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Factors associated with vaccination against mpox in people under preexposure prophylaxis against HIV in the Community of Madrid

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ABSTRACT

Introduction: In May 2022, a mpox outbreak was identified in Europe. The majority of those affected are young men with risky sexual relations. In Spain, to control the outbreak, vaccination is recommended, among others, for people on HIV pre-exposure prophylaxis (PrEP). The objective of the study is to determine the factors associated with vaccination against mpox in people included in PrEP in the Community of Madrid.
Methods: Descriptive study. The sources of information used are: the PrEP Registry, Health Card, the Vaccine Registry and the Primary Care Clinical History. The 2011 deprivation index of the Spanish Society of Epidemiology is used as a socioeconomic indicator. Factors related to vaccination against mpox are analysed and a conditional logistic regression model is fitted.
Results: 6690 people were registered for PrEP. The average age was 37.7 years, 98.8% were men and 25.1% were foreigners. 39.9% had received vaccination against mpox, 47.6% had vaccination against hepatitis A, 32.8% vaccination against hepatitis B, 53.3% vaccination against COVID-19 and 24.3% vaccination against a complaint. The variables associated with mpox vaccination were age, country of birth, influenza vaccination, hepatitis A vaccination, COVID-19 vaccination, and deprivation index.
Conclusions: Men who had sex with men (MSM) on PrEP treatment, young adults, born in Spain, with a history of vaccination against influenza, hepatitis A and COVID-19 have a greater probability of vaccination against mpox. The proportion of vaccinated subjects decreases as the deprivation index increases (as socioeconomic level decreases).

Factores asociados a la vacunación frente a mpox en personas en profilaxis preexposición frente al VIH en la Comunidad de Madrid

Palabras clave:
mpox
Brote
Vacunación
Profilaxis preexposición al VIH (PrEP)

RESUMEN

Introducción: En mayo de 2022 se identifica un brote de mpox en Europa. La mayoría de los afectados son hombres jóvenes con relaciones sexuales de riesgo. En España para el control del brote se recomienda la vacunación en personas en profilaxis preexposición al VIH (PrEP). El objetivo del estudio es determinar los factores asociados a la vacunación frente a mpox en las personas incluidas en PrEP en la Comunidad de Madrid.
Métodos: Estudio descriptivo. Las fuentes de información han sido: el Registro PrEP, Tarjeta Sanitaria, el Registro de Vacunas y la Historia Clínica de Atención Primaria. Se utiliza como indicador socioeconómico el índice de privación 2011 de la Sociedad Española de Epidemiología. Se analizan los factores relacionados con la vacunación frente a mpox.

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Resultados: Se registraron 6.690 personas en PrEP. La media de edad fue de 37,7 años, el 98,8% eran hombres y el 25,1% eran extranjeros. Un 39,9% habían recibido vacuna frente a mpox, 47,6% frente a hepatitis A, 32,8% frente a hepatitis B, 53,3% frente a COVID-19 y 24,3% frente a gripe. Las variables asociadas con la vacunación frente a mpox fueron la edad, el país de nacimiento, la vacunación frente a gripe, la vacunación frente a hepatitis A, la vacunación frente a COVID-19 y el índice de privación.
Conclusiones: Los hombres que tenían relaciones sexuales con hombres, adultos jóvenes, nacidos en España, con vacunación frente a gripe, hepatitis A y COVID-19 presentan una mayor probabilidad de vacunación frente a mpox. La proporción de sujetos vacunados disminuye según aumenta el índice de privación.

Introduction

Monkeypox (mpox) is a rare viral zoonotic disease caused by the mpox virus (DNA virus), belonging to the *Orthopoxvirus* genus.

It is a potentially serious disease that causes fever, headache, myalgia, low back pain, swollen lymph nodes, general malaise and skin lesions. According to WHO data, the fatality rate in Africa is from 1% to 10%.[1]

On 14 May 2022, the UK Health Security Agency (UKHSA) reported the identification of two cases of mpox with no recent travel history and no contact with any imported case. Following notification of cases by other countries on 23 July 2022, the WHO Director-General declared the outbreak a public health emergency of international concern (PHEIC).[2]

Up to 30 March 2024 worldwide, 95,226 confirmed cases of mpox and 185 deaths had been reported from 117 different countries. Spain is the country with the third highest number of cases, after the USA and Brazil.[3]

By 5 July 2024, 27,529 cases of pox had been reported from 46 countries and territories in the WHO European Region, 27,329 of which were laboratory-confirmed. The majority of cases are men between the ages of 31 and 40. In the 97% of cases in which sexual orientation is known, they define themselves as men who have sex with men (MSM).[4]

In Spain, 8265 confirmed cases were recorded up to 24 September 2024, with the highest number (2819) in the Comunidad de Madrid [Autonomous Region of Madrid (Madrid Region)]. Only in 2024, 419 cases were reported, the majority young men (median age 37). The cases have been generally been mild and the outcome good. Out of the total number of cases, 36.1% were people diagnosed with HIV. The main mechanism of transmission was close contact during sexual relations; with 73.9% being men who had engaged in sex with other men.[5]

A third-generation vaccine is currently available in Spain for active immunisation against smallpox (IMVANEX®,[6] marketed in Europe, and JYNNEOS®,[7,8] marketed in the USA and authorised in Europe). As the mpox virus is closely related to the virus that causes smallpox, this vaccine is also recommended against mpox.

In view of the progressive increase in the number of cases, on 12 July Spain's Public Health Commission recommended pre-exposure vaccination to control the outbreak.[9] This recommendation included people with high-risk sexual practices who met the criteria for pre-exposure prophylaxis (PrEP) for HIV or who were being monitored for HIV infection.

The effectiveness of the vaccine during the outbreak in Madrid Region in PrEP was 86.4% (95% CI: 62.2–95.1%).[10] This intervention has contributed to the control of the outbreak, with a significant reduction in the number of cases detected since it was implemented.[11]

The aim of the study was to determine the mpox vaccination coverage and the factors associated with vaccination in the group of people receiving PrEP for HIV in Madrid Region.

Methods

Study design: descriptive observational study.

Study population: the study population was comprised of individuals who were on the HIV PrEP registry from 12 July 2022 (the date of inclusion of this group in the mpox vaccination recommendations for outbreak control) to 31 December 2023.

Data collection and information sources: the following sources of information were used to carry out the study:

- Madrid Region PrEP registry: HIV PrEP consists of using an antiretroviral drug to prevent HIV infection. It is indicated in subpopulations with a higher risk of acquiring HIV and effectively prevents infection when the medical prescription is followed correctly.[12,13] The registry is completed in all public hospitals in the Madrid Region and in the Sandoval Health Centre by specialist doctors with experience in the management of patients with HIV, antiretroviral drugs and sexually transmitted infections, as it is linked to a protocol for prescribing, dispensing and monitoring PrEP. From this registry, we obtained the people to be included in the study, in addition to information related to the PrEP indication criteria.[14] Vaccination against hepatitis A and hepatitis B is recommended for people on PrEP.
- Health card database (CIBELES): population information system where identification data, location, recognition of the right to health benefits, and allocation of healthcare resources are recorded for people residing in Madrid Region and displaced people who access the Madrid public health system.[15] Information on the identity of the study subjects and their sociodemographic characteristics was obtained from this system.
- Madrid Region Vaccination Registry (Sistema de Información de Salud Pública y Alimentación; SISPAL [Public Health and Food Information System] vaccines): nominal registry that collects information on vaccines administered in both public and private centres in Madrid Region.[16] Information on the subjects' vaccination status was obtained from this registry.
- Primary care medical records: we used information collected in the primary care medical records regarding whether subjects had chronic diseases. We included the conditions identifiable by International Classification of Primary Care (ICPC) code according to the table in the appendix.

Variables: Código de Identificación Personal Autonómico (CIPA) [Autonomous Region Personal Identification Code], Documento Nacional de Identidad (DNI) [National Identity Document], date of birth, gender, PrEP indication criteria, PrEP start date, country of origin, autonomous region of residence, town of residence, district of residence, census section of residence, vaccination against hepatitis A, vaccination against hepatitis B, vaccination against influenza (in the last two seasons), vaccination against mpox, vaccination against COVID-19 (in the last two seasons), chronic disease and census section-based deprivation index.

The 2011 deprivation index of the Sociedad Española de Epidemiología [Spanish Society of Epidemiology] (IP2011) is obtained by combining six indicators: percentage of population manual workers; percentage of population temporary workers; percentage of population unemployed; percentage of population with insufficient education; percentage of young population with insufficient education; and percentage of main residences without internet access. The data was collected from the Population and Housing Census conducted by Spain's Instituto Nacional de Estadística [National Statistics Institute] in 2011.[17] The Sociedad Española de Epidemiología IP2011 was created by census section, which is the maximum geographic breakdown allowed by the Census data. The IP2011 can be used as a continuous numerical variable or ordinal variable if we categorise it (in this case, in quintiles), with the first quintile being the one with the lowest level of socioeconomic deprivation (highest socioeconomic level) and the fifth being the one with the highest level of deprivation (lowest socioeconomic level).

Data analysis: we carried out a descriptive analysis of the characteristics of all subjects included in the study and those vaccinated against mpox. Chronic diseases were grouped into a single variable. The PrEP indication criterion variable was grouped into two categories: MSM and the rest. Age was grouped into three categories.

Factors related to vaccination were analysed using univariate analysis. The Chi^2 statistic was used with a significance of 95%. For multivariate analysis, a conditional logistic regression model was fitted. For the statistical analysis, we used the SPSS® v.26 program.

Ethical considerations: approval was obtained from the Independent Ethics Committee for research with medicines of Hospital Universitario de La Princesa. According to Spanish Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights,[18] as this is a Public Health study carried out within the scope of its powers, it would not be necessary to request informed consent from the subjects. The information systems used guarantee a level of security appropriate to the risk, in accordance with EU Regulation 2016/679.[19]

Results

There were 6690 subjects registered on PrEP in Madrid Region from 12 July 2022 to 31 December 2023. The subjects' characteristics are shown in Table 1. The main group with indication for PrEP was MSM (97.2%).

The subjects' ages ranged from 17 to 76, with a mean age of 37.7 years (median 36.0 years).

Of the 6690 subjects on PrEP, 2666 had received at least one dose of mpox vaccine (39.9%) and 1630 (24.4%) had received two doses; 3.1% of vaccinated subjects had received the mpox vaccine as post-exposure prophylaxis.

Table 2 shows the percentage of mpox vaccination according to the main variables of interest.

A statistically significant association was found between gender and mpox vaccination status, with a higher proportion of vaccinated men than women (40.3% vs 18.1%) (p = 0.000).

The average age of subjects vaccinated against mpox is 37.6. The highest rate of vaccinated people was in the 30–49 age group (46.8%), showing differences with the rest of the groups (p = 0.000).

We found an association between the PrEP indication criteria and mpox vaccination, with a higher proportion of vaccinated MSM (40.6%), followed by transsexual subjects (17.6%) (p = 0.000).

The proportion of subjects born in Spain vaccinated against mpox was higher than in foreigners (46.1% vs 31.1%; p = 0.000).

We found no differences between the presence of chronic diseases and mpox vaccination (p = 0.240).

Table 1
Characteristics of the study subjects.

	Frequency	Percentage
Type of indication for HIV PrEP		
MSM	6503	97.2
Transsexuals	85	1.3
Sex workers	34	0.5
Cisgender women and men	52	0.8
Intravenous drug use	16	0.2
Gender		
Male	6582	98.8
Female	83	1.2
Age groups, years		
Under 30	1050	16.7
30–49	4589	72.8
Over 49	664	10.5
Born in Spain	4719	74.9
Have some chronic disease	1699	25.4
Vaccinated against mpox	2666	39.9
Vaccinated against influenza[a]	1.624	24.3
Vaccinated against hepatitis A	3186	47.6
Vaccinated against hepatitis B	2193	32.8
Vaccinated against COVID-19[b]	3568	53.3
IP2011		
Quintile 1 (highest socioeconomic level)	1218	20.1
Quintile 2	1207	19.9
Quintile 3	1210	20.0
Quintile 4	1210	20.0
Quintile 5 (lowest socioeconomic level)	1209	20.0

[a] Flu vaccination in the last two seasons was considered.
[b] Vaccination against COVID-19 in the last two seasons was considered.

Table 2
Distribution of subjects by mpox vaccination status according to the different variables.

	Vaccinated n = 2666	Unvaccinated n = 3999	p
Type of indication for HIV PrEP			<0.001
MSM	2639	3864	
Transsexuals	15	70	
Sex workers	4	30	
Cisgender women and men	4	48	
Intravenous drug use	4	12	
Gender			<0.001
Male	2651	3931	
Female	15	68	
Age groups, years			<0.001
Under 30	335	715	
30–49	2148	2441	
Over 49	183	481	
Chronic disease	698	1001	0.240
Born in Spain	2174	2545	<0.001
Vaccinated against influenza[a]	838	786	<0.001
Vaccinated against hepatitis A	1581	1605	<0.001
Vaccinated against hepatitis B	970	1223	<0.001
Vaccinated against COVID-19[b]	1709	1859	<0.001
IP2011			<0.001
Quintile 1 (highest socioeconomic level)	575	643	
Quintile 2	544	663	
Quintile 3	519	691	
Quintile 4	515	695	
Quintile 5 (lowest socioeconomic level)	418	791	

[a] Flu vaccination in the last two seasons was considered.
[b] Vaccination against COVID-19 in the last two seasons was considered.

An association was found between mpox vaccination and vaccination against influenza (p = 0.000), hepatitis A (p = 0.000), hepatitis B (p = 0.000) and COVID-19 (p = 0.000).

Table 3 shows the factors related to mpox vaccination in the univariate and multivariate analysis. The variables that showed sig-

Table 3
Results of univariate and multivariate analysis of factors related to mpox vaccination.

	Univariate analysis		Multivariate analysis	
	OR (95% CI)	p	OR (95% CI)	p
Type of indication for HIV PrEP				
MSM/rest	4.05 (2.68–6.10)	<0.001	2.71 (1.74–4.21)	<0.001
Gender				
Male/female	3.06 (1.74–5.36)	<0.001	–	–
Age groups, years				
Under 30	1		1	
30–49	1.88 (1.63–2.17)	<0.001	1.64 (1.41–1.91)	<0.001
Over 49	0.81 (0.66–1.01)	0.057	0.54 (0.43–0.68)	<0.001
Country of birth				
Spain/other country	1.90 (1.68–2.14)	<0.001	1.57 (1.38–1.79)	<0.001
Influenza vaccination				
Yes/no	1.89 (1.69–2.11)	<0.001	1.53 (1.35–1.74)	<0.001
Hepatitis A vaccination				
Yes/no	2.20 (1.99–2.43)	<0.001	1.62 (1.45–1.81)	<0.001
Hepatitis B vaccination				
Yes/no	1.31 (1.18–1.45)	<0.001	–	–
COVID-19 vaccination				
Yes/no	2.08 (1.88–2.30)	<0.001	1.74 (1.56–1.95)	<0.001
Deprivation index in quintiles	0.89 (0.86–0.93)	<0.001	0.90 (0.86–0.93)	<0.001

nificance in the multivariate analysis were the criteria for indicating PrEP, age group, country of birth, influenza vaccination, hepatitis A vaccination, COVID-19 vaccination and the deprivation index. Gender and hepatitis B vaccination were no longer significant and were therefore removed from the model.

MSM on PrEP, young adults, born in Spain, with a history of vaccination against influenza, hepatitis A and COVID-19, are more likely to have been vaccinated against mpox. The proportion of vaccinated subjects decreases as the deprivation index increases (as the socioeconomic level decreases).

Discussion

The mpox epidemic in Spain and in the Madrid Region has been concentrated in people with risky sexual practices. As this is a difficult group to identify, we selected the subjects included in PrEP as the study population, as this group is defined as a target in the agreed vaccination strategy; 43.9% of mpox cases in Madrid Region in 2022 were HIV positive, and 17.0% were on PrEP.[11]

Vaccination coverage against mpox in people on PrEP is low (39.9% with at least one dose), despite being funded and not involving any cost for this population.

Vaccination hesitancy depends on different factors, the independence and relative influence of which are difficult to identify, and they also vary with time, place and the vaccine involved. According to the so-called "3C model", the main factors related to vaccination hesitancy are trust (in the safety and efficacy of vaccines), complacency (perception of the risk of the disease a person is going to be vaccinated for), and convenience (accessibility).[20] Lack of trust is generally associated with negative attitudes about the safety and efficacy of vaccination. Greater general knowledge about vaccines and health tends to be associated with positive attitudes towards them. In a study on the determinants of hepatitis B vaccination-related behaviours in MSM, vaccination was found to be more likely among those who considered themselves more susceptible to infection and who perceived the infection as more severe.[21] This study shows that influencing perceived susceptibility by improving health knowledge is more important than using fear tactics to increase the perception of severity. The low vaccination coverage found in our study may also be related to a perception of low severity of the disease.

In the Madrid Region, priority was given to provide access to the entire population considered eligible for the vaccine in the agreed vaccination strategy. Information on mpox vaccination was provided for this and disseminated through NGO and institutions that work with the groups for which vaccination is indicated. Initially one unit was set up, and this was then expanded to two during the first three months of the vaccination campaign. Although centralising the vaccination was for operational and efficiency reasons, it may have led to difficulties in access, added to the initial low availability of the vaccine, which required strict control of the doses.

In our study population, one aspect that may have influenced the limited coverage achieved could be not having actively recruited people on PrEP, so our coverage results would not be comparable to those in areas where different interventions were carried out. Due to vaccine shortages, a single dose was initially recommended. However, when vaccine availability was greater, active recruitment was carried out among those vaccinated with a first dose, to complete the vaccination schedule, and we found that 61% of those vaccinated completed their schedule. In terms of reasons for not completing the vaccination schedule, both the epidemiological situation, with the decrease in the number of cases, and specific aspects of vaccination may have contributed (intradermal administration can cause skin discolouration in the injection area,[9] which could lead people to avoid a second dose).

In adults, the importance of social group, health and health behaviours on vaccination status has been described as disease-dependent.[22] In our study, the population on HIV PrEP may be more aware and committed to preventive practices. The association of mpox vaccination with vaccination against influenza, hepatitis A and COVID-19 may indicate a more favourable attitude towards preventive practices. In addition, a history of vaccination against other diseases may reflect greater confidence in vaccines.

Among the factors related to vaccination, the role of gender has not been identified as a conclusive factor.[23] In the case of our study, although in the univariate analysis we found an association of vaccination against mpox with being male, in the multivariate analysis, gender was no longer significant, maintaining the association with the MSM group, the majority in the study population.

Studies indicate that the main reason at an individual level for reluctance to be vaccinated is the perceived risk; that is, the perceived likelihood of developing the disease, the susceptibility to the disease and the seriousness or severity of the disease.[24] The higher vaccination coverage in the MSM group is probably also due to the higher risk sexual behaviours in this group.

Studies on the association between age and vaccination have produced inconsistent results. In a study with representative sampling, a tendency was observed for people over 65 to declare more positive attitudes towards vaccines than the younger population.[25] In our study, there was a higher proportion of vaccinated people among young adults, which may be partly due to the fact that the strategy did not initially include the indication for people with a history of smallpox vaccination. It is also plausible that younger people have been vaccinated more, because they are at greater risk of exposure to the disease due to the behaviours they practice.

It has been found that people living in socioeconomically disadvantaged areas tend to be less likely to have the flu vaccine than people in wealthier areas. However, both high and low incomes have been associated with lower vaccination rates.[23] In our study, we found subjects with a lower deprivation index (higher socioeconomic level) to have greater vaccination coverage. This may be due to greater knowledge of the disease or awareness of preventive measures, along with factors related to accessibility to vaccination.

The higher vaccination coverage in subjects born in Spain may be related to accessibility to the healthcare system. In a study of a hepatitis A outbreak among MSM in Berlin, a higher incidence was found among those reporting high-risk behaviour and higher vaccination coverage among those born in the country.[26]

Limitations of our study include the fact that the data come from different information sources and that by cross-referencing databases by personal identifiers, it is not possible to obtain complete information on all variables of interest. In terms of the deprivation index, being a variable collected at the population level as an individual approximation, it may come with a certain degree of ecological bias.

The factors that influence the decision to accept, delay or reject vaccination have been described as falling into three categories: contextual; individual or group; and vaccine-specific.[27] In our study we focused on sociodemographic factors and vaccination history against other diseases, available in the information sources we used. Other factors that may be specific to each group could not be addressed in this study. In our study, it was not possible to assess the type of risky sexual behaviour carried out by the subjects, as this is sensitive information which had not been recorded.

The main conclusion of our study is that mpox vaccination coverage in December 2023 among people on PrEP was low. Young adult MSM born in Spain, with a history of vaccination against influenza, hepatitis A and COVID-19, are more likely to be vaccinated, as are those with a higher socioeconomic level.

To promote vaccination in these groups and to be able to control the incidence of the disease, we need to consider routine preventive interventions in the high-risk population, incorporating mpox vaccination as part of the preventive activities in the services providing care to these subjects.[28] In this regard, currently in Madrid Region, vaccination against mpox has been incorporated into the preventive activity of two specialised centres for sexually transmitted infections. This has led to an increase in vaccination of this population at high risk of mpox.

Declaration of competing interest

None.

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Appendix A

Risk condition	ICPC codes
Chronic cardiovascular diseases (excluding isolated arterial hypertension)	K74: Ischaemic heart disease with angina K75: Acute myocardial infarction K76: Ischaemic heart disease without angina K77: Heart failure K78: Atrial fibrillation/flutter K82: Pulmonary heart disease K83: Valvular heart disease K84: Other heart diseases K91: Cerebrovascular disease
Lung diseases including asthma	R96: Asthma R95: COPD R79: Chronic bronchitis R84: Malignant neoplasm bronchus/lung R85: Malignant neoplasm respiratory, other R89: Congenital anomaly respiratory
Diabetes mellitus	T90: Diabetes insulin dependent T89: Diabetes non-insulin dependent
Chronic kidney disease and nephrotic syndrome	U88: Glomerulonephritis/nephrosis U99.01: Chronic kidney disease
Rheumatoid arthritis	L88: Rheumatoid arthritis
Haemoglobinopathy and anaemia	B78: Hereditary haemolytic anaemia B82: Anaemia other/unspecified
Chronic liver disease	D72: Viral hepatitis D97: Cirrhosis
Severe neuromuscular diseases	N86: Multiple sclerosis N87: Parkinson's disease P70: Dementia
Immunosuppression (including that caused by malignant blood disease and other neoplasms)	B72: Hodgkin's disease/lymphoma B73: Leukaemia B74: Malignant neoplasm blood other B76: Ruptured spleen traumatic B79: Congenital anomalies blood/lymph other A79: Malignancy not otherwise specified D74: Malignant neoplasm stomach D75: Malignant neoplasm colon/rectum D76: Malignant neoplasm pancreas D77: Malignant neoplasm digest other/not otherwise specified F74: Neoplasm of eye/adnexa H75: Neoplasm of ear K72: Neoplasm cardiovascular L71: Malignant neoplasm musculoskeletal N74: Malignant neoplasm nervous system S77: Malignant neoplasm of skin U75: Malignant neoplasm of kidney U76: Malignant neoplasms of bladder U77: Malignant neoplasm urinary other X75: Malignant neoplasm cervix X76: Malignant neoplasm breast female Y77: Malignant neoplasm prostate T71: Malignant neoplasm thyroid
Disorders and diseases that lead to cognitive dysfunction	A90: Down syndrome, neurofibromatosis and other syndromes

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