NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

Results Reporting for PCTs

Draft Template

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Background

- CONSORT guidance exists, but
  - CONSORT was last updated in 2010 (Moher 2010 BMJ)
  - Pragmatic trial extension was developed in 2008 (Zwarenstein 2008 BMJ)
  - Numerous other CONSORT extensions are potentially useful for PCT reporting: PROs, CRTs, Harms, Abstracts
- Lessons learned from the Demonstration Projects can inform the need for updated guidance on reporting

CONSORT and Extensions

Description	Link
CONSORT website	http://www.consort-statement.org/
Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c869. PMID: 20332511	Moher 2010, PubMed abstract
CONSORT checklist and explanations	http://www.consort-statement.org/checklists/view/32-consort/66-title
CONSORT extensions	
Designs	
	Cluster trials
	Noninferiority and equivalence trials
	Pragmatic trials
	N-of-1 trials
Interventions	
	Herbal medicinal interventions
	Nonpharmacologic treatment interventions
	Acupuncture interventions
Data	
	Patient-reported outcomes
	Harms
	Abstracts

Selected Sections Added

- We looked to the CONSORT guidance and extensions to devise a template that follows the checklist headings.
- New areas are emerging related to the conduct of PCTs that the CONSORT checklist and guidance may not address adequately, which we added guidance for:
  - Wider stakeholder and health system involvement in conduct of PCTs
  - Human subjects protection
  - Secondary use of EHR data

Stakeholder engagement

METHODS

Stakeholder engagement (p 3)

Because PCTs are generally conducted as part of routine care and are meant to immediately inform the delivery of care, engagement with relevant stakeholders—patients, delivery system leaders, IT personnel, clinicians, and other frontline providers—is important. Briefly describe the extent to which stakeholders were involved (e.g., defining the study question, designing the study, developing workflows, assessing feasibility).

Human subjects protection

METHODS

Human subjects protection (p 4)

Describe approval by an ethics committee (e.g., an institutional review board). Include details of the type (written, oral, information sheet) and mode (electronic, mail, in-person) of informed consent used, or explain if the trial was determined exempt from requiring informed consent. If applicable, describe the existence of a data monitoring committee. For CRTs, indicate whether consent was obtained from cluster representatives or individual cluster members, or both. Describe whether consent was obtained before or after randomization.

EHR data use

METHODS

EHR data use (p 5)

If the source of data was from a clinical or billing database instead of one created primarily for research, describe:

- The steps used in gaining permission to use the data
- How the population of interest was identified (i.e., development of phenotypes, use of ICD-10 codes)
- The process for linking data from different sources
- Assessment of the quality of the data
- Data management during the study
- The plan for archiving or sharing the data after the study

Questions

- Are the reporting elements in this template appropriate?
- Are the elements comprehensive?
- Do we want to include a checklist similar to CONSORT's?