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Reducing Problem Records in the Johns Hopkins University ClinicalTrials.gov Protocol Registration and Results System (PRS)

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OBJECTIVES/SPECIFIC AIMS: The Johns Hopkins University Clinicaltrials.gov (CT.gov) Program has previously reported on a study showing reduction of "Late Results – per FDAAA" from 111 to 0. What we hope to do here is to focus on non-late results records. Over the years, some institutions spend their efforts solely on late results in order to avoid any penalties from the Food and Drug Administration (FDA). However, there are a number of variables that labels "problem records" within the Protocol and Registration System (PRS). These records are also subject to penalties. Our goal has been to minimize problem records and establish processes to improve and maintain our institutional compliance in regards to regulations governing clinical trials registration and results reporting. METHODS/STUDY POPULATION: The Johns Hopkins University implemented a Clinicaltrials.gov program solely mandated to assist Principal Investigators (PIs) and other study team members with clinical trial registration and results reporting. The program has developed processes in its duty towards reducing problem records in the PRS. Full-time staff have been assigned to assist research teams with registration and results reporting, while ensuring compliance with all relevant regulations. Several methods have been utilized to track metrics, such as monthly reports and internal databases. Features within the PRS have also been used to draw attention to newly-identified problem records on a daily basis in order to rectify these issues with the study team promptly. In order to ensure compliance, our office communicates with study teams regarding the problems within their CT.gov record that requires attention. In challenging cases, our program will also collaborate with the CT.gov PRS Team at the NIH to facilitate the process and avoid multiple review cycles, which can delay registration or the posting of results. Our Program has also formed internal collaborations with the Institutional Review Board (IRB) which allows us to verify study status and view active study team members. This is especially useful in cases where the study team members who are listed on the CT.gov record cannot be reached or the contact information is outdated (a common occurrence with older studies). With access in the IRB, we can contact the current study team members who may not be listed in CT.gov and assist them to resolve any outstanding issues of non-compliance within their CT.gov record. RESULTS/ANTICIPATED RESULTS: From September 2015 (before our program was established) to September 2016 (three months after the institution of our program), the total amount of problem records increased from 44% (339/774) to 45% (383/852). Since then, the processes we have developed resulted in a decline in problem records to 30% (282/955) in September 2017, and a further decline to 8% (83/1075) as of September 2018. The short rise that was observed in 2016, was a potential indicator that if our program was not instituted, it would have been more difficult to maintain compliance. DISCUSSION/SIGNIFICANCE OF IMPACT: According to the FDA Draft Guidance released in September 2018 referring to the Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank, there are a number of ways to violate the FDA regulations, resulting in potential monetary penalties, which include "failing to submit required clinical trial information or submitting clinical trial information that is false or misleading". These regulations apply to results as well as registration and study status updates. By paying attention to all problems that are identified by the PRS, institutions can rectify errors and remain complaint with all regulations that govern clinical trial registration and results reporting.

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Relationship between dental fluorosis, water and serum levels of fluoride and chronic kidney disease in children: Data from National Health and Nutrition Examination Survey

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OBJECTIVES/SPECIFIC AIMS: The aim of the study is to examine the relation between dental fluorosis, serum and water levels of fluoride and Chronic Kidney Disease (CKD) among children. A link between dental fluorosis, fluoride level and CKD can be an indicator of the blind danger of fluoride toxicity that poses a great threat to the human health. METHODS/STUDY POPULATION: Dental fluorosis, serum and water levels of fluoride and CKD were examined in children 6-19 years old, using data from the National Health and Nutrition Examination Survey1999-2012 and 2013-2016. We used multiple logistic regression to adjust for the confounders (demographics, insurance, dental visit, and co-morbidity) to assess the relation between dental fluorosis, serum and water levels of fluoride and CKD. STATA 14.0 was used to analyze the data (sample design and weight). $P < 0.05$ is statistically significant. RESULTS/ANTICIPATED RESULTS: The prevalence of CKD was 13.9% and dental fluorosis was 34.3%. In the multivariate model, plasma fluoride level was independently associated with CKD (Adjusted Odds Ratio (AOR) = 1.68, 95% Confidence Interval (CI) = 1.06-2.68, p = 0.029) but not with dental fluorosis (AOR = 1.4, 95% CI = 0.87-2.2, p = 0.17) or water fluoride level (AOR = 0.91, 95% CI = 0.59-1.396, p = 0.659). DISCUSSION/SIGNIFICANCE OF IMPACT: Results indicated that serum fluoride level is independently associated with CKD but dental fluorosis and water fluoride level were not related to CKD. Increase awareness and screening for fluorosis in children are needed for early detection and prevention of organ damage. Prospective studies related to fluorosis and tissue damage are needed.

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Stanford MedTech: An Innovative CTSA-Supported Pilot Program

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OBJECTIVES/SPECIFIC AIMS: Helping researchers assess and effectively translate innovations into healthcare improvements is a complex process (Terry et. al., 2013). The Clinical Translational Science Awards (CTSA)—supported by the National Institute of Health (NIH) under the auspices of the National Center for Advancing Translational Sciences (NCATS)— provide the resources and support needed to strengthen our nation's clinical and translational research (CTR) enterprise. In 2008, Stanford University was awarded a CTSA from the NIH, establishing Spectrum (the Stanford Center for Clinical and Translational Research and Education). Under the Spectrum umbrella, the Byers Center for Biodesign manages the

https://doi.org/10.1017/cts.2019.287 Published online by Cambridge University Press

MedTech Pilot Program with the goal of translating discoveries into novel health technologies that address important unmet health needs. The MedTech Pilot Program is an innovative funding mechanism that seeks to (1) stimulate clinical translational research, (2) help promising projects bridge the gap between the bench and the patients' bedside, and (3) encourage collaborative, transdisciplinary work. Specifically, the Pilot Program offers up to $50,000 to support projects involving medical devices and mobile technologies used for (1) therapeutic applications and (2) device-based patient-specific (or POC) diagnostic applications. This analysis of the MedTech Pilot Program will: 1) describe the Program's structure and process; 2) highlight the intensive, hands-on mentorship and practical guidance awardees receive that enables them to more efficiently and effectively advance their projects toward patient care; and 3) characterize the progress of the 36 funded projects. METHODS/STUDY POPULATION: Key elements of the Pilot Program's infrastructure and mentoring processes as they relate to project outcomes were identified. Additionally, outcomes data were collected from two sources: (1) annual survey of Pilot Awardees and (2) publicly available information relevant to the pilot projects. RESULTS/ANTICIPATED RESULTS: The Pilot Program's framework and infrastructure has supported a diverse group of transdisciplinary projects. These projects were evaluated using both traditional and non-traditional metrics (e.g., patents, startups, publications). The initial investment of $1.5 million to fund 36 projects has led to over $88 million dollars in additional funding. Additionally, taking full advantage of the expertise in Silicon Valley, strong mentorship has helped advance projects along the clinical and translational path. DISCUSSION/SIGNIFICANCE OF IMPACT: The Pilot Program has benefited Stanford innovators and researchers by providing seed funding to help promising projects bridge the gap between the bench and the bedside. The intensive, hands-on mentorship, early pilot funding, and practical guidance pilot awardees receive effectively help translate their technologies into patient care.

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Symptom profile of chronic rhinosinusitis versus obstructive sleep apnea in a tertiary rhinology clinic

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OBJECTIVES/SPECIFIC AIMS: Patients with undiagnosed obstructive sleep apnea (OSA) will often present to an otolaryngologist with symptoms of chronic rhinosinusitis (CRS). Differentiating CRS from OSA may help obviate unnecessary and costly work-up for CRS. This study analyzes symptom profiles of such patients to help identify which require polysomnography. METHODS/STUDY POPULATION: This is a three-year retrospective analysis of adult patients seen in an academic practice with a rhinologic chief complaint. The 22-Item Sinonasal Outcomes Test (SNOT-22) survey, which is a validated patient-reported outcome measure widely adopted for CRS featuring a symptom scale of 1 (least severe) to 5 (most severe), was completed by patients with untreated OSA confirmed on polysomnography without CRS (OSA group) and a control group of CRS patients (CRS group). Results were compared using Chi-square test (categorical) and Wilcoxon rank-sum test (continuous) with Bonferroni correction, and multiple logistic regression. RESULTS/ANTICIPATED RESULTS: 43 patients were included in the OSA group [mean apnea-hypopnea index: 27.9 (SD: 21.2)] and 124 patients were included in the CRS group. The CRS group demonstrated significantly higher scores in nasal ($p < 0.001$), extra-nasal ($p < 0.001$) and ear/facial symptom domains ($p = 0.001$) while the OSA group reported higher psychological ($p = 0.028$) and sleep symptom domain scores ($p = 0.052$). As for the cardinal symptoms of CRS, nasal discharge and loss of smell were significantly higher in the CRS group (both $p < 0.001$), whereas facial pain ($p = 0.117$) and nasal obstruction ($p = 0.198$) were not significantly different between the two groups. After adjustment, for every 1-point increase in a patient's score for ear pain, thick nasal discharge and loss of smell or taste, their odds of having CRS increased by a factor of 3.18 [(95% CI 1.61-6.29), $p = 0.001$], 1.60 [(95% CI 1.22-2.10], $p = 0.001$] and 1.36 [(95% CI 1.04-1.78), $p = 0.025$], respectively, compared to having OSA. OSA patients were more likely to choose a sleep-related symptom as a "most important complaint" (MIC) ($p < 0.001$). Facial pain and nasal obstruction were the most common MIC in the rhinologic domain for OSA patients, whereas thick nasal discharge and post-nasal discharge were the most common MIC for CRS patients. DISCUSSION/SIGNIFICANCE OF IMPACT: For patients presenting with rhinologic symptoms, the SNOT-22 can help identify those with undiagnosed OSA. OSA should be suspected in patients with sleep and psychological dysfunction as their primary complaints without the significant nasal drainage and anosmia that characterizes CRS.

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The association of corticosteroid use with inpatient mortality in acute exacerbation of idiopathic pulmonary fibrosis

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OBJECTIVES/SPECIFIC AIMS: Objective: To assess the impact of corticosteroid therapy on in-hospital mortality in IPF patients admitted with acute respiratory failure. METHODS/STUDY POPULATION: Methods: Patients with IPF were retrospectively identified in the University of California San Francisco medical center's electronic health records from January 1, 2010 to June 1, 2018. Cases with IPF were defined as age 50 years or older, having at least two codes one month apart for idiopathic fibrosing alveolitis or post-inflammatory fibrosis (ICD-9 516.3, 516.31 or 515.0 or ICD-10 codes J84.9, J84.10, J84.111 or J84.112), and a subsequent hospitalization for acute respiratory failure or acute respiratory symptoms. The prevalence of pre-selected co-morbidities, clinical events (ICU admission, mechanical ventilation, lung transplantation) and clinical outcomes were assessed. A propensity score model for corticosteroid use was constructed using a multivariable logistic regression with inclusion of corticosteroid-associated demographic and baseline variables (univariate p-value < 0.25). A marginal structural model (MSM) was used to address time-dependent confounding and mediating effects of ICU admission and mechanical ventilation by applying inverse probability weighting for receipt of corticosteroid treatment. Secondary outcome analysis was performed on patients who survived hospital admission. RESULTS/ANTICIPATED RESULTS: Results: A total of 132 patients with IPF and an acute respiratory admission were identified. 48 patients (36%) received corticosteroids during their admission. Applying inverse weighting to time-dependent co-variates (ICU admission and invasive mechanical ventilation) in a MSM, corticosteroid therapy was not associated with risk of in-hospital mortality (odds ratio 1.82; 95% CI, 0.47-6.99; $p = 0.39$). After adjusting for corticosteroid therapy using a propensity score, corticosteroid therapy remained unassociated

https://doi.org/10.1017/cts.2019.287 Published online by Cambridge University Press