



POSITION STATEMENT: Actions to Control Snakebite Envenoming in Sub-Saharan Africa

1. The Problem

The Global Snakebite Initiative (GSI) believes that snakebite envenoming is a neglected tropical disease that demands a sustained, coordinated global response. Snakebite disproportionately affects impoverished populations. It causes substantial morbidity, disability and disfigurement leading to stigmatization, discrimination, deprivation and mortality. It has a sudden and catastrophic impact on the lives of victims, their families and communities. Although the greatest burden is felt in tropical and sub-tropical nations of the world, few countries are immune from this disease. Snakebite envenoming could be controlled now, through an integrated approach, producing improved case management, provision of existing, established antivenoms, and more appropriately trained health professionals, within the national health care system. Allocation of global health resources proportionate to the magnitude of this neglected problem should provide resources for diagnosis, treatment, prevention and socioeconomic support to affected communities that result in measureable control of this disease.

2. The Need to Strengthen Health Systems

In Sub-Saharan Africa, there is an urgent need to address the crisis in provision of effective control of snakebite envenoming by health systems. For decades, nations throughout Sub-Saharan Africa have reported debilitating shortages of independently validated, demonstrably safe, and effective snake antivenoms. Some products meet these requirements, but they are usually in short supply, partly due to inconsistent demand and inadequate financial support for procurement and distribution. Despite the dearth of randomised controlled trial data, there is growing anecdotal evidence suggesting that some widely marketed antivenoms are clinically ineffective. National Regulatory Agencies (NRAs) may lack the experience, techniques and capacity properly to evaluate antivenoms submitted for registration. Health systems fail to procure, distribute and effectively use antivenoms, and to equip doctors and other health workers with the skills and resources to properly diagnose and treat victims of snakebite envenoming. Monitoring and reporting systems fail to collate and analyse data on the incidence, outcomes and costs of envenoming. Few governments have managed to address this important public health issue.

3. Coordinated International Programme

GSI supports the establishment of a centrally coordinated, international, multi-stakeholder program to reduce the burden of suffering caused by this neglected tropical disease. The program must integrate access to antivenoms and ancillary treatments with government strategies to (i) strengthen health systems, (ii) engage with and educate communities, (iii) improve the skills of health professionals, (iv) improve case management, (v) measure both the size of problem and the impact of interventions, and (vi) develop redundancies and safeguards that ensure sustainability. There must be strong leadership, adequate and reliable funding, and political sensitivity. Our solution urges recognition and comprehensive control of snakebite envenoming as a Neglected Tropical Disease (NTD). GSI prioritizes support for improved case management, and parallel assistance to existing national and international antivenom manufacturers, that incorporates programs to improve the design, quality and quantity of their products, and encourages compliance with the WHO's published antivenom production guidelines, within an integrated antivenom prequalification program, that drives improved design and technological innovation supported through access to expert guidance.

4. Global Leadership

Action to improve the situation in Sub-Saharan Africa requires leadership that can recruit the support of government, science, civil society and donor organizations. GSI believes that the World Health Organization (WHO) offers the only credible path to achieving improvements in the prognosis of snakebite victims in Saharan Africa. GSI will assist in this process. GSI calls on WHO Member States and other organizations to provide WHO with the funding and other resources necessary to implement programs for the effective control of snakebite envenoming.

5. The Role of Government

GSI calls upon governments throughout Sub-Saharan Africa, individually and collectively to support the leadership of WHO in tackling the control of snakebite envenoming. The solution to the dire snakebite situation in Sub-Saharan Africa (and elsewhere) requires strengthening of government health care systems. Improvements must encompass prevention (through health promotion), first aid, community and health worker education, health systems strengthening, policy development, improved reporting and epidemiological

surveillance, and development of disability services and rehabilitation, as well as issues surrounding antivenom production, supply and distribution.

6. Availability and Affordability of Quality Assured Antivenom

GSI rejects the view that the departure of Sanofi-Pasteur from the African antivenom market has precipitated a sudden, critical shortage of antivenom in Sub-Saharan Africa. Several manufacturers are currently producing antivenoms for Sub-Saharan Africa. Their participation will be crucial to providing a solution, but compliance with product safety, effectiveness and affordability will be mandatory. Some manufacturers already make far larger quantities than Sanofi-Pasteur did. However, the critical issue is not whether antivenom is available, but whether it is safe, effective, affordable and accessible. Existing manufacturers can be enabled to improve the quantity and quality of their antivenoms, provided they are given the necessary encouragement and technical support. Immediate steps are required to establish innovative antivenom procurement schemes (similar to other global health programs such as vaccinations, HIV antiretrovirals and numerous prequalified medicines) that remove the financial burden from victims and their families, and assist regional governments to pool procurement through collective bargaining to drive lower prices and increased supply.

7. Antivenom Manufacture

The only way to guarantee adequate antivenom availability in Sub-Saharan Africa is for several manufacturers to contribute to the generation of required volumes of affordable antivenom for the whole region, rather than relying on a single producer. Neither the short- nor long-term solutions to the problem of availability of antivenoms in Sub-Saharan Africa lie in supporting a single manufacturer. "Redundancy" must be encouraged, whereby several different manufacturers contribute. This is the only approach that will (i) ensure adequate supply to meet the required need for antivenom in Sub-Saharan Africa, (ii) provide essential safeguards for secure and durable antivenom supply, and (iii) create an environment in which healthy competition inhibits monopolistic price-fixing, stimulates innovation and encourages new manufacturers to enter the market.

8. Ensuring the Quality of Antivenom

Several antivenom manufacturers currently have products undergoing evaluation by the WHO through the Prequalification team. GSI supports the WHO evaluation process, and the incorporation of requirements for submission of preclinical and clinical data. Moreover, this program must be broadened to include all the products entering the Sub-Saharan African market, prior to achieving marketing approval by NRAs or Ministries of Health. Few randomised

controlled clinical trials (RCTs) have been attempted in the continent, despite general agreement that they are essential, and a WHO requirement for compulsory RCTs of antivenoms as part of a prequalification process is welcomed. Our position is that WHO must have the resources to establish an antivenom prequalification program that is also extended to provide technical product evaluation and assessment services for NRAs in Sub-Saharan African (and other) countries, in parallel with a program to increase the in-house capacity of NRAs to monitor and assess products marketed in their countries.

9. Expanding Antivenom Production

Within the framework of expanded manufacturing of existing antivenoms by current producers, GSI supports the establishment of new antivenom production capacity in Sub-Saharan Africa. New products must be subject to all the requirements for GMP-production, rigorous preclinical and clinical evaluation, stringent regulatory approval and licensing, and submission of candidate products to WHO for independent assessment as set out above.

10. An Action Plan for Change

The Global Snakebite Initiative (GSI), supported by Health Action International (HAI) will work closely with WHO to increase access to antivenoms and their rational use. GSI exists to 'provide a collaborative framework to address the neglected global tragedy of snakebite envenoming'. It comprises some of the world's leading experts in snakebite prevention, treatment, emergency-room management and antivenom innovation. HAI is the GSI secretariat and brings civil society capacity building, evidence-based advocacy, validated research methods and policy analysis expertise to the partnership to which they provide the secretariat. HAI works with a network of policy makers, academics, supply chain experts, advocates and civil society organizations. GSI's members are already producing first-in-class publicly-funded polyvalent antivenom and innovative treatments. A synergistic and cooperative collaboration between GSI (with HAI) and WHO, working with other international, regional and national stakeholders, will ensure an effective response to bring long standing solutions to the human tragedy of snakebite envenoming in sub-Saharan Africa and elsewhere.

Further Information

Dr David Williams, CEO, Global Snakebite Initiative

✉ david.williams@unimelb.edu.au

🌐 <http://www.snakebiteinitiative.org>

Dr Tim Reed, GSI Secretariat, Health Action International

✉ tim.reed@haiweb.org

🌐 <http://www.haiweb.org>