ecancermedicalscience

Hypofractionated radiotherapy for localised prostate cancer: the HypoAfrica experience

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Editorial

Abstract

Sub-Saharan Africa (SSA) is projected to experience the world's greatest rise in cancer burden, with prostate cancer incidence and mortality expected to be more than double by 2040. Disparities in disease outcomes are linked to genetic predispositions and limited healthcare resources. Radiotherapy (RT), essential for cancer treatment, remains underutilised in Africa due to infrastructural deficiencies, workforce shortages and limited clinical research. The HypoAfrica consortium was established in 2021 to address these gaps, focusing specifically on hypofractionated radiotherapy (HFRT), a cost-effective treatment modality proven beneficial in European populations but understudied in African populations. This paper presents our experience establishing the HypoAfrica consortium, detailing the challenges encountered, the lessons learned and outlining future directions to improve access to high-quality radiation therapy in SSA. HypoAfrica has confronted substantial challenges, including infrastructural inadequacies, regulatory hurdles, sociocultural barriers, data quality concerns and funding limitations. It implemented strategic solutions such as improved quality assurance (QA) methods, streamlined regulatory engagement, educational outreach, rigorous training programs and innovative financing models. The consortium has significantly enhanced RT capacity and quality across African centers, introducing advanced QA technologies and standardising radiation delivery procedures. These initiatives have fostered professional development and international knowledge exchange through virtual training and global oncology forums. Looking forward, HypoAfrica aims to explore ultra-HFRT to further reduce treatment costs, refine existing HFRT protocols, expand geographically and pursue new collaborations and

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ecancer 2026, **20**:ed135
https://doi.org/10.3332/ecancer.2026.ed135

Published: 30/04/2026
Received: 23/08/2025

Publication costs for this article were supported by *ecancer* (UK Charity number 1176307).

research avenues, including immunotherapy and implementation science. This work positions HypoAfrica at the forefront of enhancing cancer care accessibility and outcomes across Africa.

Keywords: *hypofractionation, radiotherapy, prostate cancer, HypoAfrica*

Introduction

In 2008, Africa had about 681,000 new cancer cases and 512,000 deaths. By 2030, these are projected to rise to roughly 1.27 million cases and 970,000 deaths due to population growth and aging [1]. Prostate cancer (PCa) is one of the leading causes of cancer morbidity and mortality in men globally [2]. In the GLOBOCAN 2012 reports, PCa incidence and mortality rates in Africa were reported to be 23.2 and 17.0 per 100,000, respectively [3]. Furthermore, PCa is the second most diagnosed and fifth deadliest cancer in men in Sub-Saharan Africa (SSA) [4]. By 2040, incidence and mortality are projected to be more than double, with a 108% increase in incidence and a 112% increase in mortality [4]. Mortality rate in SSA is concerning as it is estimated to be approximately 2.7 times higher than the global average [5]. This disparity is associated with several factors, including genetic and non-genetic factors associated with African ancestry. Individuals of African descent exhibit a higher tumour mutational burden, more genome alterations, increased harmful mutations and specific driver genes such as NCOA2, STK19, DDX11L1, PCAT1 and SETBP1, which significantly increases the risk of presenting with aggressive disease; and the limited availability of healthcare resources such as infrastructure and manpower [5].

Radiation therapy (RT) is an important treatment modality for the cure and palliation of cancer. Most people diagnosed with cancer will require RT at some point in their treatment [6, 7]. In Africa, cancer control is hindered by inadequate access to RT due to limited infrastructure, lack of training programs, skilled workforce shortages and inadequate facilities to meet the increasing need for treatment [6–8]. Similarly, cancer research and care in the Middle East, North Africa and Türkiye region are limited by economic, social and political unrest, with low research output and inadequate cancer registries highlighting the urgent need to strengthen regional capacity [10].

Despite this necessity, there are very few cancer-related trials conducted within Africa and other low- and middle-income regions. Out of 736 documented clinical trials conducted in Africa, only 26 were cancer-related interventional trials, and only six of them were in countries with a predominantly black population [9]. Factors such as cultural considerations, trust issues, concerns about exploiting vulnerable populations and limited human capacity have been suggested as potential contributors to the apparent non-inclusion of African patients in these trials. A recent review revealed that of the total 3,455 global clinical trials for PCa, only 542 were conducted in middle-income countries and none were conducted in low-income countries [11]. Efforts to bridge this research gap in Africa are evident through initiatives like the PCa Transatlantic Consortium (CaPTC), which focuses on understanding the genetic and environmental landscape of PCa in men of African descent [12] and Men of African Descent and Carcinoma of the Prostate [13]. In parallel, the African Consortium for Cancer Clinical Trials (AC^3T), which is managed by BIO Ventures for Global Health (BVGH), profiles and promotes the readiness and capabilities of clinical trial sites in Africa with the goal of easing government agencies, academic institutions and industry organisations' identification and engagement of qualified trial sites. Despite these efforts, clinical trials on RT remain scarce in the region [10, 13].

Hypofractionated radiotherapy (HFRT) improves access by delivering higher radiation doses in fewer sessions, reducing treatment duration. HFRT reduces resource strain for health care systems and improves patient convenience, making it particularly beneficial for regions with limited medical infrastructure [14]. During the COVID-19 pandemic, HFRT was advocated for its potential to improve treatment accessibility, and it has been recommended by the Lancet Oncology Commission to improve radiation treatment access in Africa [14]. However, existing data on HFRT's safety and feasibility are predominantly derived from studies of European descent populations. One example is the conventional or hypofractionated high-dose intensity-modulated radiotherapy for PCa (CHHip) clinical trial. The CHHip Trial was a large, randomised, phase 3 non-inferiority study which enrolled 3,216 men with T1b–T3a disease, who were randomised to one of three regimens: 74 Gy in 37 fractions (conventional, 2 Gy/fraction), 60 Gy in 20 fractions (3 Gy/fraction) or 57 Gy in 19 fractions (3 Gy/fraction), all delivered with intensity-modulated radiotherapy and short-course androgen deprivation therapy. Patient-reported outcomes up to 5 years showed no significant differences in moderate or severe bowel, urinary or sexual symptoms between regimens [15]. Based on these and results from other large-scale randomised trials, moderate hypofractionation is now considered a standard of care for localised PCa [16]. In addition, for low and favourable intermediate-risk PCa, stereotactic body radiotherapy or ultra-hypofractionation, is now accepted as a standard-of-care

option, as demonstrated by the PACE-B trial, though longer-term data from broader populations remain desirable [17]. However, evidence supporting the safety and feasibility of HFRT in African populations remains limited. To address this gap, the HypoAfrica consortium was established. This partnership between U.S. and African institutions aims to conduct clinical trials on HFRT for PCa across SSA, focusing on improving treatment efficacy and acceptance in African populations.

HFRT for PCa in Africa (HypoAfrica)

In 2021, BVGH collaborated with the Global Health Catalyst (GHC) and launched the HypoAfrica consortium, which involves several renowned experts from SSA, Europe and the USA. HypoAfrica, inspired by the CHHiP clinical trials findings, was created to conduct a clinical trial aimed at assessing the feasibility and safety of HFRT for localised PCa [15] in SSA.

In the initial stages of the HypoAfrica consortium, the leaders conducted a thorough assessment of radiotherapy centers across Africa that was aimed at evaluating the readiness of these centers for participation in cancer clinical trials. The findings from this comprehensive survey were crucial in shaping the design of the trial and ensuring the ethical approval process was robust, reflecting a commitment to research that is both collaborative and ethically rigorous. The consortium's engagement through regular and ad-hoc meetings at trial sites in Tanzania, Nigeria and South Africa was pivotal in facilitating the exchange of ideas, monitoring the trial's progress and addressing any emergent challenges. This collaborative process is not only focused on evaluating the feasibility of HFRT in SSA but also on identifying and overcoming the obstacles to its wider adoption. By addressing these challenges, HypoAfrica is setting the stage for more expansive clinical trials in the region, aiming to advance the scope of cancer treatment in Africa.

Challenges and recommendations

The team encountered several challenges in implementing HypoAfrica as outlined below:

Theme	Challenge	Recommendation
1. Infrastructure and quality assurance (QA)	Disparities in equipment availability and frequent machine downtime due to technical issues were significant challenges.	The consortium prioritised infrastructure improvement initiatives and collaborated with local stakeholders to enhance QA processes [14].
2. Regulatory and ethical hurdles	Africa's regulatory landscape for clinical trials remains fragmented, leading to delays and inconsistencies in approval processes.	Leveraged knowledge from each country to facilitate approval procedures. The consortium has also advocated for streamlined regulatory frameworks by engaging in proactive dialogue with regulatory authorities.
3. Sociocultural barriers	Sociocultural factors, such as mistrust of conventional healthcare systems and misconceptions about clinical trials, present formidable obstacles to patient recruitment and engagement.	Created leaflets and patient education materials/videos to raise awareness about the benefits of clinical research and dispel myths surrounding HypoAfrica.
4. Data quality and human capacity	Ensuring data integrity and building research capacity emerged as critical priorities for the consortium.	The consortium invested in comprehensive training programs for research staff and investigators. The consortium also conducted quarterly data review meetings to guide research staff and investigators and continuously emphasise the importance of standardised data collection procedures and quality control measures.
5. Funding constraints	Limited funding posed a significant barrier to the consortium's objectives, necessitating innovative financing mechanisms and strategic partnerships.	Actively sought additional funding opportunities and leveraged existing resources to sustain its operations. Mentoring clinicians to secure other grants, especially for treatment planning and QA project was a priority for the team.

The HypoAfrica consortium's journey offers valuable insights for future RT trials in Africa. Future trials should prioritise localised solutions and engage local stakeholders to address infrastructural, regulatory and sociocultural challenges effectively. In addition, all members of the oncology team, including RT technicians, physicists and oncology nurses, should be included in the research plan to optimise patient outcomes and maximise research impact. Additionally, trials must also embrace principles of diversity, inclusivity and equity, incorporating patient and community perspectives, enhancing access for underserved populations and building local capacity to ensure sustainable improvements in cancer care. Finally, human resource development has been critical to HypoAfrica's success. Future trials should focus on providing continuous support and mentorship to cultivate a skilled workforce capable of conducting high-quality clinical research in African countries. Our consortium leverages local expertise, multidisciplinary collaboration and international partnerships to ensure that the consortium's efforts are not only globally informed but also deeply rooted in local realities, enhancing the relevance and impact.

Impact and future directions

The HypoAfrica consortium has achieved notable progress in advancing RT QA and capacity building throughout the participating sites in Africa. The consortium has improved the precision and efficiency of LINAC QA procedures by introducing innovative QA tools like radiochromic film dosimetry and the Virtual EPID Standard Phantom Audit [18]. For example, at the Ocean Road Cancer Institute, the adoption of radiochromic film dosimetry resulted in significant enhancements in QA uniformity and resource effectiveness, easing staff burdens and ensuring precise radiation dose delivery. Similarly, external audits performed at the NSIA-LUTH Cancer Center have affirmed the quality and reliability of their RT practices [19]. Furthermore, the use of the Klio (Luca Medical Systems), which is an online QA data management tool, has helped promote the uniformity of machine beam outputs across various centers, guaranteeing precise radiation dosage delivery to patients irrespective of their geographic location [20].

Our efforts in education and capacity building, such as weekly virtual meetings utilising web conferencing and specialised training sessions, have provided opportunities for professionals to build capacity in QA protocols and technical competencies. Additionally, the consortium's contributions to publications and presentations at national and international forums, including the GHC Summit, Lancet Oncology Commission on Cancer in SSA launch events in 2022, the American Association of Physicists in Medicine (AAPM) Annual Meeting, American Society for Radiation Oncology Annual Meeting and African Organisation for Research and Training in Cancer Biennial Meeting in 2023, have disseminated valuable insights and best practices, encouraging knowledge sharing and cooperation within the global oncology realm [14, 19–24]. The consortium has successfully attracted funding from the BVGH's AC^{3}T Study Pool and the AAPM Micro-grant.

In the future, the HypoAfrica project is positioned to pursue transformative avenues to expand its influence and promote cancer care in Africa. We aim to investigate the feasibility of ultra-HFRT to further alleviate the financial burden of treatment for cancer patients in Africa. We also plan to continue to refine HFRT techniques for PCa treatment, integrating cutting-edge technological developments and broadening patient cohorts to amplify treatment results. We will also seek opportunities to extend our scope to additional nations and cultivate partnerships with other research entities. In addition, the HypoAfrica team plans to lead novel initiatives such as the Alliance on Radiotherapy Implementation Science for Equity, which aims to conduct implementation science research on radiation therapy in Africa and research into immunotherapy for cancer patients in Africa.

Conclusion

The HypoAfrica consortium has emerged as a pivotal force in advancing radiotherapy research and capacity building in Africa, marking a significant milestone in the quest to address cancer care disparities on the continent. Through collaborative efforts and strategic initiatives, the consortium has made remarkable progress in enhancing RT QA, fostering knowledge exchange and empowering oncology professionals. Looking ahead, the consortium's blueprint for future trials entails prioritising localised solutions, engaging local stakeholders to address infrastructural, regulatory and sociocultural challenges effectively, and ensuring the inclusion of all members of the oncology team in research plans to optimise patient outcomes.

Conflicts of interest

The author(s) declare that they have no conflicts of interest.

Funding

This study did not receive any external funding.

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Appendix A : experts involved in the HypoAfrica consortium

Leadership

- Prof. Luca Incrocci – Erasmus Medical Center, The Netherlands
- Prof. Wil Ngwa – GHC and Johns Hopkins University School of Medicine, USA
- Dr. Katy Graef – Bioventures for Global Health

Mentors

- Prof. Saiful Huq – University of Pittsburgh, USA
- Prof. Heng Li – Harvard Medical School, USA
- Prof. Joerg Lehmann – Calvary Mater Newcastle, Australia
- Prof. Stephen Avery – University of Pennsylvania, Philadelphia, USA

Africa-based investigators

- Prof. Twalib Ngoma – Muhimbili University of Health and Allied Sciences, Tanzania
- Dr. Adedayo Joseph – NSIA-LUTH Cancer Center, Lagos University Teaching Hospital, Nigeria
- Dr. Abba Mallum – University of KwaZulu-Natal, Durban, South Africa
- Dr. Solomon Kibudde – Uganda Cancer Institute, Kampala, Uganda

Team composition

Multidisciplinary team members, including medical physicists, medical dosimetrists, radiation oncologists and data analysts, collaborate to adapt hypofractionated radiotherapy (HFRT) for African clinical settings.