Snakebite as a serious Public Health problem for Nigeria and Africa

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The EchiTAb Study Group (ESG)

Foundation and Purpose:
A joint research and development project between EchiTAb Study Group, Nigeria and EchiTAb Study Group, UK

• Project formally established in June 2000
• Chairman, Nigeria - Prof Lateef Salako, CON
• Chairman, U.K. – Prof David Theakston
• Clinical Consultant - Prof. David Warrel
• Project Co-ordinator - Dr Abdulsalami Nasidi, OON
• Co-Proj Coord - Prof John Landon
• Finance/Admin Coordinator – Dr Nandul Durfa
• Key collaborating organisations: FMOH, Nigeria, Liverpool School Of Tropical Medicine, Oxford University and MicroPharm, UK
• A New MOU developed
The Problem
Africa and Nigeria Population

- Total Population Africa: 890 mln
- Total Pop West Africa: 252 mln
- Total Pop Nigeria: 140 mln
- Attack rate: About 170/100,000
- No. of States: 36 plus FCT
- No. of Health Districts: 7850

*From 2006 Census*
Africa Situation

• No regional Strategy for Production
• No Regional programme for training
• Regional Management strategy now being developed with assistance from the WHO (Nairobi meeting)
The Main Problem for Nigeria

- Estimated incidence in Nigeria – 174 bites/100,000
- This is 1/5 of all African region cases
- 90% of bites and 60% of deaths caused by the most dangerous snake – *E. Ocellatus*
- Bites occurring mostly in very fertile areas of the country during planting and harvesting periods
Importation of ASV /Affordability

- Often in-appropriate ASV (Indian ASV versus our snakes)
- High cost – affected population poor
- Expiry dates often unnecessarily early
- Fake products in circulation
- Poor or misleading inserts
- Inappropriate dosage strategy
- Liquid versus lyophilised (liquid very adequate)
- Monospecific versus polyspecific (both needed)
The Main Problem for Nigeria

Nigeria Echis with most potent venom
Regional and National Needs for ASV

- Africa - 1.6 million vials is required annually
- Nigeria: about 245,000 vials annually
- Less than 100,000 vials distributed before 1994 for the entire continent
- Most effective in the region were the IPSER-Afrique, SAIMR ASV, Berhinger-Werke products
- Presently only South African ASV available in Nigeria
- Reasons for non-availability – Economic viability for the develop country manufacturers
- Traditional healing and fake products are the only remedies available to snakenite victims
Snakebite as medical emergency in rural Nigeria

- 12 States at particular risk (mountainous and rocky)
- 4 poisonous snakes identified with 3 major ones (*Naja nigricolis*, *Bitis Arientas* and *Echis oceollatus*) as main causes of envenomation
- Nigerian Echis – the most dangerous snake in the World
Echis Ocellatus
The Sample Epidemiological Survey

• Objective
  – Assess magnitude and Distribution of Snakebites in Nigeria
  – Ascertain types of Snakes prevalent in Nigeria
  – Quantify volume of ASV required

• Study Type
  – A 5-year Health facility reviews (1989-1993)
  – Cross sectional-community survey
SAMPLING FRAME

- Country was divided into 2 areas of:
  - High Prevalent Areas (HP) and
  - Low Prevalent Areas (LP)

- Each area was stratified and selection was through randomization
- Pre-designed data collection formats used
- 4,800 households involved (16,000 from HP areas and 3,200 from LP areas)
- Data retrieved from Health Institutions of all identified areas
Results
(Frequency of bites by States)
Admissions due to Snakebites

![Bar chart showing cases of snakebites per 1000 admissions for different locations: JG, TB, BA, RV, EN, OS, KG, KT. JG has the highest cases, followed by TB, BA, RV, EN, OS, KG, and KT.]
Time of Reporting to Treatment Centre after bite

- 1-6hrs: 49 cases
- 7-12hrs: 22 cases
- 13-24hrs: 17 cases
- 25-72hrs: 2 cases
- >72hrs: 20 cases
Case Fatality Rates due to Snake Bites by State
Age Distribution of bites-
National Survey

- 0-9
- 19-Oct
- 20-29
- 30-39
- 40-49
- 50-59
- 60&>
Length of Stay in Hospital

- 1-2
- 3-4
- 5-6
- 7-8
- 9-10
- 11-12
- 13-14
- 15-16

% of total
Direct Observation at the Kaltungo Hospital 1999 to 2006
SEX DISTRIBUTION OF SNAKE BITE CASES IN GENERAL HOSPITAL, KALTUNGO

Male

Female
AGE DISTRIBUTION OF SNAKE BITE PATIENTS IN GENERAL HOSPITAL
KALTUNGO 199 - 2006.
SNAKE BITE GENERAL HOSPITAL - 1999 - 2006, KALTUNGO.

DEATH FROM SNAKE BITE 1999-2006 IN GENERAL HOSPITAL KALTUNGO.
Product Development
Objectives

• Key Objectives:
  – Develop robust and inexpensive techniques and design pilot production facilities to manufacture effective, safe and affordable anti-venoms
  – Employ such techniques to provide a minimum of 10,000 treatments per year
  – Train staff and transfer the techniques and facilities to Nigeria
  – Finalise patenting and other documentation for the commercialisation of EchiTAb
  – Completion of clinical trials and registration of EchiTAb by NAFDAC
Snakes from Nigerian Fields

Concept Design

Liverpool School of Tropical Medicine Herpertarium

MicroPharm London/Wales

Pilot Production Wales

Product Development/ Production in Wales

Clinical Trial in Nigeria

QC and QA at Liverpool

Echi TAb

Echi TAb

OBTAIN FUND AND ESTABLISH PRODUCTION LINE (MONO/POLYSPECIFIC) IN NIGERIA

Product back to the Needy in affected areas of Nigeria
Achievement of Set Objectives

- Complete clinical trials and obtained registration of EchiTAb by NAFDAC – COMPLETED 2003
- Use robust and inexpensive techniques and facilities to manufacture effective, safe and affordable antivenoms – COMPLETED (Wales project)
- Employ such techniques to provide a minimum of 10,000 treatments per year – on going
- Train staff and transfer the techniques and facilities to Finalise patenting and other documentation for the commercialisation of EchiTAb – Patenting concluded commercialization yet to start
- Develop a poly-specific (polyvalent) ASV for West Africa – the Colombian/Egyptian/Nigerian/UK collaboration – on going
Clinical Evidence of Efficacy
Results

• 500mg dosage works, particularly in early reporters
• More doses required to treat late reporters
• Could be effective against puff adder bite
• Restores coagulation within 6-12 hours
• No serious side effects reported so far
• Doctors pleased but suggested improvements due reversal of coagulation (recrudescence)
Preliminary conclusions

• EchiTAb liquid is efficacious
• Dosage to be reviewed
• Relatively safe
• Easy to handle and administer
• Relatively Stable
• Go for IgG (EchiFab G now suggested instead of EchiTAb)
CFR at Treatment Centres

- Cases in one year – 3,780
- Deaths - 23
- CFR - 0.63%
- CFR before Treat with EchiTAb – 35% – 45%
Conclusion

• The ESG has made significant progress in establishing a secured supply of antivenom for the FMOH and establishing the foundations for the transfer of the technology for ASV production to Nigeria.

• Establishing an antivenom manufacturing unit in Nigeria will provide Nigeria with a secure supply of high quality affordable antivenom and transfer valuable antibody technology and pharmaceutical manufacturing expertise to Nigeria.

• An antivenom manufacturing unit will provide Nigeria with a commercial opportunity to manufacture antivenoms for export to other countries in West Africa.

• The facility will meet the national need for ASV and even have sufficient to export to all West African countries and entire Africa, subsequently.
EchiTAB Study Group
(Bearing the Burden)