

# Impact of COVID-19 on Site Research

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HPTN annual meeting  
Wednesday, June 8<sup>th</sup> 2022

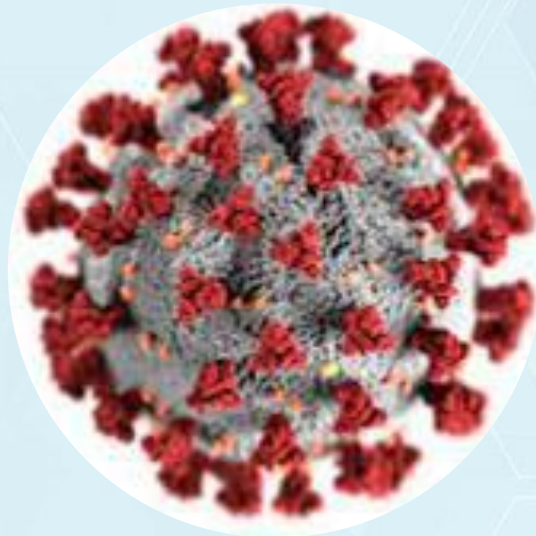


**HPTN**  
HIV Prevention  
Trials Network

**ANNUAL MEETING**  
2022

# 532,000,000


Number of COVID-19 cases globally as at 05 June 2022  
6,300,000 deaths





# Impact on Service Delivery

The ramifications of the COVID-19 pandemic extended beyond us as research sites and the HPTN as a network.



# Response to COVID-19 in Zimbabwe

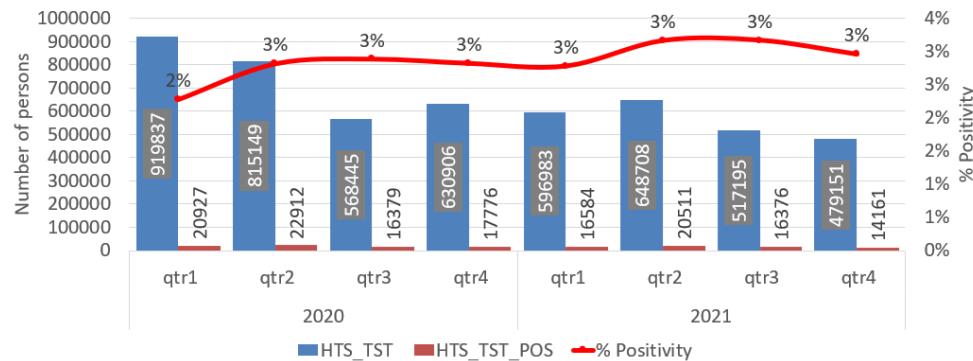
- Centralised national COVID-19 response coordinated by the Government of Zimbabwe - set policy and guidelines.
- Resources and finances redirected to address the escalating COVID-19 cases.
- Lockdowns restricted movement and forced people to spend more time indoors - limited access to health facilities.
- Interruption of essential health services – maternity, sexual reproductive health, HIV and TB services, among others.
- Facilities overwhelmed more with wave 1 and 2 - pre-vaccination.
- Vaccination started Feb 2021 - using exclusively Vero cell vaccines .



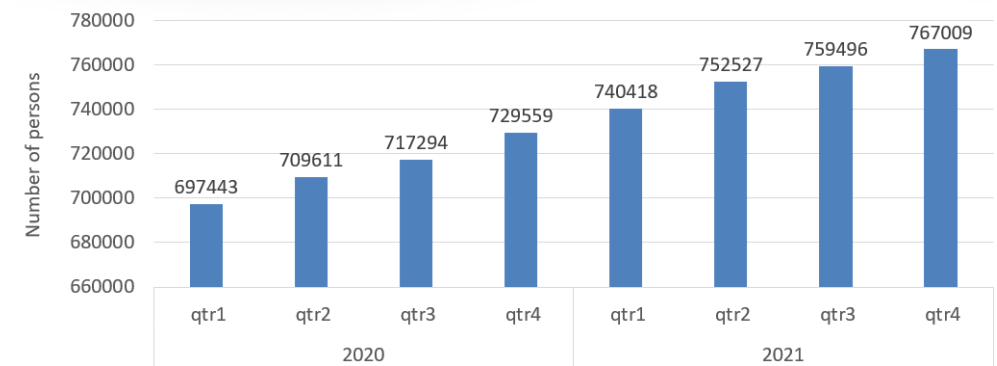
# Impact of pandemic on HIV care in Kenya

PEPFAR CDC 1200 clinics serving ~60% PLHIV in care

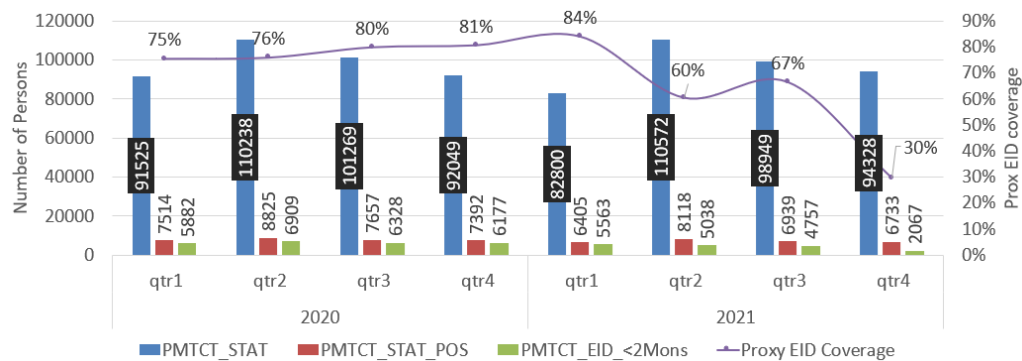
## HIV testing declined



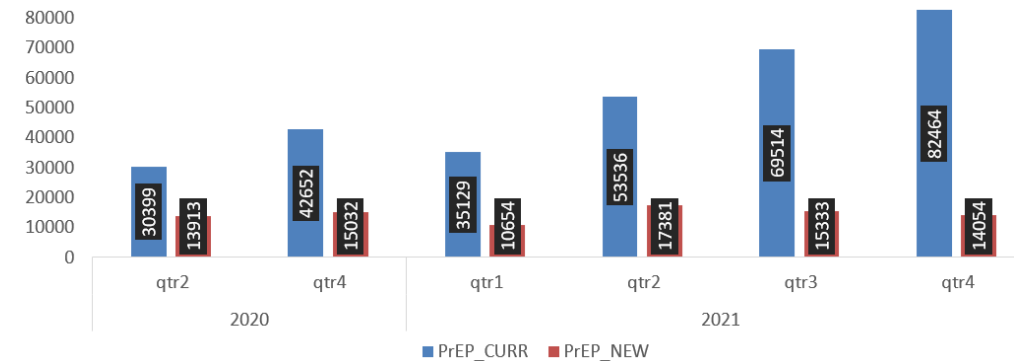
## PLHIV active on ART



## PMTCT rebound, EID decline (commodities)



## PrEP program grew



Acknowledgement: Taraz Samandari

# Kenyan health care during the pandemic

## *Kenya's Health Workers, Unprotected and Falling Ill, Walk Off Job*

Hundreds of health workers have tested positive and some have died, while health facilities are overwhelmed and government officials are accused of stealing funds for medical supplies.



## Covid-19 crisis: Covid-19 hits Kenya's frontline hard as rattled medics threaten to go on strike

15, Nov 2020



CAPITAL HEALTH

## Kenyan Doctors Threaten To Boycott Work For Lack Of PPEs

By DAVIS AYEKA  
Published 17 hours ago



# 2020

INSIDE DEVELOPMENT | HIV/AIDS

# 2021

## Supplies run low as Kenya and US standoff over HIV drugs

By Sara Jerving // 21 April 2021

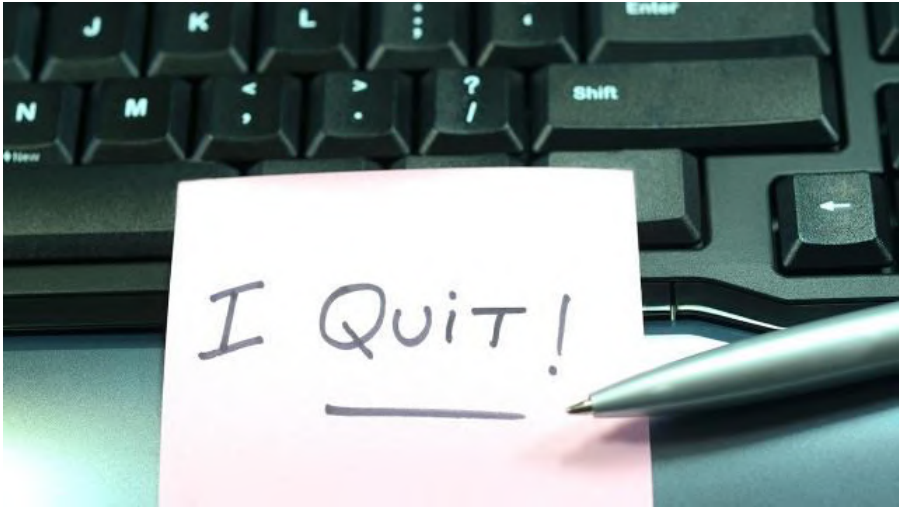
# Health service delivery in Malawi

- Missed refills/doses of family planning and medications for chronic conditions.
- Increased burden of teenage pregnancies at health facilities.
- Supply chain disruptions.
- Loss of frontline health care workers (to death or burnout).
- Early rumors about facilities ‘injecting’ COVID
  - Temporary reduction of service uptake (fear of coming to health facilities).
- Blossoming of medicine and pharmaceutical shops in the country
  - People were afraid of the hospital.
- Loss of jobs led to psychosocial challenges and other health issues.

# Impact of COVID-19 in the US

There were many challenges for the US sites as is the case across the world.

- Before COVID vaccines were available - mask and PPE shortages, staff shortages and hiring demands, need for increased building/office space and staff.
- Mid 2021 to early 2022 – staff shortages due to “The great resignation” in the US.



Acknowledgement: Sri Edupuganti

### Top reasons why U.S. workers left a job in 2021: Low pay, no advancement opportunities

Among those who quit a job at any point in 2021, % saying each was a \_\_\_ why they did so

	Major reason	Minor reason	Net
Pay was too low	37	26	63
No opportunities for advancement	33	30	63
Felt disrespected at work	35	21	57
Because of child care issues*	24	24	48
Not enough flexibility to choose when to put in hours	24	21	45
Benefits weren't good**	23	20	43
Wanted to relocate to a different area	22	13	35
Working too many hours	20	19	39
Working too few hours	16	14	30
Employer required a COVID-19 vaccine	8	10	18

\*Among those with children younger than 18 living in the household.  
 \*\*Question provided health insurance and paid time off as examples.  
 Note: Figures may not add to subtotals due to rounding.  
 Source: Survey of U.S. adults conducted Feb. 7-13, 2022.





# Impact on Research

The early days of the pandemic were extremely difficult for participants and site staff. The pandemic affected all facets of research, and our personal lives.

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## Regulatory considerations

- Expedited COVID research reviews
  - a slow-down/ backlog in review of non-COVID research
- Slower than expected startup:
  - Long pre-activation periods
  - Cost implications
  - Challenges to staff morale.

## Supply chain

- Supply chain disruptions
  - Clinic and laboratory supply outages

## Human resource

- Increased workload for staff
- Sick leave, burnout

## Financial implications

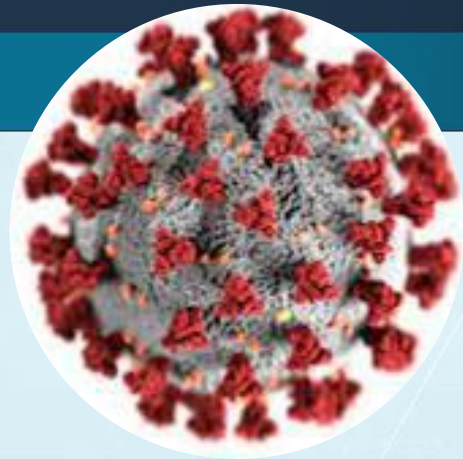
- Increased funding required for:
  - PPE
  - Testing
  - Other preventative measures



- **Missed visits** due to:
  - Study pauses
  - Travel restrictions
  - Fear of exposure to the virus during travel
- **Challenges with scheduling of participant visits** due to them being in quarantine/ isolation
- **Protocol deviations:**
  - Critical evaluations were performed outside study visit window
  - Missed visits
  - Increased reporting burden to the IRBs
- **Lost to follow up:**
  - Some participants decided to withdraw from studies to reduce travel and contact with many people..
- Decongestion of public vehicles created **restrictions related to participant transport and visit scheduling.**

# Mitigatory Strategies

Integrating multisectoral engagement was an integral pillar of responses to strengthen sites' ability to mitigate these negative consequences.



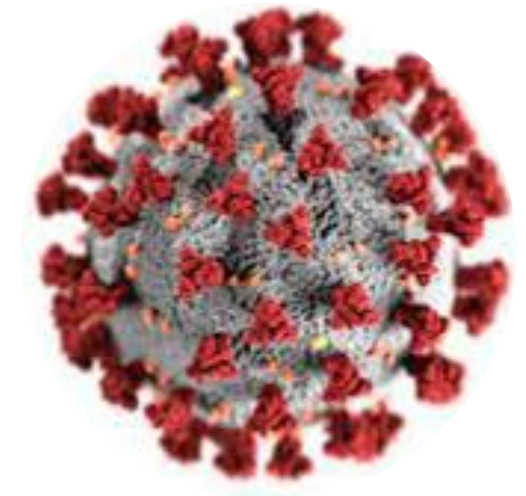
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# Risk mitigation strategies

- Establishment of COVID task forces and infection prevention and control (IPC) SOPs.
- Measures implemented include:
  - Universal IPC measures.
  - Splitting of staff into two teams - alternated working from home in the early phase of the pandemic.
  - Symptom screening of staff, study participants and visitors before entry into site buildings.
  - SARS-COV-2 antigen tests conducted on all participants at port of entry to clinic.
  - COVID isolation tents erected outside the main clinic for symptomatic participants.
  - Some laboratories set up COVID PCR testing early in the epidemic - testing of staff and participants ensued.
  - Mandatory COVID vaccination policies were instituted at certain African sites.
  - Rapid antigen testing kits provided to staff for home testing.
  - Provision of starter-pack if symptomatic (empiric antibiotics, corticosteroids, supplements).

# Risk mitigation strategies

- Reinforced relationships with the local ethics committee, CABs, partner organizations and other stakeholders.
- Well established communication links amongst staff allowed for efficient work from home where possible.
- Health information, communication and education materials.
- Conducive working environment.
- Mental health and counselling services for:
  - IPV due to quarantine, loss of income
  - Depression
  - Anxiety
  - Bereavement
- Provision of transport for participants.
- IRB-approved food hampers.



# Facilities, equipment and vehicles



## **Rearranged clinic space to enhance physical distancing**

Demarcations at designated points  
i.e reception and eating area

Waiting rooms increased with  
modified seating arrangement



## **All equipment is disinfected on a daily basis**

Use 70% alcohol-based  
disinfectant

Staff routinely trained and  
reminded on adherence to this  
disinfection practice



## **All site vehicles are disinfected at least twice daily**

Use of a knapsack sprayer with  
disinfectant

70% alcohol-based hand  
sanitizer is available in all  
vehicles

# Sample access letter - Zimbabwe

- Access letters written for staff and participants
- Participant letter:
  - Input from CAB and Zimbabwe Republic Police representative
  - Simple language i.e Doctor-in-charge vs CRS Leader or Principal Investigator
- Institutional letterhead

20 May 2020

**TO WHOM IT MAY CONCERN:**

**RE: CLINIC PATIENT/CLIENT CLEARANCE LETTER: ZENGEZA 3 CLINIC, CHITUNGWIZA CITY HEALTH DEPARTMENT**

Following the lock down declared by His Excellency the President of the Republic of Zimbabwe, your attention is brought to the fact that the Health Service, being an essential service, be expected to continue operating during the lock down period and beyond.

We are a health research organisation working in collaboration with the Chitungwiza City Health Department and the Ministry of Health and Child Care to provide essential health services in Chitungwiza. During the lockdown, we continue to provide essential health services to our patients/clients who need uninterrupted medical attention. In this regard please allow safe passage to the following client who will be travelling to and from Zengeza 3 clinic, Chitungwiza for her clinic visits during the 3-month period from 20 May 2020 to 20 August 2020.

**Full Name(s):** .....

**Designation** : Patient/Clinic Client

**ID No.** :  
.....

**Station:** Zengeza 3 Clinic, CHITUNGWIZA

Each patient/client will have on their person a clinic appointment card and her national ID. The main contacts for emergency issues are the Doctor-in-Charge Dr. Nyaradzo M. Mgodzi 0772 264 616; Sister-in-Charge Mrs Greccenia Ndhlovu 0772 283 635 and Community Advisory Board Member, [REDACTED] Police Station – [REDACTED]. Do not hesitate to contact the afore mentioned should you require further information.

Yours faithfully,

.....  
**Dr Nyaradzo Mgodzi**  
Doctor-in-Charge  
Zengeza 3 Clinic, Chitungwiza

.....  
[REDACTED]  
Community Advisory Board Member  
[REDACTED] Police Station



# Positive outcomes from the pandemic

- Major contribution to management of the epidemic at community, national and international level.
- Some laboratories assisted with community testing.
- Sites assisted with implementation of COVID vaccine role out.
- Site leadership in national COVID-19 taskforces.
- Innovations such as multi-month dispensing for ART refills from 3 to 6 months for clients stable on ART.
- The pandemic exposed gaps in the continuum of care which then led to the development of:
  - The oxygen roadmap - oxygen plants in Malawi and Zimbabwe.
  - Improved primary and secondary care through provision of equipment and capacitating human resource.
  - Review of infection prevention measures leading to improved safety measures that will be sustained beyond the acute COVID crisis.



# Success Story

## HPTN 084

With news of the rapidly spreading SARS-CoV-2 virus in Kenya and South Africa, HPTN 084 leadership immediately engaged sites for mitigatory strategies which would ensure participant/staff safety and promote operational efficiency.



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# Strong, proactive leadership

HPTN 084 protocol team leadership communicated frequently with sites.

17 March 2020

*In these uncertain and potentially scary times for both staff and participants, we are making proactive recommendations to all sites on recruitment and follow-up visits. Some guidance has already been issued by the Division of AIDS and the HPTN in the past 24 hours. We provide additional protocol-specific guidance here. These recommendations are made with the goal of ensuring both participant and staff safety and respecting the public health recommendations to minimize disease transmission.*

Screening and enrolment paused.

Clear guidance on participants in follow up.

28 May 2020

The HPTN allowed enrollment in HPTN 084 to resume as soon as it was safe to do so.

Developed to identify and track COVID-19 related data issues with respect to study conduct.

- Guidelines established to record study assessments and give clear instructions on CRF completion for
  - Missed visits
  - Phone visits
  - Partial visits
  - Complete visits
- Study product considerations.
- Protocol deviation reporting requirements.

- Wide visit windows - spaced visits out to 12 weeks instead of 8.
- Rotating staff in shifts to minimize contact.
- Worked with PAB and LC to ensure adequate supplies.
- Assured sites on securing funding for the Open Label Extension.
- Missed visits due to COVID were reimbursable to the site via the Missed Visit CRF.

# Against all odds



**Team developed study-specific risk mitigation plans**



Helped to identify, assess, respond to, monitor, and report risks



Accrual target met



Good retention



Adherence to visits and product



Data quality maintained

# Recommendations

Assume	overall responsibility to ensure that all necessary preventive and protective measures are taken to minimize morbidity and mortality.
Train	on infection prevention and control, give information, and provide clear instructions.
Provide	adequate IPC measures and PPE supplies (masks, gloves, goggles, gowns, hand sanitizer, soap and water, cleaning supplies) in sufficient quantities.
Advise	workers and participants on diligent self-assessment, symptom reporting and staying home when ill.
Maintain	a healthy working environment with appropriate working hours and breaks, be innovative and think outside the box.
Counsel	on mental health issues and offer resources for psychosocial support.

# Summary

We lost some battles, but we are winning  
the war

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- Sites were operational throughout the epidemic.
- In anticipation of country lockdowns, sites front-loaded participant visits for participants with open windows.
- Some scheduled visits were missed during the early days.
- Skeleton staff available 24/7 to address safety concerns.
- It was important to continue HIV research:
  - Developed robust mitigatory strategies
  - Aided by multisectoral engagement
  - Measures put in place to minimise transmission risk and optimise efficiency
  - Resumed study related procedures.
- After the initial few months of disruption to operations, we quickly started functioning well in the new normal.



# We lost loved ones, but we forge ahead



**James Hakim**



**Gita Ramjee**



# Thank you



[nmgodi@uz-ctrc.org](mailto:nmgodi@uz-ctrc.org)



/HIVptn

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- The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.