PCORI-Funded Hydroxychloroquine Registry and Trial
Healthcare Worker Exposure Response and Outcomes of Hydroxychloroquine Research Project (HERO)
Welcome

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Today’s Discussion

1. Introductions
2. HERO Overview
3. HERO Registry
4. Next Steps
5. Dialogue
To ask a question, raise your hand by clicking the hand icon. The organizer will unmute your microphone.

OR

Type your questions in the question box.
Introductions
Healthcare Worker Exposure Response and Outcomes of Hydroxychloroquine Research Project (HERO)
HERO Large Research Project: Significance

- Ongoing international concerns of risks to healthcare workers (HCW)
  - Reported rates of HCW conversion to COVID-19 positive status ~20%
  - Need to protect frontline HCW from clinical infection or becoming transmission vectors
  - High risk HCW (e.g., those in intensive care unit at time of intubation or resuscitation) when larger amounts of aerosolized virus present

- No existing prophylactic therapy for COVID-19

- Complements ongoing research efforts from other US and international funders (e.g., post-exposure prophylaxis)

- PCORI has the opportunity to produce and promote actionable evidence in response to the emerging public health crisis
Healthcare Worker Exposure Response and Outcomes (HERO) Registry and Trial

• PCORnet infrastructure will enable the rapid establishment of a large-scale registry and randomized controlled trial
  • Prime awardee Duke Clinical Research Institute (DCRI) serves as PCORnet Coordinating Center

• Guiding Principles:
  • Integrates fully with HCW lives to minimize burden and disruptions to workflow
  • Super rapid enrollment and reporting
  • Regulatory compliant and ethically sound

• Targeted start date for research project: Early April
  • Registry opened April 10
  • Target start date for trial: Late April
Trial Design

• Rapid, large registry of engaged healthcare workers
  • To facilitate enrollment in HERO-HCQ and future trials
  • To optimize and manage enrollment to ensure diversity and inclusion

• Ask healthcare workers preferences to be in prophylaxis trial or future studies

• As healthcare systems onboard, offer randomization to healthcare workers and rapid enrollment into clinical trial at healthcare system site
  • Confirm healthcare worker status and randomize onsite
  • Complete enrollment within 4 weeks

• Provide one-month drug supply

• Weekly web-based check-ins for symptoms, exposure history

• Baseline and end of study swab-checks for viral shedding (central lab)

• Baseline and end of study serum for sero-conversion (central lab)
HERO Registry
About the HERO Registry

• The HERO Registry invites healthcare workers across the nation to join together to share their experiences and needs to address the COVID-19 pandemic

• By understanding their concerns and interests, we can rapidly generate much needed evidence to help protect them—their health and well-being

• The HERO Registry is at the ready to engage participants in rapid research for potential protective therapies (e.g. hydroxychloroquine, vaccines, etc.)

“We’re calling on all healthcare workers to share their perspectives and expertise so that we can understand how COVID-19 is affecting them in real time and over time.”

Emily O’Brien, PhD, principal investigator, HERO Registry, Assistant Professor in Duke’s Department of Population Health Sciences
Who should join?

• Anyone who works in a setting where people receive health care
  ▪ A U.S. healthcare worker of any profession
  ▪ ≥ 18 years old

• Enrollment is free and takes only a few minutes

• Healthcare workers can participate as much or as little as they like
HERO Invites Healthcare Workers to Fight COVID-19 Together

The Healthcare Worker Exposure Response & Outcomes (HERO) Registry is a large, national clinical research community. It invites healthcare workers across America to share clinical and life experiences to understand the perspectives and problems they face on the COVID-19 pandemic front lines.

HERO Registry participants could have the opportunity to participate in future research studies to improve our understanding of COVID-19 and beyond, generating evidence to help keep healthcare workers safe and healthy. The first study, the HERO-HCO Trial, will invite 15,000 healthcare workers from the registry to evaluate whether hydroxychloroquine can prevent COVID-19 infections.

Who can Join?

The HERO Registry is open to all healthcare workers, including nurses, therapists, physicians, emergency responders, food service workers, environmental service workers, interpreters, transporters — anyone who works in a setting where people receive health care.

To join, participants must be:

- A U.S. healthcare worker in any profession
- ≥ 18 years old

You can use a work email address, gmail address, or another email address to sign up.

JOIN
What’s next?

• The HERO Registry will engage its community in future research, such as an upcoming large clinical trial of hydroxychloroquine in healthcare workers

• HERO-HCQ is a randomized clinical trial of approximately 15,000 HERO Registry participants. It will evaluate whether hydroxychloroquine (brand name Plaquenil®) is effective in preventing COVID-19 infection

• The HERO Registry will help speed HERO-HCQ and other clinical studies that address unmet needs for healthcare workers
We invite healthcare workers to unite in a mission – the HERO Registry – and join in a national response to COVID-19.

The HERO Registry will facilitate rapid-cycle response research, such as the upcoming HERO-HCQ trial of hydroxychloroquine.

Together, healthcare workers can ENGAGE to help find the answers that will PROTECT and IMPROVE the health and well-being of America’s front line.

Meet The Moment with Momentum & Help Spread The Word
HERO Program Promotional Toolkit at
https://heroesresearch.org/promotional-toolkit/

- HERO PPT overview
- Press release template
- Logo | Banner | PPT Template
- Poster & Flyer
- Social media content
- Sample news story
- FAQ
- Hero-to-Hero “join me” letter

For questions about promotional materials, contact Jenny Cook at jennifer.cook@duke.edu

For questions about the HERO Registry or HERO-HCQ trial, contact Hero-Research@duke.edu
Uniting our healthcare community to protect the health and well-being of America’s frontline workers
Next Steps

• PCORI will continue to engage national stakeholders over the course of April
• Recruitment for the HERO Registry will be ongoing
• HERO Trial will begin at the end of April
• The trial will proceed for several months
• Study results will be disseminated widely, including to participants
Additional Information

- HERO website: https://heroesresearch.org
- HERO Twitter account: https://twitter.com/HeroesResearch
Questions and Comments?
Thank you!