NIH Collaboratory Rethinking Clinical Trials®

Health Care Systems Research Collaboratory

Regulatory/Ethics Consultation Call:

Primary Palliative Care for Emergency Medicine (PRIM-ER) Trial

Monday, July 16, 2018

Meeting Participants

Corita Grudzen (NYU; study Principal Investigator), MariJo Mencini (Duke), Catherine Meyers (NIH), Tammy Reece (Duke), Marcel Salive (NIH), Jeremy Sugarman (Johns Hopkins), Wendy Weber (NIH), Alexandra Bragg (NYU), Ada Rubin (NYU)

AGENDA ITEMS	DISCUSSION July 16, 2018	PROPOSED ACTIONS July 16, 2018	CURRENT STATUS As of August 21, 2019
Review of Demonstration Project	• PRIM-ER Principal Investigator Corita Grudzen, MD, MSHS, provided an overview of the study. Briefly, PRIM-ER is evaluating the implementation of a multi-level, evidence-based educational intervention designed to provide clinicians with basic grounding in palliative care considerations. The PRIM-ER intervention utilizes widely adopted tools/curricula such as EPEC-EM[1] and ELNEC[2] and a simulation-based workshop (EM Talk[3]), as well as clinical decision support and provider audit and feedback. • **Collaborative network partners:** NYU and Rutgers University for the initial phase;		

[1] http://bioethics.northwestern.edu/programs/epec/curricula/emergency.html

[2] http://www.aacnnursing.org/ELNEC

[3] Grudzen CR, Emlet LL, Kuntz J, et al. EM Talk: communication skills training for emergency medicine patients with serious illness. BMJ Support Palliat Care. 2016 Jun;6(2):219-24.

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	expanding to 33 additional EDs nationwide for years 2-3. • **Study design:** Cluster-randomized, stepped-wedge design including 35 emergency departments (EDs) across 18 health systems. • Analysis will be performed on Medicare claims data using the Centers for Medicare and Medicaid Services (CMS) Virtual Research Data Center (VRDC).[4] The study will extract data on ED visitors aged ≥66 years and look back 1 year to identify patients at high risk for morbidity or mortality using the Gagne index.[5] Patients already receiving hospice care will be excluded from the study. ○ **Primary outcome:** Disposition from ED at 6 months: acute care vs. alternative (palliative care, hospice, home care) • The PRIM-ER study will require access to protected health information (PHI) only at the NYU site. The study has been granted a waiver of HIPAA authorization and a waiver of informed consent from the NYU IRB for the Medicare claims data analysis. Patients are at high background risk for mortality and morbidity, but the study itself has been determined to be minimal risk, with breach		

[4] https://www.resdac.org/cms-data/request/cms-virtual-research-data-center
[5] https://eprognosis.ucsf.edu/gagne.php

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	of privacy being the only likely risk. Obtaining consent would be impracticable given the circumstances and number of patients. • There is no data use agreement contemplated. • PRIM-ER study personnel and the PI have been conducting site visits, not as a formal component of the study, but because they have proven useful for obtaining study buy-in and support from health system leadership. • It was noted that because the study intervention aims to encourage referral of appropriate patients to palliative care instead of ICUs, it will be important to frame outcomes clearly and accurately to avoid misinterpretation. The study intervention is actually a standard of care with an overall goal to align patient care plans with patient goals. Because the study outcomes of interest are things that affect patient welfare, this distinction will important.		
Status of IRB approval	• The study has been approved by the NYU IRB, which has determined that study does constitute human subjects research at the NYU site but does *not* constitute human subjects research within the other 17 health systems participating in the study.		

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	• A letter is available for sites during contract negotiations affirming the IRB approval status.		
Risk classification	The IRB has made a determination of minimal risk for this study.		
Consent	• A waiver of informed consent has been granted by the NYU IRB. • A question was raised regarding whether patients were being notified that a study was ongoing. Although it was noted that individual notification seemed inappropriate, as the study was being performed with CMS datasets, others suggested that strategies such as posters or patient flyers could be used as a form of notification. It was acknowledged that post-study notification or communication about study results would most likely not be relevant to the PRIM-ER study, but plans for publication might be appropriate to include. • In response to a question about what might occur if any provider declined to participate in the study, the response was that such a scenario would most likely not come to the attention of PRIM-ER study staff.	Two Collaboratory papers on ethical/regulatory considerations in PCTs have been forwarded to the PRIM-ER team.[6,7]	

[6] Whicher DM, Miller JE, Dunham KM, Joffe S. Gatekeepers for pragmatic clinical trials. Clin Trials. 2015 Oct;12(5):442-8.

[7] Finkelstein JA, Brickman AL, Capron A, Ford DE, Gombosev A, Greene SM, Iafrate RP, Kolaczkowski L, Pallin SC, Pletcher MJ, Staman KL, Vazquez MA, Sugarman J. Oversight on the borderline: Quality improvement and pragmatic research. Clin Trials. 2015 Oct;12(5):457-66.

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Privacy/HIPAA	• The PRIM-ER study has been granted a waiver of HIPAA authorization. • No other concerns noted.		
Monitoring and oversight	The study has a Data and Safety Monitoring Plan that will draw on input from three experts with experience in palliative care research. NCCIH has worked with the PI in crafting the approach and it is consistent with their requirements.		The PRIM-ER team has identified three members to serve on the Independent Monitor Committee (IMC). All members have signed the IMC charter, and the PRIM-ER team is anticipating engaging IMC members at periodic intervals during the course of the study as outlined in the charter.
Issues beyond the study	A certificate of confidentiality has been provided as part of the grant award. This entails obligations regarding future data use, but may not be relevant to this study.		No additional issues.