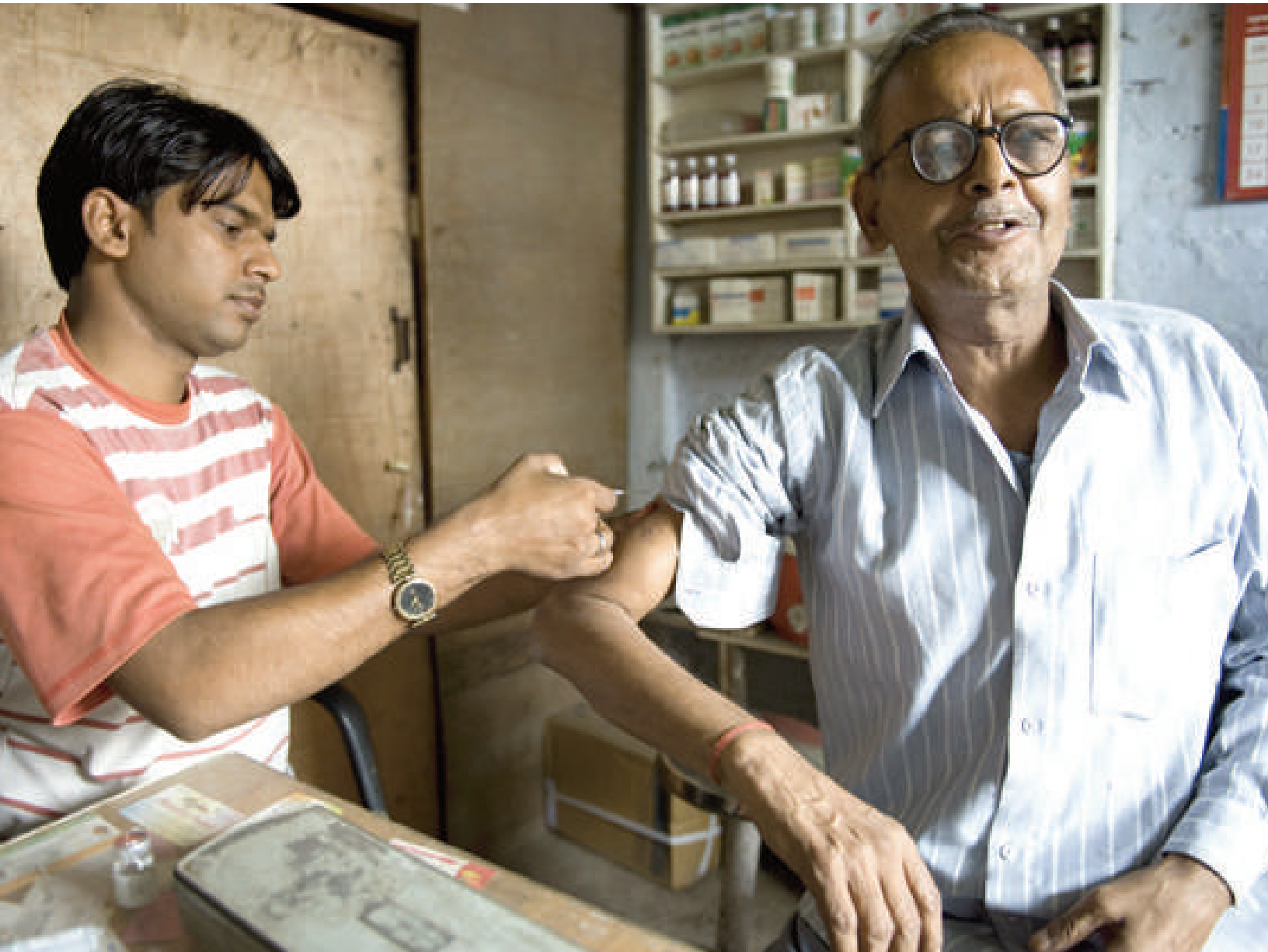
ApiLabs

When Injections Spread Disease

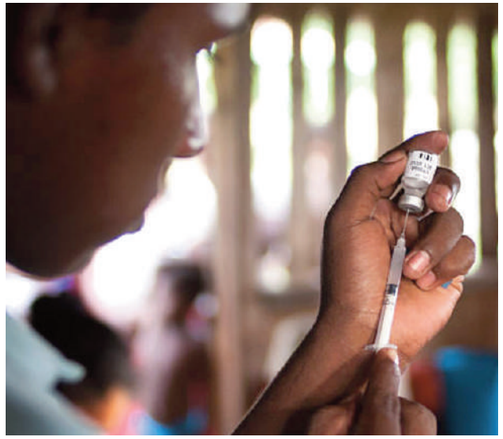
Worldwide use of contaminated vials and syringes in clinical settings leads to 1.3 million deaths per year…and spreads disease to millions.[1]



"Injection practices worldwide and especially in low- and middle-income countries (LMICs) include multiple, avoidable unsafe practices that ultimately lead to the large-scale transmission of bloodborne viruses among patients, health care providers and the community at large."[2]

DR. BENEDETTA ALLEGRANZI
COORDINATOR
WHO INFECTION PREVENTION AND GLOBAL CONTROL UNIT

Improper use of syringes and multi-dose vials often leads to contamination of equipment, which spreads disease.



Tragically, a technology designed to save lives often costs lives when used improperly.

For 165 years the global medical establishment has relied upon the same basic technology for injections. Small glass vials of medicines or vaccines are distributed to points of care around the world. From these vials, syringes are carefully filled, calibrated for the correct dose, and then injected and discarded.

In high-income countries, single-dose vials are used. The vial contains just enough vaccine or medicine for a single injection. After the injection, the vial is discarded along with the syringe, so patients can always trust that they get a safe injection. In the rest of the world, health ministries and organizations use multi-dose vials because it's more economical to buy medicine and vaccine, like everything else, in larger containers. Lower cost is why the 10-dose glass vial accounts for between 75% to 80% of global volume of injectable vaccines. In some areas, the rate is 90%.[3]

Over the decades, traditional syringes and 10-dose vials have saved countless lives – but they also cost many lives through cross-contamination and infection in clinical settings. This is a global problem. It occurs in both high-income and low-income countries.

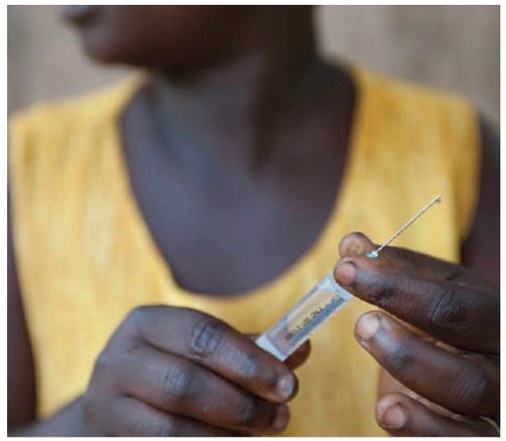
In some low-resource settings, syringes are reused over and over. When a contaminated syringe is filled from a vial, it contaminates the vial's contents and invisibly spreads diseases such as HIV and hepatitis.[4]

As recently as 2016, up to 70% of injections were still given with reused vials and syringes in some countries.[7]

In some settings, the improper reuse of syringes still occurs at an alarming rate.

It has been 18 years since WHO estimated that cross-contamination from reused vials and syringes resulted in 1.3 million early deaths per year. During the intervening years, WHO and UNICEF have implemented their policy requiring that all vaccines must be purchased in the Auto-Disable syringe format.

Yet according to Dr. Benedetta Allegranzi, coordinator of the WHO Infection Prevention and Global Control Unit, "achievements were not equal in different parts of the world. While much progress has been made in immunization, the safety of therapeutic injections remains a challenge."[5]



Table[6]

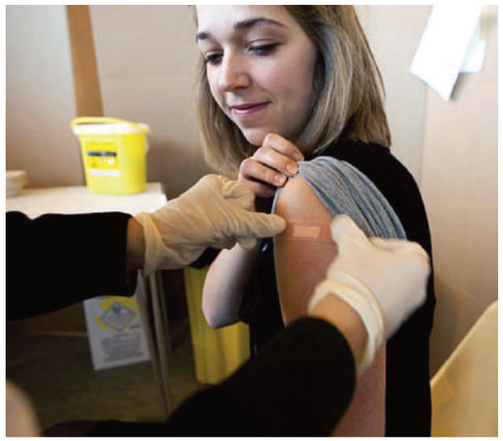
Disease or infection	Est. % of new cases caused by unsafe injections	Est. # of patients infected per year
Bacterial	7%	3 million
Hepatitis B	25%	15 million
Hepatitis C	8%	1 million
HIV	14%	340,000+
Top 20 Total	5-10% est.	10's of millions

In 2016, Dr. Allegranzi reiterated that "up to 70% of injections…are given with reused syringes and needles in some developing countries."

In fact, WHO estimates that in the year 2000, some 6.6 billion injections were given with reused equipment. That represents 39.6% of the 16 billon total injections of medicine and vaccine that WHO believes are administered each year in the developing world.

The danger of unsafe injections is classified by medical professionals with other medically-caused injuries, along with – for example – hospital acquired infections or giving patients the wrong treatment due to a mistaken diagnosis. These medically-caused injuries are common enough to have been given a collective label: the medical world refers to them as "iatrogenic" harm.

Cross-contamination during injections also occurs in high-income countries.



The problem of contaminated vials & syringes is not confined to low-income countries.

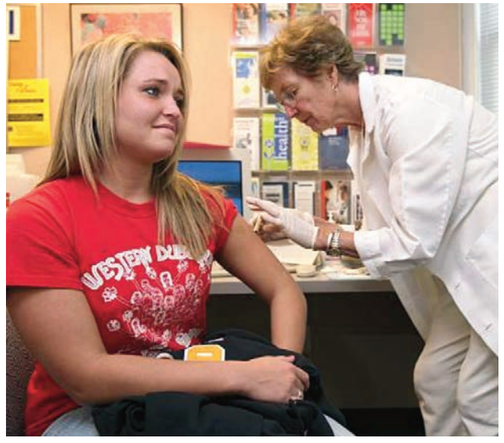
High-income countries also experience significant numbers of infections from cross-contamination when established protocols are not followed by clinical staff.

The CDC has documented dozens of U.S. outbreaks of hepatitis in the last decade.[8] Experts believe many of these outbreaks were caused by clinical reuse of contaminated syringes.

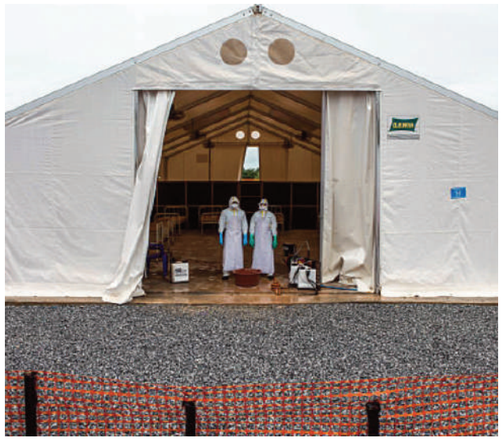
A 2010 survey of more than 5,000 U.S. nurses revealed "an alarming lapse in basic infection-control practices associated with the use of syringes, needles, multiple-dose vials, single-use vials, and flush solutions… clearly placed patients at risk for transmission of blood-borne diseases, according to information sent to the Institute for Safe Medication Practices (ISMP)."[9]

According to the survey, "Fifteen percent of respondents reported using the same syringe to re-enter a multiple-dose vial numerous times. Of this group, about 7% reported saving those multiple-dose vials for use with other patients."[10] The result is headlines like this one from *The American Journal of Infection Control* in 2013: "Hepatitis C transmission due to contamination of multi-dose medication vials: summary of an outbreak and a call to action."[11]

Or this headline from the *Morbidity Mortal Weekly Report* in 2012: "Multiple outbreaks of hepatitis B virus infection related to assisted monitoring of blood glucose among residents of assisted living facilities – Virginia, 2009-2011."[12]



Cross-contamination of vials and syringes has significantly contributed to the spread of pandemics such as Ebola.



When an entire population requires emergency vaccination, the risk of spreading disease is even greater.

In epidemics and pandemics, contaminated vials and reused syringes can be disastrous.

As researchers reported in *The Pediatric Infectious Disease Journal*, "Injections from contaminated vials, caused by employing reused syringes and improperly sterilized needles, played a major role in some areas of the early Ebola outbreaks."[13]

Ebola is the subject of many mistaken beliefs, including widespread misunderstanding of how it actually spreads. While Ebola is not transmitted through airborne dispersal like a flu, it does have mechanisms and transmission routes that extend beyond direct contact with the bodily fluids of an infected person or direct contact with the remains of an Ebola victim.

One of the most insidious of these additional transmission routes is contaminated syringes and vials. In a national emergency where authorities are arranging for mass vaccinations, syringes and vials can become infected through reuse and cross-contamination.

These in turn can be caused by hurried administration or improper technique, motivated in some low-resource settings by a desire to make maximum use of limited supplies. The motive may be understandable, but the results can be deadly.

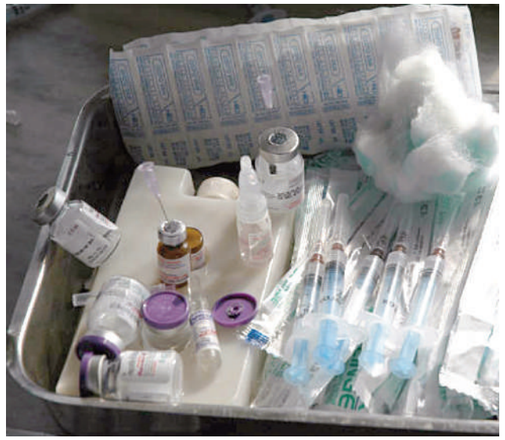
Reusing a syringe once can contaminate a vial's contents, infecting all patients injected after.

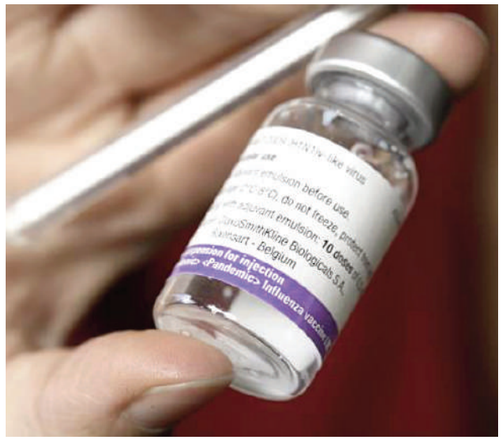
Giving injections to people who carry a blood-borne disease guarantees that syringes will become contaminated with that disease.

How do syringes and 10-dose vials get contaminated in the first place? The short answer is improper reuse of syringes. That is the reason why WHO has long mandated the use of Auto-Disable syringes for vaccines.

But in low-resource countries, the 10-dose vial remains the most popular format due to its low cost.[21]

In order to promote safe use of this format, WHO has issued strict guidelines covering its use. These guidelines include discarding each syringe after a single use. The administrator of a vaccine is supposed to use a fresh, sterile syringe to withdraw each vaccine dose from the 10-dose vial and inject the next patient. Unfortunately, in many clinical settings, these guidelines are not followed. Improper reuse of equipment creates two possible routes for contamination: contaminated syringes and contaminated vials.

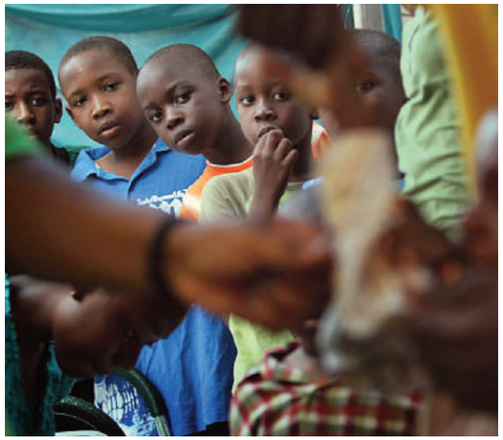




> "Injections from contaminated vials, caused by employing re-used syringes and improperly sterilized needles, played a major role in some areas of the early Ebola outbreaks."[14]

A clean, sterile syringe typically becomes contaminated when an infected patient receives an injection.

Disease spreads from one patient to several patients through a contaminated syringe in a simple, yet insidious process.

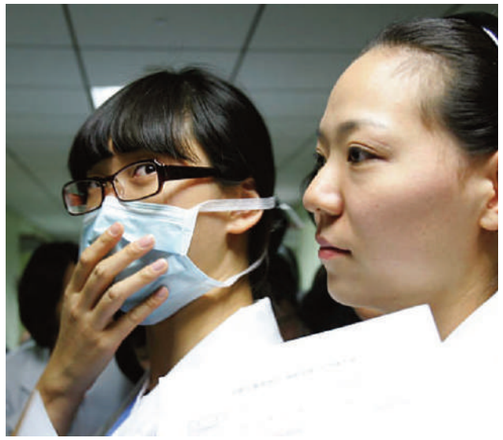


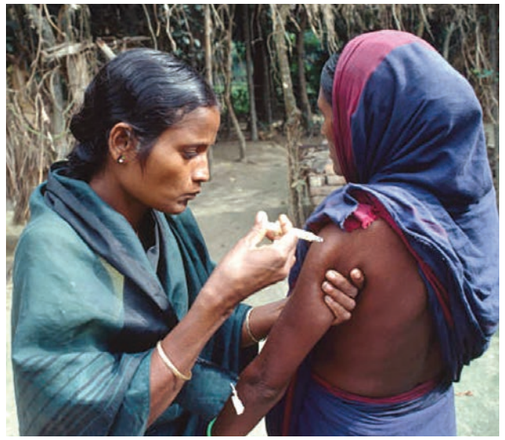
Syringes become contaminated in the ordinary course of giving injections to patients who are already infected.

Typically, a 10-step process occurs:

1. The health worker uses a fresh, sterile syringe to withdraw a dose of vaccine from a 10-dose vial.
2. The health worker uses that syringe to inject the vaccine into a patient who is carrying a disease.
3. When the health worker retracts the needle from the infected patient, microscopic droplets of the patient's infected blood are suctioned out of the patient, into the needle.

4. These infected blood droplets travel through the needle into the barrel of the syringe.
5. The syringe is now contaminated, even though the amount of infected blood may be so tiny as to be invisible.
6. In some clinics, healthcare workers routinely disregard protocols and fail to dispose of used syringes. Instead, they reuse them. The health worker may attempt to sterilize the syringe by washing it in alcohol or boiling it in water or alcohol. However, the infected blood remains and the disease's pathogens remain active.
7. When the next patient needs an injection, the health worker uses the infected syringe to withdraw a fresh dose from a vial. Even if a brand-new vial is opened, the vaccine drawn into the syringe will become contaminated when it makes contact with the microscopic blood droplets in the barrel of the syringe.
8. When the contaminated syringe is used to inject the new patient with the vaccine, the patient also receives some of the pathogen from the previous patient's blood. The infection has now been spread by the clinic. (Contaminated syringes are the first route for contamination. The second route is described below; see step 10.)
9. Once the needle of the contaminated syringe is inserted into the vial, all the contents of that vial becomes contaminated.
10. As a result, all subsequent doses withdrawn from that same contaminated vial can spread infection to additional patients. This remains a danger even if a fresh, sterile syringe is used each time for these subsequent injections. (Contaminated vials are the second route for contamination and the spread of disease.)





The first five steps in this process do not automatically result in unsafe injections but they do open the door to potential contamination and the spread of disease.

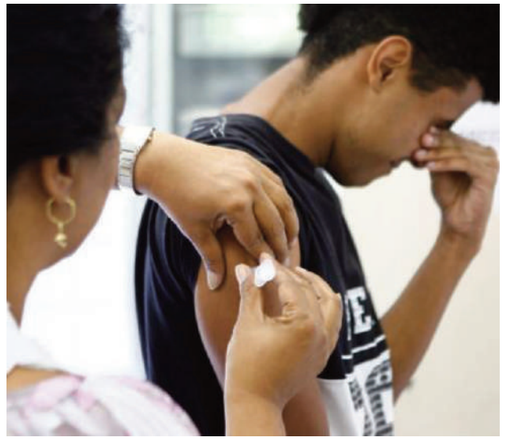
The critical steps that degrade a safe procedure into a dangerous, high-risk activity are Step 6 (attempting to sterilize a contaminated syringe), Step 7 (refilling a used syringe) and Step 8 (injecting a patient with a used syringe).

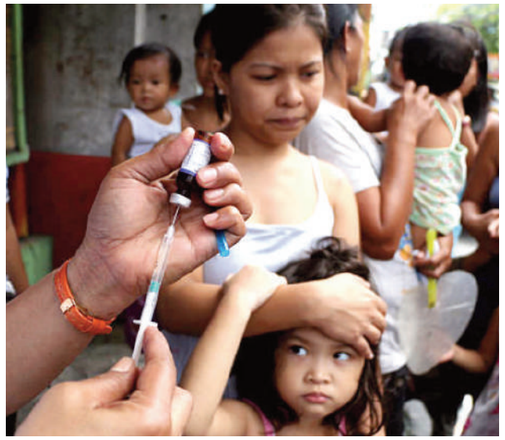
There are many reasons why reuse of syringes persists – including cost, procurement and regulatory issues.

So long as reusable syringes are provided, some health workers will continue reusing them.

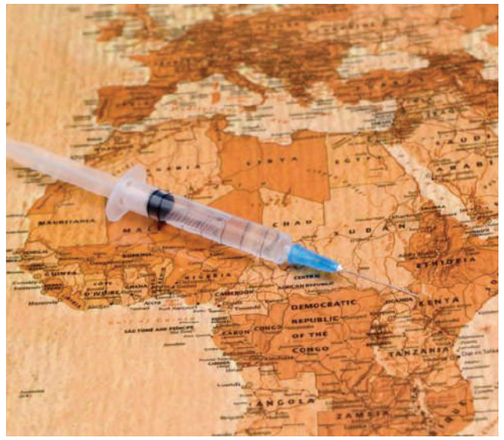
Given that Auto-Disable syringes have become the global standard for vaccines, and have become more affordable in recent years, it may seem puzzling that reusable syringes continue to be used for most of the other 90% of medical injections, which are therapeutic injections. There are several reasons for this, including:

1. Cost factors: Prefilled Auto-Disable devices such as Uniject™ have become price-competitive with single-dose vials, but they remain more expensive than 10-dose vials and do not scale to large quantities.
2. Procurement practice: According to WHO's Dr. Allegranzi, in some countries, syringes are not procured in the same market chain as injectable medicines, and the responsible health ministries may not know about injection safety needs.[15]
3. Regulatory environment: Syringes are not well regulated in certain nations. Consequently, their markets are often "flooded with substandard product."[16]
4. Unqualified or poorly trained health workers: Healthcare workers in some countries have "ingrained" habits of reusing syringes, said Dr. Allegranzi.[17] And, in some regions, unqualified individuals falsely calling themselves "injection doctors" travel among rural populations, giving injections to unschooled patients who don't know any better. Waste scavenging and repackaging of used syringes remains an issue in some countries as well.[18]





Recent headlines in the news demonstrate that contaminated syringes remain a deadly problem.



No matter how strict the protocols, they will inevitably be broken at times.

Contaminated Measles Vaccine Kills 15 Kids in South Sudan (Jun.02.2017)

JUBA, South Sudan – Fifteen young children have died in a botched measles vaccination campaign…The United Nations said the children died of "severe sepsis/toxicity" from the contaminated vaccine... One syringe was used for all the children during the four-day campaign, and the vaccine was stored without refrigeration the entire time.

Fake doctor in India infects villagers with HIV by using tainted syringes (AP February 6, 2018)

LUCKNOW, India – A fake doctor treating poor villagers in northern India for colds, coughs and diarrhea has infected at least 21 of them with HIV by using contaminated syringes and needles, a health official said Tuesday.

Patients being tested for HIV after nurse reused syringes (Jun.12.2018)

TAHLEQUAH, Okla. – A Cherokee Nation hospital in Oklahoma is testing more than 180 patients for HIV and hepatitis after allegations that a nurse reused syringes to administer medications. The nurse violated protocols by using the same vial of medication and syringe to inject multiple intravenous bags at W.W. Hastings Hospital in Tahlequah, according to Cherokee officials.[19]

ApiJect's Prefilled Injector* is designed to deliver only one dose. There is no vial to cross-contaminate.

Injections with low contamination risk can also be economical.

Can the global health community prevent the spread of blood-borne disease through improper injections? Yes – with innovative injector design and manufacturing. ApiJect is a new, prefilled delivery system* that is designed to prevent any reuse of contaminated syringes. In addition, ApiJect eliminates any possibility of cross-contaminating the contents of a vial, because it does not use vials.

The ApiJect Prefilled Injector* will consist of three parts: (1) a prefilled plastic container; (2) a Connector; and (3) an attachable Needle Hub with a hypodermic needle and safety cap. The three parts will ship separately, ready for push-to-assemble activation.. Once assembled, the needle cannot be detached or reused. Since ApiJect is prefilled, there is no need to withdraw liquid from a vial.

With no vial, there is no possibility of vial contamination. (Safety is also enhanced because prefilling each ApiJect syringe at the time of manufacturing reduces over- and under-dosing risks.) Finally, once a patient is injected, the ApiJect Container would be very difficult to refill or reuse.

With ApiJect, safety also supports increased economic efficiency. ApiJect believes its Prefilled Injector will cost less per dose upfront and will also cost up to 50% less per dose delivered, depending on wastage factors. This could enable national health ministries and international health organizations to stretch their budgets farther, moving closer to full coverage and equity, while reducing contamination risk. By reducing or eliminating contamination of injection equipment, the planned ApiJect Prefilled Injector could save more than one million lives around the world every year.

* Products shown for informational purposes only, not for use in product promotion.
ApiJect's Prefilled Injector and other products have not been reviewed or cleared by FDA or other regulatory authorities for distribution.

It is a tragic irony that although multi-dose glass vials and syringes have saved countless millions of lives, they are also responsible for more than 1 million deaths per year through cross-contamination and the spread of infection in clinical settings.

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"Infection prevention and control is the backbone of good hygiene and all its preventive power." [20]

DR. MARGARET CHAN
FORMER DIRECTOR-GENERAL, WHO