

UTOPIAN Clinical Research Group Meeting MINUTES

April 28, 2022
Time: 4:00 PM – 5:00 PM EST
Teleconference (Zoom)

Action Items:

1. A call will be sent out for research staff to join a research community – please circulate within your circles.

Review & Approval of Minutes

- Minutes from the previous UTOPIAN Clinical Research Group (CRG) meeting were **approved**.

Lecture Series 4: Recruitment Challenges and Solutions in Primary Care Trials

Presenter: Dr. Eva Grunfeld

Challenges and Solutions

- Many randomized controlled trials do not meet their original recruitment target on time.
- A sufficient sample size is important for powering a study, generalizability of findings, and budget.
 - In Canada, less than 5% of cancer patients are enrolled in a clinical trial.
 - Recruitment in primary care is especially challenging because there are fewer eligible patients in a single setting.
- Major initiatives have been introduced in Canada and Ontario to improve and facilitate clinical trial enrollment (e.g., Clinical Trials Ontario: streamlined the ethics process and improved infrastructure for clinical trials in Ontario; Canadian Cancer Clinical Trials Network: a national initiative funded to improve recruitment, efficiency, and quality of clinical cancer trials, etc.)
- The problem is complex, involving:
 - Health Care Providers
 - Play a gatekeeper role and can introduce substantial bias, limiting generalizability. They may not be interested in or support the study. In contrast, a supportive physician is a major facilitator for retention.
 - Administrative Burden
 - Consent process, data collection, regulatory processes, and documentation
 - Patient Factors
 - Patients are generally knowledgeable about and supportive of trials, but participation may be limited due to logistical reasons (i.e., travel, time, etc.), language, and the clinicians and/or family's attitudes.
- Strategies to improve recruitment:
 - Engage opinion leaders that may be able encourage colleagues to participate.
 - **Clinical Research Associates** are a critical part of the team for consent, data collection, and identifying patients. It is recommended that CRAs provide input in developing trial procedures and that this individual is already part of the circle of care, which also enables patient identification.
 - Use administrative data (vs. physician) to identify eligible patients. EMR prompts are more effective than a CRA in the waiting room.
 - Opt-out enrollment: all patients identified by EMR are sent a letter to say they were enrolled in a particular study, and if they wished to not participate, they were asked to contact research leads to opt-out.
 - Include patients on protocol development team and highlight how it will be beneficial to patients, provide financial support for travel, parking, childcare etc.

Equity, Diversity, and Inclusion

- The majority of patients enrolled in studies belong to a higher educational and economic stratum, while minority groups and those that are medically underserved are underrepresented. This negatively impacts generalizability.
- Barriers include language, literacy, and provider invitation. These barriers can be overcome through direct personal outreach to community providers, ongoing relationship building, and a trusted inoculator.
- Other facilitators include patient navigators, community-level strategies such as recruiting at community sites and organizations, involving communities in protocol development, hiring research staff from within the community, and providing incentives and reimbursement.

Documenting Recruitment

- Recruitment is reported using a consort diagram.
- Suggestion to keep weekly or monthly counts of enrolled patients vs. expected number and deconstruct the process (i.e., where are the flaws, where are patients potentially being lost, what are the procedures to follow-up on consent forms, does an additional site need to be added, examine data collection instruments, etc.).

Novel Trial Designs

- A number of trial designs have been developed to address recruitment and achieving a sufficient sample size:
 - **Adaptive Platform Trials** use a common control group to decrease the required sample size
 - **Pragmatic Comparative Effectiveness Trials** compare two standards of care, where there is true equipoise regarding which standard is optimum (e.g., how many days you provide antibiotics or other minimal risk studies). The clinician introduces the study and takes a verbal consent. The patient is then randomized right there and then.
 - **Cluster randomization** with a quality improvement framework. Individual consent is not required, and admin data is used for the primary outcome.
 - **Zelen design** involves patients being randomized prior to consent and is then sent consent information with respect to the arm that they have already been randomized to.
- If doing something novel, it is best practice to speak to the Research Ethics Board to get their advice and feedback.

Discussion

- UTOPIAN has started using 'agent agreements' under PHIPA, so that UTOPIAN staff can act as an agent of a particular site and conduct research activities on behalf of site staff. This takes a considerable amount of burden off front line staff.
 - A form is submitted to the REB to approve this agreement for each project.
- Trials are now also starting to use the data in the UTOPIAN/POPLAR database to narrow in on patients to recruit, improving the efficiency of the process.

Open Discussion

Update on Ongoing Clinical Trials

- A new format will be used to update the Clinical Trials Group on ongoing trials at UTOPIAN. This new form will be shared via email to members of the group, along with the agenda and other relevant documents.

Grant Application Workshop

- The workshop will outline how to prepare grant applications for CIHR project grants. The workshop will be open to primary care researchers across Canada and will take place on the morning of July 19.

Principal Investigator and Site Investigator Responsibilities

- UTOPIAN has developed [standard responsibilities](#) for principal investigators and site investigators. Based on recent experiences by site investigators and to combat the general belief that primary care is simply a source of patients rather than valuable partners on research projects, principal investigator responsibilities now include items related to involving site investigators as decision makers and collaborators across all stages of the project, from development, implementation, to knowledge translation.

Building a Community of Practice Among Research Staff

- Recent discussions with Markham Health for All FHT have included thinking about how to connect research staff who are isolated at different centers/sites, leading to an idea to create a research community for research staff. This will be a forum for research staff to share ideas, feedback, career opportunities. A call to join this group will be circulated in the coming weeks.

Recent Publications

- D'Urzo KA, Tamari IE, Chapman KR, Maleki-Yazdi MR, Greiver M, Upshur RE, Biro L, O'Neill B, Moineddin R, Aliarzadeh B, Kulasegaram K, To T, D'Urzo AD. [Primary Care Severe Asthma Registry and Education Project \(PCSAR-EDU\): Phase 1 - an e-Delphi for registry definitions and indices of clinician behaviour](#). BMJ Open. 2022 Mar 24;12(3):e055958. doi: 10.1136/bmjopen-2021-055958. PMID: 35332043
- Upshur R, Abelsohn A, D'Urzo A, O'Neill B, Asrar FM, Hashemi SB, Melwani S, Aliarzadeh B. [Air Quality Health Index in primary care: A feasibility study](#). Canadian Journal of Respiratory, Critical Care, and Sleep Medicine. 2022 Apr. DOI: 10.1080/24745332.2022.2043204 [Ahead of Print]