REthinking the way we perform Clinical Trials in Canada (REaCT)

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Objective

- "Genuine uncertainty" about the optimal care of cancer patients is common.
  - Physicians often choose between different "standard of care" treatments/procedures without the physician, patient, or society ever knowing what the "best" option is.
- Pragmatic head-to-head trials for comparing established treatments are needed.

Approach

- Development of a new research model that is more rapid, responsive, and relevant to the needs of Canadians.
- The timing of this transformative model is helped by the widespread availability of multiple funded standard treatments, established research infrastructure, powerful clinical, administrative databases and genuine desire to improve care.

Methods

- Febrile neutropenia is an important side effect of TC chemotherapy.
- Primary prophylaxis is either with G-CSF or antibiotics.
  - Both are funded standards of care
- Despite significant differences in these intervention (cost, side effects, patient convenience) optimal treatment is unknown.
- Funding received from PQ&SC Department of Medicine, Ottawa.
- Assess feasibility of performing trials using integrated consent model[1] (Figure 1).
- Planned start date: summer 2014.

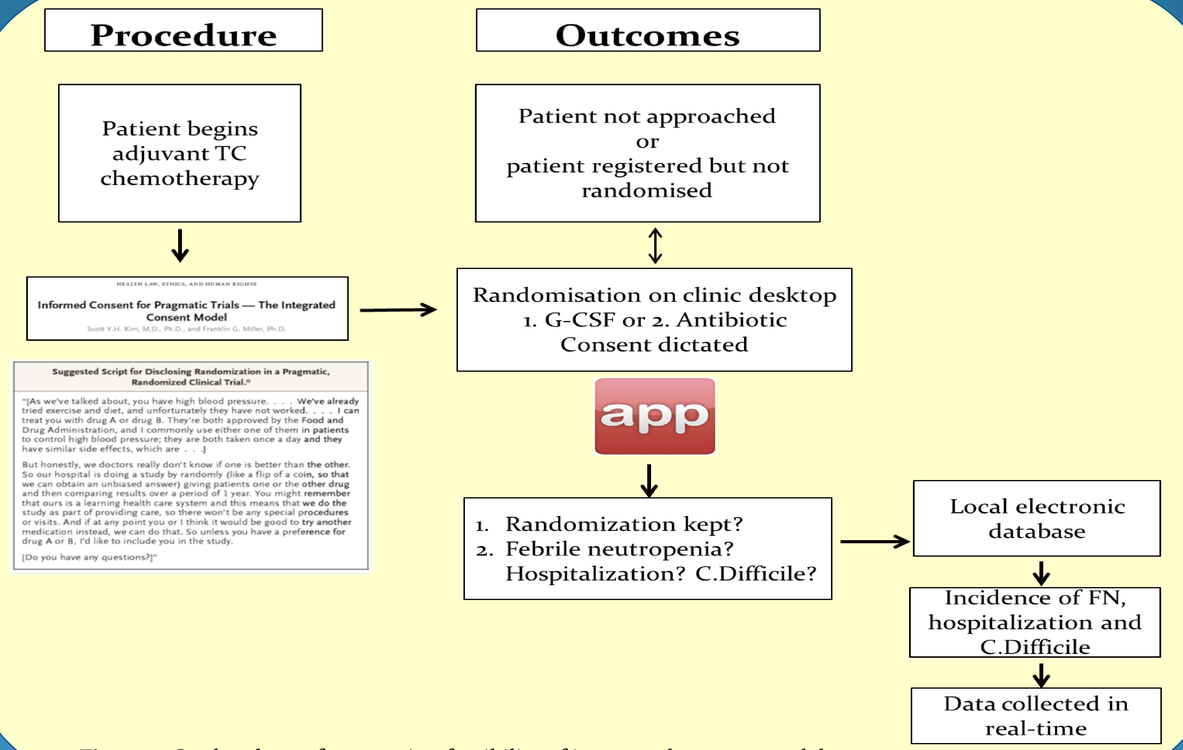

Figure 1. Study schema for assessing feasibility of integrated consent model.

Conclusion

- Current clinic trials model has many limitations for comparing standard of care treatments
- REaCT is an initial attempt to assess the feasibility of the integrated consent model

Future Directions

- Will require significant multi-partner buy-in.
- If this model is successful, it can be expanded beyond cancer care to the treatment of all patients.

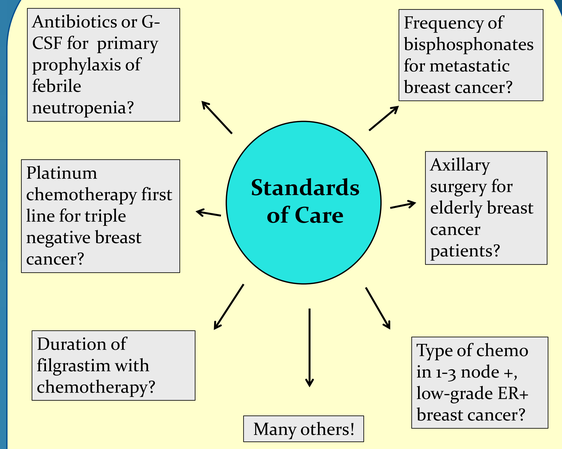

Figure 2. Breast cancer standard of care treatments.

Reference

1. Kim SY, Miller FG. Informed consent for pragmatic trials--the integrated consent model. *N Engl J Med.* 2014 Feb 20;370(8):769-72