

2567

## OHRP meets ToS: Cloud-based technologies in human subject research

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**OBJECTIVES/SPECIFIC AIMS:** To identify new ethical challenges in human subject research related to the use of cloud-based platforms for data collection. **METHODS/STUDY POPULATION:** Ethical analysis. **RESULTS/ANTICIPATED RESULTS:** The OHRP regulations protecting the data, privacy and confidentiality of human subjects and the Terms of Service regulations governing data use by cloud-based platforms are vastly different. The gap between these 2 sets of laws and regulations leaves human subjects vulnerable to harm during the data collection process via cloud-based tools. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Recognizing the risks related to data gathering via cloud-based platforms, and educating researchers and research subjects about these risks and how to minimize them will strengthen the protections of participants and will enhance the informed consent process resulting in increased trust and greater willingness to participate in human subject research.

2285

## Patient navigation training: Community-engaged workforce development

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**OBJECTIVES/SPECIFIC AIMS:** The goal of this initiative was to address this cancer health disparity in the Appalachian counties and help participants develop, implement and evaluate evidence-based "PN" that effectively and positively impacts patient and outcomes of the HealthyWomen Program. Following were the objectives of this training program: (1) To understand the broad range of roles and responsibilities associated with "PN", including care coordination and case management, in the Pennsylvania HealthyWoman Program in Pennsylvania and the National Breast and Cervical Cancer Early Detection Program. (2) To identify and assess local resources and expertise for evidence-based "PN" in the HealthyWoman Program. (3) To utilize "PN" in association with public education and targeted outreach initiatives in the HealthyWoman Program. (4) To implement strategies to manage and evaluate "PN" for the HealthyWoman Program. **METHODS/STUDY POPULATION:** The series of PN training was held at Pittsburgh, Camp-Hill, Wilkes-Barre and Philadelphia during June 2017. In total, 86 participants attended the training program at one of these 4 locations. Attendees represented organizations that provided breast, cervical and colorectal cancer outreach, screening and treatment. The participants of the training were solicited by regional program managers of the HealthyWoman Program of the PA Department of Health. The Harold Freeman model for patient navigation model was used to train the participants on the concepts of patient navigation. The training was built upon the Health Belief Model and Chronic Care Model, which defined the specific program constructs. The curriculum covered 2 important aspects, that is, clinical knowledge related to breast and cervical cancer along with aspects of patient navigation. Participants represented small, and large academic institutions/health care systems, cancer centers, federally qualified health centers, health departments as well as community-based screening programs and organizations. **RESULTS/ANTICIPATED RESULTS:** A total of 86 participants were trained; 78% had formal education and training in health-related field. In total, 62% of the participants had previous experience of patient navigation; 42% had training in social service related field and 50% had prior experience as community health worker. The demographic details reflected that majority of the participants (94%) were female. Most of the participants (30%) belonged to 50–64 years of age group followed by 30–39 years (23%) and 40–49 years (22%) of age group, respectively. As part of ethnic distribution, 70% of the participants were White Americans followed by Black/African Americans (17%). Furthermore, association of previous training in health and social service field with and without experience as a community health worker (n=84) and Navigator (n=86) was also analyzed. Among the participants, 44% had both community health worker experiences along with a prior training in social service related field whereas 42% of the respondents only had prior social service related training. This association of previous training in social service related field and prior community health worker experience was statistically significant with a p value of <0.05. Additionally, 81% of the participants who had previous experience in health-related training also possessed the prior experience as community health worker. Also, 81% of the participants who had previous training in health-related field also had a prior experience of patient navigation. In all, 38% of the participants who had a previous experience in social service field also had a prior experience of patient navigation. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The training program established a pool of patient navigators which will contribute towards reducing the cancer health

disparity in the Appalachian region of Pennsylvania. The participants reflected a wide diversity in the navigators' backgrounds and differences across programs in their choices of patient navigators. It is important to consider this diversity when designing curricula materials and the methods of delivery in a patient navigation training program. As PN training programs are developed and implemented, further data is needed to guide practitioners and administrators in their efforts to include separate curriculum and materials for experienced and lay navigators. In addition, it is also important to assess the role and involvement of patient navigators in research and clinical trials. In total, 82% of the participants when asked agreed to be contacted for participation in research studies. Specific curriculum which includes research could be designed for further development of patient navigators. PN training and implementation knowledge is critical to the development of standards and best practices in this emergent area of cancer care.

2489

## Perceptions of "translation" and the application of research across disciplines at the University of Michigan

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**OBJECTIVES/SPECIFIC AIMS:** There is no consensus on what constitutes translational research. To effectively support translation of research into practical settings, universities must determine who is involved, in which disciplines, and what results. In addition, it is unclear whether these researchers would see "translational research" as describing their work. **METHODS/STUDY POPULATION:** A survey assessing perceptions, successes, and barriers to the application of research was distributed to faculty, fellows, and graduate students within the University of Michigan. This survey included a question on the definition of translational research. **RESULTS/ANTICIPATED RESULTS:** Investigators of every rank and school participated (n=865), and all schools reported forms of applied research. Over 70% of participants said it was important to use research results beyond academia, and those responses represented diverse successes ranging from product development to artistic endeavors. Common barriers to such as lack of time and funding were also widely experienced. The definitions of translational research were divided between strictly health-oriented or broadly focused application. However, both definitions and familiarity with the term differed by field. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Translation of research is widespread throughout the university, and many would define translational research to include their research discipline. Strategic university policies could benefit society by enhancing translation and application across many disciplines.

2163

## Polypharmacy and patterns of prescription medication use among cancer survivors

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**OBJECTIVES/SPECIFIC AIMS:** The population of cancer survivors is rapidly growing in the United States. Long term and late effects of cancer, combined with ongoing management of other chronic conditions, make cancer survivors particularly vulnerable to polypharmacy and its adverse effects. We examined patterns of prescription medication use and polypharmacy in a population-based sample of cancer survivors. **METHODS/STUDY POPULATION:** Using data from the Medical Expenditure Panel Survey (MEPS), we matched cancer survivors (n=5216) to noncancer controls (n=19,588) by age, sex, and survey year. We defined polypharmacy as using 5 or more unique medications. We also estimated proportion of respondents prescribed specific medications within therapeutic classes and total prescription expenditures. **RESULTS/ANTICIPATED RESULTS:** A higher proportion of cancer survivors were prescribed 5 or more unique medications (64.0%, 95% CI 62.3%–65.8%) compared with noncancer controls (51.5%, 95% CI 50.4%–52.6%), including drugs with abuse potential. Across all therapeutic classes, a higher proportion of newly ( $\leq 1$  year since diagnosis) and previously ( $> 1$  years since diagnosis) diagnosed survivors were prescribed medications compared to controls, with large differences in central nervous system agents (65.8% vs. 57.4% vs. 46.2%), psychotherapeutic agents (25.4% vs. 26.8% vs. 18.3%), and gastrointestinal agents (31.9% vs. 29.6% vs. 22.0%). Specifically, nearly 10% of cancer survivors were prescribed benzodiazepines and/or opioids compared to about 5% of controls. Survivors had more than double prescription expenditures (median \$1633 vs. \$784 among noncancer controls). Findings persisted similarly across categories of age and comorbidity. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Cancer survivors were frequently prescribed

a higher number of unique medications and inappropriate medications or drugs with abuse potential, increasing risk of adverse drug events, financial toxicity, poor adherence, and drug-drug interactions. Adolescent and young adult survivors appear at increased risk of polypharmacy.

2506

### Post-discharge opioid prescriptions and their association with healthcare utilization in the Vanderbilt Inpatient Cohort Study

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**OBJECTIVES/SPECIFIC AIMS:** Opioid prescribing is common and increasing in certain areas of the country with known risk of misuse and dependence. Our study examined the association of opioid prescription at discharge after hospitalization for acute coronary syndrome (ACS) or acute decompensated heart failure (ADHF) with emergency department (ED) care or all-cause readmission, intended healthcare utilization (follow-up with physician within 30 d of discharge and cardiac rehab participation), and all-cause mortality. **METHODS/STUDY POPULATION:** The Vanderbilt Inpatient Cohort Study is a prospective cohort of hospitalized patients age >18 enrolled with either ACS or ADHF between 2011 and 2015 (index hospitalization). We then excluded those who died during the index hospitalization, patients with hospitalization <24 hours, patients discharged to hospice care, or those who underwent coronary artery bypass surgery because of the high probability of receiving opioids. In addition, we limited the analyses to patients whom we had complete covariate data. The primary predictor variable was an opioid prescription at the time of hospital discharge. We collected healthcare utilization behavior for 90 days after discharge, and mortality data until March 8, 2017. Time-to-event analysis using Cox proportional hazard models was performed for both unintended healthcare utilization behavior and mortality outcomes. Logistic regression was performed for intended healthcare utilization (adherence to follow-up appointments and cardiac rehabilitation). All models were adjusted for demographic data, opioid use prior to index hospitalization, severity of illness, and healthcare utilization prior to the index hospitalization. **RESULTS/ANTICIPATED RESULTS:** There were 501 patients discharged with an opioid prescription and 1994 with no opioid prescription at discharge. Among patients with opioids at discharge 235 (47%) experienced unplanned healthcare events (71 ED visits and 164 readmissions) and among nonopioid patients 775 (39%) experienced unplanned healthcare events (254 ED visits and 521 readmissions) (aHR: 1.06, 95% CI: 0.87, 1.28). Patient mortality in the opioid group was 131 versus 432 in the nonopioid group (aHR: 1.08, 95% CI 0.84, 1.39). Patients in the opioid at discharge group were less likely to attend follow up visits or participate in cardiac rehab (OR: 0.69, 95% CI 0.52, 0.91,  $p=0.009$ ) compared with those not discharged on opioid medications. Sensitivity analysis of patients who were prescribed prehospital opioids (including prehospital opioids in the exposure group with postdischarge opioids) did not reveal a statistically significant increase in mortality (aHR: 1.09, 95% CI 0.91, 1.31) or unintended healthcare utilization (aHR: 1.12, 95% CI 0.89, 1.41) among opioid users. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Morbidity and mortality related to opioid use is a public health concern. Our study demonstrates a statistically significant reduction in physician follow-up and participation in cardiac rehab among opioid users, both of which are known to decrease patient mortality. We did not find a statistically significant increase in unplanned healthcare utilization or mortality. Sensitivity analysis combining prehospital and posthospital opioid prescriptions did not reveal a statistically significant association between opioid use, hospital readmissions, or mortality. The hospital provides unique patient interactions where providers can make significant medical changes based on their patient's clinical status. Continuing to understand the association between opioid use, healthcare utilization, morbidity, and mortality in recently hospitalized cardiac patients will provide data to support reduction in total opioid dose to improve clinical outcomes.

2418

### Post-traumatic stress symptoms in caregivers of pediatric hydrocephalus population

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**OBJECTIVES/SPECIFIC AIMS:** The goal of this study is to characterize traumatic events and post-traumatic stress symptom severity experienced by caregivers of children with hydrocephalus. Results will eventually be evaluated and compared with demographic and medical characteristics. This study is part of a

larger research project that aims to (1) determine the prevalence and risk factors for post-traumatic stress symptoms in pediatric hydrocephalus patients and their caregivers; (2) develop a targeted intervention to mitigate its effects and pilot test the intervention. **METHODS/STUDY POPULATION:** Caregivers of children with hydrocephalus that have received surgical treatment (CSF shunt or ETV/CPC) were enrolled during routine follow up visit in a pediatric neurosurgery clinic. Caregivers completed the PTSD Checklist for DSM-5 (PCL-5), a 20-item self-report measure that assesses the presence and severity of post-traumatic stress disorder (PTSD) symptoms. **RESULTS/ANTICIPATED RESULTS:** Participant responses ( $n=56$ ) revealed that 57.14% of caregivers indicated that their most traumatic event was directly related to their child's medical condition. In total, 23.21% of caregivers did not specify their most traumatic event and 1.79% of caregivers indicated that they had never experienced a traumatic event. Median Total Symptom Severity Score was 11 (mean: 15.32  $\pm$  14.92), and scores ranged from 0 to 67; 32.14% of caregivers scored 19 or greater, and 16.07% of caregivers scored 33 or greater, a value suggestive of a provisional diagnosis of PTSD. Severity scores by DSM-V clusters were as follows: cluster B—intrusion symptoms (mean: 4.91  $\pm$  4.77, median: 4, range: 0–20), cluster C—avoidance symptoms (mean: 1.27  $\pm$  1.87, median: 0.5, range: 0–8), cluster D—negative alterations in cognition and mood (mean: 4.86  $\pm$  6.07, median: 2, range: 0–22), and cluster E—alterations in arousal and reactivity (mean: 4.29  $\pm$  4.07, median: 3, range: 0–17). **DISCUSSION/SIGNIFICANCE OF IMPACT:** Preliminary results from this study indicate that post-traumatic stress symptoms are prevalent among caregivers of children with hydrocephalus. These results suggest that psychosocial issues such as PTSS may be a significant problem in need of treatment, that is not traditionally addressed as part of routine care for families of children with hydrocephalus. Characterizing post-traumatic stress symptoms in this population sets the foundation for the development of screening and treatment protocols for post-traumatic stress symptoms in caregivers of children with hydrocephalus. This study is the first step towards fundamentally improving routine clinical care and quality of life for patients with hydrocephalus and their caregivers by understanding and addressing the effects of traumatic stress.

2110

### Prenatal near roadway air pollution exposure and early neurodevelopment in young Mexican-American children: Findings from the CHAMACOS prospective birth cohort study

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**OBJECTIVES/SPECIFIC AIMS:** Previous studies suggest that prenatal exposure to environmental pollutants can have an adverse effect on brain development. We examine the association between prenatal near roadway air pollution (NRAP) exposure and early neurodevelopment. **METHODS/STUDY POPULATION:** The Center for the Health Assessment of Mothers and Children of Salinas (CHAMACOS) Study is a prospective birth cohort that began in 1999 with 605 mother-child pairs of primarily Mexican-American descent. Maternal residence during pregnancy was geocoded using ArcGIS and prenatal NRAP exposure was assigned using the CALINE4 line source dispersion model. We used composite Bayley Scale scores for cognitive and motor development, and created separate linear regression models at 6, 12, and 24 months of age. **RESULTS/ANTICIPATED RESULTS:** After adjusting for relevant maternal and child characteristics, preliminary estimates suggest that prenatal NRAP exposure is associated with a nonsignificant increase in Bayley Scale scores at 6 and 24 months (cognitive:  $\beta=0.13$ ,  $p$ -value = 0.20 and motor:  $\beta=0.08$ ,  $p$ -value = 0.58 at 6 months; cognitive:  $\beta=0.16$ ,  $p$ -value = 0.42 and motor:  $\beta=0.20$ ,  $p$ -value = 0.25 at 24 months) and a nonsignificant decrease at 12 months (cognitive:  $\beta=-0.07$ ,  $p$ -value = 0.64 and motor:  $\beta=-0.12$ ,  $p$ -value = 0.56). **DISCUSSION/SIGNIFICANCE OF IMPACT:** Our preliminary findings do not suggest that prenatal NRAP exposure is associated with early cognitive development. Additional exploration of co-exposures known to effect neurodevelopment should be examined in this rural population.

2082

### Profile of pediatric potentially avoidable transfers

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**OBJECTIVES/SPECIFIC AIMS:** While hospital-hospital transfers of pediatric patients is often necessary, some pediatric transfers are potentially avoidable.