Evaluation of a covariate-constrained randomization procedure in stepped wedge cluster randomized trials

Erin Leister Chaussee | PhD Candidate | Colorado School of Public Health

Background: In stepped wedge (SW) designs, differing cluster-level characteristics or individual-level covariate distributions that differ by cluster can lead to imbalance by treatment arm and potential confounding of the treatment effect.

Setting: SW cluster randomized trials

Methods: Adapting a method used in cluster-randomized trials, we propose a covariate-constrained randomization method to be used in SW designs. First, we define a balance metric to be calculated for all possible randomizations of cluster order for a given SW design (denoted BSW). The resulting distribution of this balance metric across all possible randomizations is used to select a candidate set of randomizations with acceptable covariate balance, for example, the best tenth percentile (P10) of the BSW distribution. One cluster order is selected at random from this candidate set to be used as the cluster order for treatment implementation. In a simulation study, we implement the covariate-constrained randomization procedure and computed treatment effect estimates and average absolute bias, and estimates of type I error and power. We used these outcomes to evaluate differing cutoffs of the BSW distribution used to define the candidate set and various analysis methods, under varying SW design and confounding settings.

Results: We observed optimal statistical properties when the balance metric was used to exclude a small set of potential randomizations with the highest level of imbalance, and when analysis methods were adjusted for the potential confounders (see Figure for average absolute bias by BSW cutoff results). The covariate-constrained randomization was most beneficial in settings with a small number of clusters, low intra-class correlation, a low number of participants per cluster, and in the presence of cluster-level confounding variables.

Conclusions: We recommend researchers using the SW design carefully consider potential confounders, both cluster-level and individual-level, prior to cluster order randomization and consider a covariate-constrained randomization if appropriate. Treatment effect estimation should be adjusted for these potential confounders, and other covariates associated with the outcome of interest.
Pragmatic Trial Implementing High-Intensity Rehabilitation in Skilled Nursing Facilities

Katie Seidler PT, DPT | Post-doctoral Fellow | University of Colorado Anschutz Medical Campus, Department of Physical Medicine & Rehabilitation, Physical Therapy Pr

Background: Functional recovery during a skilled nursing facility (SNF) stay is poor1,2, likely related to inconsistent rehabilitation practices3-5. This pragmatic study evaluated the feasibility and effectiveness of a high-intensity rehabilitation protocol in improving function during a SNF stay.

Setting/Population: Older adults (Veterans) admitted to SNF following a hospitalization.

Methods: Data were collected on 103 consecutive Veterans admitted to one SNF (age 77.7 ±10 years; 89% male). The i-STRONGER Program (IntenSive Therapeutic Rehabilitation for Older Skilled NursinG HomE Residents) integrates principles of physiologic tissue overload and strength training into rehabilitation6. A comparison of usual care with i-STRONGER occurred using a staged, 2-independent group design with the SNF serving as its own control. Therapists assessed function at evaluation and discharge via the Short Physical Performance Battery (SPPB) and gait speed 7,8. Treatment fidelity of i-STRONGER was assessed with an observational checklist. Regression analyses evaluated the response of SPPB or gait speed change to treatment group.

Results: i-STRONGER participants exhibited a 0.13 meters/second greater change in gait speed than Usual Care (p=0.05). i-STRONGER demonstrated a 0.64-point greater change in SPPB than Usual Care (p=0.27). The average SNF length of stay was 3.5 days shorter during i- STRONGER (p=0.26), which equated to savings of ~$1537.38 per patient9. Adherence to i- Stronger was 99% over 11 sessions. No treatment-specific adverse events were reported.

Conclusions: High-intensity rehabilitation for patients admitted to a SNF following hospitalization effectively and safely improves function with reduced length of stay. Implications for practice: A high-intensity rehabilitation approach in SNFs appeared to improve functional outcomes in less time.

3. Pragmatic research planning methods and frameworks 

Completed research
Development of a Dissemination and Implementation Framework for an Early Childhood Obesity Prevention Program

Emily Bergling | DrPH Student | Colorado School of Public Health

Background: Dissemination and implementation (D&I) research addresses the disconnect between evidence-based research and practical application in community settings. Many current evaluation approaches to school-based health programs have a limited focus on outcome measures. This neglects to account for additional factors that influence implementation and program success. The mixed effectiveness of early childhood education (ECE)-based obesity prevention programs and the complexity added by implementing multi-component programs calls for more comprehensive evaluation, and one that includes factors related to D&I.

Setting: ECE settings are ideal for the application of D&I research due to their widespread use for implementing health interventions. The Culture of Wellness in Preschools (COWP) is a multi-component early childhood obesity prevention program, which aims to promote a “culture of wellness” in ECE settings by increasing fruit and vegetable consumption and physical activity levels.

Methods: The COWP team convened a working group to focus on the D&I constructs that were relevant to the program. An informal literature search was conducted to assess the applicability of existing D&I frameworks. Two frameworks guided the development of the COWP framework, the Consolidated Framework for Implementation Research (CFIR) and an obesity-prevention specific framework developed by Dreisinger et al. These were supplemented with additional program specific constructs.

Results: The COWP D&I framework was developed to inform the program’s implementation and evaluation efforts. The framework consists of six domains: process, stages of dissemination, system-level and contextual factors, intervention-level factors, structural and participant factors (organizational- and individual-level), and outcomes. Preliminary work applying the framework was conducted in 2019. A mixed-methods evaluation assessed D&I factors related to the one component of the COWP program: the COWP Policy, System and Environment (PSE) Change process. Findings suggest that the successful implementation of the process may be most impacted by staff attitudes and perceived importance, the current status of wellness policies, and the adaptability of the process to align with center culture and norms. Factors most related to the successful sustainability of this process may be skills, attitudes, support and engagement of the staff and leadership, and the quality rating score of the center.

Conclusions: The development of a D&I framework specific to COWP is an initial step in adopting a D&I focused approach to program evaluation and quality improvement. The COWP team plans to build off these preliminary findings to explore how to use this framework to guide the development of research questions, additional data collection, and future analyses related to the overall COWP program.

3. Pragmatic research planning methods and frameworks Work-in-progress
Parent-focused child sexual abuse prevention

Kate Guastaferro, PhD | Assistant Research Professor | Pennsylvania State University

Purpose: Child sexual abuse (CSA) affects about 60,000 children per year in the United States and has estimated societal costs in excess of $9.3 billion. Despite the proliferation of parent education programs that have successfully reduced the risk for physical abuse and neglect, these programs are not designed to prevent CSA specifically and have not affected rates of CSA. While parents are not the most common perpetrators of CSA, they are an important agent of change within the family context and they control access to children by creating a protective and safe environment. This study sought to examine the knowledge, attitude, and behavioral changes attributable to the addition of a newly-created, parent-focused CSA prevention module to existing evidence-based parent education programs commonly prescribed for parents who are deemed ‘at risk’ within the child welfare system.

Method: A cluster randomized controlled trial was conducted among six community-based organizations randomized to provide Parents as Teachers plus a one-hour CSA module (PAT+CSA) or Parents as Teachers delivered as usual (PAT Only). CSA related-knowledge, attitudes, and protective behaviors (i.e., involvement, positive parenting, and inconsistent discipline) were assessed at four time points (baseline, post-PAT Only, post-PAT+CSA, and a one month follow-up).

Results: CSA related knowledge and attitudes were significantly higher in the PAT+CSA condition than in the PAT Only condition (p = 0.032) at post-intervention. Behaviors also increased from baseline to post-intervention (p < 0.05) and remained increased at the one month follow-up assessment (p < 0.001).

Conclusion: A singular added session focused on CSA prevention can significantly improve parents’ ability to demonstrate CSA preventive knowledge, attitudes, and behavioral skills which can be maintained over time. Parents are critical in preventing CSA and these findings indicate it is possible to augment current approaches to parent education with CSA-specific curricula to impact rates of CSA.

1. Pragmatic research study design and analysis  
   Completed research
**Discharge Today: The efficacy of a multidisciplinary electronic discharge readiness tool**

Angela Keniston, MSPH | Director, Data and Analytics/Instructor | University of Colorado

**Background:** Commonly used discharge communication workflows hinder timely and efficient discharge. Studies exploring the use of the EHR for discharge planning have been limited to electronic reports constructed from EHR data elements, including barriers to discharge documented at admission, care management data, and discharge criteria or other targeted interventions such as improving discharge summaries for patients or medication reconciliation at discharge. To address these deficits, we developed an innovative EHR tool to facilitate communication in real-time between hospitalists and other clinicians about discharge readiness and barriers to discharge.

**Setting/population:** All clinicians who were scheduled to be on an inpatient Hospital Medicine service were trained and asked to use the Discharge Today tool with all patients assigned to their team.

**Methods:** This study is a prospective, single center, pragmatic, interrupted time series study. Clinicians were asked to update patient discharge readiness (Definite, Possible, Tomorrow, In 24-48 hours, > 48 hours) and any barriers to discharge, every morning and anytime patient status changed. Primary outcomes were time of day the clinician enters the discharge order, time of day the patient leaves the hospital, and hospital length of stay. Secondary outcomes were proportion of patients with a discharge order before 11 am and proportion of patients discharged before 11 am. We used linear mixed modeling and generalized linear mixed modeling with team and discharging provider included in all models to account for patients cared for by the same team and the same provider.

**Results:**
We found that, after adjusting for pre-specified confounders and effect modifiers, for every one patient increase in the morning census, there was a statistically significant reduction in the time of day the discharge order was entered into the EHR by the discharging physician (3 minutes per patient (95% CI: 42 seconds, 6 minutes), p=0.0245) for the pilot implementation period compared to the pre-implementation period, though not for the post-implementation period (p=0.4526). We also found a statistically significant reduction in hospital length of stay for the pilot implementation period compared to the pre-implementation period (56 minutes (95% CI: 52 minutes, 1 hour), p=0.0047), though not for the post-implementation period (p=0.4342).

**Conclusions:** Our Discharge Today tool is a real-time communication tool, created by hospitalists and other healthcare professionals who participate in discharge planning to not only document and communicate what tasks need to be completed before a patient can be discharged but also to help clinicians, nursing, and other staff to prioritize their work in real-time. Our analysis suggests this tool is useful for improving discharge timing, particularly as the number of patients being cared for by a team increases.

1. Pragmatic research study design and analysis | Work-in-progress
The Data Science to Patient Value (D2V) Navigation Lab

Brad Morse, PhD, MA on behalf of Michael Ho, PhD | Research Instructor | University of Colorado Anschutz Medical Campus - D2V

Background: The National Academy of Medicine defines a Learning Health System as a health system that assembles, analyzes, and interprets data. Findings are leveraged to adapt and improve delivery of patient-centered care. A challenge for a Learning Health System is responsive learning and adapting, i.e., thinking differently to address what seem like problems that can be managed with the application of traditional methods. To assist UCHealth and Children’s Hospital of Colorado with this process, the Navigation Lab (NavLab) performs interdisciplinary evaluation of health system clinical programs and initiatives.

Setting: The University of Colorado Anschutz Medical Campus/UCHealth Learning Health System. The NavLab works with physicians and departments serving the many patients that utilize the network of hospitals associated with the Learning Health System. Due to the unique setting in which the NavLab works, our projects engage a diverse spectrum of communities within the general population.

Methods: The NavLab’s multidisciplinary team includes a health economist, systems engineer, biostatisticians, qualitative analysts, clinicians, analytics developers, user experience (UX) designer, and a program manager. The NavLab utilizes an interdisciplinary approach for program evaluation including comparative effectiveness analysis, economic evaluation, workflow and staffing assessment, and user-centered design. The team engages health system partners to identify opportunities for Quality Improvement (QI). Stakeholder engagement is critical for all evaluations in terms of defining the scope of the QI and how change, effectiveness, or efficiency will be measured.

Results: NavLab evaluations include interdisciplinary outcomes related to care quality, efficiency, and cost savings from multiple perspectives to improve the healthcare system.

Conclusions: The NavLab’s next steps include expanding use of economic modelling, workflow evaluations and simulations, user-center design, and predictive analytics with operational and clinical partners.

1. Pragmatic research study design and analysis  Work-in-progress
Collaborating with patients

Rachael Kenney | Health Science Specialist | Veterans Health Administration

Background: The number of Veterans (Vets) that the Veterans Health Administration (VA) treated for Opioid Use Disorder (OUD) nearly tripled from 25,000 in 2003 to over 69,000 in 2017. In 2019, the Consortium to Disseminate and Understand Implementation of OUD Treatment (CONDUIT) formed to address this challenge. CONDUIT is a compilation of seven projects focused on increasing treatment for OUD in various settings. One aspect of CONDUIT is an Opioid Addiction and Recovery Veteran Engagement Board (OAR-VEB). The board will meet in person for a kick-off (planned for Spring 2020) and then meet monthly by phone. On each one-hour call, investigators from a project will present a challenge to troubleshoot. This Pragmatic Methods and Evaluation abstract describes the development of this board.

Setting/Population: The Denver Veteran Engagement Core (VEC) is selecting OAR-VEB members from each CONDUIT site (Table 1). Members are Vets who identify as being “in recovery” from OUD.

Methods: The VEC utilized tools from the VA and the Health Care Systems Research Network to guide board development.

The VEC created tools, conducted outreach in Denver, and assisted local contacts at the remaining CONDUIT sites with their outreach. Local contacts performed local outreach and screened Vets before providing contact information to the VEC. Outreach was conducted at VA (e.g., substance use clinics) and non-VA (e.g., Vet-Centers) entities.

Results: To date, 22 interested Vets were identified. Three interested Vets were not in recovery from OUD, two withdrew, one was not affiliated with a CONDUIT site, and one was unreachable. The remaining 15 were interviewed. None withdrew their interest after the interview. To date, 15 Vets have been interviewed and eight members from four sites have agreed to participate. (Table 1)

Conclusions: Identifying local outreach contacts was key; this allowed the VEC to focus on candidates who met the membership criteria. Advertisements, email blasts, and reaching out to outside organizations did not yield a high response.

3. Pragmatic research planning methods and frameworks Work-in-progress
EHR data mining to understand trends in association of systemic health factors and tooth loss

Nayanjot Kaur Rai | Research Associate | University of Colorado School of Dental Medicine and Clinics

Background and objective: Tooth loss is a major contributing factor to oral health quality of life. Retaining at least 20 natural teeth is essential to maintain functional and aesthetic dentition throughout life. Tooth loss has been linked to some systemic diseases including, cardiovascular diseases (CVD) and diabetes and self-reported poor health status. We aim to evaluate the association of systemic health factors, including CVD, diabetes and tobacco use with tooth loss in patients visiting the University of Colorado School of Dental Medicine (SDM) clinics over four years. Also, we aim to analyze the trends in this association for the four consecutive years, 2017, 2018, 2019, and 2020.

Methods: Data was collected through mining the electronic health records (EHRs) by the firstyear dental students and third-year advanced degree international dental students and 2709 current patients were included (≥55 years of age). The EHRs were reviewed for age, gender, ethnicity, self-reported systemic diseases including, CVD, diabetes, and tobacco use and the number of natural teeth present in the oral cavity (<20: yes/no), which was chosen as the outcome of interest. Univariate and multivariate logistic regression analysis was performed to test the association between patients having <20 natural teeth and self-reported systemic diseases. Also, trends in the odds of having <20 teeth and percentage of <20 teeth in the oral cavity varying by reported systemic health factors were analyzed.

Results: Of the 2709 patients, 37% had <20 natural teeth. The odds of having <20 teeth were higher in patients who reported having CVD (OR=1.3, 95% CI=1.1, 1.5, p=0.0007) and diabetes (OR=1.6, 95% CI=1.4, 2.0, p<0.0001) compared to patients who did not report CVD and diabetes respectively. Similarly, the odds of having <20 teeth were found to be more than two times greater in patients reporting tobacco use (OR=2.4, 95% CI=1.8, 3.0, p<0.0001) compared to patients who never used tobacco. The trends analysis results demonstrated an increase in the odds of having <20 teeth from the years 2017 to 2019 in the adults who reported having diabetes followed by a decrease in 2020 (Figure 1). The odds of having <20 teeth increased in adults reporting CVD over the four years (Figure 1a). An overall increasing trend in the odds of having <20 teeth was also seen in adults reporting tobacco use.

Conclusion: The results have shown that patients reporting CVD, diabetes, and tobacco use are more likely to have tooth loss, and the odds have increased since 2017. The results indicate the need for educational programs to educate the SDM patients and students. The knowledge gained can lead to the design and implementation of evidence-based interventions at the school and community levels, thereby benefiting the overall health of the population.
COPRHcon 2020 Virtual Poster Sessions

Live Question and Answer Discussions are scheduled on Tuesday, August 11, 2020, from 4:30 to 6:00 PM Mountain. Note the track and start time for each session below

**How Pragmatic are Trials in International Nursing Home Settings?**

Kate Magid | Health Science Specialist | Rocky Mountain Regional Veterans Affairs Medical Center

**Introduction**
At the 2019 AMDA-The Society for Post-acute and Long-term Care Medicine symposium, researchers discussed the implementation of pragmatic trials in nursing homes. Relatively few pragmatic trials have been conducted in nursing homes. In this abstract, we review the extent to which the design and implementation of trials presented at the AMDA symposium were pragmatic with a goal of describing approaches to improve pragmatic nursing home research study design.

**Setting and Population**
All trials were conducted in nursing homes, with sample sizes ranging from 12-175 homes. Trials were conducted in Europe and the United States. Participants varied by study and included nursing home residents, nursing home staff, and caregivers.

**Methods**
We used the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) criteria to rate the pragmatic nature of the trials. Given that these trials were conducted at the level of the nursing home, reviewers rated recruitment and eligibility for nursing homes and residents separately. Subsequently, the reviewers discussed ratings and came to consensus. A PRECIS wheel was constructed for each trial to visually represent where the trial aligned on the explanatory-pragmatic continuum.

**Results**
Figure 1 shows the PRECIS-2 wheels summarizing the pragmatic nature of the trials. Using PRECIS-2 criteria, the domains identified as most pragmatic across the trials were setting, primary outcome, and primary analysis. All studies were conducted in nursing homes that resembled usual care, collected primary outcomes relevant to participants, and almost all conducted an intention-to-treat analysis. In contrast, organization, nursing home recruitment, and nursing home eligibility were the least pragmatic. Several trials hired staff for intervention delivery or evaluation, implemented trainings, or provided resources beyond what is available in usual care, thus making the organization domain more explanatory. The eligibility criteria and recruitment for nursing homes were less pragmatic due to excluding homes based on; resident census, location, existing interventions and recruiting homes through advertisements or mailings. Four trials required residents or their legal guardian to provide informed consent to participate, making resident recruitment less pragmatic.

**Conclusion**
The application of PRECIS-2 criteria to the trials presented at the AMDA symposium suggests that the implementation of pragmatic trials in nursing homes have pragmatic and explanatory components. Future studies should explore how requiring residents to provide consent might lead to participants not being fully representative of the usual care population, especially given the prevalence of dementia in nursing homes. To better suit cluster pragmatic trials, researchers should rate the eligibility and recruitment of facilities and participants separately.

2. Pragmatic research measures and evaluation

Completed research
Research and Practice Team Engagement: A checklist to enhance research and practice team collaboration

Rodger Kessler, PhD, ABPP | Professor | Arizona State University

Background
This poster describes a strategy to develop shared understanding between research and practice teams. Often, during the conduct of on the ground practice research, issues arise from assumptions between research and clinical teams that interrupt and often threaten projects viability and impact. Many of these issues can be identified and addressed in the implementation planning and we generated a brief checklist to be completed collaboratively by research and practice team members, to generate shared assumptions and implementation expectations. We are currently testing this work in one community implementation project.

Practice-based research often includes partners with limited capacity for research participation. There may be no protected time for research; IRB policies or communication lines between research administration and clinical management may not be clear. This may lead to different assumptions or expectations that may impede the project.

Checklists are a common feature in manufacturing and a growing feature in health care systems, including research. However, most practice-based checklists do not mutually engage researchers and partners collaboratively, are lengthy, and do not examine and clarify assumptions and solutions to identified challenges. The purpose of this pragmatic checklist is to increase the chance of collaboration success by identifying and resolving unclear assumptions and expectations.

Setting
The application of this work is an Arizona Health System that owns and contracts with primary care practices. They initiated development of a primary care/ academic researcher team to engage in care and practice improvement by implementing evidence supported care pathways.

Method
We generated a 12 item checklist based on a careful review of existing scientific literature, our own experience, and constructs from the Consolidated Framework for Implementation Research (CFIR). Table 1 Identifies the 12 content domains. It is completed together by research and practice teams, identifies areas of consensus and those needing further resolution and key members from both teams to further discuss and generate resolution strategies to then be reviewed and endorsed by the full team. It includes four crucial time events: Before Signing a Memorandum of Agreement; Before Submitting to the IRB; Before Entering the Setting; and Before Collecting Data.

Conclusions
Researcher teams can use the checklist to verify whether the relationship with the community partner is clear, and to identify any potential problems and support team consensus. We are currently using the checklist in an Arizona State University research team collaboration with a local primary care setting and will report on results.

2. Pragmatic research measures and evaluation Work-in-progress
**S.T.A.T. ECGs**

Andy Levy | Assistant Professor, Medicine-Cardiology | Denver Health, CU School of Medicine

**Introduction/Background**
The Division of Cardiology at the University of Colorado reviewed a “near-miss” patient safety event related to delayed performance of a STAT priority electrocardiogram (ECG) in a floor unit patient with high-risk chest pain. While the importance of prompt ECG completion (<10 mins) during pre-hospital and emergency room care is well-established, no similar measures exist for hospitalized patients. Meanwhile, delays in ECG acquisition contribute to delayed diagnosis and treatment of in-hospital STEMI. There are few published attempts to improve ECG completion times among hospitalized patients.

**Methods:** Analysis of 25,159 completed, time-stamped inpatient ECGs completed at UCH between 1/1/2018 and 10/30/2018 was completed. Descriptive statistics for ECG volume, ECG completion delays and total AHT staffing levels were calculated and correlations between ECG characteristics and delays were examined. Between February and April 2019, a trained qualitative researcher completed interviews and observations with UCH staff involved in ECG completion, focusing on work processes and the workplace environment. Based on these initial quantitative and qualitative analyses, a simulation model was developed to evaluate changes in 1) technician staffing models; 2) the proportion of STAT orders; and 3) nurse training to help perform ECGs.

**Results**
ECGs were ordered with a STAT priority in 40% of cases and, among individual providers, use of the STAT priority varied from 7% to 95%. ECG completion was delayed (>15 minutes) for 35% of STAT ECGs, compared to less than 10% of non-stat ECGs. In qualitative interviews, technicians described a “cascade” effect to delays resulting from a compounding effect of a series of late ECGs and supported by the quantitative observation that delays are strongly correlated with STAT ECG volume. Technicians also described spikes in ECG ordering during hours in which staffing levels are low and for non-emergency reasons (such as discharge), a finding again supported by quantitative analysis. Results of discrete event simulation suggest: adding technician staffing hours during the day outperforms reducing the proportion of STAT ECGs; short shifts (4-8 hours) may be a cost effective way to add personnel; ECG training for Cardiology nurses could offload technicians and reduce delays; the negative effect of technician “attrition” – e.g. a technician calls in sick and is not replaced – is more powerful than the positive effect of any intervention.

**Conclusions**
In light of the above findings, UCH operations leadership trained charge nurses on Cardiology units to perform STAT ECGs and are discussing new ECG technician staffing models. The NavLab plans to create a dashboard for leadership to review ECG timeliness and the performance of ECG technicians.

2. Pragmatic research measures and evaluation Work-in-progress
High-Intensity Rehabilitation plus Mobility

Julie Stutzbach | PT, DPT/PhD Trainee | Physical Therapy Program, Department of Physical Medicine and Rehabilitation, University of Colorado, Aurora, CO, USA

Background: Following a hospitalization and skilled nursing facility (SNF) stay, patients are often unprepared for the transition to home, as evidenced by enduring deficits in physical function and continued dependence for activities of daily living (ADLs) at time of discharge.1 Our previous research has shown that just days before discharge, patients in SNFs took only 916 steps per day and were sitting or lying down 87% of their waking hours.2 To put this finding into context: participants took far fewer than the ~2,500 steps per day considered basal activity (i.e., the minimum requirement to perform activities of daily living) were ~85% more sedentary than community-dwelling older adults.3 To combat this pressing problem, we designed High-Intensity Rehabilitation plus Mobility (HeRo), a pilot pragmatic intervention to improve mobility and physical function while in the SNF.

Setting/population: Older adults (veterans) admitted to a single SNF following a hospitalization.

Methods: A mobility coach with certified nursing assistant credentials will deliver a structured mobility program to complement the progressive rehabilitation intervention that has been successfully implemented at the SNF facility. We will use a pragmatic, pre/post-test design to compare 2 historical cohorts (usual care, progressive rehabilitation alone) to HeRo (progressive rehabilitation coupled with structured mobility). Implementation will be iteratively developed and refined in collaboration with patients and SNF staff to increase adoption and utilization of the intervention.

Qualitative interviews with patients and focus groups with providers will complement quantitative measures of effectiveness and implementation in a convergent, embedded mixed-methods design. Program implementation will be evaluated using the Consolidated Framework for Implementation Research4 and the RE-AIM Framework.5 Percent of patients admitted to the SNF who receive the intervention will determine reach. Effectiveness will be measured based on patient-centered outcomes including changes in gait speed, physical function, and physical activity. Focus groups, conducted at regular intervals with rehabilitation and nursing staff throughout the project, will explore how HeRo is integrated into daily practice as key indicators of adoption and potential for maintenance/sustainability. Direct observations of treatment fidelity sessions, documentation audits, and step count goal adherence will serve as indicators of implementation.

Conclusions: Throughout the development of HeRo, design decisions will be made in close consultation and collaboration with end-users of the intervention and in response to the context of the clinical setting in a rigorous mixed methods approach. This pilot will inform multi-site trials and future dissemination efforts.

2. Pragmatic research measures and evaluation Work-in-progress
Background
Data dashboards are a common audit and feedback approach to support changes in processes and behavior. The rural Transitions Nurse Program (TNP) is a care coordination intervention for high-risk Veterans. An interactive dashboard was used to provide real-time performance metrics to sites. The feedback goal was to increase TNP Veteran discharges. One-year post implementation, discharge goals were not met. Control theory suggests that feedback using diverse methods can positively influence performance. Nudge emails can draw attention to performance metrics to improve awareness of current state. This study evaluated whether Veteran discharges and site communication increased when feedback occurred through a dashboard plus weekly nudge email versus dashboard alone.

Setting/Population
This observational study reviewed discharge counts of urban, rural, and highly rural Veterans who were hospitalized and discharged from four VA hospitals participating in TNP. Transitions nurses and site champions implementing TNP at each site were surveyed.

Methods
Veteran discharge counts during the dashboard phase were compared to discharges during the dashboard plus weekly nudge email phase. The emails included run charts (figure) with site discharge averages and weekly discharge counts. The difference of means for weekly discharges between the two phases was calculated using Poisson distribution. After 3 months of nudge emails, project time was calculated and a survey assessing nurse and champion perceptions of the nudge emails was distributed.

Results
Our sample included four VA medical centers. The average weekly discharges for all sites during the ~20-month dashboard phase was 4.23 Veterans. The weekly average during the 3-month dashboard plus nudge email phase was 4.21 Veterans. The difference in means was -0.03 (p=0.73). Adjusting for time trends had no further effect. Project time to create and communicate nudge emails was ~14 hours over 3 months. Four nurses responded to the survey. Two reported neutral and two reported positive perceptions of the nudge emails. No site champions responded to the survey.

Conclusion
Drawing attention to metrics, through nudge emails, maintained, but did not increase TNP Veteran discharges compared to dashboard feedback alone. These findings suggest the nudge effort has no effect on TNP.
Outcomes of a pragmatic cluster-randomized trial of home-based postpartum contraceptive delivery in Southwest Trifinio, Guatemala

Margo S Harrison | Assistant Professor | University of Colorado

Background: Postpartum contraception is important to prevent unintended, undesired, and closely-spaced pregnancies. If women receive comprehensive contraceptive education, around 11% will choose to use the contraceptive implant. Prior research from our community has found barriers to the use of long-acting reversible contraceptives (LARC) include lack of spousal approval, difficulty accessing methods, lack of knowledge, and fear of adverse effects. We hypothesized addressing access by bringing contraceptives to women’s homes would result in increased implant uptake.

Setting/Population: In our study population of interest in the Southwest Trifinio, analysis of historical unpublished data suggests that about 88% of women in the region are using or are interested in using contraception by forty days postpartum. Of these users, 0.5% used condoms, 0.5% pills, 0.5% lactational amenorrhea, 1.5% natural family planning, almost 4% long-acting reversible contraceptives (around 3% using the implant), 21% sterilization, and 72% opted for injectable contraception.

Design: Our study was a cluster-randomized parallel arm pragmatic trial to observe the association of home-based postpartum contraceptive provision, including the contraceptive implant, with implant utilization rates at 3 months post-enrollment.

Methods: In a region of rural Guatemala referred to as the Southwest Trifinio, twelve communities are served by a community-based antenatal and postnatal care program. The communities were combined into eight clusters based on 2017 birth rates and randomized to receive the home-based contraceptive delivery (condoms, pills, injection, implant) during the routine 40-day postpartum visit. All participants receive comprehensive contraceptive counseling beginning at the first antenatal visit, so control clusters received this as part of routine care; this education preceded the study intervention.

Results: Of 208 women enrolled in the study, 108 were in four intervention and 100 in four control clusters. Three-month contraceptive initiation rates were 56.0% in the control clusters compared to 76.8% in the intervention clusters, p < 0.001. Women in control clusters overwhelmingly opted for the injectable contraceptive (94.6%) while women in intervention clusters chose both the injection (61.5%) and the implant (33.7%), p < 0.001. Implant use by 3 months, the primary outcome of the study, was significantly higher in the intervention arm (25.9%) compared to the control arm (2.0%), p < 0.001, OR 18.8 CI [4.3, 81.4].

Conclusion: Our study was designed to respond to previously identified barriers to contraceptive uptake, and it was successful. It increased overall use of contraception by 3 months, by shifting use away from short- in favor of long-acting methods, with high continuation and satisfaction rates and no adverse outcomes reported.

2. Pragmatic research measures and evaluation Completed research
Evaluating the Implementation of the Medication for Opioid Use Disorders Pilot Program in Rural Colorado

Claudia R. Amura | Research Assistant Professor | CU College of Nursing

Background

Opioid use disorders (OUD) are a huge burden for both those suffering of addiction and the community. Colorado ranks 12th nationally in non-medical use of opioids, with rural counties having the highest use and overdose-deaths. The Colorado Senate funded an evidence-based Medication for Opioid Use Disorders (MOUD) Program to increase access to care for Coloradans with OUD in rural areas. We review implementation outcomes from this pilot program.

Setting/population: SB17-74 focused on two counties with disproportionately high overdoses deaths, Pueblo and Routt. Three agencies were funded to either start or expand MOUD services. Patients served used either heroin, opioid drugs or prescription painkillers other than in as prescribed.

Methods: The grantees advertised services through local partnerships. From 12/17 to 06/19, the agencies reported on services provided, outreach, barriers and successes, and submitted de-identified patient-level data via REDCap, both at baseline and after 6 months. The Addiction Severity Index was used to measure OUD’s impact across various life domains. Pre-post changes in patient outcomes were tested using 2 and t-tests.

Results: Over the first 18 months, this pilot project added 15 Nurse Practitioners and Physician Assistants and served 1,005 individuals. Patients were mostly 25-44 y.o. (66%), high rate Hispanic (42%), not married (77%), uninsured (47%) or Medicaid (91%), unemployed (65%) or part-time worker (26%). The majority reported less than good health, and use of opioids (42%), heroin (48%), and other substances (32-38%). After 6 mo of MOUD, 28.7% patients remained in treatment, with 30% missing data. In the previous month, patients used less heroin (13.0 vs. 3.68 d, p<.001, prescription opioids (3.66 vs. 1.86 d), p=0.029, and sedatives (2.59 vs. 1.10 d), p=0.001, and alcohol (3.12 vs 1.67 d), p=0.000. There was no difference in meth, barbiturates or cannabis use. After treatment, patients also had improved health (53.4% vs 68.2 %), p=0.036, with less days unable to carry out normal activities (8.69 vs. 6.51 d), p=0.016. The number of clients with symptoms significantly dropped (64.1% vs 55.2%), p=0.000. They overall reported lower pain (p=0.000), worry about their health (p=0.000) or medical treatment (p=0.001). There were no changes in emergency room visits or incarcerations. Patient-centered approach, availability and referrals were successful strategies, while education was needed to reduce stigma.

Discussion: While results are limited to patients in treatment with high lost to follow-up, this pilot study shows implementation success, decreased substance use, and improved health after treatment. Research is needed on retention and long-term effects. Lessons learned for barriers and facilitators encountered during implementation could inform new programs to address one of the state’s major public health crises.

2. Pragmatic research measures and evaluation

Completed research
An Interactive Interface to Explore Patient Venipunctures at a University Hospital

Andrew Hammes  |  Research Instructor  |  Colorado School of Public Health

Background: During a hospitalization, patients routinely receive blood draws (i.e. venipunctures) in the course of diagnosis and treatment of their conditions. From the patient perspective, frequent blood draws can be distressing and decrease patient satisfaction with care. From the hospital perspective, blood draws represent an expense to the hospital both in terms of personnel time and material cost. Even though venipunctures impact patient care and hospital expenditures, integrated aggregate data on the patients receiving blood draws, the personnel performing the blood draws and overall trends in volume are not currently available to decision makers at the University of Colorado Hospital.

The University of Colorado SOM NavLab seeks to address this issue by developing a clinician-usable interface which will allow clinical leaders to examine the number and timing of venipunctures done to patients.

Setting/Population: This study was performed at the University of Colorado Hospital, including inpatient data between March 2019 and April 2020. All inpatient venipunctures were potentially candidates to be included in the interface.

Methods: Data was acquired from the Clarity tabulation of the EPIC Electronic Health Record including all tests done on inpatient venipuncture blood draws between March 2019 and April 2020. Consultation with the Ancillary Health Technician leadership informed the aggregation of tests for summarization. Tests were collapsed into individual patient draws in a five-minute rolling window, that is any vials which were recorded as collected within five minutes of the previous vial within a contiguous patient and collector pairing were considered one stick. This was done to allow many potential tests from one draw to be correctly subset into a single draw. Individual patient sticks were then aggregated to yield the number during a calendar day per-patient, as well as totals by the collecting user. All data aggregation was done in R v 3.6.0.

Aggregated data was transferred from R to Microsoft Power BI for visualization and dissemination. Summaries of data including daily tracking of number of tests and sticks, sticks by patient, sticks by user, and comparisons of sticks between groups were built within Power BI. Having these within Power BI also allowed the use of filtering, such as by date, user, or department, to be done by the end-user without additional effort by the team. Updates to the completed Power BI will be automated using stored commands within EPIC and R to load updated data into the report.

Conclusions: Excessive venipunctures can impact patient satisfaction and hospital resources. To address this problem in a data-driven way data must be presented to decision makers. The University of Colorado NavLab produced a Power BI report which allows clinicians and leadership to examine data on their own in a dynamic way with informative visualizations of the data.

2. Pragmatic research measures and evaluation Work-in-progress
How Understanding Change Experience In Smoking Cessation Might Inform Treatment Development

Adrienne L. Johnson, PhD | Postdoctoral Fellow | University of Wisconsin Center for Tobacco Research and Intervention; William S. Middleton Memorial Veteran's Hospi

Introduction: Cigarette smoking is the leading preventable cause of death and disability in the U.S., accounting for almost half a million deaths per year1,2. Despite ongoing efforts to improve cessation rates through treatment development and dissemination of evidence-based practices, less than one-third of the population use proven cessation methods and the average quit rate is 7.4%. Qualitative research methodologies have the potential to highlight limitations and identify novel approaches or adaptations to existing behavioral treatments4 that may increase engagement, adherence, and success. Using a mixed methods approach, we examine whether smokers have insight into changes needed to quit smoking and how this insight affects actual changes made during a smoking cessation attempt as well as cessation success.

Method: Stratified random sampling5 (Figure 1) was used to select 100 current cigarette smokers participating in an aided smoking cessation attempt as part of a larger comparative effectiveness trial. Bachelors level Health Counselors completed brief individual qualitative interviews at baseline and two-week post-quit visits. Interviews were audio-recorded and transcribed, then entered into a MS-excel file for coding purposes. Rapid data analytic methods6,7 are being used to examine three separate domains: planned changes, used changes, and consistency in changes.

Results: Initial themes for planned changes prior to quitting include: changing routines (no plan), change alcohol consumption, limiting smoking urges, focus on benefits of quitting, reduce exposure to social smoking cues, identify other coping mechanisms for stress, get support from friends/loved ones, make other health changes, reduce stress (no plan), get partner to quit, identify problem (no plan), planned changes unknown. Initial used changes themes include: reduce exposure to non-social paraphernalia/smoking cues, distraction/keep busy, make other health changes, changed daily routine, change mindset, reduce exposure to social smoking cues, get support from friends/loved ones. Consistency between planned and used changes revealed participants use both planned and unplanned changes, while some reported not knowing what to do prior to quitting and others identified additional changes needed.

Discussion: Ongoing rapid content analysis6 revealed multiple themes for smoker-identified planned and used changes to improve cessation success, but analyses need to be completed. We will then examine distribution of themes based on race, gender, psychiatric history, and nicotine dependence as well as the ability of smokers to identify and make changes. Exploratory analyses will descriptively examine differences between smokers who did and did not identify changes on cessation success. Findings will guide treatment development and adaptations for behavioral smoking cessation treatments.

2. Pragmatic research measures and evaluation Work-in-progress
**PRECIS-2 can assess pragmatic aspects of ongoing cervical cancer screening trials to generate implementation evidence**

Prajakta Adsul | Assistant Professor | University of New Mexico

**Introduction:** The growing burden of cervical cancer in low- and middle-income countries (LMIC) has led to the introduction of new screening technologies, i.e. HPV based DNA tests, prompting recent guideline changes both in screening and treatment approaches. Several clinical trials have evaluated novel screening tests; however, limited information can be extracted from these trials to inform the implementation of the screening processes in real-world settings.

**Methods:** ESTAMPA is a multi-centric screening and triage study recruiting 50,000 women aged 30-64 years, in 12 sites from 9 Latin American countries.[1] The goal of the study is to evaluate different triage methods for HPV positive women and the feasibility of country/setting-specific implementation process. Using the Pragmatic Explanatory Continuum Indicator (PRECIS-2) [2] we conducted a facilitated group discussion with the primary coordinating team from the International Agency for Research on Cancer (IARC) and separately with the country specific study teams. In addition, we surveyed study teams (n=107) using previously validated measures [3] to assess acceptability, appropriateness, and feasibility of conducting the screening process in their context.

**Results:** Overall, the PRECIS-2 tool allowed for a formal approach to assess pragmatic aspects ESTAMPA from the perspectives of the coordinating team that discussed the study with respect to the nine domains (scores in parenthesis) (Eligibility (5); Recruitment (3); Setting (5); Organization (3); Flexibility of delivery (4); Flexibility of intervention (2); Follow-up (4); Primary outcome (4); and Primary analysis (5). We are currently engaging with the country teams to generate a discussion using PRECIS-2 about the implementation of the trials in their settings. Results from the survey conducted on staff teams show overall acceptability at 63%, appropriateness at 80%, and feasibility at 71%.

**Conclusion:** Although ESTAMPA was not designed as a pragmatic trial, we found that it lies mostly in the pragmatic end of the continuum. The trial was conducted with “future implementation in mind” and followed the IARC model of conducting studies where participating countries were considered as partners in research and the study was implemented keeping in mind existing system characteristics. Using PRECIS-2 can help facilitate discussion surrounding the implementation of interventions and processes. This research can help contextualize research findings and provide decision making guidance for future implementation of effective HPV cervical cancer screening programs in LMICs.

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3. Pragmatic research planning methods and frameworks

*Work-in-progress*
A Community Based Participatory Research Initiative Addressing Alcohol Use in the Refugee Population from Burma

Benjamin P. Fuller  |  Medical Student  |  University of Colorado School of Medicine

BACKGROUND: The country of Burma (Myanmar) has been riddled with conflict, strife, and sectarian violence for over 30 years. Since 2006, the United States has taken in just over 150,000 refugees from Burma, of which an estimated 5,000 reside in Colorado. Once granted refugee status in the United States, the challenges that this population faces are enormous, including finding sustainable employment, affordable housing, and the lack of access to culturally competent healthcare. The newfound challenges of refugee life can be incredibly taxing both physically and mentally. When previous mental stressors, such as exposure to trauma in their home country, are combined with these newfound challenges, refugees are over two times more likely to exhibit Substance Abuse Disorder as defined by DSM-IV. The specific purpose of this study is to assess the effects of alcohol use on the local refugee population from Burma and formulate an appropriate intervention utilizing a community based participatory research (CBPR) model.

SETTING/POPULATION: This research was undertaken in full partnership with the refugee community from Burma and its stakeholders in the greater Denver area.

METHODS: A multiphase community-based participatory research model was utilized to conduct this research. True to the CBRP model, the first phase was establishing a partnership with the community, and subsequent identification of an issue ripe for intervention. A group of young adults from the refugee community were recruited to form the Youth Advisory Board. They identified alcohol use as the dominant health-related concern within their own community. With this issue identified, the project moved into phase two. Phase two involved conducting semi-structured one-on-one, audio-recorded interviews with members of the refugee community from Burma. The data from these interviews was then analyzed using immersion crystallization methodology. The next phase to be undertaken is presentation of the findings to the community and generation of a culturally competent intervention.

RESULTS: The analysis of the ten audio-recorded surveys showed the emergence of several qualitative themes related to the use of alcohol within this community. The use of alcohol as a coping mechanism for the stressors of refugee life is highly prevalent among males and this has a direct negative impact upon the family unit. In addition, there is a sense of personal responsibility and a lack of resources aiding cessation within the community.

CONCLUSIONS: This project expands upon current literature regarding the scope and impact of alcohol use within the community of refugees from Burma. In partnership with the community and its stakeholders, the qualitative themes generated from this research have identified a need for a culturally appropriate intervention to effectively address alcohol use in this vulnerable population.

3. Pragmatic research planning methods and frameworks  Work-in-progress
Adaptation and Implementation of the Invested in Diabetes Study

Dennis Gurfinkel | Sr. PRA | ACCORDS

Background: Diabetes group visits are historically challenging to implement in primary care. Pragmatic trials optimally use existing staff to deliver the intervention and allow flexibility in adherence and delivery.

Objectives:
1. To describe use of the Replicating Effective Programs for adapting and implementing an evidence-based intervention for use in real-world care settings.
2. To describe methods for establishing fidelity and adaptations to a study protocol to ensure rigor and feasibility of the conduct of a pragmatic trial.

Methods: The Invested in Diabetes study is an ongoing pragmatic cluster randomized comparative effectiveness trial testing two group visit models for delivering the Targeted Training in Illness Management (TTIM) curriculum for diabetes in primary care.\(^1\) In one model, TTIM is delivered by a health educator, with set topic order. In the other model, TTIM is delivered by a multidisciplinary care team, with topic order selected by patients. Practices are supported using the Replicating Effective Programs (REP) implementation framework plus intensive practice facilitation.\(^2\) Patient and practice stakeholder input was used to adapted TTIM curriculum and the study protocol and outcome measures. Dedicated research staff were used to help practices implement the project and collect outcomes data (patient-reported outcomes and Electronic Health Record data). Finally, the study team observes one session per practice/quarter to monitor fidelity to the TTIM curriculum and study core elements, documenting adaptations to content or delivery.

Results: Study team members rated the pragmatic design of the study protocol according to the PRECIS-2 guidelines\(^3\) (Figure 1). Core elements of the study were identified and described to ensure fidelity. Stakeholder-led adaptations of the protocol outside of core elements were identified pre-implementation, including 6 two-hour sessions instead of 12 one-hour sessions and streamlining patient-reported outcomes to those with clinical utility and patient preference. Twelve in-person and virtual trainings have been conducted to date; trainings have progressively highlighted importance of skill building activities for SMA facilitators. Around 80 practice coaching sessions have been done to help practices start and sustain their group visits. Practices delivered test data extracts in summer 2019; data quality assessments revealed variability in accuracy and completeness. Thirteen months into the 24-month implementation period, 86 cohorts have gone live with 613 out of the goal of 1440 patients enrolled in group visits. Ongoing practice support is maintained through dedicated practice coaches to help troubleshoot issues and maintain fidelity to the study protocol.

Conclusion: To retain rigor in the study design, the REP framework allowed for adaptation to context while establishing core elements that must remain in place for hypothesis testing. The Invested in Diabetes study implementation processes help to ensure rigor of the design as well as feasibility of delivery in real-world primary care practices.

3. Pragmatic research planning methods and frameworks Work-in-progress
Acceptability of sharing behavioral risk and glucose data between patients and clinicians – a pilot study

Amy Huebschmann | Associate Professor, Clinician-Investigator, Division of General Internal Medicine | University of Colorado Center for Women’s Health Research

Background: Medically complex patients with uncontrolled type 2 diabetes face diabetes self-management challenges, including managing blood glucose levels and lifestyle behaviors. Technology packages have improved clinical outcomes by allowing patients to share data with clinic teams on home glucose (Glooko©) and behavioral health risk data (My Own Health Report, MOHR). However, adoption of Glooko and MOHR remains low in primary care. In a pilot study to inform implementation efforts, we evaluated the acceptability of Glooko/MOHR among key stakeholders: patients and clinicians.

Setting/population: We recruited eligible patients with uncontrolled type 2 diabetes mellitus (Hemoglobin A1c >8%) and their treating clinicians from three academic primary care clinics.

Methods: Participants provided acceptability ratings after a demonstration of the process of sharing Glooko/MOHR data between patients and clinicians. We considered ratings of ≥70% in each of the 7 Technology Acceptance Model (TAM) domains as acceptable. All quantitative data are reported as mean ± SD. We considered survey ratings of 70-80% and >80% as moderately and highly acceptable, respectively.

Results: Patients enrolled (n=12) were adults (age = 65.7 ± 12.8 years), 33% non-white, 58% female, and 50% reported use of internet to manage health issues. Clinicians (n=11) had 13.2 ± 9.9 years of practice experience.

Patient acceptability for Glooko data sharing: Intention to use (91.5±12%), Perceived usefulness (89.5±8.1%) and Social influence (83±0%). No unacceptable ratings.

Patient acceptability for MOHR data sharing: Perceived usefulness (85.5±8.1%), Self-efficacy (83.5±12%) and Social influence (83±0%). One TAM domain was rated as unacceptable: Resistance to change (58.5±12%), including 33% of patients agreeing that s/he did not want MOHR to change how s/he managed diabetes.

Clinician (n=11) acceptability of sharing Glooko and MOHR data: Highest ratings were for Perceived usefulness (88.1 ± 4.2%), Facilitators (84.2 ± 8.6%) and Intention to use (82 ± 15.6%). The Subjective Norms/Others’ support was unacceptably rated (50.2 ± 16%), including anticipation of low perceived support among patients (27%), colleagues (55%), and health managers (55%).

Conclusions: Medically complex patients with diabetes and their clinicians expressed intention to use technology to share glucose and behavioral risk data between visits. However, to reach the promise of using remote technology and patient-reported data to address health challenges, clinics will need to identify and address factors leading to clinicians’ perceptions of limited support from others to use remote data monitoring, particularly patients, and also better discern why some patients are resistant to using MOHR as part of their diabetes management.

3. Pragmatic research planning methods and frameworks Work-in-progress
Nurse home visiting with relationship education to prevent perinatal teen dating violence

Qing Li | Non-Degree Seeking Student, Colorado School of Public Health | Center for Behavioral Epidemiology and Community Health, School of Public Health, San Die

Background: Perinatal teen dating violence (PTDV) is a serious public health issue. Among pregnant teens, the lack of a vision of commitment to make future-oriented decisions (e.g., precocious coresidential unions, infidelity, jealousy, and second pregnancy) is a core generator of relationship instability and often leads to PTDV. A promising venue to prevent PTDV may be the home visitation methods of the Nurse Family Partnership (NFP), an evidence-based preventive intervention in a service delivery model. Relationship education programs (e.g. the Prevention and Relationship Enhancement Program, PREP) have already shown promise in reducing dating violence and intimate partner violence (IPV). However, commitment and relationship education have been underemphasized in NFP—only one trial in Oregon taught them. According to Hirschi’s control theory (1969), we hypothesize that weak social bonds and lack of commitment are modifiable precursors of PTDV.

Setting/Population: In a secondary data analysis of this randomized controlled trial (RCT), first-time and low-income mothers were recruited and randomly assigned to (1) NFP group or (2) NFP and PREP (called NFP+) group in Multnomah County, Oregon from 2007 to 2011. After 238 women completed the baseline survey, retention was 81% after 1- and 2-year follow-up surveys. Among 67 mothers aged 15-17, we analyzed the effectiveness of NFP+ program to increase commitment and prevent PTDV.

Methods: The primary prevention component was teaching the adapted Within My Reach (WMR) Curriculum based on the PREP, when commitment was taught along with decision-making (e.g. decide, do not slide, select a mate). We operationalized commitment as being married or engaged. The sum of any type of physical and sexual victimization and/or perpetration in the past 12 months in the Revised Conflict Tactics Scale was coded as a continuous outcome and 0 across 3 time points indicated free of violence.

Results: Among 67 teen moms, the NFP+ and NFP groups had no difference in age and educational status (both p=0.82). There were more Hispanic mothers (59%) in NFP+ group and more White, non-Hispanic mothers (42%) in NFP group. There were 22 teens who reported commitment (being engaged or married) at least once in 3 time points. In the NFP+ group, 6 of 11 teens started without violence and 4 (66%) stayed free of violence 2 years later. In the NFP group, only 2/5 (40%) stayed free of violence. More teens in NFP+ stayed in committed and stable relationship with the child’s father (3 engaged and 4 married vs 5 engaged and 2 living together and dating exclusively).

Conclusions: Preliminary findings show that this enhanced NFP program improved commitment and relationship stability and prevented PTDV. We plan an R34 pilot study and then an RO1 powered cluster RCT to perform covariate constrained randomization and linear mixed models and evaluate commitment as modifiable precursors to prevent PTDV.

3. Pragmatic research planning methods and frameworks

Work-in-progress
Designing a Pragmatic Advance Care Planning Group Visit Intervention for Individuals with Mild Cognitive Impairment

Andrea E. Daddato, MS, MS | Professional Research Assistant, PhD Candidate | Division of Geriatric Medicine, University of Colorado School of Medicine

Background: Among older adults without cognitive impairment, a novel advance care planning group visit (ACP-GV) intervention increased ACP documentation and readiness to engage in ACP. For individuals with mild cognitive impairment (MCI), planning for their future medical wishes and values of importance before further cognitive decline is important. A key question is whether a pragmatic intervention can be adapted to support people with MCI and their family care partners.

Setting/Population: Individuals with MCI and study partners recruited as dyads from an academic healthcare system in Aurora, Colorado.

Methods: To design for pragmatic implementation, we used a human-centered design process, rapid-cycle prototyping, and qualitative methods guided by the frameworks of the NIH Stage Model for Behavioral Intervention Development to adapt an ACP-GV intervention to individuals with MCI and their study partners (dyads).1,2 We convened a longitudinal cohort of six dyads in three focus groups to suggest adaptations. We also conducted a single arm study of four ACP-GV prototypes (n=13 dyads total) that were iteratively refined with adaptations from the longitudinal cohort and participant feedback. We used interviews after each prototype to gather feedback.

Results: Six dyads met three times from February-October 2019 to discuss intervention adaptations, such as what ACP decision tools should be used and what outcomes would be meaningful for an ACP-GV intervention adapted for individuals with MCI. Stakeholder feedback informed four n-of-1 adapted ACP-GV interventions with an average of 3.25 dyads per group visit. Following the completion of each ACP-GV, 20 participants were interviewed for feedback of whether the intervention met their expectations and goals related to ACP, effectiveness of the tools/resources, format of the intervention, and recommendations for future ACP-GVs. Feedback from the interviews were reported back to the longitudinal focus group for further input. Overall, interviewees found the group visit setting helpful to hear others perspectives and to initiate tough conversations about end-of-life planning. Most felt the size of the ACP-GV's were appropriate, the videos and resources were helpful, and would recommend the intervention to others. The longitudinal focus group reported ACP as a priority for individuals with MCI and described the need for ACP in a group setting. An additional theme was to include candid conversation about the diagnosis of MCI and how it relates to the need for ACP.

Conclusions: Use of a pragmatic research approach with rapid prototyping and stakeholder engagement allowed testing of different resources and tools aimed at helping individuals with MCI and their partners discuss ACP. Future work is needed to understand the feasibility of implementing an ACP-GV intervention for individuals with MCI into clinical settings.

3. Pragmatic research planning methods and frameworks

Completed research
Improving measurement of patient responsiveness using a mixed methods approach

Nicole Wagner | PhD | Kaiser Permanente Colorado Institute for Health Research

Background: Uptake of a new health intervention is dependent on patient acceptance and responsiveness.1 Patient report is frequently used to assess patient responsiveness due to the low cost and limited labor requirements.2 However, patient report is prone to errors, such as over-reporting and missing data.2,3 Incorporating measures of patient responsiveness from multiple sources presents an opportunity to sustain the low cost and labor requirements while increasing data accuracy and comprehensiveness. Measures from multiple sources may also provide an opportunity to identify strategies for adaptation.4 To assess the value of a mixed methods approach, this study describes the use of electronic health record (EHR) data, patient report, and implementor logs for measuring patient responsiveness in a pragmatic intervention trial.

Setting/Population: Just in Case (JIC) was a cluster randomized intervention trial, designed to increase the uptake of naloxone, an overdose antagonist medication, in patients on chronic opioid therapy. JIC was conducted between 2017 and 2019 at Denver Health Medical Center, a safety net health system serving the Denver metro area. Patients 18 years and older filling chronic opioid medications were eligible to receive naloxone co-dispensing. Eligible patients were recruited to complete surveys at baseline, 4 months, and 8 months (patient report). Pharmacy staff in the intervention arm recorded naloxone co-dispensing events and reasons for nonacceptance in a pharmacy fidelity log (implementor log).

Methods: Patient responsiveness measures included naloxone uptake and barriers to naloxone uptake. Naloxone uptake was captured in the EHR using naloxone dispensing data. Reasons for not accepting naloxone were coded for common themes in patient report surveys and implementor log.

Results: Using EHR pharmacy records, 527 eligible patients were identified with 204 naloxone fills. Barriers to naloxone uptake from patient report included lack of knowledge on naloxone (40%), not thinking they needed it (88%), and fear of repercussions from pharmacists or doctors (20%). Barriers to naloxone uptake from implementors included patients already had naloxone (36%) and weren’t willing to pay for naloxone (28%).

Conclusions: A mixed methods approach using measures from the EHR, patients, and implementors provides a comprehensive assessment of patient responsiveness with increased accuracy. Each measure contributed unique data to inform potential opportunities for improvement and adaptation. EHR data contributed accurate counts of acceptance. Patient report identified a knowledge gap indicating a more robust education program may be needed. Implementors reported cost issues indicating a potential protocol modification could improve uptake.

3. Pragmatic research planning methods and frameworks Work-in-progress
Evaluation of a closed-loop referral platform for addressing patient’s social needs

COPRHcon 2020 Virtual Poster Sessions

Live Question and Answer Discussions are scheduled on Tuesday, August 11, 2020, from 4:30 to 6:00 PM Mountain. Note the track and start time for each session below

Cheryl Kelly | Investigator | Kaiser Permanente Colorado

Background
Kaiser Permanente (KP) is investing in a close-loop social needs referral platform called Thrive Local. Thrive Local links clinical care to social care through data integration with community-based partner organizations. Thrive Local consists of three key functions: a resource directory that provides up-to-date and searchable information on community resources; geographically-based networks of social service organizations (i.e., Community Network); and a technology platform that engages clinicians and staff, members, and employees of community organizations to make rapid, secure referrals between health care providers and social care providers and track the outcomes of those referrals. The purpose of this poster is to describe the methods and approach being used to evaluate this initiative designed for real-world impact.

Setting/Population
There are several study populations included in the evaluation. KP providers and staff who are trained to deliver the intervention and must modify existing workflows to integrate screening and referral of basic needs. Community-based organizations (CBOs) that are part of the community partner network in each region and are likely to experience an increase in referred clients seeking services. KP members who are screened for basic social needs and referred for services.

Methods
An evaluation of Thrive Local across eight KP regions is being led by Dr. Allen Cheadle from the Center for Community Health and Evaluation and Dr. Cheryl Kelly from the Partners in Evaluation & Research Center using the RE-AIM framework. The implementation evaluation methods include interviews with KP providers, CBOs, and patients as well review of secondary sources (e.g., progress reports and other documents generated). Reach is being measured by data generated by the referral platform on the number and type of referrals and their resolution. Effectiveness is being measured by a patient-reported outcomes and secondary use of electronic health records. The patient survey will assess whether social needs are being met and whether patients they are able to address needs that may arise in the future. Additionally, data on referrals and progress towards closing social needs will be matched to patient medical record number to assess longer-term changes in health outcomes and healthcare utilization.

Conclusions
This study is beginning implementation despite several challenges, including variability of implementation across regions, a diverse set of stakeholders, and a staggered roll-out of a common tool to screen for social needs. This poster presentation will share the evaluation methods and measures and details about how we are incorporating patient-reported outcomes and objective measures of health and healthcare utilization to evaluate the impact of a closed-loop referral platform to address patient’s social needs.

2. Pragmatic research measures and evaluation
   Work-in-progress
Translation from Concept to Clinic

Jeremy Graber | PhD Student | University of Colorado Anschutz Medical Campus

Background
Rehabilitation after total knee arthroplasty (TKA) is typically generic and based on population-level estimates of recovery. Individualized, patient-centered care improves orthopedic outcomes1 and is desired by patients after TKA.2, 3 However, clinicians lack the necessary tools to deliver this kind of care consistently. We developed a novel approach for generating individualized recovery trajectories in rehabilitation to improve patient-centered care for patients with TKA.4 We worked closely with relevant stakeholders to incorporate our approach into a clinical support tool—the Knee Recovery App—designed for TKA rehabilitation. The purpose of this project is to evaluate the effectiveness of the Knee Recovery App while gathering information about its implementation using the RE-AIM framework.5

Setting/Population
The Knee Recovery App will be implemented as standard of care in two physical therapy clinics in Greenville, SC, owned by ATI Physical Therapy. The app will be used directly by physical therapists to generate individualized recovery information for all patients between the ages of 40 and 90 seeking rehabilitation after TKA (n=30).

Methods
We will use a Hybrid Type 1 design to test the effectiveness of the Knee Recovery App while gathering information about its implementation potential.6 Physical therapists will use the app to generate patient-specific recovery estimates to (1) inform patients of their expected recovery and (2) develop a patient-centered plan of care. Outcomes will be collected prospectively throughout the episode of care and compared to a retrospective cohort of age and sex-matched patients (n=60) in ATI’s quality improvement database of patients with TKA. Group differences will be examined using linear models and effect size will be calculated with Cohen’s d. Effectiveness outcomes will include functional measures and surveys related to patient-centered care (Table 1).

We will evaluate the implementation potential of our app using a mixed-methods approach informed by the RE-AIM framework (Table 1).7 Our qualitative approach will consist of directed content analysis of semi-structured interviews with representation from all stakeholders (n=30).8 Quantitative implementation outcomes will be extracted from three sources: (1) ATI’s quality improvement database, (2) information stored on the Knee Recovery App, and (3) survey administered to clinicians.

Conclusion
Our novel approach for individualized rehabilitation has the potential to improve patient-centered care and outcomes in TKA rehabilitation. The RE-AIM framework informed our implementation strategy and will provide the structure to examine barriers and facilitators to clinical use of the Knee Recovery App. We anticipate the results of this project will inform a future cluster randomized trial in the ATI system guided by the PRISM framework.

2. Pragmatic research measures and evaluation Work-in-progress
Too Much of Good Thing

Tyler Anstett | Assistant Professor | University of Colorado School of Medicine

Background
Optimal utilization of blood products requires a balance between clinical benefit and unnecessary costs and risks associated with transfusions. Excess packed red blood cell (pRBC) transfusions are associated with harm to patients and additional costs to patients and health systems. The American Association of Blood Banks recommends a restrictive threshold of a pre-transfusion hemoglobin (Hgb) level of less than 7.0g/dL and single unit pRBC transfusions for the vast majority of hospitalized patients. Other institutions have significantly improved pRBC utilization through Electronic Health Record (EHR) focused interventions. In this project, we sought to conduct a needs assessment across the UCHealth system and evaluate the optimal strategy for encouraging prudent transfusions.

Setting/Population
We examined the inpatient transfusion practices at five UCHealth hospitals across three regions: North, South, and Denver Metro between 2/1/2019 – 1/31/2020.

Methods
Data was acquired from the Clarity tabulation of the EPIC EHR. We included adult patients (> 17 years), who received a blood transfusion during an inpatient encounter. We excluded both perioperative hospital units and outpatient transfusions. We analyzed the data by the pretransfusion hemoglobin value as well as the number of pRBCs transfused for each Hgb value. We also examined the blood transfusion ordering interfaces at each hospital to evaluate for trends.

Results
18,055 units of pRBCs were transfused during 13,804 transfusion administrations across all regions during the study period. 7,015 (51%) of transfusions were for pre-Hgb >/= 7.0, and of all transfused units 3,471 (25%) of transfusions included two or more units of pRBC for pre-Hgb greater than 6.0. There was some heterogeneity across the institutions with transfusions for >/= 7.0 ranging from 44% to 68%. Analysis of the ordering interface revealed regional differences that did not impact ordering practices, with University Hospital having the least directive interface but the lowest percentage of transfusions for Hgb <7.0g/dL at 41%. None of the blood transfusion ordering interfaces include proven strategies for reducing unnecessary transfusions.

Conclusions/Next Steps
As demonstrated by the pre-Hgb level of the transfusions and number of units transfused each time, these data support the need for improvement across the UCHealth system. We are embarking on a clinician level randomized user-centered, design-focused pragmatic factorial trial manipulating the blood transfusion ordering interface to evaluate the most effective method for reducing unnecessary blood transfusions. The trial design will account for the two main interventions (Overutilization of pRBC for pre-Hgb >/= 7.0 and multiple units per transfusion order with pre-Hgb >/= 6.0). We currently working with UCHealth leadership for approval of the design.

2. Pragmatic research measures and evaluation Work-in-progress
From Clinic to Community: Adapting Evidenced-Based Weight Management for Overweight Latino Children in Immigrant Families

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Background: US born Latino children with immigrant parents, who comprise half of Latino children, have a higher rate of childhood obesity than other Latino children. The US Preventive Services Task Force recommends referral of all obese children to intensive weight management programs to decrease body mass index. When available, intensive programs are limited to clinical settings and do not address social determinants of health among Latino immigrant families. Active and Healthy Families (AHF), a Spanish-language, culturally tailored group visit program for children has demonstrated effectiveness in decreasing body mass index.1 AHF does not address families’ barriers to frequent engagement with the healthcare system nor social determinants’ barriers other than immigration. Adapting the intervention for community-based delivery may increase acceptability and family engagement.

Purpose: To engage a stakeholder network in identifying adaptations of an evidence-based weight management intervention for community-based implementation.

Methods: Guided by the intervention mapping-adapt process, we solicited feedback from a stakeholder network from Aug 2018-Dec 2019.2 The network included 4 subcommittees: 1) Latino immigrant families including those who had participated in AHF delivered in a healthcare setting; 2) members of and leaders of community organizations; 3) healthcare services delivery leaders; and 4) researchers in health disparities and Latino health. Subcommittee activities included applying user-centered design principles and Photovoice, a participatory action research method.

Results: Stakeholders identified three functions3 (i.e. essential components) of the evidence-based intervention: a collaborative, multidisciplinary facilitation model, use of the transtheoretical model of change to prompt family-level behavior change tailored to cultural values, and a financially sustainable reimbursement model. The network reached consensus on forms (strategies to meet each function) needed for community-based implementation. Form changes included: 1) different professional roles of facilitators to better align with availability of community experts, family preferences, and to contain costs; 2) incorporation of social determinants facilitators and barriers to behavior change and strategies to mitigate these barriers into the curriculum; and 3) addressing financial sustainability using the Medicare Diabetes Prevention Program as a model. (See Table 1)

Conclusions: Stakeholder engagement as part of an intervention mapping process defined functions of an evidence-based weight management intervention and key form changes for community-based vs. clinic-based implementation. Community-based implementation may better address some social determinants of health barriers to healthy weight for Latino children in immigrant families.
Conducting Pragmatic Community-Based Autism Research

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Background
In 2014, the NIMH's Autism Spectrum Disorder Pediatric, Early Detection, Engagement and Services (ASD PEDS) Network was formed to develop and test systems innovations that rapidly engage young children with ASD in diagnostic and treatment services. Five studies across nine states were funded, each testing a different model of care (i.e., family navigation, enhanced community identification, enhanced primary care identification, online screening and identification with provider training, identification in Part C early intervention). The current paper represents an effort to learn from the collective experience of the five diverse ASD PEDS Network projects. Specifically, we evaluate where each study falls on the pragmatic (i.e., "real-world") to explanatory (i.e., "ideal condition") continuum in order to inform future implementation efforts and identify research priorities for early ASD identification and intervention services.

Methods
The Pragmatic Explanatory Continuum Indicator Summary–2 (PRECIS-2) was used to assess the five ASD PEDS Network studies. First, investigator teams from each study completed the Template for Intervention Description and Replication (TIDieR) checklist for their specific study. Second, a group of independent reviewers with expertise in community ASD services and trial design reviewed the checklists and rated each study on the nine PRECIS constructs (i.e., eligibility, recruitment, setting, organization, delivery, adherence, follow-up, outcomes, analysis) from 1 (most "explanatory") to 5 (most "pragmatic"). Third, a modified Delphi approach was used to reach agreement for each study in each domain.

Results
The domains rated as most pragmatic (i.e., most reflective of usual care) were those measuring the inclusiveness of data in the analyses (M=5.0, SD=0) and the flexibility allowed in providers' adherence to the intervention protocol (M=4.34, SD=1.19). Domains rated as most explanatory (i.e., least reflective of usual care) included the time and effort devoted to follow-up data collection (M=2.23, SD=0.66) and the resources and expertise needed to deliver the intervention (M=2.32, SD=0.81).

Discussion
Overall, there was considerable variability across ASD PEDS Network studies and PRECIS-2 domains. The least pragmatic aspects of these studies were the settings in which they were conducted and the manner in which outcome data were collected, suggesting that these areas may pose particular challenges for community-based trials focused on early detection and service access for ASD. To achieve the goal of increasing pragmatic research trials and "real-world" applicability for ASD research, future research might benefit from using the PRECIS-2 during initial trial design, developing more pragmatic outcome measures, and improving methods for integration of research into "real-world" settings.

1. Pragmatic research study design and analysis
   Completed research
Web-based Sample Size Calculator for Cluster-Randomized and Stepped-Wedge Designs

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Background
Cluster-randomized and stepped-wedge are pragmatic trial designs that have become increasingly popular in recent years. Due to feasibility or logistical constraints, individual-level randomization is often not possible, and interventions must be implemented at the cluster (e.g., site, clinic) level. Power/sample size calculations are used to identify whether a proposed design is feasible for detecting a clinically meaningful effect of an intervention. Tools that perform these calculations are thus essential in the planning of an effective study and for assessing various design options.

Setting
Power calculations for cluster-randomized and stepped-wedge designs incorporate the correlation between multiple observations in the same cluster. They also require additional consideration such as the number of clusters, and individuals per cluster. There are trade-offs when evaluating each of these two designs, and often one is considered when the other is not feasible and/or does not provide sufficient power. With a free, web-based applet, we unify the power/sample size calculations for these two clustered study designs in a single application, allowing for easy comparison and evaluation of alternative designs.

Methods
Using an R Shiny application, we implement methodology developed for cluster-randomized and stepped-wedge designs for sample size/power calculations. We incorporate recent extensions, such as cluster auto-correlation, washout effects, and hybrid designs. The application will use a guided step-by-step process, where users will specify the parameters of their trial design. Users will provide inputs related to the outcome of interest and study design, such as number of clusters, individuals per cluster, desired power, type I error rate, outcome distribution, effect size, and the intraclass correlation coefficient. Outputs will include a visualization of the study design, and a summary statement describing the design, assumptions, and power/sample size values.

Results
The R Shiny calculator will be hosted online as a web applet that can be used by clinicians and statisticians to help plan their trial design. A range of examples will be presented to demonstrate the use of the calculator.

Documentation for the methods and references be provided. Code for the application and power calculations will be shared using Github, where users can provide feedback and request modifications or extensions.

Conclusions
With this online calculator, we aim to increase the accessibility of current and emerging sample size methodology for researchers who are considering pragmatic design alternatives to answer their research question.

1. Pragmatic research study design and analysis  
   Work-in-progress
Getting everyone on the same page: Development and implementation of a multidisciplinary electronic discharge readiness tool.

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Background: Typical solutions for improving discharge planning often rely on one-way communication mechanisms and static data entry into the eHR. We have designed a discharge readiness tool that has been integrated into the electronic health record (eHR), which allows providers to communicate the status of patient discharge readiness in real-time to all clinical staff providing care. This information will enhance prioritization of care and patient flow. Stakeholder engagement to inform user-centered design was imperative to ensure our discharge readiness tool is successfully integrated into existing workflows such that all clinical staff will use this tool with every patient.

Setting/population: To engage hospitalists, nurses, other clinical staff, patients, families and caregivers, and hospital leadership, we met with different stakeholder groups across the inpatient setting to obtain feedback about tool design and functionality.

Methods: We employed multiple user-centered design strategies, including exploring current functionality for documenting discharge readiness and directing discharge planning, iterative low-fidelity mock-ups, multi-disciplinary stakeholder meetings, Brainwriting Premortem exercise, and pre-production user testing (Figure 1). Utilization and feedback were evaluated using EHR and survey data.

Results: We found most providers who responded to the survey reported that the tool either saved time or did not change the amount time required to complete their discharge workflow (21, 87.5%). During the pilot phase, 352 care team members, including hospitalists, residents, nurses, care managers, and physician therapists, have added the tool to their workflow. At the conclusion of the post-implementation phase, 467 care team members have added the tool to their workflow. In addition, providers assigned a discharge status to 84.9% of patients discharged during the pilot implementation period and 87.4% of patients discharged post-implementation. The most common barriers identified by providers were medical improvement (40.9%), placement (12.3%), subspecialty consults (9.6%), physical therapy (9.3%), and social work or care management (8.9%).

Conclusions: Typical solutions for improving discharge planning often rely on one-way communication mechanisms and static data entry into the EHR or in-person meetings for discharge rounds. We have designed a dynamic EHR discharge readiness tool, allowing the care team to communicate the status of patient discharge readiness and patient discharge needs in real-time across hospital settings. Survey and EHR data suggest that this electronic discharge readiness tool has been successfully adopted by providers and clinical staff. Frequent stakeholder engagement and iterative user-centered design was critical to the successful implementation of this tool.

2. Pragmatic research measures and evaluation

Completed research
Implementing physical activity behavior change counseling in an existing exercise program for cancer survivors

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Background: Evidence from randomized controlled trials indicates that supervised exercise and behavior change counseling improves long-term physical activity (PA) adherence in cancer survivors. However, translating this work to real-world settings remains a challenge. This study examined the feasibility and acceptability of implementing PA behavior change counseling (PABCC) sessions into an existing cancer-exercise program.

Setting & Population: Cancer survivors enrolled in BfitBwell, a 12-week exercise program at the Anschutz Health and Wellness Center.

Methods: Participants were randomized to receive (1) the standard BfitBwell program, or (2) BfitBwell plus six evidence-based PABCC sessions. Feasibility was assessed by participant representativeness, process fidelity, and time and cost to deliver the PABCC sessions. Acceptability was based on reasons for declining participation, adherence, and participant satisfaction with the PABCC sessions.

Results: From July 2019- February 2020, N=93 enrolled in the BfitBwell program and N=33 (35.5%) enrolled in the study. Study participants were mostly female (63.6%), diagnosed with breast cancer (39.3%), and an average age of 54.3 ± 12.37 years. There were no differences in age, sex, or cancer diagnosis between those who consented to the study, and participants in the BfitBwell database In the 26 applicable fidelity measures, no items were missed. To date, 42 hours have been spent delivering the PABCC sessions, and costs were printed workbooks ($21.75 per workbook). Reasons for declining to participate in the study were not interested (n=8), not able to guarantee class attendance (n=15), unable to make scheduled class times (n=12), or other (n=19). PABCC participants (n=6) attended M= 5.33±0.52 PABCC sessions (89% adherence rate). The satisfaction questionnaire has been completed by n=5, and 100% reported they enjoyed the PABCC sessions, most (80%) thought attending PABCC sessions will improve their ability to continue to exercise after BfitBwell, and 100% reported PABCC sessions were an added time burden.

Conclusion: Study participants were representative of BfitBwell participants, and found the PABCC sessions useful, but time intensive. Reasons for declining to participate in the study suggest that alterations in time commitment or intervention modality should be considered for continued implementation of PABCC in BfitBwell. To date n=13 have completed the study, and n=6 are currently enrolled. Data collection will continue through May, 2020.

2. Pragmatic research measures and evaluation  Work-in-progress