WHO Director-General addresses vaccine and immunization research forum

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Distinguished conference participants, experts in science and public health, representatives of sister UN agencies and industry, ladies and gentlemen,

WHO is proud to join the Bill and Melinda Gates Foundation and the National Institutes of Allergy and Infectious Diseases as an organizer of this event. The combination of cuttingedge science, down-to-earth public health experience, and well-conceived and generous funding is unbeatable.

The Forum further benefits from the engagement of industry and its commitment to develop new vaccines and constantly improve existing ones, with a particular focus on the needs of users in remote and understaffed areas.

In this Decade of Vaccines, we have much to celebrate, much to do, and many lessons to consolidate. In my view, immunization programmes have matured to the point that they can now serve as a model for the delivery of preventive interventions for multiple health strategies and problems. They have already demonstrated their ability to provide a platform to substantially increase coverage of non-vaccine interventions.

This capacity arises from a long history of research and innovation, with discovery science producing breakthroughs and delivery science showing how these breakthroughs can best work to save lives.

The Expanded Programme on Immunization was born out of success at a time of tremendous optimism about the game-changing potential of immunization. EPI was established in 1974 as the world moved closer to smallpox eradication.

Confidence was high that, with international commitment and cooperation, other vaccinepreventable diseases could be conquered. The 1979 certification of smallpox eradication was taken as proof of the power of vaccines to permanently improve the world.

The success of smallpox eradication demonstrated the critical importance of constant research and innovation, and of flexible operational approaches that can respond quickly to advances in knowledge and technology. EPI inherited these guiding principles as well, and has acted upon them, as the agenda for this Forum so clearly demonstrates.

Over the past four decades, EPI has remained true to its privileged birthright. It numbers among the most successful of all public health programmes. Its achievements continue to

inspire optimism about the world health situation, especially as many innovations represent solutions to long-standing weaknesses in health systems.

Moreover, since the very beginning, EPI has been a pathfinder for universal health coverage. The World Health Assembly Resolution that called for the Programme's creation gave it the explicit objective of providing universal access to four vaccines.

At that time, only 5% of the world's children were protected from the six killer diseases targeted by the vaccines. Today, that figure is 83%, with some developing countries reaching 99% immunization coverage.

Since 1974, the number of public health vaccines intended for universal protection has more than doubled. New vaccines have also been developed for diseases of regional significance, like epidemic meningitis and Japanese encephalitis.

New vaccines that protect against cancers of the liver and cervix, two of the most common cancers in the developing world, have opened a whole new frontier with massive preventive potential. More new vaccines against high-burden diseases are expected from a robust R&D pipeline.

Today, WHO estimates that immunization programmes save the lives of around 2.5 million people each year and protect many millions more from illness and disability.

But the most important statistics are these. Some 22 million children are still being missed. If access to existing vaccines can be improved, another one million lives could be saved each year.

It is the unrealized potential of vaccines and immunization, including these 22 million children who are missing out, that underpins the Decade of Vaccines, the Global Vaccine Action Plan, and much of the research agenda for this Forum.

The Decade of Vaccines set the stage for intensified innovation in vaccine and immunization research. The Global Vaccine Action Plan provided the framework to achieve the Decade's vision by delivering universal access to vaccines. The Action Plan has been described as "one of the largest and most ambitious public health initiatives ever launched."

The research being discussed during this Forum maps the way forward, right now and for decades into the future, in areas ranging from the use of nanotechnology in discovery R&D to improvements in product formulation, presentation, and packaging.

Immunization programmes naturally gravitate towards universal coverage, propelled, as they are, by a strong ethical imperative. No child should be denied the right to highly effective preventive interventions for unfair reasons, including those with economic or social causes. All barriers must be overcome.

In fact, this has been the history of EPI, as one barrier after another has been uncovered and overcome. This relentless quest to do more things better has created a host of innovative research methodologies, mechanisms, partnership models, collaborative strategies with

industry, and networks, such as the one that unites vaccine manufacturers in developing countries.

This is the source of lessons that can be consolidated to the profit of health system reforms currently under way. As I said, immunization programmes have been a pathfinder for universal health coverage.

Ladies and gentlemen,

Since publication of the 2010 World Health Report on health systems financing, more than 80 countries, at all levels of development, have sought WHO technical assistance in moving their health systems towards universal health coverage.

I am deeply encouraged by this trend, especially at a time when inequalities, both between and within countries, have reached their most extreme levels seen in half a century. These are inequalities in income levels and in opportunities, especially for youth. And these are shocking inequalities in health outcomes.

Leading economists and policy analysts view inequality as an especially dangerous force that squeezes the middle classes, disrupts social cohesion, and destabilizes society. It is also bad for economies. In January, the World Economic Forum ranked income inequalities as number four in its list of the top ten risks to the global economy.

Universal health coverage is one of the most powerful social equalizers among all policy options. It is the ultimate expression of fairness, as it operationalizes the right of all people to receive essential health care, without risking financial ruin.

A health system designed to deliver universal care, including preventive care, provides the foundation for tackling all health problems, for reaching all health goals, in a fair, integrated, and efficient way.

As countries reform their health systems to make them more inclusive and fair, including through the provision of social protection, the use of services increases. Health spending increases. We know this.

There is no free lunch. If user fees are removed, more money will need to come from other sources. Yet a growing number of countries are willing to take on these added responsibilities and incur these additional costs because it is the right thing to do.

It is the right thing to do in a world where an estimated 2.7 billion people live in countries with no form of social protection to cover the costs of health care.

It is the right thing to do in a world where an estimated 100 million people are driven below the poverty line each year by out-of-pocket payments for health care. For people living on the margins of survival, even the cost of essential medicines can push them over the edge. This is a world where chronic noncommunicable diseases have overtaken infectious diseases as the world's biggest killers. This is a seismic shift in the disease burden, with vibrations felt in health systems and economies all around the world.

These are extremely costly and burdensome diseases. Prevalence is increasing at a time when budgets are shrinking, costs are soaring, and public expectations are rising.

As the 2011 UN Political Declaration on the prevention and control of noncommunicable diseases concluded, prevention must be the cornerstone of the global response to these diseases.

A commitment to universal coverage creates the space and the mindset for bringing prevention to the fore and engaging multiple non-health sectors in the effort. It also creates the space to extend the benefits of immunization to every age group, throughout the life course, which is another welcome objective in this Decade of Vaccines.

For public health, the previous century was an era of treatment that relied on the technologydriven medical model to combat infectious diseases. With the shift in the disease burden, this century must be an era of prevention, with immunization leading the way.

Many innovations and strategies that have improved access to vaccines also advance the aims of universal health coverage. Again, immunization can lead to way.

Ladies and gentlemen,

The agendas for immunization and universal coverage share many points of convergence. They are built on a foundation of shared principles.

Both give equitable coverage of services and equitable access to care high priority as a core component of the right to health. Both seek to leave no one behind for any reason. Both pursue inclusiveness as a poverty reduction strategy. If we miss the poor, we miss the point.

Both seek to ensure that costs are not a barrier to access that punishes the poor, keeping them sick and poor. Most immunizations are delivered to populations, at no cost, through routine health services. Universal coverage uses pooled financing mechanisms to protect the poor from financial risks.

Both see reductions in waste and inefficiency as a route to expanded coverage. As with national immunization programmes, universal coverage stresses country ownership as a guiding principle.

Both initiatives know that solutions must be tailored to specific regional, country, and community contexts. Both recognize that research and innovation are the most expedient route to better programme and health system performance.

Perhaps most important, both recognize that reaching individual health goals, including the MDGs, depends on a well-functioning health system that delivers quality care and quality-

assured medical products, and puts a premium on the safety of recipients and health workers alike.

Some of the most innovative and broadly relevant work on immunization has taken place in this area.

Immunization programmes have dealt with problems of poor procurement policies, poor supply chains, infrequent supportive supervision, insufficient planning, and inadequate engagement of community leaders. Universal coverage faces similar barriers and has much to gain from EPI experiences and solutions.

Ensuring an uninterrupted supply of quality-assured vaccines, pharmaceuticals, medical devices, and medical supplies is a central part of any effort to improve the performance of health systems.

Immunization programmes, and the research that supports them, also have some very specific lessons for countries aiming to reform their health systems to reach universal coverage.

Let me mention five that I find particularly instructive.

First, the best research to develop new products or improve existing ones is highly strategic. It starts with an unmet need, looks at where and how the product will be used, looks at potential supply and delivery barriers, and uses good product design to overcome or circumvent these barriers.

The creation of Preferred Product Characteristics has institutionalized this approach, as you have been discussing.

The Meningitis Vaccine Project provides an excellent practical example. The project was launched at the request of ministers of health in Africa's meningitis belt.

They knew the characteristics of the ideal vaccine, including a price of no more than one dollar per dose. As one minister of health said at the time, "A vaccine that is too expensive for Africa is worse than no vaccine at all."

The Meningitis Vaccine Project delivered on these and other expectations. Since December 2010, when the vaccine was launched, more than 150 million children have been immunized. Not a single group A meningitis case has been detected among these children.

Second, research must continue long after a new product has been licensed and put in use. Many attribute the long time needed for insecticide-treated nets to have an impact on malaria morbidity and mortality to the fact that implementation research was stopped much too early. Too many barriers to delivery and use were too poorly understood, and this delayed the impact by at least a decade.

Thanks to continuing research on MenAfriVac, last month saw the publication of two breakthrough studies. Both arose from the first use of a controlled temperature chain in a mass immunization campaign.

The first study demonstrated that the vaccine remained viable when stored outside the cold chain for up to four days, relieving vaccinators of a burden that allowed them to reach "last mile" populations in the most remote areas.

The second study reached an equally welcome conclusion. Keeping vaccines at ambient temperatures for short periods during immunization campaigns could cut storage and transportation costs in half. I have no doubt that researchers will be exploring whether other vaccines can break out of the cold chain.

The studies also have a broader relevance. About one third of medicines manufactured in Europe and North America are now being tested and labelled for storage at controlled room temperature, and this proportion is increasing.

A third lesson responds to the need for flexibility and places emphasis on multiple solutions to the same problem. As just one example, research to develop heat-stable vaccines is taking place in parallel with the use of simple vaccine vial monitors that signal when vaccines need to be discarded.

Fourth, engage industry. Make industry a partner. For example, many new vaccines are presented and packaged in ways that can create serous difficulties for transportation and storage in countries with weak infrastructures.

The establishment of a Vaccine Presentation and Packaging Advisory Group, which operates through monthly teleconferences, opened a much-needed dialogue with industry, with a focus on needs and constraints in poorer countries.

Industry has been highly responsive. Manufacturers have changed the presentation or packaging of their vaccine products in significant ways, often requiring substantial investments.

In some cases, improvements in vaccine presentation have brought a four-fold reduction in storage space requirements. Compact, prefilled, single-use auto-disposal devices reduce the risk of human error and can be safely used by health workers, especially in remote areas where skilled staff are in short supply.

As a recent study shows, the Advisory Group generated a sense of trust and partnership between health officials and vaccine manufacturers. The achievements also appeal to donors, who appreciate innovations that ease delivery in resource-constrained settings. This is more value for money that stretches the impact of development dollars.

I thank vaccine companies for their responsiveness, and their investments.

A final lesson arises from the expense associated with newer vaccines, which makes supply chain issues extremely important as a way of reducing vaccine waste. When working with industry, time-limited projects tightly focused on a discrete set of problems can generate incentives to innovate, especially in areas where novel products are badly needed.

A good example is Project Optimize, a five-year collaboration between PATH and WHO that has now finished its work. The project was established to identify ways in which supply chains can be optimized to meet the demands of an increasingly large and costly portfolio of vaccines.

The Project stimulated industry innovation in cold chain equipment, including a solar directdrive refrigerator that needs neither electricity nor lead batteries and can reduce the health and environmental hazards associated with kerosene-fuelled refrigerators.

The refrigerator, in various models, is now on the market and has been prequalified by WHO.

These and other innovations were made possible by eliminating key market barriers and providing incentives to manufacturers to meet performance, quality, and safety specifications set by WHO.

Taken together, these lessons provide an encouraging message for all health programmes. When the barriers to good programme performance are identified, research can help break them down, often through simple and ingenious solutions.

Ladies and gentlemen,

The Global Vaccine Action Plan makes polio eradication an early milestone of achievements during the Decade of Vaccines.

Last month, I travelled to India to celebrate the country's remarkable polio-free status for the past three years. India's success tells the world there is no such thing as impossible.

This has been the spirit of EPI during its four decades of evolution. This is the spirit of the Decade of Vaccines and the cutting-edge science being presented during this Forum.

This is the spirit of the Bill and Melinda Gates Foundation: set ever higher goals and use research to make them feasible.

Immunization, like universal coverage, is a magnet for solidarity that transcends borders and sectors. It has compelling public and political appeal, and is an especially rewarding investment for national governments and donors.

And it still has tremendous unrealized potential.

In a sense, immunization programmes have matured to the point where they can now take a great leap ahead. And in this sense, we are just getting started as we aim ever higher.

Thank you.