have found the Liaison Service to be a popular addition to research support, and plan to continue the service. We will continue to evaluate its user satisfaction and usefulness. Additional focus will be placed on whether the Service can improve approval times for human subjects research for protocols using the Liaison Service.

3080

Ensuring Quality in Investigator-Initiated Clinical Trials through Monitoring Concepts Training

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OBJECTIVES/SPECIFIC AIMS: Because clinical trial results are instrumental in the approval of a new drug or changes to the practice of medicine, ensuring the accuracy and validity of collected data is critical in the clinical trial process. This function, routinely carried out by clinical trial monitors in industry-sponsored trials, is often lacking in investigator-initiated trials (IITs) conducted in academia. To address this challenge, we have developed a self-study module that can be used to cross-train academic researchers in essential concepts and practical approaches to monitoring. Furthermore, we are applying a framework drawn from implementation science in the development and launch of this initiative. This framework, as used in other educational programs, is employed here to close the gap between initiative and practice, thereby effectively disseminating this training would improve the quality of clinical trials in academia. METHODS/STUDY POPULATION: This research project applied exploration, installation and implementation stages of the implementation science process by 1) exploring the need for a new initiative, 2) disseminating results, 3) engaging stakeholders, 4) creating standard operating procedures (SOPs) for installation and implementation, 5) studying user satisfaction and effectiveness, 6) addressing feedback and 7) conducting implementation. RESULTS/ANTICIPATED RESULTS: From literature review and internet searches we determined that although numerous GCP training resources exist, most are too broad and lack the practical approaches to meet the complex requirements of monitoring. Moreover, most of the offerings identified are costly or inaccessible. With only about 65% of IITs reported as being monitored (Figures 1 and 2), it appears that there is a clear need for training tools that are easily available to a broader audience. And because monitoring skills are substantially different from those associated with research coordination, it is not surprising that research professionals believed that they would need additional training to become proficient. To address this need, we began developing a monitoring module. We engaged key stakeholders from academia and industry to gain insights into their needs. The results indicated that although our training module was effective, supplementary information on the fundamentals of clinical trials should be included for those new to the field. After incorporating suggested changes and completing the module, we conducted user testing to determine if our module is ready to be broadly disseminated (Figures 3 and 4). Following positive feedback from the group, we are currently in the process of disseminating our module and studying its impact. DISCUSSION/SIGNIFICANCE OF IMPACT: IITs are instrumental in translating academic research into product development. Deficiencies in the quality control of these trials can lead to inadequacies in data accuracy and validity that could lead to significant delays in bringing innovative therapies to patients. Recent NIH policies require data and safety monitoring for all of the trials it supports. The latest addendum to ICH GCP, E6(R2), discusses a need for quality management across the clinical trial lifecycle. As we continue to disseminate and share information during the development of our self-study monitoring module, we are engaging key stakeholders from academia, government, and private institutions to understand and address quality challenges in conducting clinical trials. Finally, this research informs dissemination and implementation research, specifically for creating training for academic research professionals.

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Findings from the first year of California's Workplace Violence Prevention in Healthcare standard (Title 8, Section 3342)

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OBJECTIVES/SPECIFIC AIMS: This research project aims to: 1) describe the incidents of workplace violence that have been reported to CalOSHA through the Workplace Violent Incident Reporting System for Hospitals; 2) determine if there are any relationships between the types of violent incidents reported and the unit or hospital where the event occurred; 3) describe what mitigation strategies facility representatives report having utilized immediately following a violent incident, such as changes to practice or involvement of law enforcement. METHODS/STUDY POPULATION: Reports submitted to CalOSHA pursuant to the Workplace Violent Incident Reporting System for Hospitals are considered public record and are available through the state's Public Records Act (PRA) mandate. Records from 7/1/17 – 9/30/18 were obtained through the CalOSHA PRA request process. Descriptive statistics and correlations were calculated using Stata. RESULTS/ANTICIPATED RESULTS: Records reporting 11,116 individual events of violence were analyzed. These results do not include reports submitted by the five California State Hospitals, a group of facilities which treated nearly 13,000 patients in 2017, many of whom have a psychiatric diagnosis and are undergoing treatment mandated by judicial decision. For each record, 111 variables were reported, including description of the event itself, characteristics of the workers involved, factors which may have triggered the event, and what measures were taken to mitigate the situation during and after the incident. All events identified an aggressor; 10,357 (93%) described this individual as a patient. 11,048 reports had a unit or hospital location listed to describe where the incident occurred. Of these, 9393 (84.5%) were inpatient, behavioral health, or surgical units. A physical injury was reported in 3672 events (33%) and stress/psychological impairment was reported in 536 (5%) of the incidents. Police officers were deployed to the scene following the incident in 1122 (10%) of reported events, resulting in arrest of the perpetrator in 402 (3.6%) of the reported incidents. DISCUSSION/SIGNIFICANCE OF IMPACT: While the impulse to address the high prevalence of workplace violence towards healthcare providers has led to deserved attention from policy makers, safety regulators, and healthcare unions, plans for ensuring that new initiatives are achieving their desired effect for workers have yet to fully materialize. An ongoing concern is that incidents are known to be under-reported through official mechanisms, leading to challenges in determining the scope of the problem itself and evaluating the efficacy of interventions to address it. CalOSHA's new reporting requirement and online interface provides a new channel for improving validity of prevalence data, as early findings indicate that less serious events are being reported through the system. In addition, information describing how hospital leaders report

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responding to incidents in their immediate aftermath will provide needed insight into what additional efforts are needed to support victims of violence given the unique challenges present in the healthcare industry.

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Innovative Approaches to Clinical Research on Placebo Effects: A Regulatory Science Perspective

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OBJECTIVES/SPECIFIC AIMS: To analyze contemporary study design methods and clinical trial approaches in placebo research. METHODS/STUDY POPULATION: An analysis was conducted on the following studies: I. "Managing" the Placebo Effect: The Single-Blind Placebo Lead-in Response in Two Pain Models by RN Haden, et al. The objective of the study was to consider elements of the placebo response in the context of two pain models using a "single-blind placebo lead-in" design (SBPLI) by engaging the "placebo response" prior to randomization to active drug and placebo-controlled conditions. The methods of the study included two pilot drug trials using knee osteoarthritis (KOA) and non-radicular low back pain (LBP) subjects, SBPLI protocols were conducted. In the first study, 36 subjects with non-radicular CLBP were enrolled in a double-blind, randomized, placebo-controlled trial of hydromorphone ER. In the second study, a total of 42 subjects with chronic KOA pain were enrolled in a double-blind, randomized, placebo-controlled study of milnacipran. Gender and/or diagnosis affected placebo responses as observed in changes in patient self-reported pain, depressive and pain anxiety symptoms were examined. Additionally, the placebo response on performance-based tests (stair climbing, range of motion (ROM), sit to stand repetitions, and 6-minute treadmill distance) was evaluated. II. Randomized Placebo-Controlled Placebo Trial to Determine the Placebo Effect Size by L. Gerdesmeyer, et al. The objective of the study was to analyze the pure placebo effect on clinical, chronic pain through a blinded RCT. The methods of the study included 182 patients suffering from chronic plantar heel pain for over 6 months, who failed to respond to conservative treatments, were screened and 106 of these patients were enrolled into this study. The patients were randomly assigned to receive either a blinded placebo shockwave treatment or an unblinded placebo shockwave treatment. The primary outcome measure was the differences in percentage change of visual analogue scale (VAS) scores 6 weeks after the intervention. The secondary outcome measure was the differences in Roles and Maudsley pain score (RMS) 6 weeks after intervention. III. Open-label placebo treatment in chronic low back pain: a randomized controlled trial by C. Carvalho, et al. The objective of the study was to investigate whether placebo effects in chronic low back pain could be harnessed ethically by adding open-label placebo (OLP) treatment to treatment as usual (TAU) for 3 weeks. The methods of the study included 97 randomized participants in a 3-week randomized control trial comparing current treatment plus OLP to current treatment alone (TAU). RESULTS/ANTICIPATED RESULTS: N/a DISCUSSION/SIGNIFICANCE OF IMPACT: The aforementioned studies provide placebo researchers with contemporary and reliable methodologies to examine placebo effects on participants. These methodologies provide scientists with clinical translational research methodology styles based on the foundation of regulatory science.

Science and Health Policy/Ethics/Health Impacts/Outcomes Research

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Assessing Racial Disparities in Hepatitis C Retention of Care

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OBJECTIVES/SPECIFIC AIMS: The objective of this study is to assess differences in outcomes between African Americans (AAs) and whites along the HCV care cascade. Primary outcome was retention in the HCV care cascade, measured in two ways. For viral RNA confirmation, retention was a percentage of those having screened antibody reactive. For hepatic ultrasound, primary care, HCV specialty clinic, treatment initiation, and sustained viral load (SVR), retention was a percentage of those found chronically infected by positive RNA viral load. Secondary outcome was time to follow-up from antibody screening to each subsequent step in the care cascade. METHODS/STUDY POPULATION: A retrospective cohort study was performed. AA and white patients who tested HCV antibody reactive from March to October 2015 at the University Medical Center (UMC) Emergency Department in New Orleans, LA were included in this study. Outcomes were assessed using the HCV Continuum of Care model, delineating successive stages of care from identification to cure. RESULTS/ANTICIPATED RESULTS: A total of 728 patients screened HCV antibody reactive, including 446 AAs and 282 whites. AAs (53.5 years, SD 10.2) were disproportionately older than whites (46.7 years, SD 11.9) ($p < 0.001$), more likely to be insured (89.2% vs 78.7%, $p<0.001$), had higher rates of Medicare (28.0% vs 12.1%, $p<0.001$), and less frequent history of intravenous drug use (IVDU) (32.3% vs 46.1%, $p<0.001$). For AAs, retention in the treatment cascade was 96.2% for viral RNA confirmation, 50.9% for hepatic ultrasound, 26.8% for primary care, 35.2% for HCV specialty clinic, 14.5% for treatment initiation, and 9.6% for sustained viral response (SVR). Among whites, retention in the treatment cascade was 96.8% for viral RNA confirmation, 37.8% for hepatic ultrasound, 16.1% for primary care, 23.3% for HCV specialty clinic, 8.8% for treatment initiation, and 7.8% for SVR. AAs had a higher likelihood of receiving a hepatic ultrasound (OR=1.70; CI=1.19-2.25; $p<0.005$), following up with primary care (OR = 1.91, CI=1.21-3.02, $p<0.005$), and attending the viral hepatitis specialty clinic (OR=1.79, CI=1.20-2.68, $p<0.005$), as compared to their white counterparts. After adjusting for age, insurance, and history of IVDU, AAs did not have a higher likelihood of receiving a hepatic ultrasound (aOR=1.09, CI=0.995-1.19) or seeking primary care (aOR=1.05, CI=0.98-1.14). AAs had attenuated odds of attending viral hepatitis specialty clinic (aOR=1.09, CI = 1.01-1.19). There was no statistically significant difference in follow-up time in the treatment cascade for AAs versus whites. DISCUSSION/SIGNIFICANCE OF IMPACT: Race alone cannot explain differences in achievement along the care cascade. Significant differences in retention along the HCV care cascade appear to be related primarily to differences in age and insurance status. In our population, older AAs are disproportionately insured through Medicare, thereby expanding their access to health resources. Their white counterparts are younger and more

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