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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 CTSA hubs 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 International[®]). 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