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STUDY PROTOCOL

REVISED Protocol for the development and psychometric validation of the COM-B readiness to promote vaccination questionnaire for healthcare professionals in four European countries

[version 3; peer review: 1 approved, 1 approved with reservations]

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Abstract

Introduction Annual seasonal vaccinations for influenza and COVID-19 are considered to have high public health and economic benefits. Healthcare professionals (HCPs) have a crucial role in individuals' vaccination decision. However, encouraging HCPs to actively promote vaccination remains challenging. The Capabilities, Opportunities, Motivation-Behaviour (COM-B) model of behaviour offers a framework for identifying individual and contextual factors influencing HCPs' readiness to promote vaccination. To our knowledge, there are currently no quantitative tools measuring HCPs' readiness to promote vaccination based on the COM-B Model. Objectives To develop a questionnaire informed by the COM-B model on the readiness of HCPs to promote COVID-19 and influenza vaccination, to assess the cross-national adaptation of the questionnaire across the co-

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OPERATOR consortium countries (Cyprus, Greece, Italy, Portugal), and to evaluate the validity, reliability, and acceptability of the different language versions. Protocol The questionnaire will be developed in three phases: Item development, questionnaire development, and questionnaire evaluation. Items were developed using deductive methods applied through literature review and assessment of existing scales and items tapping on COM-B domains. Content validity was tested using an Expert Consensus Study. Forward-backward translations will be employed to translate the tool from English into the target languages, and local experts will provide feedback on the suitability of the translated equivalent versions. Cognitive interviews with end-users will take place to assess the understandability and usability of the questionnaire, and appropriateness of response options. The questionnaire will subsequently be distributed to HCPs in the different countries to evaluate its metric properties (e.g., construct validity, reliability) and users' acceptability. A sub-sample of participants will complete the questionnaire twice, with a 2-week interval. Conclusion A valid and reliable theory-based questionnaire can be used in various clinical settings in different countries to provide measurable, comparable outcomes and performance metrics to support policymaking decisions and vaccination promotion strategies.

Plain Language Summary
Vaccine recommendations by healthcare professionals (HCPs), such as General Practitioners and community nurses, can significantly influence an individual's decision to get vaccinated. However, HCPs do not always recommend vaccinations, including influenza and COVID-19 vaccination. This may be due to personal factors, such as insufficient knowledge about the vaccines, socio-cultural beliefs and norms, or systemic and structural issues, such as the lack of time during consultations to discuss vaccination and its benefits. We used a well-established theoretical model, the Capabilities, Opportunities, Motivation-Behaviour (COM-B) model, to develop a questionnaire which aims to identify the barriers and facilitators of COVID-19 and influenza vaccination promotion by HCPs. The development of the questionnaire involved sourcing the first pool of questions from the literature, followed by expert evaluation and forming the final draft by consensus. Translation, cultural adaptation, and interviews with HCPs will be carried out in Cyprus, Greece, Italy, and Portugal to ensure that questions and response options are clear, easy to understand, and well-adapted to the local language, cultural context, and healthcare system. The questionnaire will then be administered to HCPs in the different countries to examine its validity (e.g., ability to tap on the distinct domains of the theoretical framework each item is purported to measure), reliability (e.g., the degree of consistency in responses to items classified under the same domain and stability in repeat measurements), and acceptability (e.g., the experience of users when completing the questionnaire such as whether it was interesting or boring) using statistical analyses. If the questionnaire is confirmed to be a valid, reliable, and acceptable tool, it can be applied across

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different settings to identify factors influencing HCPs' promotion of COVID-19 and influenza vaccination. This information can guide decision-makers in implementing strategies to overcome barriers and enhance vaccine recommendation.

Keywords
co-OPERATOR, vaccine hesitancy, questionnaire development, psychometric properties, healthcare professionals, COVID-19, influenza, vaccination promotion, COM-B.

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REVISED **Amendments from Version 2**

We have now added a paragraph to the Discussion section of the protocol (pages 15-16) explicitly acknowledging that contextual factors (including healthcare system organisation, vaccination programme financing, HCPs' roles, public trust, and sociocultural norms) are expected to produce between-country variation in questionnaire scores, that this variation is theoretically meaningful and informative, and that the planned measurement invariance analyses will formally determine the conditions under which cross-national comparisons are appropriate.

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Introduction

Annual vaccinations have emerged as the most significant interventions to reduce the clinical and economic impact of COVID-19 and influenza, particularly among high-risk populations such as the elderly and individuals with comorbidities (de Fougerolles *et al.*, 2024; Su *et al.*, 2021; Utami *et al.*, 2023). The European Center for Disease Control and Prevention has emphasised the importance of timely and adequate COVID-19 and influenza vaccination coverage, especially among risk groups, ahead of the winter season when infection rates reach their peak (ECDC, 2024; Liu *et al.*, 2021; Nypaver *et al.*, 2021). Notably, the co-administration of COVID-19 and influenza vaccines has emerged over the past few years as a critical strategy to enhance vaccination coverage (Achterbergh *et al.*, 2024). Nevertheless, both COVID-19 and influenza vaccination rates are suboptimal across several European countries (Chen *et al.*, 2022; Lazarus *et al.*, 2023; Mathieu *et al.*, 2020). For example, influenza vaccination rates among the general population range from 12% in Hungary to 52% in Greece (Chen *et al.*, 2022). With regards to COVID-19 vaccines, 70% of the population in Europe has received at least one dose of the COVID-19 vaccine (Our World in Data, 2024a) and 67% have completed the initial vaccine protocol up to August 2024 (Our World in Data, 2024b). Despite vaccines availability, vaccination is sometimes compromised by vaccine hesitancy (Salmon *et al.*, 2015), defined as the delay in acceptance or refusal of vaccines (MacDonald, 2015).

Healthcare professionals (HCPs) play a pivotal role in their patients' decision to get vaccinated (Griffin *et al.*, 2018; Karafillakis *et al.*, 2016). During the COVID-19 pandemic, recommendations by HCPs were among the strongest predictors of vaccination uptake (Karlsson *et al.*, 2021; Meissner, 2022). Being among the most trusted advisors in vaccination decision-making, HCPs should be at the forefront of efforts to enhance vaccine uptake (Paterson *et al.*, 2016). However, encouraging HCPs to provide recommendations and actively promote vaccination remains a significant challenge. In the post-COVID-19 era, understanding HCPs readiness to promote annual vaccines, including COVID-19 and influenza vaccines, and, indeed, defining it in behaviour terms, is essential to inform targeted intervention and policy strategies.

Insights from behavioural theories are useful to better understand the barriers and facilitators of promoting vaccination by HCPs. The Capabilities, Opportunities, Motivation-Behaviour (COM-B) theoretical model was developed to understand the determinants of any health behaviour, based on 19 frameworks of behaviour change (Michie *et al.*, 2011). It has been adapted by the World Health Organisation (WHO) for their Tailoring Immunization Programmes (TIP) approach (Habersaat & Jackson, 2020). The COM-B model asserts that for any health behaviour to occur, 'Capability', 'Opportunity', and 'Motivation' need to be present (Michie *et al.*, 2011). It offers a comprehensive theoretical framework to identify both individual and contextual barriers and facilitators of vaccination promotion by HCPs. Capability taps on individual-level determinants (such as lack of information, distrust or misperceptions), opportunity is largely influenced by context or interaction of the person with others (including social, cultural, institutional, and political factors) and motivation contains elements of both individual level (beliefs and perceptions) and context determinants (rewards, recognition, professional roles and responsibilities). These determinants can then be mapped to evidence-based intervention functions and subsequent policy domains.

Current evidence related to the determinants of vaccination promotion or delivery by HCPs confirms that factors in all three domains of the COM-B model are relevant (Bolsewicz *et al.*, 2022; Flood *et al.*, 2023; Musa *et al.*, 2020; Nnaji *et al.*, 2023; Norman *et al.*, 2022; Overmars *et al.*, 2022; Randall *et al.*, 2021; Thomas *et al.*, 2018; Thomas *et al.*, 2019; Tuckerman *et al.*, 2020; Zaouk *et al.*, 2020; Zhou *et al.*, 2023). For example, previous studies on influenza vaccination have highlighted the role of inconsistent vaccine supply (Randall *et al.*, 2021), time pressure (Randall *et al.*, 2021), lack of educational resources (Randall *et al.*, 2021), ineffective communication with patients (Tuckerman *et al.*, 2020), knowledge of vaccine recommendations (Tuckerman *et al.*, 2020), and perceived responsibility towards recommending or delivering the vaccine (Norman *et al.*, 2022; Tuckerman *et al.*, 2020). Previous evidence, however, derives solely from qualitative studies. None of previous quantitative measures have been designed to measure HCPs' readiness to promote vaccination based on the COM-B model. The newly-developed questionnaire will be used in various clinical settings and

in different countries to provide quick, measurable, and comparable outcomes as well as metrics of performance to support the development of targeted vaccination promotion strategies and policymaking decisions.

The proposed study is part of a larger, ongoing project entitled 'Developing a Country-Observatory for Sharing Best Practices for Vaccination Promotion (co-OPERATOR), funded by the European Health and Digital Executive Agency (EU4Health scheme). The overarching aim of the co-OPERATOR project is to develop an innovative and citizen-centered digital solution with an evidence-based virtual observatory to increase vaccine literacy and uptake among participating countries (Cyprus, Greece, Italy, Portugal) and beyond. One of the primary objectives of the co-OPERATOR project is to assist decision-makers in understanding the barriers and facilitators influencing COVID-19 and influenza vaccination promotion by HCPs and to translate scientific evidence into effective intervention strategies at regional, national, and European level. These cross-country efforts are important as certain factors may exhibit specificity to particular countries, reflecting the different challenges faced within diverse socio-cultural and system-level local and regional contexts.

Study objectives

The objectives of the proposed study are a) to develop a questionnaire informed by the COM-B theoretical model taping on the readiness of HCPs to promote COVID-19 and influenza vaccination, b) to translate and culturally adapt the questionnaire to be administered in Cyprus, Greece, Italy, and Portugal, and c) to examine the validity (content, discriminant, factorial, predictive, cross-cultural), reliability (internal consistency, test-retest), and acceptability of the Greek, Italian, and Portuguese versions of the scale.

Protocol

Methods

Study design

The COM-B Readiness to Promote Vaccination Questionnaire will be developed in three phases (Boateng *et al.*, 2018): Item development (which has been completed), questionnaire development (in progress), and questionnaire evaluation (pending). This study adheres to the ethical principles outlined in the Declaration of Helsinki (latest version, 2024), which governs research involving human participants. Ethical approval was obtained from Cyprus National Bioethics Committee (reference number: ΕΕΒΚ ΕΠ 2024 01 238, date of approval: 21/08/2024) for Cyprus (Cyprus University of Technology) and Greece (University of Crete), the University of Pisa Bioethics Committee (reference number: 56/2024, date of approval: 8/10/2024), and the Ethics Council of the Lisbon Nursing School (reference number: 5380/2024, date of approval: 23/10/2024). The item development phase initiated in February 2024, but research activities involving participants in each country take place after obtaining ethical approval.

Phase 1: Item development

Deductive methods have been applied by the lead author (LP) through literature review and assessment of existing scales and items tapping on the COM-B model domains. Only two questionnaires based on the COM-B model were identified, measuring factors associated with Human Papilloma Virus and dengue vaccination in the population, respectively (Cordoba-Sanchez *et al.*, 2022; Shafie *et al.*, 2023). A 6-item COM-B questionnaire has also been developed to assess perceived capabilities, opportunities, and motivation in HCPs (Keyworth *et al.*, 2020). This brief, generic measure targets any health behaviour rather than vaccination or vaccination promotion specifically. Quantitative measures informed by the COM-B model have been developed, although these primarily target other HCPs' behaviors. Examples include delivering physical activity advice to cancer patients (Webb *et al.*, 2016), implementing falls prevention programs in acute hospitals (Ayton *et al.*, 2017), applying health interventions after cardiac surgery (Jordens *et al.*, 2024), and adopting hand hygiene practices (Zheng *et al.*, 2022). A more relevant instrument, the Pro-VC-Be (Health Professionals Vaccine Confidence and Behaviors) questionnaire, has been developed to measure psychosocial determinants of HCPs' vaccination behaviors (own vaccine uptake and recommendations) but it is not structured around the COM-B model (Verger *et al.*, 2022). Concluding, none of these scales have been specifically designed to measure HCPs' readiness to promote vaccination based on the COM-B, hence do not adequately serve the purpose of this work.

In contrast, the TIP guide (WHO, 2019) has been identified as a useful and comprehensive tool for the purposes of this study. Specifically, the TIP approach, which is grounded on the COM-B model, has been developed by the WHO Regional Office for Europe to help countries achieve increased and equitable vaccination uptake through integrating research and behavioural insights into immunisation program planning and policy in each country (WHO, 2019). While the guide does not provide specific questionnaire items, it includes a long list of relevant topics for exploring HCPs' experiences, mapped onto the COM-B model domains and sub-domains. Thus, it provided a useful basis to inform and guide the item development phase of the questionnaire. Based on the TIP guide, the questionnaire items were developed to capture the different sub-domains of the COM-B model: *Psychological Capability*: a) knowledge, b) resilience,

stamina, willpower, surplus energy, c) skills and trust in own skills. *Physical Capability*: a) physical fitness and ability. *Physical Opportunity*: a) convenience, appeal and appropriateness of vaccination, b) structural efficiency, c) availability of information, d) rights, regulation and legislation. *Social opportunity*: a) social, cultural and professional demands and support, b) social and cultural cues, norms and values. *Reflective Motivation*: a) attitudes, perceptions and risk assessment, b) values and beliefs, c) confidence and trust. *Automatic Motivation*: a) emotions, impulses and feelings, b) intentions.

Eighty-six items were initially developed, including both close-ended (45 items with on a 5-point Likert-type response scale ranging from 1 = not at all/completely disagree to 5 = to a great extent/completely agree) as well as open-ended (6 items) questions. Several items were included twice in order to refer to COVID-19 and influenza vaccines separately. In the first instance, the items were developed in the English language to allow input from international experts. Appendix 1 includes the first version of the COM-B Readiness to Promote Vaccination Questionnaire.

Content validity was assessed through an Expert Consensus Study carried out in October 2024 to evaluate whether the items adequately measure the COM-B domains and sub-domains. The group of experts consisted of five members, selected through the research team's professional networks, to combine expertise on the COM-B model, questionnaire development, and/or vaccination policy. Experts were asked to review the questionnaire items and rate the degree to which they agree or disagree with the inclusion of each item using a scale from 1 = strongly disagree to 5 = strongly agree. Each item was provided with examples as well as the specific sub-domain is intended to measure, to allow experts to evaluate its validity. The experts could suggest re-wording of the items and/or response options as well as propose additional items to include. They were also asked to provide free comments regarding the relevance of each item and the representation of the domain of interest. During an online meeting, experts were asked to elaborate on their written feedback and justify any low-rating items (scores < 4). Disagreements between experts were resolved through discussion in order to come to a consensus on the items included, excluded, and modified based on majority opinion. Experts' ratings will be analysed to provide inter-rater reliability, while qualitative feedback (written and verbal) will be summarised thematically and discussed internally within the research team in order to revise the questionnaire accordingly.

Phase 2: Questionnaire development

The previous phase will result in a revised version of the questionnaire, which will be translated and culturally adapted in Greek, Italian and Portuguese. To ensure clarity and transparency, we will follow the ISPOR Task Force guidelines (Wild *et al.*, 2005), which provides structured steps for forward and backward translation, expert review, and pre-testing with the target population to achieve conceptual and cultural equivalence across all languages and all countries. More specifically, the following procedure will be carried out in all countries: forward and backward translations will be first conducted by two independent translators at each stage, fluent in English and the local language, one who is familiar with the topic (i.e. member of each local research team) and one lay translator. Linguistic and semantic equivalence approach will be followed to allow for the closest direct counterparts in structure, grammar, and vocabulary between the target languages. Expert reviewing of translation will then follow; Local experts (N=4–7) who are fluent in both English and the local language and have an expertise on the topic, will be invited to provide written feedback on the suitability of the translated questionnaire including whether it is well-adapted to the local language, preserving the meaning and intention of the original item, and in keeping with the socio-cultural context and healthcare system. Experts' written feedback will be addressed by each local team in order to revise each translated version of the questionnaire accordingly.

Cognitive interviews with end-users will follow (N=5–15 per country) to assess the readability, understandability, and usability of the questionnaire, as well as the appropriateness of the response options. This approach follows the standard cognitive interviewing framework described by Tourangeau *et al.* (2000) and Willis (2005), which outlines the four stages of survey response: comprehension, recall, judgment, and response. More precisely, participants will be asked to complete the questionnaire and provide their ratings on whether the questions are a) clear, b) easy to understand, c) well-adapted to the local language, d) socio-cultural context, and e) healthcare system, as well as on f) the appropriateness of the response options. Respondents will be asked to verbalise the mental process entailed in completing the questionnaire and to provide written and verbal comments and suggestions, both for specific items as well as for the overall questionnaire. Cognitive interviews will take place either online or in-person. Respondents' ratings will be analysed descriptively and qualitative feedback (written and verbal) will be summarised thematically in a consistent, though informal way to facilitate comparisons and discussions between the research teams in the different countries to identify ways to address feedback. General comments (e.g., questionnaire's length) will be resolved by the research team by amending the original English version of the questionnaire whereas specific comments which apply only to a certain country will be resolved locally (e.g., adapting and fine-tuning a question to the local language/cultural context/ healthcare system).

Inclusion criteria for cognitive interviews
The same eligibility criteria as in the main survey will be applied for the cognitive interviews. These are described below.

Phase 3: Questionnaire evaluation
Once the questionnaire development phase is completed, a larger sample of HCPs will be recruited cross-sectionally in each country to complete an online survey. Before progressing to the main recruitment, a purpose sample of HCPs (10% of final sample), stratified by occupational group as per inclusion criteria, will be invited to complete the online survey twice, with a 2-week in-between. Codes will be issued to preserve anonymity, and both the two measurements will be carried out online.

Inclusion criteria for cross-sectional survey
HCPs in the primary and secondary healthcare setting, medical doctors under specialisation training, nursing professionals (including midwives), health visitors (who work primarily in the community to support families particularly with child health, parenting, and preventive care), pharmacists, medical/nursing/pharmacy trainees who a) reside and b) practice in the country in which the questionnaire will be administered, and c) who have a duty to promote COVID-19 and influenza vaccinations to the people they see in practice as part of their job role will be eligible to take part to the study. Information on the occupational group, country, and vaccination promotion duty will be provided by self-report.

Sampling and sample size calculation
The sample size for this validation study was calculated using precision analysis for the estimates of interest (e.g., percentage of participants reporting agreement with a particular questionnaire item). With no prior knowledge, the prevalence was set to 50%, for which a larger sample size will be required. The margin of error was set at 5% for the 95% confidence interval. Based on these parameters, we determined the total sample size of respondents necessary to achieve the required statistical precision (N = 376 participants per country).

Convenience sampling will be used to recruit participants from all occupational groups through the professional networks of the research team in each country as well as by invitation via professional associations' emailing lists. REDCap software (projectredcap.org/software/) will be used for data collection across all sites. Occupational group will be monitored and efforts will be made to promote the survey in under-represented groups in order to maximize the heterogeneity of participant profile in the overall sample.

Study variables
Apart from the newly developed COM-B Readiness to Promote Vaccination Questionnaire, HCPs will also provide information on sociodemographic characteristics and place of work, own vaccination behaviour and intention, and their behaviour towards COVID-19 and influenza vaccination promotion as described below.

Sociodemographic characteristics
We will collect information on age, gender (man, woman, non-binary, other), and number and age of children.

Place of work
Participants will be asked to provide their place(s) of work (private office/clinic, public hospital/health centre, nursing home, pharmacy, Ministry of Health/Public Health Authority, University/Education sector, other.

Own vaccination behaviour and intention
We will obtain information on latest influenza vaccination (during last season, some time in the past, never), latest COVID-19 vaccination (within the last 6 months, within the last 12 months, some time in the past, never), and intention for annual vaccination with separate reference for COVID-19 and influenza vaccines (with responses ranging from 1 = I definitely would not to 5 = I definitely would).

Vaccination promotion behaviour
Questions relating to vaccination promotion practices will also be included, with separate reference for COVID-19 and influenza vaccines. More precisely, HCPs will be asked whether they actively promote COVID-19/influenza vaccination to the people they see in practice (no, yes to high-risk adults, yes to all adults) and whether they intend to actively promote annual COVID-19/influenza vaccination in the future to the people they see in practice (no, yes to high-risk adults, yes to all adults).

Data analysis
A common statistical analysis plan will be employed across sites to evaluate the questionnaire's metric properties. Statistical analyses will be carried out for the overall sample and separately for each country and for each vaccine type.

For continuous variables, descriptive statistics will be summarised as means and standard deviations for variables which follow the normal distribution and medians and interquartile range for variables which do not follow the normal distribution. For categorical variables, descriptive statistics will be summarised as absolute (*n*) and relative (%) frequencies. Independent samples *t*-tests and Analyses of Variance will be carried out to explore differences and associations between readiness to promote vaccination and socio-demographic characteristics, place of work, and own vaccination behaviour and intention. The level of significance will be set at 0.05. Statistical analyses will be carried out in STATA 18.0 (Stata Corp, College Station, TX, USA) and R programming language. To deal with missing data, full information maximum likelihood (Enders & Bandalos, 2001) and multiple imputation (Gottschall *et al.*, 2012; Kenward & Carpenter, 2007) have been proven useful for questionnaire development, and will be considered in analyses.

Content validity will be examined using floor and ceiling effects calculated for each of the items. Discriminant validity will be tested with inter-item *Pearson's* correlations which will be carried out to examine the extent to which scores on one item are related to scores on all other items of the same domain and to test the correlations between item scores and the sum domain score of the rest of the items excluding itself. Given the established COM-B framework guiding the development of the scale, the domains of the questionnaire were determined *a priori*: capabilities, opportunities, and motivation. Thus, a theoretical 3-factor model tapping on domains measuring capabilities, opportunities, and motivation will be explored. To explore the dimensionality and structure across the items of the questionnaire, exploratory factor analysis will be used. Items which cross-load will be examined and items with inadequate factor loadings or slope coefficients will be eliminated at this stage. Reliability testing will be used to explore the internal consistency of each identified factor using Cronbach's alpha coefficient. To explore the factor structure further and verify the fit of a 3-factor model, a confirmatory 3-factor model consisting of domains measuring capabilities, opportunities, and motivation will be applied.

Test-retest consistency between two independent measurements will also be investigated with a 2-week interval time. The 2-week interval between survey administrations was considered a reasonable time frame. Longer intervals are typically used for more stable characteristics, while shorter intervals help minimise participant attrition. We acknowledge, however, that a 2-week interval may introduce some recall bias, and this potential limitation will be taken into account when interpreting the results. The intraclass correlation coefficient and measurement error will be calculated, and Bland-Altman plots will be used to examine any systematic differences between test and retest scores. High variability between the two measurements (intraclass correlation coefficient < 0.50), if applicable, will be addressed by reviewing items for clarity, wording, and response format followed by items revision, upon discussion with the research team.

Predictive validity will be carried out using multivariable binary regression analyses to examine the degree to which the questionnaire score(s) are associated with vaccination promotion behaviour. Cross-cultural validity will also be examined by testing measurement invariance across participating countries using multi-group confirmatory factor analysis. Contextual factors, including healthcare system organisation, vaccination programme financing, HCPs' roles, public trust, and sociocultural norms, are expected to contribute to between-country differences in questionnaire scores. Such variation is theoretically meaningful, given that the questionnaire is designed to be sensitive to contextual factors, and the planned measurement invariance analyses will formally determine the conditions under which cross-national comparisons are appropriate. Criterion (concurrent) validity testing will not be performed as there is currently no gold standard measurement available to facilitate comparisons.

Finally, users' acceptability will be investigated using missing data analyses, close-ended questions to assess perceived ease of understanding, interest, balance and fairness of the questionnaire, and a content analysis of open-ended comment boxes.

Conclusions

Expected outcomes

The expected outcomes of the proposed study are a) to develop a COM-B Readiness to Promote Vaccination Questionnaire on the readiness of HCPs to promote COVID-19 and influenza vaccination informed by the COM-B theoretical model, b) to translate and culturally adapt the questionnaire to be administered to HCPs in Cyprus, Greece, Italy, and Portugal, and c) to evaluate the validity (content, discriminant, structural, predictive, cross-sectional), reliability (internal consistency, test-retest), and acceptability of the Greek, Italian, and Portuguese versions of the questionnaire.

Impact

A novel questionnaire measuring the readiness of HCPs to promote COVID-19 and influenza vaccination will be developed, translated, culturally adapted, and validated in four European countries. Should the questionnaire be confirmed as psychometrically sound, it will be used in various clinical settings and in different countries to support

decision-makers understand the determinants of promoting COVID-19 and influenza vaccination by HCPs hence develop effective vaccination strategies and campaigns focusing on the specific concerns and needs in order to tackle barriers and facilitate vaccine recommendation.

Risks
We anticipate no risks to study participants derived from their participation to the proposed survey.

Dissemination
Results from this study will be disseminated to the scientific community and the general public through Open Science Framework (osf.io) and open-access peer-reviewed publications.

Open science framework
The co-OPERATOR project is registered to the Open Science Framework:

https://osf.io/9fcdu/

DOI 10.17605/OSF.IO/9FCDU

Ethics and consent
This study adheres to the ethical principles outlined in the Declaration of Helsinki (latest version, 2024), which governs research involving human participants. Ethical approval was obtained from Cyprus National Bioethics Committee (reference number: ΕΕΒΚ ΕΠ 2024 01 238, date of approval: 21/08/2024) for Cyprus (Cyprus University of Technology) and Greece (University of Crete), the University of Pisa Bioethics Committee (reference number: 56/2024, date of approval: 8/10/2024), and the Ethics Council of the Lisbon Nursing School (reference number: 5380/2024, date of approval: 9/9/2024).

Informed consent and privacy notification
Every participant will be provided with an information sheet online and an explicit consent form that explains the purpose of data collection, storage, and processing in compliance with European General Data Protection Regulation. Before proceeding with the completion of the online survey, all participants will be requested to provide their informed written consent to take part.

Data availability
Underlying data
No data associated with this article.

Extended data
Extended data associated with this study (cognitive interview guide template, consent forms, advertisement and email template to be disseminated via social media and professional organisations, respectively, during the data collection phase) will be openly available on Open Science Framework:

https://osf.io/9fcdu/

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Software availability statement
This study will use REDCap. Access to the software requires a valid license which can be obtained from Vanderbilt University. For research purposes, institutions may apply for access through the REDCap website: https://projectredcap.org/partners/join/. Data will then be transferred into statistical software (STATA and R) to be analysed. Data in STATA and R will be free and open access.

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Version 2

Reviewer Report 26 June 2026

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✓ **Violeta Getova-Kolarova**
[1] Medical University of Sofia, Sofia, Bulgaria
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The article presents an innovative approach to assessing healthcare professionals' attitudes towards the promotion of vaccination. The overall rationale of the study is scientifically sound, clearly articulated, and addresses an important public health issue.

My main concern relates to the sensitivity of the proposed instrument to local and regional specificities. While the questionnaire is intended to provide a standardized approach for evaluating healthcare professionals' attitudes and behaviors, these attitudes are often shaped by contextual factors that vary considerably across healthcare systems and cultural settings.
For example, factors such as the organization and financing of vaccination programmes, the role of healthcare professionals in vaccine delivery, population health literacy, public trust in the healthcare system, and prevailing sociocultural attitudes towards vaccination may substantially influence responses. It remains unclear how the proposed algorithm and scoring framework account for these contextual determinants or whether they may affect the comparability of results across different settings.
The authors may wish to further discuss the potential impact of these factors on the validity and generalizability of the instrument and clarify whether any mechanisms are envisaged to adapt or calibrate the questionnaire for use in diverse healthcare environments.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Pharmaceutical regulation, pharmacovigilance, pharmacoepidemiology, clinical trials.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 02 Jul 2026

Laura Panagi

We thank the reviewer for this thoughtful comment and agree it deserves a more substantive response than our initial reply addressed. The concern is primarily conceptual on whether the scoring framework can produce meaningful, comparable results when the structural and sociocultural conditions shaping HCPs' vaccination behaviours differ so substantially across settings. We would like to clarify why the COM-B model questionnaire is particularly well-suited to address rather than be undermined by this heterogeneity. The COM-B model was specifically designed to capture both individual-level and contextual determinants of behaviour within a single unified framework. This is not incidental but central to its purpose. The "Opportunity" domain explicitly encompasses structural efficiency, availability of resources, rights, regulation and legislation, social and cultural norms, and professional demands, precisely the factors you identify as locally variable. Consequently, the questionnaire is not designed to produce context-free scores but rather, it is designed to be sensitive to contextual variation. Differences in scores across countries are expected and interpretable as reflecting genuinely different barriers and facilitators shaped by local healthcare systems. This is the intended use of the instrument. Regarding comparability specifically, the measurement invariance testing using multi-group confirmatory factor analysis is planned across participating countries. Where invariance holds, cross-country comparisons at the latent construct level will be valid regardless of mean score differences and where it does not, country-specific interpretations will be employed. In either case, the instrument provides actionable, context-sensitive information to support country-level policymaking, which is the primary objective of the co-OPERATOR project that led to this publication. We have now added a paragraph to the Discussion section of the protocol (pages 15-16) explicitly acknowledging that contextual factors (healthcare system organisation, vaccination programme financing, HCP roles, public trust, and sociocultural norms) are expected to produce between-country variation in COM-B scores, that this variation is theoretically meaningful and informative rather than a limitation, and that the planned measurement invariance analyses will formally determine the conditions under which cross-national comparisons are appropriate. We hope this clarifies the conceptual grounding of the instrument and its intended scope of application.

Competing Interests: No competing interests were disclosed.

Version 1

Reviewer Report 03 October 2025

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Patricia Soares
[1] National Institute of Health Doutor Ricardo Jorge, Lisbon, Portugal
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This manuscript addresses an important gap by proposing the development and validation of a questionnaire to assess HCW readiness to promote vaccination. Overall, the protocol has many strengths, particularly its theoretical grounding and multi-step validation plan. Addressing the methodological clarifications outlined below will increase transparency and reproducibility, helping to ensure the resulting questionnaire can be applied confidently across various settings. With these revisions, the study has the potential to make a valuable contribution to both implementation research and vaccination promotion strategies.

The use of a conceptual model is a strong point, as it provides a theoretical basis for what the instrument intends to measure. However, while the authors mention that items were developed deductively and guided by COM-B, it remains unclear how each domain was operationalised in practice. The methods section would be strengthened if the authors could provide their conceptual model and indicate which subdimensions were considered. For example, showing which items correspond to capabilities, opportunities, motivation, and behaviour. This mapping is crucial for evaluating the content validity of the instrument. This information will also enable the reader to compare it with existing questionnaires further, allowing them to understand which dimensions were not considered.

Content validity was assessed through an “Expert Consensus Study,” but the manuscript does not provide sufficient detail about this process. Since the term encompasses a range of approaches (e.g., Delphi rounds, nominal group technique, calculation of a Content Validity Index), the authors should clarify how experts were selected, how disagreements were resolved, and the criteria used for item retention, revision, or exclusion. Additionally, were experts provided with a definition of each item, to assess whether the item actually measures the intended dimension? Providing these details would allow readers to assess the rigour of the content validation process.

The use of cognitive interviews to assess readability, understandability, usability, and appropriateness of response options is appropriate. To strengthen the methodological description, the authors should explicitly reference the standard cognitive interviewing framework (Tourangeau, 1984; Willis, 2005), highlighting the four stages of survey response (comprehension, recall, judgment, and response). It would also be helpful to clarify whether a structured thematic analysis approach (e.g., Braun & Clarke, inductive or deductive coding) will be applied to

qualitative feedback or whether the thematic summary will be informal.

The pilot test–retest is a strong approach to identify items with potential measurement error. The manuscript would benefit from specifying how variation between the two measurements, if applicable, will be addressed before the survey.

Additionally, justification of the two-week interval is recommended, as short intervals may allow participants to recall previous responses. In contrast, longer intervals (e.g., three months) are sometimes recommended to capture independent responses more effectively. Though in practice, this is challenging to implement. Nevertheless, authors should acknowledge how the interval might impact their responses.

The translation and cross-cultural adaptation procedures are described as following a “linguistic and semantic equivalence approach,” but it is unclear which established framework was followed (e.g., WHO, ISPOR, TRAPD, Brislin).

Several aspects of the questionnaire itself warrant further detail. For instance, vaccination history items should account for differences in vaccination schedules across countries, particularly regarding COVID-19 boosters. Some countries had winter and spring boosters, while others don’t.

Similarly, questions regarding the promotion of vaccination should consider country-specific guidelines and free vaccination policies.

The inclusion criterion requiring participants to have a duty to promote vaccination may introduce bias if professionals do not perceive this as part of their role.

Clear definitions of professional categories, such as “health visitors,” would also aid clarity.

The statistical analysis section is currently vague. While the manuscript mentions that “appropriate statistical tests and models” will be used to examine associations, it would be preferable to specify which associations are of interest and which analytic approaches will be applied, even briefly. At the same time, the authors should emphasise that the primary focus of this protocol is questionnaire development and validation.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I'm a public health researcher with a background in epidemiology and statistics, and I am currently developing a questionnaire using the COMB framework.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 06 Nov 2025

Laura Panagi

This manuscript addresses an important gap by proposing the development and validation of a questionnaire to assess HCW readiness to promote vaccination. Overall, the protocol has many strengths, particularly its theoretical grounding and multi-step validation plan. Addressing the methodological clarifications outlined below will increase transparency and reproducibility, helping to ensure the resulting questionnaire can be applied confidently across various settings. With these revisions, the study has the potential to make a valuable contribution to both implementation research and vaccination promotion strategies.

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We agree with the reviewer that the Methods section would be strengthened by including the conceptual model and specifying the sub-dimensions considered. This information has now been added on page 9. In addition, Appendix 1 now provides the first version of the questionnaire, listing all items along with their corresponding domains and sub-domains of the COM-B model.

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In response to this comment, we now provide a justification for the 2-week interval time and acknowledge potential recall bias on page 15.

The translation and cross-cultural adaptation procedures are described as following a "linguistic and semantic equivalence approach," but it is unclear which established framework was followed (e.g., WHO, ISPOR, TRAPD, Brislin).

The framework underpinning the translation and cross-cultural adaptation process has now been specified on page 10.

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Indeed, vaccination schedules may differ across countries and, therefore, cognitive interviews were carried out with end users in each participating country to collect feedback on whether the questions and response options were appropriate and applicable within their specific country and healthcare systems. If measurement variance is identified, analyses will be conducted separately for each country. Conversely, if measurement invariance is established, pooled or cross-country comparative analyses will be considered. In interpreting the results, participants' country of residence and the

corresponding national vaccination guidelines will also be taken into account.

The inclusion criterion requiring participants to have a duty to promote vaccination may introduce bias if professionals do not perceive this as part of their role.

We acknowledge that healthcare professionals (HCPs) who do not perceive promoting vaccination as part of their role may not be eligible or find the survey applicable. The survey is specifically designed for HCPs who do see vaccination promotion as part of their professional duties but may face challenges in applying this behaviour due to factors such as capabilities, opportunities, or motivation. Most questions are not applicable to HCPs who do not consider vaccination promotion within their professional role hence the eligibility criterion.

Clear definitions of professional categories, such as “health visitors,” would also aid clarity.

Further information was added on page 12 to aid clarity of professional categories.

The statistical analysis section is currently vague. While the manuscript mentions that “appropriate statistical tests and models” will be used to examine associations, it would be preferable to specify which associations are of interest and which analytic approaches will be applied, even briefly. At the same time, the authors should emphasise that the primary focus of this protocol is questionnaire development and validation.

In response to this comment, the first paragraph of the Statistical Analysis section on page 14 has now been revised to reflect the primary focus of the protocol, which is questionnaire development and validation. Additionally, associations of interest and analytic approaches have now been added on page 14.

Competing Interests: Not any.

Author Response 09 Feb 2026

Laura Panagi

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Competing Interests: No competing interests were disclosed.