



Evaluation of Hainan's Multifaceted Approach to Promote System-level Digital Therapeutics Development: A Mixed-Methods Study

Jin Xu^{1,2}, Xinxin Xia¹, Yuguo Ye^{1,3}, Ziming Wang¹, Weijia Lu¹, Qingyue Meng^{1,3}

1. Peking University China Center for Health Development Studies; 2. WHO Collaborating Center for Universal Health Coverage; 3. Hainan Institute of Health Development Studies

Background

Digital therapeutics (DTx), driven by software, offer emerging interventions with significant potential for prevention, treatment and management for medical conditions. Their scaling up faces various bottlenecks. Hainan Province in China has pioneered comprehensive policies to promote province-wide development of digital therapeutics.

Aim

This study aimed to analyze the impacts of the DTx-related policies on development of digital therapeutics in Hainan Province, as well as factors promoting and hindering progress.

Methods

We extracted DTx-related information in China on the Clinical Trial Registry and State Food and Drug Administration website from 2014 to 2024 H1. Document analysis was conducted for Hainan's policies on digital therapeutics. 35 representative stakeholders were interviewed. We also studied the effects of DTx three tracer conditions of autism, diabetes, and elderly cognitive disorders, for which digital therapeutics have been rolled out in the province.

Results

Six pillars of Hainan's Pro-DTx policies

- Clinical research;
- Registration and approval;
- Promotion of application;
- Payment innovation;
- Industrial cluster;
- Standards and security.

Results

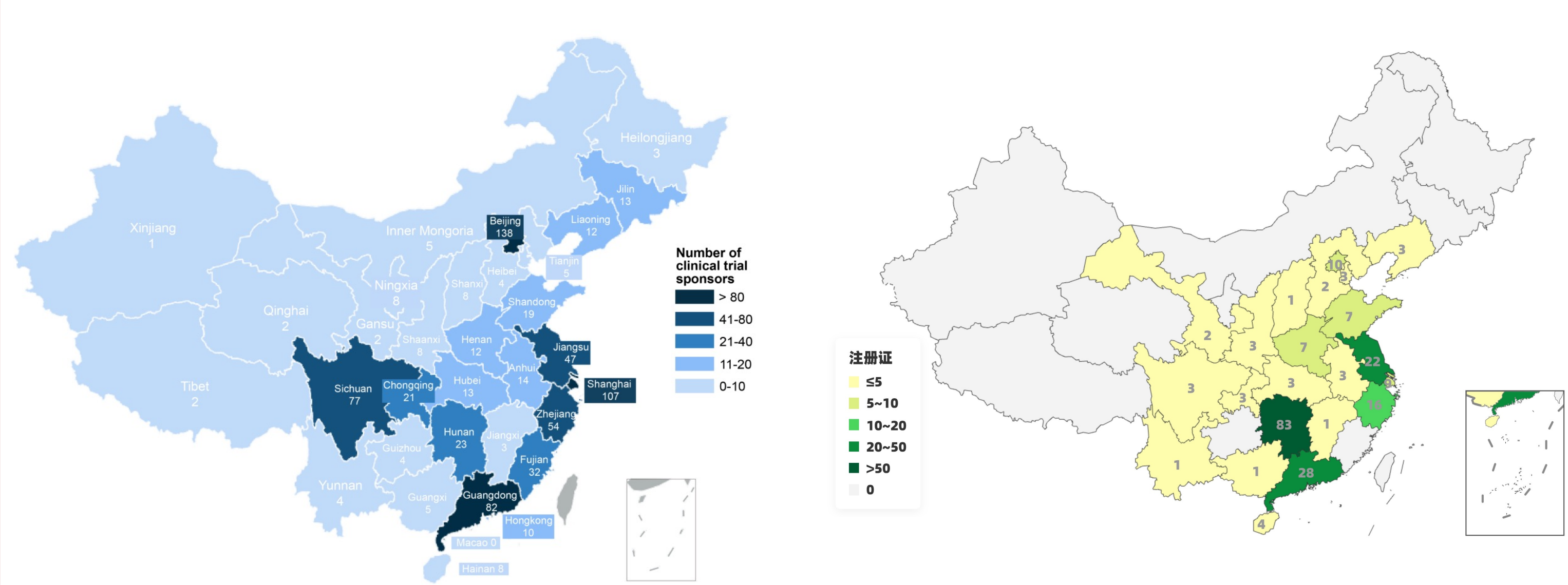


Figure 2. Number of DTx trials and approved products China's mainland, HK and Macau SAR (2014 – mid-2024)

Utilization of DTx promoted through demonstration projects:

- Children with autism: 900 users in total, including 300 out of all 430 children with autism at Provincial Maternal and Child Health Center alone.
- Diabetes management: 3,953 patients in Lingshui County.
- Elderly with cognitive impairment: 38,000 people received cognitive rehabilitation, 4.8 million sessions of training, or 16 million minutes.

Influence on service

- Innovative: more automated through AI; new ways of interaction with patients, e.g. game-based, VR.
- Improved efficiency, reduced repetitive workloads, but may require initial education for patients and caregivers, while shifting care towards home-based settings.
- Reduced marginal costs; potentially increased out-of-pocket expenses in the short term.
- Promoting care for the vulnerable previously neglected.

Sustainability

- Growing acceptance from both professionals and patients, along with support from government policies and financial resources; but not yet covered by social health insurance.

Lessons

- Multifaceted DTx policies address interlinked bottlenecks facing scaling up of DTx innovation.
- Effective patient and provider involvement is need in developing DTx that can be scaled up.
- Prioritization of research on primary care empowerment with DTx may respond better to health system challenges.
- DTx demonstration projects accelerate the integration of DTx into daily health services.
- Coverage of cost-effective DTx by social health insurance is critical in promoting DTx application.

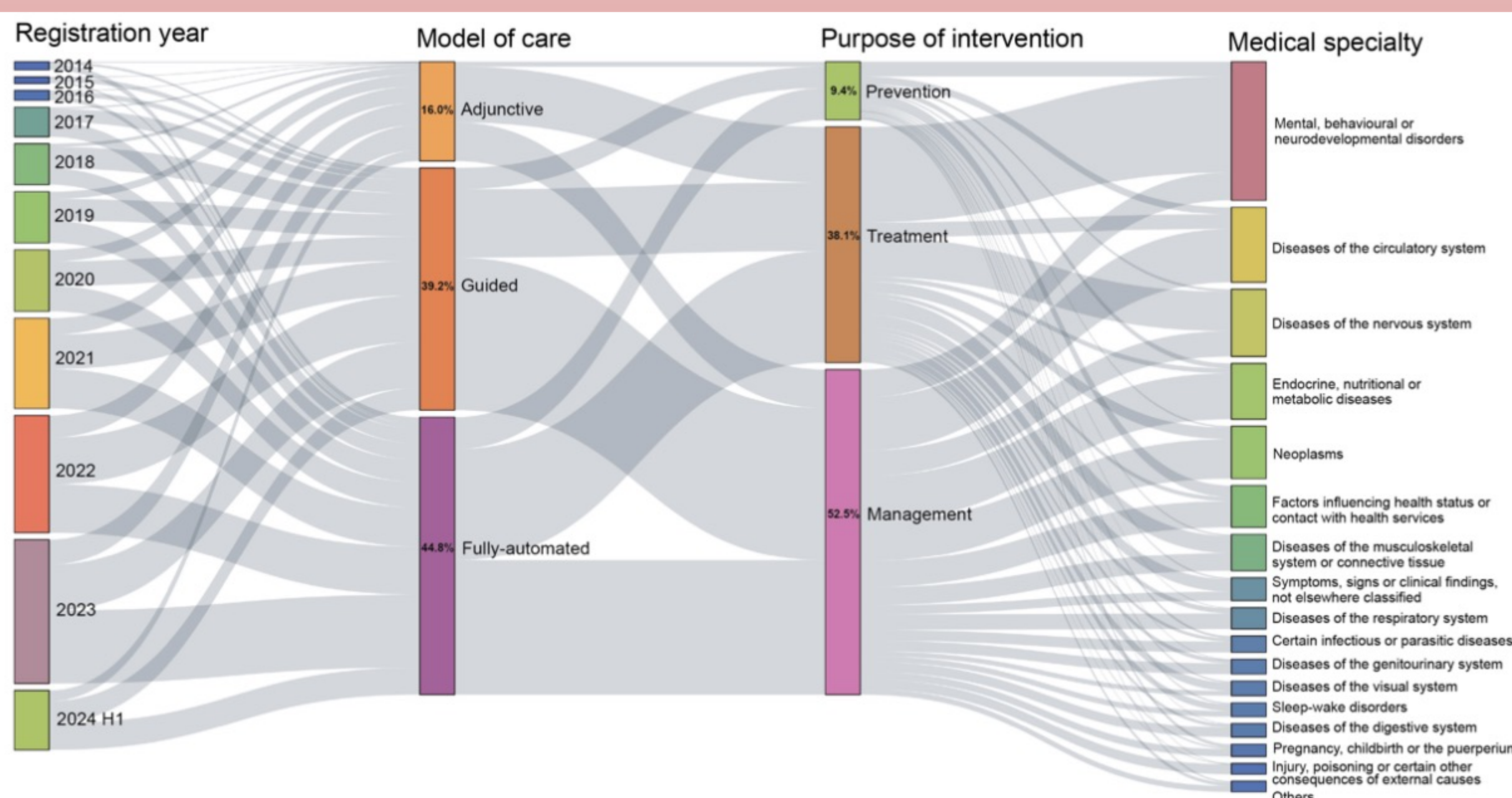


Figure 1. Characteristics of China-based DTx clinical trial

Research gate follow:



Email: xujin@hsc.pku.edu.cn