

Study protocol for Vaccine knowledge, attitudes and practices among men who have sex with men (VAC-M): a global cross-sectional study

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Abstract

Introduction

Men who have sex with men (MSM) are disproportionately affected by several vaccine-preventable diseases (VPDs), including human papillomavirus (HPV), hepatitis A virus (HAV), hepatitis B virus (HBV), meningococcal disease and mpox. Although vaccination is recommended for MSM in many countries, vaccine uptake remains suboptimal and varies considerably across settings. Vaccine confidence, vaccine hesitancy and access to vaccination services may contribute to these disparities. However, most existing studies have focused on a single vaccine or a single country, limiting understanding of global patterns of vaccine-related knowledge, attitudes and practices (KAP) among MSM. Our Vaccine knowledge, attitudes and practices among men who have sex with men (VAC-M) study aims to investigate vaccine-related KAP, vaccine confidence, vaccine hesitancy, vaccination willingness and vaccine coverage among MSM across multiple countries and regions.

Methods and Statistical Analysis

VAC-M is a global multicenter cross-sectional study that will be conducted in approximately 10 countries and regions across continents. Eligible participants are individuals aged 18 years or older who have resided in a participating country or region for at least six months and self-report having sex with men. Participants will be recruited through sexual health clinics, hospitals, community-based organizations and online social networking platforms targeting MSM populations. A minimum of 500 participants will be recruited from each participating country or region.

Data will be collected using anonymous self-administered questionnaires assessing sociodemographic characteristics, sexual behaviors, awareness of vaccine-preventable diseases, vaccination history, vaccination willingness, vaccine confidence and vaccine hesitancy. Descriptive analyses will summarize vaccine-related outcomes across countries. Multivariable logistic regression and mixed-effects regression models will be used to identify factors associated with vaccine uptake and vaccine hesitancy while accounting for country-level clustering. Subgroup analyses will be conducted according to demographic and behavioral characteristics.

Ethics and Dissemination

This study has been approved by the Human Research Ethics Committee of the School of Public Health, Fudan University, the coordinating institution for this study (approval number: H2026163). Where required, ethical approval will also be obtained from relevant ethics committees in participating countries and regions before study initiation at each site. Participation will be voluntary and anonymous, and no personally identifiable information will be collected. Study findings will be disseminated through peer-reviewed publications,

conference presentations and reports to inform evidence-based vaccination policies and interventions for MSM populations globally.

Strengths and Limitations of This Study

- This study will provide one of the first multinational assessments of vaccine-related knowledge, attitudes, willingness, hesitancy and vaccination coverage among MSM across diverse geographical settings.
- Standardized questionnaires and harmonized data collection procedures will facilitate cross-country comparisons.
- Recruitment through both online and offline channels may improve population reach and diversity.
- The cross-sectional design precludes causal inference.
- Self-reported vaccination history may be subject to recall and social desirability bias.

Introduction

Vaccination is widely recognized as one of the most cost-effective public health interventions for preventing infectious diseases and plays a critical role in reducing disease morbidity, mortality, and the associated socioeconomic burden^(1, 2). In recent years, international public health agencies and national health authorities have developed and updated vaccination recommendations and prevention strategies for a range of vaccine-preventable diseases (VPDs), including human papillomavirus (HPV)-related infections and diseases, hepatitis A and hepatitis B (caused by hepatitis A virus [HAV] and hepatitis B virus [HBV], respectively), meningococcal disease, and mpox, with the aim of reducing disease burden and transmission risk among high-risk populations^(3, 4).

Men who have sex with men (MSM) are disproportionately affected by several infectious diseases because of specific behavioral patterns and social network characteristics. Previous studies have demonstrated that the prevalence of HPV, HAV, HBV, and meningococcal infections is substantially higher among MSM than in the general population. More recently, the global mpox outbreak has further highlighted the importance of this population in infectious disease prevention and control efforts. Consequently, MSM are widely recognized as a priority population for vaccination against multiple infectious diseases in public health guidelines across many countries^(3, 5). However, despite clear vaccination recommendations, the actual uptake of recommended vaccines among MSM remains heterogeneous across countries and regions. A systematic review and meta-analysis, primarily including studies conducted in the United States, reported an average vaccine acceptance rate of 63% (median = 72%; range: 30%–97%), a vaccination uptake rate of 45% (median = 42%; range: 5%–100%), and a vaccine series completion rate of 47% (median = 45%; range: 12%–89%) among MSM⁽⁶⁾. A cross-sectional survey conducted among gay, bisexual, and other men who have sex with men (GBMSM) in the United Kingdom found that approximately two-thirds of eligible participants had received recommended vaccines, including mpox vaccine (69%; 95% confidence interval [CI]: 66%–72%), HAV vaccine (68%; 95% CI: 65%–70%), HBV vaccine (72%; 95% CI: 69%–74%), and HPV vaccine (65%; 95% CI: 61%–68%). Among eligible GBMSM, vaccine series completion rates ranged from 75% for HBV vaccination to 89% for HAV vaccination⁽⁷⁾. In contrast, evidence regarding comprehensive vaccination coverage among MSM in low- and middle-income countries and economically less developed regions remains limited.

Vaccination coverage is influenced by multiple factors, among which vaccine hesitancy has been identified as a major barrier to vaccine uptake. The World Health Organization Strategic Advisory Group of Experts (SAGE) on Immunization defines vaccine hesitancy as the delay in acceptance or refusal of vaccination despite the availability of vaccination services. Vaccine hesitancy is shaped by a complex interplay of factors, including perceptions of vaccine safety, effectiveness, and necessity, as well as trust in healthcare systems and vaccine providers⁽⁸⁾.

Existing studies suggest substantial heterogeneity in adult vaccine hesitancy among MSM across vaccine types, countries, and sociocultural contexts. An online cross-sectional study conducted among MSM in France reported that nearly 90% of participants exhibited moderate or high levels of hesitancy toward at least one of the HBV, HAV, or HPV vaccines, while 54% demonstrated generalized vaccine hesitancy⁽⁹⁾. In contrast, a nationwide cross-sectional study involving 7,538 MSM in China reported a relatively low level of mpox vaccine hesitancy, with only 5.59% (421/7,538) of participants expressing hesitancy toward vaccination⁽¹⁰⁾. To date, systematic cross-national comparisons of vaccine hesitancy among MSM remain scarce.

Most existing studies on vaccine hesitancy and vaccination behavior have focused on either the general population or populations within a single country. Research involving MSM has largely concentrated on individual vaccines or specific geographic settings, limiting the ability to comprehensively assess how differences in public health environments, vaccination policies, and sociocultural contexts influence vaccine perceptions and vaccination behaviors across countries. In particular, multinational studies simultaneously examining vaccine awareness, vaccination intention, vaccination uptake, and vaccine hesitancy across multiple vaccines remain relatively rare. Against this background, conducting a multinational cross-sectional survey to systematically evaluate vaccine attitude, knowledge, confidence, and hesitancy toward multiple key vaccines among MSM is of substantial importance. Such research would facilitate the identification of cross-national differences and their determinants, provide evidence for developing more precise and population-centered vaccination promotion strategies, and support public health decision-making aimed at improving vaccine accessibility and uptake among high-risk populations.

Study objectives and hypothesis

Objectives

Primary Objective: To assess the current status of vaccine-related knowledge, attitudes, and behaviors among MSM across different countries and regions worldwide.

Secondary Objective: To identify factors influencing vaccine-related knowledge, attitudes, and behaviors among MSM in diverse global settings.

Hypothesis

Due to variations in economic development, cultural context, and national vaccination policies, significant differences exist in vaccination uptake and vaccine-related behaviors among MSM across countries and regions.

Methods and analysis

Study design

This study is a global, multicenter, cross-sectional survey designed to assess vaccine-related

knowledge, attitudes, intentions, uptake, and vaccine hesitancy among MSM. The study will be conducted between July 2026 and December 2028 across selected countries and regions across continents, including:

- (1) Mainland China
- (2) Hong Kong SAR, China
- (3) Singapore
- (4) Thailand
- (5) Vietnam
- (6) Indonesia
- (7) Philippines
- (8) Malaysia
- (9) The United Kingdom
- (10) Colombia

Additional countries and regions may be included during the study period as new collaborating research teams join the study.

Inclusive criteria

Participants will be eligible for the study if they meet all of the following conditions:

- (1) Have resided in a participating country or region for at least six months.
- (2) Are aged 18 years or older.
- (3) Self-identify as MSM, with eligibility in certain participating countries and regions potentially extended to transgender women and non-binary individuals who have sexual relations with men, using the same questionnaire.

Exclusive criteria

Participants will be excluded if they meet any of the following conditions:

- (1) Are aged under 18 years.
- (2) Decline to participate in the study or fail to complete the online informed consent process.
- (3) Have not resided, or do not currently reside, in a participating country or region.
- (4) Submit duplicate responses from the same IP address or device.
- (5) Fail data quality checks, including automated or fraudulent submissions and failure to pass human verification procedures.

Sample size

The sample size was calculated based on the vaccination uptake rate among MSM. According to a previous systematic review and meta-analysis, the estimated average uptake was 45%. Using a two-sided alpha level of 0.05 and standard assumptions for estimating a population proportion, the required sample size was calculated using the formula:

$$n_0 = \frac{Z_{\alpha/2}^2 \times p \times (1-p)}{d^2}$$

where $Z_{\alpha/2}$ is the standard normal deviate corresponding to the desired confidence level, p is the estimated prevalence, and d is the desired precision. Based on this calculation, the minimum required sample size was approximately 396 participants per country or region. Accounting for an anticipated non-response or invalid-response rate of 20%, the target sample size was set at 500 participants per country or region.

Recruitment and data collection

Participants will be recruited through a combination of online, offline, clinical, and community-based channels. Offline recruitment will occur through sexually transmitted infection clinics, hospital dermatology and venereology departments, and other relevant healthcare settings. Online recruitment will be conducted through MSM-oriented social networking and dating platforms, such as Blued, Grindr, and Jack'd, as well as broader social media platforms including Weibo, Facebook and X. Participants may also access the questionnaire by scanning a study-specific QR code. In addition, recruitment will be supported by local MSM community-based organizations and, where appropriate, community outreach in general community settings.

Data will be collected using an anonymous self-administered questionnaire. The questionnaire is expected to take approximately 15 minutes to complete and will not collect personally identifiable information. The survey will include screening questions on sexual orientation, sex of sexual partners, and country or region of residence, with skip logic used to ensure that valid responses are obtained from the target population. Each participating country or region will adapt the questionnaire to the local context. The English version will be translated into local languages by collaborating teams and reviewed by bilingual researchers to ensure linguistic accuracy, cultural appropriateness, and cross-country comparability.

Measures

The survey will assess participants' sociodemographic characteristics, vaccine-related knowledge, vaccination attitudes, vaccine confidence, vaccination intention, vaccine hesitancy, and self-reported uptake of key vaccines recommended for MSM or other high-risk populations. Vaccines of interest include, but are not limited to, vaccines against human papillomavirus, hepatitis A, hepatitis B, meningococcal disease, and mpox.

Vaccination uptake will be assessed separately for each vaccine and, where applicable, by dose completion status. Vaccine intention will be assessed among participants who have not yet received the relevant vaccine. Vaccine hesitancy will be classified according to participants' responses regarding vaccination intention and behavior, for example as vaccinated, willing but not yet vaccinated, uncertain or hesitant, and unwilling to be vaccinated. Vaccine confidence

and vaccination attitudes will be assessed using questionnaire items on perceived vaccine safety, effectiveness, necessity, and trust in health systems and vaccine providers. These variables will be analyzed either as categorical indicators or quantitative scores, depending on item structure and distribution.

A key analytic construct will be the gap between vaccination willingness and actual vaccination behavior. Participants who report willingness to receive a vaccine but remain unvaccinated will be identified as a distinct group to characterize potential structural, informational, or access-related barriers.

Statistical analysis plan

All analyses will be conducted using R (version 4.5.0, R Core Group, Vienna). Descriptive statistics will be used to summarize participant characteristics and vaccine-related outcomes. Categorical variables will be presented as frequencies and proportions with 95% confidence intervals. Continuous variables will be summarized using means and standard deviations or medians and interquartile ranges, depending on distributional characteristics.

Vaccination uptake, completion, intention, and hesitancy will be estimated overall and separately by country or region, vaccine type, and relevant participant characteristics. Between-country and between-group differences will be examined using chi-square tests or Fisher's exact tests for categorical variables and t tests, analysis of variance, Mann–Whitney U tests, or Kruskal–Wallis tests for continuous variables, as appropriate.

To identify factors associated with vaccine-related outcomes, multivariable regression models will be fitted for key outcomes, including vaccine uptake, vaccine hesitancy, and willingness-but-unvaccinated status. Logistic regression will be used for binary outcomes, and multinomial or ordinal regression will be considered for multi-category hesitancy or intention outcomes, depending on the final outcome structure. Candidate explanatory variables may include age, education level, country or region, recruitment channel, vaccine-related knowledge, perceived vaccine safety and effectiveness, perceived necessity, trust in healthcare systems or vaccine providers, and other relevant behavioral or contextual factors.

Given the multinational design, country or region will be handled explicitly in the analysis, either as a fixed effect or, where appropriate, through multilevel models with participants nested within countries or regions. Stratified and subgroup analyses may be conducted to compare vaccine-related outcomes across demographic groups, countries or regions, recruitment channels, and vaccine attitude profiles. Statistical significance will be assessed using two-sided P values, with $P < 0.05$ considered statistically significant.

Study duration

The study will be conducted from July 2026 to December 2028. The study period will include

ethics approvals and study preparation (July–December 2026), participant recruitment and data collection (January–June 2027), data cleaning and analysis (July–December 2027), and dissemination of findings through manuscript preparation and publication (January–December 2028).

Outcomes

The primary outcome will be vaccine uptake for each of the five vaccines recommended to MSM: HPV, hepatitis A, hepatitis B, meningococcal, and mpox vaccines. Vaccine uptake will be assessed based on participants' self-reported vaccination history at the time of survey completion. For each vaccine, participants will be classified according to whether they have ever received at least one dose of the corresponding vaccine. Vaccine-specific uptake will be reported as the proportion of participants who have received the respective vaccine among those eligible to respond.

Secondary outcomes will include vaccine attitude, knowledge, confidence, and hesitancy. These outcomes will be assessed using questionnaire items and, where applicable, multi-item scales. Scale-based outcomes will be summarized using predefined scoring algorithms, with higher scores indicating higher levels of the corresponding construct unless otherwise specified.

Compensation

Participants may receive a small incentive in accordance with local ethical and regulatory requirements. In mainland China, participants who complete the survey will receive a compensation of ¥30 (approximately US\$4, depending on the prevailing exchange rate). Compensation arrangements in other participating countries and regions will be determined by local collaborating institutions and approved by the relevant ethics committees. The incentive is intended to compensate participants for their time and effort and is not expected to unduly influence participation.

Ethical Considerations

Ethics Submission

This study has been approved by the Human Research Ethics Committee of the School of Public Health, Fudan University, the coordinating institution for this study (approval number: H2026163). Where required, ethical approval will also be obtained from relevant ethics committees in participating countries and regions before study initiation at each site. Any protocol amendments will be submitted for ethical review and approval in accordance with applicable local regulatory requirements.

Guidelines for Good Clinical Practice

Although this study is observational and involves no clinical intervention, it will be conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice

(GCP) guidelines. All study procedures will comply with applicable ethical and regulatory requirements in participating countries and regions.

Risk to Participants and solutions

This study involves minimal risk to participants. The primary potential risk is the collection of sensitive information, including sexual behaviors, sexual orientation, vaccination history, and sexually transmitted infection (STI) status, which may cause mild psychological discomfort or concerns regarding privacy and confidentiality.

To minimize these risks, several measures will be implemented. First, the survey will be conducted anonymously, and no personally identifiable information will be collected. Second, participants will be informed that all data will be used solely for research purposes and will not be disclosed to any third party. Third, all study personnel will receive training on research ethics, confidentiality, and data protection procedures prior to study initiation. Finally, study data will be stored on password-protected computers and secure servers, with access restricted to authorized members of the research team in accordance with data security protocols. These measures are designed to ensure the confidentiality, privacy, and security of participant information throughout the study.

Benefits of Participation

This study will contribute to a better understanding of vaccine-related knowledge, attitudes, and behaviors among MSM globally. The findings may help inform future vaccination policies, health promotion strategies, and interventions aimed at improving vaccine uptake and reducing the burden of vaccine-preventable diseases among MSM and other key populations.

Publication plan

The study findings will be disseminated through peer-reviewed journal publications and presentations at national and international scientific conferences. The primary publication will report vaccine-related knowledge, attitudes, vaccine hesitancy, and vaccination uptake among MSM across participating countries and regions. Additional analyses may be conducted to explore factors associated with vaccine uptake and cross-country differences.

Authorship

Investigators who make substantial contributions to the study design, data collection, data analysis, interpretation of findings, or manuscript preparation will be eligible for authorship in accordance with the recommendations of the International Committee of Medical Journal Editors (ICMJE). All authors will be required to critically review the manuscript, approve the final version for publication, and accept responsibility for the integrity and accuracy of the work.

Authorship order will be determined based on the relative scientific contributions of participating investigators and will be agreed upon by the authors prior to manuscript

submission. The first author will typically be the investigator who leads the analysis and manuscript preparation, while the senior (last) author will be the principal investigator or supervising researcher responsible for overall study oversight.

Reference

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Appendix 1. Online informed consent form

Study Title: Vaccine knowledge, attitudes and practices among men who have sex with men (VAC-M): a global cross-sectional study

Thank you for participating in this study. This online informed consent form provides information about the study. If you agree to participate, you will be asked to sign this informed consent form.

1. Study Purpose

This study is conducted by the School of Public Health, Fudan University. The study aims to assess vaccine-related knowledge, attitudes, and practices and their associated factors among MSM in different countries and regions worldwide.

This study is funded by Professor Huachun Zou's research start-up fund. We hope that the findings of this study will provide scientific evidence for developing more precise, population-oriented vaccine promotion strategies and support public health decision-making to improve vaccine accessibility and uptake among high-risk populations.

2. Study Procedures

If you decide to participate in this study, you will be asked to complete a questionnaire that takes approximately 15 minutes. You will be asked about your sociodemographic characteristics, sexual behaviors, vaccination status for HPV/mpox/hepatitis A/hepatitis B/meningococcal vaccines, and health-related perceptions.

3. Potential Risks

You may be asked about sensitive information, such as your history of sexually transmitted infections and sexual behaviors. We will obtain informed consent from every participant and ensure that your personal information will not be disclosed to any third party.

4. Potential Benefits

You will receive free information about MSM vaccination.

5. Compensation for Participation

At study sites in China, each participant who completes the survey will receive RMB 30 as compensation. At sites in other countries, compensation arrangements will be determined locally subject to approval by the respective ethics committees.

6. Confidentiality of Study Records

All study data will be kept confidential and stored on password-protected, dedicated computers. Only members of the research team will have access to this information.

7. Rights of Participants

Your participation in this study is entirely voluntary. You may choose whether or not to participate and may withdraw from the study at any time without any consequences. Participation in this study will not affect any of your existing rights. If you have any questions about the study, please contact: Feiyang Yin, email: fyyin25@m.fudan.edu.cn. You may also contact the Ethics Committee of the School of Public Health, Fudan University, at 021-54237051. This committee will represent and protect your interests.

8. Informed Consent

I have read, or have had read to me, and understood the information above. All of my questions have been answered to my satisfaction.

☐ **I am willing to participate in the study described above**