Data recording and reporting to inform action: how adult vaccines coverage rates and vaccines effectiveness are monitored and what are the current findings

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6 – 7 December 2023 Hotel Baglioni, Florence, Italy

Outline

This session consists of the following elements

1. Background & Definitions
2. Vaccination coverage monitoring methods
3. Estimating vaccine effectiveness
4. Current findings

Vaccination schedule

Vaccino	0gg-30gg	3° mese	4° mese	5° mese	6° mese	7° mese	11° mese	13° mese 15° mese	⇨	6° anno	12°-18° anno	19-49 anni	50-64 anni	> 64 anni
DTPa**		DTPa		DTPa			DTPa			DTPa***	dTpaIPV	1 dose dTpa**** ogni 10 anni		
IPV		IPV		IPV			IPV			IPV				
Epatite B	EpB-EpB*	Ep B		Ep B			Ep B					3 Dosi: *Pre Esposizione* (0, 1, 6 mesi) 4 Dosi: *Post Esposizione* (0, 2, 6 sett. + booster a 1 anno) o *Pre Esposizione imminente* (0, 1, 2, 12)		
Hib		Hib		Hib			Hib							
Pneumococco		PCV		PCV			PCV	PCV^^		PCV/PPSV (vedi nota)				PCV+PPSV
MPRV								MPRV		MPRV				
MPR								oppure MPR + V		oppure MPR + V	MPR	MPR + V^	2 dosi MPR***** + V^ (0-4/8 settimane)	
Varicella														
Meningococco C/ACWY								Men C			MenACWY coniugato			
Meningococco B*^		Men B	Men B		Men B			Men B						
HPV											HPV°: 2-3 dosi (in funzione di età e vaccino)			
Influenza						Influenza°°					Influenza°°			1 dose all'anno
Herpes Zoster														1 dose#
Rotavirus		Rotavirus##												
Epatite A								EpA###			EpA###		2 dosi (0-6-12 mesi)	

during pregnancy

during pregnancy

Vaccination coverage monitoring methods

- National Vaccine Registry (AVN/AVC)
- Flu vaccination registration system
- Surveys
  - ISTAT Multipurpose survey on households
  - «Passi» Surveillance

The **National Vaccine Registry (AVN) was established in 2017** aiming to ensure the monitoring of vaccination programs on the national territory

The **National Vaccine Registry** collects data from the Regional Vaccine Registries

MINISTERO DELLA SALUTE

DECRETO 17 settembre 2018.

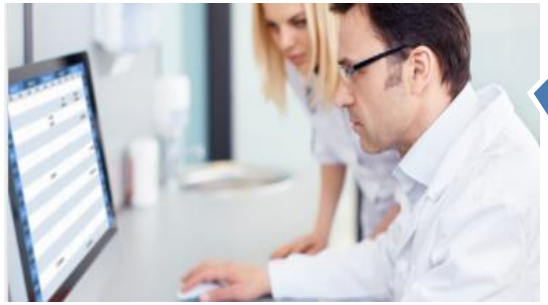
Istituzione dell'Anagrafe nazionale vaccini.

IL MINISTRO DELLA SALUTE

Visto l'art. 32 della Costituzione italiana;

Visto il decreto-legge 7 giugno 2017, n. 73, convertito, con modificazioni, dall'art. 1 della legge 31 luglio 2017, n. 119, recante: «Disposizioni urgenti in materia di prevenzione vaccinale, di malattie infettive e di controversie relative alla somministrazione di farmaci» e, in particolare, l'art. 4-*bis*, che prevede che con decreto del Ministro

Ministero della Salute



NATIONAL VACCINE REGISTRY (AVN)

Homogenous indicators across Regions/AP

Homogenous instruments for reading and analysis

AVN – data collected

Anagrafe Nazionale Vaccinazioni

Regions/AP transfer data to the AVN:

Registry information	Personal information contained in a subject's vaccination status card.
Vaccinations	Details on reported vaccination events: dates of administration, used antigens, number of administered doses, vaccine names.
Lack of vaccination	Details on vaccine events scheduled but not performed due to health reasons or because the patient could not be reached.

ON A QUARTERLY BASIS

Total patients in AVN: 56,092,384 (last update June 30, 2023) of which:

44,226,748 born before 2000 (**96% of ISTAT residents** for these age groups)
11,865,636 born after 2000 (**94% of ISTAT residents** for these age groups)

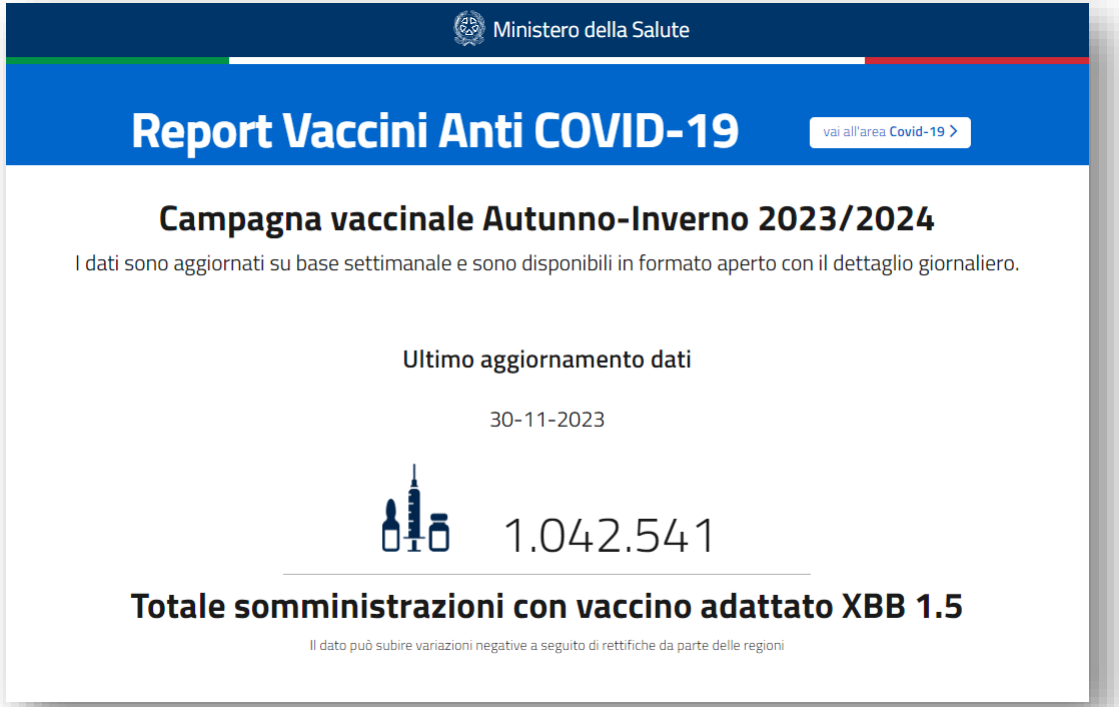
Ministero della Salute

AVC

Anagrafe Nazionale Vaccinazioni anti-Covid 19

The **National Vaccine Registry for COVID-19** (**AVC**) receives daily data on COVID-19 vaccinations from the Regions and Autonomous Provinces since **January 2021**

ON A DAILY BASIS

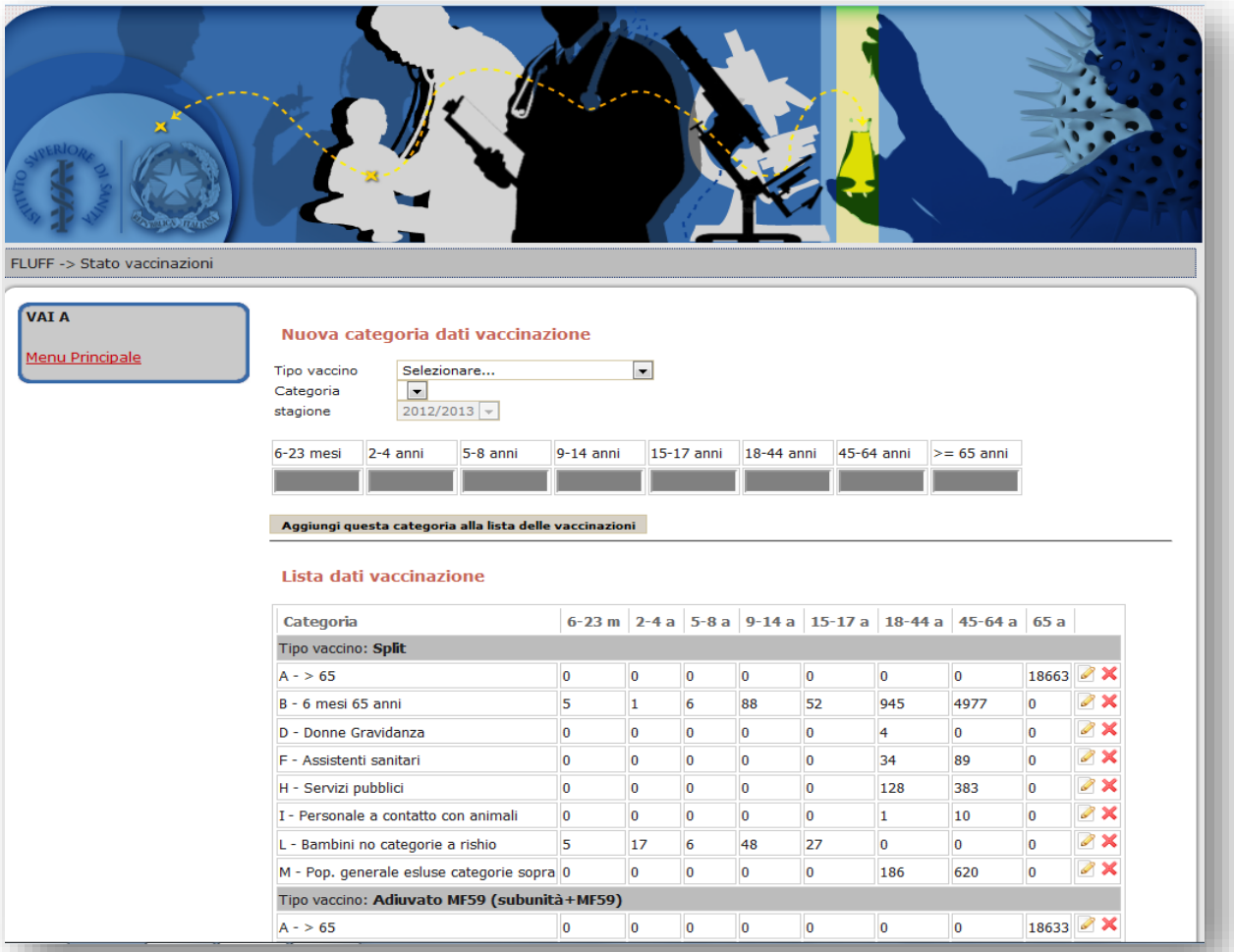


https://www.governo.it/it/cscovid19/report-vaccini/

Influenza vaccination coverage data collection website

Doses administered by:

- Vaccine type/brand
- Risk group
- Age group

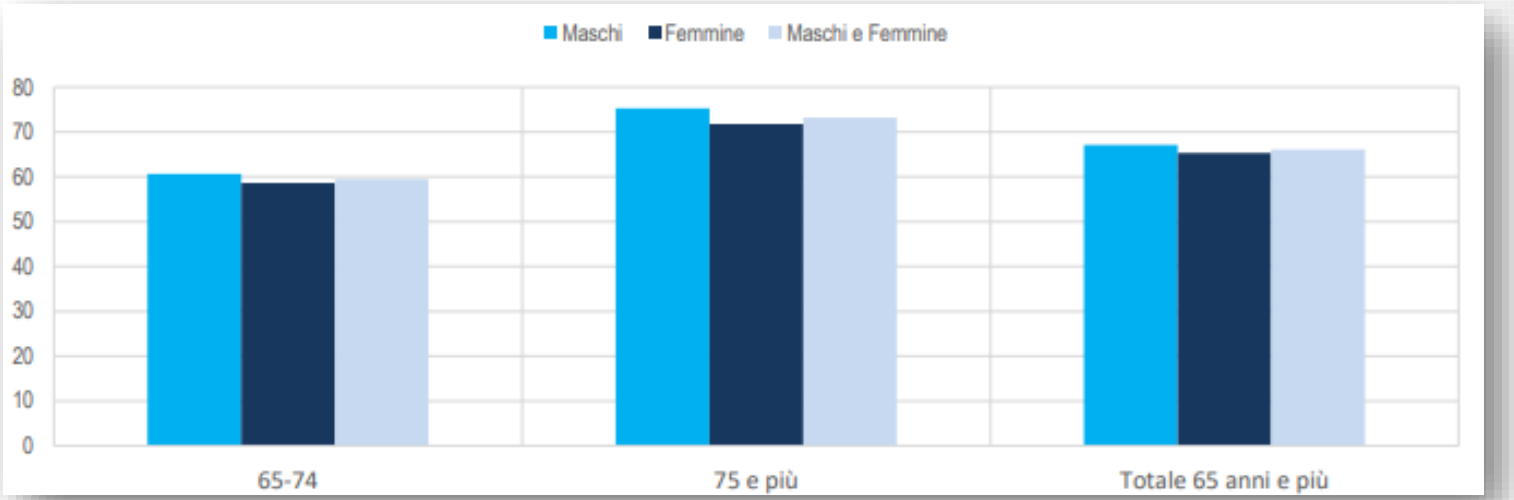


Categoria	6-23 m	2-4 a	5-8 a	9-14 a	15-17 a	18-44 a	45-64 a	65 a
Tipo vaccino: **Split**								
A - > 65	0	0	0	0	0	0	0	18663
B - 6 mesi 65 anni	5	1	6	88	52	945	4977	0
D - Donne Gravidanza	0	0	0	0	0	4	0	0
F - Assistenti sanitari	0	0	0	0	0	34	89	0
H - Servizi pubblici	0	0	0	0	0	128	383	0
I - Personale a contatto con animali	0	0	0	0	0	1	10	0
L - Bambini no categorie a rischio	5	17	6	48	27	0	0	0
M - Pop. generale esluse categorie sopra	0	0	0	0	0	186	620	0
Tipo vaccino: **Adiuvato MF59 (subunità+MF59)**								
A - > 65	0	0	0	0	0	0	0	18633

Influenza vaccination coverage

Ministry of Health – Istituto Superiore di Sanità; data from Regions/AutonomousProvinces - 20 July 2023

ISTAT Multipurpose survey on households



People aged 65 and over who have reported receiving a flu vaccination in the past 12 months, categorized by gender and age group. Year 2021, per 100 persons aged 65 and over.

https://www.epicentro.iss.it/passi/dati/VaccinazioneAntinfluenzale

«Passi» Surveillance

Indicatori - PASSI 2021-2022

	Copertura vaccinale nei 18-64enni	Copertura vaccinale nei 18-64enni con almeno 1 patologia cronica	Copertura vaccinale nei 18-64enni senza patologie croniche
Abruzzo	11.4	30.4	7.4
Basilicata	10.3	23.8	7.4
Calabria	15.2	45.0	10.3
Campania	11.5	28.1	8.3
Emilia Romagna	18.9	34.2	15.1
Friuli Venezia Giulia	15.4	26.6	12.3
Lazio	17.3	32.0	14.0
Liguria	15.9	24.2	14.0
Lombardia			
Marche	11.1	20.0	9.4
Molise	17.7	49.4	12.9
Piemonte	11.3	18.8	9.6
Provincia di Bolzano	6.2	16.7	4.1
Provincia di Trento	14.8	38.1	9.8
Puglia	13.9	34.3	12.1
Sardegna	14.6	20.0	12.7
Sicilia	12.7	25.4	10.2
Toscana	15.9	31.1	13.6
Umbria	9.6	27.9	6.4
Valle d'Aosta	2.6	8.3	1.5
Veneto	11.2	28.7	6.8
Italia	**13.9**	**28.7**	**10.9**

peggiore del valore nazionale simile al valore nazionale migliore del valore nazionale

Rubella

Influenza

lower than the national average

similar to the national average

higher than the national average

Indicatori - PASSI 2017-2020

	Donne in età fertile vaccinate per la rosolia	Donne in età fertile suscettibili alla rosolia	Donne in età fertile non consapevoli dello stato immunitario	Donne in età fertile suscettibili alla rosolia o non consapevoli dello stato immunitario
Abruzzo	43.5	2.2	33.4	35.5
Basilicata	39.7	2.5	49.0	51.5
Calabria	36.9	1.8	47.5	49.3
Campania	33.9	3.1	43.3	46.4
Emilia Romagna	55.6	1.5	32.1	33.6
Friuli Venezia Giulia	43.8	2.3	37.9	40.2
Lazio	40.4	1.6	38.9	40.4
Liguria	51.5	1.2	30.7	31.9
Lombardia				
Marche	50.5	0.5	33.4	33.9
Molise	40.4	2.2	49.5	51.8
Piemonte	42.5	2.2	38.1	40.3
Provincia di Bolzano	55.4	1.1	28.3	29.5
Provincia di Trento	53.3	1.0	36.7	37.7
Puglia	31.8	1.5	46.6	48.1
Sardegna	41.9	2.7	30.5	33.2
Sicilia	45.0	2.0	35.4	37.4
Toscana	52.0	0.9	34.6	35.6
Umbria	45.7	2.7	34.1	36.8
Valle d'Aosta	31.5	6.1	39.9	46.1
Veneto	65.0	0.9	27.9	28.8
Italia	**44.9**	**1.8**	**37.3**	**39.1**

peggiore del valore nazionale simile al valore nazionale migliore del valore nazionale

Estimation of vaccine effectiveness

- Retrospective cohort study

  -> 1-IRR

- Case-control study (test negative controls as ideal)

  -> 1-OR

- Screening method (case / population)

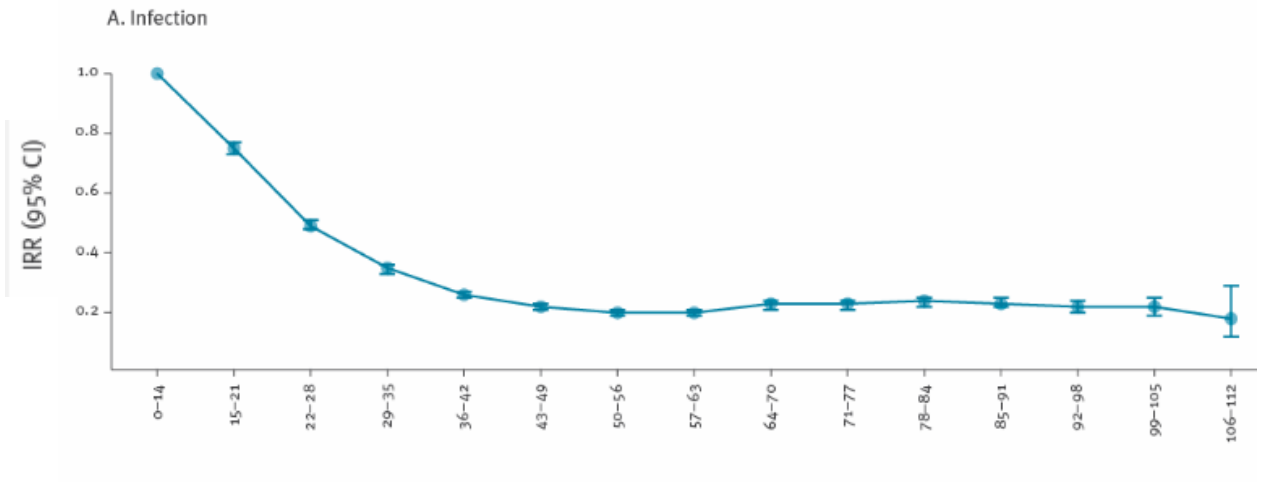
  -> VE = PPV-PCV / PPV (1-PCV)

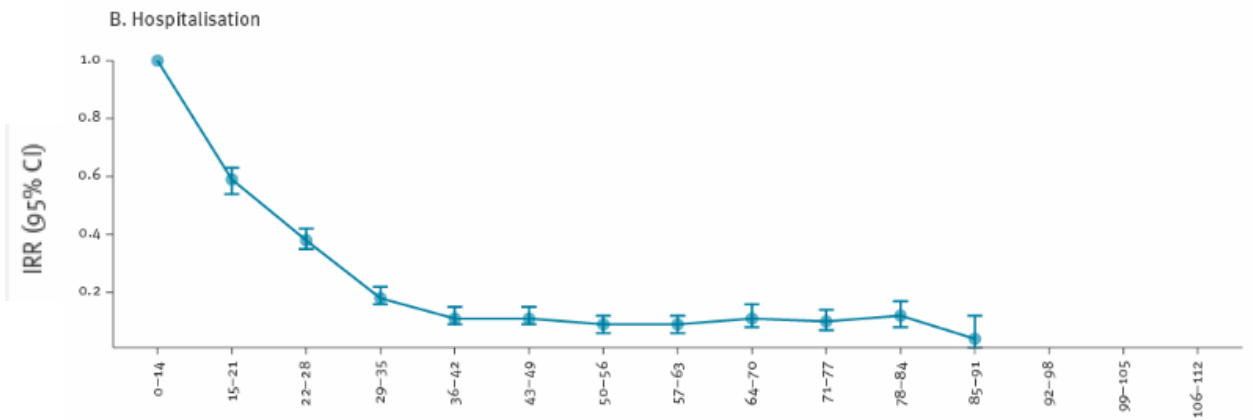
Issue of bias: unbalance between vaccinated and unvaccinated; need for adjustment, stratification, matching

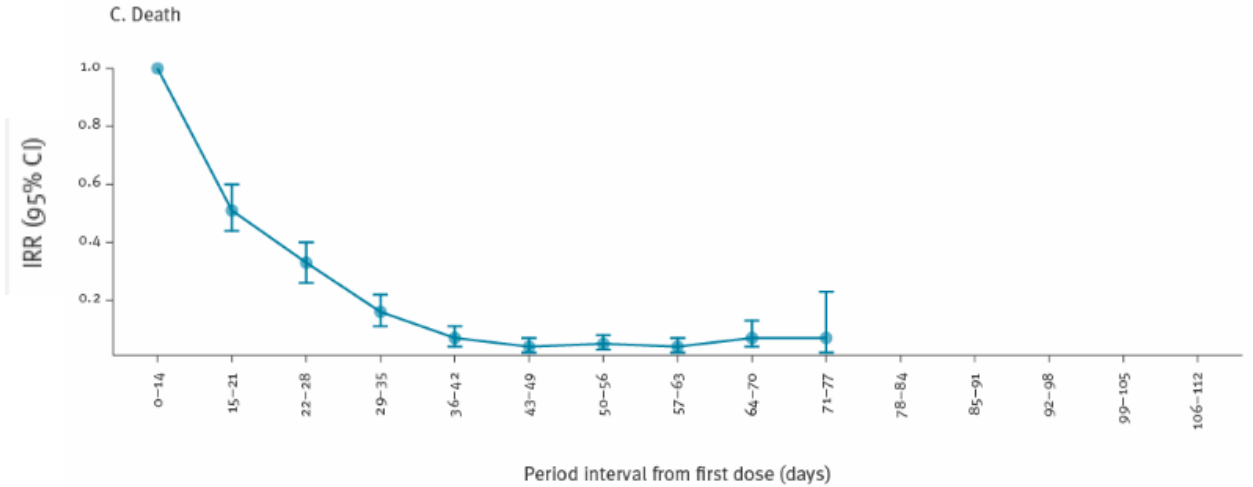
How to monitor the Italian National campaign vaccine effectiveness for COVID-19

1. Vaccination doses administered available in the National Covid-19 Vaccine Registry (AVN/AVC).
2. SARS-CoV-2 infections, hospitalizations, and Covid-19-related deaths reported by the National Integrated Surveillance system.
3. Observational retrospective population-based cohort studies on the national population after record linkage (fiscal code) of the two previously described databases.
4. Linkage possible due to a decree law
5. To estimate infection risk reduction and averted cases (infections, hospitalizations, deaths)

Estimated incidence rate ratios (IRR) of SARS-CoV-2 infections and waning in Italy; January – April 2021







- **Vaccine effectiveness: 1-IRR**
- **All vaccines admnistered (70% mRNA vaccines)**
- **Effectiveness rapidly increases after first dose administration and become stable after 40 days (no evidence of waning)**
- **Higher effectiveness for severe disease and for death compared to infection**

Mateo-Urdiales et al. Risk of SARS-CoV-2 infection and subsequent hospital admission and death at different time intervals since first dose of COVID-19 vaccine administration, Italy, 27 December 2020 to mid-April 2021. Euro Surveill. 2021;26(25):pii=2100507. https://doi.org/10.2807/1560-7917.ES.2021.26.25.2100507

Vaccine effectiveness of non-mRNA vaccines

Original Investigation | Public Health

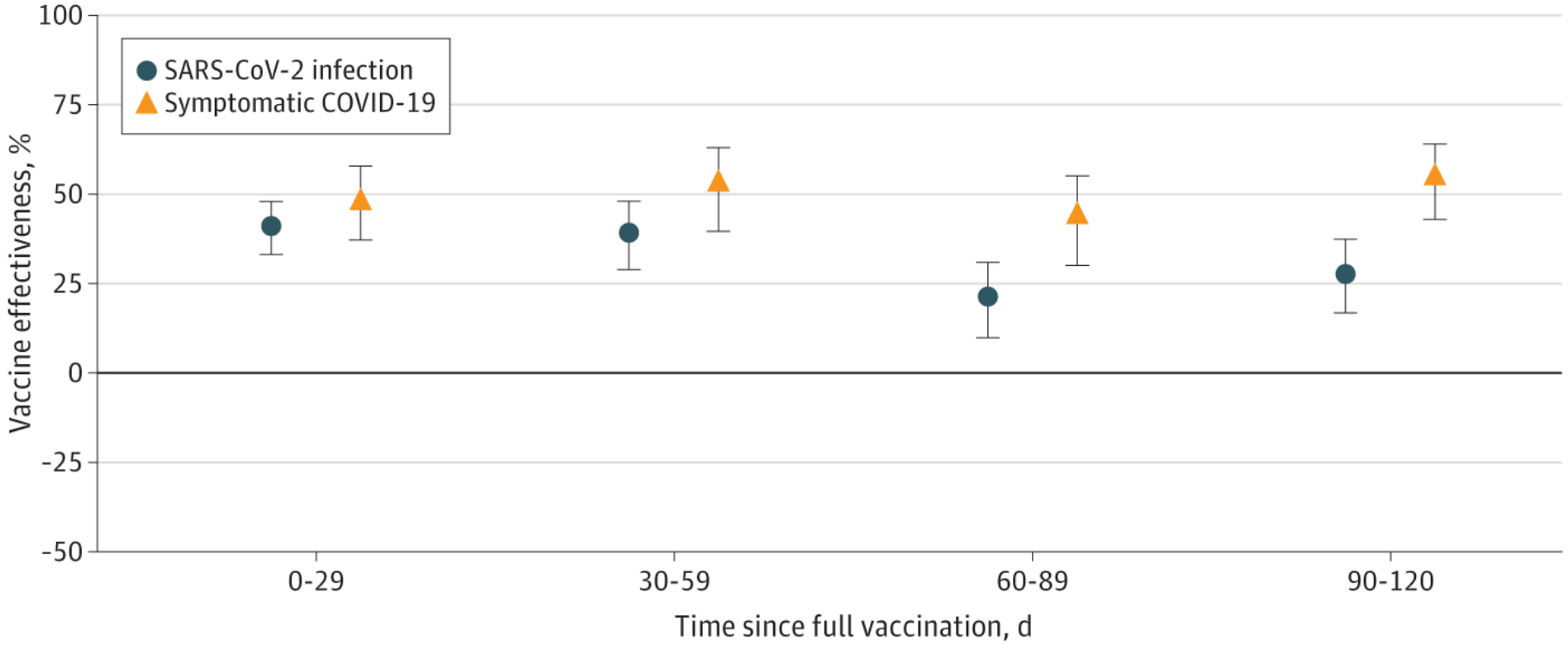
October 4, 2023

Estimated Effectiveness of a Primary Cycle of Protein Recombinant Vaccine NVX-CoV2373 Against COVID-19

Alberto Mateo-Urdiales, PhD[1]; Chiara Sacco, PhD[1,2]; Daniele Petrone, DSTAT[1]; et al

» Author Affiliations | Article Information

JAMA Netw Open. 2023;6(10):e2336854. doi:10.1001/jamanetworkopen.2023.36854



Meningococcal C conjugate vaccine effectiveness before and during an outbreak of invasive meningococcal disease due to Neisseria meningitidis serogroup C/cc11, Tuscany, Italy

Pezzotti P, Miglietta A, Neri A, Fazio C, Vacca P, Voller F, Rezza G, Stefanelli P. Meningococcal C conjugate vaccine effectiveness before and during an outbreak of invasive meningococcal disease due to Neisseria meningitidis serogroup C/cc11, Tuscany, Italy. Vaccine. 2018 Jul 5;36(29):4222-4227. doi: 10.1016/j.vaccine.2018.06.002. Epub 2018 Jun 9. PMID: 29895504.

Table 1
Number and incidence rate (IR) per 100,000 population of serogroup C invasive meningococcal diseases cases by year and vaccination status, Tuscany, Italy, 2006–2016.

Year	Vaccinated (n)	Not vaccinated (n)	Total (n)	IR (per 100,000)	Coverage^
2006	0	2	2	0.06	8.7
2007	0	3	3	0.08	13.0
2008	0	5	5	0.14	17.8
2009	0	4	4	0.11	22.5
2010	0	0	0	0.00	35.5
2011	0	1	1	0.03	45.5
2012	0	4	4	0.11	57.6
2013	0	3	3	0.08	65.0
2014	0	2	2	0.05	68.9
2015	3	28	31	0.83	74.1
2016	9	21	30	0.80	83.6

^ Coverage refers to birth cohorts 1994–2015.

- **Vaccine effectiveness: 1-IRR**
- **No vaccine failures occurred in the pre-outbreak period (2006–2014), while 12 (21% of 61) vaccine failures were reported in 2015–2016.**
- **VE was, 100% (95%CI not estimable, p = 0.03) before the outbreak (2006–2014) and 77% (95%CI 36–92, p < 0.01) during the outbreak; VE was 80% (95%CI 54–92, p < 0.01) during the overall period.**

Estimating COVID-19 vaccine effectiveness by age group

TABELLA 6 - STIMA EFFICACIA VACCINALE [IC 95%] PER FASCIA DI ETÀ DAL 03/01/2022

Gruppo	Fascia di età	Vaccinati con ciclo completo entro 90 giorni	Vaccinati con ciclo completo da 91 - 120 giorni	Vaccinati con ciclo completo da oltre 120 giorni	Vaccinati con ciclo completo + dose aggiuntiva/booster
Diagnosi (2022-01-03/2022-09-25)	12-39	32,2 [31,9-32,5]	27,4 [27,1-27,7]	48,8 [48,6-48,9]	41,5 [41,4-41,7]
	40-59	31,8 [31,4-32,1]	25,6 [25,2-26,0]	37,4 [37,2-37,6]	38,5 [38,3-38,6]
	60-79	53,1 [52,6-53,6]	43,6 [42,9-44,3]	39,5 [39,2-39,8]	52,4 [52,2-52,6]
	80+	63,0 [62,1-63,8]	59,3 [58,1-60,5]	71,6 [71,3-72,0]	67,2 [67,0-67,5]
	Totale	**31,4 [31,2-31,6]**	**22,4 [22,1-22,6]**	**44,7 [44,6-44,8]**	**43,9 [43,8-44,0]**
Malattia severa (2022-01-03/2022-09-04)	12-39	45,5 [42,2-48,6]	59,5 [56,8-62,1]	73,3 [72,2-74,4]	75,9 [74,9-76,7]
	40-59	50,2 [46,7-53,6]	53,8 [50,0-57,4]	60,5 [58,9-62,1]	69,8 [68,8-70,8]
	60-79	67,4 [65,5-69,3]	67,0 [64,4-69,3]	61,0 [59,9-62,0]	82,5 [82,1-82,9]
	80+	79,5 [78,2-80,8]	77,8 [75,9-79,6]	80,4 [79,9-80,9]	89,0 [88,8-89,2]
	Totale	**62,8 [61,7-63,9]**	**64,5 [63,2-65,8]**	**69,3 [68,8-69,7]**	**82,6 [82,3-82,8]**

Note:
- Per maggiori dettagli vedere Nota metodologica paragrafo 4.6 – 4.7.
- I dati relativi all'efficacia nella fascia di età 5-11 anni sono disponibili nel seguente studio ISS: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01185-0/fulltext
- L'efficacia vaccinale riportata in tabella potrebbe essere sottostimata in quanto considera a rischio tutte le persone tranne quelle che sono state diagnosticate e riportate alla sorveglianza negli ultimi 3 mesi. A causa dell'elevato numero di nuove infezioni, spesso non diagnosticate o autodiagnosticate e quindi non riportate alla sorveglianza, il numero delle persone a rischio considerate per la stima dell'efficacia è verosimilmente sovrastimato, in particolare nelle fasce 12-39 e 40-59. È inoltre verosimile la presenza di una più elevata sottonotifica delle diagnosi nella popolazione non vaccinata e vaccinata da oltre 120 giorni.

Task force COVID-19 del Dipartimento Malattie Infettive e Servizio di Informatica, Istituto Superiore di Sanità. Epidemia COVID-19. National epidemiological update: 28 september 2022

Conclusions (1/2)

1. Accurate recording and reporting of data represent crucial components of public health campaigns.
2. The monitoring of vaccination coverage and effectiveness plays an important role in determining immunisation programmes and strategies.
3. Adult vaccination coverage rates are tracked through various means, including surveillance systems, healthcare records, and immunisation registries.

Conclusions (2/2)

4. Vaccine effectiveness is continuously assessed through clinical trials, observational studies, and post-licensure monitoring.
5. The results indicate different protection levels, with certain vaccines showing considerable effectiveness in preventing severe illness and hospitalization and averted death.
6. Frequent updates on vaccination coverage and effectiveness in adults are a crucial resource for policy making and strategies aimed at improving overall public health outcomes.

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