
4.e.	SEISMIC (Andrew Pinto)	**P:** families of children aged 0-5 **I:** screen, refer, and connect to community resources (help with navigation) **C:** given information (not navigation and additional staff support); emailed information about community supports **O:** 1) measures of quality of life reported by family, 2) changes in social needs [visits to emergency departments or hospital use] The SEISMIC study considers how primary care can better integrate health and social care for children. The study proposes that practices should be equipped with tools and resources to start to routinely screen for social needs all families who come in with children aged 0-5 years. One example of a resource would be a patient navigator.		
4.f.	CHC involvement	Jennifer Rayner represents a number of community health centres in Ontario. She would like to see enablement of curiosity and mentorship that will help build engagement and participation of community physicians in primary care trials. Community health centres can help identify sites, and later, propose study	Michelle and Andrew to connect with Jennifer Rayner with this vision in mind.	MG, AP, JR

		ideas of their own. Michelle Greiver and Andrew Pinto envision visits to community health centres to present UTOPIAN as a resource and opportunity for research.		
Meeting adjourned at 5:05 p.m.				
Next meeting: Thursday, February 27th, 2020; 4:00 p.m.-5:00 p.m. Room 552				