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


https://doi.org/10.1017/cts.2024.1121