

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

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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

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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

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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