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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cases where the study team members who are listed on the CT.gov record cannot be reached or the contact information is outdated (a common occurrence with older studies).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

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