

# SMART INJECTION PROGRAMME

PROPOSED BY SAFEPOINT TRUST



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# Smart Injection Programme: Summary

## Aim: to stop disease being spread through medical injections

### Why the Smart Injection Programme? (page 2)

Medical injections should save lives. They are administered to protect people from disease, or cure them from infections. But unsafe injections, using dirty or unsterile syringes or needles for example, can end lives. They pass diseases like HIV and Hepatitis from one patient to another, to health workers, and waste collectors. According to the World Health Organisation (WHO), unsafe injections lead to 1.3 million deaths and \$540 million in financial costs every year. One child dies every 24 seconds from an unsafe injection.

This tragic and unnecessary burden is preventable and can be eradicated. Syringes are reused for a number of reasons: there may be insufficient product supply; some healthcare workers do not understand the risks that reuse poses; or it is perceived as 'cheaper' to reuse or recycle devices, even if they only cost a few cents.

Injection safety projects are not new. GAVI's work in immunisation and PEPFAR's in therapeutic care have produced some very successful programmes, covering around 6% of all injections given. But for injection safety to be effective, it must be universal. The Smart Injection Programme is an innovative proposal that builds on existing successful initiatives and allows countries to implement a comprehensive, holistic injection safety programme to cover all types of injections. The challenge is to bring sustainable safe injection practices to the whole healthcare system.

### What is the Smart Injection Programme? (page 3)

Smart proposes co-funding by countries and donors to bridge the financial and information gap between unsafe and safe injections. It addresses the different reasons for reuse through four key components:

1. Full quantities of safety syringes - enough for every injection given in the country. To protect people effectively, injection safety cannot discriminate between types of injection or drug. Safety syringes are designed to prevent reuse and protect the patient, the healthcare worker, and the environment from harm. To be eligible for co-funding, safety syringes must be able to show conformity with accepted international quality standards. The Smart Programme is product-independent.
2. Waste management planning and resources. WHO suggests that currently syringes are reused on average seven times in developing countries. Using one syringe for one injection will clearly increase the amount of waste and the need for sharps protection is clear. Waste disposal is already a problem in many countries, so this must be addressed with quick and comprehensive action.
3. Training for healthcare workers on injection safety. To promote the rational use of injections, and to allow healthcare workers to carry out their duties in safety to themselves, the patient, their co-workers and the environment.
4. Public information on injection safety. Patients have a right to know about injection safety: why injections can be dangerous, and how to receive a safe one. Today many are not aware of the risks.

Co-funding to cover these four complimentary, essential components, is around 5 US\$ cents per injection. Using Kenya as an example, with 32 million people, and 4 injections per person per year, this amounts to \$6.4 million required in co-funding per year. This is equivalent to the treatment costs for less than 1% of the HIV sufferers in the country. To cover the whole of Sub-Saharan Africa would require approximately \$129 million a year. Funding requirements are likely to fall over time as market prices of safety syringes and standard syringes converge, and raised public awareness reduces training and education costs.

### How will it work? (page 7)

The Smart Programme aims to bring together all the key stakeholders needed to achieve comprehensive and sustainable injection safety. These include national ministries of health representing the patients: local populations; medical and nursing bodies representing the healthcare providers; the donor agencies; and the suppliers of goods and services. The Programme will be piloted in a small number of key countries prior to a broader roll out. Kenya and Uganda are excellent pilot candidates given their commitment to developing injection safety to date and their success in addressing HIV prevalence rates.

The 2007 East Central and South African (ECSA) Health Ministers' meeting in Arusha, Tanzania was the forum where the Smart Programme was launched and brought to a wider audience. The result, a ground-breaking resolution on injection safety approved by all ten member states, is included in the Appendix. Implementation is now underway with a follow up technical meeting completed in October 2007 and a further progress update scheduled for Q1 2008.

# Why the Smart Injection Programme?

**Problem:** syringes are reused seven times on average in developing countries, spreading disease between patients.

The social and economic costs of unsafe injections are overwhelming. 21 million people are infected with Hepatitis B (around a third of all new cases), 2 million with Hepatitis C, and 230,000 with HIV<sup>1</sup> through unsafe injections globally each year. These figures are more shocking because these infections are iatrogenic (caused by medical treatment). All are *preventable*.

During an injection with a used syringe or needle, blood-borne pathogens from one patient can be transferred to another, otherwise healthy person. Syringe reuse on such a scale as described above may seem almost inconceivable. But unsafe injection practices range from accidental pricking with a used needle to improper sterilisation of glass syringes to wholesale industrial recycling of used syringe and needle parts. WHO data suggests that over 50% of injections in developing countries are unsafe; in some areas, many more. Why does reuse occur, with a device so basic and affordable as a disposable syringe? Syringes are reused for a number of reasons: because they can be; because there is insufficient product supply, in remote areas for example; there is insufficient understanding of the risk of reuse; and it is perceived as 'cheaper' - wholly ignoring the true humanitarian and economic impact.

**Solution:** a comprehensive safe injection approach - making every injection safe.

The Smart Programme proposes co-funding between countries and donors to bridge the gap between the cost of a safe and an unsafe injection. It allows countries to overcome these reasons for reuse, through four essential complimentary components:

- 1) Full quantities of safety syringes - enough for every injection given in the country.
- 2) Waste management planning and resources.
- 3) Training for healthcare workers on injection safety.
- 4) Public information for all people on injection safety.

The cost of upgrading to a safe injection is small. 5 US\$ cents can be sufficient to cover all four components. Market prices for non-reusable syringes are for example currently 2-3 cents more than standard syringes. Needle protection devices ("anti-needlestick") are currently expensive but falling. Training, education and waste disposal can be provided for less than one cent each per injection<sup>2</sup>. If people receive on average 4 injections per year, for a country such as Kenya with 32 million people, this amounts to a total annual funding requirement of \$6.4 million. 'Prevention is better than a cure': this investment in prevention is equivalent to treatment costs for less than one percent of current HIV/AIDS sufferers in the country.

Safe injections save lives. But for safe injections to be effective, they must be universal. Most people, including some healthcare workers, do not know that injections can be dangerous. The Smart Programme will compliment the successes of safe injection programmes by United Nations Children's Fund (UNICEF) and GAVI Alliance<sup>3</sup> that have focused on immunisation, and the United States' President's Emergency Plan for AIDS Relief (PEPFAR) in therapeutic healthcare. The Smart Programme is a sustainable and efficient expansion of these initiatives. With injections used so widely in developing countries to administer medication for routine health problems, injection safety must be laid as a foundation upon which all other successful health interventions can be built. Developing countries to date, for example, have procured standard syringes for the bulk of public healthcare needs, while also receiving safety syringes from donors for specific programmes such as child immunisation. The Smart Programme enables countries to upgrade comprehensively to safe injections by providing co-funding for each of the complimentary four components.

*"If AD syringes were the same price as normal syringes, I would buy 5 per person (the average annual use), as I know the public will be supported and support this."*

Dr. Otaala, Minister of State for Primary Health, Uganda.

*"What works for immunization can work for the curative sector as well."*

UNICEF and WHO publication (Western Pacific Region) "From Harm to Hope"

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<sup>1</sup> Hauri et al, International Journal of STD AIDS 2004; 7-16

<sup>2</sup> Estimates from WHO Safe Injection Global Network (SIGN). National context will determine exact level of co-funding required.

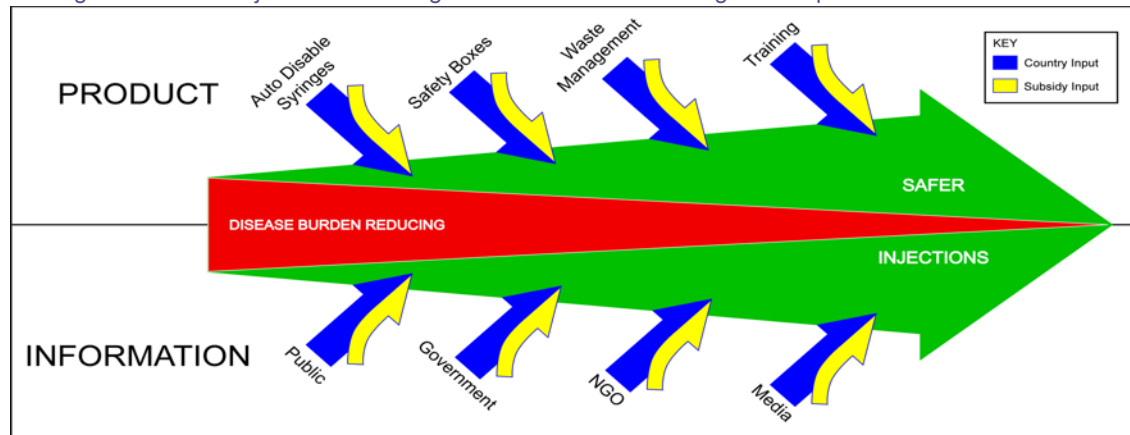
<sup>3</sup> [www.gavialliance.org](http://www.gavialliance.org)

# What is the Smart Injection Programme?

The Smart Injection Programme is a co-funding proposal to remove the perceived financial barrier and information gap between unsafe and safe injections.

**Definition:** A safe injection is one that does no harm to the healthcare worker administering it; to the patient receiving it; or to the environment where disposal might occur (WHO).

Moving towards safe injections: reducing the disease burden through better products and better information:



As outlined on the previous page, the following four components are core to the Smart Programme:

## 1. Safety syringes: one injection, one syringe.

Safety syringes are designed to reduce the risk of injury to the patient (from reuse) or to the healthcare or waste worker (from 'needlestick' accidents from used needles and sharps) or to the environment (from exposed sharps, or improper recycling methods). Auto disable syringes for example are used worldwide in immunisation campaigns by UNICEF and others. These safety syringes disable automatically and are rendered useless after a full dose is administered.

The Smart programme proposes augmenting country spending on injection devices to cover the unit price difference between standard and safety syringes. The co-funding covers *sufficient devices to cover the complete injection needs of a country*, including immunisation and all therapeutic injections. Injection safety must be universal to protect people effectively; it cannot differentiate between types of injection or drug; nor between healthcare scenarios.

Requirements must be tailored to country circumstances, but in general, safety (non reusable) syringes currently cost 2-3c more per piece than normal syringes. Devices to prevent needlestick accidents remain more expensive but prices are falling. People in developing countries receive on average 3-5 injections per year<sup>4</sup>.

Use of safety syringes is already well established, through the immunisation initiatives of GAVI for example, and there are a number of competitors producing devices. The Smart Injection Programme is independent of any particular product type or manufacturer. However in order to ensure quality, only products which comply with accepted international standards will be eligible for co-funding. Manufacturers will be obliged to prove compliance with the relevant standards.

There are two international manufacturing standards published specifically for safety syringes: ISO 7886-3 and 7886-4 (see *Technical Data in Appendix for more details*). These standards encompass a range of safety syringe products including devices which include protection for the patient, and the healthcare worker. Different medical circumstances and risk scenarios require different products. Following ISO guidelines, the most appropriate type of product should be used in each case. There do not currently exist standards for anti-needlestick devices.

## 2. Waste disposal planning and resources.

Waste disposal includes the comprehensive handling of sharps, injection devices and infectious agents from the point of injection to final safe disposal. A common part of waste disposal in many developing countries is the cardboard safety box which is used to store used syringes and sharps after injection and transport them to a final disposal site (eg by incineration). The WHO estimates that standard syringes are used seven times on average in developing countries. Clearly volumes of syringes will greatly increase when safety syringes mean that one syringe is used for each injection. Waste disposal is already a major problem in many developing countries, and it is one which must be addressed with quick action. This component therefore includes funds to help countries plan for the safe and appropriate disposal of

<sup>4</sup> Sources: World Health Organisation

medical waste. Needle protection devices will greatly improve the safety of waste workers and the community. This is a crucial part of injection safety but one that must be made according to local needs.

### 3. Healthcare worker training.

As the Program for Appropriate Technology in Health (PATH) have noted, “safety syringes compliment, but do not replace, injection safety awareness.”<sup>5</sup> Comprehensive training for healthcare workers is essential for the success of the Programme. This will allow them to carry out their duties in safety to themselves, the patient, their co-workers and the environment.

Training also includes the rational use of injections: promoting behavioural change at medical practitioners to encourage them to administer oral medicine in place of injectable drugs where it is appropriate, and with patients to encourage them to accept alternative forms of medication. In many countries injections are overused: Pakistan for example has one of the highest rates in the developing world, with over 13 injections per person per year. A 2006 study estimates that over 90% of these are unnecessary<sup>6</sup>.

Like the safety syringe products, there are also good precedents for healthcare worker training on injection safety. Through the Making Medical Injections Safer (MMIS) programme administered by PEPFAR 25% of all nursing staff in Kenya and Uganda have received comprehensive injection safety training. Model Injection Centres (MICs) have also been set up in major cities in India by the International Epidemiology Network (INCLIN) which are primary health centres dedicated to universal use of injection safety practices and products.

### 4. Public information.

Injection safety is a simple but life-saving message that should be known and used as universally as how to cross the road safely. Better public awareness can significantly reduce the number of injections demanded and prescribed, and promote safe practices for the injections that remain.

A public information campaign should include why injections are important; what a safe injection is, and how to receive one. It should also strongly advocate the rational use of injections, since it is very often the patients themselves that demand injections as the ‘best’ form of treatment. Dissemination of the simple, essential safe injection message will allow patients to make informed decisions to protect themselves and their families.

There are good examples of public health information programmes working with success, such as campaigns on water sanitation and use of condoms. Mass media (TV, radio, newspapers, community theatre) is an excellent vehicle to carry public health messages. SafePoint ([www.safepointtrust.org](http://www.safepointtrust.org)) is a trust established by Marc Koska OBE in 2006, dedicated to solving basic healthcare problems through better information for the general public. SafePoint uses WHO guidelines to create educational materials and disseminates them through existing NGOs and developing country mechanisms. It is one solution therefore for this aspect of the Smart Programme.

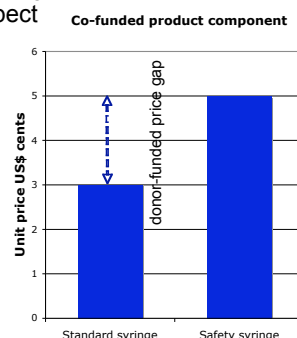
### Cost/ benefit analysis: safe vs. unsafe injections

The 5c (US\$) difference between a comprehensive safe injection and an unsafe injection is significant compared to the healthcare provisions of poorest governments, where annual health spend may be as low as \$5 per person per year, but it is a tiny fraction of the socioeconomic costs it is designed to prevent.

National studies are needed to quantify accurately the gap that exists in each component and the estimates given below are approximate.

The components are:

1. Safety syringes.  
As a traded commodity product, this component is the most easily priced. Depending on market circumstance, unit price differences between standard and safety syringes are usually 2-3 US\$ cents.
2. Disposal. Data from WHO’s Safe Injection Global Network (SIGN)<sup>7</sup> suggests that the cost of safe disposal is less than one cent per injection.
3. and 4. Healthcare worker training and Public information. These are harder to estimate or generalise but preliminary feedback from MMIS and several Ministry of Health sources suggest it is appropriate to allocate one cent or less for each component.



<sup>5</sup> Carib Nelson, PATH presentation at SIGN Mexico 2006

<sup>6</sup> Source: Altaf, Janjua and Hutin, JCPSP 2006, Vol. 16 (9), 622-624

<sup>7</sup> Yves Chartier, WHO

Example: cost analysis for selected countries and region

REGION	POPULATION (MILLIONS)	NO. INJECTIONS PER PERSON (EST'D ANNUAL AVERAGE)	TOTAL INJECTIONS (MILLIONS)	CO-FUNDING PER INJECTION (US\$)	TOTAL ANNUAL CO-FUNDING (US\$ MILLIONS)
Kenya	32	4	128	0.05	6.4
Uganda	26	4	104	0.05	5.2
Sub-Saharan Africa	643	4	2,572	0.05	128.6

The impact of co-funding will be tangible.

Treatment costs - both humanitarian and economic - are already unmanageable. With a growing cohort, the approach must be to address cost-effective disease prevention. The Smart Injection Programme presents clear returns, limiting the growth of the disease burden in financial terms, and saving lives.

Benefits can be permanent but donor obligations need not be.

1. Product co-funding is required primarily because of the current gap in market prices between standard disposable and safety syringes.

Syringe manufacturing is highly competitive and commoditised, and market pricing is dependent on scale manufacturing. Many safety syringe designs can be manufactured for a similar unit cost as standard syringes if produced at high enough volume, despite incorporating additional safety features to prevent reuse and needlestick accidents. But while safety syringe production is now significant in absolute terms it is low relative to the total syringe world market: 2-3%<sup>8</sup>. This lack of scale contributes heavily to the current price differential. However through the Smart Injection Programme countries will be encouraged to commit to procuring full quantities of safety syringes to satisfy all country demand (not for example just immunisation). This increased volume will enable safety syringe manufacturers to gain scale advantages, and for prices to drop accordingly over time. Thus the need for product co-funding will reduce.

2. Education and training costs should also fall over time.

As injection safety is incorporated more comprehensively in general public awareness and healthcare worker practice the cost of educating the second and third generations of healthcare workers and public will reduce. Once injection safety has been established as a foundation for good healthcare and public care, this will allow donor funds to move to other sectors needing financial attention.

<sup>8</sup> Source: UNICEF, WHO

# How will the Smart Injection Programme work?

## Participation.

There are three groups of participants: the health ministries, and the populations and healthcare providers that they represent; the donors; and the suppliers of goods and services. The Smart Programme suggests a format to bring these together. Smart is a Programme that can be applied globally but of course local context will define country-level implementation. To launch the Programme successfully, two or more pilot countries will be used. Kenya and Uganda are excellent candidates for the pilot stage. Both have good records to date in making injections safe and have shown impressive commitment in addressing HIV prevalence rates. All key groups in both countries are supportive of taking the Programme forwards.

## Process.

- I. Benchmarking: to determine national policy and target activities, in accordance with WHO SIGN guidelines. Stakeholders' meeting to present the Programme including all groups of participants.
- II. National analysis to assess the country needs under the Smart Programme. This analysis can be done based on existing and past programmes, namely under GAVI, EPI and MMIS for example.
- III. Using the parameters for country-wide implementation, Smart can be launched as a pilot in selected provinces.
- IV. Following data collection, monitoring and feedback, the Programme will be modified and improved to enable a broader roll-out to succeed, nationally and then to other countries.

In general the toolkit produced by WHO SIGN is used as a guide for policy planning and implementation. All countries are encouraged to use these tools as part of scaling up their injection safety programmes within the Smart framework.

The East, Central and Southern African Health Community (ECSA)<sup>9</sup> meeting in March 2007 in Arusha, Tanzania was the forum where the Smart Programme was launched and brought to a wider audience. This resulted in a resolution adopted by all the member states based on the four components of the Smart Programme, accompanied by a clear timetable. This was the first regional resolution of its kind. The substance of the Resolution is in the Appendix below.

Implementation of this resolution has now begun with a successful follow-up meeting held in Nairobi in October 2007, and a further progress update scheduled for Q1 2008.

## The co-funding will enhance, not replace, existing country systems and processes.

### 1. Procurement.

The co-funding will operate through existing procurement channels. National tenders for syringes will operate as before on an open bidding process and be open to all qualifying products: normal syringes will be allowed to compete in the tender assessment with safety syringes. However only International Standards Organisation (ISO) 7886-3 certified syringes (for immunisation) and ISO 7886-4 certified syringes (for therapeutic use) will be eligible for co-funding. Import tariffs on non eligible syringes could be a practical accelerator to full compliance and conversion. Unfortunately no quality standards nor specifications exist for needlestick prevention devices, and we seek guidance from international bodies such as WHO on best practice.

### 2. Administration, implementation and monitoring.

Lessons have already been learnt in the administration of safe injection programmes due to the successful GAVI/ UNICEF and PEPFAR/ MMIS programmes. The Smart Injection Programme would use these infrastructures and existing WHO SIGN guidelines to deliver and monitor a comprehensive solution including safety aspects for the patient, healthcare worker, waste disposal and the environment. Smart has secured broad support from PATH and MMIS to help achieve this. Similarly, the monitoring of the programme would be administered through existing groups and structures.

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<sup>9</sup> East, Central and Southern African (ECSA) Health Community, formerly known as Commonwealth Regional Health Community Secretariat  
<http://www.crhcs.or.tz/>

# Technical data and Appendix

We propose a detailed country needs analysis to provide an implementation plan for the Smart Injection Programme on a national basis. Surveys such as WHO's Tool C (+ MMIS) can be used as a common assessment framework with local adaptations. Local contexts will clearly dictate much of the logistics but many of the core details of the Programme will be applied across all countries. For example:

## 1. Manufacturing standards for safety syringes.

The Smart Programme calls for procurement of full quantities of safety syringes to cover all injection needs within the country. The International Association of Safe Injection Technologies (IASIT) is an independent body representing many of the competing safety syringes manufacturers in the world.

A. The International Organization for Standardization ([www.iso.org](http://www.iso.org)) has established a specification for safety syringes: ISO 7886.

Part 3 relates to syringes for immunisation (auto disable syringes for fixed dose).

Part 4 relates to syringes for curative or therapeutic use.

A number of products meet these specifications. As the standard notes, the syringe most appropriate for the medical situation should be selected.

Part 3 defines precisely the specification for an immunisation syringe, including the barrel size, and needle gauge, length and attachment for example. Part 4 in contrast covers syringes to be used in all therapeutic applications: a much broader range of medical situations.

SafePoint urges that the safest syringes are used to prevent deliberate or unplanned reuse. These are syringes which disable automatically when the injection is completed (Type 1). Other syringes require an elective additional action by the healthcare worker to disable the device (Type 2).

In addition the specification allows for syringes that can aspirate (draw fluid from the patient just prior to full injection to check the injection site) in different ways. This is often important in therapeutic injections. Syringes that can aspirate once prior to injection are Type A. Other syringes can perform multiple aspirations (Type B).

There are several syringes on the market from established suppliers that are both Type 1 (automatic disabling) and allow multiple aspiration (Type A).

B. The World Health Organization ([www.who.int](http://www.who.int)) perform an independent testing procedure on all products used in programmes such as UNICEF. This is called PQS (Performance, Quality, Safety). Products are independently tested and listed on their website:

[http://www.who.int/immunization\\_standards/vaccine\\_quality/pqs\\_prequalified\\_devices/en/index.html](http://www.who.int/immunization_standards/vaccine_quality/pqs_prequalified_devices/en/index.html)

Injection devices must hold ISO 7886 in order to qualify for PQS so the products listed here are comprehensively endorsed.

## 2. Manufacturing standards for safety boxes and needlestick prevention devices.

Currently no ISO specification exists for needlestick prevention devices nor for safety boxes for the disposal of used sharps and syringes. However performance specifications and test procedures for safety boxes have been developed for use by WHO:

[http://www.who.int/immunization\\_standards/vaccine\\_quality/equipmentperformance/en/index.html](http://www.who.int/immunization_standards/vaccine_quality/equipmentperformance/en/index.html)

# East, Central and South African (ECSA) Community

## Resolution 11: Injection Safety

### Preamble

Recognising that injections are a common medical intervention and provide the foundation of delivery of most health-care programmes in developing countries;

Recognising the health burden caused by unsafe injection practices, especially the transmission of HIV, Hepatitis and other blood-borne pathogens;

Aware that injections are often over prescribed;

Noting that for injection safety to be effective it must apply to all types of injections (immunisations and curative services); and that it must be operated on a national scale;

Recognising the progress made to date in injection safety programmes in member states;

Further noting that there are cost effective interventions that address injection safety.

### Member states are urged:

1. To implement, support or scale up existing comprehensive injection safety programmes by November 2009.

These programmes should include four complementary components at levels that correspond to country needs:

I. Injection safety devices: supply adequate levels of safe injection devices, to ensure appropriate use.

II. Sharps waste disposal: appropriate management of infectious sharps waste.

III. Healthcare worker training: provide continued training on safe injection practices.

IV. Public information: to decrease demand for unnecessary injections and instill awareness of safe injection practices.

2. Ensure appropriate quality safe injection devices through the adoption by the National Regulatory Agencies of international standards on product quality (ISO 7886:1-4 and WHO PQS where relevant), within the same time frame as above.

3. Support the implementation of, or introduce, national policies on injection safety by November 2007.

### ECSA Secretariat is directed to:

1. Host a forum of participating ECSA member states to share and discuss key points of programme implementation.

2. Facilitate communication among key stakeholders.

3. Consider linkages to other ECSA activities, such as proposed regional revolving funds or other activities related to ensuring affordable continuous supplies.

March 2007, Arusha, Tanzania

## Background

1.3 million people die as a result of unsafe injections every year. The spread of disease through syringe reuse does not discriminate between types of injections: total injection safety can and must be an absolute aim. Of the 16 billion injections that are administered in developing countries every year, it is estimated that half are 'unsafe' ie cause some harm to the healthcare worker, the patient, or the environment. Tragically this creates 22 million Hepatitis B and C and 230,000 HIV (iatrogenic) infections. With 5-10% of HIV infections caused by unsafe injections, this directly leads to potential treatment costs of \$1000 every year per person – if treatment is received. In many cases it is not and the true social and economic cost is far greater. The cost of preventing infection by ensuring a safe injection is a few cents; the cost of treatment is perhaps 100,000 times that. The Smart Injection Programme delimits the funds needed to treat disease by blocking this transmission route for disease.

Securing injection safety in immunisation provides a healthy foundation for all other medical interventions. With this foundation in place, the country can direct resources to other development areas, whether in health or elsewhere. Looking after injection safety is an indicator to the domestic population and the international community alike that a country is committed to serving its healthcare needs responsibly. The deaths of 3000 people worldwide can be prevented every day.

Safe Injection pledge and street plays:



In November 2006 SafePoint Trust toured India working with a number of grass root NGOs to educate parents and children about unsafe injections and how to avoid them. In this picture taken in the largest slum in Indore, the crowd are pledging to make sure they only have an injection from a syringe which comes directly out of a sealed packet, that it is only used once and then destroyed (by choosing a disabling syringe) and is disposed of in a sharps box.

Mothers told the author (Marc Koska) that due to four exposures to this message over one year they now walk 5 miles to buy an safety syringe when an injection is required in their family. There were 40,000 mothers in this slum.

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6, 7, 8, 9 Sources: World Health Organisation