

Antivenin stock-outs – a dangerous situation

Bites of venomous snakes are an ever-present danger in India, particularly in the countryside. Every year, an estimated 40,000 to 60,000 lives are lost as a result of envenomation. The only specific antidote for a poisonous snake bite is an antivenom serum or antivenin appropriate to the species biting. As the offending snake cannot be identified definitively in most cases, a polyvalent antivenom preparation is used in India of which there are currently four manufacturers. A minimum of 5 vials is required for treatment (there is no maximum limit) and at Rs. 250 to 400 per vial in the retail market, the treatment is quite costly for the average Indian.

In this situation, public health facilities are meant to stock polyvalent antivenom as an essential drug. The reality in many parts of the state of West Bengal is that no antivenin is available for substantial parts of the year. Precious time is therefore lost in transferring the hapless victim of envenomation from one health facility to another till one stocking antivenin is located. For those facing stock-outs, it is a most undesirable situation and speaks of poor pharmaceutical management. The excuse of inadequate funds will not hold in this situation, as this product would fall in the vital category by any analysis and therefore should be available at any cost.

The problem is compounded by many other factors. Snake bites are enshrined in a lot of mystical beliefs and practices in rural Bengal and there are many faith healers professing to cure envenomation through their magical rituals. It is a fact that majority of bites are from non-poisonous snakes and even with venomous snake bites, some are apt to be 'dry'. Whatever the bite, the initial manifestations in the victim are often of an acute anxiety and panic reaction state, which can be quite dramatic. Apparently, therefore, the faith healer succeeds through his reassurances and rituals. If the bite is really from a poisonous snake and substantial envenomation has occurred, precious time is lost and the victim may succumb even if antivenin administration can be started.

Storage is another aspect. Antivenin preparations available in India are either lyophilized powders or readymade solutions that require storage at 2 – 8 °C and even at this temperature have a relatively short shelf-life of 18 – 24 months. Hence the potency of the preparation would be suspect unless the cold chain has been maintained properly. It is a moot point whether, given the frequent power cuts in interior areas and the breakdown of equipment, cold chain maintenance is optimal.

Administration of antivenin is also difficult if the victim is of allergic disposition, has a history of reaction to previous use of equine antiserum preparations or demonstrates a positive skin test reaction. Appropriate drugs and oxygen is therefore necessary to revive the patient in case of acute hypersensitivity reaction (anaphylaxis) to antiserum use or even the skin test. Indeed, use of antivenin is downright dangerous without basic resuscitating drugs and equipment at hand.

The stocking of antivenin and the capability for its use can thus be taken as a marker for assessing the state of public pharmaceutical procurement and distribution system in West Bengal. Unfortunately many public health facilities will not pass this 'antivenin test'. What is true of antivenin is true for a number of other essential drugs. It is high time that a rigorous assessment of the pharmaceutical supply system in this state is undertaken as the first step towards strengthening and rationalizing pharmaceutical management. Till then many unfortunate victims of venomous snake bites and other illnesses will continue to suffer.

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Poisonous snake bites

Avijit Hazra

Approximately 15 percent of the 3000 species of snakes found worldwide are considered to be dangerous to humans. Of these some 52 are encountered in the Indian subcontinent. A large number of mortalities are reported in India (an estimated 40,000 to 60,000 every years) from bites of venomous snakes. Typically, victims of poisonous snake bites are adult males involved in outdoor activity. Majority of bites occur on the extremities and often result from deliberate attempts to handle, harm, or kill the snake. Most bites occur in the monsoon and post-monsoon periods. Alcohol intoxication of the victim may be a contributory factor in some venomous snake bites. The Indian cobras, the Common and Banded kraits, Russell's viper and Saw-scaled viper are considered as the big four venomous snakes in India, considering the frequency of their involvement in serious and fatal cases. Snake antivenin available in this country is geared to tackle envenomation from these species.

Venomous snake varieties

All venomous snakes existing in nature belong to the following families:

1. *Colubridae* [include genera *Lampropeltis*, *Heterodon*, *Coluber*, *Dispholidus*, *Thelotornis*, *Boiga*, *Rhabdophis*, etc. Common names are King snake, Hognose, Racer, Bird snakes, Boomslang, etc.]
2. *Elapidae* [include genera *Naja*, *Bungarus*, *Dendroaspis*, *Micrurus*, *Calliophis*, *Maticora*, etc. Common names are Cobras, Kraits, Mambas, Coral snakes, etc. Most venomous snakes of Australia belong to this family.]
3. *Viperidae* [The largest snake family. The true vipers (*Viperinae* subfamily) include *Vipera*, *Echis*, *Bitis*, *Cerastes*, etc. Common names are vipers, asps, adders, etc. The pit vipers (*Crotalinae* subfamily) have a heat-sensing foramen or 'pit' between each eye and nostril and elliptical pupils and include genera *Crotalus*, *Sistrurus*, *Agkistrodon*, *Bothrops*, *Lachesis*, etc. Common names are Rattlesnakes, Cottonmouth, Copperheads, Fer-de-lance, Bushmaster, etc.]
4. *Hydrophiidae* [These are the true sea snakes. They are the most poisonous snakes existing with extremely potent venoms. There are some 50 species belonging to genera like *Hydrophis*, *Lapemis*, *Pelamis*, etc. Fortunately, human bites are rare and most do not cause systemic envenomation.]

Some other snake families may occasionally produce human envenomation (e.g. *Atractaspididae* in Africa and the Middle East) but such bites are rare.

The *Colubridae* family includes both venomous and non-venomous species. The poisonous members are rear-fanged snakes i.e. they have enlarged teeth in the rear part of their mouth. When

attacking, these snakes seem to chew their victims. They do not have true venom glands. However, there is the Duvernoy's gland which is an evolutionary modification of the salivary gland. The secretion produced by this gland may also be toxic to man but is less dangerous than other snake venoms.

The other venomous snakes are front-fanged snakes because they have venomous teeth (fangs) in the front of the upper jawbone. The fangs of *Viperinae* and *Crotalinae* serpents are retractable. When their jaws close, the two fangs are folded under the roof of the mouth and covered with a fleshy sheath. When attacking a prey, as the snake opens its mouth, the fangs are rotated forward when the upper jaw sets in a vertical position. Each fang has a channel, through which the venom is rapidly injected into the bite. The *Elapidae* have immovable fangs projecting from their upper jaw – short fangs attached to the maxillary bones. There are some species, the so called 'spitting' cobras, which eject their poison under pressure, in a jet, from a distance of 2 to 2.5 meters by rapid powerful contraction of muscles around the venom glands. Poison on healthy skin or mouth is not dangerous (if there are no wounds), but in the eyes or nose, or in any wound or ulcer, the poison may be quickly absorbed into the body, producing effects similar to a bite. If the eyes are affected, blindness may result. The *Hydrophiidae* have fangs similar to the elapids.

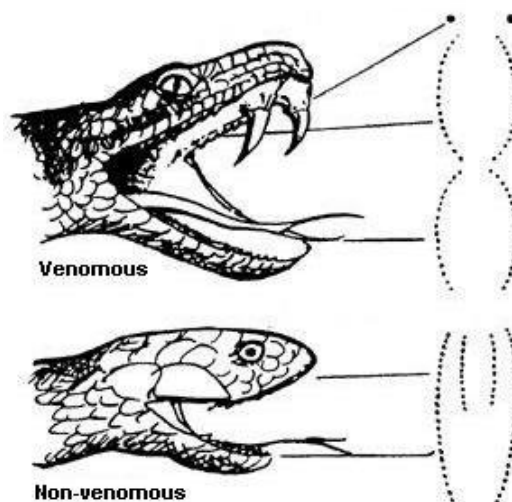


Fig 1. The fang marks in venomous snake bites

Diagnosis of snake bite cases

The common dilemma in deciding to treat snake bite victims is whether the bite has been inflicted by a venomous or nonvenomous species. Majority of bites are from nonpoisonous snakes and the initial signs and symptoms are due to the acute anxiety and panic state of the victim. Definitive diagnosis requires positive identification of the snake and

clinical manifestations of envenomation. The snake may be brought into the health care facility – alive or dead, whole or in parts – for identification, though this is not very common. If the snake is not available, it may be possible to distinguish the bite as that of a venomous snake, by the pattern of fang marks, from that of a nonvenomous species (see Fig 1) or another animal, like rats, and from puncture wounds caused by inanimate objects. In the absence of positive identification, objective signs and symptoms of envenomation become the mainstay of diagnosis.

Characteristics of snake venoms and the clinical manifestations of envenomation

Snake venoms are chemically complex mixtures of proteins ranging from 6 to 100 kDa in size. Many of the proteins have enzymatic properties. Although enzymes contribute to the deleterious effects of venom, the lethal components may be the smaller low-molecular-weight polypeptides. Over 80 biologically active large and small proteins and polypeptides have been characterized, either fully or partially, from snake venoms. The quantity, composition, and lethality of venom vary with the species and age of the snake, the geographic location, and the season. Venom is stable and is resistant to temperature changes and drying. Since the venom of most snakes is capable of affecting various organ systems of the body due to its mixed nature, it is misleading to label venom from a species as 'neurotoxic', 'hemotoxic', 'cardiotoxic', or 'myotoxic'. However, it is true that the most deleterious effects are seen on the nervous, hematologic, cardiovascular, and respiratory systems. The manifestations are also influenced by protective clothing, general health of the victim, pathogens in the mouth of the snake (tetanus for instance), type of first aid rendered, and individual patient susceptibility.

Elapid bites can cause local burning pain lasting for a few hours and some local edema, but the color of the skin is not changed. Hemorrhages, bruises, blisters and local tissue necrosis are less common. Lymphadenopathy and lymphangitis may occur. Systemic neurotoxic effects start within 30 to 60 minutes (range 10 minutes to several hours) of envenomation and manifest as cranial nerve palsies (heaviness of eyelids, blurred vision, ptosis, pupillary dilatation, dysphonia, dysarthria, salivation), abdominal pain, vomiting, diarrhea, disturbed gait, respiratory weakness and paralysis. The neurotoxic effects are progressive but are reversible with antivenin and prolonged supportive care (upto 7 days). The venom of the African spitting cobras is not neurotoxic to humans but may cause intense ocular pain with blepharospasm, palpebral edema, corneal erosions, panophthalmitis and blindness.

The viperine and crotaline poisons consist of proteolytic ferments that destroy different kinds of proteins, including proteins of vascular wall and blood cells. Envenomation causes hemorrhages because of breaches of vascular wall as well as disturbances of the coagulation system. Rapid swelling, erythema, and ecchymosis can develop, involving the entire affected body part, along with pain. Blistering and tissue necrosis follows. The microcirculation is disturbed and hypotension may occur, partly contributed by the release of biogenic amines from affected tissues. Nausea, vomiting, perioral paresthesias, myokymia, altered sensorium, tachycardia, tachypnea, and respiratory distress may also occur depending on severity. Many snake venoms can provoke disseminated intravascular coagulation (DIC) syndrome manifesting as petechiae, bleeding from gums and puncture sites, hematomas, melena, epistaxis, and hematuria. This is most common with Viperidae bites. Table 1 presents the grading of severity in Viperidae attacks

Table 1. Grading of the severity of envenomation in Viperidae snake bites

	Local manifestations	Systemic manifestations	Laboratory findings
Mild	Swelling, erythema and ecchymosis are limited to the immediate area.	None or insignificant.	Normal, including all coagulation parameters
Moderate	Swelling, erythema and ecchymosis extending beyond bite area.	Non-life-threatening signs and symptoms - nausea, vomiting, perioral numbness, myokymia, and mild hypotension.	Mildly abnormal coagulation profile without clinically significant bleeding. Mild abnormalities on other laboratory tests.
Severe	Rapid swelling, erythema, or ecchymosis involving the entire body part. Blistering and tissue necrosis.	Marked systemic disturbance. Systolic blood pressure < 80 mmHg, altered sensorium, tachycardia, tachypnea, vomiting and respiratory distress. Neurological signs. Bleeding from multiple sites.	Coagulation profile is abnormal, including unmeasurable prothrombin time (PT) and partial thromboplastin time (PTT), platelet count less than 30,000/ μ L, and reduced or even undetectable fibrinogen. Other tests may also be markedly abnormal.

Note: The ultimate grade of severity of any envenomation is determined on the basis of the most severe sign-symptom, or laboratory abnormality. For example, systolic blood pressure < 80 mmHg in the absence of local swelling should be graded as a severe envenomation. Elapid bites may not have prominent local manifestations.

First aid for venomous snake bites

- REASSURE THE VICTIM. Most bites do not result in severe envenomation, if at all.
- Allow bite to bleed freely for some time, say for a minute.
- Cleanse and rapidly disinfect area with Povidone iodine ointment, assuming that the subject is not allergic to iodine. In case of iodine allergy, use another antiseptic.
- Remove all constrictive clothing, watch, jewelry, bands, etc, close to the injured place.
- If bite is on hand, finger, foot or toe, wrap leg/arm rapidly with 3" to 6" crepe bandage (not a tourniquet) past the knee or elbow joint. Leave area of fang marks open. Wrap no tighter than one would for a sprain. Make sure pulses are present.
- In some places a venom extractor (e.g. Sawyer Extractor) is available. In this case, if the person is trained in its use, a venom extractor is applied immediately until there is no further drainage from the fang marks.
- SUCKING OF THE WOUND IS NOT RECOMMENDED – it can be dangerous for the rescuer if there are cuts or bruises in the mouth or lips and can further contaminate the wound with oral bacterial flora.
- If extractor is not available, apply hard direct pressure over bite using a sufficiently large gauze pad folded in half twice. The gauze pad may be soaked in Povidone iodine solution if available. Strap gauze pad firmly in place with adhesive tape
- Overwrap dressing above and below bite area with crepe bandage, but not too tight. Make sure pulses are present. Otherwise reapply.
- Immobilize bitten extremity, use splinting if available, and ask the victim to remain still. It should be noted that snake poison is absorbed mainly through lymphatics. Lymph circulates more slowly through an immobilized extremity, and therefore, when immobilized, general symptoms of poisoning progress much more slowly.
- If possible, try and keep bitten extremity at heart level or in a gravity-neutral position. Raising it above heart level can cause antivenom to travel into the body. Holding it down below heart level can increase swelling.
- Bites to face, torso or buttocks are more of a problem. Disinfect, shave hair and apply pressure dressing with gauze pad and tape. Crepe bandaging can not be applied to such bites but an extractor may be used if available.
- TRANSPORT VICTIM TO THE NEAREST HEALTH FACILITY WHERE ANTIVENIN IS AVAILABLE AS SOON AS POSSIBLE.
- Antivenom is the only specific treatment for snakebite and must not be delayed waiting for prominent signs of envenomation to appear.
- Remember envenomation is likely to be much more serious in a child or frail person. Also, bites in the head and neck region are apt to be more serious because of the possibility of damage to the large veins, leading to rapid systemic spread of the venom.

What not to do if bitten by a venomous snake

- Do not eat or drink anything unless okayed by the doctor.
- Do not drink any alcohol or use any systemic medication.
- Do not engage in physical activity. Injured person should not move or sit because it may cause dizziness, weakness and collapse. Patients should be transported after they have been immobilized and in supine position.
- Do not apply mouth suction to bite.
- Do not cut into, incise, burn, cauterize, or apply electric shocks to bite marks.
- Do not apply either hot or cold packs.
- Do not apply a narrow, constrictive tourniquet such as a cord or a belt.
- Crepe bandaging or other wide strapping must not be wrapped so tight as to cut off systemic venous or arterial circulation. Properly applied, such bandages will NOT compromise the systemic circulation.
- Strapping should be applied above and below the injury, but should not cover an edema. If the edema increases rapidly, the bandaging should be loosened in order to avoid additional pressure to extremity.
- Do not remove dressings / wraps until arrival at hospital and antivenom is ready.
- Do not waste time or take any risks trying to kill, capture or bring in offending snake. However, make a mental note of its features and narrate that to the medical personnel.
- Do not waste time in getting treatment from by well-meaning faith healers. They succeed apparently in some cases because these bites are 'dry'. Once systemic envenomation develops, antivenin is the only specific treatment.
- Do not attempt to administer antivenin outside a health facility to avoid undesirable complications.

Treatment of snake bites

After a bite from any venomous snake, the victim should be moved beyond striking distance, and placed at rest, kept warm, and transported immediately to the nearest medical facility where antivenin is available. The injured part of the body should be immobilized in a functional position at the level of the heart. Rings, watches, and constrictive clothing should be removed, and no stimulants should be administered. If paramedical personnel are involved in transportation of the victim, they should concentrate on support of the airway and breathing, administration of oxygen, and establishment of intravenous access in the unaffected limb, during transport. If a tourniquet or constriction band has been placed as first aid, it should be left in place until the victim is evaluated in hospital and, if appropriate, infusion of antivenom is initiated. Subject must be reassured throughout the journey.

In hospital aggressive supportive care is required. Once airway, breathing, and circulation have been

established, a rapid but adequate history should be obtained, including time of the bite, description of the snake, first-aid measures, coexisting medical conditions, drug and food allergies, and allergy to horse serum. The physical examination should be complete, with special attention to the cardiovascular, pulmonary, and neurologic systems. The bite should be examined for fang and teeth marks, scratches, edema, erythema, and ecchymoses. During initial evaluation, baseline circumferential measurements at points above and below the bite area helps in assessment of edema later on.

Baseline laboratory studies should include a complete blood count including platelet count, coagulation profile (international normalized ratio of prothrombin time, activated partial thromboplastin time, fibrinogen level), serum electrolytes, blood urea nitrogen and serum creatinine, and urinalysis. Ideally, laboratory studies should be repeated after each infusion of antivenom serum. Additional tests like measurement of creatine kinase, blood grouping with cross-matching, chest radiography, and electrocardiography may be indicated on the basis of the victim's age or medical history or the severity of the envenomation. Tetanus toxoid should be administered if indicated by the history.

Since manifestations of envenomation can be delayed, it is desirable that all patients be under observation for a minimum of one day. If no clinical or laboratory manifestations have presented during this time, the patient may be discharged. A mild envenomation syndrome at one hour could progress to a severe syndrome within several hours and, without continuous observation and appropriate supportive and antivenin treatment, lead to death. Monitoring in an intensive care unit is recommended for all patients of severe envenomation treated with antivenom. There have been no controlled trials to establish the efficacy of pretreatment with adrenaline, antihistamines and corticosteroids in snake bites but some clinicians pretreat routinely. Anticholinesterase drugs may be successful in partially overcoming the neurotoxicity of cobra venom.

Antivenin appropriate to the species biting, or polyvalent antivenin, is the only specific treatment for poisonous snake bites available in India. Currently there are four manufacturers of polyvalent antsnake venom serum – namely M/s Bharat Serums & Vaccines Ltd [product branded as ASVS], M/s Serum Institute of India Ltd [brand SiiASVS], M/s Haffkine Biopharmaceutical corporation Ltd [product known by the generic name of Lyophilized Polyvalent Antsnake Venom serum] and M/s Vins Bioproducts Ltd [brand VINS ASVS]. All products are available in 10 mL vials, priced between Rs. 250 to 400 per vial in the open market. Of these, ASVS is available as a ready to use solution, the others are lyophilized products requiring reconstitution with the supplied diluent prior to use. In general all polyvalent antsnake venom serums available in India are purified immunoglobulin preparations of equine origin (horse serum) and have a shelf-life of 2 years

under appropriate cold storage (2 – 8 °C) conditions. Each vial is capable of neutralizing 0.6 mg each of *Naja naja* and *Vipera russelli* venoms and 0.45 mg each of *Bungarus caeruleus* and *Echis carinatus* venoms. The use and the possible complications of antsnake venom serum are outlined in the next section.

Rigorous follow-up care is also important. The injured extremity should be maintained in a functional position. The wound should be cleaned and covered with a sterile dressing. Blebs, vesicles, and necrotic tissue may require surgical debridement after several days. Assessment and follow-up treatment should aim at preservation of joint mobility and muscle strength.

The complications of snake bites include pain, wound infection, DIC, compartment syndrome, respiratory paralysis and renal failure. Pain can be excruciating at the site of the bite wound and in the affected limb. Analgesics must be administered but opioid analgesics should be avoided if the venom is known to have neurotoxic components. Secondary bacterial infection of the bite wound is unlikely if adequate care is taken but possible. Some authorities routinely administer prophylactic cephalosporins or other broad spectrum antibiotics. Tetanus immunization, however, should be brought up to date. Antibiotics should be administered if there is clinical and microbiologic evidence of wound infection. Respiratory support is the most important part of management in cobra bites. Even an adequate dose of neutralizing antivenin may not restore normal respiration quickly or prevent the onset or worsening of respiratory failure. However, antivenin does reduce overall ventilatory dependence substantially.

Consumption coagulopathy or DIC, compartment syndrome and renal failure are serious complications that will require management in intensive care units.

Using polyvalent antsnake venom serum

Snake venom antiserum is administered by intravenous (IV) route, either undiluted at the rate of not more than 1 mL per minute or else diluted in IV fluid (normal saline or 5% dextrose; 500 mL – 1000 mL in adults and 20 mL/kg in children) and infused as rapidly as tolerated over 1 – 4 hours. Lyophilized powder preparations will require reconstitution prior to use. The initial reconstitution should be with the diluent supplied by the manufacturer, before subsequent dilution. It is always advisable to consult the package insert first. When reconstituting or diluting antivenin, it should be mixed by gentle swirling rather than shaking to avoid foaming. It is NOT ADVISABLE to inject antivenin locally at the site of the bite.

The initial dose depends upon the estimated severity of envenomation: 5 vials (50 mL) are recommended for mild, 5 – 10 vials (50 – 100 mL) for moderate and 10 – 20 vials (100 – 200 mL) for severe cases. Additional infusions should be

repeated hourly until progressive swelling in the bitten part is arrested and systemic symptoms abate.

Precautions: Before administration of any product prepared from horse serum precautions are necessary to avoid dangerous hypersensitivity reactions. Allergic reactions upon prior exposure to horse serum, if any, must be enquired into and the clinical history must be taken carefully, including any report of urticaria, asthma or other conditions suggestive of allergic predisposition. A skin test **MUST** then be performed in every patient, regardless of the history.

SKIN TEST: Inject intradermally 0.02 – 0.03 mL of a 1:10 dilution of the antivenin using a disposable tuberculin syringe. A control test in the opposite extremity using normal saline, facilitates interpretation. A positive reaction to a skin test will occur within 5 – 30 minutes. The shorter the interval between injection and the onset of the skin reaction, the greater is the sensitivity.

If there is no history of allergy and the skin test is negative, proceed with administration of antivenin.

If the history is negative but the skin test is mildly positive, proceed as follows. Prepare in separate sterile syringes 1:100 and 1:10 dilutions of the antivenin. Inject subcutaneously 0.1, 0.2 and 0.5 mL of the 1:100 dilution, at 15 minute intervals, keeping a resuscitation kit for anaphylactic reactions handy. Repeat with 1:10 dilutions and finally, if no major untoward reactions occur, with undiluted (reconstituted) antiserum. If no reactions still, proceed with administration of the suitably reconstituted and diluted antivenin. If a systemic reaction occurs after any injection, place a tourniquet proximal to the site of injection and administer Adrenaline 1:1000 injection [0.5 – 1.0 mL in adults by intramuscular or subcutaneous route, repeatable several times at 10 minute intervals according to blood pressure and pulse] proximal to the tourniquet or into another extremity. Wait at least 30 minutes before injecting another dose of antivenin. If no further reaction occurs, continue till 0.5 mL of the undiluted antivenin has been administered. Then switch to the intramuscular route and continue doubling the dose

at 15 minute intervals until the entire dose has been injected intramuscularly.

If allergy history is present, and the skin test is also strongly positive, use of the antivenin may be dangerous, specially if the positive skin reaction is accompanied by other allergic manifestations. In such cases the risk of administering antivenin must be weighed against the risk of withholding it, keeping in mind that significant envenomation may be fatal. Patients who do develop signs of impending anaphylaxis on skin test or injections of graded dilutions of antiserum present a very difficult choice and expert consultation should be sought.

How to avoid being bitten by a snake

It is misconception that snakes are always venomous and dangerous because majority of snakes are harmless to humans. Even if venomous, in general, most snakes avoid confrontation with humans but will strike if provoked or feeling threatened. Remember the following to avoid snake bites:

- Never pursue or persecute a snake.
- When in the countryside or in potential snake territory, do not blindly put hands or feet under stones, in crevices, or within leaf litter or other debris. Similarly, do not blindly lift up stones, twigs, straw or dry grass.
- Avoid high grass. Have a long stick to make a check path in the grass.
- Wear proper (closed) shoes that a snake cannot bite through.
- Use an electric torch at night.
- Phenol (carbolic acid) is not an effective snake repellent. When camping outdoors at night, bleaching powder would probably do the job better.
- Do not take even a dead snake casually in your hand: reflex actions may cause bites up to 1 hour after a snake has died, even after decapitation.

Overall remember that **PREVENTION IS BETTER THAN CURE.**

Recent additions to our library

- **British National Formulary 44 [September 2002]. London: British Medical association & The Royal Pharmaceutical Society of Great Britain, 2002.**
- **Dickson M. Where There Is No Dentist. Palo Alto, California: The Hesperian Foundation, 1983 [Tenth printing - January 2002].**
- **Bhattacharya A, Bandyopadhyay S, editors. Swasthya Jekhon Bhabay [in Bengali]. Calcutta: New Bengal Press, 2001.**
- **Bandyopadhyay K. Nirapad Matritya [in Bengali]. Calcutta: West Bengal Voluntary Health Association, 1999. [A Bengali translation of the book: Clean S. A Book for Midwives: A Manual for Traditional Birth Attendants and Community Midwives. Palo Alto, California: The Hesperian Foundation, 1997.]**

A rational drug policy to ensure rational drug management in West Bengal

Santanu Kumar Tripathi

Any health care delivery system that accommodates essential components like curative, preventative, rehabilitative and promotive services, utilizes drugs as integral elements. A government committed to cater to the health care needs of the people, following the basic principle of equity, cannot but consider an optimum management of the supply and utilization of drugs. Supply involves procurement, storage, distribution and inventory control of drug items on one hand and their quality assurance on the other. Utilization of drugs refers to their prescribing and dispensing. Prescribing should be evidence-based and conform to the supply menu as far as practicable. Dispensing should be patient-friendly and must ensure patient compliance.

The government health care delivery system in the state of West Bengal strives to cater to the health needs of the people through its primary, secondary and tertiary care services. Since 1992, when the decentralized model of drug supply management in government health facilities came into being in West Bengal, the Central Medical Stores [CMS] has been responsible for preparing and periodically revising the drugs and chemicals catalogue, for selecting the vendors or suppliers, and deciding the procurement price for each item.

The District Reserve Stores [DRS] as well as big hospitals procure on their own the CMS-catalogued items from such selected vendors at the selected price. However, big hospitals that have super-specialty care facilities often need to procure medicines other than the CMS-catalogued ones in order to respond to the 'legitimate' demands of their specialists. Usual norms are followed in procurement of such non-catalogued items at the local level.

Based on our experience within the health care delivery system a SWOT analysis may be done of the drug management system as it exists today in government health facilities in West Bengal.

Strengths

West Bengal remains one of the few states in India where the government subsidizes a major share of peoples' health care expenditure. Government health facilities here have a wide and vast network distributed and spread in different levels or tiers e.g. Primary, Secondary and Tertiary. A vast majority of the care-seekers in such health facility hardly, if at all, have to bear any out-of-pocket expenses for the medical attention and the treatment they receive. Medicines being the most significant elements in modern health care, have remained a matter of much attention. Procuring drugs for health care facilities in West Bengal has always followed a competitive bidding system through open tender. This has kept the cost of drugs quite low, thereby enabling the government to cater to the needs of a greater number of people. In identifying the drugs, which are procured

for use in government health facilities, the essential drugs philosophy has been followed.

Weaknesses

Although the CMS in West Bengal has been engaged in procuring medicines based on a limited list of drug items for long [the CMS Catalogue may be considered as good as an essential drug list (EDL) for government health facilities] there appears to exist a 'perception gap' among the prescribers in regard to the very justification of the catalogue or the drug items listed in the same. Many physicians believe that these drugs are just not enough, that many newer drugs should have been there, or even that some CMS-catalogued items are outdated or obsolete and hence merit deletion in lieu of other items. They do not have much 'faith' on the quality of the drugs available through government supply and there is hardly any 'system-friendly' mechanism of quality testing available.

CMS often fails to select any vendor for a number of CMS-catalogued items, probably because of non-submission of tenders by potential suppliers. No clear guidelines are available as to how to procure such items at the local [health facility] level. The inventory management at the DRS or at the health facilities is of extremely poor quality, often resulting in important drug items going out of stock.

A poor inventory and financial management has resulted in a situation akin to a 'debt-trap'. The vendors who owe a huge sum as dues, more often than not, take advantage of such weakness and flout the terms and conditions of procurement-supply and yet are not brought to book.

In order to accommodate the huge need against limited budget, much attention has been paid to containing costs which has sometimes led to quality compromise. The principles followed in the selection of vendors is consciously biased in favor of the local small-scale industry. This is with the well-meaning intention of encouraging their growth. However, in the bargain, the people's right of access to medicines of optimum quality sometimes takes a back seat.

Other important areas like warehousing and storage practice, distribution and inventory control, also have not received proper attention. Prescribing and dispensing behavior of medical and pharmacy personnel in government health facilities, specially the smaller ones, leaves much room for improvement. Essential Drug Formulary (EDF) and Standard Treatment Guidelines (STG) – considered as two of the three important tools for rational drug use [the other being the EDL] – are non-existent.

It has been realized only recently that the matter of equitable access to pharmaceutical care is too complex to be resolved just by an attempt to

decentralize procurement. It demands an in-depth, objective analysis of the situation in order to identify the inherent weaknesses and pitfalls. And then serious attempts may be made to harness the loose ends.

Opportunities

India is a vast country with a complex and diverse social, cultural, economic and political fabric. Health remains primarily a State subject. Although health policy and drug policy are formulated and revised periodically by the Government of India, the major responsibility for their implementation remains with the state governments. Further, for quite a good number of health and disease areas, vertical national programs are in place. There is always a possibility of unnecessary duplication at the state level for covering such areas. This results in undue wastage of scarce resources. Further, the issue of drug supply management in the State Government health facilities obviously is not covered in the national drug policy. This, and many other important issues relevant to a State Government, may be considered in a state level drug policy document.

In the wake of our universal appreciation of the key issues of rational drug management and of the growing accumulation of our knowledge and skills in such areas, a great opportunity for optimizing and harnessing the drug management system as prevailing in West Bengal is in sight. All the stake holders seem to be sensitized and the environment is right. Very little extra resource would be required; rather a properly managed system can result in substantial savings. Through an organized team approach much can be achieved and for optimum planning, the whole action plan can be formulated and given the shape of a local policy document – the drug policy for the state of West Bengal. With the application of collective wisdom a lot can be achieved. There is no paucity of intellectual and technical resources in West Bengal for achieving the same. What is needed is political will and public commitment.

Assuring quality of essential drugs is another important matter that has not received due attention yet. It is high time that we seriously consider setting-up of an adequate number of quality testing laboratory facilities in our state. The existing expert manpower and space available in the departments of pharmacology and pharmacy in medical colleges and pharmacy institutions may be utilized for this purpose. This matter should be

addressed with due emphasis in the drug policy document of West Bengal.

Adverse drug reaction monitoring and post-marketing surveillance centers may be established with fullest utilization of the expert manpower already available in the government medical colleges. Selected pharmacology departments may also be utilized for setting up of drug information centers that would engage in dissemination of unbiased information on drugs, serve as poison control centers, and ensure ethical promotion of pharmaceutical products in the state.

Drugs & Therapeutics Committees (DTCs) may be constituted at the state level and also at all big hospitals. These should be involved in adopting the state level EDF and STG to local needs, rationalizing local procurement, dealing with quality complaints and in organizing seminars and workshops for prescribers and dispensers on issues relating to rational drug use and drug supply management. The hospital DTC will also be engaged in formulating, implementing and periodic updating of an antibiotic policy for the hospital.

Threats

The way the system of drug management is prevailing in West Bengal today has raised much concern. Unfortunately the system lacks optimum checks, balances and guards. Pilferage and stock-outs are rampant. In the face of the recent spread of substandard and counterfeit drugs throughout the world, with India being no exception, any public sector drug management system ought to be sufficiently robust to keep away such evils. Unfortunately the system in West Bengal today is not robust enough. If the beneficiaries lose confidence in the drug procurement and distribution system, sooner or later it will have its obvious impact on the greater canvas of healthcare services in general.

In view of the foregoing, we recommend a serious re-look at the whole system of pharmaceutical procurement and distribution in public health facilities in West Bengal. Following this evaluation, it is necessary to formulate and implement a drug policy for West Bengal embracing all necessary components of rational pharmaceutical management in and by the government health facilities. This task must be taken up with the topmost priority. The cost of delay would be incalculable.

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