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Introducing seasonal influenza vaccine in Bhutan: Country experience and achievements

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Abstract

Bhutan successfully introduced multiple vaccines since the establishment of the Vaccine Preventable Disease Program in 1979. Surveillance and subsequent introduction of influenza vaccination became a public health priority for the Ministry of Health following the influenza A(H1N1)pdm09 pandemic. Sentinel surveillance for influenza in Bhutan began in 2008, and a study of severe acute respiratory infection was conducted in 2017, which found the highest influenza burden in children aged <5 years and adults ≥50 years. Following review of surveillance and burden of disease data, the National Technical Advisory Group presented recommendations to Bhutan's Ministry of Health which approved influenza vaccine introduction for all five high-risk groups in the country. Upon the official launch of the program in June 2018, the Vaccine Preventable Disease Program began planning, budgeting, and procurement processes with technical and financial support from the Partnership for Influenza Vaccine Introduction, the United States Centers for Disease Control and Prevention, the Bhutan Health Trust Fund, and the World Health Organization. Influenza vaccination for high-risk groups was integrated into Bhutan's routine immunization services in all health care facilities beginning in November 2019 and vaccinated all populations in 2020 in response to the COVID-19 pandemic. Coverage levels between 2019 and 2022 were highest in children aged 6–24 months (62.5%–96.9%) and lowest in pregnant women (47.7%–62.5%). Bhutan maintained high coverage levels despite the

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Ethical clearance

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Declaration of Competing Interest

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COVID-19 pandemic by continued provision of influenza vaccine services at health centers during lockdowns, conducting communication and sensitization efforts, and using catch-up campaigns. Bhutan's experience with introducing and scaling up the influenza vaccine program contributed to the country's capacity to rapidly deploy its COVID-19 vaccination program in 2021.

Keywords

Influenza; Bhutan; Vaccination; Surveillance; Planning; Implementation

1. Introduction

Bhutan is a small landlocked lower-middle income country in South Asia with both mountainous and subtropical terrain, and an estimated population of approximately three-quarters of a million people [1,2].

Bhutan's free universal health care system provides both traditional and allopathic services through a three-tiered delivery approach [3]. The primary care level includes a network of 186 primary health centers, 552 outreach clinics, and three thromde (municipal administrative unit) health centers. The secondary level includes 48 hospitals, and the tertiary level of care includes three referral hospitals located in three regions of the country. Bhutan has made significant progress in achieving universal health coverage targets. Diphtheria, pertussis, and tetanus toxoid immunization coverage has been >95% since 2010. Service availability, infrastructure, and human resources have drastically improved over the years as a result of public financing of the health sector [4]. Health system challenges include accessibility across difficult geographical terrain and rural areas, inadequate workforce, and increasing out-of-pocket expenditures to access care within and outside the national system despite the provision of government-subsidized health care.

Bhutan's Vaccine Preventable Disease Program (VPDP), formerly known as the Expanded Program on Immunization, was established in 1979. Since then, 13 different antigens have been introduced into Bhutan's routine immunization services, including seasonal influenza in 2019 [5,6]. Bhutan achieved universal child immunization in 1991 and has sustained routine immunization coverage above 90% for the last several years [7,8]. During three decades, Bhutan achieved several immunization program milestones including certification of elimination of neonatal tetanus in 1994, polio in 2014, measles in 2017, rubella in 2023 and certification of control of hepatitis B in 2018. Bhutan has sustained high (>90%) coverage for new vaccines introduced across age groups including mumps vaccine (MMR) introduced in 2016, pneumococcal conjugate vaccine introduced in 2019, and human papilloma vaccine (HPV) for boys introduced in 2020 [5,6]. These achievements are attributed to the country's strong health infrastructure, motivated healthcare workers, and commitment from political leaders.

The introduction of seasonal influenza vaccination into Bhutan's routine immunization program was prioritized following the influenza A (H1N1)pdm09, when it was recognized that the country lacked experience in adult vaccination programming. Furthermore, frequent outbreaks of H5N1 in poultry in the country highlighted the need to strengthen pandemic

preparedness and ensure rapid deployment of vaccine, readiness of health facilities, and integration of new vaccines into routine immunization [9]. The Ministry of Health recognized the potential of a national seasonal influenza vaccination program to improve adult immunization delivery as well as strengthen the country's pandemic response capacity. This was experienced during COVID-19 vaccination campaigns that was built on a national influenza vaccination program. Although, the experience has not yet transferred for other adult vaccine but the same experience will be used for the introduction of new adult vaccines into the routine immunization service. Bhutan's National Influenza Preparedness and Response Plan was developed and aligned with the World Health Organization's pandemic influenza preparedness and response guidance, and includes introduction of seasonal influenza vaccination to the general population as part of pandemic influenza planning and preparation [8–10].

2. Evolution of Bhutan's influenza vaccination program

Fig. 1: Process and timeline of Bhutan's seasonal influenza vaccine introduction.

2.1. Establishing Bhutan's influenza surveillance system (2008–2017)

Acute respiratory diseases cause significant morbidity in Bhutan every year [3]. Prior to 2008, there was no surveillance in place to assess incidence of acute respiratory diseases or detect specific pathogens; all respiratory-related diseases were classified based on clinical presentation and reported using broad case definitions from the International Code for Diseases [11].

Understanding the temporal characteristics of influenza is essential for planning seasonal influenza vaccination program. In 2008, the Royal Centers for Disease Control (RCDC), formerly known as the Public Health Laboratory, recognized the need for a robust sentinel surveillance system for influenza to inform introduction of seasonal influenza vaccination in Bhutan. The RCDC started influenza surveillance with the support from the United States Army Medical Directorate's Armed Forces Research Institute for Medical Sciences. Surveillance was initiated in three sentinel sites adjacent to the RCDC (Punakha, Paro and Thimphu) because of limitations in specimen shipment capacity. The onset of the influenza A(H1N1)pdm09 emergency accelerated the growth of Bhutan's influenza surveillance network and expansion of sample transportation services using ambulances and the postal service. Six additional sentinel sites (Chukha, Trongsa, Tsirang, Sarpang, Mongar, and Trashigang) were established in 2009 and two sites in 2010 (Samtse and Samdrup Jongkhar), for a total of eleven sentinel sites—seven sites for influenza-like illness and eleven sites for severe acute respiratory infection (SARI) [12]. These sentinel sites remain in operation [13]. In 2012, the RCDC and the United States Centers for Disease Control and Prevention (CDC) entered into a cooperative agreement to further strengthen influenza surveillance capacity.

2.1.1. Surveillance findings - influenza epidemiology—In 2017, the burden of influenza-associated respiratory hospitalization was estimated using SARI surveillance data from six districts [14,15]. This study found an annual incidence rate of 50 influenza-associated respiratory hospitalizations per 100,000 persons of all ages (95% CI: 45–55) in

2015 and 118 per 100,000 persons of all ages (95% CI: 110–127) in 2016. The highest rates were among children aged <5 years and among adults ≥50 years. The estimated influenza-associated respiratory hospitalizations among all ages was 376 (95% CI: 339–413) in 2015 and 896 (95% CI: 830–962) in 2016 respectively [9]. Temperate countries in the Northern hemisphere typically experience three months of peak seasonal influenza. However, surveillance data showed that Bhutan's influenza activity occurs during six months and has two seasonal peaks; one during winter (December to March) and the second coinciding with monsoon season (July to September) [16,17]. The disease burden varies vastly among age groups and across seasons making it difficult to ascertain the true disease burden [18].

2.2. 2017–2022: Planning, preparation, and implementation of Bhutan's national influenza vaccination program

2.2.1. Decision making and planning for influenza vaccine introduction—The initial phase of influenza vaccination program planning began in 2017, when the RCDC presented findings from the 2017 Thapa *et al.* study of influenza-associated respiratory hospitalizations to the National Immunization Technical Advisory Group (NITAG) [15]. NITAG developed a recommendation that seasonal influenza vaccine should be introduced to all high-risk groups defined by the WHO Strategic Advisory Group of Experts (SAGE) on immunization [19]. These groups include health workers, individuals with comorbidities and underlying conditions, older adults, pregnant women, and children aged 6 to ≤24 months depending on national disease goals, capacity, epidemiology, and disease burden. Rather than prioritizing certain high-risk groups, Bhutan decided to introduce vaccination to all high-risk groups after considering evidence from other countries [20–23] and to align with the National Influenza Preparedness and Response Plan [9,10]. The VPDP presented NITAG's recommendations to the High-Level Committee of the MOH, which concurred with NITAG's recommendation and approved the introduction of seasonal influenza vaccine for all high-risk groups.

Following the MOH's final policy decision, NITAG met to discuss the timing of vaccine introduction. Bhutan's surveillance data indicated higher transmission of influenza during the monsoon season than in winter; however, surveillance experts believed that winter transmission was also likely to be high given Northern hemisphere patterns [15,17]. Therefore, NITAG recommended the introduction of vaccination in the winter season and integration of seasonal influenza vaccination into routine immunization services to maximize human and financial resources.

2.2.2. Establishing partnerships and financing—In 2018, the CDC extended technical and financial support through the Partnership for Influenza Vaccine Introduction (PIVI) for seasonal influenza vaccine introduction in Bhutan [24]. PIVI and the MOH developed a five-year implementation plan (2019–2023) that included procurement of influenza vaccine, technical and operational support. PIVI's support covered vaccine introduction starting with health workers and pregnant women in 2019–2020 and expanding to include children aged 6 to ≤24 months in 2021–2023. The MOH subsequently engaged the Bhutan Health Trust Fund (BHTF) to finance vaccine procurement to cover all high-

risk target groups during the five-year period, including older adults and individuals with comorbidities. BHTF was established by the Royal Government of Bhutan in 2000 to ensure a continued and timely supply of vaccines and essential drugs in public health system in Bhutan. The fund status as on 2021 was USD 42 million and almost 12 % of BTHF budget of USD 5.2 million was allocated for routine vaccine purchase in year 2020–21 [25].

2.2.3. Procurement—The Royal Government of Bhutan formally launched the seasonal influenza vaccine program on June 4th, 2018, coinciding with the celebration of Her Majesty the Queen's 28th birthday. However, implementation did not begin until November 2019 because of the timing of finalization of agreements with partners, estimation of doses required, and formal proposal of the procurement budget. The influenza vaccine procured was influenza trivalent inactivated vaccine from the Green Cross Corporation, South Korea.

The population of target high-risk groups was calculated using National Statistics Bureau and dzongkhag (administrative unit or district) data [2]. Based on these estimates, PIVI and BHTF procured a total of 613,000 doses for the five-year implementation period (see Fig. 2). The MOH submitted the influenza vaccine dossier for registration and authorization by the Drug Regulatory unit of the Bhutan Food and Drug Authority per the regulatory requirements of the 2003 Medicines Act of the Kingdom of Bhutan [26]. Vaccine shipments were received at the Paro International Airport and shipped to the national VPDP stores. Following lot release, vaccines were distributed to regional stores and health facilities in refrigerated vans. Bhutan has a well-established supply chain system for distribution of antigens for the routine immunization services; the introduction of domestic flights and helicopter service to remote regions has improved delivery times and the cold chain [6].

Fig. 2: Number of influenza vaccine doses procured annually by the Bhutan Health Trust Fund (BHTF) and Partnership for Influenza Vaccine Introduction (PIVI).

2.2.4. Workforce training, public engagement, and advocacy—Guidelines for health workers were developed to support the influenza vaccine program's implementation, monitoring, and reporting. Adverse events following immunization (AEFI) training was conducted using existing AEFI guidelines of the VPDP, and training of trainers was carried out by NITAG and cascaded to immunization service workers in 20 districts.

The Health Promotion Division of the Department of Public Health, Ministry of Health developed an information, education, and communication plan to address public concerns and create awareness about the importance of the vaccine. Leaflets about influenza vaccination were produced in local languages and messages were disseminated through national television, radio and local newspapers across the country. The Health Promotion Division also engaged key decision-makers and influencers; district health officers played a critical role in advocating for support of the vaccination program to district governors, block leaders, and stakeholders.

2.2.5. Campaign implementation (2018–2019)—Seasonal influenza vaccination was integrated into Bhutan's routine immunization services and rolled out in all healthcare facilities in the country from November 1 through December 31, 2019. Integration into

the national health care system streamlined human resource requirements to implement the program within health facilities. Additional vaccination posts were set up by the Jigme Dorji Wangchuk National Referral Hospital in Thimphu and Phuntsholing Hospital to serve large urban populations, staffed by providers from the Khesar Gyalpo University of Medical Sciences. Door-to-door vaccination services were also provided to older adults by staff of local health facilities to ensure equitable access for this high-risk population. In order to verify that high-risk target groups were being reached, pregnant women and parents of children were instructed to bring their maternal and child health handbook, older adults were asked to present their Citizenship ID card, and persons with chronic medical conditions were instructed to provide their health book for verification of diagnoses.

2.2.6. Coverage of high-risk groups (2019–2022)—Bhutan achieved influenza vaccination coverage of >75% for three of four high risk groups in the first year of implementation: children aged 6– ≤24 months, health workers, individuals with chronic medical conditions, and people aged 65 years and above (see Fig. 3). Less than 50% coverage was achieved for pregnant women in 2019.

Coverage rates for most high-risk groups have remained near or above 75% since 2019. Several areas require more analysis to understand lower rates of coverage and demand drivers. For instance, coverage of pregnant women has increased but remains below other groups. The dip observed in HCW coverage in 2021 might be attributable to vaccine fatigue related to COVID-19 vaccination and the low incidence of influenza cases seen during the pandemic because of COVID-19 safety protocols, but the true cause is unknown.

No serious AEFI was reported during the introduction in 2019, and in subsequent years, only one serious AEFI (anaphylaxis) was reported in 2020 (0.0008% of administered doses); the reaction was managed effectively by the reporting health centers and the individual fully recovered.

Fig. 3: Coverage rates by high-risk group in the first four years of Bhutan’s introduction of seasonal influenza vaccine.

2.2.7. Vaccine wastage rates—Influenza vaccine wastage rates have been below 15% since 2019 (2.5% to 13.16%), an acceptable rate per WHO guidance [27]. The wastage rate improved after 2019 because of improvements in coverage rates and reduction of doses procured (Table 1). Wastage was further minimized by delivering influenza vaccination alongside routine immunization services in October and November during dedicated immunization days at health facilities.

2.2.8. Impact of COVID-19—Bhutan sustained its high coverage of routine immunization for all antigens including influenza during the COVID-19 pandemic. The country experienced the first outbreak of COVID-19 in the southern towns bordering India in July 2020. The MOH chose to vaccinate the general population in addition to high-risk groups during the 2020 influenza season in order to avert hospitalizations because of influenza illnesses and preserve limited hospital beds and intensive care unit capacity for the COVID-19 response. The total population vaccinated against influenza in 2020 was

416,422, including high-risk groups. The general population vaccination against influenza was one time decision based on risk assessment during COVID-19 pandemic. Currently there no influenza vaccine policy for the general population.

The importance of receiving an influenza vaccination to avoid serious illness because of coinfection with the SARS-CoV-2 virus was emphasized through communication on social media platforms for all high-risk groups, with special focus on reaching older adults. The VPDP implemented several strategies to ensure sustained high coverage of both childhood immunization and influenza vaccination during pandemic lockdowns. Parents with children and other high-risk groups were allowed to visit their nearest health center for immunization, and strict COVID-19 safety protocols were in place at health centers. Catch-up campaigns to vaccinate children who missed their scheduled vaccination were conducted by health centers after the lifting of lockdowns. Furthermore, older adults who could not walk to health centers were provided influenza vaccination by health workers during home visits. Co-administration of influenza and COVID-19 vaccine was not carried out in Bhutan during pandemic because of timing issue. However, co-administration is possible in the near future once high-risk groups is identified by NITAG for COVID-19 routine vaccination based on WHO SAGE recommendation.

Planning and implementing mass influenza vaccination provided valuable experience that informed the first COVID-19 vaccination campaigns in March and July 2021. Influenza vaccination required micro-planning at the dzongkhag level to identify vaccination posts and vaccinators, develop vaccine deployment strategies, assess cold chain capacity, and implement systems to manage AEFI. These activities facilitated COVID-19 vaccination efforts, and Bhutan was able to achieve 94% coverage for the first dose of COVID-19 vaccine in adult >18 years within two weeks using a mass population vaccination approach in the end of March 2021 [5,6].

3. Discussion

Bhutan successfully introduced the influenza vaccine into routine immunization services within only a few years and has successfully achieved high coverage rates of nearly all high-risk populations. The main factors contributing to Bhutan’s successful influenza vaccine introduction were the establishment of the influenza surveillance system, use of evidence to inform planning, strong leadership, and political commitment. High coverage can be attributed to strong immunization services, the country’s robust network of health infrastructure, and community trust in public health immunization services. Coordinated financial support from the BHTF and PIVI enabled the country to launch the influenza vaccine program. Furthermore, BHTF allotted USD $340,000 to procure influenza vaccine for the 2022–2023 fiscal year compare to $ 327,000 for the 2021–2022 fiscal year which is increase of 3.8%. However, the allocation depends on the vaccine doses requirement and dollar exchange rate. BHTF has committed to procure vaccine annually along with other routine immunization antigens for all high-risk groups to sustain routine influenza vaccination after PIVI phases out its support.

The country's primary challenges are data-related, though progress is being made to address these issues. Estimating vaccine doses required for every season is a challenge, as the populations of high-risk groups are dynamic. Determining reliable estimates of denominators for high-risk groups is a challenge, particularly individuals with chronic medical conditions. Coverage data, vaccine inventory reporting, and AEFI reporting are not streamlined across the health system; the experience of introducing influenza vaccination highlighted the need for a centralized digital database for recording and reporting of data and AEFI in real time at the dzongkhag and national levels. A new digital platform for vaccination, the Bhutan Vaccine System, was implemented in 2021 to support COVID-19 vaccine introduction, and this system included a module for tracking influenza vaccination of high-risk groups. The system includes a dashboard featuring the total number of individuals registered for vaccination, doses administered, AEFIs, and vaccine inventory. This module will facilitate estimation of influenza vaccine requirements and support procurement planning.

Procurement challenges are also present. Orders must be placed eight months in advance but delays in receipt of vaccine supply from UNICEF impacts planned immunization activities. Furthermore, the type (s) of trivalent inactivated influenza vaccine and dosage requirements differ every year which presents operational challenges for vaccinators.

Bhutan's experience introducing influenza vaccine highlighted the importance of a robust surveillance system that provides high quality data to estimate disease burden and make data-driven, cost-effective technical recommendations and policy decisions. To further improve the implementation, program evaluation needs to be conducted to identify causes of relatively low coverage in pregnant women and other areas for improvement. Conducting a cost effectiveness analysis of the vaccination would also aid un sustainability of program. While the policy decisions to introduce influenza vaccine incorporated high-quality surveillance and careful consideration of burden of disease estimates, this approach has not been consistently carried for all new vaccines introduced in Bhutan because of lack of capacity. Therefore, the MOH and VPDP should focus on maintaining and expanding national capacity for evidence generation to support policy decisions for expanding influenza vaccination for non high-risk group.

4. Conclusion

Bhutan successfully introduced seasonal influenza vaccine into routine immunization services for all high-risk groups as recommended by the WHO SAGE. The country achieved high coverage for most high-risk groups, and the progress made during four years since introduction is encouraging. Furthermore, the experience of planning and implementing the influenza vaccination program paved the way for the rapid introduction of COVID-19 vaccination in 2021.

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Data availability

Data will be made available on request.

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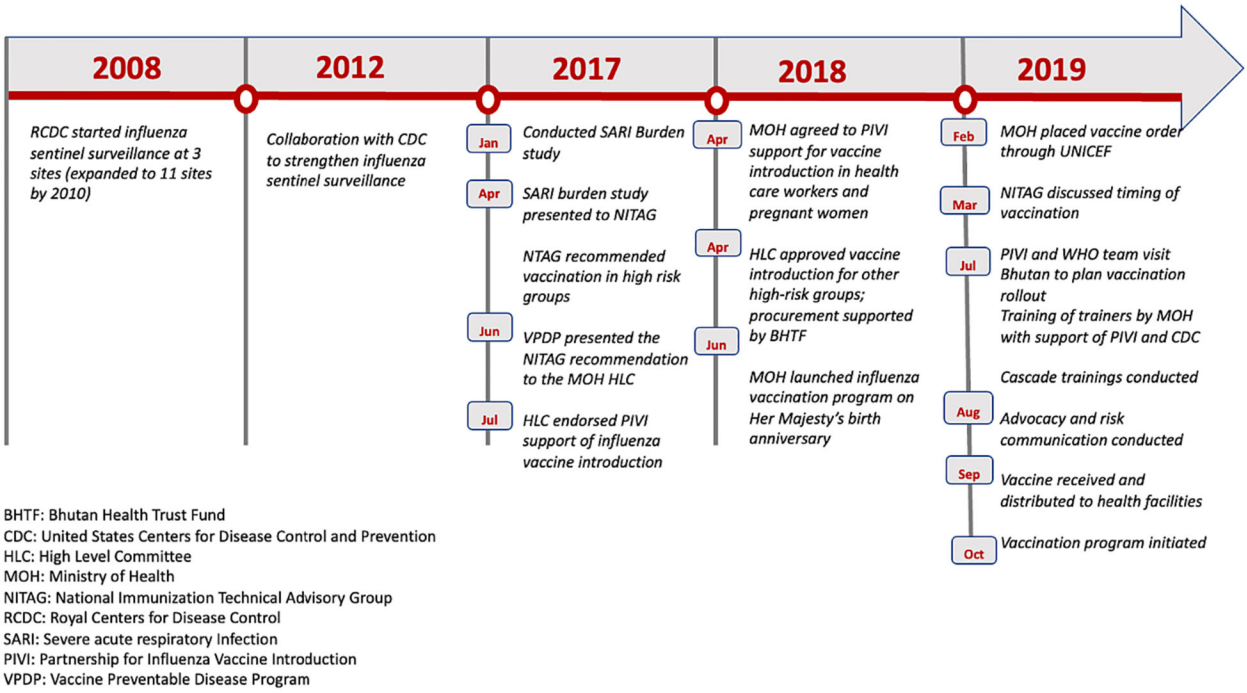

Fig. 1.

Bhutan introduced seasonal influenza vaccination in 2019 after an extensive process of data collection and analysis, building partnerships, and planning.

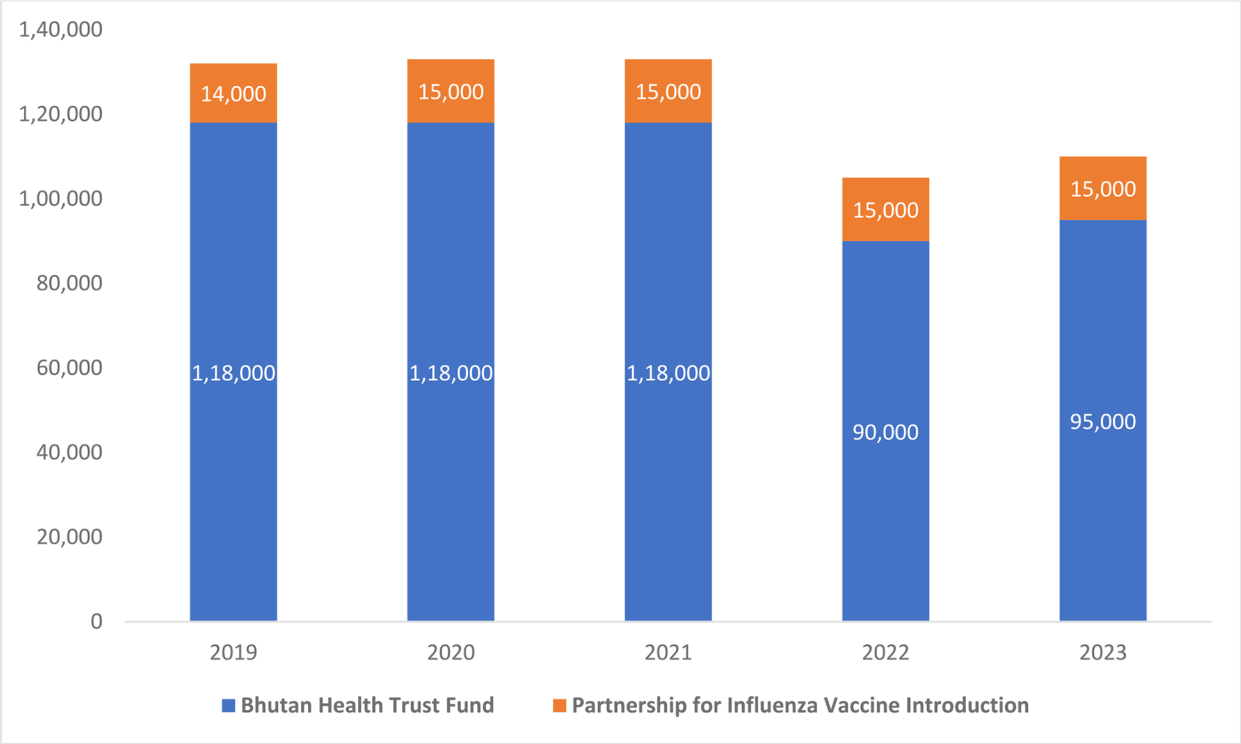

Fig. 2.

PIVI's support covered vaccine introduction starting with health workers and pregnant women in 2019–2020 and expanded to include children aged 6 to ≤24 months in 2021–2023. BHTF financed vaccine procurement to cover the remaining high-risk target groups including older adults and individuals with comorbidities.

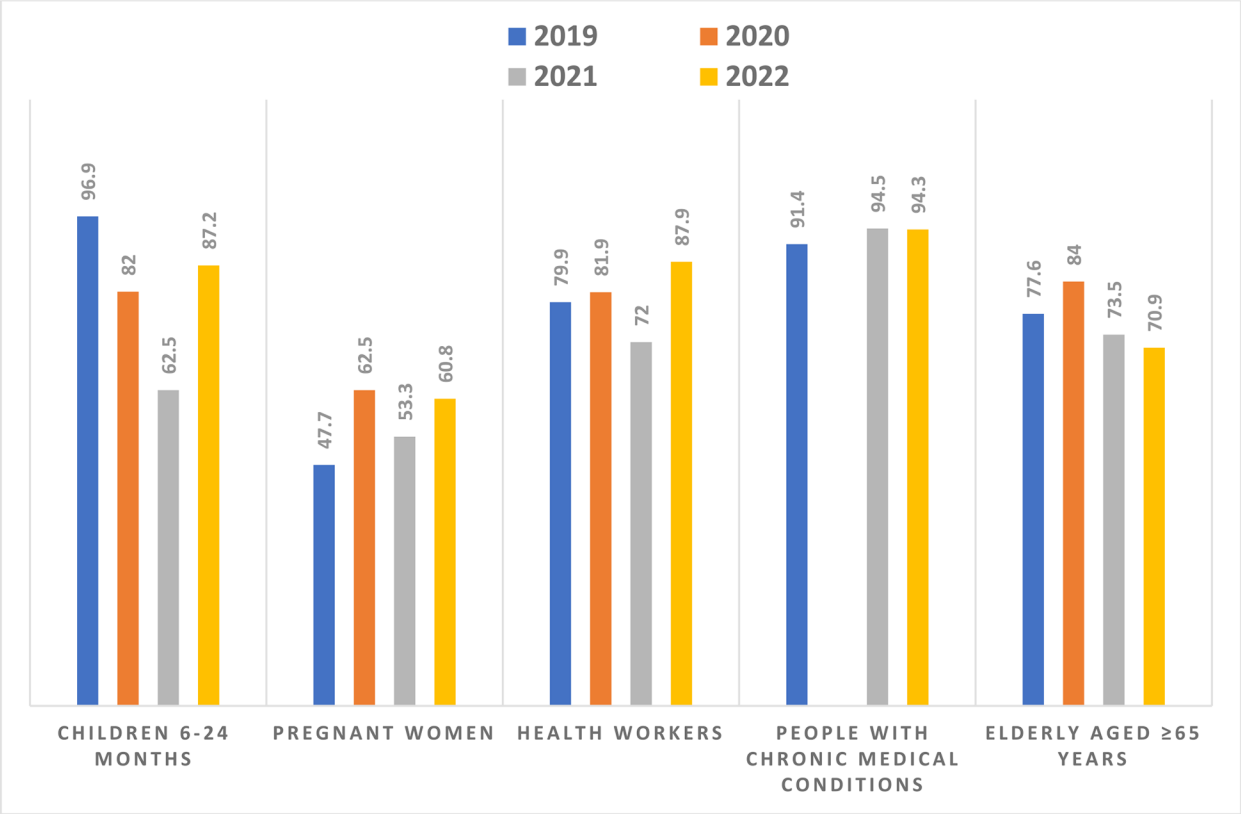

Fig. 3.

Influenza vaccination coverage by high-risk group, 2019–2022. Coverage ratios are based on denominator estimates for each high-risk group using National Statistics Bureau and District Administrative data. Note: Coverage of individuals with chronic medical conditions was grouped with the general population in 2020.

Table 1

Bhutan's seasonal influenza vaccination program's vaccine utilization and wastage rates.

Year	Doses procured*	Doses administered*	Utilization rate (%)	Wastage rate (%)
2019	132,000	114,629	86.84	13.16
2020	133,000	117,845	88.61	11.39
2021	133,000	130,000	97.60	2.4
2022	105,000	95,951	91.38	8.62

* Data Source: Vaccine Preventable Disease Program.