

ABSTRACT: 2014 ELAM Institutional Action Project Poster Symposium

Project Title: Development of One Florida: Pragmatic Clinical Trials and Comparative Effectiveness Research Infrastructure

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Collaborators: David Nelson, MD, Myra Hurt, PhD, Michael Muszynski, MD, Richard Bookman, PhD and the One Florida Network

Background, Challenge or Opportunity: The University of Florida (UF) has an outstanding research infrastructure and clinical facilities. However, UF does not have a practice-based research network (PBRN) to support the conduct of pragmatic clinical trials and large-scale comparative effectiveness research (CER) studies. This kind of translational research and the PBRN infrastructure is essential to examine heterogeneity of treatment effects (i.e., what works well for whom under what circumstances) in “real world” settings.

Purpose/Objectives: Our goal was to develop the research infrastructure necessary to carry out pragmatic clinical trials and CER through the establishment of a statewide PBRN, in collaboration with other academic centers and diverse clinical practice settings. If successful, this network will provide a statewide infrastructure for CER and Pragmatic Clinical Trials. *The size and diversity of Florida and the composition of One Florida is critical for a range of CER studies and pragmatic clinical trials.* The diverse patient populations, physician specialties, and practice types within our network create significant opportunities to address important design issues related to ecological validity and scalability.ⁱ

Methods/Approach: Our network development leveraged the resources of the UF Clinical and Translational Science Institute including the availability of an integrated data repository and the development of a unified Institutional Review Board. The One Florida Network is comprised of seven unique systems with a combined catchment area covering all of Florida’s 67 counties and representing almost 8 million lives. One Florida includes: the University of Florida Health System (UF Health), the Orlando Health System (OH), Florida Hospital-Orlando, Health IMPACTS (Integrating Medical Practice and Community-based Translational Science) Practice-Based Research Network (PBRN), Florida Emergency Medicine Research Network (FLEMNet), the Agency for Health Care Administration (AHCA) who is responsible for Florida Medicaid and the Children’s Health Insurance Program (CHIP), and the Florida Department of Health (DOH). In 2012, One Florida provided care for 7,506,370 unique patients, or 39% of all Floridians, through a network of facilities and practices that include 22 hospitals, 416 practices, and 3,250 physician providers (Figure 1). One Florida also has unique Patient and Caregiver as Scientist (PCS) and Clinician Engagement Programs. Portions of the network have carried out two pilot studies to demonstrate the ability to implement a study, recruit practices and patients, and effectively gather data.

Outcomes and Evaluation Strategy: Qualitative and quantitative approaches related to assessing: functioning of the One Florida Steering Committee, development of a scientific review process, ongoing successful expansion of key infrastructure components (clinical research associates, webportal for study tracking), and strategic development to obtain federal funding. Successful implementation of additional pilot projects and applications submitted for federal and foundation funding with competitive scores and subsequent awards.

Development of One Florida: Pragmatic Clinical Trials and Comparative Effectiveness Research Infrastructure

Elizabeth Shenkman, PhD

Mentors: David Nelson, MD & Michael Good, MD

Collaborators: Myra Hurt, PhD; Mike Muszynski, MD, Richard Bookman, PhD and the One Florida Network

Challenge

UF has an outstanding research infrastructure and clinical facilities. However, UF does not have a practice-based research network (PBRN) to support the conduct of pragmatic clinical trials and large-scale comparative effectiveness research (CER) studies. This kind of translational research and the PBRN infrastructure is essential to examine heterogeneity of treatment effects (i.e., what works well for whom under what circumstances) in “real world” settings.

Objective

To develop the research infrastructure necessary to carry out pragmatic clinical trials and CER through the establishment of a statewide PBRN, in collaboration with other academic centers and diverse clinical practice settings.

Methods

Found Pilots:

- 1) UF Clinical and Translational Science Institute Infrastructure,
- 2) Strong project partners (FSU, UM, and diverse practice settings) who wanted to collaborate in CER and pragmatic clinical trials,
- 3) UF Big Data Initiative and focus on biomedical informatics.

IAP:

- 1) Strategic Planning with One Florida Partners;
- 2) Implementation of Pilot Projects;
- 3) Development of Joint Grant Applications; and
- 4) Obtain Federal Funding for Pragmatic Clinical Trials or CER That Uses the Network.

Approach/Outcomes/Evaluation Strategy

Background: In 2010, Dr. Nelson (UF-CTSI) and Dr. Shenkman began working on a strategy to build One Florida with the support of Dr. Good and the UF COM. The network development leveraged the resources of the CTSI and ongoing work including the availability of an integrated data repository (IDR) and the development of a unified Institutional Review Board (IRB). The One Florida Network is comprised of seven unique systems with a combined catchment area covering all of Florida's 67 counties and representing almost 8 million lives. One Florida includes: the University of Florida Health System (UF Health), the Orlando Health System (OH), Florida Hospital-Orlando, Health IMPACTS (Integrating Medical Practice and Community-based Translational Science) Practice-Based Research Network (PBRN), Florida Emergency Medicine Research Network (FLEMNet), the Agency for Health Care Administration (AHCA) who is responsible for Florida Medicaid and the Children's Health Insurance Program (CHIP), and the Florida Department of Health (DOH) who are providing vital statistics and cancer registry data. In 2012, One Florida provided care for 7,506,370 unique patients, or 39% of all Floridians, through a network of facilities and practices that include 22 hospitals, 416 practices, and 3,250 physician providers (Figure 1). One Florida also has unique Patient and Caregiver as Scientist (PCS) and Clinician Engagement Programs that are integral to the network along with a One Florida Institutional Review Board (IRB). Portions of the network have carried out two pilot studies to demonstrate the ability to implement a study, recruit practices and patients, and effectively gather data.

My IAP focused on:

- 1) Strategic Planning with One Florida Partners – formation of a Steering Committee, development of a scientific review process, implementation of key infrastructure components (clinical research associates, webportal for study tracking), and strategic development to obtain federal funding.
Outcomes: Steering Committee meets regularly with agenda and minutes, pilot studies reviewed and implemented, infrastructure elements in place, ongoing strategic plan with key milestones.
- 2) Implementation of Pilot Projects – pilot projects are essential to build trust.
Outcomes: Successful implementation of pilot projects to form foundation for future work.
- 3) Development of Joint Grant Applications – grant applications submitted for federal funding.
Outcomes: Applications submitted with competitive scores.
- 4) Obtain Federal Funding for Pragmatic Clinical Trials or CER That Uses the Network
Outcomes: Applications successful.

Acknowledgments

I would like to thank David Nelson, MD, Associate Dean for Clinical Research, College of Medicine, and Assistant Vice President for Research and Michael Good, MD Dean, College of Medicine for being my mentors. I would also like to thank Marian Limacher, Senior Associate Dean for Faculty Affairs and Professional Development, for her support throughout this process. Finally, I want to thank the wonderful faculty and staff of One Florida.

Presented at the 2014 ELAM® Leaders Forum.

Discussion

Interpretation: IAP 1 & 2 : The One Florida Steering Committee was formed and meets regularly for subsegments of participants. The Steering Committee needs to be broadened to incorporate other One Florida Members. CRAs are in place and webportal and other software development is complete. A more robust strategic plan is being formulated with key Steering Committee members in April 2014. Two pilot projects were successfully implemented. Three papers are in press based on this work and four presentations given. A third project, in collaboration with the Florida Medical School Quality Network was developed and will be implemented in September 2014. IAP 3: In addition, the One Florida group is collaborating on the development of an R18 application to the Agency for Health Care Research and Quality. The One Florida Network was invited through a competitive process to submit a PCORI clinical data research network application but was not funded. However the score was a competitive 3.2 (averaged across all sections). IAP 4: In progress.

Impact: If successful, this network will provide a statewide infrastructure for CER and Pragmatic Clinical Trials. Florida's diversity in terms of race/ethnicity, income distribution, age, and geography (urban/rural) provides an excellent setting for randomized and observational comparative effectiveness research (CER) designed to address the question of “what works best for whom, under what circumstances.”

Summary

In summary, several major steps were completed. We will continue to build on this foundation to develop collaborative grant proposals and obtain federal funding.