EAST AFRICAN SNAKEBITE SYMPOSIUM

12 June 2025

Response-Med
REMOTE MEDICAL SUPPORT

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MEDICINE KENYA FOUNDATION

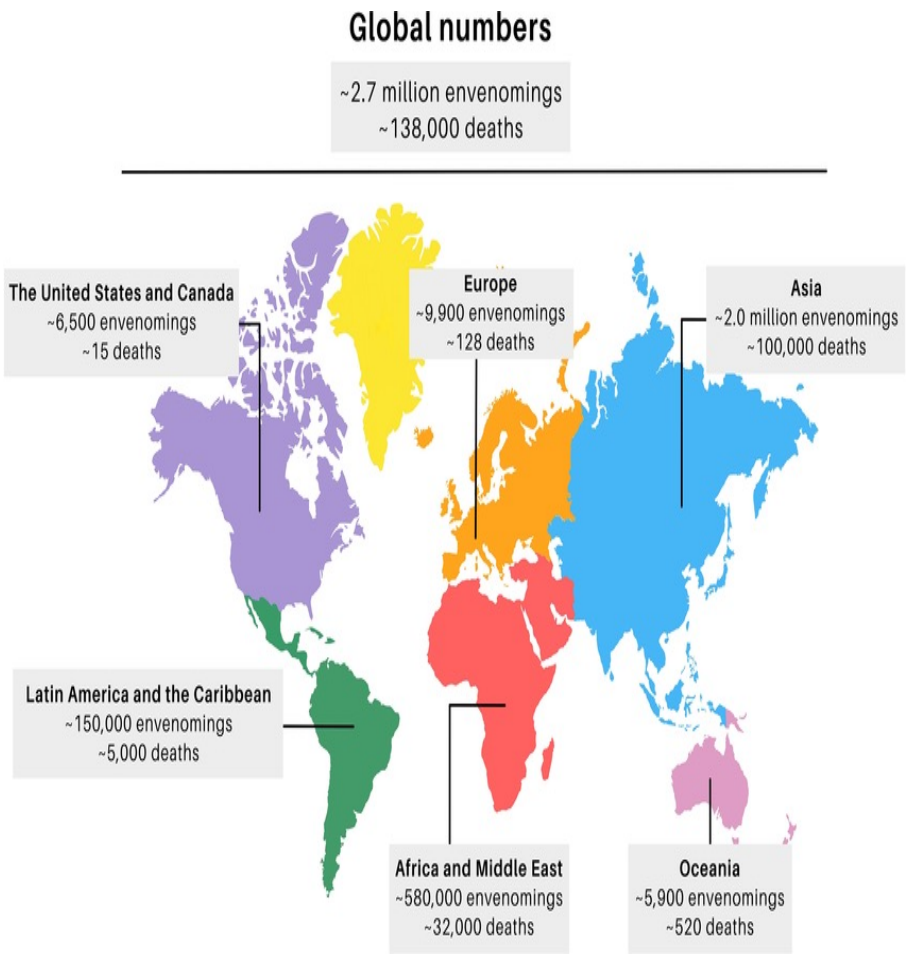
GSI GLOBAL SNAKEBITE INITIATIVE

A SITUATION REPORT ON THE POST MARKETING SURVEILLANCE STUDY OF PANAF-PREMIUM™ SNAKEBITE ANTIVENOM

Dr. Mitchel Okumu

(B. Pharm, MSc, PhD, Pharmacology and Toxicology)

Background



Source: Halilu et al., 2019; Adriao et al., 2022

Snakebite in Africa

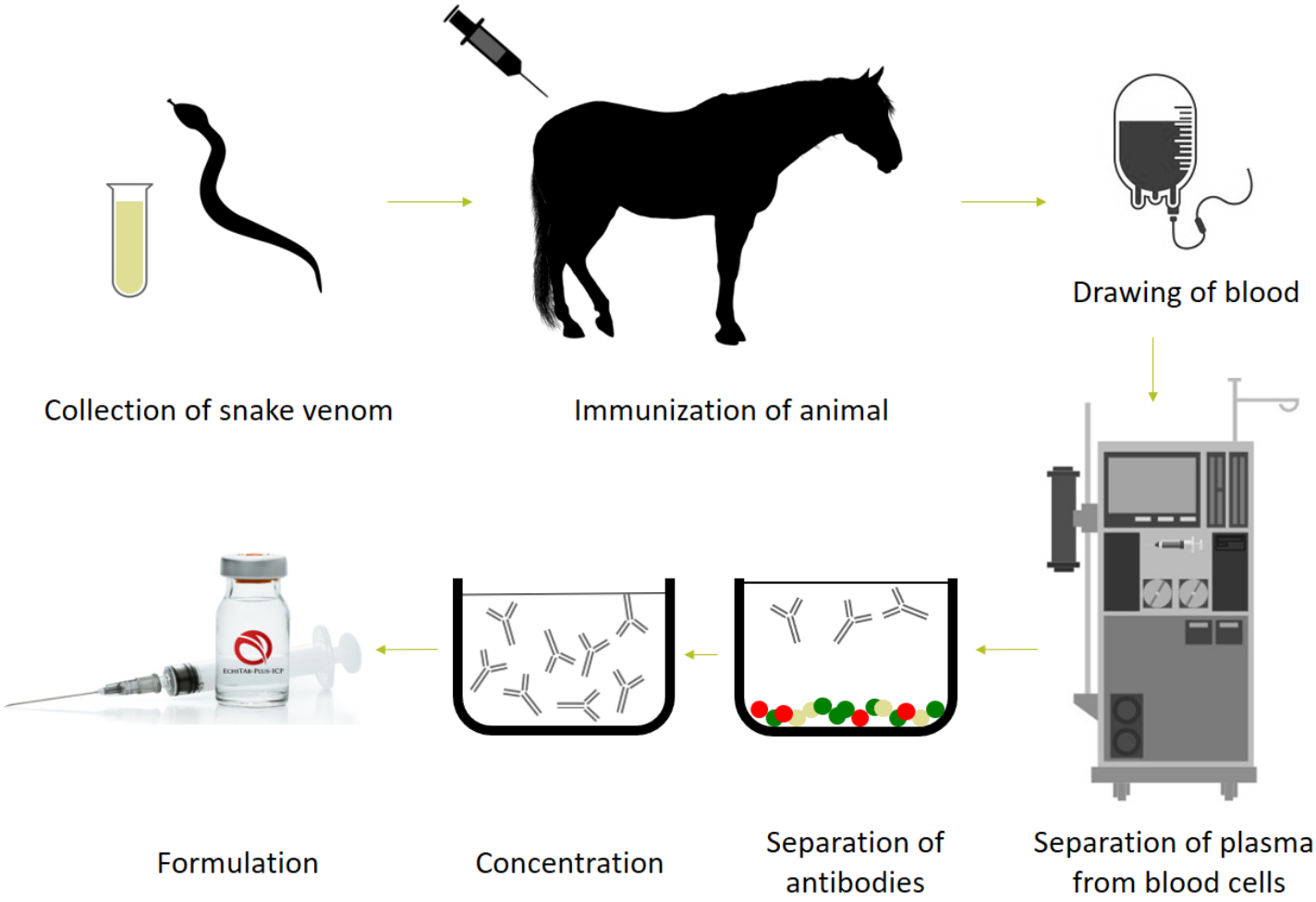
Country	Mean number of cases	Mean number of deaths	Mean number of amputations	Mean number of PTSD	Life expectancy at SBE
Nigeria	43,049	1,927	2,368	8,882	41
Ethiopia	35,633	1,669	1,960	7,336	45.6
Congo DR	24,078	1,108	1,324	4,962	43.9
Kenya	15,411	719	848	3,174	43.8
Uganda	13,801	648	759	2,841	42
Tanzania	13,504	618	743	2,783	44.5
Sudan	12,837	584	708	2,647	46
South Africa	10,998	476	605	2,273	38.5

Syndromes of envenomation

SYNDROME	SYMPTOMS	MEDICALLY IMPORTANT SNAKE GENERA
CYTOTOXIC	Painful progressive swelling, necrosis	Spitting cobras (Naja spp), adders (Bitis spp), saw-scaled/carpet viper (Echis spp)
HEMATOXIC	Aka ‘viperid syndrome’ bleeding, non-clotting	Saw-scaled viper/carpet viper (Echis spp), rarely adders (Bitis spp) and Boomslang (Dispholidus typus)
NEUROTOXIC	Aka ‘elapid syndrome’ progressive weakness and paralysis	Non-spitting cobras (Naja spp), mambas (Dendroaspis spp)

Source: Potet, Smith, and McIver, 2019

Manufacture of Antivenom (Immunized horses)



History of antivenom in sub-Saharan Africa (2014-2018)

Brand name	Company	Country of origin	Type of IgG
Polyspecific			
ASNA antivenom C (ASNA C) (ASNA D)	Bharat Serums + Vaccines	India	F(ab)'2-equine
EchiTabPlus (ET-Plus)	ICP	Costa Rica	Intact IgG-equine
Inoserp	Inosan	Mexico/Spain	Fab)'2-equine
Antivipmyn-Africa A (antivip-A)	Instituto Bioclon/Sinales	Mexico	F(ab)'2-equine
Snake Venom Antiserum (PanAfrica) Premium-A	Premium Serums	India	F(ab)'2-equine
Snake Venom Antiserum (Central Africa) Premium-CA	Premium Serums	India	F(ab)'2-equine
Fav-Afrique A (FAV-A)	Sanofi-Pasteur	France	F(ab)'2-equine
SAIMR Polyvalent (SAIMR-Poly)	SAVP	South Africa	F(ab)'2-equine
Snake Venom Antiserum Polyvalent (equine) (VACSERA-Poly)	VACSERA	Egypt	F(ab)'2-equine
Afriven, Snake Venom Antiserum (African, Vins-A)	Vins Bioproducts	India	F(ab)'2-equine
Anti Snake Venom Serum Central Africa (Vins-CA)	Vins Bioproducts	India	F(ab)'2-equine

History of antivenom in sub-Saharan Africa(2014-2018)

Brand name	Company	Country of origin	Type of IgG
Monospecific			
EchiTabG (ET-G)	MicroPharm	UK	IgG-Ovine
SAIR Echis ocellatus/Echis pyramidum (SAIMR-Echis)	SAVP	South Africa	F(ab)'2-equine
SAIMR-Boomslang (SAIMR-Boom)	SAVP	South Africa	F(ab)'2-equine
Snake Venom Antiserum Echis Ocellatus (VINS-Echis)	VINS Bioproducts	India	F(ab)'2-equine

Clinical efficacy of antivenom

- Antivenoms differ by:

1. The composition of the immunizing mixtures
2. Animal immunization protocols
3. The fractionation and purification processes
4. The fragmentation (or otherwise) and concentration of immunoglobulins.

- The WHO recommends the evaluation of snake antivenom products in pre-clinical and clinical studies before their commercialization (WHO, 2018).

Categorization of clinical studies on snakebite antivenom (Chippaux et al., 2010)

Categorization	Notes	Quality
Anecdotal clinical report	• Exclusively retrospective in nature • Prospective with limited data on clinical effectiveness and safety (small cohort, aim is to assess the therapeutic effect or safety of antivenom)	Lowest quality
Observational cohort study	Prospective study methodology analyzing the therapeutic efficacy/safety of an antivenom	Moderate quality
Non-randomized comparative clinical study (CCS)	Prospective study methodically analyzing the therapeutic effects/safety of several antivenoms-patient allocation is not random but dependent on other circumstances e.g. shortages, symptomatology	Moderate quality
Randomized clinical trial (RCT)	Prospective study that methodically analyzes the therapeutic effects/safety of several antivenoms-patient allocations are random	Highest quality

SitRep on the clinical study in Kenya

Objectives of the study

1. To document the clinical syndromes of snakebite victims presenting to JOOTRH, Marigat SCH, Malindi SCH
2. To determine the early and late adverse events following the intravenous administration of PANAF-PREMIUM™ in snakebite victims at JOOTRH, Marigat SCH, and Malindi SCH
3. To determine the number of vials of PANAF-PREMIUM™ required to reverse the clinical symptoms of snakebite in victims presenting to JOOTRH, Marigat SCH, and Malindi SCH
4. To determine the duration of recovery among snakebite victims who receive PANAF-PREMIUM™ at JOOTRH, Marigat SCH, and Malindi SCH

SitRep on the clinical study in Kenya (JOOTRH-18th November 2024)

SitRep on the clinical study in Kenya (Marigat SCH, Baringo County HQ 20th November 2024)

SitRep on the clinical study in Kenya (Malindi SCH, meeting with County leadership_22nd November 2024)

Situation Report on the clinical study on PANAF-PREMIUM™ in Kenya

REPUBLIC OF KENYA

MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT
(Cap.244, Sub. Leg.)
(The Pharmacy and Poisons Rules)

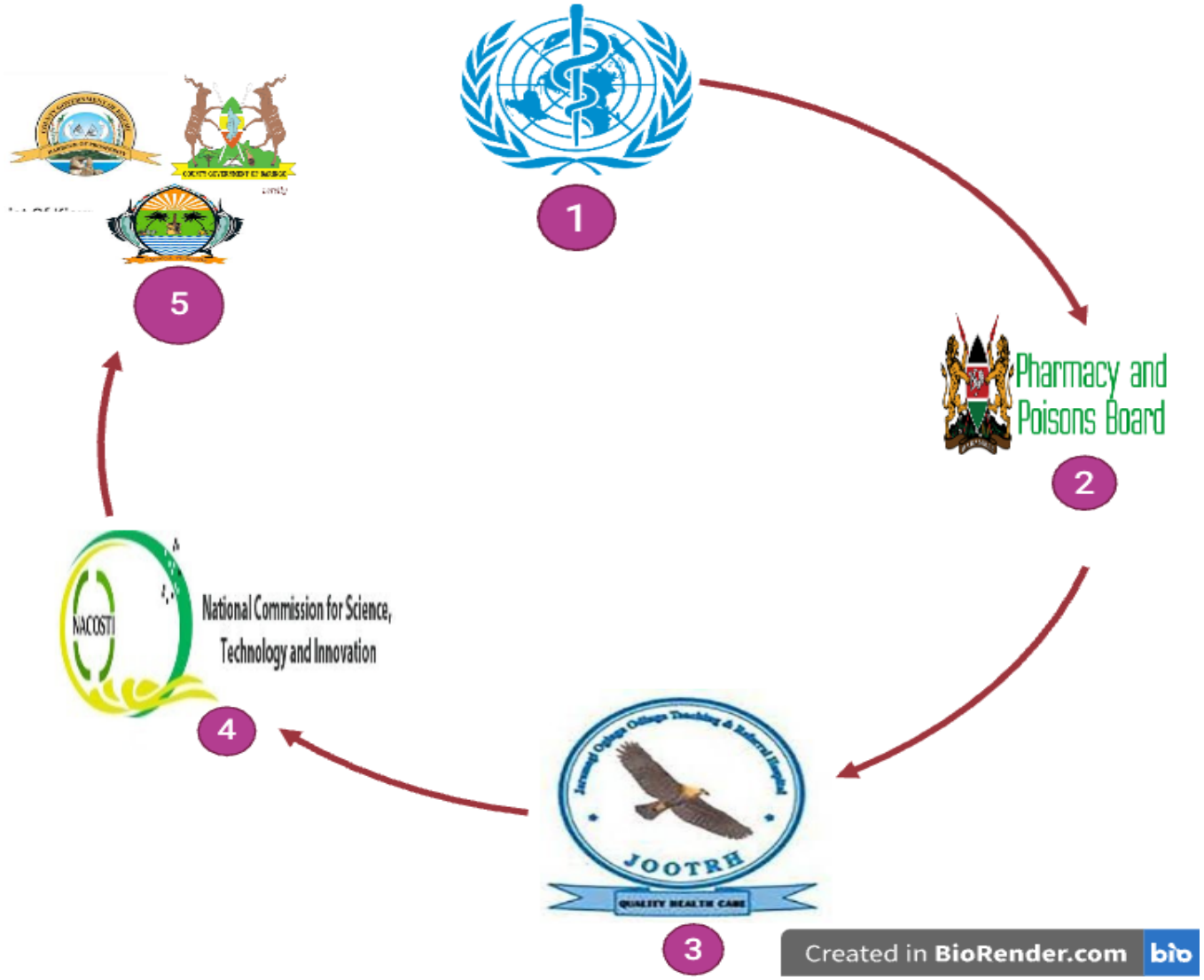
DRUG RETENTION LICENSE

PRODUCT ID	YEAR OF RETENTION	VALIDITY PERIOD	DOCUMENT SERIAL NO.
14347	2025	31st December 2025	63873

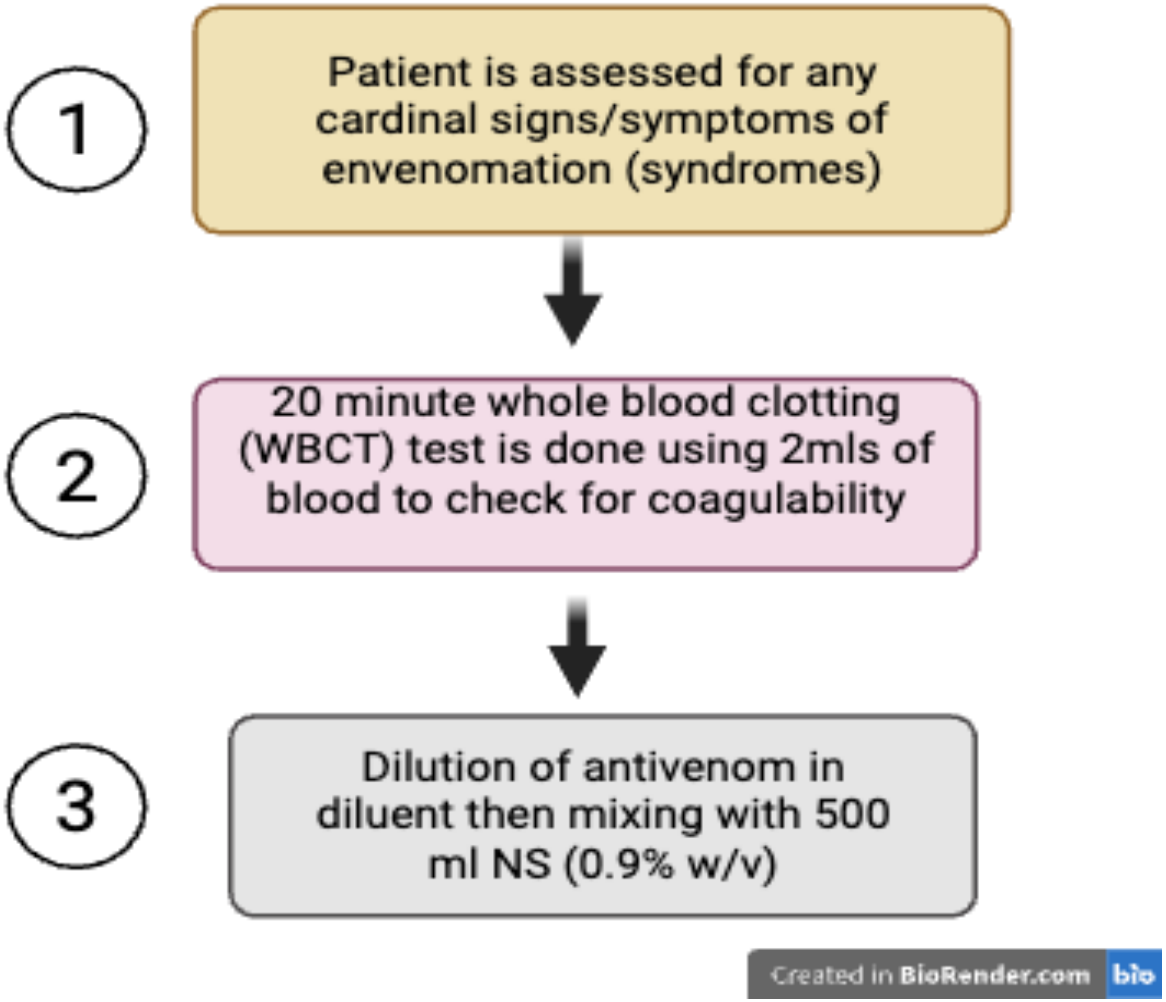
PRODUCT PROFILE	
PRODUCT REGISTRATION NO	H2020/CTD7496/14347
TRADE NAME	PANAF-Premium
INN OF API	Combipack of Snake Venom Antiserum with Sterile Water for Injection (Pan African)
STRENGTH OF API	Bitis arietans, 25 LD50, Bitis gabonica, 25 LD50, Bitis nasicornis, 20 LD50, Bitis rhinoceros, 25 LD50, Echis leucogaster, 25 LD50, Echis ocellatus, 25 LD50, Echis carinatus, 25 LD50, Naja haje, 25 LD50, Naja melanoleuca, 20LD50, Naja nigricollis, 20LD50, Dendroaspis polylepis, 25LD50, Dendroaspis viridis, 25LD50, Dendroaspis jamesoni, 25LD50, Dendroaspis angusticeps, 25LD50
SHELF-LIFE	36
DOSAGE FORM	Injection
PACK SIZE	VIAL
BATCH SIZE	100,000
FPP MANUFACTURING SITE	PREMIUM SERUMS AND VACCINES PVT LTD
MAH NAME	Premium Serums and VaccinesPvt. Ltd
LTR NAME	NAIROBI ENTERPRISES LTD
APPROVED VARIATIONS	Check Annex 1

SR. No: d41d8cd98f00b204e9800998ecf8427e

Approvals for the study



Management of the study participants (SOPs)



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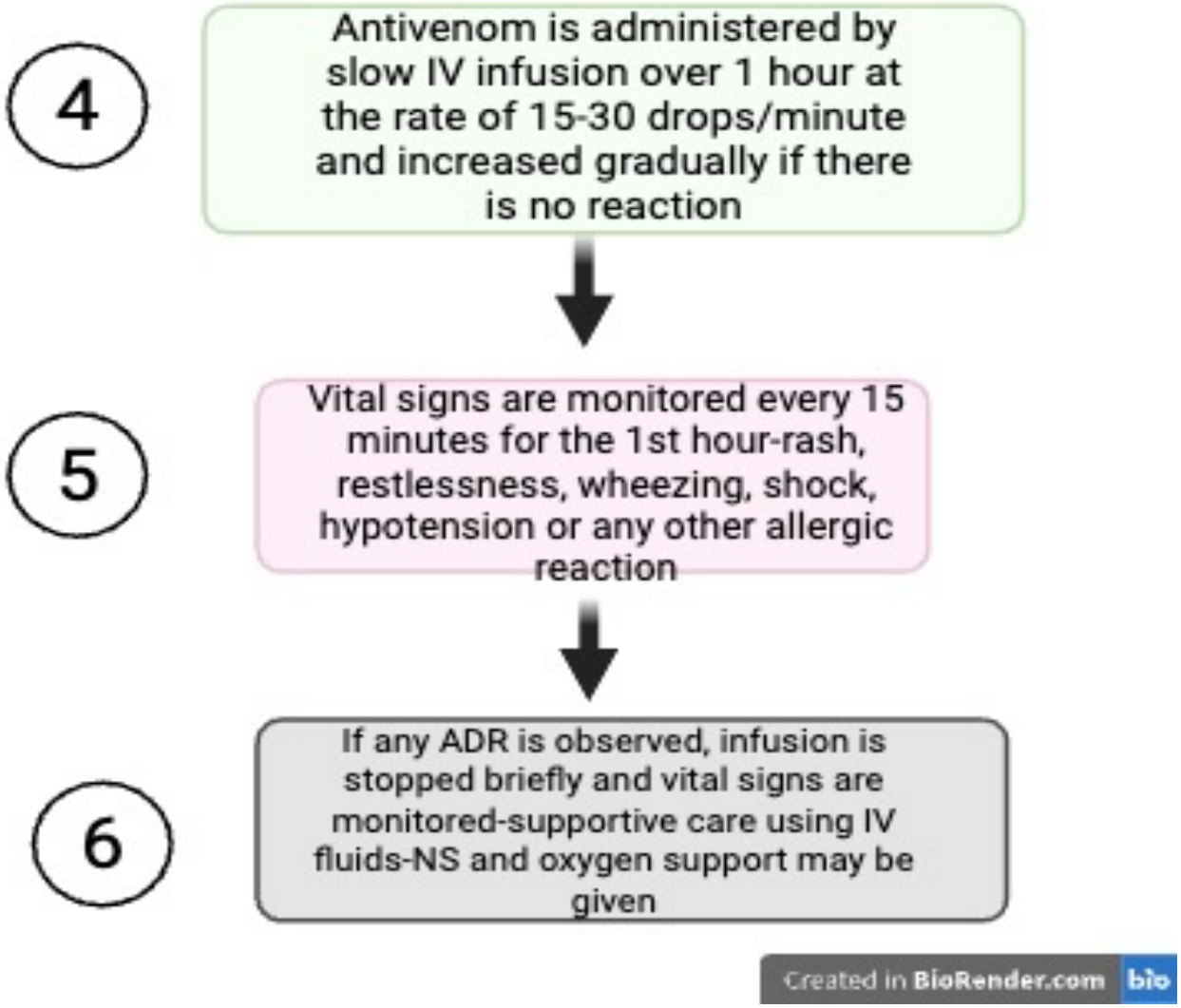

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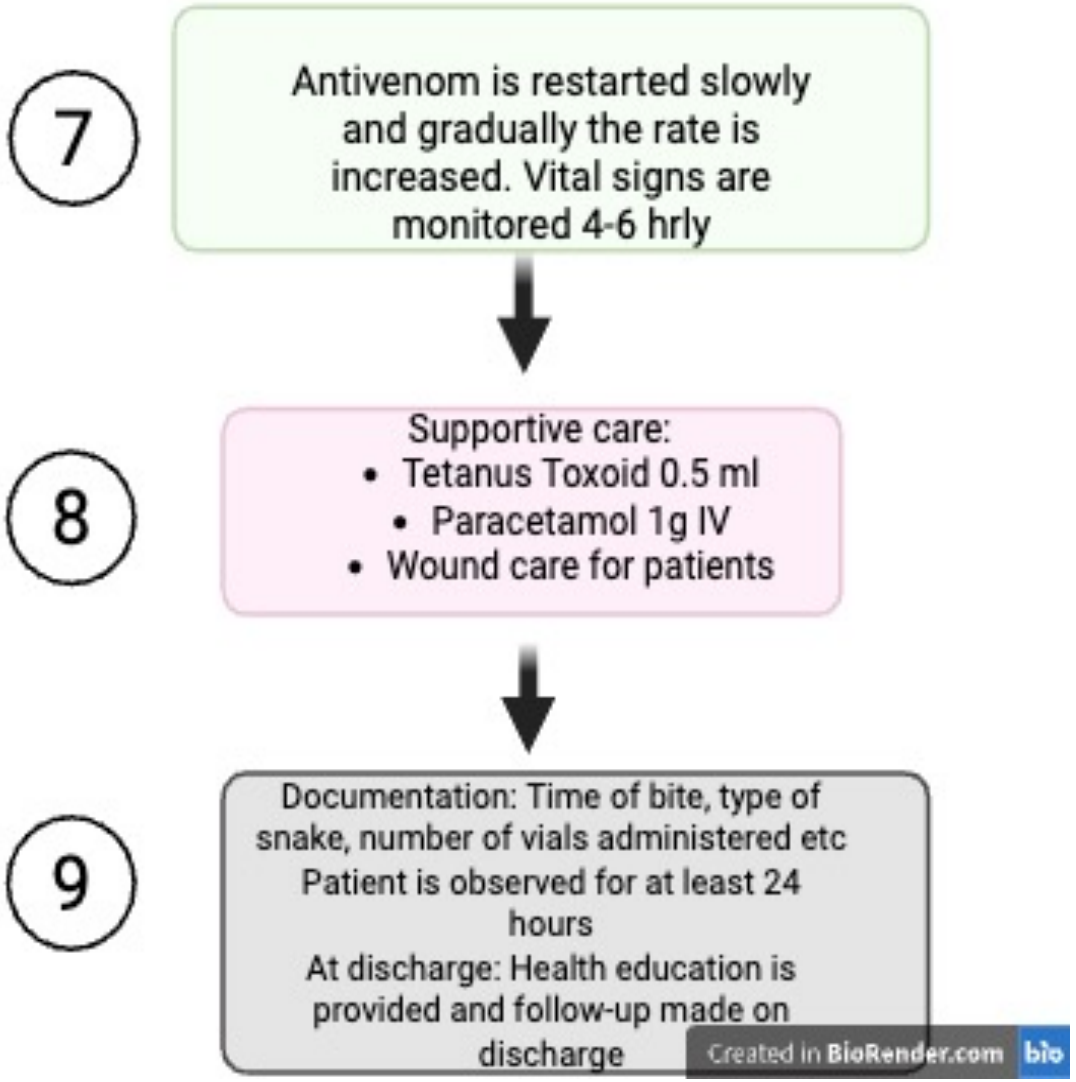


Results (Socio-demographics_Age)

Age (n=51)	Site		
	Baringo	Kisumu	Malindi
0-9	5	0	0
10-19	4	0	4
20-29	4	6	1
30-39	6	1	2
40-49	3	3	1
50-59	2	2	2
60-69	0	1	2
70-79	1	0	0
>80	1	0	0

Results (Socio-demographics_Gender)

Gender (n=51)	**Site**		
	Baringo	Kisumu	Malindi
Male	14	7	8
Female	12	6	4

Results (Socio-demographics_type of snake)

Type of snake (n=51)	**Site**		
	Baringo	Kisumu	Malindi
B. arietans	1	0	0
N. nigricollis	2	0	0
N. pallida	7	0	0
D. polylepis	0	1	0
Unidentified	16	12	12

Results (Objective 1: n=51: Clinical syndromes)

Study site	Clinical syndrome	Description
JOOTRH	Cytotoxic, neurotoxic, hemotoxic	Painful progessive swelling, bleeding, difficulty in breathing
Marigat SCH	Cytotoxic, neurotoxic	Painful progressive swelling, vomiting, difficulty in breathing, tingling sensation, ptosis, restlessness
Malindi SCH	Cytotoxic	Painful progressive swelling, necrosis

Results (Objective 2: n=51): ADR's

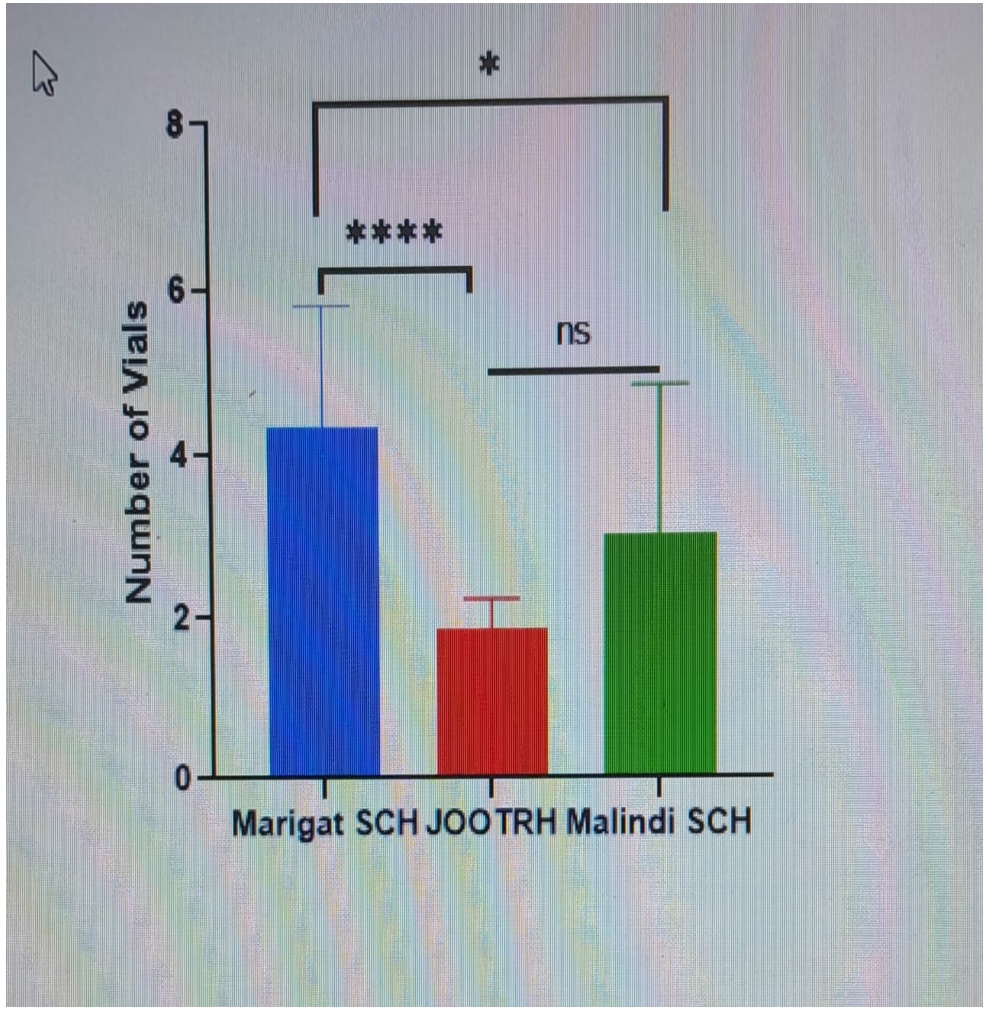
Study site	Adverse event	
	Early	Late
JOOTRH	Itching, tachycardia, fever, urticaria, chills, hypotension, sweating	None
Marigat SCH	Urticaria, fever, itcing, hypotension, tachycardia (7,17,27)	None
Malindi SCH	Itching, backache	None

Results (Objective 3: n=51): Number of vials used

Study site	Number of vials	
	Absolute	Mean
JOOTRH	24	1.85 ± 0.38
Marigat SCH	115	4.33 ± 1.45
Malindi SCH	36	3.00 ± 1.81

Results (Objective 3: n=51): Multiple comparisons (No of vials)

Comparisons	P value
Marigat Vs JOOTRH	P<0.0001
Marigat Vs Malindi	P=0.0207
JOOTRH Vs Malindi	P=0.1036

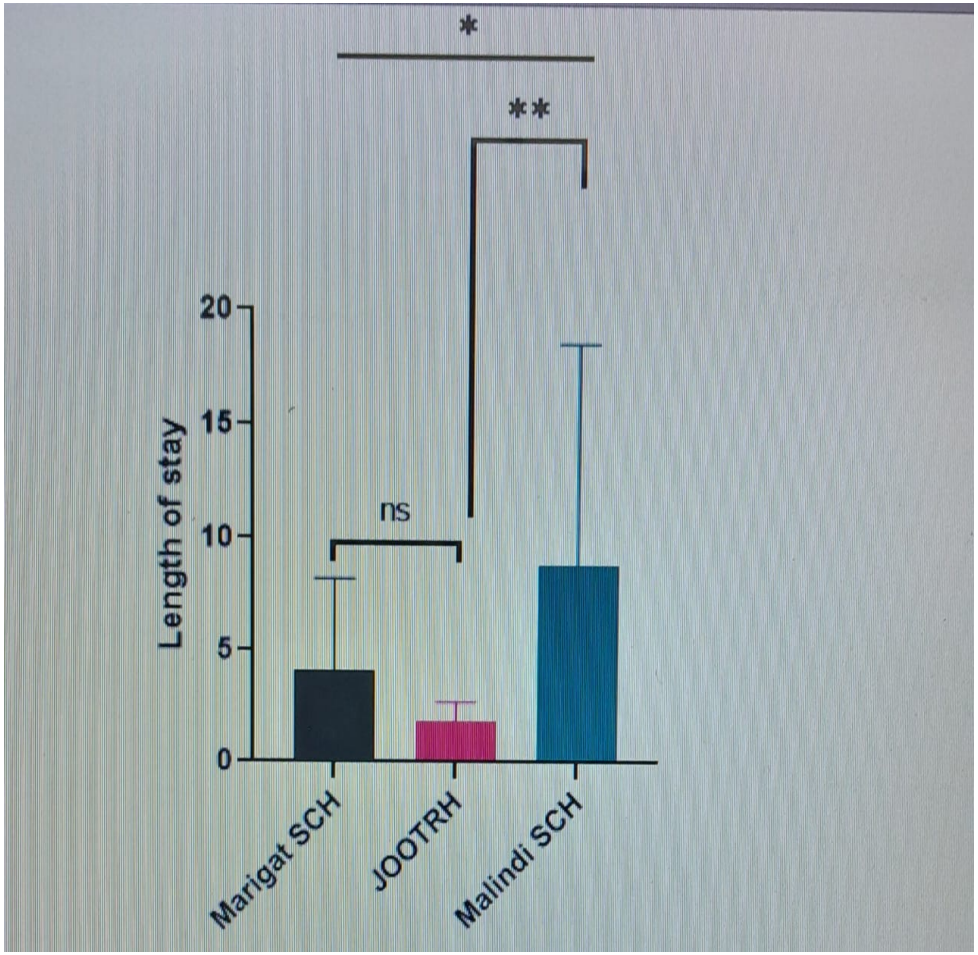


Results (Objective 3: n=51): Length of hospital stay

Study site	Length of stay	
	Absolute	Mean
JOOTRH	24	1.86±0.86
Marigat SCH	115	4.12±4.11
Malindi SCH	36	8.83±9.73

Results (Objective 3: n=51): Multiple comparisons (Length of stay)

Comparisons	P value
Marigat Vs JOOTRH	P=0.4346
Marigat Vs Malindi	P=0.045
JOOTRH Vs Malindi	P=0.061



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THANK YOU!