



Seasonal influenza vaccination policies in the 194 WHO Member States: The evolution of global influenza pandemic preparedness and the challenge of sustaining equitable vaccine access



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ABSTRACT

Introduction: As of 2018, 118 of 194 WHO Member States reported the presence of an influenza vaccination policy. Although influenza vaccination policies do not guarantee equitable access or ensure vaccination coverage, they are critical to establishing a coordinated influenza vaccination program, which can reduce morbidity and mortality associated with yearly influenza, especially in high-risk groups. Established programs can also provide a good foundation for pandemic preparedness and response.

Methods: We utilized EXCEL and STATA to evaluate changes to national seasonal influenza vaccination policies reported on the WHO/UNICEF Joint Reporting Forms on Immunization (JRF) in 2014 and 2018. To characterize countries with or without policies, we incorporated external data on World Bank income groupings, WHO regions, and immunization system strength (using 3 proxy indicators).

Results: From 2014 to 2018 there was a small net increase in national seasonal influenza vaccination policies from 114 (59%) to 118 (61%). There was an increase in policies targeting high-risk groups from 34 in 2014 (34 /114 policies, 29%) to 56 (56/118 policies, 47%) in 2018. Policies were consistently more frequent in high-income countries, in WHO Regions of the Americas (89% of countries) and Europe (89%), and in countries satisfying all three immunization system strength indicators. Low and low-middle income countries, representing 40% of the worlds' population, accounted for 52/61 (85%) of countries with no evidence of a policy in either year.

Conclusion: Our results demonstrate that national influenza vaccination policies vary significantly by region, income, and immunization system strength, and are less common in lower-income countries. Barriers to establishing and maintaining policies should be further examined as part of international efforts to expand influenza vaccination policies globally. Next generation influenza vaccine development should work to address barriers to influenza vaccination policy adoption, such as cost, logistics for adult vaccination, country priorities, need for yearly vaccination, and variations in seasonality.

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1. Introduction

The turn of the 21st century marked the beginning of unprecedented global cooperation toward pandemic influenza preparedness [1]. The World Health Organization (WHO) released its 1st Influenza Pandemic Plan in 1999 [2] outlining the responsibilities of WHO and all national authorities to prepare and plan for a pandemic. The plan stressed the need to enhance influenza research,

surveillance, and emergency preparedness and expand vaccine and antiviral drug production and distribution [3]. The 58th World Health Assembly of 2005 further strengthened the concept of pandemic preparedness being a global responsibility by approving a new set of legally binding International Health Regulations [4] (resolution WHA58.3) and an influenza preparedness resolution (WHA58.5) [5] which called on WHO to improve surveillance and increase global vaccine availability.

Governments' financial commitments to pandemic preparedness in 2006 reached \$1.8 billion according to World Bank reports and by 2010 totaled \$4.3 billion [6]. The trademark of early pandemic planning and preparedness efforts hinged on expanding influenza vaccine access [1] by increasing manufacturing capabilities worldwide. The WHO's Global Action Plan for Influenza Vaccines (GAP) [7] catalyzed an increase in seasonal and pandemic influenza manufacturing capacity from 500 million and 1.5 billion doses, respectively in 2006, to 1.5 billion and 6.2 billion in 2013 [8]. This global momentum to ensure the availability of influenza vaccines slowed following the 2009H1N1 [6] pandemic when "pandemic fatigue" possibly contributed to a decrease in manufacturing capacity and influenza dose distribution [9].

A heightened sense of preparedness is hard to sustain in the absence of an emergency. Newer pandemic preparedness efforts, such as the WHO's *Global Influenza Strategy (GIS) of 2019–2030* [10], map out a more integrated whole systems approach through strengthening health infrastructure and improving or expanding seasonal influenza vaccination policies and programs worldwide. Seasonal influenza vaccination programs can reduce influenza-associated disease burden, reduce hospitalizations and mortality, and also provide a strong infrastructure for pandemic response. The GIS builds on the strength of successful programs [11], such as the *Global Influenza Surveillance and Response System (GISRS)* [12], which provides coordinated global monitoring, surveillance, and response for influenza and other respiratory pathogens in 122 WHO Member States. GIS works within the *Pandemic Influenza*

Preparedness (PIP) Framework, whose goal is to encourage sharing of viruses and increased access of vaccines for developing countries [13]. GIS approaches pandemic preparedness as a function of strong infrastructure and capacity to establish and maintain successful seasonal influenza vaccination programs. In parallel, GIS strives to improve influenza vaccines, drugs and diagnostics making them more accessible to all countries.

Prior to 2006, 5 countries in Africa had the capacity to test for influenza, compared to 25 countries today. When H1N1 hit Africa in 2009 and 2010, those countries with established influenza programs and testing capacity were equipped to diagnose H1N1 [14]. The Ebola Outbreaks in West Africa revealed the need for a coordinated, global, disease surveillance system [15]. Although an influenza vaccination program and its associated infrastructure and respiratory disease surveillance do not replace a coordinated, global surveillance program, they do cultivate local capacity and understanding of basic epidemiology of influenza transmission and risk and provide infrastructure for reporting, specimen processing and testing, and data collection and analysis [16]. The current COVID-19 pandemic illustrates synergistic opportunities which may arise out of a pandemic. Three new diagnostic tests are currently being evaluated by the Food and Drug Administration which simultaneously test for influenza and COVID-19 [17].

The starting point of any seasonal influenza vaccination program is a National influenza vaccination policy [18,19]. The *WHO/ UNICEF Joint Reporting Form on Immunization [20–21]* (JRF) tracks yearly immunization practices and program performance in the 194 WHO Member States. As of 2014, the JRF added influenza policy-related information and became the first standardized, yearly, data collection instrument to capture global seasonal influenza vaccine policy and influenza vaccination coverage data [22]. Prior to this, influenza policies were estimated from infrequent surveys [23] or proxy indicators, such as influenza vaccine dose distribution [24].

Table 1
WHO/UNICEF Joint Reporting Form (JRF) on Immunization's influenza-related policy questions in 2014 and 2018.

2014	
... ..Does the country have a formal national seasonal influenza vaccination policy? (Yes / No)	
... ..Which risk groups, if any, are recommended for seasonal influenza vaccination?	
Children (if yes, specify age range in comment field)	(Yes / No)
Older persons (if yes, specify age range in comment field)	(Yes / No)
Chronic illness (pediatric)	(Yes / No)
Chronic illness (adult)	(Yes / No)
Pregnant women	(Yes / No)
Health care workers	(Yes / No)
Haj or other travelers	(Yes / No)
Any other risk group (if yes, specify in comment field)	(Yes / No)
All persons >6 months are recommended to receive vaccine	(Yes / No)
No groups are specified for influenza vaccine receipt	(Yes / No)
... ..What seasonal influenza vaccine formulation was used in 2014? (Northern Hemisphere / Southern Hemisphere / Both)	
2018 (additional questions added by 2018)	
... ..Are influenza vaccines licensed by your national regulatory authority?	(Yes / No)
... ..Were influenza vaccines available in your country this season/year?	(Yes / No)
... ..Does your country have a formal national (governmental) influenza vaccination policy? (Yes, public sector / Yes, private sector / Yes, public and private sectors / No)	
... ..Which types of vaccines were used?	
Trivalent	(Yes / No / NR)
Quadrivalent	(Yes / No / NR)
High dose	(Yes / No / NR)
Adjuvanted	(Yes / No / NR)
... ..Are live attenuated influenza vaccines (LAIV) used in your country? (Yes / No / NR)	

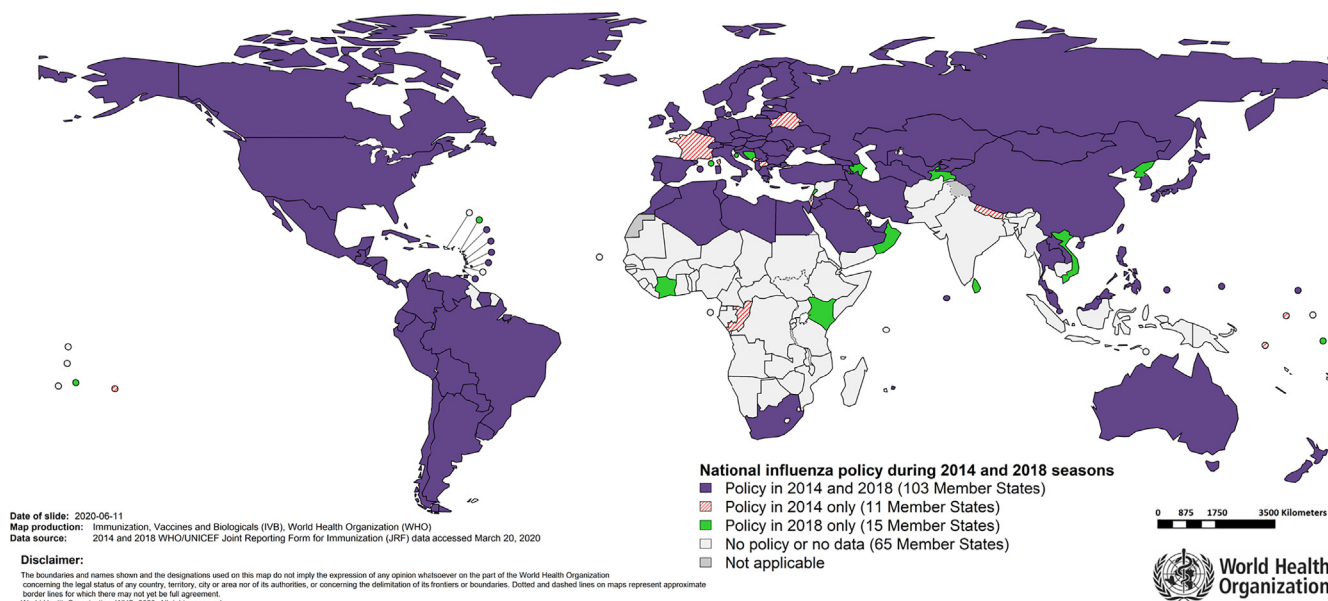


Fig. 1. Changes in national influenza vaccination policies in the WHO Member States from 2014 to 2018*. **2014 influenza season as noted in the manuscript is the 2013/2014 influenza season in the Northern Hemisphere and the 2014 influenza season in the Southern Hemisphere.

In order to better understand the global landscape of influenza vaccination policies and provide a baseline for international efforts to strengthen or expand seasonal influenza vaccination programs as part of a larger pandemic readiness worldview, we evaluated seasonal influenza vaccination policies in the 194 WHO member states as reported in the JRF for 2014 and 2018. By characterizing influenza vaccination policies by region, income, and immunization program strength, we can provide preliminary evidence of global prioritization of influenza vaccination as well as potential barriers to establishing and maintaining these policies.

2. Methods

2.1. Primary data source

We utilized influenza-related policy data extracted from the WHO/UNICEF JRF on March 20, 2020. The data focused on the 2013–2014 Northern Hemisphere/2014 Southern Hemisphere influenza seasons (denoted 2014 from here forward) and the 2017–2018 Northern Hemisphere/2018 Southern Hemisphere influenza seasons (denoted 2018 from here forward). A detailed description of the JRF has been previously described [22]. Examples of influenza-related policy questions from 2014 and 2018 are listed in Table 1.

2.2. Additional data sources

We supplemented data from the JRF with the following country indicators for our data analysis: the latest World Bank income group classifications as listed in July 2019 [25]; Gavi, the Vaccine Alliance [26] Phase 2 support eligibility (73 countries; see Appendix and ANNEX for additional information) [27]; whether the country has a functioning National Immunization Technical Advisory Group (NITAG) (WHO/IVB/EPI Strategic Information Group); the status of Maternal and Neonatal Tetanus (MNT) elimination (WHO/IVB/EPI Strategic Information Group [28]); WHO and UNICEF estimated coverage for the third dose of *Diphtheria/tetanus toxoid/pertussis* containing vaccine (DTP3) $\geq 95\%$ [29]; introduction status of hepatitis B birth dose for all newborns, pneumococcal conjugate vaccine (PCV), rotavirus vaccine (Rota) or human papilloma virus vaccine (HPV) [30].

2.3. Data handling and analysis

The JRF and supplemental data were merged and managed in MS Excel (Redmond, Washington, USA), and later analyzed using both Stata 14.2 (College Station, Texas USA) and Excel. We employed descriptive statistics to explore global JRF data of all 194 WHO Member States, and regionally within the six WHO regions: Africa (AFR), 47 countries; Americas (AMR), 35 countries; Eastern Mediterranean (EMR), 21 countries; Europe (EUR), 53 countries; South-East Asia (SEAR), 11 countries; and Western Pacific (WPR), 27 countries [31]. Our analysis excluded non-Member States and territories.

As previously described [22], we used supplementary data on Gavi eligibility, functioning NITAG, and other vaccine-related target indicators as proxy measures of the strength of the country immunization program. We tested the independence of distributions of proxy indicators between countries with and without an influenza vaccination policy using a Pearson's chi-square test.

We considered countries to have a national influenza policy if they responded affirmatively to the question, "Does your country have a formal national (governmental) influenza policy?", OR if they responded "No" (or did not report data) yet DID report a national recommendation in one of the target risk group categories.

To be in line with the 2012 influenza vaccine recommendations from WHO's Strategic Advisory Group of Experts on Immunization (SAGE) [32], we diverged from the JRF questionnaire's long list of high-risk groups (Table 1) and redefined "all high-risk groups" to include pregnant women, children, persons with chronic illnesses, elderly, healthcare workers, and 'other' (which was determined as a "YES" to one of the following: 'other' non-specified, long-term care residents, or Haj/travelers.).

3. Results

3.1. Influenza vaccination policies in the 194 WHO Member States

In 2014, 93% (180 countries) of the 194 WHO Member States reported influenza-related data through the WHO/UNICEF JRF, including 114 countries (59% of all WHO members) with a seasonal influenza vaccination policy, and 66 (34%) without a policy. In

Table 2
Comparison of WHO Member States with and without national influenza vaccination policies during 2014 and/or 2018.

	Number of countries (as of 2018)	Countries with a national influenza vaccine policy			Countries without a national influenza vaccine policy in either year
		2014	2018	In both years	
Number of countries, n (%)	194	114	118	103	61
Country wealth (USD\$)					
Median/IQR per capita health expenditure	186*	796 / 1511	648 / 1497	809 / 1500	62 / 70
WHO World Regions					
Africa	47 (24)	4 (3)	5 (4)	3 (3)	41 (67)
Americas	35 (18)	31 (27)	32 (27)	31 (30)	3 (5)
E. Mediterranean	21 (11)	12 (11)	13 (11)	11 (11)	6 (10)
European	53 (27)	47 (41)	47 (40)	42 (41)	0
South-East Asia	11 (6)	3 (3)	4 (3)	2 (2)	6 (10)
Western Pacific	27 (14)	17 (15)	17 (14)	14 (13)	5 (8)
World Bank Income Group, n (%)‡					
High-Income	57 (29)	51 (45)	52 (44)	48 (47)	1 (2)
Upper-Middle-Income	58 (30)	44 (39)	45 (38)	40 (39)	8 (13)
Lower-Middle-Income	46 (24)	17 (15)	18 (15)	15 (15)	24 (39)
Low-Income	31 (16)	1 (1)	2 (2)	0	28 (46)
Eligible for Gavi Phase 2 Support**					
No	121 (62)	99 (87)	99 (84)	91 (88)	12 (20)
Yes	73 (38)	15 (13)	19 (16)	12 (12)	49 (80)
New and under-utilized vaccine introduction, n (%)†					
Introduced hepatitis B birth dose vaccine	109 (56)	73 (64)	76 (64)	66 (64)	24 (39)
Introduced pneumococcal conjugate vaccine	140 (72)	84 (74)	86 (73)	78 (76)	44 (72)
Introduced rotavirus vaccine	97 (50)	53 (46)	54 (46)	50 (49)	37 (61)
Introduced human papilloma virus vaccine	87 (45)	70 (61)	69 (58)	66 (64)	12 (20)
Strength of immunization system, n (%)					
Functioning NITAG††	114 (59)	76 (67)	80 (68)	72 (70)	28 (46)
Eliminated MNT**	182 (94)	114 (100)	118 (100)	103 (100)	51 (83)
National DTP3 coverage > 95%‡‡	84 (43)	61 (53)	64 (54)	56 (54)	13 (21)

Data are reported as number of countries (percent of total number of countries for the respective column).

*Reflects 2016 current health expenditure data, the most recent data available at the time of the analysis, for 186 countries.

**This includes the 73 countries eligible for Phase 2 Gavi support (please see ANNEX for a list).

†Reflects the World Bank income classification for each country as of July 2019 for 2018. Two countries, Cook Islands and Niue, are not classified.

‡By the end of 2014, 93 countries had introduced universal hepatitis B birth dose, 116 countries had introduced pneumococcal conjugate vaccine, 71 countries had introduced rotavirus vaccine, and 57 countries had introduced human papilloma virus vaccine.

††By the end of 2014, 81 countries were classified as having a functional NITAG.

**In 1999, 57 countries were considered as not having achieved MNT elimination; this number increased to 59 with independence of Timor-Leste in 2002 and South Sudan in 2011 (meaning 135 countries had eliminated MNT, 194–59 = 135). As of 2014, 35 of these 59 countries had been validated as having achieved MNT elimination (135 + 35 = 170 countries eliminated MNT); by August 2019, this total was 47 of the 59 countries, leaving 12 countries outstanding.

‡‡ Reflects coverage based on the 2018 revision (completed July 2019) of the WHO and UNICEF estimates of national immunization coverage. A total of 89 countries had DTP3 coverage > 95% in 2014.

2018, only 79% (154 countries) of the Member States reported influenza data through the JRF, including 118 (61%) with a policy and 36 (19%) without (see Fig. 1 and Table 2).

Although there was a net increase (4 countries) in the total number of national seasonal influenza vaccination policies from 2014 to 2018, 11 countries either removed their policy (Congo, Nepal, and the Solomon Islands) or did not report at all (Belarus, Nauru, Cook Islands, France, Israel, Kuwait, North Macedonia, Montenegro) from 2014 to 2018 (see Fig. 1). In 2014, only one low-income country (Nepal) had an influenza policy, which was revoked by 2018.

In 2018, 15 new countries added influenza policies, including two low-income (LIC) countries (Tajikistan and The People's Democratic Republic of Korea), three lower-middle income countries (Côte d'Ivoire, Kenya, and Viet Nam), and 9 upper-middle and high-income (HIC) countries (Azerbaijan, Bosnia and Herzegovina, Saint Kitts and Nevis, Lebanon, Sri Lanka, Monaco, Oman, San Marino, Tuvalu). We do not assume that a previously reported policy is still in place, when there is an absence of reported data. Similarly, the lack of influenza-related data from 40 countries in 2018 may not reflect an absence of policies in those countries, but rather a delay in reporting to WHO or the choice or lack of information from the country immunization manager filling in the JRF form.

In 2014 and 2018, 103 countries consistently had influenza vaccination policies; whereas 65 consistently provided no evidence of

a policy (61 reported that they did not have a policy and 4 did not report data on influenza). In both 2014 and 2018, policies were most frequent in the WHO Regions of AMR (89% of countries) and EUR (89%), and less frequent in the countries of WPR (62%), EMR (57%), SEAR (27%), and AFR(11%).

3.2. Risk group prioritization

The number of countries prioritizing each risk group mentioned in the JRF (see Table 1), excluding chronic diseases, increased from 2014 to 2018. In addition, countries targeting: all high-risk groups, as was defined in the methods section, increased from 34 to 56; all persons > 6 months of age (classified as *universal vaccine*) increased from 22 to 29 countries; and all-risk groups or *universal vaccine* increased from 43 (data not shown) to 62 countries from 2014 to 2018. Most of these shifts towards wider prioritization of risk groups occurred in high or middle-income countries (see Figs. 2 and 3 and Table 3)

3.3. Immunization system strength indicators of countries with influenza vaccination policies (see Table 2)

Countries were 2 – 8 times more likely to have an influenza policy in place when satisfying either one or all proxy indicators

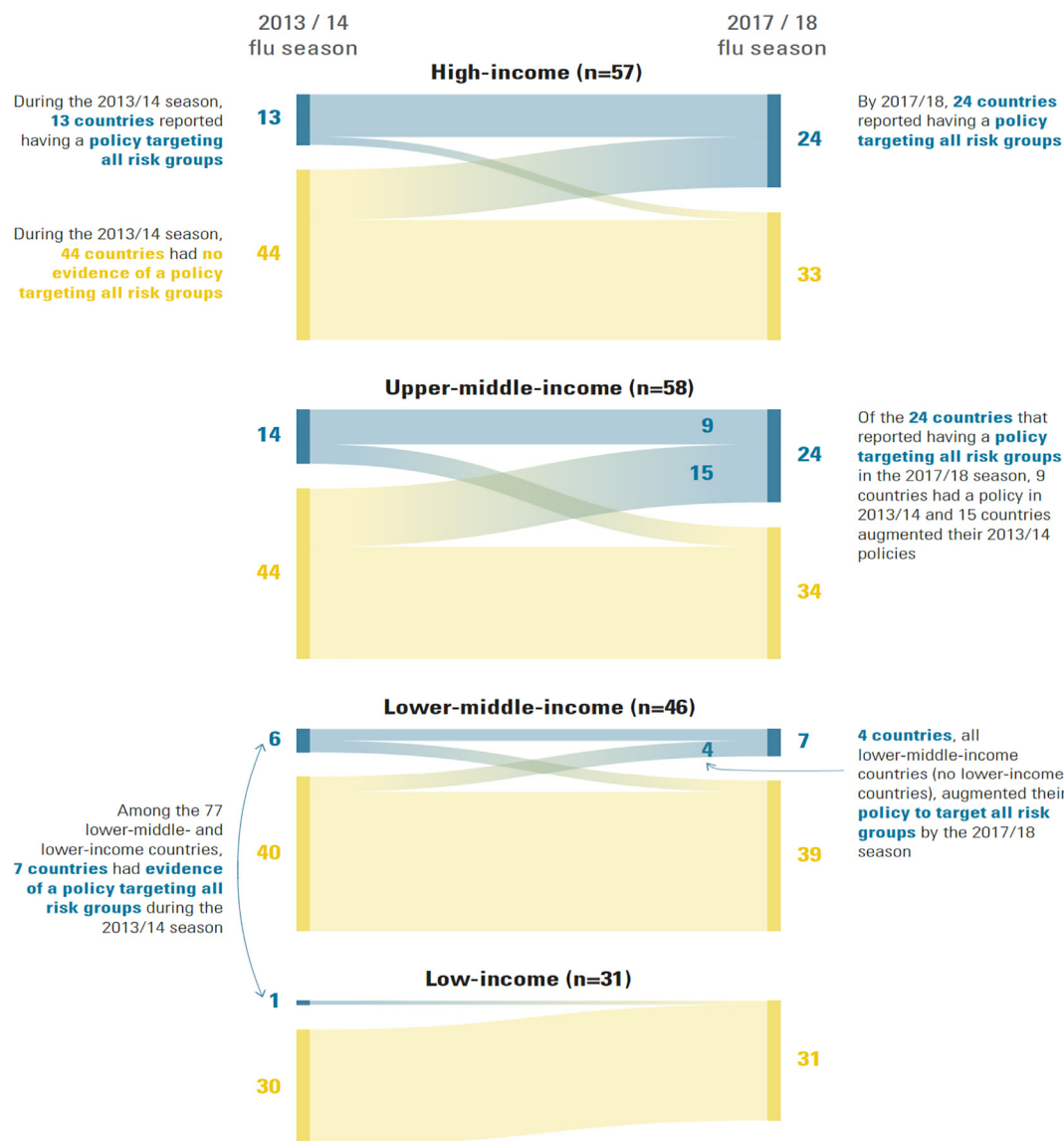


Fig. 2. WHO Member States with seasonal influenza vaccine policies and the changes to risk group prioritizations from 2014 to 2018. *All risk groups indicates a country targeting children, persons with chronic illness, pregnant women, health care workers, elderly, and at least one other (travelers, Haj pilgrims, long-term residents, other).

of immunization system strength. Countries were more than twice as likely to have an influenza vaccine policy in 2018 if they also had a functioning NITAG (relative odds yes/no 2.6; 95%CI: 1.4, 4.8)¹. Countries were three times more likely to have a policy in 2018 (relative odds: 3.3; 95%CI: 1.7, 6.4) if National DTP3 coverage \geq 95%. Countries were 8.5 times (95%CI: 3.1, 23.3) more likely to report a national policy when satisfying all three system strength indicators (n = 54), or 4.5 times more likely with two of the proxy indicators satisfied (95%CI: 2.1, 9.9) - compared to those satisfying none or just one. All countries with a policy had eliminated MNT. Countries that satisfied all 3 of the system strength indicators (n = 54) were nearly 3 times (95%CI: 1.1, 7.5) more likely to have a universal influenza vaccination policy or to target all high-risk groups (as defined) compared to those satisfying none or just one of the indicators.

3.4. Influenza vaccine formulations

In 2018, a total of 78 countries reported use of Northern Hemisphere (NH) influenza vaccine formulations; 21 countries reported

Southern Hemisphere (SH); and 9 countries reported use of both. Not surprisingly [33], the NH formulation was more common in Europe, and the SH formulation was more common among countries in the Americas (see Table 4 and Fig. 4).

Half of the countries (n = 96 countries) reported use of trivalent influenza vaccine (TIV) during 2018 (Table 4), and nearly one quarter (n = 42) reported use of quadrivalent influenza vaccine (QIV). Quadrivalent influenza vaccines were more frequently used in high-income countries. Data were not available on vaccine type in more than one-third of countries (n = 75) overall; 84% of low-income countries did not report information on vaccine type.

3.5. Influenza vaccination coverage

Only 62 countries reported complete administrative numerator, denominator, and coverage data (all three components) for 2018 by high-risk group. Some countries reported one or more, but not all three components. Among the 86 countries that reported numerator data, an aggregate total of 276 million influenza doses were reportedly administered. However, 99 countries did not report any administrative data. Due to the limitations of adminis-

¹ Assumes no policy and/or NITAG if no data is provided in JRF

Table 3
Risk group recommendations in WHO Member States with national influenza immunization policies.

Region	Number of countries	Has national influenza		Children		immunization policy** Persons with chronic illness	High-risk groups targeted by national influenza immunization policy												
							Pregnant women		Health care workers		Elderly		Other groups		All risk groups^^		Data Not Available		
		2014	2018	2014	2018	2014	2018	2014	2018	2014	2018	2014	2018	2014	2018	2014	2018	2014	2018
All countries	194	114	118	60	76	105	102	87	96	98	103	97	105	83	95	34	56	58	75
WHO Region																			
Africa	47	4	5	2	3	4	3	3	2	3	2	3	4	3	3	2	1	27	41
Americas	35	31	32	21	26	28	31	24	30	28	32	25	29	15	27	11	19	4	3
Eastern Mediterranean	21	12	13	6	11	11	11	8	11	10	13	9	12	12	13	4	10	9	6
European	53	47	47	19	23	44	44	38	41	43	43	43	44	39	42	10	19	4	7
South-East Asia	11	3	4	2	1	2	1	2	1	2	1	2	1	3	1	2	0	5	8
Western Pacific	27	17	17	10	12	16	12	12	11	12	12	15	15	11	9	5	7	9	10
World Bank Income Group*																			
High-Income	57	51	52	24	30	49	49	41	46	44	49	45	52	42	47	13	24	5	5
Upper-Middle-Income	58	44	45	27	33	40	38	35	37	38	39	38	37	27	34	14	24	11	15
Lower-Middle-Income	46	17	18	8	12	14	13	10	12	14	14	12	15	12	12	6	7	20	26
Low-Income	31	1	2	1	0	1	1	1	0	1	0	1	0	1	1	1	0	21	28
Eligible for Gavi Phase 2 Support ⁽¹⁾																			
No	121	99	99	52	66	92	89	76	85	85	91	86	93	73	84	28	50	19	22
Yes	73	15	19	8	10	13	13	11	11	13	12	11	12	10	11	6	6	39	53

Data are reported as number of countries within each category.

^^ All risk groups indicates a country targets children, persons with chronic illness, pregnant women, health care workers, elderly, and others (travelers or Haj pilgrims).

* Reflects the World Bank income classification for each country as of July 2019. Two countries, Cook Islands and Niue, are not classified.

⁽¹⁾ This includes the 73 countries eligible for Phase 2 Gavi support (please see ANNEX for a list).

** Due to inconsistencies in the reported data, the summed number of countries reporting that influenza policy targeted a specific high-risk group may not sum to the value for 'Any' influenza policy.

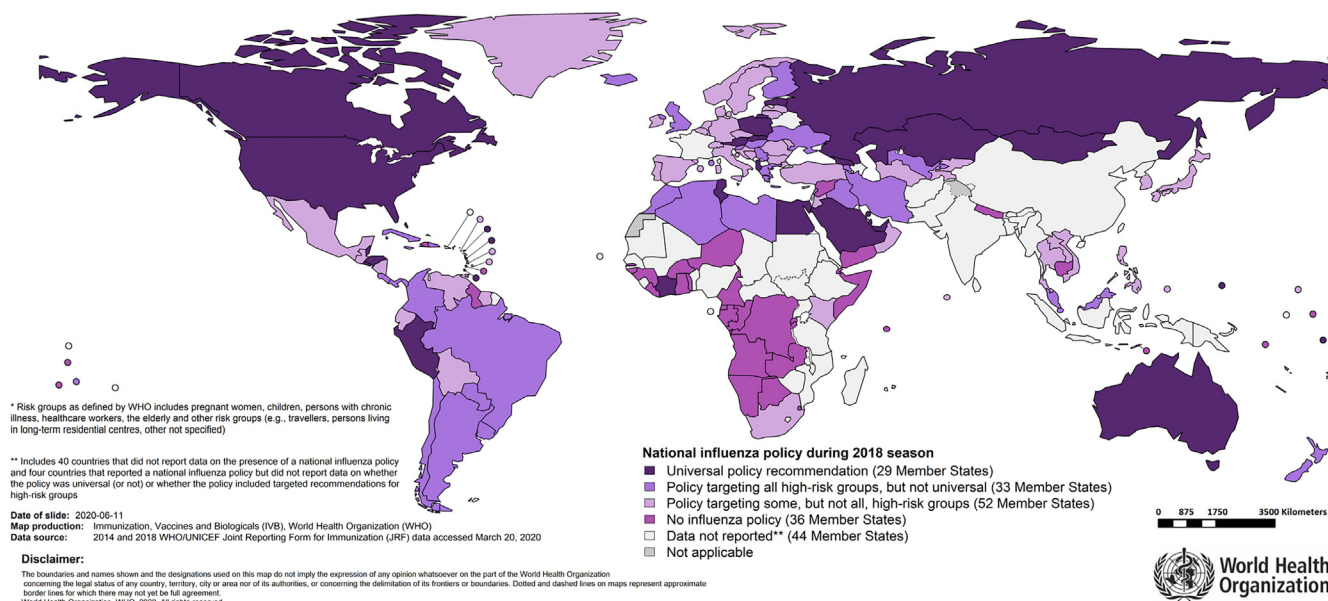


Fig. 3. National influenza vaccination policies in 2018 with a universal vaccine recommendation (all persons > 6 months) or a recommendation of ALL high-risk groups or SOME high-risk groups.

trative data reporting by countries, it is difficult to analyze patterns in influenza vaccination coverage across countries.

4. Discussion

A seasonal influenza vaccination policy is a country's first step towards developing a coordinated and sustainable seasonal influenza vaccination program. Despite unprecedented global commitment to increase equitable access to pandemic and seasonal influenza vaccines through successful partnerships and initiatives [7,34–35], our results reiterate the persistent challenges that low and middle-income countries (LMICs) [36,37] face in adopting and sustaining seasonal influenza vaccination programs. High and upper-middle income countries accounted for 85% of the 103 countries which maintained policies from 2014 through 2018; whereas, low and low-middle income countries, representing 40% of the world's population, according to the United Nations Population prospectus [38], accounted for 85% of the 61 countries without an influenza vaccination policy in either 2014 or 2018.

From 2006 to 2016, the *Global Action Plan for Influenza* [7] (GAP) was an instrumental part of expanding influenza production capacity in several low and middle-income countries (LMICs). However, country sustainability surveys administered upon completion of the program [39] captured how competing priorities, infrastructure challenges, and low demand may make sustaining high production of influenza vaccine a challenge. The surveys also highlighted that government motivation to sustain the increased supply may also be weak in the absence of a severe influenza pandemic.

Although the total number of countries with influenza vaccine policies increased only slightly, we found an increase in policies targeting more high-risk groups or recommending universal vaccination for all persons > 6 months of age. This suggests that although few new countries are adopting policies, countries are expanding policies to be more inclusive and include more high-risk groups. This fulfills one of the GIS objectives to prioritize and vaccinate all high-risk groups [10], especially health workers. As witnessed in the ongoing COVID-19 pandemic, health workers are absolutely essential to maintaining and implementing health services during any outbreak or pandemic. They are also influential

to vaccine acceptance among high-risk groups [40,41]. New research finds that patients are more likely to accept a vaccine if their vaccination is recommended by a health worker, and health workers are more likely to recommend [42] influenza vaccines if vaccinated themselves. This illustrates the dual role health workers have to maintain the health system and to support vaccine promotion and implementation.

Existing seasonal influenza vaccine presentations and formulations, which were developed for temperate regions of the Northern and Southern Hemispheres, will most likely not provide plausible and justifiable long-term solutions for LMICs. A previous review of influenza-related JRF data highlights that research and development strategies to identify new, suitable vaccine technologies for LMICs must preemptively consider cost and programmatic suitability, vaccine implementation and logistics, and the need for better estimates of vaccine impact on public health outcomes [14,27,28].

In 2017, the WHO highlighted the need to improve influenza vaccines in the *WHO Preferred Product Characteristics for Next – Generation Influenza Vaccines* [43] and the WHO GIS of 2019–2030 stresses the need to develop new influenza vaccine technologies which improve the suitability of influenza vaccines for all countries [10]. Current formulations and approaches to yearly influenza vaccine selection, development, and timing do not consistently address the needs of non-temperate, tropical or subtropical regions, where seasonality and circulating viruses may vary from those influenza vaccines released each year [44–46]. This reduces the reliability and efficacy of yearly vaccines in these countries, creating an additional barrier to influenza vaccine policy adoption, aside from competing priorities faced in these countries [47–48]. Vaccine development for next-generation seasonal influenza vaccines must be directed to overcome these and other challenges, if the expectation is to increase global access and adoption of influenza vaccination in all contexts.

Decision-making around influenza policy adoption or influenza vaccination implementation presents another challenge to expanding influenza vaccination policies. Often times, a country's needs and objectives differ, the evidence base is not complete, and the social-benefit and cost-effectiveness data are limited [37,49–50]. Decision-making processes and protocols differ across countries,

Table 4
Influenza vaccine-related data reported by WHO Member States in 2014 and 2018.

	Total countries	Reported influenza vaccine characteristics, 2018	Vaccine type										Reported influenza vaccine formulation used by Hemisphere In 2014							In 2018								
			Vaccine licensed by NRA		No		Data not available		TIV		QIV		High-Dose		Adj.		LAIV		Data not available		NH		SH		Both		Data not available	
			Yes	No	Data not available	TIV	QIV	High-Dose	Adj.	LAIV	Data not available	NH	SH	Both	Data not available	NH	SH	Both	Data not available									
All countries*	194	98	59	37	96	42	3	15	17	75	62	19	11	102	78	21	9	86										
WHO Region																												
Africa	47 (24)	12(12)	27(46)	8 (22)	3 (3)	0	0	0	0	38 (51)	1(2)	2 (11)	0	44(43)	2 (3)	0	0	45 (52)										
Americas	35 (18)	24(24)	11(19)	0	28(29)	6 (14)	2 (67)	4 (27)	7 (41)	1 (1)	14(23)	10(53)	3(27)	8 (8)	16(21)	14(67)	1(11)	4 (5)										
Eastern Mediterranean	21 (11)	10(10)	5 (8)	6 (16)	12(13)	2 (5)	0	0	0	8 (11)	7(11)	0	3(27)	11(11)	7 (9)	0	5 (56)	9 (10)										
European	53 (27)	35(36)	3 (5)	15 (41)	42(44)	23(55)	0	9 (60)	9 (53)	7 (9)	35(56)	0	1 (9)	17(17)	47(60)	0	0	6 (7)										
South-East Asia	11 (6)	4 (4)	6 (10)	1 (3)	3 (3)	1 (2)	0	0	0	8 (11)	0	2 (11)	0	9 (9)	0	2 (9)	1(11)	8 (9)										
Western Pacific	27 (14)	13(13)	7 (12)	7 (19)	8 (8)	10(24)	1 (33)	2 (13)	1 (6)	13 (17)	5(8)	5 (26)	4(36)	13(13)	6 (8)	5 (24)	2(22)	14 (16)										
World Bank Income Group**																												
High-Income	57 (30)	42(43)	7 (12)	8 (22)	44(46)	28(68)	3(100)	11(73)	11(64)	5 (7)	30(48)	5 (26)	6(55)	16 (16)	41 (53)	7 (33)	4(44)	5(6)										
Upper-Middle-Income	58 (30)	34(35)	11(19)	13 (36)	37(39)	11(27)	0	4 (27)	3 (18)	14 (19)	25(40)	10(53)	3(27)	20 (20)	25 (32)	9 (43)	5(56)	19(22)										
Lower-Middle-Income	46 (24)	18(19)	18(31)	10 (28)	15(16)	2 (5)	0	0	3 (18)	29 (39)	7 (11)	3 (16)	2(18)	34 (33)	10 (13)	5 (24)	0	31(36)										
Low-Income	31 (16)	3 (3)	23(39)	5 (14)	0	0	0	0	0	26 (35)	0	0	0	31 (30)	1 (1)	0	0	30(35)										
Eligible for Gavi^^																												
Phase 2 Support																												
No	121 (62)	77(79)	21(36)	23 (62)	80(83)	39(93)	3(100)	15(100)	13(76)	24 (32)	57(92)	18(95)	8(73)	38 (37)	68 (87)	15(71)	9(100)	29(34)										
Yes	73 (38)	21(21)	38(64)	14 (38)	16(17)	3 (7)	0	0	4 (24)	51 (68)	5 (8)	1 (5)	3(27)	64 (63)	10 (13)	6 (29)	0	57 (66)										

TIV, trivalent influenza vaccine; QIV, quadrivalent influenza vaccine; LAIV, live attenuated influenza vaccine Data are reported as number of countries (percent of total number of countries for the respective column).

*Two countries (Cook Islands, Niue) are not classified by the World Bank into one of the income groups. Income classifications reflect those as of July 2019.

**Reflects the World Bank income classification for each country as of July 2019. Two countries, Cook Islands and Niue, are not classified.

^^This includes the 73 countries eligible for Phase 2 Gavi support (please see ANNEX for a list)

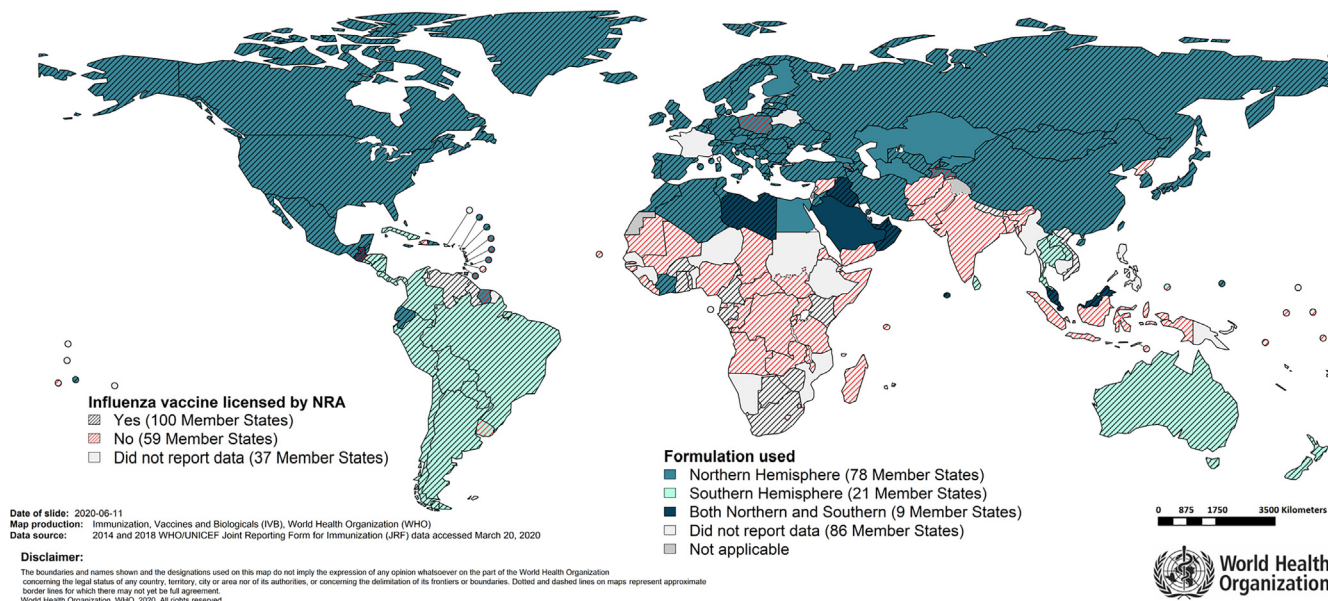


Fig. 4. Influenza vaccine formulations and national regulatory authorities (NRA) in WHO Member States in 2018.

as do data availability to inform decision making. Next generation vaccines, should facilitate decision-making for policy makers by providing value propositions that effectively communicate the utility and cost-benefit of influenza vaccines in their context. Vaccines should also solve supply-related logistical challenges, address variations in seasonality, and be affordable and accessible for all [37].

Pharmaceutical companies may not be tempted by current market conditions in LMICs to drive innovation for the next generation of influenza vaccines. An investment from Gavi, who is currently evaluating influenza vaccination in health workers as a part of a new learning agenda [51–52], could move things forward. However, it may also be time to explore other funding opportunities, such as CEPI (<https://cepi.net>), which has traditionally focused on new and emerging infectious diseases. Considering the plausible interconnectedness of seasonal and pandemic vaccine development and implementation, an argument could easily be made that seasonal influenza vaccine innovation is a stepping-stone to pandemic influenza vaccine innovation.

The unwavering force of the COVID-19 pandemic is an unfortunate illustration of the impact a pandemic can have on the health system, the economy, and the population as a whole. Yearly seasonal influenza vaccination programs can provide a platform to reduce the impact of influenza on the health workforce, reduce morbidity and mortality in the population, and monitor, respond, and potentially vaccinate adults and children against new and emerging, such as COVID-19.

Limitations to our study include the reliance on data reported to WHO and UNICEF through the WHO/UNICEF JRF, which had response rates lower than 93% in both years. The data may have been improved by direct contact with countries. Therefore, this data may not be representative of all policy-related information for the 194 WHO Member States, especially those countries which did not provide data in 2014 or 2018, or in cases where different data points provided by a country were contradictory. The strength of the data collected through JRF is also dependent on the knowledge of the country immunization program managers who input the data. Since the JRF has traditionally gathered information on childhood vaccines for the Expanded Programme on Immunization, it is possible that immunization managers may not be as

familiar with influenza vaccinations as the other immunizations. Our study was largely descriptive and did not analyze the cost-benefit of an influenza vaccination or evaluate all respiratory diseases of interest to those countries who did not have an influenza policy. Our study may be biased to suggest a relationship between the presence of an influenza policy and our chosen variables and does not include an extensive number of variables for comparison. We excluded the administrative coverage and vaccine dose-related data from the JRF due to concerns over both data completeness and the absence of periodic, independent assessments of the administrative data in many countries. Our data analysis of countries targeting “all risk groups” included the category of ‘other’ as listed in the JRF which may not match previous analyses where “all risk groups” excluded the category of ‘other’.

Influenza policies are the foundation of an influenza vaccination program [53]. At present, six of the most populous nations, as projected by the United Nations Population Division’s population prospectus [54], are without an influenza policy and 95% of the influenza vaccine supply is distributed to 5% of the world’s population [55]. Our study provides an overview of national seasonal influenza vaccination policies in the 194 WHO Member States and highlights the need for better understanding of the barriers to establishing influenza vaccination policies worldwide. Future studies could evaluate additional determinants of decision making and influenza policy adoption, such as variations in decision-making protocols or processes, the results and utilization of economic evaluations, and the role of seasonality. International efforts to expand global access to influenza vaccinations should consider the challenges for LMICs with respect to vaccine efficacy, seasonality, and cost-benefit in the face of competing priorities, demand, and logistics. Data recording and reporting practices need to be improved to ensure accurate reporting of influenza-related data in the JRF.

5. Disclosure

The authors have no conflicts of interest to declare. P Lambach, C Steulet, L Dumolard, M Friede and A Moen work for the World Health Organization (WHO). The authors alone are responsible for the views expressed in this publication and they do not neces-

sarily represent the decisions, policy or views of the WHO. All authors reviewed the final manuscript submitted for peer review.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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