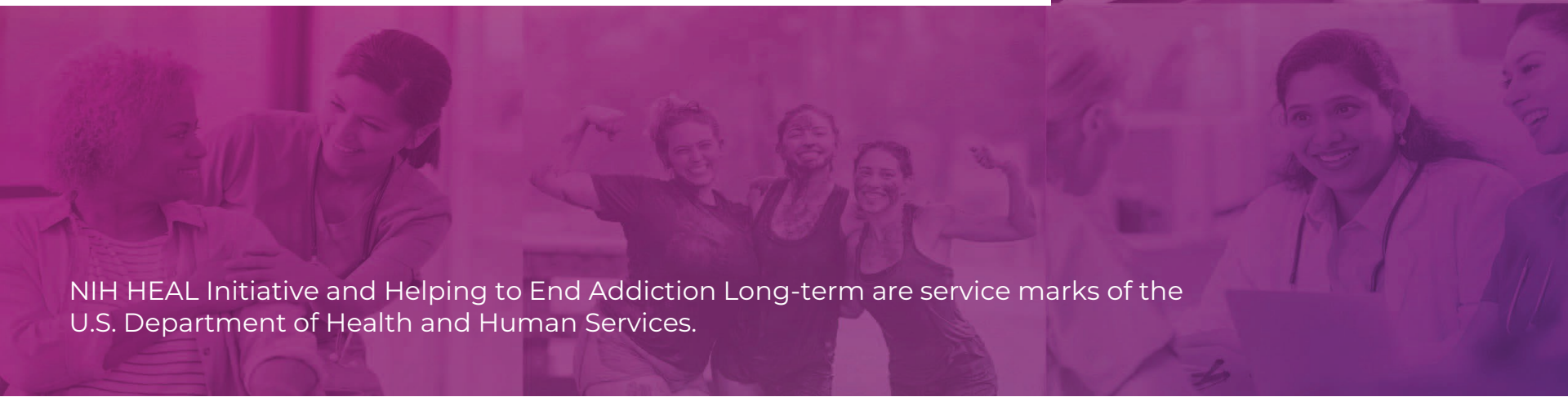
NIH HEAL INITIATIVE

BACPAC Back Pain Consortium

COVID-related challenges: Tech site experiences



Clinical Research in the COVID Era: UC San Francisco Experience

- Novel imaging of endplate biomarkers in chronic low back pain (Fields/Krug)
  - Cross-sectional MRI study of cLBP patients

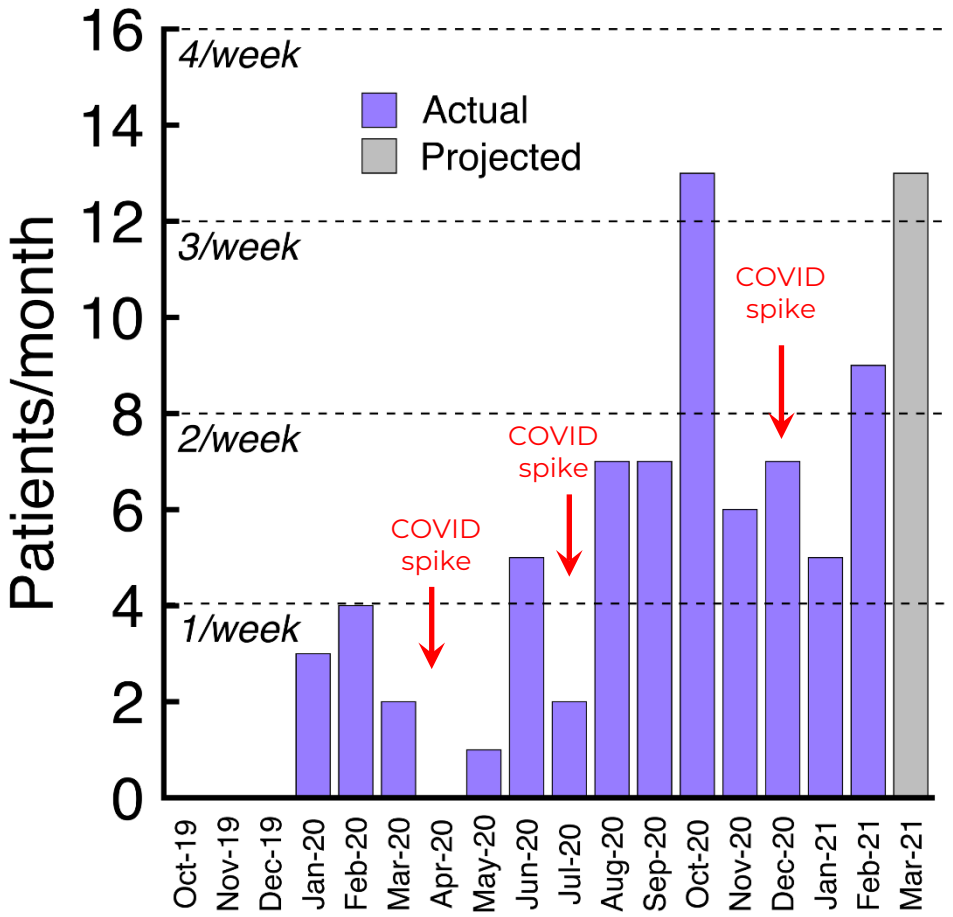
Changes to research protocols

- Changes to in-person clinical research
  - Phone screening for current/recent symptoms
    - All recruitment activities are conducted remotely instead of in-clinic
  - Social distancing and reduced personnel density
  - MRI cleaning in between patients

- Changes to non-essential basic research: all remote
  - New software required for personal computers
  - Increased time required for computationally intensive operations

Recruitment inconsistencies

- Lower recruitment following local spikes in COVID case rates
  - State-mandated shelter-in-place orders
  - Reduced clinical volume
  - Patients concerned about visiting medical center
- Result = inconsistency
  - Creates irregular workflows ("whiplash effect")
  - Scheduling difficulties



Challenges/solutions

- Lower clinic volume/reduced enrollment
    - CTSI EMR query and email/letter service
        - >50% drop in response rate compared to pre-COVID (7.6% response rate vs. 18% response rate)

- Safety concerns about using public transit
    - ~~Provide private transportation vouchers, e.g. Uber/LYFT~~

- Remote work = fewer patients commuting to San Francisco

- Remote learning = parents unable to leave home during the day

- Remote work and remote learning has made collaboration and communication between members of the research team difficult
    - Slack/Zoom/Teams (imperfect)

- Inventory shortages for critical supplies (cryovials, conicals)

Pre-clinical Translation Research in the COVID Era: University of Utah Experience

- MR-guided Focused Ultrasound Neuromodulation of the Dorsal Root Ganglion for the Mitigation of Low Back Pain
  - Large animal pain model – swine neuritis neuropathic pain model
  - Multi-disciplinary (Engineering, MR expertise, neurophysiology, neurology, pain medicine, spine intervention)

UH2: Pre-clinical Translation

- Challenges
  - Scheduling (2-4 mon- now 6 mon in advance)
    - Experts, vet staff, MRI scanner availability
    - Limitations on when MRI and EEG/SEP experiments could be performed (limited vet staff)
  - Personnel restrictions
    - No undergraduate or graduate students from March until December
    - University hiring freeze
    - Multiple COVID exposures led to limitations of experts or vet staff available due to quarantine

UH2: Pre-clinical Translation

- Challenges
  - Animal restrictions
    - Complete moratorium of animal experiments –waiver to complete animal studies for those animals that were already in house (March – June)
    - Limitations on number of animals we could bring in at any one time after moratorium expired

UH2: Pre-clinical Translation

- Experiments
  - Limited number of investigators (2-3)
  - Closely enforced 6 feet separation
    - Challenging for surgeries
    - Participating in animal behavior testing (QST)
  - MRI-guided focused ultrasound procedures require different expertise
    - Engineers, FUS, MRI, clinical
    - Lab manager
    - Vet staff
  - EEG/SEP recording require expertise in neurophysiology, clinical neurology and pain management
    - Lab manager
    - Vet Staff

UH2: Pre-clinical Translation

- Delayed experiments
- Delayed data acquisition
  - Manuscripts
  - Preliminary data for future grants
- Delayed transition to UH3

Discussion: common challenges

- Revisions to research protocols to accomplish research goals/objectives under COVID constraints
- Scheduling of in-person research activities
- Unforeseen changes to workflow and increased time associated with performing data processing/analysis remotely