

STORIES OF PROGRESS:

VACCINES

Saving, protecting and enhancing lives

TRANSFORMING LIVES

PRESENT DAY...

SARA RECEIVES VACCINATIONS

As a young child, Sara receives routine vaccinations: polio, meningitis, rotavirus, hepatitis A, hepatitis B, pneumonia, TDAP (typhoid, diphtheria and pertussis), MMR (measles, mumps and rubella), BCG, yellow fever, and Hib. She receives the HPV vaccine when she is 11.



FIFTY YEARS AGO...

In 1968, Sara would have received far fewer vaccines: smallpox, polio, measles, mumps and DTP (for diphtheria, tetanus and pertussis).

IN THE FUTURE...

Sara hopes her children and grandchildren will benefit from hoped-for vaccines to protect them from malaria and HIV/AIDS.

In 1796, Edward Jenner carried out what would become one of the most famous medical experiments when he vaccinated James Phipps against smallpox. Today, vaccines are viewed as one of the most effective and cost efficient medical technologies ever developed,⁷⁴ resulting in the control, elimination or near elimination of numerous infectious diseases.

Immunization saves between two and three million children's lives per year.⁷⁵ The continuing development of vaccine science and growing partnerships for delivery have enabled the benefits of immunization to be realized across the globe, dramatically decreasing the spread of infectious disease and supporting efforts to achieve global health security. However, one in five children still miss out on routine life-saving immunization.⁷⁶

50 YEARS OF VACCINES

THE ERADICATION OF SMALLPOX UNIQUELY COMBINED PRODUCT INNOVATION, PROCESS INNOVATION AND POLICY INNOVATION - WITH AN UNPRECEDENTED LEVEL OF STAKEHOLDER COLLABORATION. ”

Mariângela Simão,
WHO


Research and development is, and always has been, at the heart of immunization success. Germ theory – the identification of organisms that cause disease - has been central to vaccine advances in the second half of the 20th century,⁷⁷ with the development of the first vaccines for smallpox, diphtheria, tetanus, anthrax, cholera, plague, typhoid, TB, and polio.

As vaccine science continued to develop during the 20th century, improvements in cell culture technologies welcomed in a second golden age of vaccines. Scientific innovations at this time led to the creation of vaccines for measles, mumps, rubella, hepatitis A and B, chicken pox, pneumonia, and influenza. Notable is the work of Maurice Hilleman, who developed over 40 vaccines and eight of the 14 routinely recommended today.⁷⁸ Hilleman is credited with saving more lives than any other medical scientist in the 20th century across his career.

Innovation also led to improved vaccine delivery technologies which have helped reduce the global infectious disease burden. For example, advances in vaccine thermostability has reduced the need for refrigeration and increased access to vaccines globally.⁷⁹ Development of delivery techniques such as microneedles and intradermal devices has enhanced vaccine effectiveness and make it easier for health workers to administer immunizations. Combination vaccines have been developed to reduce the number of shots a child needs while maintaining the same level of protection, such as the MMR combination vaccine licensed in 1971.⁸⁰

In the 50 years since IFPMA was founded, smallpox has been eradicated and polio nearly so across most of the world. Great strides have been made in reducing measles infections. To date, vaccines have been developed to prevent 26 diseases, including more recently developed vaccines for hepatitis B, hepatitis A, HPV and meningococcal group B.⁸¹ IFPMA members have been at the forefront of science to achieve these developments.

KEY MILESTONES

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- 1971:** Measles, Mumps and Rubella vaccine approved, providing protection against three highly infectious illnesses at the same time, via one shot.⁸²
- 1974:** The Expanded Programme on Immunization is established to develop and expand immunization programs, initially targeting diphtheria, whooping cough, tetanus, measles, poliomyelitis, and TB, towards the goal of providing universal immunization for all children by 1990.⁸³
- 1980:** Worldwide vaccination programs result in the eradication of smallpox, a contagious virus with no known cure, which killed an estimated 300-500 million people in the 20th century.⁸⁴
- 1986:** Hepatitis B recombinant vaccine is licensed.⁸⁵
- 1988:** Establishment of the Global Polio Eradication Initiative, which has contributed to the 99.9% reduction in global incidence of polio.⁸⁶
- 1995:** Hepatitis A vaccine is licensed.⁸⁷
- 2000:** Launch of Gavi, the Vaccine Alliance, a public-private global health partnership committed to increasing access to immunization in poor countries.⁸⁸
- 2000:** Pneumococcal conjugate vaccine PCV7 is licensed, tackling one of the biggest killers of children under five – pneumonia. This breakthrough vaccine improves earlier versions that did not generate consistent immunity in children.⁸⁹
- 2006:** HPV vaccine approved in the US, providing protection from cervical cancer, a common cancer among women under 35.⁹⁰
- 2006:** Approval of vaccine for rotavirus, the most common cause of diarrheal disease among infants and young children.⁹¹
- 2012:** Global Vaccine Action Plan adopted by World Health Assembly as a roadmap to prevent millions of deaths by 2020 through equitable access to vaccines.⁹²
- 2015:** First dengue vaccine licenses obtained.⁹³
- 2015:** RTS,S vaccine became the first vaccine candidate to get approved for use against malaria.⁹⁴
- 2016:** Americas region is the first region in the world to be declared measles-free.⁹⁵
- 2017:** The Coalition for Epidemic Preparedness Innovations launched to finance and coordinate the development of new vaccines to prevent and contain infectious disease epidemics and contribute to global health security.⁹⁶

ACHIEVING ERADICATION OF POLIO

The development of polio vaccines and the effort put into eradicating the disease shows how innovations and partnerships can come together to eliminate a disease across much of the world.

Polio is caused by a virus that reproduces in the gut from where it can spread to the nervous system. In the pre-vaccine era, when poliovirus was the leading cause of permanent disability in children, almost all children became infected by poliovirus, with one in 200 susceptible individuals developing the paralyzing poliomyelitis.⁹⁷

With effective vaccines available, health policymakers began to look at eradicating polio.⁹⁸ In 1974, the World Health Assembly recommended the oral polio vaccine (OPV) as the vaccine of choice.⁹⁹ In 1985, Rotary International launched their PolioPlus program financially supporting the public health ambition to rid the world of polio.¹⁰⁰ In 1988 the 41st World Health Assembly adopted a resolution for the worldwide eradication of polio.¹⁰¹ The Global Polio Eradication Initiative (GPEI) brought national governments, WHO, Rotary International, the US Centers for Disease Control and Prevention, UNICEF and a number of key partners such as the Bill & Melinda Gates Foundation (BMGF) together.¹⁰² Industry contribution, led by Sanofi Pasteur providing almost 10 billion doses of OPV worldwide, including more than six billion doses to UNICEF, has proven to be instrumental in taking polio to the brink of eradication. Since GPEI was launched, the number of polio cases has fallen by over 99.9%.¹⁰³ In 1994, the Americas were certified polio-free, followed by the WHO Western Pacific Region in 2000, the WHO European Region in 2002, and the WHO South-East Asia region in 2014.¹⁰⁴ Poliovirus transmission levels are currently at the lowest point in history and eradication is a realistic expectation.¹⁰⁵

The infrastructure introduced to enable mass immunization has broader impacts in strengthening delivery of health services. For example, in Nigeria medicines for malaria are being delivered on a mass scale as part of the infrastructure for delivering the polio vaccine.¹⁰⁶ Evolving and strengthening this infrastructure can support access to a wider range of medicines and vaccinations.

A SHIFT TO LIFE COURSE VACCINATION - HUMAN PAPILLOMA VIRUS VACCINE

A more recent example of vaccine development is the development of the first ever vaccine targeting cancer. The WHO defines the preventative, life-course approach as one that aims at increasing effectiveness of interventions throughout a person's life. It addresses the causes and not the consequences of ill health at all stages of life.

As NCDs such as cancer, diabetes and Alzheimer's disease become epidemic in the ageing populations of both the developed and developing world, research is looking at vaccines, which have previously been mainly seen as a solution to infectious diseases for children. This perception can be damaging: In the US, more adults die of vaccine preventable illnesses than children. Innovation in the industry is shifting to life-course vaccines to target people's needs throughout their life as and when they need them. A life-course approach to immunization can help reduce disease burden, relieve pressure



on caregivers and allow older populations to not only benefit from the preventative power of vaccines, but remain active members of the community.

The HPV vaccine provides the first great example of a shift in research and development towards life-course vaccines. In 1976, Harald zur Hausen made the connection between cervical cancers and infection with HPV (work for which he shared a Nobel Prize in Medicine in 2008).¹⁰⁷ It is estimated that cervical cancer affects more than 500,000 women each year, 80% of whom live in the developing world.¹⁰⁸ Screening programs have been effective in early stage diagnosis to catch and treat cervical cancer, but they have been less widely implemented in LMICs than in developed economies. The HPV vaccine is ideally given to boys and girls at a young age to prevent cancer. In 2006, a quadrivalent (four-strain) vaccine was licensed followed by a bivalent (two-strain) vaccine for girls in 2007 and in 2014 a nine-strain HPV vaccine was approved. The impact of immunization on cervical and other HPV-related cancers will be evident in the next decades – but a marked decrease in HPV infections, precancerous lesions and genital warts is already dramatic in the vaccinated populations.¹⁰⁹

IMMUNIZATION FOR ALL

Today, vaccines are a key part of the ambition for UHC and the UN SDGs to help end poverty, protect the planet, and ensure prosperity for all. Vaccines offer the opportunity of truly global and equitable healthcare.

The resurgence of measles in some parts of the world today serves as a reminder of the potential impacts of infectious diseases, which are easily preventable with vaccines.¹¹⁰

Immunization not only saves lives and improves health, it also unlocks the potential of the community. A vaccinated community is healthier, stronger, and more productive. Vaccination reduces the global burden of infectious disease; not only by protecting vaccinated individuals, but by indirectly protecting unvaccinated individuals through community protection or ‘herd protection’.¹¹¹

However, without successful immunization programs and collaborations, the benefits of vaccine innovation will not be fully realized. The new programmatic approach to developing the recent dengue and malaria vaccines shows that, more than ever before, industry needs to work hand-in-hand with governments, civil society, and global health policymakers to enable the benefits of vaccination to extend to all. Several landmark initiatives demonstrate the potential for such collaboration and impact, including:

- The Expanded Programme on Immunization initiated by the WHO in 1974 with the goal of making vaccines available to all children.¹¹²
- The founding of Gavi in 2000 by the BMGF, the World Bank, WHO, UNICEF and vaccine manufacturers including Sanofi Pasteur, Pfizer, MSD, GSK, Novartis and Janssen.¹¹³
- The creation of the Developing Countries Vaccine Manufacturers Network in 2000 with the aim of protecting all people against infectious diseases by increasing the quality and affordability of vaccines for all.¹¹⁴
- The Global Vaccine Action Plan’s Decade of Vaccines, 2011-2020, endorsed by 194 member states with the aim of delivering universal access to immunization regardless of where children were born, who they are or where they live.¹¹⁵
- The Humanitarian Mechanism, launched in 2017 by WHO, UNICEF, Médecins Sans Frontières and Save the Children, to enhance access to vaccinations for traditionally ‘left behind’ populations such as refugees and displaced people.¹¹⁶

FUTURE INNOVATION

INVESTMENT IN
VACCINES IS CRITICAL
TO ADDRESS AMR.
VACCINES CAN PREVENT
ILLNESS AND DEATH
AND ELIMINATE THE
NEED FOR THE USE OF
ANTIMICROBIALS IN THE
FIRST PLACE.

David Heymann,
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Industry is committed to driving vaccine innovation to help achieve global health security, prevent unnecessary disease and to address challenges presented by ageing populations. Together, vaccine development and immunization programs can strive to eliminate, contain, and prevent infectious diseases and NCDs.

The next phase of innovation will be driven by a greater understanding of pathogens and immune responses as well as data and technology-led developments in research.

Smarter technologies will also play a big role in the development of vaccines in the future. For example, vaccines that utilize messenger RNA (mRNA) are developing quickly. They work by providing instructions to our cells to make whatever we need to prevent disease, including antibodies. mRNA vaccines offer prompt and flexible design, cost-optimized production, and safer administration.¹¹⁷ Other projects are underway to bring vaccine adjuvants – which can improve vaccine efficacy by aiding its effect on the immune system – to market.¹¹⁸ Today there are 264 vaccines in the pipeline in the US alone, including a mix of life-course and infectious disease vaccines.¹¹⁹

Vaccines can also play a vital role in the fight against AMR, reducing infections and limiting their transition, enabling less reliance on antibiotics as well as reducing the inappropriate use of antibiotics for viral infections.

Vaccines remain the safest, most effective, and cost-effective medical technology ever developed. They are deployed globally to all, regardless of gender or location. Global vaccination programs have introduced key infrastructure to improve broader access to medicines in the developing world. Vaccines also offer alternative solutions to life-course diseases and an ageing population.

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