1.2 ACP in Primary Care (themed session)

O07

Assessing Models of ACP in Primary Care, the Meta-LARC Trial: Part 1 Design and Realization of a US-Canada Study

A. Totten[1], L. Michaels[1], L. Fagnan[1], D. Dorr[1], F. Legare[2]
[1]*Oregon Health & Science Univ., Portland, United States of America*
[2]*Universite Laval, Quebec, Canada*

Background and aims: Advance care planning (ACP) has the potential to reduce suffering and improve outcomes in serious illness, but its implementation has been limited. A consortium of seven Practice Based Research Networks (PBRNs) in the US and Canada known as Meta-LARC designed a cluster randomized comparative effectiveness trial of two models of ACP in primary care practices.
Methods: Meta-LARC facilitated identification of primary care concerns and topics through collaboration among researchers, PBRN directors, clinicians and patient /family advisors. Over 2 months, we used the PBRNs to quickly assess interest, develop options, assess feasibility, refine ideas and obtain buy-in. Through this iterative process, we identified an existing ACP program to study (the Serious Illness Care Program by Ariadne Labs) and developed a proposal, research protocol and a stakeholder engagement plan.
Results: The trial, agreed to by all seven PBRNs, was funded by the Patient Centered Outcomes Research Institute and began in November 2017. This panel will discuss the key decision steps and drivers for the trial design (Part 1) and the accomplishments to date including engaging stakeholders (Part 2), adapting ACP training for teams (Part 3), obtaining ethics approval in two countries (Part 4), supporting ACP implementation in diverse primary care practices (Part 5) and developing patient-reported measures of goal concordant care (Part 6).
Conclusion: PBRN networks provide an important infrastructure that can facilitate design of a large, complex study of ACP with the potential to influence the spread of ACP in primary care practices in at least two countries.

O08

Assessing Models of ACP in Primary Care, the Meta-LARC Trial: Part 2 Engaging Patient and Family Advisors in Research

A. Totten[1], A. Combe[1], M. Minitti[2], D. Dokken[2], M. Simpson[3], R. Siddiqui[4]
[1]*Oregon Health & Science Univ., Portland, United States of America*
[2]*Institute for Patient- and Family-Centered Care, Bethesda, MD, United States of America*
[3]*University of Colorado School Of Medicine, Denver, CO, United States Of America*
[4]*University Of Toronto, Toronto, Canada*

Background: Patient and family engagement is essential to community-based pragmatic research. After our study of advance care planning (ACP) in primary care was funded, we expanded the proposal and developed a detailed Engagement Plan (EP) to accompany the study protocol.
Methods: We established a cohort of 11 Patient and Family Advisors (PFA) to guide the project; seven associated with participating PBRNs and four unaffiliated or at-large PFAs (2 US; 2 Canadian). During project initiation, the joint coordinating center established a working committee to develop an EP using the PCORI template. We surveyed PFAs about goals, solicited feedback from PBRNs and engagement experts, distributed planning assignments, and shared drafts with stakeholders.
Results: The EP was developed based on a quality improvement approach in which monitoring, measuring and improving engagement is the focus. Monitoring engagement includes baseline assessment of needs, quarterly surveys and annual check-ins. Engagement measurement tracks stakeholder inputs and resulting impact on the project and establishes processes to support participant recruitment and retention. PFA-identified goals form QI targets and inform strategies to clarify expectations, forms of participation, and documenting and communicating the impact of PFA contributions**.** The EP will be updated twice annually.
Conclusion: Creating a formal EP allowed operationalization of our commitment to PFA engagement and integration into multiple aspects of the study. Making the plan a living document allows us to identify challenges, address issues, and document our experience. Approaching engagement as a component of trial design and execution facilitates development of best practices and science around engagement.

O09

Assessing Models of ACP in Primary Care, the Meta-LARC Trial: Part 3 Theory-based Design of an Interprofessional Team Training

A. Totten[1], D. Caron[2], S. Izumi[1], S. Guay-Belanger[2], F. Legare[2]
[1]*Oregon Health & Science Univ., Portland, United States of America*
[2]*Universite Laval, Quebec, Canada*

Background and aims: Implementing advance care planning (ACP) in primary care practice has been challenging. An approach incorporating interprofessional (IP) team members has potential to facilitate ACP conversations though teams may lack ACP training. We adapted and pilot tested a program to train IP teams in ACP.
Methods: We developed an ACP conversation training program for primary care teams by adapting the Serious Illness Care Program by Ariadne Labs and incorporating the Interprofessional Approach to Shared Decision Making Model. The training materials were reviewed by eight health professionals and three patient and family advisors for acceptability and feasibility, then pilot tested with six interdisciplinary members of a primary care team. Reviewers' comments and post training interviews were analyzed using qualitative descriptive analysis methods.
Results: The training program consists of a 1.5 hour online module and a 1.5 hour in-person interactive session.

Reviewers' comments included: both concerns about and support for non-physician team members discussing prognosis; questions about how to share the responsibility/time for conversations; and need for communication within teams and with patient/families. Post pilot training interviews also revealed barriers to ACP, and lack of clarity about how to share and communicate the conversations across team members. We modified the training and created scenarios showing various team-based approaches for ACP.
Conclusion: Initial assessment indicated the need to adapt ACP approaches for interprofessional team members. In the next step, we are testing the effectiveness of the modified IP ACP conversation training in primary care practices in the US and Canada.

O10
Assessing Models of ACP in Primary Care, the Meta-LARC Trial: Part 4 Cross US-Canada Ethics Challenges and Experience
A. Totten[1], L. Michaels[1], D. Caron[2], S. Guay-Belanger[2], K. Grant[3], M. Greiver[3]
[1]Oregon Health & Science Univ., Portland, United States of America
[2]Universite Laval, Quebec, Canada
[3]University of Toronto, Toronto, Canada

Background: We designed a collaborative, US-Canadian study to increase generalizability and explicitly consider potential for spread across different systems. Addressing ethical requirements for multiple Institutional Review Boards (IRBs) and Research Ethics Boards (REBs) presents challenges when conducting one trial in two countries.
Methods: Our trial includes 42 primary care practices from practice-based research networks (PBRNs) in 5 US states and 2 Canadian provinces. A centralized, single IRB process was used in the US with Clinical and Translational Science Award authorization to the PI for the 5 IRBs to rely on one unassociated IRB. In Canada ethics oversight required different approaches in each province. Ontario used a partially centralized and an institutional REB while Quebec used a fully centralized REB. Similar study protocols were submitted to all IRBs/REBs. The joint coordinating center harmonized research workflows and procedures to respond to a variety of concerns and requests.
Results: The number and nature of concerns requiring clarifications and modifications varied across the IRBs and REBs. The IRBs/REBs considered the trial to present different levels of risk and viewed the training, implementation and evaluation of ACP differently. There were differences regarding informed consent, survey language and data sharing. While the process and approvals took longer than expected and posed issues for consistency, addressing them facilitated development of a robust intervention and protocol.
Conclusion: Differences in research ethics perspectives and procedures could be significant barriers to US-Canada research. We demonstrated that variation could be addressed, knowledge-sharing strengthened the project protocol, and future collaborations are possible.

O11
Assessing Models of ACP in Primary Care, the Meta-LARC Trial: Part 5: Planning and Supporting Implementation
A. Totten[1], D. Dorr[1], L. Michaels[1], S. Izumi[1], N. Shankle[1], S. Strauss[2]
[1]Oregon Health & Science Univ., Portland, United States of America
[2]University of Toronto, Toronto, Canada

Background: Implementation of ACP is challenging, requiring a multi-pronged approach in primary care. We sought to provide a toolkit that would facilitate practices' adoption of the Serious Illness Care Program, as a means of improving the quality of care and engaging patients in serious illness care discussions and planning.
Methods: The joint coordinating center established a working committee to compile implementation resources. We used an iterative approach to identify key issues, materials, and discussion points necessary to engage practices in ACP implementation. We involved stakeholder groups representing patients, clinicians, practice facilitators, researchers, and informaticians. The group identified, adapted, and reached consensus on materials and approaches to facilitating ACP in primary care practices.
Results: We identified potential implementation barriers, including knowledge, attitudes, workflow, health information technology constraints, and sensitivity of the topic to engaging practices in ACP. We gathered materials to address these barriers including checklists, adaptable templates for dissemination and documentation, and developed a guide to facilitate conversations with practices. The key topics included practice readiness, patient identification, use of prognostic algorithms, workflow enhancement, effective documentation, and sustainability. We are using the TiDier checklist to monitor implementation fidelity to the ACP models in the trial.
Conclusion: We created a toolkit to support implementation of ACP in primary care practice that can be used by practice facilitators. It covers the major topics identified by stakeholders as essential for ACP implementation. We will evaluate and revise this, making an enhanced implementation guide available to the trial practices as well as to others.

O12
Assessing Models of ACP in Primary Care, the Meta-LARC Trial: Part 6 Developing Patient-Reported Measures of Goal Concordant Care
A. Totten, D. Dorr, L. Michaels, S. Izumi
Oregon Health & Science Univ., Portland, United States of America

Background and Aims: Patient-reported goal concordance in serious illness care is an important primary outcome; however, no validated measure exists. As part of a trial of ACP, we sought to design and validate items for our trial that could form the basis for future measure development.
Methods: To draft items we reviewed the literature for validated measures in goal attainment, shared decision-making, and concordance. We engaged stakeholders, including patients, providers, and researchers, to discuss

what goal concordant care means, developed draft items, and reviewed these in two focus groups with patient and family advisors as well as with research teams from other funded advance care planning and palliative care projects.
Results: Our draft instrument consists of 3 parts representing different approaches. The first part asks the patient whether their current care supports what is important to them and if any care received was unwanted. The second part is derived from the Life Preference Scale developed by Ariadne Labs. This asks patients to report on whether health care supports what they identify as their three most important goals. The third part includes process measures based on the content of serious illness conversations and asks patients if each step or activity happened.
Conclusion: It is possible to develop a patient-reported measure of goal concordant care that has face validity based on measures of related or similar constructs and the input of a range of stakeholders. Validation and ongoing refinement of the measure will be conducted in parallel with the trial.