JULY 25, 2025

REVIVE Global Newsletter

From the REVIVE Trial Steering Committee

The REVIVE trial has been actively recruiting participants for just over two years now, including the vanguard phase which included a limited number of countries. The trial has now expanded to 46 sites in 10 countries, with a further 3 countries preparing to join the trial before the end of 2025 (Kenya, Cameroon, and Ethiopia). Exciting news is that Mozambique, the tenth country, has recently opened to recruitment and enrolled their first 5 participants in the trial. We are very excited to have Mozambique contributing to the trial meaning we now have active participation from Lusophone, Francophone and Anglophone countries.

Another important milestone was on the horizon for the trial. As of 25 July 2025, a total of **3000** participants had been recruited across all sites. The trial is consistently recruiting over 200 new participants per month, meaning that we remain on course to achieve target accrual of 8000 participants before the end of 2027. This progress has only been achieved because of the collective efforts of investigators at each of the sites for which the trial leadership is extremely appreciative.

It is important to emphasize that the success of REVIVE in answering the key scientific question around azithromycin's efficacy and safety in advanced HIV disease is also dependent on the completeness and reliability of the data collected and ensuring adequate follow-up and ascertainment of relevant outcomes for all participants. We congratulate all sites on what they are achieving in relation to these key activities. We also thank investigators who have started performing verbal autopsies, a critical aspect of our work to understand causes of death among people with advanced HIV, and we will continue to roll this out across the network.

Finally, we know that many of our participants have progressed to having advanced HIV disease because of upstream challenges with ART adherence and remaining in care. Having such patients enrolling in the trial presents us with the opportunity to ensure these patients are adequately supported after they return to care and empowered with the necessary information that will enhance their long-term adherence and retention. We hope that participation in REVIVE can make a difference in their long-term engagement in HIV care, enabling them to experience the lifelong benefits of ART once re-established in care with immune recovery.

Thank you again to all in the REVIVE trial team for your hard work and commitment to the trial.

Graeme Meintjes

Chair of the REVIVE Trial Steering Committee

REVIVE Milestones

We are absolutely thrilled to share that the REVIVE trial has reached an incredible milestone of **3000** participants! We have made remarkable progress, and our 3000th participant was enrolled at Site 110 (The Aurum Institute- Klerksdorp), Dr James Craig Innes (PI), and Dr Charlotte Schutz (NL) . Only 5000 more enrollments to go to reach our target, and we have no doubt that we will achieve this before the projected date of LPFV!

Spotlight on Verbal Autopsies

The verbal autopsy (VA) component of REVIVE is being implemented in a phased approach. Sites are currently at different stages of start-up, with some already conducting VAs. The VA is integrated into the main protocol, and all sites will participate in completing VAs for all deaths that occur in REVIVE.

Important Reminders

Start-Up Requirements
• Notification to ethics committee (site dependent) • Training of staff who will conduct the VA
Medical Records
• In addition to the VA, all relevant medical records must be uploaded to the death report CRF in DFExplore • All medical records, including death certificates, must be de-identified before uploading
Adjudication
• Adjudication will proceed once sites are comfortable with completing the VA • Additional training documentation will be provided before adjudication commences • No adjudication is required from sites *until this training has taken place*

Frequently Asked Questions:

When can a verbal autopsy (VA) be completed?

VAs can be conducted from **4 weeks up to 3 years after death**. For accuracy, we encourage sites to complete VAs as close to the 4-week mark as possible.

Can a VA be conducted telephonically?

Yes. VAs may be conducted **either in person or telephonically**, depending on site feasibility and the respondent's preference.

Do we add additional symptoms from hospital/medical notes into the VA?

No. VAs must be based **solely on the respondent's account**. Medical records should be uploaded separately and must not influence the responses entered on the VA form.

What if there is no death certificate

If a **death certificate is not available or accessible**, and all reasonable efforts to obtain it have failed, it is acceptable to proceed without one.

How long does the VAs take to complete?

On average, a VA interview takes approximately **30 minutes**, though this may vary.

Do we reimburse respondents?

If a respondent travels to the site for the interview, reimbursement for transport and time should be provided in line with local regulatory guidance.

Are retrospective VAs performed?

Yes. All eligible deaths (within 3 years) should have a VA completed, provided this is permitted by local ethical approvals.

How do we handle a non-cooperative respondent?

Respect cultural sensitivities around death. Clearly and respectfully explain the purpose of the VA. If the respondent declines, their decision must be respected. Where appropriate, an alternative respondent may be approached.

Dr Keisha De Gouveia

REVIVE Project Officer

Worth the Read: Insights That Matter

Mental Health and HIV/AIDS: A Call for Integrated Care

Despite major biomedical advances in HIV treatment and prevention, the goal of ending the HIV epidemic cannot be reached without addressing the mental health needs of people living with or at risk for HIV. Research shows that mental health conditions, especially depression, anxiety, and substance use disorders, are significantly more common among these populations than in the public. These conditions contribute to higher rates of HIV acquisition and poorer health outcomes across every step of the HIV care cascade, from testing and diagnosis to treatment adherence and viral suppression.

Biologically, HIV itself may worsen mental health through chronic inflammation and immune system impacts. Socially, stigma, poverty, violence, and structural barriers exacerbate mental illness and reduce access to care. Alarmingly, most people with mental health disorders, especially in low- and middle-income countries, go undiagnosed and untreated.

However, effective mental health screening tools and evidence-based interventions already exist. Strategies such as task-shifting, stepped care, and integrating mental health services into HIV care show promise. Community-led initiatives like U=U (Undetectable = Untransmittable) also reduce stigma and psychological distress.

To truly “bend the curve” of the epidemic, mental health must be prioritized as part of HIV programs. Integrating mental healthcare into HIV services will not only improve health outcomes for individuals but also strengthen public health systems overall.

As the authors of this article remind us: **There is no health without mental health!**

Read The full article here:
https://pmc.ncbi.nlm.nih.gov/articles/PMC6635049/

Why Are People Living with HIV Still Hospitalised?

New Global Insights (2014–2023)

A major systematic review and meta-analysis published in *The Lancet HIV* reveals the leading causes of hospitalisation among people living with HIV (PLHIV) over the past decade. Drawing from 106 studies across 42 countries, this landmark paper provides the most comprehensive global picture to date, highlighting that despite progress in antiretroviral therapy (ART), hospitalisations remain common and are largely preventable.

The study found that tuberculosis (TB) continues to be the top cause of hospitalisation globally, followed by bacterial infections, malignancies, and neurological disorders. Opportunistic infections (OIs) still account for a significant portion of hospitalisations, especially in low- and middle-income countries, pointing to late ART initiation, advanced HIV disease, and gaps in early diagnosis and care.

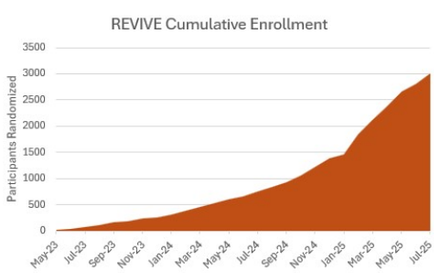
Alarmingly, nearly half of hospitalised patients presented with advanced HIV disease (CD4 <200). This reinforces the need to strengthen prevention, screening, and early treatment efforts.

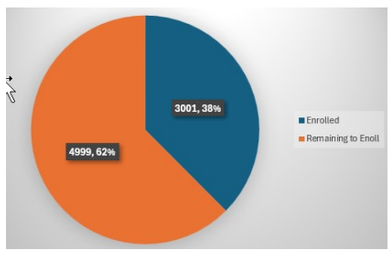
The findings make a compelling case for improving access to timely ART, optimising management of advanced HIV, and integrating TB and mental health services within HIV care.

Read The full article here:
https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(24)00347-3/fulltext

Newsletter (Page 4)

Country	Regulatory Status	Sites			Randomizations	
		Planned	Activated	Enrolling	Last 30	Total
South Africa	Approved	21	16	16	58	735
Sierra Leone	Approved	5	3	3	25	473
Uganda	Approved	5	4	4	58	711
Nigeria	Approved	11	11	11	46	549
Ivory Coast	Approved	3	3	3	7	43
Zambia	Approved	3	3	3	37	334
Malawi	Approved	3	1	1	8	49
Ghana	Approved	3	3	3	9	87
Rwanda	Approved	1	1	1	3	15
Mozambique	Approved	1	1	1	5	5
Ethiopia	Pending	4	0	0	0	0
Kenya	Pending	1	0	0	0	0
Cameroon	Pending	3	0	0	0	0
Total		**64**	**46**	**46**	**256**	**3001**





Spotlight on Excellence

Celebrating Dr. Yasmine Hardy (Ghana)

In this edition of the REVIVE newsletter, we are honoured to spotlight Dr. Yasmine Hardy, a leading force in infectious disease care, clinical research, and health system strengthening in Ghana. With over a decade of experience bridging patient care, research, and policy, Dr. Hardy exemplifies the kind of leadership that fuels the success of the REVIVE trial and drives real-world impact in Africa.

A Career Rooted in Clinical Excellence

Dr. Hardy currently serves as the Head of the Infectious Diseases Unit at Komfo Anokye Teaching Hospital (KATH), one of Ghana's foremost tertiary care institutions. Her clinical journey began with a medical degree from the School of Medical Sciences at KATH, and her career has since been shaped by global academic training, including a Diploma in Tropical Medicine and Hygiene from the London School of Hygiene & Tropical Medicine and a prestigious Arthur Ashe Endowment Fellowship at Weill Cornell Medical College in New York. She is a Fellow of the West African College of Physicians and an alumna of the HIV-Research-for-Cure Academy, hosted by the International AIDS Society at the Wits Institute in South Africa.

Leadership in Crisis: Ghana's COVID-19 Response

During the COVID-19 pandemic, Dr. Hardy emerged as a national leader. She played a pivotal role in establishing KATH's COVID-19 Treatment Centre, leading efforts to deliver critical care across the Ashanti Region and beyond. Her dedication and coordination earned her a Presidential Honour for Distinguished Service — a testament to her relentless commitment to public health during one of the most challenging periods in modern medicine.

Influencing Policy and Building Capacity

Dr. Hardy's contributions extend beyond the hospital setting. She serves on Ghana's Technical Working Group for COVID-19 Test and Treat Guidelines and has collaborated with the National AIDS Control Programme to train healthcare providers in HIV care nationwide. Her ability to move between the frontlines of care and national health policy has made her a vital bridge between evidence generation and implementation.

Driving Research: From COVID-19 to Advanced HIV and Sepsis

An active and accomplished clinical researcher, Dr. Hardy was the site Principal Investigator for Ghana's participation in the internationally acclaimed RECOVERY Trial for COVID-19 therapeutics. She now serves as the National Leader for the REVIVE Trial in Ghana, leading efforts across three trial sites focused on reducing mortality in adults with advanced HIV disease. In addition, she is a co-Principal Investigator for the STAIRS (sSA consorTium for the Advancement of Innovative Research and Care in Sepsis) initiative — a research platform building much-needed awareness and capacity in the field of sepsis across sub-Saharan Africa.

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A Voice in Global Conversations

Dr. Hardy's influence is also felt on the international stage. She has presented at numerous HIV conferences and served as a scholarship reviewer for the International AIDS Society Conferences in 2022 and 2023 — helping shape the next generation of global health leaders.

Grounded in Faith and Service

Beyond her professional accomplishments, Dr. Hardy is deeply committed to community outreach and spiritual service. She leads the medical division of COEVAHCOP (Community Evangelism and Health Conservation Programme), delivering free medical care, health education, and the Gospel to underserved communities in Ghana.

A Catalyst for Change

Dr. Yasmine Hardy brings to the REVIVE trial a unique blend of clinical insight, research leadership, and compassionate service. Her presence ensures not only the rigorous implementation of trial protocols but also the strengthening of health systems and capacity that will benefit communities long after the trial concludes.

We celebrate her leadership and thank her for being a vital part of the REVIVE mission.

REVIVE Monthly Seminars

The UCT Project Office is proud to present the 3rd quarter webinars for 2025, addressing subjects of interest to the REVIVE study network.

28 August at 15H00 SAST (13H00 GMT)

ART Adherence - Panel Discussion

- Dr Olukemi Adekanmbi (Senior Lecturer & Academic Researcher, Department of Medicine, University of Ibadan & REVIVE National Leader—Nigeria)
- Prof Catherine Orrell (HIV Clinician and Clinical Pharmacologist—UCT),
- Prof David Meya (Infectious Disease physician and lecturer in the department of Medicine at the College of Health Sciences, Makerere University, Uganda)
- Lynn Wilkinson (Technical Consultant with the International AIDS Society and a Research Associate at the University of Cape Town)

An invitation and link to these seminars will be sent out a week in advance and we would like to encourage you to circulate this within your network.

We are inviting you to please e-mail ***reviveteam@uct.co.za*** if you would you like to do a presentation in 2025/26 including your suggested topic.

Please look out for the next edition on 25 October 2025
