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The Role of Antiretroviral Treatment Patenting on Consumer Pricing: Declining Viral Suppression and Treatment Non-Adherence Among HIV Patients in Los Angeles County

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OBJECTIVES/GOALS: Antiretroviral treatments (ART) suppress retroviruses, like the human immunodeficiency virus (HIV). The goal is to understand how antiretroviral drug patents contribute to overpriced HIV medications, thereby causing cost-related treatment non-adherence and inhibiting viral suppression. METHODS/STUDY POPULATION: Currently, HIV affects 57,700 individuals in Los Angeles County (LAC). Data was compiled from Centers for Disease Control and Prevention (CDC), hiv.gov, lacounty.HIV, publichealth.lacounty.gov, and the U.S. Patent and Trade Office. A review of existing literature examined the role of ART patents on cost-related non-adherence and declining viral suppression on individuals living with HIV in LAC. Lastly, a comparison of HIV medication prices of expired and non-expired patents was conducted, indicating the effects of undue extensions of market exclusivity on ART regimen pricing, and how this affects treatment adherence. RESULTS/ANTICIPATED RESULTS: Of the ten ARTs examined, four had expired patents and six had active patents. Those with active patents cost more than those with inactive patents because active patent status prevents price reductions. Patent strategies–pay-for-delay settlements and patent evergreening–unduly extend market exclusivity, keeping ART at prohibitive costs and preventing generic competition. Individuals facing cost-related non-adherence were less virally suppressed at their last viral load test (64%) and at all tests during the year (54%). Thus, over-patented ARTs increase treatment prices, causing cost-related non-adherence to ART regimens. The implications include disease progression and less viral suppression. DISCUSSION/SIGNIFICANCE: The U.S. has the highest ART prices, yet the lowest rate of HIV viral suppression (54%) among all well-resourced countries. Undue extensions of market exclusivity cause ARTs to remain at prohibitive costs, preventing some patients from affording ART treatments, minimizing their viral suppression.

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Mapping Clinical Trial Outcome Measures for Atopic Dermatitis

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OBJECTIVES/GOALS: Atopic Dermatitis (AD) affects 10% of people globally and is studied widely in clinical trials. However, clinical outcomes assessment (COA) for AD are not standardized, hindering easy comparisons across different studies. This study examines AD studies to identify the most used COAs. METHODS/STUDY POPULATION: Clinicaltrials.gov was searched to identify AD trials conducted between 2011 and 2021. Ongoing and completed trials were classified according to the therapeutic modality: Biologic, Immunosuppressive, or Other (botanicals and antibiotics). Further, AD trials were examined to determine which of the COAs listed in the FDA compendium issued in 2021 were included: the Investigators Global Assessment (IGA), the Eczema Area and Severity Index (EASI-75), and the Pruritus Numeric Rating Scale (NRS). The results were analyzed to determine which COA is most frequently used and if there were differences across therapeutic modalities or trial phases. RESULTS/ANTICIPATED RESULTS: Across a total of 50 AD trials registered in clinicaltrials.gov, EASI-75 was the most used COA; the item was included in 12 of 16 biologics, 5 of 14 immunosuppressives, and 7 of 20 other products. Moreover, AD trials of biologics included more of the FDA-suggested COAs than those studying other modalities. There were also differences across the clinical trial phases in that most phase III AD trials (83.33%, n=8) included two of the three COAs listed (IGA and EASI-75) compared to less than half of phase I/II trials (vs. 43.75%, n=32). DISCUSSION/SIGNIFICANCE: Findings from this study indicate a lack of COA harmonization across AD trials, impeding comparative analysis of the trial results. Establishing a common standard for COA would foster communication and transparency among key stakeholders including researchers, healthcare providers, and patients.

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Successful Conversion of a Hybrid Idea Competition and Funding Mechanism to Fully Virtual: A Case Study

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OBJECTIVES/GOALS: The University of Michigan Frankel Cardiovascular Center (FCVC) Innovation Challenge is an annual competition offering funding for innovative ideas to improve cardiovascular care. Due to the COVID-19 pandemic, administrators converted the recruitment process and pitch event to fully virtual. METHODS/STUDY POPULATION: We detail the process of converting the event from a hybrid process (virtual and in-person recruiting and in-person event) to a fully virtual one. Changes to the event included implementing a virtual recruiting process utilizing short video recordings as submission format; a new tool for storing and displaying submissions; fully virtual finalist selection and coaching; and a fully virtual pitch and judging event. The submission process tracked information about submissions that include the type of idea (process or product), role of team lead, and department of team lead. RESULTS/ANTICIPATED RESULTS: The FCVC Innovation Challenge was successfully converted to a fully virtual event. Methods and tools will be shared to allow similar institutions to replicate a successful virtual pitch event. These include methods and tools utilized to allow participants to describe their ideas, strategies to select and coach finalists, and to host a virtual pitch event. Data will be shared on the number of ideas and category (product/process) of projects submitted, and number and category of finalists selected. DISCUSSION/SIGNIFICANCE: This case review can demonstrate how institutions can use a similar virtual idea submission and pitch process to (1) catalyze innovative ideas that can impact patient care by accessing its communitys ideas and (2) fund innovative ideas that do not fit traditional mechanisms.

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