

the low primary care odds ratio of rivaroxaban use, relative to dabigatran, may be indicative of a gradient of uptake of later-generation NOACs, although interpretability is limited by the small number of patients in the rivaroxaban group.

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Improving ClinicalTrials.gov compliance: A coordinated effort for success

Scott Patton, Elaine Basaca and Jennifer S. Brown

Stanford University School of Medicine

OBJECTIVES/SPECIFIC AIMS: ClinicalTrials.gov (CTgov) compliance has received much international attention as a significant regulatory, scientific, and ethical responsibility. Compliance rates for both industry and academia are held up for scrutiny by transparency advocates, but solutions for achieving compliance in academia have proven to be—because of its focus on innovation and multiple disciplines—significantly more complex than those employed by industry. Added challenges for academic medical centers (AMCs) are both increased researcher responsibilities under the new NIH Policy on Clinical Trial Dissemination and system-wide changes to requirements for “clinical trial only” Funding Opportunity Announcements. At Stanford University, a multifaceted approach toward improving CTgov outreach, education, and reporting led to a dramatic turnaround in compliance over 17-month period. **METHODS/STUDY POPULATION:** Stanford University School of Medicine’s Senior Associate Dean for Research and PI of Stanford’s CTSA applied a 3-part strategy to address unacceptable rates of results reporting. The strategy included (1) regular compliance reports to department chairs, (2) establishment of a central office, Clinical Research Quality (CRQ), to provide consistent training and support, and (3) interdepartmental cooperation across the school and university. Compliance reports, identifying all studies late for results reporting were sent monthly to all department chairs, with heightened focus on departments that conduct the most clinical trials. Senior leadership described the process in executive meetings and set improvement goals. Reports included multiple data points to help departments mobilize resources and identify trends; half-way through the period, soon-to-be late study records were included. CRQ hired 2 fulltime employees tasked with all aspects of managing the CTgov process and designed a portfolio of activities including: (1) a master list of all Stanford studies in the CTgov system; (2) a process for generating and distributing monthly reports; (3) an education program; and (4) support services, including an administrator working group. **RESULTS/ANTICIPATED RESULTS:** Since December 2015, Stanford has had the second-highest compliance rate improvement out of the 20 schools of medicine that receive the most NIH funding (+ 62%). **DISCUSSION/SIGNIFICANCE OF IMPACT:** Managing ClinicalTrials.gov compliance requires a high degree of technical knowledge of regulations, NIH policy, and the CTgov system. But without an equally high degree of engagement from senior leadership, results would not have been achieved. Central resources are critical to set policy and establish consistent processes, but without regular and repeated interactions between faculty, a multitude of administrators and staff, more central resources would have been required. By working simultaneously “down from the top” and “up from the bottom,” communication and education expanded rapidly, ineffective efforts were quickly transformed, and what began as an irritating and cumbersome problem became an occasion for collaboration and celebration of increased transparency.

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Integrating ethics support as culture change in a translational science environment

Bernadette McKinney¹, Emma Tumilty² and Joseph Kotarba³

¹ University of Texas Medical Branch at Galveston; ² University of Texas Medical Branch; ³ University of Texas Medical Branch and Texas State University

OBJECTIVES/SPECIFIC AIMS: To outline 4 categories of ethics needs identified at a translational science center. To map how research ethics has been further integrated into the center’s culture in response to these needs. To provide insights into how research ethics can be integrated into the translational team science environment. **METHODS/STUDY POPULATION:** The Institute for Translational Sciences (ITS) at the University of Texas Medical Branch is studied on an organizational level using polyphonic organizational theory and the results of an ethics needs assessment completed in 2010. **RESULTS/ANTICIPATED RESULTS:** The results will be a map indicating how research ethics has been further integrated into the culture of the ITS in response to the needs identified to ensure the responsible practice of translational science. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Successful translational science requires shared understanding of communication and values. Achieving agreement in

these areas requires the development of strategies for communicating and reinforcing common goals. Research ethics has often been considered an “add on” rather than a “part of” science. Through integrating ethics into various aspects of translational science, the ITS has taken important steps toward achieving the goal of culture change. The map of how the ITS has integrated ethics into organizational activities and structures will serve as a model for other organizations and institutions.

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Is less more? Examining the relationship between food assistance generosity and childhood obesity

Megan M. Reynolds¹, Melanie Beagley², Ashley M. Fox³, Ming Wen², Michael W. Varner² and Ken R. Smith²

¹ The University of Utah School of Medicine; ² The University of Utah; ³ University at Albany, State University of New York

OBJECTIVES/SPECIFIC AIMS: In combination with 3 waves of individual-level data on children age 5–18 from the Panel Study of Income Dynamics, we exploit exogenous variation at the level of the state to determine whether SNAP generosity modifies the effect of SNAP participation on overweight/obesity status. We do so using a newly created and powerful data set including information on state-level SNAP generosity between the years 1996 to 2011. **METHODS/STUDY POPULATION:** Data and sample. We drew individual-level data from the Child Development Supplements of the Panel of Income Dynamics (PSID), a nationally representative longitudinal study gathering data since 1968 on US individuals and the families in which they reside. Aged 0–12 years in 1997, these children of PSID sample members were surveyed roughly every 5 years through 2007. The total number of observations over the study period is just over 8093, representing 3563 children. We drew state-level data from the State Welfare Generosity Index. This is a decomposable index of State welfare generosity capturing state policy variation across 4 programs (TANF, SNAP, Unemployment Insurance and Medicaid/CHIP) and 2 dimensions (eligibility requirements and benefit levels). Measures. Child weight status was determined using the Center for Disease Control (CDC) body mass index (BMI)-for-age gender-specific growth charts: underweight (BMI <5th percentile), healthy weight (BMI >5th percentile and BMI <85th percentile), overweight (BMI >85th percentile and BMI <95th percentile) or obese (BMI >95th percentile). From this, we constructed an indicator for overweight/obese Versus normal or underweight status. SNAP participation is a dichotomous indicator based on the head-of-households or their spouses reported receipt of SNAP benefits during the previous calendar year from the interview. SNAP generosity is scored on a scale of 0–100, with more generous states receiving higher scores than less generous states. Covariates include sex, race, age, head-of-household years of education and a continuous measure of household income adjusted for family size. Estimation techniques. We merged the child, parent/caregiver, family and main PSID files to obtain the most comprehensive data on each sample child. We first generated, descriptive statistics for the Wave 1 sample of 3563 children. We then present the mean, standard deviation and the ratio of the 2 (coefficient of variation) for state-level variables. We present χ^2 tests of difference for non-SNAP compared to SNAP participants in terms of overweight/obesity, and pairwise correlation coefficients among the 3 state-level variables. Next, we conducted a series of simple and multivariate logistic regressions estimating the odds of being overweight or obese. As we are assessing the risk of adverse weight status, those of normal or underweight status are the reference group for all regression analysis. Because height and weight reports are known to be unreliable below the age of 5, regression analyses impose an age restriction of greater than 5 years old. We include adjustment for the clustered nature of data. **RESULTS/ANTICIPATED RESULTS:** The individual-level statistics indicate that roughly one-third of the CDS sample is overweight or obese at Wave 1 in 1997. About a fifth of them live in families receiving SNAP. The mean SNAP generosity score is 10 on a possible range of 0 to 1 (observed range of 0.037 to 0.290 not shown). Variation across state-years is greatest for the SNAP participation variable, as reflected by the coefficient of variation. In the period 1997–2007, the proportion of children who are overweight or obese is 5% higher among those in families receiving SNAP program benefits than among those in families not receiving SNAP benefits. Similarly, SNAP participation is positively, moderately and significantly (with an α of 0.05) correlated with overweight/obesity. Examines the relationship between overweight/obesity and the SNAP measures using individual-level data on overweight/obesity and SNAP participation and state-level data on SNAP generosity. Model 1 estimates and exponentiates the log odds of overweight/obesity based on individual-level SNAP participation. Model 2 does the same using state-level SNAP generosity as the predictor. Results indicate that both variables are positively associated with a child’s chance of being overweight/obese. But only in the case of SNAP participation is the SNAP

variable statistically significant. Children living in families receiving SNAP benefits are more likely to be overweight/obese by a factor of 1.23. A set of potential confounders to the analysis and tests for interaction effects between SNAP participation and SNAP generosity (Model 3). Controlling for a variety of demographic and socio-economic factors, the positive effect of SNAP participation on overweight/obesity is rendered negative. The nonsignificant effect of SNAP generosity remains. In Model 3, the interaction effect for SNAP participation and generosity is positive and marginally significant. This suggests that the generosity of benefits changes the basic relationship between SNAP participation and overweight/obesity among children in families receiving benefits. To help convey the meaning of this coefficient, we generated marginal effects of SNAP participation based on SNAP generosity, setting all covariates equal to their means. This figure shows a small negative effect of SNAP participation at the lowest levels of generosity (a score of around 4, the sample minimum). This negative effect crosses 0 at a score of around 12, then becomes positive. The magnitude of the positive effect grows up to the sample max (index = 28), although with widening confidence intervals. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The focal interest of this study lies in the potential interaction effect between SNAP generosity and SNAP participation on overweight/obesity. Although the effects were only marginally significant, we find that SNAP generosity does interact with SNAP participation. More specifically, the effects of SNAP participation appear negative at lower levels of generosity, becoming positive as generosity scores exceed the sample mean (index = 10). In other words, state-level SNAP generosity appears to exacerbate the adverse effects of SNAP participation on overweight/obesity. Although we submit that our current findings contribute to the literature on the SNAP-health link, we intend to strengthen our analysis in several ways. First, we will fit models that exploit the strengths of the PSID and the welfare generosity index in terms of causal inference. We will use fixed effects models to control not only for potential unobserved confounders related to the child but also observable baseline characteristics. Leveraging the fact that PSID samples up to 2 children from each family, we will further refine our estimates towards a causal interpretation with the use of sibling fixed effects, in which we additionally account for unmeasured time-invariant family-level variables that encapsulate a variety of factors including learned behaviors, cultural influences, genetic predispositions that contribute to child health outcomes. Second, research has clearly shown that compared with higher-SES individuals, lower-SES individuals have higher BMI regardless of welfare program participation. These selection effects are addressed somewhat by the PSID's intentional over-representation of low-income individuals. But we can much more convincingly address these potential problems with endogeneity by refining our analyses to compare SNAP participants to SNAP-eligible nonparticipants, thereby isolating the effect of the SNAP "treatment." Lastly, we intend to include a wide array of state-level covariates that may be related to our independent and dependent variables of interest, such as poverty rate, unemployment rate, and racial/ethnic composition.

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Johns Hopkins School of Medicine ClinicalTrials.gov Program challenges and successes

Anthony Keyes, Nidhi M. Atri and Prince S. Nuamah
Johns Hopkins University School of Medicine

OBJECTIVES/SPECIFIC AIMS: Educate the general public, investigators, and institutional leadership on the importance of clinical trial registration and results reporting. Share success as a means to develop national best practices. **METHODS/STUDY POPULATION:** Developed a Project Charter; Spoke to several peer institutions; Update institutional policy. **RESULTS/ANTICIPATED RESULTS:** Since launching the Program in June 2016, the number of records submitted to ClinicalTrials.gov has increased 14% (852–971). At the same time, compliance with late results has increased by over 92% (111–9). **DISCUSSION/SIGNIFICANCE OF IMPACT:** Clinical Trial registration and results reporting is sub-par at many institutions. We have established a successful program that others can emulate. Institutions can increase transparency of clinical trials as well as prevent civil monetary penalties (\$11,569/d/study) and loss of grant funding.

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Long-acting reversible contraceptive uptake in female sex workers and single mothers in Rwanda and Zambia

Jessica Li, Rachel Parker, Kristin Wall, Lisa Haddad and Susan Allen
Emory University

OBJECTIVES/SPECIFIC AIMS: Long-acting reversible contraception (LARC) has been well established as the most cost-effective form of contraception, but

LARC usage in developing countries remains low. As part of a multi-center parent study on HIV incidence, we implemented an integrated family planning program to increase LARC uptake in single women in Rwanda and Zambia. We aim to evaluate rates of LARC uptake, LARC discontinuation and incident pregnancy following family planning counseling. **METHODS/STUDY POPULATION:** We enrolled 3 cohorts of single sexually active HIV-negative women between the ages of 18–45 years: single mothers (SM) in Zambia, female sex workers (FSW) in Zambia and FSW in Rwanda. Participants were followed every 3 months for up to 5 years. At each visit, we discussed fertility goals and counseled participants on HIV risk reduction and contraceptive options. Eligible participants (not pregnant, already using a LARC method, or using a permanent contraceptive method) were offered a LARC method, specifically the copper IUD or Jadelle implant. Data was collected on demographic factors, sexual behavior, sexual and reproductive history, and gynecological exams and laboratory tests were performed if necessary. **RESULTS/ANTICIPATED RESULTS:** In total, 458 Rwandan FSW, 555 Zambian FSW, and 521 Zambian SM were enrolled, with a median follow-up time of 6 months, 12 months, and 9 months, respectively. Accounting for any LARC uptake during longitudinal follow-up, our preliminary results show an increase in LARC usage from 21% at screening to 51% at the end of follow-up among Rwandan FSW, an increase from 12% to 42% in Zambian FSW and an increase from 18% to 44% in Zambian SM. We hypothesize that demographic factors (e.g., younger age, higher education level) and sexual history (e.g., greater number of sexual partners, any STIs or reproductive health disturbances) will be associated with increased rates of LARC uptake. We also hypothesize that LARC users will have significantly lower proportions of contraceptive method discontinuation and incident pregnancy compared to non-LARC users. **DISCUSSION/SIGNIFICANCE OF IMPACT:** FSW and SM are disproportionately affected by high rates of unintended pregnancy, which can lead to obstetric complications and poor psychosocial outcomes. It is imperative that family planning interventions in developing countries target these populations to overcome obstacles in reproductive health and promote gender equality. Our study will provide necessary insights to an integrated family planning program, which will guide future efforts to design, implement and evaluate family planning initiatives for high-risk populations.

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Nutritional outcomes in pediatric oncology patients less than 3 years of age

Daniel Runco, Ann Mertens and Karen Wasilewski-Masker

Department of Pediatrics, Children's Healthcare of Atlanta, Emory University

OBJECTIVES/SPECIFIC AIMS: Brain tumors are the most common solid tumor diagnosed in children and their location predisposes patients to oromotor dysfunction leading to feeding difficulties. Brain tumor patients experience feeding difficulties more frequently than other pediatric malignancies, largely due to central nervous system directed chemotherapy, radiation, and surgery. Treatment increases the risk of malnutrition and increases risk for infection, ICU admissions, and death. Infants and children (less than 3 years of age) are at higher risk for malnutrition due to rapidly changing nutritional requirements and the underdevelopment of motor skills. Incidence and prevalence of malnutrition in pediatric cancer patients is not well known. **METHODS/STUDY POPULATION:** This is an observational, retrospective study of our center's pediatric cancer patients. Patients are classified by diagnosis, treatment intensity (ITR-2), vital status, and heights and weights (with standardized Z-scores) will be recorded with through 2 years after diagnosis. Adaptation of Intensity of Treatment Rating ITR-2. Nutrition consultation, ICU admissions, and use of parenteral or enteral nutrition will be recorded. Weight loss greater than a 5-percentile point change or Z-score decrease greater than 0.5 will be treated as a binary outcome and considered significant weight loss. **RESULTS/ANTICIPATED RESULTS:** Preliminary analysis has identified 465 eligible subjects as described above: brain tumor (n = 45) and nonbrain tumor patients (n = 420). Patient Schema. This study is still in progress and aims to better identify incidence of malnutrition during pediatric cancer therapy. It is expected that a greater number of nonbrain tumor patients compared with brain tumor patients will be malnourished as defined by decrease in Z-score greater than 0.5 at any point in therapy or falling below the 5th percentile of weight for age. Weight loss will be associated with higher number of ICU admissions and higher treatment intensity score. Finally, we expect to find that patients with a larger decrease in Z-score for age will be more likely to die during therapy. **DISCUSSION/SIGNIFICANCE OF IMPACT:** In addition to this study being valuable in better defining incidence of malnutrition, this data will serve as preliminary data in defining target populations for focused nutritional intervention during cancer therapy. Using this established and published intensity rating scale, we may be able to identify better methods of identifying and preventing malnutrition during cancer therapy.