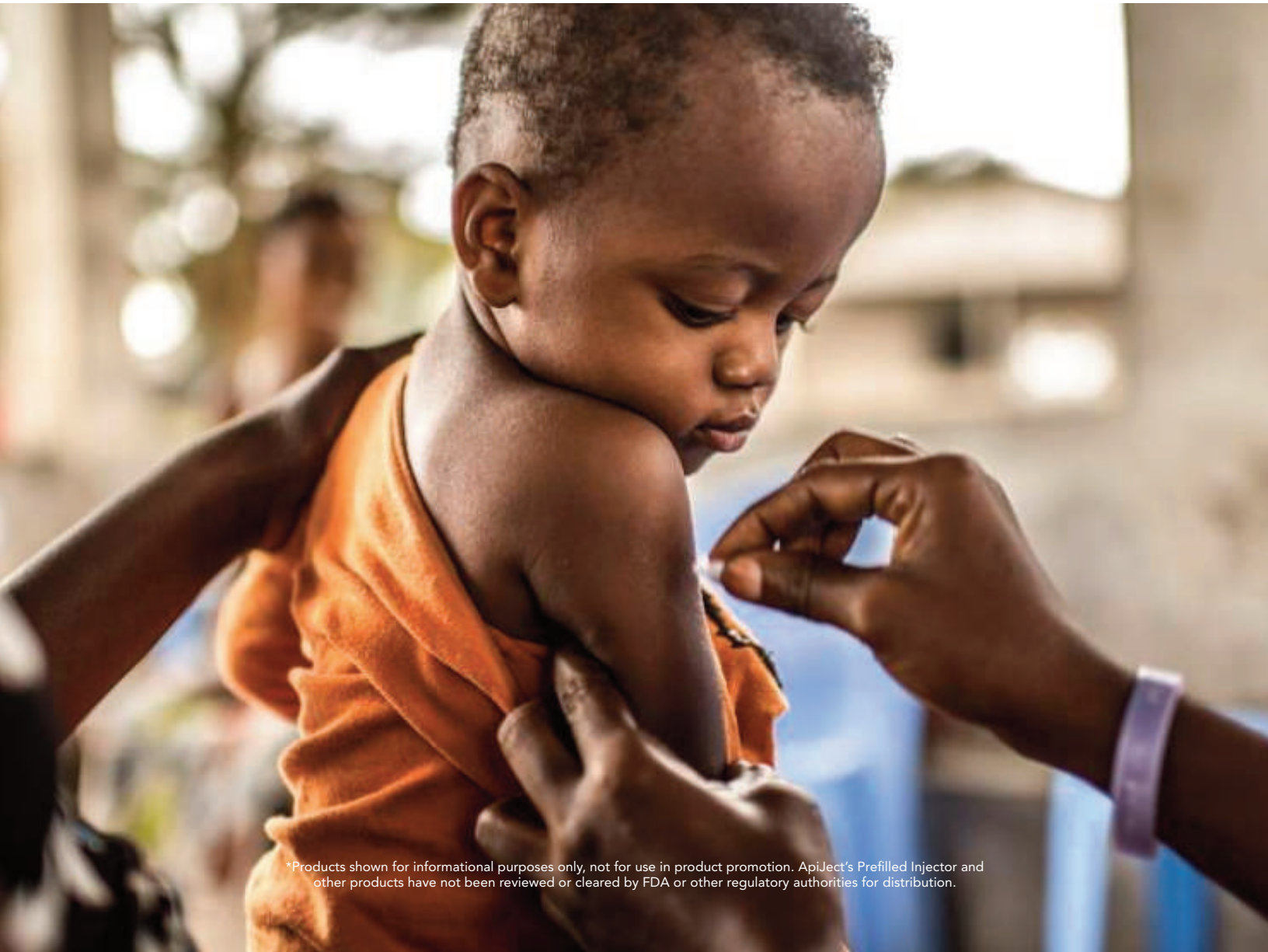
ApiLabs

Blow-Fill-Seal Prefilled Injectors Support Many Use Cases for Global Impact

An affordable, single-use prefilled injector* could open new opportunities for coverage, access and equity for billions of people around the world.



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Making single-dose injection formats available using Blow-Fill-Seal technology could support cost and time savings throughout health delivery systems and supply chains, while also supporting greater coverage and equity of access in the last mile.

Affordable single-dose injection formats could help vaccines and medicines make it to the last mile.

In environments where cost is the primary factor, glass vials are not an ideal choice. Manufacturing glass vials is expensive and their weight imposes higher transport costs.

Excluding vaccine cost (and not counting waste), the cost for transportation and cold chain storage for glass vials is the greatest contributor to the Total Cost of Delivery for vaccines.[1] Glass vials are heavy to transport, and susceptible to breakage and delamination (flaking) when traveling to the end user, which can affect product safety and efficacy.

In many remote locations most in need of vaccines and medicines, these interventions need to be carried by people or transported on bikes or other small vehicles, where weight and size are prohibitive factors. Replacing glass vials and syringes with a new, affordable, single-dose format* that is small-sized and light-weight could potentially the "last mile" health delivery system and supply chain, ensuring medicines and vaccines reach more people who need them.[2]

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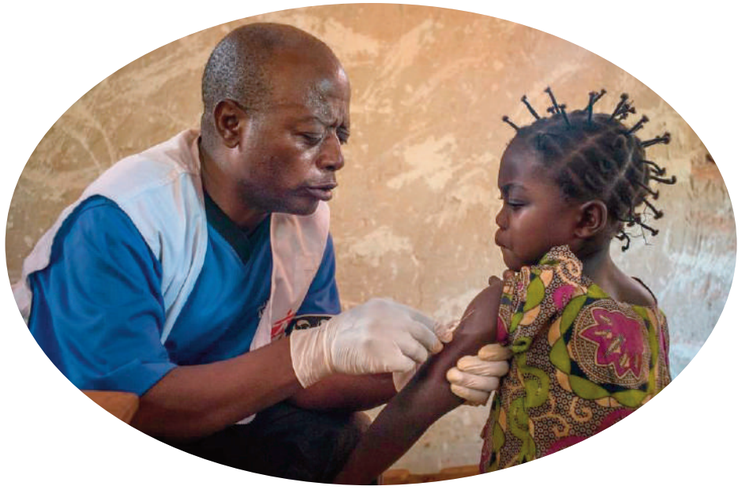

Prefilled injectors could potentially support greater coverage and equity by enabling more patients to be served with existing budgets.

Compact, prefilled, single-dose BFS injectors can be efficient and scalable.

The ApiJect Prefilled Injector* is designed for high-quality, highly scalable production, potentially supporting widespread coverage and access, even at the same healthcare budgets. The device is planned to leverage the scale and efficiency of the Blow-Fill-Seal (BFS) filling process to create aseptically filled, single-dose Containers that become prefilled injectors when married with ApiJect's attachable Needle Hubs.* In addition, ApiJect's devices will be lightweight, for low shipping costs and low breakage risk during transit.

With ApiJect's device, health workers can potentially save time because there is no preparation of a new needle and syringe for each patient; no withdrawal from a vial; and no checking of proper dosage. Due to efficient use of labor, single-dose injection formats have been shown to require up to 50% less time to perform the injection than traditional vials and syringes.[3]

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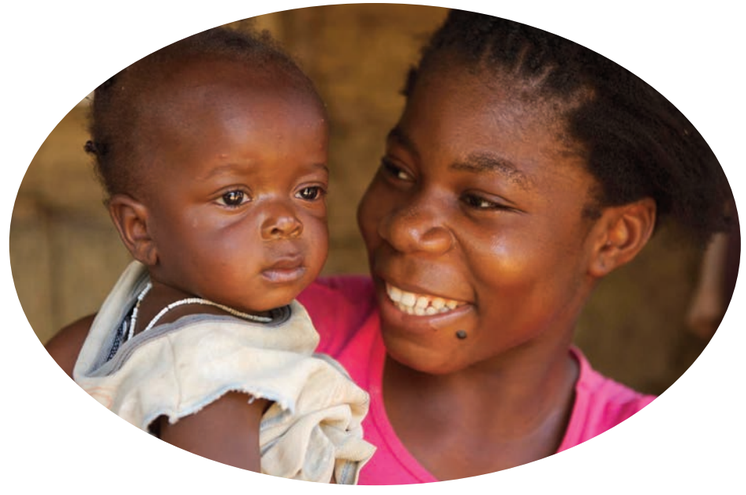

Wider Use of Contraceptives

Many societies discourage contraception for social or religious reasons. Taking pills at home is highly "visible," so many women don't do it. With discreet quarterly self-injection (where permitted by law and approved by regulatory authorities), more women would potentially be able to control their reproductive choices.

Family planning is not only fundamental to the well-being and autonomy of women, but also to the health and development of communities.[4] And when women and adolescent girls have access to a variety of contraceptives, they are more likely to find and use a method that meets their needs and preferences.[5]

Self-injectable contraceptives have the potential to be that option as they are highly effective, safe, and private, as well as able to increase access and empower women to manage their reproductive health.[6] This is confirmed by the World Health Organization (WHO) supporting self-injection where women have access to training and support.[7]

Short SC and ID needles become possible with a prefilled single-dose format.

Longer needles are needed to withdraw liquid from glass vials, but they require Mantoux-style injections (often inaccurate) for shallow intradermal injections, important for some vaccines and medicines.

Needles and syringes limit accessibility to needed medicines and vaccines by requiring a trained medical professional to administer them in clinical settings. Intradermal injections – those into the skin – require simple training for a healthcare worker to administer, and can even enable patients to self-inject, eliminating the need for a healthcare worker to administer a vaccine or medicine, as well as the need to prepare a needle and syringe.[8]

Access for 400+ Million People

In many countries, vaccines and medications are wasted because there aren't enough medical staff to deliver them. Where permitted, a prefilled single-dose device can enable millions of community health workers to administer vaccines and medicine to millions of children, new mothers and adults.

It is estimated that approximately 7.2 million health workers are needed to provide essential health services worldwide.[9] That need is met not only by doctors and nurses, but community health workers (CHWs). Even with an estimated 1.3 million CHWs in the world,[10] there is a shortage of healthcare workers, leaving communities vulnerable to death and disease. If CHWs were empowered with tools adaptable to rural and fragile settings, they could help fill the gaps in access to care.

As Dr. Henry Perry, senior scientist at Johns Hopkins Bloomberg School of Public Health, stated, "If CHWs are used to deliver the interventions they are capable of delivering, and if 100% coverage could be attained, then the lives of 3.6 million children would be saved every year."[11]

Oxytocin and Hep-B at Childbirth

In the developing world, 60% of women give birth with no medical professional present. As a result, 800 mothers a day die from hemorrhage. Often the birth dose of Hep-B is not administered as well. A prefilled injector could be used to administer HepB and low-cost Oxytocin to save lives.

Poor women in remote areas are the least likely to receive adequate health care; this is especially true for regions with low numbers of skilled health workers. Other barriers to maternal health include poverty, distance, lack of information, inadequate services, and cultural practices. These obstacles result in millions of births each year unassisted by a midwife, a doctor, trained nurse, or other skilled health personnel.[12]

Almost all maternal deaths (99%) occur in developing countries, where access to healthcare workers can be limited.[13] Women die as a result of complications during and following pregnancy and childbirth; however most of these complications are preventable or treatable.[14] One of the leading causes of maternal death, post-partum hemorrhage, can kill a healthy woman within hours if she is unattended. But injecting Oxytocin immediately after childbirth reduces the risk of bleeding and saves lives.[15]

Patient Adherence Opportunities

For drugs requiring self-injection, a low-cost single-dose format* that requires very little training could potentially make adherence more likely. Crucial for regimens such as TB and potentially other diseases in countries or populations where cost is a critical factor.

For many patients, adhering to a medical protocol can be challenging due to many factors, such as cost, but self-injection (when approved at the option of regulatory authorities) can address some of those issues.

For example, the ability to self-inject contraceptives can encourage continuation of contraceptive coverage as it addresses some of the reasons why women discontinue use, such as travel expenses, long distances to the clinic, and long waits at the clinic.[16]

For young women and adolescents, who often have higher rates of contraceptive discontinuation, and also highly value their privacy, self-injection can offer independent and discreet contraception use over a longer period of time.[17]

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Wider Coverage of Injectable HIV PrEP Treatments

New injectable HIV therapeutics are in development that will require injections every month or two. The option for self-injection (where permitted at the option of regulatory authorities) or injection by community health workers dramatically expands access.

New antiretroviral (ARV) treatments in injectable format are in development for treatment of HIV and have been well received by patients in a trial. Patients preferred receiving treatment every four or eight weeks with the injectable format rather than taking daily pills, which also helped them avoid what they felt was a daily reminder of their HIV status.[18]

Trial participants found the new dosing protocol more convenient and more private.[19] The participants also said that the injections were more convenient and made for easier adherence to their HIV treatment regimen.[20]

WHO Seeks Improved Coverage, Based on Wider Access to Injectable Polio Vaccines

WHO has called for a global changeover from oral to injectable polio vaccines. As that transition occurs, ApiJect Prefilled Injectors* could potentially support it.

In May 2012, the World Health Assembly of WHO declared poliovirus eradication to be a programmatic emergency for global public health.

Under this plan to achieve and sustain a polio-free world, it recommends that the use of Oral Polio Vaccine (OPV) must eventually be stopped worldwide, and that at least one dose of Inactivated Polio Vaccine (IPV), an injection, must be given in addition to OPV, to protect against type 2 poliovirus and to boost population immunity.[21]

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Surge Production in Medical Crises

When epidemics break out, cities or countries need to ramp up in a hurry to get vaccines or medicines to a broad population. Making glass vials requires a lead time of up to 6 months or more. Instead, a single BFS manufacturing line can start producing up to 25,000 finished units* an hour within days of regulatory clearance of the vaccine or medicine on the line.

The traditional aseptic filling process can require up to 12 steps, involves numerous people, and can take months to complete, even when the bulk vaccine is available.[22] These requirements are less than ideal when addressing epidemics. ApiJect's manufacturing process has the potential to reduce risk of human contamination, and could potentially result in fewer raw materials needed, smaller facilities required, less use of utilities such as water, and fewer steps in the production process because separate stations for cleaning, sterilizing, and filling aren't necessary.[23]

This simplified process is potentially valuable when rapidly producing and shipping medicines and vaccines to save lives.

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First Responders Need Fast Help

Soldiers, police and firefighters don't always have a medic, doctor or clinic nearby when injury occurs. An easy-to-use, prefilled single-dose injector* could potentially support first responders' needs to carry medicine for immediate injection, and patients' needs for immediate treatment.

On-call emergency workers operate in the field without all of the resources and equipment that a hospital or clinic provides. Having to measure and withdraw the precise amount of medicine from a glass vial and then change needles to inject patients in need while in a high-pressure situation adds complexity to an already stressful circumstance.

The convenience of a planned prefilled, single-dose injection device* that could be quickly scaled when speed is critical, coupled with the high quality and durability of the BFS format, could potentially offer benefits for emergency personnel and their patients.

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Allergies and Anti-Opioid Applications

Epinephrine and Narcan are very expensive in today's formats. With additional R&D, and subject to the need for approval from regulators, injections using ApiJect Prefilled Injectors* could become available, requiring smaller doses and resulting an economic alternative format.

Costs of medicines such as Epinephrine and Narcan have steadily risen, resulting in them being less available, just as the need for them increases.[28] Using single-dose, prefilled BFS injectors, such as ApiJect's,* could potentially provide more coverage due to their more affordable manufacturing costs.[29]

The potential for dose sparing, along with the convenience of a prefilled single-dose could potentially benefit patients and health workers delivering medicines in emergency situations, such as when administering Epinephrine and Narcan.

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Veterinarians and Pet Owners

Veterinarians spend much time dosing injections for the world's 500+ million pets. ApiJect Prefilled Injectors* could potentially eliminate that step, saving time. And, if the law permits and regulators approve, vets could have the option to prescribe injections for pets, given by owners at home, so more pets could potentially get treated.

Injecting pets with needed medicine and vaccines can be a difficult task. This especially true for aggressive pets or pets with a history of abuse that don't trust humans. Reducing the steps required for a vial and syringe injection, could potentially make it easier for the vet administering the injection and less stressful or traumatizing for the animal.

Additionally, permitting pet owners to care for their pet in their home environment by injecting their pets themselves – at the option of regulatory authorities – would not only be more convenient, but also a better experience for the pet. These interventions could potentially support coverage of more pets, help reduce the number of pets that otherwise would go unvaccinated or untreated.

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Animal Health on Small Farms

Worldwide an estimated 70 billion farm animals are raised for food. In low-and middle-income countries, far fewer farm animals receive medicinal injections than in the West. A prefilled single-dose device* could potentially help small subsistence farmers and disadvantaged families treat animals showing signs of illness.

Farmers in low- and middle-income countries are often on their own when it comes to guaranteeing their farm animals' health and productivity. When treating a sick animal, it is imperative that the proper dose of medicine is used, as too much of the medicine can kill an animal, while too little won't cure the disease ailing the animal.[30]

If a prefilled single-dose device such as an ApiJect Prefilled Injector* were available to farmers and approved at the option of regulatory authorities, could potentially assist farmers to support the health of their animals, on which they depend for sustenance and livelihood.

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