

and outcome. All patients had symptoms of synucleinopathy, manifesting with autonomic failure, REM behavior disorder, and parkinsonism. Four met criteria for idiopathic PD, and one was diagnosed with pure autonomic failure but had concomitant symptoms of parkinsonism and REM sleep behavior disorder. RESULTS/ANTICIPATED RESULTS: Our patients had no significant cognitive or behavioral symptoms before the initiation of droxidopa. The average decrease in blood pressure upon standing was 27 mmHg systolic and 17 mmHg diastolic. Behavioral disturbances were observed early in the titration period and at relatively low doses of droxidopa (total daily doses ranging from 300 to 800 mg/day; droxidopa therapeutic dose range 900–1800 mg/d). The most common symptoms reported were mania, irritability, and confusion. Symptoms resolved with dose reduction in 4 patients, and droxidopa was discontinued in 1 patient due to persistent irritability. No other medical comorbidities or alternative etiologies were identified to explain these effects. DISCUSSION/SIGNIFICANCE OF IMPACT: Droxidopa is a prodrug designed to act peripherally, but may also have important, yet poorly described, central effects. We hypothesize that these behavioral manifestations result from an “overdose” of key NE networks linking orbitofrontal and mesolimbic regions. Further studies are warranted to better characterize central NE effects in patients treated with droxidopa.

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### Delirium and catatonia: Age matters

Jo E. Wilson<sup>1</sup>, Richard Carlson<sup>1</sup>, Maria C. Duggan<sup>2,3</sup>, Pratik Pandharipande<sup>4</sup>, Timothy D. Girard<sup>5</sup>, Li Wang<sup>6</sup>, Jennifer L. Thompson<sup>6</sup>, Rameela Chandrasekhar<sup>6</sup>, Andrew Francis<sup>7</sup>, Stephen E. Nicolson<sup>8</sup>, Robert S. Dittus<sup>3,9</sup>, Stephan Heckers<sup>1</sup> and E. W. Ely<sup>3,9</sup> For the Delirium and Catatonia (DeCat) Prospective Cohort Investigation

<sup>1</sup> Department of Psychiatry, Vanderbilt University Medical Center, Nashville, TN, USA; <sup>2</sup> Department of Medicine, Division of General Internal Medicine and Public Health, Vanderbilt University School of Medicine, Nashville, TN, USA; <sup>3</sup> Veteran's Affairs TN Valley, Geriatrics Research, Education and Clinical Center (GRECC); <sup>4</sup> Department of Anesthesiology and Critical Care; <sup>5</sup> Department of Critical Care Medicine, Clinical Research, Investigation, and Systems Modeling of Acute illness (CRISMA) Center, University of Pittsburgh School of Medicine, Pittsburgh, PA, USA; <sup>6</sup> Department of Biostatistics, Vanderbilt University Medical Center, Nashville, TN, USA; <sup>7</sup> Department of Psychiatry, Penn State Medical School, Hershey Medical Center, Hershey, PA, USA; <sup>8</sup> Department of Psychiatry, Beth Israel Deaconess Hospital-Plymouth, Plymouth, MA, USA; <sup>9</sup> Department of Medicine, The Center for Health Services Research, Division of Pulmonary and Critical Care, Vanderbilt University Medical Center, Nashville, TN, USA

OBJECTIVES/SPECIFIC AIMS: Background: Delirium is a well described form of acute brain organ dysfunction characterized by decreased or increased movement, changes in attention and concentration as well as perceptual disturbances (i.e., hallucinations) and delusions. Catatonia, a neuropsychiatric syndrome traditionally described in patients with severe psychiatric illness, can present as phenotypically similar to delirium and is characterized by increased, decreased and/or abnormal movements, staring, rigidity, and mutism. Delirium and catatonia can co-occur in the setting of medical illness, but no studies have explored this relationship by age. Our objective was to assess whether advancing age and the presence of catatonia are associated with delirium. METHODS/STUDY POPULATION: Methods: We prospectively enrolled critically ill patients at a single institution who were on a ventilator or in shock and evaluated them daily for delirium using the Confusion Assessment for the ICU and for catatonia using the Bush Francis Catatonia Rating Scale. Measures of association (OR) were assessed with a simple logistic regression model with catatonia as the independent variable and delirium as the dependent variable. Effect measure modification by age was assessed using a Likelihood ratio test. RESULTS/ANTICIPATED RESULTS: Results: We enrolled 136 medical and surgical critically ill patients with 452 matched (concomitant) delirium and catatonia assessments. Median age was 59 years (IQR: 52–68). In our cohort of 136 patients, 58 patients (43%) had delirium only, 4 (3%) had catatonia only, 42 (31%) had both delirium and catatonia, and 32 (24%) had neither. Age was significantly associated with prevalent delirium (i.e., increasing age associated with decreased risk for delirium) ( $p=0.04$ ) after adjusting for catatonia severity. Catatonia was significantly associated with prevalent delirium ( $p<0.0001$ ) after adjusting for age. Peak delirium risk was for patients aged 55 years with 3 or more catatonic signs, who had 53.4 times the odds of delirium (95% CI: 16.06, 176.75) than those with no catatonic signs. Patients 70 years and older with 3 or more catatonia features had

half this risk. DISCUSSION/SIGNIFICANCE OF IMPACT: Conclusions: Catatonia is significantly associated with prevalent delirium even after controlling for age. These data support an inverted U-shape risk of delirium after adjusting for catatonia. This relationship and its clinical ramifications need to be examined in a larger sample, including patients with dementia. Additionally, we need to assess which acute brain syndrome (delirium or catatonia) develops first.

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### Depression, anxiety, and planning for the future: Associations with advance care planning

Ryan McMahan<sup>1</sup>, Evan Walker<sup>2</sup> and Rebecca Sudore<sup>3</sup>

<sup>1</sup> San Francisco School of Medicine, University of California, CA, USA; <sup>2</sup> Department of Internal Medicine, University of California, San Francisco, CA, USA; <sup>3</sup> Department of Medicine, San Francisco VA Medical Center, Division of Geriatrics, University of California, San Francisco, CA, USA

OBJECTIVES/SPECIFIC AIMS: Millions of diverse, older adults live with serious and chronic illness for which they will face complex, ongoing medical decisions. Advance care planning (ACP) has been conceptualized as a health behavior that supports adults in understanding and sharing their values, goals, and preferences for future medical care. Depression and anxiety are known barriers to participation in health behaviors. It is unknown whether depression and anxiety are associated with ACP participation or with patients' values for future medical care. Understanding whether depression and anxiety are associated with ACP would be important to tailor ACP interventions. METHODS/STUDY POPULATION: In total, 908 English-speaking and Spanish-speaking participants  $\geq 55$  years of age were recruited from a San Francisco county hospital. We measured depression (Patient Health Questionnaire 8-item scale) and anxiety (Generalized Anxiety Disorder 7-item scale), dichotomized into none-to-mild Versus moderate-to-severe. We measured ACP engagement using a validated survey of Behavior Change Processes (e.g., knowledge, self-efficacy, readiness; 5-point Likert) and Action Measures (e.g., ask, discuss, and document one's wishes; yes/no). We elicited values concerning life extension categorized as “life is always worth living no matter the health situation” Versus “some health situations would make life not worth living.” To explore associations, we used  $\chi^2$ , Mann-Whitney tests, linear and logistic regressions. RESULTS/ANTICIPATED RESULTS: Mean participant age was 64 years  $\pm 6$ , 80% were non-White, 40% had limited literacy, 45% were Spanish-speaking, and the prevalence of depression and anxiety was 12% and 10%, respectively. Depression and anxiety were not associated with ACP Engagement,  $p>0.05$ . However, participants with depression had an increased odds of reporting “some health situations would make life not worth living” than those not depressed,  $p=0.02$ . In multivariate linear and logistic regression, controlling for age, gender, literacy, and health status, having depression increased the odds of not valuing life extension OR 2.9 (CI: 1.7–4.9). Anxiety was not associated with values concerning life extension,  $p>0.05$ . DISCUSSION/SIGNIFICANCE OF IMPACT: Depression and anxiety were not associated with prior ACP engagement suggesting engaging patients in ACP does not increase these conditions. However, depression was associated with an increased odds of not valuing life extension and, therefore, may influence treatment choices. Longitudinal randomized controlled trials of an ACP intervention are currently underway to investigate these associations further.

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### Development of a statin risk communication tool for use in cancer survivors: A pilot

Nirupa J. Raghunathan, Nassim Anderson, Emily Tonorezos and Deborah Korenstein

Memorial Sloan Kettering Cancer Center

OBJECTIVES/SPECIFIC AIMS: There are currently over a million survivors of childhood, adolescent, and young adult cancer in the United States, many of whom were treated with radiation therapy. Chest radiation with fields including the coronary arteries is a risk factor for cardiovascular disease. Of note, survivors are often unaware of this increased cardiovascular disease risk or, if they are aware, do not know how to mitigate the risk. Visual aids and communicating risk in terms of absolute risk reductions are shown to improve patients' understanding. The Institute of Medicine recommends use of decision aids to optimize patient discussions of benefits and harms of therapies. Our goal is to develop and pilot test a statin therapy risk communication tool for use in high-risk cancer survivors to improve shared decision making and patient knowledge of coronary artery disease risk. METHODS/STUDY POPULATION: Participants were recruited from the adult long-term follow-up clinic at Sloan Kettering Cancer Center into 2 arms, usual care Versus

intervention with the statin risk communication tool. The post-visit assessment used Likert-like scales to explore patient perceptions of statin use. The study was not powered for significance as it was a feasibility study; descriptive statistics were run to compare the 2 groups. RESULTS/ANTICIPATED RESULTS: Participants (n = 45) had a mean age of 45. In the intervention group, 92% felt the information given was right compared with 73% of the usual care group. In all, 63% of the intervention arm felt the information was helpful, compared with 47% of those in usual care. And 53% of usual care would recommend the method to other patients and for other treatment choices compared to 67% of those in the intervention arm. DISCUSSION/SIGNIFICANCE OF IMPACT: This risk communication tool was assessed for acceptability and found to be more acceptable compared with usual care. In addition, we will gather further information on knowledge enhancement and decisional conflict as well as qualitative data regarding the shared decision making experience. With this information, a future randomized-controlled trial across institutions could provide information on how childhood, adolescent, and young adult survivors approach shared decision making with risk communication tools.

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## Development of an instrument to identify factors influencing point of care recruitment in primary care settings: A pilot study at University of Utah Health

Teresa Taft, Charlene Weir, Heidi Kramer and Julio Facelli  
The University of Utah School of Medicine

OBJECTIVES/SPECIFIC AIMS: Electronic health records have become the fulcrum for efforts by institutions to reduce errors, improve safety, reduce cost, and improve compliance with recommended guidelines. In recent times they are also being considered as a potential game changer for improving patient recruitment for clinical trials (CT). Although the use of CDS for clinical care is partially understood, its use for CT patient identification and recruitment is young and a great deal of experimental and theoretical research is needed in this area to optimize the use of CDS tools that personalize patient care by identifying relevant clinical trials and other research interventions. The use of CDS tools for CT recruitment offers a great deal of possibilities, but some initial usage has been disappointing. This may not be surprising because, while the implementation of these interventions is somewhat simple, ensuring that they are embedded into the right point of the care providers workflow is highly complex and may affect many actors in a clinical care setting, including patients, nurses, physicians, clinical coordinators, and investigators. Overcoming the challenges of alerting providers regarding their patient's eligibility for clinical trials is an important and difficult challenge. Translating that effort into effective recruitment will require understanding of the psychological and workflow barriers and facilitators for how providers respond to automated alerts requesting patient referrals. Evidence from using CDS for clinical care that shows alerts become increasingly ignored over time or with more exposure (1, 2). The features, timing, and method of these alerts are important usability factors that may influence effectiveness of the referral process. Focus group methods capture the shared perspectives of a phenomenon and have been shown to be an effective method for identifying perceptions, attitudes, information needs, and other human factors effecting workflow (3, 4). Our objective was to develop a generalizable method for measuring physician and clinic level factors defining a successful point of care recruitment program in an outpatient care setting. To achieve this we attempted to (a) Characterize provider's attitudes regarding CTs referrals and research. (b) Identify perceived workflow strategies and facilitators relevant to CT recruitment in primary care. (c) Develop and test a pilot instrument. METHODS/STUDY POPULATION: The methods had 3 phases: focus groups, development of item pool, and tool development. Focus group topics were developed by 4 experienced investigators, with training in biomedical informatics, cognitive psychology, human factors, and workflow analysis, based upon a knowledge of the literature. A script was developed and the methods were piloted with a group of 4 clinicians. In all, 16 primary care providers, 5 clinic directors, and 6 staff supervisors participated in 6 focus groups, with an average of 5 participants each, to discuss clinical trial recruitment at the point of care. Focus groups were conducted by the development team. Audio recording were content coded and analyzed to identify themes by consensus of 3 authors. Item Pool generation involved extracting items identified in the focus group analysis, selecting a subset deemed most interesting based on knowledge of the recruitment literature and iteratively writing and refining questions. Instrument development consisted of piloting an initial 7-item questionnaire with a local primary provider sample. Questions were correlated with the item pool and limited to reduce provider burden, based on those that the study team deemed most applicable to information technology supported recruitment. Descriptive statistical analysis was performed on the pilot survey results. An online survey was developed based on the findings of the focus groups and emailed to 127 primary care

providers who were invited to participate. In total, 36 questionnaires were completed. This study was approved by the University of Utah Institutional Review Board. RESULTS/ANTICIPATED RESULTS: The results section is organized into 3 sections: (a) Focus groups, (b) Item generation; and (c) Questionnaire pilot. (1) (1) Focus Groups. Themes identified through a qualitative review are presented below with illustrative comments of participants. The diversity of attitudes and willingness to support clinical trial recruitment varied so substantially that no single pattern emerged. Attitudes ranged from enthusiastic support, to interest in some trials to disinterest or distrust in trials in general. Compensation for time spent, which could be monetary, informational, or through professional recognition; and provider relationship with the study team or pre-selection of specific trials by a clinic oversight committee, and importance to providers practice positively affected willingness to help recruit. "I would love to get people into clinical trials as much as possible... If it works for them you are going to help a whole lot of other people." If we felt like we have done every possible thing that was already established as evidence-based and it didn't work out, then we would consider the trials. I think that studies are more beneficial for specific specialists... There might be a whole slew of things that I never deal with or don't care about because it's not prevalent for my patient population. Local and reputable... A long distance someone asking to do something is just not the same as someone in the trenches with you. The bottom line is how much work is involved at our end and if there is going to be any compensation for that. I think also the providers would like have feedback on what they referred them to. And how did it go? So did we pick the right patient? ... It helps us to know, did they even sign up for the study? Getting your name on a research paper would be nice too. Lack of information regarding trials reduced support for recruitment of patients. Providers stated that they do not know how to quickly find information about studies, nor do they have time to find the information, and therefore cannot efficiently counsel patients regarding trial participation. Notifications regarding clinical trials that were deemed to be important included: Trial coordinator intention to recruit patients, enrollment of a patient in a clinical drug trial, trial progress and result updates, and reports of effectiveness of provider recruitment efforts. Perceived information needs regarding trials that providers are referring patients to included: trial purpose, design, benefits and risks, potential side effects, intervention details, medication class (mechanism of action), drug interactions with study drug, study timeline, coordinator contact information, link to print off patient handouts, enrollment instructions, and a link to study website. (2) It's just we don't know any of the information ... and it can't take any of our time. ... I don't have time to research it. Sometimes the patients ask me questions about it and I would like to be in a position where I have some information about it before I am asked. It would be nice to be notified if they [my patients] are enrolled in the trial, when it turns into actual recruitment. I do like to know if they're in [a trial] so that when they come in for problems, I at least know that they might be on a study medication so I can be safe. I'll get an ER message, "The patient got admitted. There blood pressure's, you know, tanked, because they're on a study drug I didn't know anything about." if there's certain side effects that I need to be watching out for. It would also be good to have a contact person from the study in case we need to notify them of. "this person's possible having an adverse event. Look into it more." (3) Provider burden associated with patient recruitment appeared to be a deterrent. These burdens included adding to the providers task list, increasing the time required to complete a visit, and usurpation of control over the patients care plan with the associated effect on provider quality scores. We don't have time. I mean, we don't even take a lunch break. I have 15 minutes and now this is taking this many minutes away from my 15 minutes. I am just sick of extra work. We already have so much extra work. It's just more stuff to do. We are maxed out on stuff to do. Right now, part of our compensation depends on having our patients AICs controlled. And so if we're taking a chance that maybe they're getting a medicine, maybe they're not, maybe it'll help, maybe it won't, its gonna further delay our ability to get paid. Cause they're like "I'm not going to let you go mess up my patient and I'm going to have to deal with the consequences is kind of the way they think. If you're going to put the patient in a study, being able drop them from our registry so we don't get penalized for a negative outcome [is important]. (4) Patient's needs were a priority among factors influencing likelihood to help recruitment patients. Providers considered perceived benefit or risk to the patient, such as additional healthcare services, increased monitoring, financial assistance, or access to new treatments when other options have been ineffective, important; as well as continuance of established care that has proven effective, and ethical recruitment that addresses language and mental health to ensure that patients can make decisions regarding study participation. If there's something great that's gonna benefit a patient, I would definitely wanna know about it to give them that option. You know that's what we wanna try to do is make our patients better. Someone who is really well controlled and doing well, I would not tend to put them toward the study. Just keep going with what's working right now. Sometimes there's financial incentives for them to participate, so you know, if its a good fit its easy to at least offer that to the patient. They get treatment maybe that they can't afford.