

components and enhancing the activity of cytokines. Interleukin-4 (IL-4) is incorporated into the coating to be released in a controlled manner upon implantation. In vitro controlled release profiles were assessed to demonstrate efficient and local release of IL-4. Utilizing a New Zealand white rabbit surgical model, we implant mesh using the “gold standard” abdominal sacrocolpopexy procedure and evaluate the changes in the host immunologic response at early (14 d) and tissue remodeling outcomes at late stages (90 and 180 d) of implantation. The mesh-tissue complex was removed from each rabbit and processed for histological staining as well as immunolabeling of immune cells, such as macrophages. Determination of matrix metalloproteinases and fibrotic capsule formation also helps characterize the overall inflammatory response associated with each implant. RESULTS/ANTICIPATED RESULTS: We have developed a clinically relevant rabbit surgical model to implant different conditions of surgical mesh into 2 different sites, including the vagina and the abdomen. The results of this study show that implants into vaginal tissues elicited an increased host inflammatory response at 14 days as compared with those in the abdominal wall. However, at chronic time points the inflammatory response in the vagina was reduced as compared to that in the abdominal cavity. The present study also demonstrates the scale-up of a previous methodology for nano-scale coating. We present a nanometer thickness, tunable, and uniform coating capable of releasing bioactive IL-4. In vitro assays confirm the bioactivity and the controlled local release allowing for shifts in the immune response to promote implant integration. Improved remodeling has been observed to correlate with a shift in the early host response from an M1 to an M2 phenotype, however, there is limited information on the exact mechanism. Our strategy to achieve enhanced tissue remodeling demonstrate outcomes such as minimal changes to the structural properties of the mesh and a controlled release profile to sufficiently polarize macrophages around the mesh to a pro-remodeling state. DISCUSSION/SIGNIFICANCE OF IMPACT: Pelvic organ prolapse is a condition where the pelvic floor muscles weaken over time resulting in the downward shift of the pelvic organs into the vaginal canal. Moreover, factors such as obesity, age, and vaginal birth increase the susceptibility of being diagnosed with pelvic organ prolapse. Direct costs of reconstructive procedures exceed \$1 billion each year in the United States. Synthetic mesh has been used to repair abdominal hernias for over half a century. Biomedical companies, through 510k and the 1976 Medical Device Amendments Act, were able to resell their hernia repair mesh as a treatment for pelvic organ prolapse. However, women who have had vaginal mesh implants have reported an increasing number of complications including chronic pain and mesh erosion/exposure at rates as high as 10%–20%. In fact, in 2008 and 2011, the US Food and Drug Administration issued warnings to doctors and patients about the mesh. In January 2016, the FDA officially had to reclassify surgical mesh for transvaginal repair of pelvic organ prolapse from a class II, moderate risk device, to a class III, high-risk device. Presently, data for the use of synthetic mesh has largely derived from abdominal hernia repair, instead of vaginal repair of prolapse. In the rodent model, the vagina is too small to implant mesh in an analogous manner to human implantation. Instead, implantations are done in the abdomen, a different tissue composition and host response profile than the vagina. Primate models of pelvic organ prolapse have been utilized, but are associated with high costs and investigation of acute immune responses are not considered ethical due to the short time of survival. Thus, our presented work will not only show the development of an improved material for implantation, but also the development of an in vivo model clinically relevant to understanding the early host response to mesh.

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### A quantitative disintegration method to evaluate polymeric films

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OBJECTIVES/SPECIFIC AIMS: To establish an in vitro quantitative method for the evaluation of polymeric film disintegration that can be applied to predict in vivo behavior. METHODS/STUDY POPULATION: Two clinically advanced vaginal microbicide film products containing tenofovir and dapivirine were used as model films throughout this work. Films were made using the solvent cast manufacturing method in which polymers, excipients, plasticizer, and APIs were either dissolved or dispersed in water, mixed, and cast on a heated substrate. The novel, quantitative method was developed using a TA.XT Plus Texture Analyzer<sup>®</sup> (Texture Technologies) in combination with a TA-1085S fixture and the TA-8A: 1/8” diameter rounded end ball probe. Exponent<sup>®</sup> was used as the data analysis software. In this method, the film was placed and secured in the fixture, the probe applied a constant force to the film product, and a biologically relevant amount of fluid was applied to the film. The probe was able to penetrate the film upon disintegration resulting in an applied force of zero at that point. A curve of force Versus time was plotted, and disintegration time was defined as the time between fluid addition until the probe force reached zero. Test parameters were optimized in order to reduce error. Visual observation of film

disintegration was conducted in the in vivo macaque model using films that included a water-soluble blue dye for film visualization. Colpophotography was also used to confirm film disintegration. In vitro results were compared with in vivo findings. RESULTS/ANTICIPATED RESULTS: The Texture Analyzer disintegration method developed provided quantitative disintegration times and did not rely on user defined endpoints which is common in many visual disintegration tests. The disintegration method was able to distinguish differences between the 2 clinical film products and produced reproducible disintegration times for the tenofovir and dapivirine films. The tenofovir film had a shorter disintegration time ( $41.28 \pm 2.85$  s) compared with that of the dapivirine film ( $88.36 \pm 9.82$  s). This method was also able to distinguish changes made to these 2 clinical film products in terms of volume and formulation alterations. In vitro and in vivo disintegration times differed by orders of magnitude, with in vitro time being measured in seconds and in vivo time being measured in days, for a variety of factors, mainly the application of constant force to the film product. Regardless of these differences, the rank order of film disintegration remained constant for in vitro and in vivo disintegration and an In Vitro In Vivo Correlation (IVVC) trend could be seen. DISCUSSION/SIGNIFICANCE OF IMPACT: Standardization of preclinical in vitro assessments which minimize user bias are crucial to the field of pharmaceutical film development. As this field continues to develop and more products advance for pharmaceutical application, this method has the potential to become a standard assessment of film functionality. This study represents a first step in the process of developing an IVVC. More films will need to be tested using both in vitro and visual methods in order to establish an accurate factor to predict in vivo behavior.

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### Clinical determinants of clopidogrel responsiveness in a heterogeneous cohort of Caribbean Hispanics

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OBJECTIVES/SPECIFIC AIMS: To determine the association between clinical characteristics and platelet reactivity in Hispanic patients on clopidogrel therapy. METHODS/STUDY POPULATION: A cross-sectional pilot study was performed in 58 Puerto Rican patients diagnosed with any type of vascular disease and actively receiving a maintenance dose of clopidogrel for at least 7 days. The study population was divided into 2 groups: Group I with non-high on-treatment platelet reactivity (TPR); Group II with high TPR. To determine the platelet function, P2Y<sub>12</sub> reaction units (PRU) were obtained by VerifyNow<sup>®</sup> P2Y<sub>12</sub> assay (Accumetrics, USA). RESULTS/ANTICIPATED RESULTS: We studied a heterogeneous cohort of patients with coronary artery disease (57%), peripheral artery disease (30%), carotid artery stenosis (7%), cerebral artery aneurysm (3%), and stroke (3%) on clopidogrel therapy for secondary prevention of thromboembolic events. The mean TPR was  $205 \pm 49$  PRU (range: 61–304), with a prevalence of 28% patients with high TPR (PRU  $\geq$  230). No significant clinical differences were found between the non-high TPR and high-TPR groups ( $p > 0.05$ ). However, multivariable logistic regression analysis showed that both diabetes mellitus (OR = 7.5; CI: 1.01–51.9) and proton-pump inhibitors (OR = 13.6; CI: 1.3–142.0) were independently correlated with high TPR ( $p < 0.05$ ) after adjusting for other clinical variables. DISCUSSION/SIGNIFICANCE OF IMPACT: These results provide new insight into the importance of clinical characteristics on platelet reactivity in this Caribbean population. Further studies are warranted to determine whether important clopidogrel pharmacogenes are related with platelet function in Hispanics, as well as the role of TPR in guiding antiplatelet therapy and predicting future adverse cardiovascular events in this population.

## OUTCOMES RESEARCH/HEALTH SERVICES RESEARCH/COMPARATIVE EFFECTIVENESS

2025

### Institutional and community involvement establishing ARresearch.org and innovative recruitment results in diverse registrants

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OBJECTIVES/SPECIFIC AIMS: To establish a state-wide research registry of diverse participants. METHODS/STUDY POPULATION: We garnered broad institutional and community support by involving TRI's Community Engagement team, its Community Advisory Board (CAB), and 3 UAMS patient CABs in

selecting Web site content, images, and colors. Using this feedback, the TRI Recruitment Unit (RU), in conjunction with UAMS Communications and the Center for Health Literacy, developed the materials and crafted comprehensive communication and recruitment strategies. The UAMS Center for Pacific Islander Health, Hispanic faculty, and CAB members translated materials. UAMS IT programmed the user-friendly site to allow registration from smartphones and i-Pads and linked to UAMS patient electronic health messages. RESULTS/ANTICIPATED RESULTS: The RU committee implemented successful innovative strategies, including recruiting at the Arkansas State Fair and ballgames, attended by people of all races, ages, and socio-economic levels. Using i-Pads at the sites, recruitment took <5 minutes/registrant. Within 8 months, >2400 participants from across Arkansas had joined the registry: 14% African-Americans, 8% Pacific Islanders, 5% Hispanic, and 3% Native American. DISCUSSION/SIGNIFICANCE OF IMPACT: Involving CAB multi-disciplinary input to design and implement recruitment materials was highly successful. Despite challenges of recruiting under-represented groups, the registry includes 30% minorities. By tracking registrants' demographics with Lime Survey software, the RU will prioritize future recruitment events to maximize diversity of registrants.

2058

### Are atrial fibrillation patient-reported outcomes associated with person and environment characteristics?

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OBJECTIVES/SPECIFIC AIMS: (1) Determine person (sex, age, education level), environment (marital status, living alone, insurance), and health and illness (BMI, type of AF, comorbidities) characteristics that are associated with outcomes (QOL, symptom severity, and emotional and functional status). (2) Determine the association of symptom management strategies (ablation, cardioversion, and rate and rhythm control medications) and outcomes (QOL, symptom severity, and emotional and functional status). (3) Test person (sex, age, and education level) and environment (marital status, living alone, insurance) characteristics as moderators of the effect of symptom management strategies (ablation, cardioversion, and rate and rhythm control medications) on outcomes (QOL, symptom severity, and emotional and functional status). METHODS/STUDY POPULATION: AF patients ( $\geq 18$  years of age) already enrolled in the PaTH study will be included. To date, 1026 total participants have been enrolled. Based on the enrolled participants, 92% (945) of our study population are Caucasian and 36% (362) are female. The age range of the enrolled participants is: 2% (16) 18–39, 4% (42) 40–49, 11% (108) 50–59, 33% (343) 60–69, 34% (353) 70–79, and 16% (162) 80+. Participants are recruited through in-person, email, phone, patient portal messaging and post mail techniques to ensure a representative sample. The PaTH study integrates electronic health record and insurance claims data with patient-reported outcome measures collected through online surveys. RESULTS/ANTICIPATED RESULTS: We hypothesize that sex, older age, low education level, living alone, absence of partner, absence of insurance coverage, high BMI, and a high number of comorbidities will be associated with lower QOL, high symptom severity, and low emotional and functional status. We further hypothesize that symptom management strategies will be associated with higher QOL, low symptom severity, and high emotional and functional status, and that these associations will be moderated by person and environment characteristics. DISCUSSION/SIGNIFICANCE OF IMPACT: The proposed research is an important first step in determining potential causes of person and environment differences in symptom severity. It will lead to tailored symptom management interventions for individuals most at risk for experiencing high symptom severity.

2061

### Prevalence, associated characteristics, and diagnostic and treatment process experiences of women seeking emergency department care after being strangled: A mixed methods study

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OBJECTIVES/SPECIFIC AIMS: Aim 1—estimate prevalence and associated characteristics of nonfatal, non-self-inflicted strangulation among women ages 18 and older who presented to a US emergency department between 2006 and 2013. Aim 2—explore care-seeking behaviors, the context of the care seeking, treatment expectations and perceived diagnosis in a sample of women ages 18 and older who present to a US emergency department and report being strangled by an intimate partner. Aim 3—merge and synthesize findings from

both the quantitative and qualitative strands to provide a more complete understanding of post-strangulation emergency care of women. METHODS/STUDY POPULATION: This mixed-methods study will use a convergent parallel design, with a single phase of concurrent and independent data collection. Analysis of quantitative and qualitative data will be performed separately then compared, with main findings integrated during the interpretation phase and presented in a merged data analysis display. IRB review and approval will be obtained before initiating this study. Aim 1 will include a cross-sectional analysis of 2006–2013 Nationwide Emergency Department Sample (NEDS) data, from the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project (HCUP). NEDS is the US's largest all-payer emergency department (ED) database, providing national estimates of hospital-based ED visits from ~120 to 135 million ED visits/year (weighted). For this study, we will examine data from patients meeting inclusion criteria with an International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM; Medicode, 1996) code of strangulation. For this strand, females aged 18 years or older who presented to a US emergency department between 2006 and 2013 will be included. The outcome variable will be non-fatal, non-self-inflicted strangulation, defined using at least one of the ICD-9-CM codes for strangulation. These codes are: 994.7 ("asphyxiation and strangulation"), E963 ("assault by hanging and strangulation"), E983.8 ("strangulation or suffocation by other specified means undetermined whether accidentally or purposely inflicted"), and E983.9 ("strangulation or suffocation by unspecified means undetermined whether accidentally or purposely inflicted"). Patients with a concurrent ICD-9-CM code for suicide attempt (E953, "Suicide and self-inflicted injury by hanging, strangulation and suffocation") will be excluded, to minimize self-inflicted assault events. Aim 2 will employ a narrative descriptive approach, with semistructured individual interviews to gather more information about women's experiences when engaging the health care system after being strangled. Medical records related to the strangulation event will also be reviewed for diagnostic codes and other nursing and/or medical notes that may relate to diagnoses, treatment and referrals. For this strand, women aged 18 years or older who present for care to an urban, academic ED will be recruited, purposely sampling those reporting strangulation as a reason for their visit. We anticipate interviewing ~20–30 women to achieve saturation of information. RESULTS/ANTICIPATED RESULTS: Data from the NEDS from 2006 to 2013 will be analyzed for prevalence and associated characteristics of women seeking care after being strangled. Individual interviews and medical record reviews of a small sample of adult women will be conducted to explore women's in-depth experiences within the health care system. Results from both the quantitative and qualitative analyses will then be collectively compared and interpreted to better synthesize the evidence from this work. Convergent and divergent findings will be presented in a merged data analysis display (Creswell and Plano Clark, 2011). Qualitative data will be used to fill the knowledge gap remaining from the quantitative analysis, and to explain and contextualize some of the findings. Such integration will help expand the current limited evidence on care of strangled women, and will identify additional research questions that will guide future research in this area. DISCUSSION/SIGNIFICANCE OF IMPACT: To our knowledge, this study will be the first to explore this issue using a nationally representative sample of adult women who sought emergency medical care for strangulation analyzed in conjunction with a detailed qualitative analysis of strangled women's experiences with the health care system. The resulting knowledge will be critical to informing clinical assessment, intervention and prevention efforts for this vulnerable population, as well as public policy and future research regarding this specific violence tactic.

2087

### Better Together Lebanon County: A collaboration to improve the health environment and reduce obesity through community-owned initiatives

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OBJECTIVES/SPECIFIC AIMS: Improving public health requires effective community-engaged approaches. The Better Together Lebanon County initiative plans to create opportunities for improved health and quality of life by aligning strategies of local organizations, previously working independently. METHODS/STUDY POPULATION: Better Together began with a 1-day summit, convening stakeholders with the goal of coordinating efforts and maximizing resources in the Lebanon community. Key stakeholders were identified using the socioecological model to assist with planning, goal setting, and developing outcomes for this initiative. Representation included community members, hospital systems, restaurants, school administrators, nonprofit organizations (including YMCA, American Heart Association), grocery stores and policy makers such as the mayor, health departments, and state representatives. RESULTS/ANTICIPATED RESULTS: The Better Together