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COMMENTARY

Zero-dose or under immunized: Where should the emphasis lie?

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Abstract
Vaccine preventable diseases (VPD) pose significant morbidity and mortality globally. Two years after the endorsement of Immunization Agenda 2030 (IA2030), the number of children not fully vaccinated increased from 19 million pre-COVID-19 to 25 million post-COVID, with 72% (18.2 million) of these labelled as zero-dose, i. e those who did not receive DPT 1 vaccine. While children who do not initiate vaccination early (zero-dose) may be at a greater risk of missing subsequent vaccinations, we most respectfully suggest that this term zero-dose may be problematic, lending itself to misconceptions among policy makers and health professionals. Firstly, zero-dose is currently set at six weeks DPT1 vaccination point and not at birth for children 12-23 months of age. Secondly, assessing zero-dose in children 12 to 23 months of age, delays corrective or remedial action because by month 12, the children have missed key vaccines before they are flagged as zero dosers. Thirdly, in poor settings, many children who initiate vaccination do not complete the schedule, with DPT1 coverage always higher than measles vaccine coverage. Additionally, the children in poor countries who miss the first DPT dose face similar challenges and deprivations and barriers as those who fail to complete their immunization schedule. The problems of poverty, inability to fully access immunization services, hesitant caregivers and poorly equipped immunization programs affect all children across sub–Saharan Africa and other poor countries. This review seeks to discuss the importance of looking at the entire recommended immunization schedule over and above highlighting those who miss DPT1 alone and proposes that "under-immunized" children as an entity be equally emphasized as "zero dose" children in low- and middle-income countries to ensure that adequate attention is given to both vulnerable groups.

Concerns around the definition of zero dose

Since the inception of the World Health Organization's (WHO) Expanded Programme on Immunization (EPI) in 1974, significant strides in child health have been realized following the introduction and uptake of routine childhood vaccines. However, vaccine preventable diseases (VPDs) continue to cause appreciable morbidity and mortality among children, more so, in low-and middle-income countries (LMICs)(1-3). In August 2020, the 73rd World Health Assembly endorsed the Immunization Agenda 2030, a global strategy to achieve the vision of a world where everyone, everywhere, at every age fully benefits from vaccines for good health and well-being(4). Three impact goals were developed to track progress towards this vision. By 2030, the global community aims to "(1) reduce mortality and morbidity from VPDs for everyone throughout the life course; (2) leave no one behind, by increasing equitable access and use of new and existing vaccines; and (3) ensure good health and well-being for everyone by strengthening immunization within primary health care (PHC) and contributing to

universal health coverage and the sustainable development goals (SDGs)"(4). However, over 18 million infants in 2021 missed the first dose of the combination diphtheria, acellular pertussis and tetanus (DPT1) vaccine globally (5-9). These infants are defined as zero-dose children and are indicators of missed communities. The focus of the SDGs has been to ensure equity, especially when more than two thirds of zero-dose children come from families living below the recognized international poverty (5-8), and to make sure no one is left behind. Consequently, there is the need to consider communities where these children come from as part of any future strategy. Marginalized communities should have as much focus as vaccination coverage in these countries.

One of the key points in addressing concerns with VPDs in children has been to define a *"zero-dose child"*. There has been confusion between a *"child who has failed to receive any routine immunization"* versus a child who missed DPT1, with two approaches currently being applied. The first approach uses a single vaccine as a proxy for zero dose status definition. The second approach uses a given subset of vaccines in identifying the children that have missed all recommended routine vaccines (10, 11). However, consensus is now emerging that the former represents a more precise definition of a zero-dose child, while the later provides a simplified definition for the purposes of monitoring that an infant has received the DPT1 vaccine. Consequently, the focus should be on routine immunization as opposed to campaign-based immunization, as this strategy aims to estimate the reach of the programmatic measured immunization services and their performance in the communities (5, 12-15). The ultimate goal of immunization services is to reach all communities (16). While one could consider other vaccines as proxies, for example, DTP3 vaccine uptake is often the preferred indicator for global IA2030 monitoring of coverage, especially given that the coverage for other vaccines, including polio or measles, usually measures uptake through household indicator surveys that could contain a mix of routine and campaign-delivered vaccine doses (10, 11).

The high proportion of zero-dose children constituting 72% (18.2 out of 25 million in 2022) as a proportion of all children globally that should be vaccinated, emphasizes the reason why urgent strategies to address this problem are long overdue. It is indeed true that reaching zero-dose children can serve as a catalyst to enhance the uptake of additional vaccines. This is evidenced by recent surveys which showed that children either missed all vaccines or received 3 or 4 doses of vaccines, suggesting that the initiation of DPT1 offers promise for subsequent doses to be received (7, 8, 17, 18). Consequently, reaching zero-dose children is an important focus of any country immunization program that is seeking to ensure immunization coverage achieves expected targets. This is because children that receive at least one dose of scheduled vaccines will most certainly be able to receive the other doses of vaccinations. The challenge arises when we estimate zero-dosers as currently defined among children 12 to 23 months of age (11) – which is almost 11 months or more from when the 6-weeks DPT1 dose vaccine would have been missed. This bracket (12 – 23 months old children) and not 6-10 weeks (the period between DPT1 and DTP2) or 18 weeks (the period when DPT3 should have been received) adds to the confusion. Typically, zero would represent the beginning, at OPV0 (oral polio vaccine) and BCG at birth, and not at 6 weeks. Additionally, 6 weeks point is not the reference for all countries for DPT1, as some countries utilize a 2-, 3- and 4-month schedule. The very confusing nature of terminology and timing may lead to confusion in target communities and local immunization health centres.

Zero-dose or under immunized?

There exists a second strong counter argument besides defining the concept of *"zero-dose"* as the focus should be on efforts to address the current decline in immunization coverage and access to services, enhanced since the start of the COVID-19 pandemic. It is believed that the many different factors (or barriers) that determine whether a child will complete the recommended immunization schedule or not, are the same ones likely to drive the number of zero-dose children. The majority of zero-dose children are currently found in LMICs, which currently account for 87% of the worldwide total of 18.2 million zero-dose children (7, 8, 15, 19). In the 2021WHO report, where just 10 countries account for 62% of zero-dose children, and the same countries also account for 59% of the children missing out on a

measles vaccine (20). It was observed that 6 countries with large-populations contributed a large proportion of zero-dose children, namely India at 15% (2.7 million), Nigeria at 12% (2.2 million), Indonesia at 6% (1.1 million), Ethiopia at 6% (1.1 million), Philippines at 6% (1 million) and Democratic Republic of Congo at 3.8% (700,000) (20). These countries accounted for almost half of all the zero-dose children globally in 2021 (5, 7, 8, 15, 18, 19). Furthermore, these countries have many poor communities, low literacy levels, and poverty with some riddled with conflict or post conflict communities (10, 11). While children from these communities are likely to miss starting the recommended immunization schedule, they are also likely to not complete the vaccination journey(21).

These poor communities have key barriers to immunization (9, 10, 22-25). Inequities in the rates of vaccination are appreciable contributors to disparities currently seen in childhood health and survival and failure to complete immunization schedules across countries (26, 27). The factors driving this under-immunization in poor countries include transportation and difficult terrain, language difficulties, migrant refugee communities, inadequate caretaker and health care education (9, 28-30). Additional factors resulting in sub-optimal immunization programmes include religious and cultural beliefs against immunization, adolescent or young caregivers, and increasing anti-vaccine messages contributing to vaccine hesitancy (9).

Other barriers to access to immunization, including long distances to health facilities, poor road network, lack of male partner support, cultural and religious barriers, all need to be assessed for their impact on zero-dose numbers (5-8, 11, 13-15, 17, 18, 31). These factors are as much a concern not only for zero-dose children but also for the entire group of under-immunized children Given that both a zero-dose child, and an under-immunized child, are likely to face many different barriers to access to immunization services, there is need to understand the various social, or political or economic situations and contexts in which zero-dose children or the under-immunized child and their families exist to address current concerns (5, 7, 8, 11, 12, 15, 18, 19). COVID-19 related disruptions contributed to widespread delay in vaccination, increasing the likelihood of involved children missing subsequent doses of scheduled vaccines or even defaulting the recommended schedule all together before concluding the full series of their vaccines before the second birthday (32-34).

The concern about the decline in vaccination in this vulnerable group is the largest drop witnessed in many years, arguably since the inception of the global EPI program. While there is indeed a concern that COVID-19 and associated measures played an appreciable role in the recent decline, it is important to realize that these problems existed before the COVID-19 pandemic. Indeed 19.2 million children did not complete their immunization in 2019 (35), with the COVID-19 pandemic making the situation worse. The bigger worry is not the fact that COVID-19 disruptions and associated lock-down measures caused delays and declines in immunization numbers, but that this decline is continuing (16, 36, 37). Whereas it is important to increase the number of children starting immunization and thus reduce the zero-dose numbers, there is the greater need to catch-up on the numbers of eligible children who have already missed their vaccine doses (16, 36, 37). These are the children targeted in the 'Big Catch-up' which is a coordinated effort by WHO, UNICEF and GAVI, alongside IA2030 Partnership, to support countries towards implementing immunization programmes in 2023 and beyond(38).

With Immunization Agenda 2030 (IA2030), partners and stakeholders have called on concerned governments as well as relevant role players and actors to intensify the efforts for ensuring catch-up vaccination for all eligible children. (31, 32, 39-46). The objective is to address or stop the ongoing backsliding and stagnation affecting the routine immunization programs, and to expand outreach services in the EPI programs. Consequently, expanding access to essential vaccines to underserved areas of the population to ensure coverage for all children who missed vaccines as well as implement timely campaigns to help prevent future VPD outbreaks. Additional expectations are for countries to

implement and put in place evidence-based, and people-centered plans and strategies, deliberately tailored towards building trust in vaccines and the immunization program as a whole. There is therefore a need for intensified VPD pandemic response efforts with corresponding allocation of resources and energy to support the rapid and deliberate scale-up and delivery of necessary vaccines, surveillance, cold chain capacity, healthcare worker training and social mobilization to address this critical issue. This is the time to strengthen PHC services and routine immunization as the main integral component of VPD pandemic preparedness (16, 19, 21, 47, 48).

Without effective planning and preparation, to secure and allocate the necessary financing, data management and advocacy, programs will continue to lag behind (16, 36, 37). In future, programs will continue to be strained due to shrinking budgets and low numbers and a poorly motivated healthcare work force. As we transition from the COVID-19 pandemic and its associated emergencies, projections paint a concerning picture, with countries experiencing declining budgets with smaller amounts of revenue generated and increasing borrowing costs (49-56). The recent World Bank projections show that up to 40 countries (where 29 are in the middle- and low-income category) may never even manage to return to the pre-COVID-19 pandemic county vaccine coverage rates, even by 2026 (16, 19, 21, 47, 48). This will affect government planning and domestic budgets as well as PHC services, especially immunization.

Conclusion

The use of the term zero-dose, as currently defined, may easily be misunderstood and thus result in misconceptions. Zero-dose as currently set is not at birth but at the age the child receives the DPT1 vaccine. When zero-dose definition is used as currently proposed, delays in corrective or remedial response action may result since some children will have missed many vaccines before they are flagged as zero-dose children. Additionally, in most settings in SSA, a significant portion of those who start the recommended immunization schedule actually do not finish the journey. Over the years, reports on coverage and immunization levels have shown that there is usually a steady decline along the immunization journey from DPT1 to measles containing vaccine 2 (MCV2). The coverage for MCV2 is often lower than that of DPT3 and MCV1. Consequently, the under-immunized or non-immunized children should as well receive equal focus as given to zero-dose children to reduce VPDs. This way, the population of the not (fully) immunized children will be reduced.

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