Planning for Real World Impact

Methods, models, & frameworks for planning pragmatic research.

August 11: 8am - 6pm MDT

August 12: 7:30am - 4:30pm MDT

Breakfast Session

Early Career Investigator Consultations

Colorado Pragmatic Research in Health Conference
Pragmatic Research Planning Group Consultation Opportunity

NAME/EMAIL: Lauren D Gulley; lauren.gulley@childrenscolorado.org

POSITION TITLE: Clinical Instructor, University of Colorado School of Medicine; Research Scientist, Colorado State University

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of Denver, Denver, CO	Ph.D.	08/2017	Child Clinical Psychology
Colorado State University, Fort Collins, CO	Postdoc	08/2019	Obesity and Type 2 Diabetes
Colorado Dept of Regulatory Agencies	License	08/2019	Licensed Psychologist

Funding Agency/Grant Mechanism

I submitted a Letter of Intent and was subsequently invited to submit a full proposal to the Society of Pediatric Psychology's Targeted Research Grant program, which provides $20,000 of funding for 1 year. The goal of the program is to allow early career investigators (<10 years from PhD) to collect pilot data to aid in securing major grant funding. More specifically, my proposed pilot study for this Targeted Research Grant will lay crucial groundwork for a career development award (K23: Mentored Patient Oriented-Research). The proposed K23 research plan will be a pragmatic and adaptive clinical trial testing a behavioral intervention integrated into healthcare practice for adolescents with depression and diagnosed medical comorbidities of obesity (e.g., type 2 diabetes, polycystic ovary syndrome) receiving care at Children's Hospital Colorado's Lifestyle Medicine Clinic.

Moreover, special consideration will be given to Targeted Research Grant proposals that address one of the priority areas as defined by the Office of Behavioral and Social Sciences Research. My proposed pilot addresses Priority #3, which is to facilitate the adoption of behavioral and social sciences research findings in health research and in practice. My proposed pilot will implement an evidence-based behavioral intervention for depression – interpersonal psychotherapy (IPT) – for adolescents with polycystic ovary syndrome (PCOS) receiving care in the Lifestyle Medicine Clinic. This pilot has strong potential to increase access to and engagement with mental health treatment by pilot testing the feasibility/acceptability and preliminary effectiveness of integration into healthcare practice in a pragmatic, sustainable, and cost-effective manner.

Draft Aims/Hypotheses

Obesity (body mass index [BMI; kg/m^2] >95th %ile)[1] in adolescents is significantly associated with PCOS[2], an endocrine disorder linked to increased insulin resistance and risk for long-term cardiometabolic problems.[3] Meta-analyses in women with PCOS show greater odds of depression (OR 2.79)[4] and disordered eating (OR 3.05)[5] compared to controls. Research in adolescents with PCOS is limited; however, data from our own pediatric PCOS clinic suggests a high prevalence of elevated depression symptoms (60%).[6] Relatedly, depression and disordered eating in adolescents with obesity increase cardiometabolic risk.[7,8] Mental health treatment for adolescents with PCOS may reduce depression/disordered eating and prevent health problems; however, there are barriers to access.[9] Integrating behavioral interventions within healthcare settings or utilizing innovative delivery formats (i.e., telehealth, guided self-help) may increase access.[10,11] IPT is an evidence-based intervention that decreases depression and disordered eating in adolescents at-risk for and with obesity.[12,13] IPT has also been delivered to adolescents in primary care with high feasibility/acceptability.[14,15] IPT's model purports that interpersonal stressors trigger negative affect, which leads to disordered eating to cope.[16] IPT teaches strategies to increase support and manage conflict, thus decreasing negative affect and disordered eating.

The overarching goal of this work is to improve cardiometabolic outcomes for adolescents with PCOS by decreasing depression and disordered eating through pragmatic delivery of behavioral interventions within pediatric specialty care. We propose a 2-arm randomized controlled pilot and feasibility trial of an evidence-based treatment for adolescent depression and disordered eating - IPT - delivered in a pediatric PCOS specialty care clinic via two formats: 1) telehealth group and 2) individual guided self-help, to N=30 girls (12-18y).

Specific aims are:

1. **Evaluate feasibility/acceptability of IPT delivered via telehealth group or individual guided self-help to N=30 12-18y girls in a pediatric PCOS clinic**. Feasibility will be assessed by CONSORT guidelines for recruitment, enrollment, and retention. We expect ≥70% randomization of eligible teens, ≥70% retention at post-intervention follow-up, and better engagement with telehealth vs. guided self-help. Acceptability will be assessed via structured interview. We expect above-average (≥80%) acceptability themes and ratings.
2. **Explore effects of IPT on depression, disordered eating, metabolic risk, and cost-effectiveness**. We hypothesize that IPT in both delivery formats will decrease depression, reduce disordered eating, and improve metabolic risk factors for girls with PCOS. We predict IPT will show patterns of cost-effectiveness.

Draft Approach

Participants will be N=30 patients recruited from a multidisciplinary pediatric PCOS clinic. Inclusion criteria will be: 1) age 12-18y; 2) PCOS; 3) depression symptoms (Center for Epidemiologic Studies-Depression Scale [CES-D][17] score ≥16); and 4) presence of disordered eating (Loss of Control Eating Disorder Questionnaire [LOC-EDE-Q][18]). Exclusion criteria will be: 1) unable to speak/read/write in English; 2) major medical condition not related to PCOS; and 3) weekly psychotherapy. Baseline assessment will coincide with a clinic visit to reduce burden and will include consent/assent and measures routinely collected in clinic, including screeners of depression/disordered eating, BMI, and metabolic factors. Participants will be randomized to IPT 1) telehealth group or 2) individual guided self-help. Three cohorts will run in parallel (n=5/condition x 2 conditions x 3 cohorts: N=30). Telehealth groups will occur 1x/week, for ~1 hour, for ~6 weeks during non-school hours. Individual guided self-help will follow parallel pacing with weekly phone check-ins. Post-intervention follow-up will coincide with the next clinic visit. Adolescents will repeat baseline measures and also an acceptability interview. Resource and healthcare costs will be measured to ascertain cost-effectiveness. Participants will be compensated.

Pragmatic Study Designs/Frameworks

Top Choice:

1. RE-AIM

Secondary Choices:

2. EPIS
3. CFIR
4. PRISM

Challenges and Key Questions

Framework (Primary): What framework may be best suited to carry out this 1-year pilot study, with the ultimate goal of the pilot being to provide compelling preliminary data for a K23 research/training plan? My clinical research background has been primarily explanatory, with a focus on randomized controlled efficacy trials utilizing behavioral interventions to prevent youth depression and adverse health outcomes, including obesity and risk for obesity-related medical comorbidities (e.g., type 2 diabetes, polycystic ovary syndrome). Future directions of this independent program of research involve conducting pragmatic trials to integrate these behavioral interventions in routine healthcare delivery. This is my very first pragmatic study proposal, and so I would like to select a framework not only suitable to complete specific aims of the pilot, but also a framework that can be carried forward and serve as the foundation for a K23 research/training plan.

Design (Secondary): What pragmatic design, methods, or measures would you recommend for a 1-year award? After reviewing my Letter of Intent, the review committee specifically wrote to me, saying I must ensure that my proposed research can be completed within the scope of the 1-year award period. Alternatively, if it is not feasible to complete all proposed aims during the award period, the committee said I may narrow the scope of the proposed research to focus on a subset of the originally proposed aims. There are several phases within frameworks and a multititude of constructs within phases, and so I would like to refine the study design, methods, and measures to fit within a suitable framework, but also to be cleary feasible to complete within a 1-year period.

Literature Cited

1. Ogden CL, Kuczmarski RJ, Flegal KM, et al. Centers for Disease Control and Prevention 2000 growth charts for the United States: Improvements to the 1977 National Center for Health Statistics version. *Pediatrics.* 2002;109(1):45-60.
2. Christensen SB, Black MH, Smith N, et al. Prevalence of polycystic ovary syndrome in adolescents. *Fertil Steril.* 2013;100(2):470-477.
3. Ramezani Tehrani F, Amiri M. Polycystic ovary syndrome in adolescents: Challenges in diagnosis and treatment. *Int J Endocrinol Metab.* 2019;17(3):e91554.
4. Brutocao C, Zaiem F, Alsawas M, Morrow AS, Murad MH, Javed A. Psychiatric disorders in women with polycystic ovary syndrome: A systematic review and meta-analysis. *Endocrine.* 2018;62(2):318-325.
5. Lee I, Cooney LG, Saini S, Sammel MD, Allison KC, Dokras A. Increased odds of disordered eating in polycystic ovary syndrome: A systematic review and meta-analysis. *Eat Weight Disord.* 2019;24(5):787-797.
6. Benson J, Severn C, Hudnut-Beumler J, et al. Depression in girls with obesity and polycystic ovary syndrome and/or type 2 diabetes. *Can J Diabetes.* Manuscript accepted for publication.
7. Shomaker LB, Tanofsky-Kraff M, Stern EA, et al. Longitudinal study of depressive symptoms and progression of insulin resistance in youth at risk for adult obesity. *Diabetes Care.* 2011;34(11):2458-2463.
8. Tanofsky-Kraff M, Shomaker LB, Stern EA, et al. Children's binge eating and development of metabolic syndrome. *Int J Obes (Lond).* 2012;36(7):956-962.
9. Gulliver A, Griffiths KM, Christensen H. Perceived barriers and facilitators to mental health help-seeking in young people: A systematic review. *BMC Psychiatry.* 2010;10:113.
10. Myers K, Nelson EL, Rabinowitz T, et al. American Telemedicine Association Practice Guidelines for Telemental Health with Children and Adolescents. *Telemed J E Health.* 2017;23(10):779-804.
11. Hodgkinson S, Godoy L, Beers LS, Lewin A. Improving mental health access for low-income children and families in the primary care setting. *Pediatrics.* 2017;139(1).
12. Tanofsky-Kraff M, Shomaker LB, Wilfley DE, et al. Targeted prevention of excess weight gain and eating disorders in high-risk adolescent girls: A randomized controlled trial. *Am J Clin Nutr.* 2014;100(4):1010-1018.
13. Tanofsky-Kraff M, Shomaker LB, Wilfley DE, et al. Excess weight gain prevention in adolescents: Three-year outcome following a randomized controlled trial. *J Consult Clin Psychol.* 2017;85(3):218-227.
14. Mufson L, Rynn M, Yanes-Lukin P, et al. Stepped care interpersonal psychotherapy treatment for depressed adolescents: A pilot study in pediatric clinics. *Adm Policy Ment Health.* 2018;45(3):417-431.
15. Mufson L, Yanes-Lukin P, Anderson G. A pilot study of Brief IPT-A delivered in primary care. *Gen Hosp Psychiatry.* 2015;37(5):481-484.
16. Tanofsky-Kraff M, Wilfley DE, Young JF, et al. Preventing excessive weight gain in adolescents: Interpersonal psychotherapy for binge eating. *Obesity (Silver Spring).* 2007;15(6):1345-1355.
17. Radloff L. The CES-D scale: A self report depression scale for research in the general population. *Appl Psychol Meas.* 1977;1(3):385-401.
18. Altman DR, Tanofsky-Kraff M, Shank LM, et al. Assessment of loss-of-control eating in healthy youth by interview and questionnaire. *Int J Eat Disord.* 2020;53(5):510-519.

Feedback Application info for Early Career Investigator Consultations at the COPRH conference, August 11-12, 2020

Dear application committee,

I have included our Research Abstract and our Specific Aims page below for your review. I also answered a few more questions that were on the website that I could not answer on the application drop down questions. Let me know if you have other questions for me.

Any pragmatic study designs or frameworks you are considering for your project:
We are considering using CFIR since I have a lot of experience applying and using it, to study implementation of our pragmatic tools.

Any target funding agencies you are considering (e.g., NIH, AHRQ, PCORI) or grant mechanisms (e.g., K23, R01, other) and any important context we should know about any request for proposals to which you are applying
This application is in response to the NIH R01: https://grants.nih.gov/grants/guide/pa-files/PAR-19-250.html
Environmental Influences on Aging: Effects of Extreme Weather and Disaster Events on Aging Populations (R01 Clinical Trial Optional)

Challenges and Key Questions you would like to discuss with Group and Pragmatic Research Faculty Experts (pick 1 key issue below that you want to discuss in this consult, and/or write-in no more than 3 different key challenges/questions):
I think our main question is about our quant aim 1, which might be too specific for feedback. Otherwise, I can take general feedback about pairing studying flooding with COVID-19 in the same study. We think there are strengths to do this since we are developing pragmatic tools to assist aging veterans and their caregivers before, during, and after disasters, and having two distinct types is an advantage. Otherwise we have some creative plans in the research strategy of our grant to work with key stakeholders, but always open to more discussion on this. We are planning to submit for the next deadline in early November, but will likely submit earlier since we have most things ready. Let me know if you would like to see a draft of the research strategy, too!
Thanks,
Dr. Haverhals

Abstract:
As our population rapidly ages, older adults are seeking to remain independent and at home, despite managing complex medical conditions and the mounting frequency and severity of disasters. Buoyed by advancements in healthcare technology and coupled with increasing funding for long-term services and supports for care at home, more older adults are able to make this choice a reality, regardless of increased risk of social isolation and limited mobility. However, due to outsized impacts and costs for caring for older adults with complex medical conditions, it is critical to provide consistent care that helps prevent hospitalizations or other emergent needs, especially in disaster contexts. One significant, consistent support system present in older adults' lives is their healthcare team. These healthcare teams can serve as essential resources to older adults before, during, and after disasters. This is of particular importance because primarily homebound, medically complex older adults are at heightened risk for morbidity and mortality during disasters. Of the large spectrum of services that provide healthcare to older adults, home-based primary care programs and geriatric-focused, outpatient primary care clinics serve a key role, often becoming trusted advisors to their patients. The objective of this proposal is to develop reliable, pragmatic tools for primary care practices and programs that will build on successful strategies demonstrated by these settings in previous disasters. While the need for home and community-based services to improve disaster preparedness and recovery efforts tailored for older, community-dwelling adults is widely recognized, little has been reported on the actual efforts of these programs to increase resiliency in the face of disasters. Further, while healthcare teams are experts in providing care, they are generally not experts in emergency management. To address this, we propose studying two distinct disasters: the devastating Midwest floods of 2019 and select hotspots of COVID-19 outbreaks in 2020. At the culmination of the study, we will develop a toolkit that is a cumulative reflection of our findings to extend them both into home-based and outpatient primary care settings. A strength of this proposal is bringing together a research team with broad depth of clinical and analytic knowledge of the Department of Veterans Affairs (VA) home-based programs, including disaster preparedness and response capabilities and team effectiveness, and relevant VA geriatric clinics and ancillary support programs. The proposed research is significant because it fills a gap

between expectations and realities of what healthcare providers, both in-home and in clinic settings, can expect in response to a disaster event. Findings from implementing the tool will provide a first-step road map for expanding the greater community's attention to how to better care for medically vulnerable, older adults during and after disasters.

Specific Aims

Our goal is to assess health outcomes of vulnerable, older Veterans (Aim 1) and lessons learned of Veterans, their caregivers, and their healthcare teams following two major disasters (Aim 2) in order to inform the design and piloting of a pragmatic tool to support older Veterans, their caregivers, and their healthcare teams, before, during, and after disasters (Aim 3). We have the expertise, the collaborative relationships, and resources to execute this project, as our multidisciplinary team includes experts in geriatrics and extended care, disaster preparedness and response, home-based primary care, primary care, mixed methods, and implementation science.

Older adults living with multiple comorbidities, who often are on the cusp of requiring long-term care, face all-too-real challenges prior to, during, and after disasters, making them highly vulnerable[1–5]. More and more medically complex, older adults in the United States (U.S.) desire to remain living at home as long as possible despite medical complications, rather than move to institutionalized settings like nursing homes[6–15]. This places unique responsibilities on caregivers and healthcare teams, and is complicated by the mounting frequency and severity of disasters[16–20]. Balancing this reality—how quality care can be provided to primarily homebound older adults before, during, and following major disasters—is not only tricky on its face, it deserves far more pointed study.

To date, pragmatic tools to assist older adults and their caregivers in disaster contexts, and their applicability and compatibility to real-world situations, remain understudied. This is problematic as disasters are increasingly frequent and variable[21–24]. Healthcare providers have been identified as a key resource in the emergency preparedness and response cycles for older adults and caregivers[25,26]. As such, we plan to study two healthcare settings that support medically complex older adults: the Department of Veterans Affairs (VA) Home Based Primary Care (HBPC) program[27–36] and VA geriatric-focused outpatient primary care clinics (OPCC)[43–47]. Begun in 1972, the VA HBPC program provides in-home medical care, via an interdisciplinary team of skilled healthcare professionals, to Veterans with multiple medical conditions that have difficulty traveling to in-person medical appointments and are often homebound[6,29,35,36]. VA HBPC has grown to care for nearly 60,000 Veterans[27], and in recent years, the VA has begun studying the role teams play in disaster preparedness and recovery for its Veterans and their caregivers[52–54]. And yet, even with the growth of the VA's HBPC program, most homebound Veterans receiving care through VA continue to receive their primary care through OPCC.

Our objective is to extend the current evidence-base and develop and subsequently scale-up and spread a pragmatic tool that will more globally support vulnerable, primarily homebound older adults prior to, during, and after disasters. This research is critical because it will lay the groundwork for providing improved, high quality care for older, homebound, medically complex Veterans and non-Veterans alike in preparation for and in the wake of disasters, particularly in cases where built environment is compromised[55–57].

AIM 1a: Characterize patterns of care and correlates of clinical outcomes among patients enrolled in VA HBPC and OPCCs during and after the 2019 Midwest floods and 2020 COVID-19 initial outbreak.

AIM 1b: Identify high performing and low performing VA sites, as well as the most vulnerable population groups after these two disasters, within HBPC and OPCCs.

AIM 2: Identify VA HBPC programs and VA OPCC impacted by the two disasters to conduct observational site visits and describe mechanisms implemented and challenges faced to maintain delivery of high-quality care during response and recovery.

AIM 3: Develop, pilot, and evaluate implementation of the pragmatic tools and dissemination materials targeted to HBPC teams and OPCCs providing care and support to older, homebound patients.

The pragmatic tools and dissemination materials developed from this study are a critical next step to support and positively impact older adults, their caregivers, and their healthcare teams before, during, and after disasters.

7/14/2020

Ozkaynak's COPRHCON 2020 Consultation Application

My name is Mustafa Ozkaynak. I am a junior Associate Professor at College of Nursing (Anschutz Medical Campus). I earned my PhD in 2011. I am an industrial and systems engineer by training. My email address is Mustafa.ozkaynak@cuanschutz.edu.

My overall research interest is in health informatics. I am particularly interested in clinical decision making and clinical decision support (CDS) systems. I would like to develop clinical decision support systems that behave differently to accommodate clinicians' individual characteristics. Currently, I consider two characteristics of clinicians: fatigue and trust to technology. Therefore, I would like to design clinical decision support systems that behave differently for clinicians with different fatigue and trust to technology. I expect that the newly developed CDS will better accommodate clinicians' fatigue and eliminate patient safety events due to over- and under-trust to technology.

This research is applicable to various clinical settings. However, due to my previous research in emergency departments and antimicrobial stewardship interventions, I would like to design Electronic Health Record embedded CDS for the emergency department of Children's Hospital Colorado (CHCO). This CDS will assist clinicians prescribe appropriate antibiotics when only needed. The participants of my study will be providers who use electronic health records to prescribe antibiotics. However, I am open to apply my interventions in other clinical settings if I can find an enthusiastic collaborator in these settings.

My proposal aims to create a foundation and design guidelines for adaptable CDS. The specific aims are:
Specific Aim – 1a: To examine the impact of clinician's fatigue in using clinical decision support systems
Specific Aim – 1b: To examine the impact of clinician's trust in using clinical decision support systems
Specific Aim – 2: Develop and evaluate design guidelines for adaptive clinical decision support systems

I plan to use various data sources for Specific aims 1a and 1b. These data sources are EHR logs, surveys, capture screen movements and interviews. The findings will be utilized in design workshops to develop a CDS prototype that will be tested by clinicians in actual encounters.

I have very limited understanding of pragmatic study designs and frameworks. My goal in this consultation session to have a better understanding of how these designs and frameworks can facilitate my research. I also want to understand whether my project fits in the scope of pragmatic research or is it a more explanatory research project?

Currently I am planning submitting a parent R21 to NIH National Library of Medicine(NLM).

My specific challenges and key questions are as follows:

- How do we identify appropriate sample size (number of clinicians who will use the newly developed CDS) when we evaluate the newly developed CDS?
- Is it better to have smaller number of clinicians use the revised CDS a long time or big number of clinicians use it for a shorter time?
- I am already using a conceptual framework to justify the necessity of adaptive CDS. How do we use a domain framework and D&I framework concurrently?
- Have the D&I frameworks been used for technology implementations?