analytic tool to identify regions in the US where preterm birth interventions would be most beneficial.

4575

Implementing a Workflow Management Tool for Clinical Trials

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OBJECTIVES/GOALS: A workflow management tool is essential in order to help support consistent processes with transparency in next steps of the study process. Prior to this tool, staff has relied upon extensive training and coaching on the study process. While resources and guidelines exist, it requires additional time for staff to identify these resources and allows for confusion and rework. Implementation of a systematic workflow management tool was identified as a critical need in order to support streamlined processes, improve transparency and support business continuity, and to accelerate the study process. METHODS/STUDY POPULATION: This effort was undertaken as part of the Protocol Lifecycle Management effort to implement a comprehensive clinical trial management system for clinical research studies. Mayo Clinic has designed a workflow management tool within the Velos eResearch system. The workflow manager is dynamic and will present specific activities based on the study design and responses to data entered on the ad hoc forms. A Workflow Build group contributed to the design of the workflow in order to reflect appropriate, current operational processes. The workflow was vetted and validated with research teams. In addition to designing activities, planned dates and target timelines were established for relevant workflows to help promote transparency in the study start-up timelines and allow study staff to identify overdue activities. Study status controls were designed in the workflow to protect study staff from inadvertently changing the status until appropriate activities are complete. RESULTS/ANTICIPATED RESULTS: A dynamic workflow has been designed and implemented in the Velos eResearch system to support Mayo Clinic research sites. This system will be implemented February 24, 2020 to all consenting studies. DISCUSSION/SIGNIFICANCE OF IMPACT: The implementation of this workflow management tool is critical to help support research operations in a large, academic medical center. Benefits to implementation are expected to include improved transparency in the study status and next steps, reductions in rework due to confusion in next steps, better understanding from new staff in the appropriate study process, and improved timelines for study start-up. As we prepare for the implementation of the Velos eResearch system at Mayo Clinic, the workflow management tool has been identified in training sessions as a positive benefit.

4211

Longitudinal cohort study of the association between atopic dermatitis and depression/anxiety throughout childhood

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OBJECTIVES/GOALS: Atopic dermatitis is one of the most common chronic childhood conditions worldwide and is associated with poor mental health outcomes. Our aim is to determine whether childhood atopic dermatitis is associated with symptoms of depression throughout childhood and adolescence, and whether this association is mediated by serum inflammatory markers. METHODS/STUDY POPULATION: We will perform a longitudinal analysis of over 7000 children from an existing prospective cohort. The primary exposure is atopic dermatitis (AD) annual period prevalence measured by a standardized questionnaire at 12 time points between age 6 months and 16 years. Depression is measured using self-reported responses to the Short Moods and Feelings Questionnaire at 6 time points between 10 and 18 years of age. Cross-sectional regression analyses will be performed to compare depressive signs between children with and without AD and test for dose-response effects with AD and depression. Longitudinal analyses will be conducted using mixed-effects models to estimate the average effect across childhood. We will complete a mediation analysis to determine the extent to which IL-6 and CRP mediate this association. RESULTS/ANTICIPATED RESULTS: We anticipate that atopic dermatitis will be associated with SMFQ scores in a dose response relationship, and that inflammatory markers CRP and IL-6 will partly mediate this association. DISCUSSION/SIGNIFICANCE OF IMPACT: Childhood is a critical time for mental health. Understanding the longitudinal relationship between atopic dermatitis, depression, and inflammatory mediators is crucial as new biologic treatments targeting inflammatory cascades are approved for atopic dermatitis and have the potential to prevent mental health conditions.

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Mental Stress Induced Myocardial Ischemia as a Marker for Adverse Cardiovascular Events After MI†

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OBJECTIVES/GOALS: Young and middle-aged adults with a myocardial infarction (MI) represent an understudied group potentially with unique risk indicators such as emotional stress. We sought to investigate if mental stress-induced myocardial ischemia (MSIMI), a marker of cardiovascular vulnerability to psychological stress, is associated with poor outcomes among this population. METHODS/STUDY POPULATION: We studied 306 patients (150 women and 156 men) ≤61 years of age who were hospitalized for MI in the previous 8 months. Clinical, behavioral and psychosocial factors were assessed with standardized measures. Patients underwent myocardial perfusion imaging with mental stress (public speaking) and conventional stress (exercise or pharmacological testing). MSIMI and conventional stress-induced ischemia were defined as a new or worsening perfusion defect. Patients were followed for 3 years for adverse events, which were independently adjudicated. Cox proportional hazard models were used to estimate the association of MSIMI and CSIMI with a composite endpoint of recurrent MI or cardiovascular (CV) death with adjustment for demographic, clinical and psychosocial risk factors. RESULTS/ANTICIPATED RESULTS: The mean age of the sample was 50 years (range, 22-61). MSIMI occurred in 16% of the patients, and conventional ischemia in 35%. Over a 3-year follow-up, 28 individuals had a recurrent MI and 2 died due to cardiovascular causes. The incidence of the composite endpoint of MI or CV death was more than doubled in patients with MSIMI (20%) than those without MSIMI (8%), HR 2.6, 95%CI, 1.2-5.6. Further adjustment for demographic and clinical risk factors and depressive symptoms did not substantially change the relationship. In contrast, conventional stress ischemia was not significantly

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