COVID-related challenges: Tech site experiences

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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

![Bar chart showing patients/month from Oct-19 to Mar-21 with COVID spikes marked]
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)

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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