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Strategies for commercializing non-patentable innovations developed at CTSA hubs

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OBJECTIVES/GOALS: This presentation reports activities of a NCATS-funded collaborative working group created to promote dissemination and implementation (D&I) research within the CTSA landscape. Our working group seeks to meet both the conceptual as well as practical challenges to advancing the utilization of D&I across the translational science spectrum. METHODS/STUDY POPULATION: A fundamental focus of D&I is supporting the movement of effective health interventions into real-world use so that they benefit population health. Yet, this process remains unpredictable, with some interventions receiving widespread uptake in practice and others (of similar potential benefit) failing to translate. The value of research efforts is wasted when directed toward the "wrong" interventions. Recent discussion and experience amongst investigators in our collaborative working group has resulted in new ways of addressing this problem. Specifically, tools borrowed from business and management have shown promise in predicting which health interventions have the highest potential for commercialization and dissemination. RESULTS/ANTICIPATED RESULTS: We will conduct an environmental scan of CTSA hubs to understand their approaches to supporting commercialization and business development around research products, identifying the most promising and effective methods and processes. We will compile various tools for identifying and supporting interventions with the highest potential for commercialization, including how to form the multidisciplinary and stakeholder-engaged teams necessary to make these determinations. Finally, we will further explore the differences between patentable and non-patentable innovations and make recommendations for CTSAs in supporting the latter. DISCUSSION/SIGNIFICANCE: Commercialization of non-patentable interventions is an essential and underexplored element of the translational science spectrum. The perspectives and methods of D&I should not be relegated to late-stage translational steps, but rather inform the conduct of translational science writ large.

Science Policy and Advocacy

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Balancing science policy and patient advocacy in medical education: the case of differences of sex development.

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OBJECTIVES/GOALS: The clinical management of differences of sex development (DSDs) aims to guarantee best practices in medical care while addressing concerns related to non-reversible surgeries. Rhetorical analysis was conducted to study the balance between science policy and patient advocacy related to DSD surgeries as depicted in medical education materials METHODS/STUDY POPULATION: Unrestricted transcripts of two educational videos and text from all chapters of a handbook addressed to medical learners and faculty by the Association of American Medical Colleges (AAMC) were submitted to automated word cloud analysis (NVivo, QSR InternationalÂ®). Words with a weighted percentage > 0.19% from total words of a given source were defined as words of frequent use and were selected for further analysis after exclusion of words as conjunctions, prepositions, pronouns, or conversational fillers. Words sharing noun, adjective and adverb forms were coded and weighed as a single word following the Oxford dictionary. Discrepancies on word selection, exclusion or coding were resolved between four raters. The rhetorical context of most frequent words was identified. RESULTS/ANTICIPATED RESULTS: The word cloud analysis of the video resource intended for medical learners (n=104 words of frequent use) and the video intended for medical faculty (n= 94 words of frequent use) depicts a patient-centered approach (word people') that is based on expert opinion (word [I] think'). The handbook (n= 998 words of frequent use) makes reiterated reference to patients'; lgbt'; gender'; health'; and caring' while underscoring health concerns that are unrelated to genital variance (health'; caring' and medical'). The noun surgery' did not figure among the most frequent words in spoken language nor in written text even when summing its adjective and adverb forms. DISCUSSION/SIGNIFICANCE: Educational materials by the AAMC on DSDs accentuate patient-centered care within a medical humanism framework. However, the lack of discussion of DSD surgeries is an educational gap that should be addressed by key science policy and patient advocacy stakeholders.

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Motives for kratom self-medication: contents of public comments solicited by the FDA

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OBJECTIVES/GOALS: The present study sought to investigate kratom use motives among the U.S population with the goal of discovering previously unknown health-related reasons for kratom use by the general public. METHODS/STUDY POPULATION: To guide decisions regarding kratom regulation, the FDA solicited comments from the public regarding the abuse potential of these substances, medical usefulness, and impact of scheduling changes from July 2021 until August 2021. Comment participation was open to the public. The first 6,353 consecutive comments posted on the Federal Register website were retrieved and analyzed. Duplicate comments and comments not pertaining to kratom were excluded from the analysis. The comment submissions were reviewed and categorized using an inductive approach via thematic content analysis. RESULTS/ANTICIPATED RESULTS: Respondents reported over 108 independent health-related reasons for kratom self-medication. Most often fell under the categories of mental health (1911 counts), pain management (1873 counts), substance use disorder (1635 counts), rheumatic diseases (613 counts), and degenerative spine diseases (247 counts). Many comments (701 counts) reported use for miscellaneous purposes, which included to increase focus (212 counts), treat insomnia (127 counts), and decrease fatigue (99 counts). Neurological diseases (e.g., migraines, restless legs syndrome, and multiple sclerosis) and digestive disorders (e.g., irritable

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bowel syndrome and Crohns Disease) were also reported (147 and 96 counts, respectively). Respondents also reported on the abuse potential and adverse effects of Kratom (122 counts). DISCUSSION/SIGNIFICANCE: This is the first study to delineate and classify motives for kratom use among Americans. Individuals reported using kratom for a wide spectrum of health-related reasons. Though these results may be influenced by the placebo effect, they suggest that kratom alkaloids may possess therapeutic activity for previously unknown applications.

Team Science

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Clinical characteristics and psychosocial factors associated with temporary neuromodulation success

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OBJECTIVES/GOALS: The present work aims to use baseline data to identify demographic, clinical, and psychosocial factors associated with patients who receive analgesic benefit from temporary neurostimulation. METHODS/STUDY POPULATION: This study presents baseline data from our descriptive, prospective, longitudinal study. Consecutive patients who present to the University of Arkansas for Medical Sciences Interventional Pain Management Clinic for implantation of a neurostimulation device, have met clinical criteria for implantation of a neuromodulation device, and are able to speak and understand English are invited to participate. Prior to the placement of the temporary stimulator, each patient completes demographic and symptom-related questionnaires. Clinical characteristics are obtained through medical record review. RESULTS/ANTICIPATED RESULTS: We anticipate enrolling 50 participants in order to have 30 patients that report analgesic benefit from temporary neurostimulation. Variability in demographics, clinical characteristics, and psychosocial factors will be reported between patients who receive and those who do not receive analgesia following temporary neurostimulation. Gender differences will also be reported. DISCUSSION/SIGNIFICANCE: Despite the use of varying outcome measures, studies to date have not incorporated validated patient reported outcomes or controlled for key demographic and clinical characteristics. Our analysis evaluates clinical and psychosocial variables associated with successful temporary neurostimulation.

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Adaptation and Evaluation of Guideline-Based Family-Based Behavioral Treatment for Overweight and Obesity in Childhood Survivors of Acute Lymphoblastic Leukemia (ALL)

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OBJECTIVES/GOALS: Childhood survivors of ALL are at considerable risk for late effects which are exacerbated by excess weight. The proposed study involves the adaption and evaluation of the first empirically supported intervention for childhood survivors of ALL that is consistent with all national recommendations for the treatment of childhood obesity. METHODS/STUDY POPULATION: The proposed intervention will be adapted from family-based behavioral weight loss treatment (FBT) a multicomponent intervention which targets diet, activity, behavioral skills, parenting, and social facilitation among children and their parents. The Framework for Reporting Adaptations and Modifications-Enhanced structure (FRAME), a dissemination and implementation framework, will guide the adaptation, allowing for the incorporation of feedback previously gathered from key stakeholders. A single-arm, non-randomized trial of the adapted intervention will then be conducted to evaluate its acceptability, feasibility, and preliminary indications of efficacy including measures of relative weight change and associated health-related behaviors among 40 childhood ALL survivors and their families. RESULTS/ANTICIPATED RESULTS: Self-reported feedback from families at the end of treatment (EoT) is anticipated to demonstrate that this intervention will be regarded as both acceptable and feasible. Other measures of feasibility will include attendance and retention rates, which are expected to reflect to those of previous FBT trials (92% and 85%, respectively). Preliminary indications of the efficacy of the adapted intervention will be investigated through the comparison of a series of measurements taken at both baseline and EoT. Changes in relative weight will be assessed and are expected to meet a previously established range of clinically meaningful reduction in child percent overweight of 9 units or more. Improvements in dietary intake, physical activity, and health related quality of life are also anticipated. DISCUSSION/SIGNIFICANCE: Knowledge gained from the implementation of the first evidence-based intervention adapted for childhood survivors of ALL will be critical to the justification of a larger-scale, randomized controlled trial and holds promise to effectively modify the risk for chronic disease among a vulnerable population.

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Adapting a randomized, placebo-controlled pilot study aimed to reduce anxiety symptoms to overcome recruitment barriers

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OBJECTIVES/GOALS: Minimal human investigations have assessed the effect of synbiotics (combination of pre- and probiotics) on anxiety symptoms, despite evidence from preclinical research. Our study aimed to determine the feasibility of a randomized, placebo-controlled trial utilizing synbiotics to reduce anxiety symptoms in older female breast cancer survivors. METHODS/STUDY POPULATION: We aimed to recruit older female breast cancer survivors experiencing anxiety symptoms to a 4-week randomized, placebo-controlled clinical trial. At commencement of the project, participants were eligible if they : 1) were 50-75 years old; 2) completed primary treatment for breast cancer; 3) were experiencing clinical anxiety symptoms 4) agreed to not change dietary supplements 5) were willing to comply with daily supplement regimen; and 6) were able to read and speak English. Use of anxiolytic or microbiome-altering medications, or changes to anxiety treatment within 4 weeks of enrollment were criteria for exclusion. Due to budgetary limitations, we were unable to recruit from state cancer registries, and instead recruited via newspaper advertisements and flyer distribution. RESULTS/ANTICIPATED RESULTS: One participant has successfully been recruited and completed the duration

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