OP5: What do we know improves recruitment to trials in Primary Care: and what might improve the situation?

NEEDS & OBJECTIVES:
Almost half of all trials in primary care fail to recruit to target. Of those that do succeed, many do so only after extending the length of the trial. The objective of the systematic review was to quantify the effects of specific methods used to improve recruitment of participants to randomised controlled trials, and where possible, to consider the effect of primary care as a study setting on recruitment. This synthesis builds on and updates an earlier Cochrane review and adds recent descriptive research and considers novel methods being developed in Scotland and Toronto.

SETTING & PARTICIPANTS
45 trials with over 43 000 participants were included in the Cochrane review.

DESCRIPTIONS:
Cochrane systematic review supplemented by analysis of recent descriptive papers and description of recent EMR developments.

EVALUATION:
Some interventions are effective in increasing recruitment: telephone reminders to non-respondents (risk ratio (RR) 1.66, 95% CI 1.03 to 2.46; two studies, 1058 participants), use of opt-out procedures rather than opt-in for contacting potential participants (RR 1.39, 95% CI 1.06 to 1.84; one study, 152 participants) and open designs where participants know which treatment they are receiving in the trial (RR 1.22, 95% CI 1.09 to 1.36; two studies, 4833 participants). The effect of many other strategies is less clear however, including the use of video to provide trial information and interventions aimed at recruiters.

DISCUSSION/REFLECTION/LESSONS LEARNED:
Promising strategies for increasing recruitment to trials in primary care exist, but some methods, such as open-trial designs, use of electronic medical records and opt-out strategies, must be considered carefully as their use may also present methodological or ethical challenges. Questions remain as to the applicability of results originating from hypothetical trials, including those relating to the use of monetary incentives, and there is a clear knowledge gap with regard to effective strategies aimed at recruiters including the role of practice based research networks.

ONLINE RESOURCE URL (optional):
http://bmjopen.bmj.com/content/3/2/e002360.abstract

PRESENTERS:
Frank Sullivan

OP6: ResearchACTS: A New Tool to Collect Patient-Reported Data, Create Customized Patient Summaries, and Enable Facilitated Research in PBRNs

NEEDS & OBJECTIVES:
To facilitate research objectives in a PBRN setting, Health IMPACTS for Florida (HI) researchers sought new methods of collecting patient-reported data using a practice facilitation model, rather than relying on the physical presence of research staff during data collection. A review determined that existing software was insufficient to manage the complex user roles and data management, access, and presentation required for point-of-care risk assessment screening and research database creation. University of Florida software engineers worked with HI faculty and staff to create a web-based application (ResearchACTS) that could be accessed via tablets to collect, assess, summarize and communicate patient reported information. User interfaces were created to allow ResearchACTS to support myriad studies, thereby creating an HIT-supported data collection infrastructure for the entire PBRN.

SETTING & PARTICIPANTS
HI is a diverse PBRN in north and central Florida and includes family medicine and pediatric practices in Tallahassee, Jacksonville, Orlando, and Gainesville Florida. Represented in its membership are private practices, hospital- and academic health center-affiliated practices, Department of Health clinics, Federally Qualified Health Centers, and Community Health Centers. Member practices used a variety of EHRs and 35% of the membership has yet to implement an EHR. ResearchACTS users to date include adult and pediatric patients, clinicians, clinic staff, practice facilitators, and study coordinators.

DESCRIPTIONS:
ResearchACTS is a web-based application that collects data from any internet-connected device and was designed with touch-based input in mind. Practices were given tablets to access the web-based tool, which were cellular-capable for clinics without reliable wireless internet. A permissions-based user access model ensures that only individuals with the proper authorization will have access to particular features and data. Providers and researchers have real-time data access while HI administrators have access to network-level reports. A de-identified, geocoded, customized health resource summary can be emailed to patients while identified patient-reported data can be downloaded as a PDF for upload to an EHR or printed for integration with a paper medical record. Practice facilitators can access their assigned clinics to find a de-identified list of alerts to ensure completeness of data collection. All features have user interfaces that allow highly customized studies to be created by study coordinators rather than the software engineering team.

EVALUATION:
ResearchACTS has already been successfully used to collect data for multiple studies enrolling thousands of research participants. Feedback from investigators, coordinators, providers and patients informs the ongoing development and refinement of the tool. To date, investigators have used ResearchACTS to study teen health risk assessment (N=609), Hepatitis B screening (N=1055; study is ongoing), and HPV vaccination (N=98; study is ongoing). ResearchACTS was also adapted for the Wellness Incentives and Navigation (WIN) project, which uses health navigators and wellness spending accounts to set individualized health goals and currently tracks 750 Medicaid enrollees.

DISCUSSION/REFLECTION/LESSONS LEARNED:
ResearchACTS is an integral piece of HI infrastructure that allows the systematic collection of high-quality research data without the physical presence of study/PBRN staff. Health IMPACTS is currently exploring strategies to develop the interface between ResearchACTS and Epic and other electronic health records. This linkage will address an important need among practitioners in using the software.

ONLINE RESOURCE URL (optional):

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OP7: An Inside Look into the World of Virtual Practice Facilitation

NEEDS & OBJECTIVES:
Interest in pragmatic, multi-center clinical trials to answer questions in real world, community settings is growing. Primary care PBRNs are ideal settings for these pragmatic clinical trials (PCTs). The objective of this toolkit is to support an increase in the pool of academic investigators who understand PBRN infrastructure and who are comfortable working alongside primary care PBRNs to speed the adoption of the PCT as a research method.

SETTING & PARTICIPANTS
Collaborators from DARTNet Institute (DI) and the Clinical Translational Science Award (CTSA) PBRN Workgroup planned the development of this toolkit of resources for academic-PBRN collaborations, and held a workshop at the June 2013 NAPCRG PBRN meeting that solicited feedback from attendees on best practices for these collaborations.

DESCRIPTIONS:
DI and CTSA collaborators defined toolkit content, developed the toolkit components, and incorporated feedback received from colleagues in the PBRN and CTSA communities. By June 2014, the toolkit will be live on the DI website. The "Toolkit for Developing and Conducting Multi-site Clinical Trials in Practice Based Research Networks" includes a suite of Frequently Asked Question (FAQ) documents on 1)) Recruiting, Engaging, and Maintaining Practice Sites, 2) Communications, 3) Project Management, and 4) Budgeting. Other toolkit features include sample templates of materials useful to collaborations between academic teams and PBRNs, a glossary of terms describing PBRN research project teams, references, and links to other resources for working with PBRNs.

EVALUATION:

DISCUSSION/REFLECTION/LESSONS LEARNED:
The Toolkit for Developing and Conducting Multi-site Clinical Trials in PBRNs provides resources to guide academic investigators seeking to conduct PCTs in a PBRN setting, and to support PBRN directors and their teams in communicating their PBRN's project-specific needs with investigators.

ONLINE RESOURCE URL (optional):

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OP8: Using a Tablet and Smart-Phone Based Survey and Health Education System to Collect Information From Low-Literacy and Non-English Speaking Patients and Create the Wait Room of the Future: Research and Clinical Applications for PBRNs

NEEDS & OBJECTIVES:
Collecting information from low-literacy and non-english speaking patients is a critical element of health disparities research but can be expensive and difficult to do. In the past, this has required hiring staff able to read surveys to patients in their preferred language and who are effective in working with often marginalized populations.   In locations like Los Angeles where more than 42 different languages are spoken by patients being cared for in the safety net, this is expensive and often logistically impossible to do. In addition, unlike patients with higher literacy levels who can complete surveys privately, low-literacy patients must answer often embarrassing or personal questions in front of the staff person assisting them with the survey. To address these problems, LA Net partnered with a software development team to develop a tablet and smart-phone based program able to read questions to patients, and deliver surveys in multiple languages.

SETTINGS & PARTICIPANTS:
LA Net is a practice-based research and resource network serving the Los Angeles safety net. Its members include 23 Federally Qualified Health Centers and private practices in low-income areas of Los Angeles and Orange County. Participants include 25 practices in and outside of Los Angeles.

DESCRIPTION:
LA Net's tablet-based data collection tool -Talking Survey - runs on low-cost android based tablets and smartphones. It delivers surveys in 64 different languages and provides auditory support to patients with low reading levels. The system transmits data real time to a practice's EHR, data warehouse or registry, and generates a redacted data file for research use and a non-redacted file for clinical use. The program can also be used to obtain informed consent and deliver tailored video messages to patients.   In addition to its use for collecting research data, four LA Net practices are piloting the Talking Survey system to collect the PHQ9, MediCare Initial Health Assessment, state health screenings, and patient satisfaction surveys for clinical and practice use.

EVALUATION
More than 2000 surveys have been collected using the system to date across 25 practices. In a study of patient satisfaction with the tool (N=45), 95% of patients reported being "satisfied" or "very satisfied" with the tool. In this same study, survey completion time was reduced from 30 minutes to 15 minutes when compared to paper administration. Models of implementation include use of a research assistant to oversee use of multiple tablets in wait room, integration of tablet into patient check-in or pre-visit workflow, permanent installation of tablets in wait room using multi-tablet tables, and deployment on patients' smart phones or tablets for use in home monitoring surveys of chronic conditions.   Barriers to use include connectivity issues with practice Wi-Fi system and integration of tablet use into regular practice workflow.

DISCUSSION/REFELCTIONS/LESSONS LEARNED:
Electronic collection of patient information is the next phase in creating truly IT-enabled practices. PBRNs like LA Net are well situated to design and host these systems as they understand both clinical and research applications and their related workflows. Adoption across multiple practices can make it possible for PBRNs to collect patient survey data quickly and efficiently, and may also provide opportunities for income generation for both the PBRN and practices by offering access to the system to outside researchers, health plans and other health care stakeholders.

OPTIONAL URL:
lanetpbrn.net talkingsurvey.com

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