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From Burden to Regulation: Why Sub-Saharan Africa Should Lead on Pragmatic Phage Therapy Implementation

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Sub-Saharan Africa cannot afford to treat access to phage therapy as a distant objective. Antimicrobial resistance (AMR) is already altering clinical treatment options, prolonging hospital stays, and increasing healthcare costs. Both WHO Africa and the Africa CDC have identified AMR as an urgent continental threat that requires concrete implementation rather than further declarations [1,2]. Zambia and its neighbouring countries should immediately initiate a regulated magistral phage-access pathway, sustained through regional cooperation.

A notable policy paradox persists. Countries with robust health financing and greater access to novel antibiotics are implementing practical phage therapy pathways more rapidly than many African systems, despite the latter facing higher AMR burdens. This disparity does not indicate that phage therapy is irrelevant to Africa; rather, it highlights a lag in governance, regulatory frameworks, and delivery planning relative to epidemiological needs.

Phages should not be considered miracle cures or substitutes for antibiotics. Instead, they serve as credible adjuncts, particularly for certain multidrug-resistant infections. Lytic phages target susceptible bacteria through mechanisms distinct from those of antibiotics, may proliferate at infection sites, and can disrupt biofilms while largely preserving the commensal microbiota due to their narrower host range [3,4]. Therefore, the most practical near-term strategy is not routine monotherapy, but rather protocolised phage–antibiotic combination therapy under stewardship and microbiological oversight.

The current evidence base is promising yet inconsistent. Experimental studies and case-based clinical reports suggest that combination approaches can broaden antibacterial coverage, delay resistance development, and improve outcomes in specific high-need contexts [5-8]. While this heterogeneity is often cited as a reason to postpone policy action, it should instead be viewed as an impetus for structured, monitored, and adaptive implementation rather than informal or ad hoc approaches.

Implementation is no longer a theoretical concept. Belgium has established patient-specific phage access via magistral preparations; Georgia maintains a long-standing therapeutic practice; and countries including France, Australia, Israel, and the United States have adopted supervised compassionate-use or expanded-access pathways [9,10]. In sub-Saharan Africa, the central issue is not the absence of precedent, but rather which model can be implemented safely, affordably, and expeditiously within local contexts.

For Zambia, Angola, Botswana, the Democratic Republic of the Congo, Malawi, Mozambique, Namibia, Tanzania, and Zimbabwe, adopting a magistral-style entry model constitutes the most feasible initial step. In this model, phage preparations are produced for individual patients based on clinician prescriptions, with each batch manufactured and released in accordance with predefined quality and oversight standards [9]. This framework enables timely access without waiting for fully commercialised product pipelines, which may take years and require substantial investment. Magistral access, therefore, serves as a bridge: robust enough to ensure patient safety, flexible for immediate implementation, and structured to support the generation of local evidence.

Regional work-sharing is essential for enabling this proposal among neighbouring SADC countries. ZaZiBoNa, the SADC collaborative medicines registration mechanism, could serve as the platform to actualise this regional initiative. ZaZiBoNa convenes national regulators to jointly assess medicine dossiers and coordinate Good Manufacturing Practice (GMP) inspections, with joint recommendations informing each country's registration decisions [11]. This structure provides a practical governance platform for harmonising technical requirements, assessment standards, and regulatory expectations across countries facing interconnected AMR challenges. Through ZaZiBoNa, a hub-and-spoke model can operationalise the magistral strategy: national spoke laboratories would conduct phage isolation and initial characterisation, while a limited number of regional hubs would perform standardised, high-complexity batch-release testing (including endotoxin, sterility, identity, and potency) and maintain curated regional phage banks. A shared regional repository would support harmonised release standards, reduce duplication of costly infrastructure, improve inter-country batch consistency, accelerate phage-to-patient matching, and strengthen response capacity as resistance profiles evolve.

To finance this sustainably, countries could establish a shared regional fund with a clear cost-sharing plan. For example, each country could pay a fixed amount plus an additional amount based on GDP and testing needs. Hubs would get paid for each

approved batch from this fund. Short-term grants could help set up the hubs initially, but ongoing costs should be covered by member payments and small service fees, with free access for key public-sector patients.

Antibiotics remain essential, and this proposal does not advocate for their replacement. However, in regions with high disease burdens, inaction while awaiting ideal solutions is not acceptable. A magistral pathway managed through ZaZiBoNa offers southern Africa a pragmatic initial step that is safe, well-regulated, affordable, and adaptable to local needs.

Declarations

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