First Meeting of Pragmatic Trials Interest Group: 27/03/2019

Attended: Anthony Shakeshaft, Sara Farnbach, Libby Top, Kristie Mammen Llew Mills

Dialled in: Raimondo Bruno, Krista Siefried, Nadine Ezard

Apologies: Nick Lintzeris

Chair: Llewellyn Mills

1. Long-term Goals of the interest group:

    - To build a better understanding of what is needed to conduct a pragmatic trial in the next 1 to 2 years

    - To eventually build a framework that streamlines the process of conducting clinical trials

    - Conduct research that answers questions that are important to clinicians and consumers and which can be translated rapidly into clinical practice

2. Brief comments from individual group members
    a. **Anthony**: Conduct trials that get out of the bubble of academic research and whose findings can be translated immediately into changes in clinical practice.
    b. **Libby:** Interested in how Pragmatic trials can facilitate knowledge transfer. Would like to conduct proof of concept with existing data.
    c. **Kristie:** Potential of using the clinical information available as outlined in the COQI framework for embedding pragmatic trials within eMR and ongoing treatment outcomes data.
    d. **Sara:** Also excited about potential of conducting trials in the context of existing data systems
    e. **Bruno:** Excited about real-world, punk-rock, data collection
    f. **Krista:** Interested in research with an emphasis on effectiveness over efficacy
    g. **Nadine:** Would like to be able to set up governance processes in D&A services where every person who is admitted signs a form granting consent for their data to be used as data for future research.
    h. **Llew:** Interested in shedding some light on what D&A treatments actually work in the real-world beyond the lab, but *also* beyond the prevailing opinions in clinical folklore.

3. Some ideas for what will be required from the group going forward:
    a. Building capacity to conduct a trial
        i. Data systems
        ii. How to devise appropriate research questions
            - Llew: Consultation sessions (e.g. Tuesday afternoons at Langton) asking clinicians what sets of treatments they don't have a strong opinion on
            - Krista: Clinicians may be reluctant to share ideas

- Anthony: suggested a process for identifying trials, along the lines of:
    a. Preliminary analyses of existing clinical data to identify questions that can be answered within the constraints of the existing clinical systems
    b. Use these analyses to devise research multiple research questions (10 or so?)
    c. Consult literature around each of these questions
    d. Present these questions to clinicians to gauge which they think are the most feasible and important (e.g. via a willingness to pay exercise)

    ACTION: Anthony to write up process for comment.

4. How do we involve consumers in this process:
    a. Llew: Consumers' thoughts will be especially useful on which outcomes are important to them (i.e. drug use, treatment retention, mental health, employment etc)

<u>Initial Research Ideas</u>

Nick: Retrospective pragmatic 'faux" trial: proof-of-concept trial assessing capacity within the existing eMR system to extract the kind of data that might need to be extracted in a pragmatic trial.

<u>Research Question:</u>

Do OTP clients using methamphetamine benefit more from buprenorphine vs methadone?

- Primary Predictor: Buprenorphine vs Methadone pharmacotherapy (categorical predictor)
- Covariates: TBD
- Outcome: Days used of amphetamine, Days used of heroin/opioids, Length of Treatment Encounter

We can *pretend* we randomised them for the purposes of this trial (hence the 'faux'). Designed just to test the data extraction and analysis process. Such a study can be conducted very easily with existing data collection and interrogation methods at each LHD. Potentially could conduct on dataset we are collecting for NCCRED grant (ie COQI data for clients entering treatment for 2017/18 calendar years, with follow up data until 2022(TBC)).

<u>Actions:</u>

Anthony: Write and disseminate document outlining process for conducting pragmatic trials for comment by other members

Libby: (1) Investigate Peer-Group mentioned by Nadine, (2) talk to Anthony/Krista/Nadine and colleagues from HIV/hepatology about the ways that they have routinely collected consent for future research from their patients at intake

Kristie and Llew: create a cloud-based storage account for Journal papers that can get past organisation firewalls. Schedule next meeting.

<u>For Next Meeting:</u>

Questions to consider:

1. Research Issues: Design/Data collection/Outcomes/Consultation measurement issues
2. Governance Issues: Data governance/consent/ethics