Treatment interruption studies during COVID-19

Community HIV Cure Workshop - CROI 2021

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i-Base.info and RIO study
COVID-19 and research

- Pandemic – unexpected
- Closing international borders and travel.
- Government pay citizens.
- 115 million cases and >2.5 million deaths
- Borrowing billions/trillions of dollars.
- Availability of multiple vaccines with >90% efficacy within a year.
COVID-19 and research

• Impact on research in all countries.
  - Diverted resources (to COVID) – clinics, laboratories, doctors, researchers, test kits etc
  - Cancelled operations and treatment.
  - Safety concerns – increased risk from more travelling, higher risk at clinics, interventions (ATIs)
Cure studies and ATIs

- Special challenges from cure research with ATIs – maybe many months.
- Issues of safety and risk were not clearly defined and only just emerging.
- Community input contributed to decisions to stop / pause / start studies.
- Decisions needed to allow for change: week 1 safe, week 2 lockdown.
ATIs and local changes

Week 1: COVID rates low (for several wks)

Week 2: safe to interrupt ART (ATI)

Week 3: local COVID rates rebound (2nd wave):

Participants are now at increased COVID risk, ART is strongly recommended, more strict isolation, impact on QoL, anxiety and actual risk, study results lost.
Limited data

- Transmission risks: participants and family: masks? distancing? Hospital setting? Best prevention?
- Impact of HIV, especially off ART.
- Other COVID risks.
- Duration of COVID-19: months vs years?
Two papers


Operationalizing HIV cure-related trials with analytic treatment interruptions during the SARS-CoV-2 pandemic: A collaborative approach. Michael Peluso et al.

Principles – importance of cure research and study question.
- harm reductions approach and tracking research

Informed consent – to include COVID directly, including emerging risks, re-consent etc.

Exclusion criteria – add higher COVID risks? Age >65, serious comorbidities including diabetes, CVD, obesity? Smoking/vaping?
Race, occupation, housing not included.

Study changes – telemedicine, home bloods and fewer, masks, taxi’s etc.
Operationalizing HIV cure-related trials with analytic treatment interruptions during the SARS-CoV-2 pandemic: A collaborative approach. Michael Peluso et al.

**SARS testing** – free, baseline, before ATI, during, on request: positive result means restart ART or individualise? Opt-out permitted?

**Local COVID?** – to include plan for worsening COVID incidence.

**Social impact** – chance to track impact on participant needs, especially differences by population, sex, race/ethnicity, trans, older etc

**Limitations** – by city/region/hospital; changing technology (testing); by population etc

• **Ethics, risks and practical factors** before re-opening HIV cure clinical trials – context of RIO study.

• **Importance of cure research** – when some regions had controlled COVID19: but ATIs > 6 months, 12 months

• **Individualise decision** – based on both COVID and study details.

• **Minimise participant risk** – of catching SARS-CoV-2 from increased visits, increased inflammation, worse COVID outcomes, worse ATI outcomes, access to ART supply.
Fidler et al. 2


- **Risk assessment summary:**
  - Limit high risk groups in entry criteria.
  - Expand access to testing before and during ATI, early restart ART if COVID symptoms and confirmed PCR.
  - Limit clinic visits, home sampling.
  - Flexibility to local changes.
  - Updated and revised patient information and consent.
  - Proactive use of vaccines when available, inclusion with study?

Add to entry criteria?
Vaccine update

- Vaccines and roll out significantly changes risk.
- Will ATI studies require vaccine cover?
- Define minimum cover: one dose?
- Changing incidence of variants.
Conclusion

• HIV researchers responded rapidly to new changes from COVID-19
• Continued commitment to cure research.
• Prioritised participant safety.
• Restarting studies now being planned including RIO: i-base.info/rio
Thanks

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