

Progress Summary on Controlled Human Infection Model for HCV Vaccine Development

T. Jake Liang, M.D.

National Institutes of Health

Bethesda, MD USA



CHIMP



CHIM

Controlled Human Infection Model (CHIM)



Smallpox
(Edward Jenner, 1796)



Yellow fever
(Walter Reed, 1900)



Cholera



Malaria



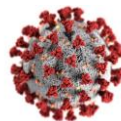
Influenza



Dengue

➤ >25 CHIM's in human application

➤ Including COVID-19



Courtesy of Annette Rid, NIH

Controlled Human Infection Model: Opportunity for HCV Vaccine Development

- NIH Workshop: 3/21/2021

N ENGL J MED 385;13 NEJM.ORG SEPTEMBER 23, 2021

SOUNDING BOARD

Controlled Human Infection Model — Fast Track to HCV Vaccine?

T. Jake Liang, M.D., Jordan J. Feld, M.D., Andrea L. Cox, M.D., Ph.D., and Charles M. Rice, Ph.D.

- Toronto Workshop: 6/9-10/2022

Controlled Human Infection Model: Rationale

- Accelerate early vaccine development
 - De-risk vaccine candidate selection; early efficacy & safety before large late phase trials
 - Reduce cost
- Inform vaccine development and design
 - Detailed immunological and virological studies and clinical correlates
- Assess promising vaccine candidates
 - Possible pathway to regulatory approval
 - More infection cases to determine efficacy than a traditional field trial for vaccine efficacy



Controlled Human Infection Model: A Systematic Approach

- Clinical parameters:
 - DAA response rate; long-term risk
- Ethical considerations:
 - Bioethicists: social value & potential risk
- Regulatory agencies:
 - US FDA and Health Canada
- Challenge inoculum: sources
- Clinical trial design: various stages



15 August 2023

Volume 77

Supplement 3



Clinical Infectious Diseases

Controlled Human Infection Model for HCV Vaccine Development



Editors: T. Jake Liang, Jordan Feld,
Naglaa Shoukry, David Thomas

https://academic.oup.com/cid/issue/77/Supplement_3?browseBy=volume

OXFORD
UNIVERSITY PRESS

academic.oup.com/cid

A Supplement to *Clinical Infectious Diseases*

Virtual Symposium on Controlled Human Infection Model for HCV Vaccine Development

Organizers: T. Jake Liang, Jordan Feld, Naglaa Shoukry, David Thomas &
Coalition for Global Hepatitis Elimination

- Ethics of HCV CHIM: Charles Wiejer, Western Univ
- Volunteering for HCV CHIM: Participant Perspectives: Jake Ebert, 1DaySooner
- Panel Discussion and Q&A #1
- DAA treatment for acute and recent HCV infection: Susanna Naggie, Duke
- Long-term consequences of resolved acute HCV infection: David Thomas, Johns Hopkins
- Panel Discussion and Q&A #2
- Break
- Challenge Inoculum for HCV CHIM: Raymond Chung, MGH
- HCV CHIM clinical trial design: Jordan Feld; Univ of Toronto
- Immunological monitoring in HCV CHIM: Naglaa Shoukry, Univ of Montreal
- Panel Discussion and Q&A #3 (poll)