

# When a Sharp Reduction of Economic Burden is Within Reach: How should U.S. foreign policy address the challenge of sterile syringes? Council on Foreign Relations Global Health Roundtable

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Needles and syringes are the most common method of delivering vaccines and medications worldwide. The World Health Organization (WHO) estimates that over 16 billion injections are administered in developing countries each year, and of these 16 billion injections, around 40% are administered with reused or unsterile syringes and needles that can transmit a host of blood-borne viruses, including hepatitis B, hepatitis C, and HIV. This means one of the most common medical practices in the world is also a leading contributor to the global spread of infections and deadly diseases. Any escalation in global health spending that increases the volume of medical injections risks spawning the spread of blood-borne diseases unless sterile syringe use is factored into all program planning.

Unsafe injection practices are commonplace in most low-income country health settings, placing patients, health care workers, and the community at great risk of infection. Each year, more than 25 million people globally are infected with hepatitis B, hepatitis C, or HIV through the use of unsterile and reused syringes. A recent WHO study found that unsafe injections annually cause 1.3 million premature deaths, 26 million years of life lost, and \$535 million in direct medical costs. The problems of syringe and needle reuse, and improper waste disposals are complex and fueled by a combination of sociocultural, economic, and structural factors. Although simple, low cost safe injection technologies do exist, a comprehensive solution on the part of international organizations, governments, health administrators, community organizations, and health workers has not emerged.

Progress has been made over the past decade to reduce syringe and needle reuse for vaccinations, by ensuring international immunization campaigns use only auto-disable (AD) syringes with locking features that physically prevent their reuse. However, childhood immunizations account for only 10% of the injections administered around the world each year. There is an acute need to expand the accessibility of other reuse prevention technologies to the remaining 90% of injections given for curative purposes.

On the evening of June 20, 2007 the Global Health Program at the Council on Foreign Relations brought together representatives from syringe manufacturers, governments, the United Nations, non-governmental organizations and the medical profession to discuss this issue and find ways in which U.S. Foreign Policy can address the challenge of sterile syringes. CFR Senior Fellow for Global Health, Laurie Garrett, moderated the four-hour meeting that was organized in collaboration with CFR term member Brett Zbar. The session was the third in the global health roundtable series developed with the Global Public Health Practice at McKinsey and Company that examines existing medical technologies that have the potential to improve millions of lives globally, yet remain under utilized and under-funded.

## Unsafe Injection Practices

An injection is a skin piercing procedure performed to introduce a substance into the body for prophylactic, curative or recreational purposes. Syringes are used around the world to

give vaccinations, medications, and vitamin supplements, as well as draw blood, flush IVs and administer anesthesia. The WHO defines a safe injection as one that does not harm the recipient, expose the health worker to avoidable risk, or result in hazardous waste that puts the community at risk. The most common unsafe injection practices involve reuse of dirty syringes, needle stick injuries to the health worker, or improper disposal of used syringes that create hazards for the community at large.

Injections are widely overused medical procedures and in many cases, the medicine and vitamins being injected through a syringe could, just as effectively, be taken orally. The WHO reports that 70-90% of injections given each year are unnecessary. The incentive factors that fuel overuse of injections for the provider, or the health seeking behavior of the patients that demand injections are not yet fully understood, although it has been documented that in many cases, health care workers make more money giving injections than prescribing pills.

Unsafe injections practices place not only patients at risk, but also compromise the health and safety of health workers. Doctors and nurses are frequently exposed to the blood of their patients in the course of their work, most commonly as a result of needlestick injuries. Health workers in poorer settings particularly where HIV rates are high, face an inordinately elevated risk of potential exposure to infection, as many are working without gloves or other protective clothing, or lack adequate training to prevent such injuries from occurring. Given that the acute shortage of health care workers is the most fundamental problem inhibiting the treatment of infectious diseases in the developing world, this issue takes on critical significance, yet has received very little funding or policy attention. As highlighted by Gary Cohen, Executive Vice President of Becton Dickinson, occupational safety of health care workers in low-income countries is a neglected and underreported issue. "Clinicians in developing countries face far higher risk than clinicians in developed countries with virtually no interventions to document, prevent, or treat those exposures. This to me becomes a human rights issue."

Other unsafe practices, such as poor collection and disposal of dirty syringes and needles, expose healthcare workers and the community at large to the risk of needle stick injuries and infection. In some countries unsafe disposal can lead to the re-sale of used syringes on the black market to be later reused again on patients. In many low resource settings, there is no waste collection system. In these cases, there is no standard WHO recommended policy on how to dispose of syringes and other infectious waste.

#### Progress on Safe Injections for Childhood Immunizations

Reuse of syringes is an age-old problem that garnered the attention of international agencies in the mid 1980s with the onset of the HIV epidemic. Over the past two decades many organizations have formed to advocate for research, funding, and training for safe injections, yet progress has been slow. Some of the key players in the effort include, the SIGN Alliance, USAID: HealthTech, Office of Population, PEPFAR: Making Medical Injections Safer, the Safe Injection Global Network, SafePoint, GAVI, UNICEF, WHO, UNFPA, and device manufacturers.

As a result of these leadership and advocacy efforts, UNICEF, the world's largest vaccine purchaser, the WHO, and the United Nations Population Fund (UNFPA) drafted a joint

policy statement on injections safety in 1999, calling for the exclusive use of auto disable (AD) syringes in all immunizations programs by 2003, to eliminate the reuse of syringes in immunization campaigns. AD syringes lock after injection, which physically prevents reuse.

Before the creation of the safe injection policy, UNICEF was responsible only for the purchase and distribution of vaccines. It was the responsibility of the receiving country to purchase an adequate number of syringes and properly manage the vaccination process. With the enactment of the policy on injection safety, UNICEF began to bundle all of its vaccines with the appropriate number of AD syringes and safety boxes to dispose of used syringes. The bundling policy eliminated many of the issues that lead to the reuse of syringes in immunization campaigns by ensuring that all supplies arrived at one time to one destination, an adequate number of syringes were purchased to match the amount of vaccines provided, and protective gear and safety boxes were included to prevent needle stick injuries.

The pediatric vaccine focused GAVI Alliance was created as a way to ensure that the poorest countries were able to not only afford immunizations, but also administer them in a safe manner. GAVI has been touted as an immensely successful model for public-private partnerships: In the first six years of its existence, the GAVI Alliance has helped to significantly increase the number of children worldwide who have access to immunizations through safe injection practices.

Overall, the efforts of UNICEF, GAVI, and the international community have had a tremendous impact on delivering childhood immunizations to much of the poor world through safe injection practices. Now over 75% of immunizations in Africa are administered with auto disable (AD) syringes, which essentially eliminate the possibility of reuse and infection. Cohen of BD attributed the achievement of this major public health success story to the alignment of many key factors: The reduction in cost of AD syringes, advocacy, political will, funding to address to the need, and effective behavior change and training at the community level.

With the success of providing safe injections for childhood immunization behind us, the world must tackle the larger challenge of how to expand this success to curative injections (which account for 90% of all global injections). As CFR Senior Fellow, Laurie Garrett aptly asked the speakers: what would be the best leverage points that would get the same power and force that fueled the immunization safety campaign into the curative injection issue?

#### Injection Safety: Curative Challenges

In contrast to immunizations that are administered in comparatively controlled conditions, curative injections are given in a wide variety of settings, ranging from large hospitals by trained physicians, to marketplace stalls administered by people with little or no formal medical training.

As Gary Cohen explained in his presentation, regulation and procurement of injection devices for immunizations is vertically managed by international organizations and government agencies, while curative injections have highly decentralized procurement processes, and little international funding or government regulation. Syringes for immunization are used only for through the skin injection; curative devices are used for

many different procedures. Immunizations are typically fixed dose, while curative injections require variable dosing. The BD auto disable syringe used for immunizations that auto locks after one push would not work for many curative applications including medications that require mixing of powder and liquid, giving insulin to diabetics, injecting drugs for intravenous users, and drawing blood. Safe injection devices for curative purposes must be able to meet the needs of the health worker and patient, while also eliminating the possibility of reuse of the device. Finally, these devices must be available to the developing world at an affordable price and must include training so that they are used properly to protect both the patient and the health worker. BD and other manufacturers have developed a range of curative injection devices designed to address these additional challenges.

“Curative safety will require more than device design - policy, funding and medical practices must all fall into alignment for change to occur,” Cohen said.

### Engineering Solutions

Industry has developed several new platforms for preventing reuse in curative injections. PATH, an international, nonprofit organization has worked on injection technology for over twenty years. Vice President and Senior Advisor for Technologies at PATH, Michael Free, presented a number of safe injection technologies currently available for use in the curative sector, including syringes with locking ring, or retracting needle, needle protection devices and disposable cartridge jet injectors. "One would predict in perhaps 20 years you will see a large number of vaccines and medications in one way or another without needles," thanks to emerging innovations, Free said.

However, technology is only part of the solution and “we must go beyond simply providing devices, we must ensure they are the right devices, and they are being used properly in the various settings injections are administered. Ultimately, the goal is to end the embedded behavior of reuse and our view is that device design serves as a stimulus or a catalyst for behavior change, but the device alone cannot change behavior on its own,” Cohen said.

### Pricing Solutions

Cost is an important factor in new device manufacturing, distribution, and uptake of new safe injection technologies. The pricing hurdle was overcome for auto disable (AD) syringes used for childhood immunizations, which now cost only \$US 0.01 more than traditional disposable syringes. The cost of the AD syringe is now US \$0.05 compared to US \$0.11 when it was first developed in 1991. At that point, it was too expensive to be widely used in mass vaccination programs. BD invested over \$33 million for the complete recapitalization of the production, finding ways to mass-produce the AD syringe at less than half the original cost.

Currently, safe injection devices that protect healthcare workers are prohibitively expensive for widespread use in most developing countries. For example, syringes with retractable needles are now priced around 16 cents each, which is still too expensive for wide scale purchase by countries and international organizations.

Free described a way in which subsidies by manufacturers and international donors could lower the price of these new safe injections technologies down to a more viable cost. Instead of subsidizing the full cost of new safe injection syringes, donors could pay the difference

between the cost of the new technology and the old. The resultant mass procurement and production of the new syringe technology would drive up economies of scale. In time, volume purchasing would reduce the price differential between the new and old technology, thereby creating a sort of natural exit strategy for donors and a sustainable procurement system for safe injection technologies.

#### Situation on the ground with curative injections

Renuka Gadde, Director of Global Health at Becton Dickinson said a survey by INCLIN in India estimates that 3-6 billion injections are administered each year, 63% through unsafe injection practices. Unsafe injection practice is an issue that has attracted significant media attention, but has resulted in little policy or behavior change. For example, in a hospital in Chennai, India over 1,500 patients enter the hospital each day for injections and only 500 syringes are used. "We are not supposed to reuse them but due to a lack of funds we do not have enough needles," explained a Chennai nurse in a TV news report shown at the Council.

At a larger policy level, India charges a 22% import duty on equipment that has specific safety features, which includes all AD syringes, thereby making the cost of using safer injection technologies more expensive for the health care provider and the patient.

One of the most powerful illustrations of the link between unsafe injection practices and a high burden of disease can be found in Egypt, said Ahmed Goma of the U.S. Centers for Disease Control, where the prevalence of Hepatitis C infection in the general population is the highest in the world as a consequence of a massive injection campaign undertaken from 1960 to 1987 for treatment of schistosomiasis. The treatment consisted of 15 to 20 injections per person, many of which were given with reused unsterile needles.

One of the most disturbing cases of widespread unsafe injection practices is in Pakistan, where over 600,000 strip-mall type 'market bazaars' exist. According to a report by the Pakistan Medical Association, these informal healthcare providers include quacks, hakeems, traditional healers and homeopaths. "You can shop to get a tooth removed or a have a couple of injections," Gadde said. According to published reports by WHO, the average person in Pakistan receives around 8.5 injections per year, 80-90% of which are unsafe. Competition between medical vendors creates a horrifying national rate of infection through syringe reuse. Economic incentives are the major driver behind syringe reuse. Recycling of improperly disposed syringes is commonplace, as children and other trash collectors can earn around US 40 to 55 cents per kg of used syringes on the black market.

"I do think international interventions are necessary to change this situation, as was done in the case of global immunizations, no matter how challenging and complex the curative setting is. We need to cut through complexity at international, national and individuals levels – there is no substitute," Gadde concluded.

#### Progress in Curative Injections

PEPFAR, the President's Emergency Plan for AIDS Relief, a JSI project partnered with PATH on the Making Medical Injections Safer (MMIS) program in 11 countries mostly in Sub Saharan Africa. The MMIS program "has done a pretty good job in introducing safety devices for injection, prevention of accidental stick and improvement in sharps waste

disposal but unfortunately, for some reason, the funding has been reduced to almost zero this year," Free said. Funding for MMIS was eliminated from FY07 PEPFAR spending.

Uganda has been lauded as a success story, having created a national safe injection policy to ban the importation of standard syringe devices to the country, allowing only AD syringes to be used. The Ugandan model may make sense in some African countries, but would prove dangerous in such places as Russia and Ukraine where key drivers of blood-borne disease are IV drug injection by narcotics users. Because AD syringes lock after a single pump action, they cannot be used for narcotics or other illicit drug injection. If traditional syringes are unavailable, IV drug users will be more likely to share injection equipment or resort to use of dangerous injection devices.

#### Recommendations for further progress

Unlike immunizations, which are vertically controlled, funded by international agencies and distributed through national government channels, the private, unregulated, highly variable nature of curative injections requires that we work with players at multiple levels to promote solutions for change to stop the costly consequences of syringe and needle reuse. Discussions and action must take place all the way from where the syringe is produced to where it is injected into the patient. This chain includes manufacturers, international organizations, NGOs, national governments, health care workers, local communities and the individual patients.

*Key actions can be taken at each level to facilitate progress:*

#### International Organizations:

- Strong leadership must come from the WHO on this issue. WHO must add reuse prevention technologies to its list of essential drugs. WHO must also agree upon a comprehensive policy for waste management of syringes and other infectious waste that is achievable in areas that do not have waste collection infrastructures.
- Work with national governments to support the development and promotion of national safe injection and waste management plans,
- Create a monitoring and tracking system to ensure that donated medical equipment meets quality assurance standards,
- Involve the private sector to support efforts – follow the ‘venture philanthropy’ model of GAVI and immunization – by laying out specific criteria to be met, monitoring the progress of activities and withdraw funding if objectives are not met,
- Establish a tiered pricing system for middle income countries, that are not eligible to receive GAVI funding for syringe procurement, yet do not have the money available to purchase safe injections technologies at market price.

#### U.S. Government:

- Create uniform safe injection standards to be applied to all foreign aid funding streams, be it UNICEF, PEPFAR, USAID, funding to private NGOs and FBOs etc that currently do not follow a single cohesive policy for the promotion of safe injection practices. U.S. Foreign policy could be an influential catalyst for change if it were to mimic its own domestic safe injection standards and apply those to all U.S. funding of international programs. The increased volume of AD syringe purchasing

would also contribute to lowering the cost of such safe injection technologies by increasing manufacturing demand.

- Continue (or restore) funding safe injection programs in all bilateral health programs, such as PEPFAR's Making Medical Injections Safer program.

#### Manufacturers

- Manufacturers, NGOs and the private sector must work together to find ways to lower the cost of reuse prevention technologies and find innovative ways to fund the uptake of such technologies in the developing world.
- Work must be done with manufacturers, international agencies and national government to build reliable and efficient procurement and supply chains so that safe injection technologies are widely available at all times and ensure that safe injection technologies are delivered in bundles with medications/vaccinations, safe boxes for waste disposal, and protective gear for health workers

#### National Governments:

- Establish national standards to evaluate domestically manufactured syringe features and quality,
- Improve logistic systems to reach all usage settings,
- Formalize recommendations on occupational safety within a legislative framework,
- Adopt a national waste management policy that can be achieved in all regions of a country,
- Reduce import tariffs on safe injection products,
- Enforce punishment for the resale of used syringes,
- Enact stronger national laws to aggressively discourage reuse.

#### Health Care Providers

- Establish policies on workplace safety and needle stick injury reporting,
- Ensure all workers have access to protective equipment and training on its proper use,
- Address the irrational overuse of injections,
- Train health care workers in proper waste disposal practices,
- Remove any systematic incentives for reuse.

#### Individual Patients

- Provide behavioral change and education to make patients aware of the danger of syringe reuse – increase demand on the part of the patient to ask for a clean syringe,
- Address the irrational overuse of injections.

Modest investments of time and resources on all levels to prevent the reuse of syringes and needles could not only save millions of lives, but could also provide significant savings in health care expenditures by eliminating the cost of treatment of millions of people that would be otherwise infected with blood-borne diseases as a result of reused injection equipment.