

You don't want to be seen as somebody who's forcing a patient... if their provider is telling them this is a good idea you are more likely to get your patient to do it. I think they have to understand what a clinical trial is, first of all, in that it's a trial. Right? We're trying to figure out if a certain treatment is good or not. It may not work. It may work. With many patients, they don't only have medical problems, but significant mental illness that sometimes interferes a lot with just our treatment of them here for their clinical problems. And so, that probably would interfere with someone's ability to understand and consent to a trial. And the patients have the right to make that choice. I don't need to be—I don't mind influencing them on things I know about, I think are invaluable, but I don't need to be a barrier to them. (5) Perceived responsibility in trial recruitment varied substantially, from no involvement at all, to prescreening, counseling, or recruiting patients. Some providers felt that they should have the right to say "no" to recruitment of their patients while others believed prescreening was an unnecessary burden, outside of their role as a primary care provider. If someone prescreens and thinks its appropriate and gives me that judgment call to say, do you think it would be a good fit? I think one of them, they sent, and I said, Oh, I don't think it would be a good fit because of this...So that would be fine. I don't think I need to be a gatekeeper for studies. I mean, if there's people that qualify for a study, and there's a great study that's been approved, and they can recruit them without me knowing, that doesn't bother me in the slightest. I liked how it was—I could do a simple referral ... someone else figured out the qualifications. If we knew of ongoing studies and if we thought a certain patient may qualify for a certain study, we just contact the coordinator, and then they just take care of the rest. I think that appropriate ... from our perspective, would be, "Are you interested?" "This is the number for a person who can sit with you, talk with you about a trial, tell you everything about it, answer your questions, and then you can make a decision." I'm not going to let you go mess up my patient and I'm going to have to deal with the consequences. (6) A clinic-implementation approach that systemizes workflow, limits the number of trials providers are asked to recruit for, and minimizes provider time burden is needed. Suggested methods for informing providers of patient clinical trial eligibility included: email, alerts, in-basket messages, texts, phone-calls, and in-person contact. People are so sick of change, change, change, change ... if there's no stability whatsoever, then people get frustrated and start to burn out. Having my staff remember how to do it correctly and I remember what studies we have going ... it becomes somewhat of a burden... it's hard for us to remember as we are flying through our day. There just needs to be a clear understanding with those roles... Who does the patient call? We don't want to look like we don't know what we are doing. There probably should be a selection committee put together from various people who have stakes in the community, at least who can say, "This would be applicable for xx clinic." (7) Provider Suggestions Providers had multiple suggestions regarding notification methods. (II) Development of item pool and construction of questionnaire The specific items were constructed from literature review on physician's attitudes and results from the focus group. The overarching concern was on readability, brief questionnaire size, and relevance. A large item were constructed and then reduced through piloting. (III) Questionnaire Pilot Results: The 7-item pilot questionnaire was completed by 36 physicians (28% response rate). In this section, we report the empirical results. DISCUSSION/SIGNIFICANCE OF IMPACT: Discussion Relevance of Methods. Overall, the described methods for determining components for a recruitment program in primary care shows early promise. The focus groups that consisted of providers, staff and administrators resulted in insights as to workflows, attitudes, and clinical processes. These insights significantly varied across clinics. This variation supported the need for an individualized clinic-based approach that will meet local needs. During the course of the study, participants were willing to participate in all activities (although some requested payment). We were able to conduct the focus groups as scheduled and obtained the desired input. The analysis of the focus group transcripts was performed using iterative discussions and did not need any special adaptation for this area of study. The pilot survey response rate was within the expected for this type of study. Focus groups can rapidly provide rich information regarding attitudes and other factors affecting provider participation at the point of care. However, findings from focus groups must always be confirmed through larger studies. It is important to keep the focus groups small and to hold multiple focus groups to offset the more vocal participants that may influence comments of others. This study shows that using our 3-step approach it is possible to gather important information on clinician's and staff perceptions and needs to participate in point of care patient recruitment for CT. The focus groups also provide an important step for survey construction. Designing surveys empirically requires multiple validation efforts, which will be conducted in the future. However, we can draw preliminary conclusions from the results of the pilot study which are quite informative and they are discussed below. Near future work will be to expand the response rate through additional local survey and conduct formal psychometric testing and validation both locally and nationally. A final validation will be proposed through the CTSA consortiums. Variation in responses. There was a lack of normal curves in our survey results. This points to the need to target education and recruitment efforts by provider type (with similar perspectives). Identification of these types would be useful.

Some specific points regarding variability that should be considered in program design. Preferences for trail recruitment methods. Many trial recruitment notification methods have the potential to be successful when used judiciously and done well, particularly if the trial coordinator/provider relationship is supported by reciprocal benefits to the provider. Consistency in workflow within seems paramount to success. Providers can pull some notifications at a time they choose, while other notifications interrupt and must be used sparingly. Some allow review of multiple patients at the same time, and some foster easy access to the patient's medical record. Conclusions. The authors recommend that recruitment HIT be customizable at the clinic and provider level by responsibility and interest to allow selection of level of information, delivery method, that is, email, text, in-basket, alert, dashboard, mail; frequency of notification, and an opt out feature. These customizable options will allow for better support of clinic workflow or goals. There is the potential with machine learning technology to monitor provider interactions with trial notifications and for the system to automatically make adjustments to the method and level that best supports each physician. Limitations: The major limitation is the focus on one site only and one delivery system (university based). The low response makes generalization difficult. Efforts to improve the rate are underway. Many populations are under-represented in Utah. Full psychometric analysis was not conducted but will part of the final project.

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### Do patient comorbidities impact the effectiveness of a COPD self-management program?

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OBJECTIVES/SPECIFIC AIMS: Chronic obstructive pulmonary disease (COPD) is a leading cause of both hospitalizations and readmissions in the United States, and about 1 in 5 hospitalized patients with COPD will be readmitted within 30 days. COPD-focused self-management programs are frequently used to help patients better manage their symptoms and prevent hospitalization. However, while the majority of patients with COPD have at least one comorbidity, most trials of COPD self-management programs either excluded patients with significant comorbidities or did not analyze the impact of comorbidities on patient outcomes. Using data from the BREATHE trial of a COPD self-management program, this study aims to determine if patient post-intervention outcomes differ based on the intensity and type of patient comorbidities. METHODS/STUDY POPULATION: In total, 240 patients hospitalized for COPD were randomly assigned to either a comprehensive self-management intervention or usual transitional care. Primary outcomes for this trial were the number of COPD-related hospitalizations and emergency department visits at 6 months and changes in COPD-specific quality of life. To determine whether patient comorbidities modify the effect of the self-management intervention on readmission and quality of life outcomes, we will compare patient outcomes across groups stratified by comorbidity burden (Charlson Comorbidity Index) and type (baseline diagnosis of congestive heart failure, diabetes, and depression). In addition, we will use regression analysis with interaction terms to test for interaction between comorbidity burden/type and intervention assignment. RESULTS/ANTICIPATED RESULTS: We hypothesize that the effect of the self-management intervention will differ in patients with greater comorbidity burden due to competing medical demands for patients with multimorbidity. DISCUSSION/SIGNIFICANCE OF IMPACT: The results of this study will help clinicians better target disease-specific self-management programs to the groups of patients with COPD who are likely to receive the greatest benefit from this type of intervention.

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### ECG and echo characteristics in familial partial lipodystrophy: The impact of Lamin A variants

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OBJECTIVES/SPECIFIC AIMS: Familial partial lipodystrophy (FPLD) is an inherited, rare syndrome characterized by selective absence of adipose tissue from extremities which is associated with severe insulin resistance, and metabolic dyslipidemia (with hypertriglyceridemia, and low HDL) Typically, 30%–50% of patients with FPLD demonstrate a pathogenic variant in Lamin A (LMNA) gene that is associated with inherited cardiomyopathy and arrhythmia syndromes. We inquired the prevalence of having abnormal ECGs and echocardiograms in FPLD and whether there is a difference in evaluated parameters with respect to genotype. METHODS/STUDY POPULATION: We conducted a retrospective review of an established cohort of 58 patients (age range: 12–71, M/F 8/50) with FPLD. Demographic characteristics, genotype, fasting triglyceride, hemoglobin