the USA, which illustrates a gap in the literature and application of this theory in this context. In the future analyses, we will examine factors influencing the adoption stage and outcomes, such as regulatory action, what best practices have been defined/implemented (if any), culture shifts in the context of clinical research, health communications, and inclusion of patient voices in clinical research. Our analysis will include a network analysis to evaluate characteristics that influence adoption of PLS in clinical research. We hope to identify who is at the forefront of innovation and why. DISCUSSION/SIGNIFICANCE OF IMPACT: Novel application of DoI theory will help lay the groundwork for a culture of change in patient-focused drug development, specifically for the dissemination of results to patients. In future studies, we plan to develop a tailored framework for the inclusion of PLS as part of a paradigm shift in the patient-focused drug development process.

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Plain language summaries (PLS): Practices, limitations, and strategies

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OBJECTIVES/GOALS: This literature review examines the current landscapes of plain language summaries (PLS), which are used to make research accessible to nonexpert audiences. It aims to identify gaps in their implementation by focusing on challenges related to consistency, accessibility, and quality across fields. METHODS/STUDY POPULATION: A systematic search was conducted using databases such as PubMed and Google Scholar, employing key search terms like "plain language summaries," "scientific communication," "health literacy," "patient education," "knowledge translation," "accessibility in research," "public engagement," "layperson," and "lay summaries." Literature from multiple sources (pharmaceutical companies/industry, nonprofit organizations, private–public partnerships, and government) was compared to assess the gaps in current PLS best practices. RESULTS/ANTICIPATED RESULTS: Search results yielded 95 articles. Of those, 37 articles fit the criteria, highlighting critical gaps in PLS implementation for clinical research. Preliminary findings suggest a lack of standards and guidelines, as well as a need for more research on the effectiveness of PLS for improving knowledge transfer and patient engagement. Key limitations were identified for investigator-initiated trials (IITs). A best practice table, comparing recommendations from each group of sources, was developed with suggestions for writing effective PLS. While there is consensus on some principles (i.e., importance of simplicity), differences emerge regarding optimal length and the use of layperson glossaries and graphics. The table aims to serve as a guide for creating effective and standardized PLS across fields. DISCUSSION/SIGNIFICANCE OF IMPACT: There are limited PLS best practice resources tailored for IITs. These findings could lead to more practical tools and a streamlined approach to enhance communication strategies for lay audiences. This would benefit trial participants and community members who rely on this information and bridge the gap between scientific communities and the public.

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Mental health care for patients with potential decision-making capacity compromise: Challenging Ontario's mental healthcare legislation

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OBJECTIVES/GOALS: How do we care for a patient whose mental health is deteriorated such that their decision-making capacity may be compromised? The high-potency opioid crisis in Ontario demands that we provide effective care for the affected population. We must also avoid patients having a subjective experience of coercion and must protect their human rights and dignity. METHODS/STUDY POPULATION: Ontario's legislation governing mental health care will be explored: the Ontario Mental Health, Healthcare Consent, and Substitute Decisions Acts. We will identify best practices/learning across locales. Patients who have been involuntarily treated/confined will be welcomed to voice what the law should contain. International strategies for: coercion reduction practices, advanced care directives, less prohibitionist care culture, and supports for social determinants of health (SDH) may also help Ontarians. Patients, family members, law enforcement, judiciary, community agencies, and healthcare professionals will be invited to contribute via focus groups to drafted mental health care legislative improvements. Thus, we ensure law enforces patient-defined quality care and practical workflows. RESULTS/ANTICIPATED RESULTS: We hope to emerge from our focus group consultation with draft legislative and procedural edits for Ontario's mental healthcare laws to ensure that the laws protect human rights and that the laws reflect patient-defined needs. We must ensure controls are in place to de-risk power imbalances and limit the incidence of potential procedural misuse. We intend to design legislated procedures to ensure that people don't get inappropriately involuntarily confined/treated. We will incorporate the perspectives and lived experiences of patients who have experienced involuntary treatment and/or involuntary medical confinement (locally in a focus group(s)) and internationally (in literature) to inform this legislative development. DISCUSSION/SIGNIFICANCE OF IMPACT: We will learn from engaged stakeholders about how to shape Ontario's legislation to support quality mental health care. We hope to identify and draft legislation improvements that voice what patients and their families' value, drafts informed by evidence-based best practices and informed innovation. Via inclusion, we create a policy that serves.

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An international comparison of the efficacy of regulatory mechanisms regarding traditional medicines (TM)

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OBJECTIVES/GOALS: To identify the most impactful regulations regarding the approval and marketing of TMs in the U.S., E.U., Japan, Australia, China, and India enacted between the years 2000 and 2022. To explore TM-related regulations in new countries, Japan and Australia, for their novel regulatory approaches in

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intersecting Western and Eastern medical practices. METHODS/STUDY POPULATION: International regulatory bodies included in this study were chosen based on the country's long history with TM and/or the existence of review processes specific to TM. TM-related regulatory changes that were enacted between the years 2000 and 2022 were identified and categorized into special departments, changes in clinical trials, or specialized tracks. The impact of these TM policies was measured via the number of TM-related INDs, approved applications, marketed drugs, and rejected applications per decade since 2000. This data was then organized alongside policies to draw conclusions about the influence of these regulatory changes. All data was collected using official government websites and journals published by independent, external research institutions accessed via USC's library services. RESULTS/ANTICIPATED RESULTS: Previous research revealed each country made efforts to integrate TMs into existing drug practices, such as clinical trials and safety requirements, although the extent and methods for the integration differed. Countries with a longer history with TMs are predicted to have regulatory systems that are more accommodating to the unconventional nature of TMs, making the approval and marketing of TMs much easier in these countries. As TM-related policies are more refined and increase in number in a given country, the number of TM-related applications and TMs marketed as legitimate, prescribable medications will also increase. DISCUSSION/SIGNIFICANCE OF IMPACT: Timelines and charts displaying the impact of new TM-related regulatory changes will help identify a successful model for increasing TM IND submissions, approvals, and marketed TM drugs.

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The unheard voices of clinical trials: A preliminary inquiry into the knowledge and sentiments of people experiencing homelessness (PEH) on clinical research

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OBJECTIVES/GOALS: The purpose of this pilot study is to conduct a survey interview to understand the knowledge and attitudes of people experiencing homelessness (PEH) toward clinical trial participation, provide insights for future engagement strategies, and begin bridging the gap between clinical researchers and this marginalized group. METHODS/STUDY POPULATION: A 14-question survey, developed in collaboration with the street medicine (SM) team at the University of Southern California and other key stakeholders in PEH research, was administered in a survey–interview style to PEH in SM's East Side Los Angeles area of operations. The questions were designed to assess PEH's knowledge and attitudes toward the significance of clinical research and their potential participation. No identifying information was collected. To ensure diversity in responses, the surveys were conducted in different SM healthcare providers' areas of operations. The responses were then analyzed both quantitatively and qualitatively, taking into account the broader perspectives that PEH may have toward clinical trial research. RESULTS/ANTICIPATED RESULTS: A total of 9 PEH were surveyed. When asked to share their thoughts on "clinical trials" (CTs), most described the need to travel on-site to a practitioner to be studied/tested. They indicated that they knew what CTs were and that the FDA's official definition was easy to understand. Only one respondent reported being part of a diagnostic trial, and one declined to answer. Four respondents indicated a willingness to participate in a CT. Four answered "maybe" and one answered "no." Of note, most believed that CTs have a positive impact, and only one responded that they think researchers do not maximize health benefits and minimize risk. Outside of the allowed answer choices, respondents also shared that there should be payment for participation in a CT, even if they don't expect any. DISCUSSION/SIGNIFICANCE OF IMPACT: The survey results could significantly influence the future of clinical research, guiding it to be better tailored to PEH's unique circumstances, thereby potentially improving their participation rates. A key objective for the future will be to increase the sample size of the survey to improve the applicability and impact of the results.

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Telemedicine trends during the COVID-19 pandemic – World Trade Center Health Program, 2020–2021

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OBJECTIVES/GOALS: The World Trade Center (WTC) Health Program (Program), a limited federal healthcare program for eligible people exposed to the terrorist attacks on September 11, 2001, expanded telemedicine services during the COVID-19 pandemic. We analyzed service use trends from 2020–2021 to describe how the program implemented telemedicine services. METHODS/STUDY POPULATION: We estimated use rates of telemedicine-eligible services and telemedicine services by all included program members and by subgroups of members defined by member type (responder or survivor) and selected characteristics for the study period 2020–2021. We described the use trends of total telemedicine-eligible visits, telemedicine visits, and in-person visits, respectively, by quarter. We calculated the quarterly rates of telemedicine use per 1000 living members. We used a multivariable logistic regression to examine associations between member characteristics and telemedicine use rates. RESULTS/ANTICIPATED RESULTS: About 75% of telemedicine visits were related to mental health services. In the second quarter of 2020 (April–June), telemedicine use rate (367 visits/1000 members) increased, exceeding in-person service rate (152 visits/1000 members) by 1.4 fold. Telemedicine use rate decreased gradually in the rest of the study period but still represented 38% of total visits by the end of 2021. Regression models showed differences in telemedicine use rates by member type and by demographic characteristics. Survivor members (vs. responder members), those self-identified as non-Hispanic Other races (vs. non-Hispanic White), those with preferred non-English language (vs. preferred English), and those not living in the New York metropolitan area (vs. living in the New York metropolitan area) were less likely to use telemedicine. DISCUSSION/SIGNIFICANCE OF IMPACT: The expansion of telemedicine service provided members uninterrupted access to necessary health services during the COVID-19 pandemic. It underscored the importance of extensive partner collaboration, the capacity to rapidly develop necessary technical guidance, and the flexibility to timely address frequent regulatory guidance updates.

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