Perspectives

Problem Solving and Drug Sourcing by Donation, Does it improve Treatment in the Emergency Room or is it More 'Dead Aid': a Review with Examples from Global Snakebite and Anti Snake Venom Provision

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ABSTRACT

Seeking donor funding to attempt to improve patient access to expensive drugs and services is nothing new. Aid and donor contributions have been the mainstay of the developed world approach to providing development to developing countries. This approach has been compellingly criticised as 'Dead Aid' in that it does not improve circumstances for developing country poor. Despite this fact, the pressure to secure donor funding is both current and ongoing. In addition to failing to provide targeted improvements, donor funding generates other unintended consequences, which are sub optimal. This paper reviews the donor funding approach to solving medical problems and identifies a number of negative consequences in both the seeking and distribution of donor funds. The medical problem of snakebite is utilised to provide some useful examples of the pitfalls and potential tactical responses to improve the process.

Keywords Funding, Health Economics, Snake Bites, World Health Organisation, Antivenoms, Epidemiology.

INTRODUCTION

Aid and financial donation has been the mainstay of attempting to increase development and provision of services in developing countries for decades [1]. So much so that Government macro level schemes such as the Marshall Plan of the 1940s and 1950s, have been joined by modern equivalents e.g. the Millennium Development Goals (MDG), the Gates Foundation and the Global Alliance for Vaccines and Immunisation (GAVI). However, the donor/aid approach has been seen to fail both in terms of effectiveness and fostering a dependence culture [1].

Despite these observations donor funding remains at the heart of many activities in developing countries. "Western donors have an industry to feed, farmers to placate (vulnerable when trade barriers are removed), liberal constituencies with 'altruistic intentions to allay, and, facing their own economic challenges" [1].

The objective of this review is to examine the approach of seeking donor funds to solve a medical problem e.g. snakebite, and examine the unintended and negative consequences of the approach for the solution of the medical problem itself, and to suggest potential tactical responses that might be better able to provide

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practical solutions to patients in emergency settings. It is convenient to segment these problems into those resulting from the acquisition of the funds and those concerned with dispersal.

THE BIDDING WAR

The potential availability of finite funding drives activity to obtain those funds and this leads to a bidding war as experts within competing medical conditions fight for a share of the funding. As Paxman put it, "The difficulty lay in devising an overwhelming argument why International Sludge Incorporated should sponsor research into, say Byzantine theology" or indeed snakebite [2]. In any bidding war the preferred strategy is to bid high in order to carry the day and outbid other competitors for the funds [3]. The unintended consequence is that epidemiology becomes, not a means to determine levels of a disease or a means to determine resource need, but a means to outbid other conditions [3]. It therefore becomes an exercise in stating the highest possible figures, whether they are accurate or not and scientific objectivity and method are abandoned in the pursuit of bidding high [4-5].

At a recent meeting of WHO and snakebite experts the following was proposed as a strategic approach to obtaining donor funds for snakebite, "I think that rather than reinventing the wheels about how to do this, if we could somehow get onto the GAVI bandwagon" [3]; clear recognition that to get the funds you need big friends and that whether conditions are related or not, the trick becomes how to make them appear so [3]. Anti snake venom (ASV) is not a vaccine and yet if the definition is broadened then perhaps funds can be redeployed from critical vaccines to ASV. The fact that ASV is injectable and snakebite, as an animal bite, is related to rabies enables a tenuous similarity and thus a possible route to GAVI funds [3].

The overstating of epidemiology data, in order to increase the perceived impact of disease burden has the unintended consequence of making product forecasting for suppliers unreliable, making market entry perilous [6]. The need for "earlier emphasis on producing rigorous forecasts that manufacturers could rely upon" has been previously highlighted as a problem in the GAVI approach and is being repeated in snakebite [7]. The priority to secure GAVI or other funding for snakebite management is negating the provision of good, accurate demand forecast data.

ALTERNATIVE STIFLING

In order to support the bidding strategy for funding, an accompanying strategy is to show that other effective lower cost alternatives are unavailable in order to convince funders that committing scarce funds to the target disease is appropriate. The unintended consequence is that this leads to potential low cost solutions being ignored in order to gain the funds. With respect to the provision of anti snake venom (ASV), this strategy has taken the form of inhibiting market entry of new suppliers by:

1. Emphasising the failure of a number of current suppliers without analysing why, that ASV is complicated and difficult to produce and that current suppliers are best placed to produce any shortfall [8].

2. Ensuring that guidelines produced with the expressed purpose of enabling production are largely produced by current ASV suppliers or institutions that benefit from guidelines that are inadequate for the task and indeed ignore key issues [5,9].

3. Paying little heed to lower cost interventions whilst stressing the pharmaceutical solution, a practice for which WHO has previously been criticised in relation to H1N1 [8-10].

4. Providing advocacy for the aid/donor approach and omitting reference to low cost alternatives and thus providing an unbalanced approach [11-13].

WHO's approach to large current suppliers of drugs and reluctance to support inexpensive drugs alternatives has been reported previously, 'It's disappointing. The [WHO] should have supported drug access and

promoted the study of quality and inexpensive drugs for the sake of the global population rather than supporting pharmaceutical giants' [14-15]. This received further attention: "Much to the dismay of many, Chan praised the pharmaceuticals industry, promoted drug donation as a solution to the problem of poor access to medicines and suggested that the Thai government's recent issuing of three compulsory licences to import and/or produce locally generic copies of patented drugs for HIV/AIDS and heart disease was counterproductive" [15].

It is interesting that production of ASV is described as difficult, requiring major attention to quality aspects of production [9]. This, despite the fact that the production of ASV is the result of two main, well-established methods, used many times to produce ASV with different venoms. No guidelines have been given as to the relative safety of producing ASV, such as those provided by the CDC in 2009 for the production of flu vaccines [9,16]. Quality standards are thus clearly capable of being 're-evaluated when western pharmaceutical companies require the capability to increase market access to drugs but the standards are also capable of inhibiting market entrants, particularly if current suppliers are included in quality standard meetings [8,9].

CORRUPTION AND THE DISTORTION OF SUPPLY

Despite the inadequate state of snakebite epidemiology, the bulk of the snakebite mortality problem is reported to be within 10 countries (Table 1&2) [4]. These ten countries have a very poor record of corruption as defined by Transparency International (Table 1&2) with the highest absolute score of 3.6/ 10. Corruption is endemic and often culturally acceptable in these countries and not limited to small discrete areas that have no impact on health [17].

Table 1: Top Ten Highest Snakebite Mortality Countries (80% of the Total World Mortality) using the Low Range Estimated by W.H.O. and the Country Ranking on the 2009 Transparency International Corruption Index Giving the Countries Position Amongst the 180 Countries measured. Score = Achieved Level versus the Least Corrupt Score of 10.

Country	Mortality Per Annum	Transparency International Ranking	Transparency International Score
India	10,835	84	3.4
Bangladesh	1,680	139	2.4
Pakistan	1,200	139	2.4
Benin	650	106	2.9
China	450	79	3.6
Ethiopia	373	120	2.7
Myanmar	336	178	1.4
Democratic Republic Congo	224	162	1.9
Papua New Guinea	200	154	2.1
Philippines	200	139	2.4

Table 2: Top Ten Highest Snakebite Mortality Countries (70% of the Total World Mortality) using the High Range Estimated by W.H.O. and the Country Ranking on the 2009 Transparency International Corruption Index Giving the Countries Position Amongst the 180 Countries measured. Score = Achieved Level versus the Least Corrupt Score of 10.

Country	Mortality Per Annum	Transparency International Ranking	Transparency International Score
India	15,000	84	3.4
Indonesia	11,000	111	2.8
Nigeria	9,900	130	2.5
Pakistan	8,264	139	2.4
Bangladesh	8,000	139	2.4
Vietnam	4,368	120	2.7
China	4,091	79	3.6
Democratic Republic Congo	2,305	162	1.9
Afghanistan	1,368	179	1.3
Mali	1,365	111	2.8

Corruption manifests in the health system in many ways. For example:

1. Health Ministers and Secretaries purchase inflated priced medicines or equipment with Government health budgets, sharing in the additional profit with the supplier. This requires either a high value/low volume product to generate corrupt funds or a low value/high volume product e.g. antibiotics

2. Government purchased drugs intended for free supply to patients are sold into the market place often by falsifying patient records that a drug such as ASV was administered followed by referral to another hospital [18].

3. Major health projects are assigned a project manager from the doctor prepared to allocate the most project funds to the Minister

4. Government service doctors pay bribes to health administrators to ensure plum postings in areas where the local population are most wealthy [19].

5. Doctors employed by Government to provide free service to patients minimise time at the hospital to enable them to run private clinics involving payment from victims not seen in the hospital [18,20]

In many developing countries, corruption forms a 'fixed' element of the health budget. In Cambodia it has been reported that 5% of the total health budget is lost to corruption before dispersal from central government, in Ghana 18% [18,21]. In Pakistan, 30% of most projects are 'charged' by the health official for 'awarding' project management positions to a doctor or official. The amount available for health spending can be represented as a function of the funds allocated to health less the corruption percentage (Figure 1).

Figure 1. Health spending equation in developing countries with a significant corruption problem showing that number of patient treatments is a key dependant on the average cost of treatment per patient. Health Budgets are not increasing and corruption percentage leakage of health budget remain fixed.

T X Ct = Hb X Cp

Key

T = Number of patient treatments

Ct = Average Cost per treatment

HB = Health Budget

Cp = Corruption percentage

In such an environment where corruption is a reality, the proposal to provide donated funds to produce or supply ASV is doomed to failure [22]. Even when apparently possible options where funds are either,

1. Dispersed to the supplier to produce the ASV which is then provided free to countries

2. Provided directly to countries to purchase the ASV,

the donated ASV still retains a high value due to the known high costs currently in place. A vial of ASV that costs $80 in Africa still has a value of $80 even if provided free. The corrupt official or doctor still knows that value and is able to charge that money from victims in order to provide it. Providing high cost ASVs at no cost only encourages corruption and does not alleviate victim suffering; "More grants mean more graft" [1]. Donor funded health programmes failing due to corruption has been reported from Haiti and many other countries [22,23].

An additional problem resulting from the level of corruption is the notion of using abstract measures such as Quality Adjusted Life Years (QALY) in order to justify focus and spending on conditions such as snakebite. QALY represents extreme academic western, developed world thinking in assuming that measures such as this enter the thinking of the corrupt official who is in reality responsible for funds dispersion and drug acquisition [24-25]. The health official who has just negotiated a drug purchase deal for five times it's actual worth, funded from public funds, with the expectation of a massive kick-back, is unlikely to embrace an increase in QALYs as a 'revision of belief'. Focusing on QALYs may be useful in trying to convince western donors which condition to prioritise but has no value in convincing Governments to address the problem [24-25].

FOSTERS DEPENDENCE

The case that aid simply fosters dependence at the expense of local capacity building has been well made [1]. In the case of ASV production this is a real risk and there are signs that it is underway. In the last decade the ASV shortage in Africa has been well reported and yet we have not seen market entry from new suppliers to cover the shortfall. The requirement for Africa has been estimated at 1.5 – 2.0 million vials per annum, current supply is around 50,000 vials [26]. The current focus from W.H.O. and expert opinion appears to be that existing suppliers if given the right aid in terms of financial donation will fill this gap. However, simple maths shows that this argument is obviously flawed [8-9].

In order to evaluate the magnitude of the target of 1.5 – 2.0 million vials per annum, it is useful to examine current supply. Only one country, India, currently produces 1.0 million vials per annum [27]. Two suppliers that use caprylic acid fractionation in their production process, produce the vast majority of ASV in India. Any one off, rapid transition from ammonium sulphate precipitation to caprylic acid fractionation, which enables volume of final product to be doubled, is therefore not possible. Apart from a producer in the Peoples Republic of China, most current producers produce less than 100,000 vials per annum [11]. In order to satisfy the projected shortfall, an additional 15-20 suppliers are required for Africa plus others for Asia, each producing 100,000 vials per annum.

These new suppliers can only come from new market entrants; ideally increases in local, African or Asian based capacity. An ASV production unit is a typical Small/Medium-sized Enterprise (SME), employing approximately 100 people [11]. One of the weaknesses of Africa is the poor ratio of people employed in SMEs compared to wealthier countries. SMEs account for 80% of employment in European countries such as Italy and Greece and 60% in Japan; in Africa this is only 20-40% [1]. Clearly, establishing new entrants locally benefits both ASV production and the African economy. Cost can be minimised due to reductions in labour and distribution costs and the adverse impacts on price that we see with current suppliers providing additional volume can be avoided.

The current target of snakebite experts to provide donation funding has demonstratively not succeeded in solving the problem:

"GAVI initially envisioned that after 5 years of "bridge" funding, countries would have figured out how to finance and provide the increased immunizations themselves. But that's not happening" [28]. This is given further emphasis: "Also, the high cost of expensive new vaccines will be difficult to sustain if GAVI funding stops at the end of the five year commitment" [29]. In addition, "More analysis of the economics of vaccine production and vaccine markets, and development of strategies to create competitive and sustainable vaccine markets is needed" [7]. In the case of ASV production, WHO have specifically excluded any analysis of the economics of production or sustainability preferring instead to concentrate on increasing quality standards and thus inhibiting market entry [9].

THE PROFITEERING CONSEQUENCE

The provision of aid or donor funds removes the control of prices by competition and market forces. If donors can be persuaded to fund ASV provision, particularly to a small number of existing suppliers, the imperative to keep the price of ASV affordable is absent. Indeed the WHO has specifically stated that in their attempt to increase ASV supply, cost is not a factor that is worthy of immediate consideration [9]. The practical consequences of this have already been noted as a criticism of the current key target donor for ASV, GAVI [7]. The temptation for institutions to charge higher prices for drugs, vaccines or ASV will be great and is already evident.

In September 2009 a new ASV product was announced for Papua New Guinea (PNG), which had previously imported Australian ASV, as PNG has no indigenous production. The new product, a whole IgG monovalent ASV, was lauded as a major improvement versus the "current very expensive price" [30]. The pricing of the two products was K650 PNG ($258) per vial of the new ASV versus the previous price for imported CSL ASV of K4, 500 ($1,787) per vial [30]. On the surface this seems to be a step forward in supplying ASV at affordable prices to poor countries. However, the organisation cited as producing the ASV, is currently supplying a polyvalent ASV product in South and Central America for approximately $40 per vial, produced using the same method. The price differential presumably represents a hugely profitable opportunity for the organisation/s producing/supplying the ASV, but still falls very far short of affordable and therefore sustainable ASV based on value [11].

Personnel from the institution producing the ASV and the institution delivering the ASV are key members of the Global Snakebite Initiative, including WHO, that is proposing to 'increase ASV availability' in developing countries [12-13]. This example of setting pricing levels massively above production costs, simply because the developing world has previously paid even more inflated prices, is both unsustainable and raises ethical questions.

Profiteering and over charging for drugs also reduces profitability as a barrier to entry for fake drugs. High prices encourage the market for fake and alternative drugs to be introduced. Lower price levels for legitimate products reduces the propensity to supply fake drugs as profit levels are severely reduced.

A POSSIBLE TACTICAL APPROACH

Tactical approaches should be based on increasing effective support to regions where the problem resides and not generating headlines for academics from where the current solution is provided [12-13].

CREATING LOCAL AND SUSTAINABLE CAPACITY FOR LOWER COST DRUGS

The health budget equation (Fig 1) demonstrates that whilst increasing health budgets and reducing corruption are admirable tasks at the macro level, at the micro level the key variable to increase number of treatments is average cost of treatment. The

approach to provide lower cost drugs to developing countries is often criticised in terms of providing a second-class service by 'depriving' developing countries of drugs that are 'western standard'.

This is a misleading depiction as

1. It is becoming ever clearer that developed countries cannot afford to provide drugs at ever increasing cost levels; this underpins the current health debate. One in six dollars in the US is spent on health care and this is unsustainable. The belief that the western approach to drug provision should be used as the 'standard' is dubious.

2. These quality production standards are based on highly dubious science and when required can be rapidly bypassed i.e. H1N1 vaccine testing [16].

Partly the problem of drug pricing is determined by the infrastructure where the drugs are produced. If ASV is to be produced at large typically non-developing word pharmaceutical companies, with large research and development costs, corporate overhead to write off, prices will be high. Partner this with a 'quality' approach that involves over engineered standards with no demonstrable need and drug costs will be high [9]. However, ASV is a legacy drug and the process is not subject to patent. It need not be produced at a large R&D driven entity; rather a production unit dedicated to its production and with a relevant cost structure, preferably in a developing world country when greater numbers of SMEs would benefit the economy in addition to the medical condition. Prices would be dramatically reduced and therefore ASV becomes affordable, sustainable and less subject to corrupt transactions as the price is lower [11]. ASV has an advantage that it is not a bulk product and therefore a lower price does not mean that corrupt funds are readily obtained by taking a smaller corrupt percentage on a larger number of transactions.

VISIBLE MARKET PRICES

A clear statement detailing the most efficient method for the production of the lowest sustainable cost per vial for ASV is available; specifying the likely cost per vial and this should be widely disseminated [11]. Currently the price range of various ASVs is $8 - $1,700 per vial, which enables prices to be charged which provide both unreasonable returns and purchasing authorities with the view that they are getting a good deal when they are not [30]. There are encouraging signs that once the true price of a drug is widely available, prices fall and attempts to charge inflated prices becomes diminished as do corrupt sales opportunities [18,23,30-31]. Benchmark data is now available, which lists the key factors that determine the likely price of an ASV although this had been excluded from recent snakebite literature [11-13]. These can be readily utilised to calculate the best locations to site the production units of the new ASVs e.g. those countries with low cost grazing land would be ideal as this represents a large proportion of the capital costs. Governments can thus be engaged with both the medical and economic imperative of local production and the accruing benefits.

ACTION ORIENTATION

None of these solutions or other improvements such as unified treatment protocols will be implemented unless WHO and related snakebite interested parties adopt an action orientation and make practical meaningful interventions, as opposed to the decades of failure they have presided over to date [8,9,32-33]. It is regrettable that the WHO and their activity arm, the Global Snakebite Initiative have now been working together for 18 months and the only outputs are a number of articles and a 'new' website which sadly contains the same data that has been available on another website for many years [34-35]. There is no need for more lists and pictures of snakes

but an urgent need for recommended ASVs or treatment guidelines. The provision of two websites, when snakebite is a problem of poor developing countries, with limited infrastructure, clearly demonstrates the lack of operational understanding of the problem they are trying to address. How many rural doctors are able to log on to websites to check which species they are dealing with and is this really necessary to treat snakebite?

These outputs may look good on WHO or academic lists of yearly accomplishments at appraisal time, but they do little to improve the lot of victims. Despite the exultation at the original GSI meeting to "put aside our differences with each other, our power plays and politics and all the rest of it and actually co-operate", little has changed [3]. Simple practical solutions have been provided in the form of treatment protocols and affordable and sustainable ASV, but are continually excluded in favor of websites and inactivity. [11-36].

It is time for another agency to take the lead in managing the effort to improve snakebite management. WHO have been engaged in this effort for many decades and the results have been dismal [8-9,12-13,32-33]. Their reliance on western academics for policy, with their own agendas, little in theatre experience and reputational capital invested in the current status quo, has yielded little.

CONCLUSION

Many critical medical issues reside within developing countries where endemic corruption is a reality that impacts political and medical systems, a situation that will not change in the near or medium term. The resort to donor funds to increase drug supply is appealing but fraught with problems. Unintended consequences can undermine the scientific process by which priorities are determined and the ultimate benefit to both the society and specific victims. The key need is to develop tactical approaches that can increase capability to manage medical conditions but can also improve local capacity to reduce opportunities for corrupt interventions. In the case of serious medical conditions, the Christian maxim 'it is better to give than receive' is sorely misplaced. It is easy to ask and for donors to give funds, but this is useless unless the victim receives the benefit. 'Dead Aid' and dead patients are synonymous, strategies that improve patient access to drugs and reduce potential for corrupt/ineffective interventions are clearly required.

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