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Advancing preclinical models for head and neck cancers: Comparative analysis of syngeneic murine heterotopic and orthotopic tumor microenvironments and development of an orthotopic tumor resection model*

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OBJECTIVES/GOALS: Clinical relevance of preclinical animal models is commonly in question. Herein, we investigated locoregional tumor immune microenvironment (TIME) differences in tumor-bearing murine oral cancer models, unresponsive to traditional immunotherapy, and also developed an oral tumor resection model to ultimately enhance translational relevance. METHODS/STUDY POPULATION: Here, we utilized carcinogen-induced, HPV-negative preclinical oral cancer models. For TIME studies, ROC1 cells were maintained as published. ROC1 tumors were established in the murine flank and oral cavity of wildtype C57Bl/6 mice, and tumor growth kinetics were assessed at each site. At distinct stages of tumor growth, tumors were harvested, as well as their respective corresponding inguinal and cervical tumor-draining lymph nodes (tdLNs). Multiparameter 28-marker spectral flow cytometry was performed to analyze immune cell populations at each site. For tumor resection studies, MOC2 tumors were similarly maintained and established in the oral cavity. MOC2 tumors were accessed via midline transcervical incisions. Upon tumor excision, wounds were closed with multiple interrupted Vicryl sutures. RESULTS/ANTICIPATED RESULTS: We anticipated no differences between heterotopic and orthotopic tumor sites. Both sites displayed an initial period of delayed ROC1 tumor growth followed by rapid progression. Comprehensive analyses revealed low T cell infiltration overall and increases in select myeloid cells (i.e., macrophages and dendritic cells) over time in both models. Other immune cell types, however, generally increased over time in the flank. Differences between corresponding tdLNs further indicate deviating changes in immunosuppressive phenotypes (i.e., regulatory T cells and macrophages) and immune checkpoint marker expression. Additionally, MOC2 oral tumors were successfully resected with no visible remaining tumor. No subsequent healing complications were observed, and tumor recurrence occurred within 1 week post-surgery. DISCUSSION/SIGNIFICANCE OF IMPACT: Tissue-specific TIME and tdLN differences may impact antitumor treatment and response. Ability to resect orthotopic tumors allows for modeling of standard-ofcare treatment for oral cancer. These studies can enable tailoring of therapeutic strategies and provide insight into model selection and data interpretation from translational studies.

Diversity, Equity, Inclusion and Accessibility

Disparities in cervical cancer prevention among non-Hispanic Black and Hispanic women

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OBJECTIVES/GOALS: This study aim to identify cervical cancer prevention barriers and facilitators, assess the associations between

social determinants of health factors and cervical cancer prevention, and examine the association between levels of health literacy and willingness to undertake HPV vaccine and cervical cancer screening among Black and Hispanic women. METHODS/STUDY POPULATION: To achieve Aim 1, we will conduct a quantitative survey on barriers and facilitators to cancer prevention among non-Hispanic Black and Hispanic women. For Aim 2, we will assess the relationship between Social Determinants of Health and HPV vaccination/cervical cancer screening using the AHC Health-Related Social Needs Screening Tool. For Aim 3, health literacy will be measured using the SAHL-S&E test and its association with willingness to vaccinate or cervical cancer screening. We will analyze the results using chi-square and logistic regression models. Participants will be recruited through multiple methods. We will recruit 250 individuals who were assigned female at birth and identify as non-Hispanic Black or Hispanic, aged 18-26 years, from Caddo and Bossier Parishes. RESULTS/ANTICIPATED RESULTS: We expect to identify several barriers and facilitators to cervical cancer prevention among non-Hispanic Black and Hispanic women, including factors like access to care, cultural beliefs, and knowledge gaps. Social determinants of health (SDOH), such as income, education, and healthcare access, will likely show a strong association with lower HPV vaccination, Pap smear, and HPV screening rates. Additionally, we anticipate that lower health literacy will correlate with reduced willingness to vaccinate or screen for HPV. These findings can bridge the gap between research and practical health applications by guiding the design of community-based behavioral interventions that enhance cervical cancer prevention among minority populations. DISCUSSION/SIGNIFICANCE OF IMPACT: This research is the first to assess how SDOH factors impact cervical cancer prevention among Blacks and Hispanic women in North Louisianawhile also exploring the role of health literacy in HPV vaccination and screening. Findings will drive practical interventions to reduce disparities and improve outcomes.

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Association of gestational age and neurodevelopment delays in childrens exposed to NICU

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OBJECTIVES/GOALS: Explore the association of gestational age of LPIs and neurodevelopment delay in children exposed to the neonatal intensive care unit (NICU). Compare between groups if exposure to NICU affects neurodevelopment in children who were born between 34 and 37 weeks of gestation. METHODS/STUDY POPULATION: This is a cross-sectional study design to study the association of gestational age and neurodevelopmental delays in a birth cohort in Puerto Rico of children exposed to the NICU. Their neurodevelopment will be measured with the Bayley III. Statistical analysis will be performed using IBM SPSS Statistics 27.0. Descriptive statistics will be used, and normality distributions among all continuous variables, frequency distribution for categorical variables. We will recruit 30 infants between 18–24 months of age

that were born between 34–37 weeks of gestation. Infant will be divided with regard to their exposure to NICU experience. RESULTS/ANTICIPATED RESULTS: We anticipate identifying neurodevelopment delays among children born prematurely between 34 to 37 weeks of gestation. We anticipate that our controlled group will have better outcomes when compared to the controlled expose group. We also expect that gestational age impacts adversely neurodevelopment in children who were born between 34 and 37 weeks of gestation. DISCUSSION/SIGNIFICANCE OF IMPACT: Approximately 84% preterm birth are considered LPIs. Prematurity is described as a chronic condition; adverse long-term neurodevelopment consequences. Our study promotes early detection and interventions that can reduce the consequences of the neurodevelopment delays in LPIs.

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Assessing the inclusion of women and minority populations in ClinicalTrials.gov results in studies focused on type 2 diabetes and GLP1 drugs

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OBJECTIVES/GOALS: This study aims to evaluate diversity of participants in GLP-1 T2DKM clinical research with regard to sex, race, and ethnicity by using results data available through the ClinicalTrials.gov database. Sample population estimates for studies were calculated using the 2020 Census and compared within groups with respect to sex, race, and ethnicity. METHODS/STUDY POPULATION: The public ClinicalTrials.gov database was searched for interventional studies with GLP1 inclusion as treatment (n = 2,397). This search was then filtered to studies where results were reported (n = 772). From these studies, 466 studies focused on type 2 diabetes as a condition and thus became the analysis dataset. Participant and protocol information for these 466 studies were obtained from the clinical trials transformation initiative (CTTI) as an AACT data download. Observed to expected ratios were calculated for each subgroup-based population estimates from the 2020 Census and using the baseline counts of participants for studies where sex, race, and ethnicity were provided. In addition to within group comparisons, study characteristics (e.g. phase) were included in models to assess influence of covariates. RESULTS/ ANTICIPATED RESULTS: Of the 466 studies, 430 (92%) reported sex, 171 (37%) reported race, and 145 (31%) reported Hispanic ethnicity. Among those found to be underrepresented in studies (defined as a ratio < 1): females (mean = 0.89, median = 0.92); Black/African Americans (mean = 0.88, median = 0.39). Hispanic or Latinos mean ratio was 1.16 (95% CL: 0.97, 1.35) but had the least available data. When including covariates in the models, there were statistically significant differences in ratios with respect to sex as females had significantly lower odds compared to males (ratio > = 1), with the odds being about 21% of those for males. With respect to race, Black or African American individuals had significantly lower odds (about 32% of those of White individuals) (ratio > = 1). DISCUSSION/SIGNIFICANCE OF IMPACT: This study reveals significant underrepresentation of females (mean ratio 0.89) and Black/African Americans (mean ratio 0.88) in clinical trials for GLP-1 drugs in type 2 diabetes. These disparities highlight the

need for more inclusive research to ensure diverse populations benefit equally from medical advancements.

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Innovative strategies to enhance engagement by rural adolescents with obesity into the TEENS+ randomized clinical trial

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OBJECTIVES/GOALS: Despite persistent health disparities, rural individuals are underrepresented in clinical trials, due in part to access barriers. We investigated if targeted strategies enhanced recruitment, engagement, and retention of rural adolescents in the TEENS+ randomized clinical trial, a 4-month family-based behavioral weight loss intervention. METHODS/STUDY POPULATION: Adolescents (12-16 y) and parents with obesity were eligible for TEENS+. Treatment converted to virtual in COVID-19, allowing eligibility to expand to more rural areas. We leveraged Informatics, a practice-based research network, and direct marketing to identify potential rural participants. Targeted engagement strategies included: rural physician outreach, physicianendorsed letters, providing tablets and mobile hotspots, reimbursing travel, and offering in-person or remote assessment visits. Chisquare tests evaluated differences in screener completion and enrollment of rural families before (T0) and after (T1) changes were made. Noninferiority tests evaluated rural vs. nonrural retention and engagement (% attendance, % dietary self-monitoring) and engagement based on digital tool receipt. RESULTS/ANTICIPATED RESULTS: N = 211 dyads enrolled (n = 54 in T1: 48% male; 41% Black). Screener completion by rural families significantly increased from T0 (9.8%) to T1 (15.1%; p = .043). Yet, there was no significant change in rural adolescent enrollment (T0 = 10%; T1 = 9%; p = .844). Sixteen adolescents (30%) received study tablets, and none needed mobile hotspots. Mean adolescent attendance was 75%±28% for group and 94%±18% for individual sessions, with no significant differences based on rural status or tablet use. Rural adolescent self-monitoring (via app) was 28%, compared with 50% for nonrural adolescents (p = .074). Retention was 94% at 4m and 89% at 8m for T1 participants, with no differences based on rural status. At the primary endpoint (12 m), retention was significantly higher for rural (100%) vs. non-rural (87%) participants; p = .013. DISCUSSION/SIGNIFICANCE OF IMPACT: Rural adolescent screener hits increased yet enrollment was unchanged. However, rural attendance was comparable and retention exceeded, compared to nonrural participants. Strategies to yield equitable representation and engagement in clinical trials are essential for geographic generalizability and to reduce rural health disparities.

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Facilitating social physical activity among trans and gender diverse adolescents: Parents' perspectives

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OBJECTIVES/GOALS: Inclusive physical activity (PA) interventions could improve trans and gender diverse (TGD) adolescents'