Design and content validation of a survey questionnaire assessing the determinants of human papillomavirus (HPV) vaccine hesitancy in France: A reactive Delphi study

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MANUSCRIPT

INTRODUCTION

In a global study conducted by the Wellcome Trust in over 140 countries, France was identified as the country with the lowest confidence in vaccine safety with “one in three people disagree that vaccines are safe”(1). In this context, vaccination to prevent human papillomavirus (HPV) infection, the most common sexually transmitted infection (STI) worldwide and the etiological agent of a range of conditions including anogenital and oropharyngeal cancers, is one of the most challenging in France.

In 2019, HPV vaccination in France is recommended for all girls aged 11-14 years and for those aged 15-19 years as a catch-up strategy. It is also recommended for girls and boys with immune deficiency conditions at ages 11-19, and for men who have sex with men (MSM) up to the age of 26 (2). The Ministry of Health is considering widening the target groups to include boys as the same ages of girls. Recently, the French National Authority for Health (HAS) (an independent public scientific advisory body) issued a favourable opinion on the widespread vaccination of boys (3).

HPV vaccination in France relies on individual initiative, requires parental authorization for those under 18 years, and is prescribed and administered by medical doctors. It can also be administered by nurses with a medical prescription. It is costly and only partially (65%) reimbursed by the National Health Insurance Fund, but those covered by a voluntary private health insurance (more than 95 % of the French population (4)) or by the Subsidized

Supplementary Health Insurance ("Complémentaire santé solidaire"/ CSS, granted for individuals whose income is below a given ceiling) are fully reimbursed.

Twelve years after its introduction, HPV vaccine uptake in France remains low, despite the extensive safety data accumulated for this vaccine both nationally and internationally (5–8). In 2018, the estimated coverage rate for full (two-dose) HPV vaccination was estimated at 23.7% in girls aged 16 years (9), well below the objective of a 60% coverage for a two-dose vaccination set by the National Cancer Control Plan (NCCP) 2014-2019 (10), and the coverage reached in other European countries, which ranged from less than 40% in Germany (11) to more than 85% in the United Kingdom (12).

Addressing the challenge of improving HPV vaccine coverage has been on the French government's and public health agencies' agenda since 2009. The second NCCP (2009-2013) aimed to improve the uptake of HPV vaccination in 14-year-old girls through the dissemination of appropriate information to the public on the HPV vaccination while emphasizing that cervical cancer screening using a cervical smear is still essential from the age of 25 onwards (13). The current (third) NCCP 2014-2019 has aimed to improve the uptake by increasing access to the vaccines in free vaccination canters and by training healthcare professionals (10).

The reasons for the low HPV vaccination coverage in France remain unclear (14–17). There are conflicting data on the role of socioeconomic status in vaccine uptake. In a large study using the French National Health Insurance Database, the authors concluded that no clear factor was identified as a vaccination determinant; they suggested that complex associations between socioeconomic and cultural factors could explain the low HPV vaccination coverage (15). A

European survey estimated that only 56% of French parents intended to have their eligible daughters vaccinated (versus 67% in the United Kingdom) (18). Furthermore, Verger and colleagues have found in a national panel of 1 712 general practitioners (GPs) that 28% did not recommend HPV vaccines to young girls (19), raising the issue of the negative influence of GPs in vaccination decision-making.

The phenomenon known as “vaccine hesitancy” may partly explain low HPV vaccine coverage in France. This term refers to a complex, multifaceted phenomenon which occurs within a spectrum, from full and partial, to no vaccination. It is defined by the World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE) vaccine hesitancy working group as “the delay in acceptance or refusal of vaccines despite availability of vaccination services (…) It is influenced by factors such as complacency, convenience and confidence”(20). The prevalence of vaccine hesitancy is estimated to be 48% (95% confidence interval [CI] 45.1-51.4) among French parents of adolescent girls aged 11-15 years; it is particularly high among those with a higher education level (21).

Hesitancy and its adverse impacts on vaccine uptake rates have been increasingly recognized by the WHO Strategic Advisory Group of Experts (SAGE) on Immunization, leading to the publication in 2015 of a compendium of tools to measure vaccine hesitancy (22). These tools include a matrix of vaccine hesitancy determinants organized in three main categories of survey questions: (i) contextual influences (e.g., cultural reasons, communication and social media), (ii) individual and group influences (e.g., immunization as a social norm versus not needed/harmful, distrust in the vaccine and lack of perceived benefit of the vaccine), and (iii) vaccine/vaccination-specific issues (e.g., vaccination schedule, costs, and strength of the

recommendation and/or attitude of healthcare professionals). This tool is a useful comprehensive approach to help diagnose major determinants of vaccine hesitancy (**Figure 1**). However, it was not designed as a survey-ready format for straightforward use in investigational activities, as acknowledged by the Working Group (22). Besides, the questions displayed in this matrix address vaccines in general, not the HPV vaccine in particular. This matrix was developed following a systematic review of existing research, the findings from an immunization managers' survey of vaccine hesitancy and expert consultation (23).

The problem at the heart of the failed efforts to increase HPV vaccination coverage may lie in the inability in identifying and addressing the actual root causes of vaccine hesitancy and refusal. It is, therefore, crucial to gain a greater understanding of the determinants of HPV vaccine hesitancy in the French context so that targeted interventions can be developed accordingly. There is currently no specific tool to assess the determinants of HPV vaccine hesitancy in France. This study aimed to develop and validate a specific French Survey Questionnaire for the Determinants of HPV Vaccine Hesitancy (FSQD-HPVH) to be later administered to mothers of girls of eligible to HPV vaccination, using the SAGE Working Group Determinants of Vaccine Hesitancy Matrix. Preliminary validation was undertaken through assessment of the items for content validity, i.e., the extent to which they are reflective of the factors considered in the SAGE working group model (24).

MATERIALS AND METHODS

Study Design

A two-round modified electronic Delphi methodology was implemented using an instrument developed in the online Research Electronic Data Capture (REDCap) survey system hosted at the Pierre Louis Institute of Epidemiology and Public Health (IPLESP), Paris Sorbonne University. REDCap is a secure, web-based software platform designed to support data capture for research studies (25). We used a Delphi approach since it is a universally recognized scientific technique for tapping individual judgments among experts from varying practices to build consensus (26,27). The Delphi methodology, developed by the Rand Corporation, is a structured approach to group interaction using self-completed questionnaires. Through an iterative process of consultation rounds, the members of the group (the "experts") can reconsider their responses to the questionnaire after receiving feedback about how their responses compare to those from the rest of the group. The numbers of iterations of experts review and consensus criteria were established before starting the study (28,29). Each panel member responded to the questionnaire individually and independently, unbiased by the identity and opinions of other panellists.

Delphi panel selection

The study scientific committee (comprised of FD, PC, and OL) identified potential participants providing a range of expertise and professional representation to ensure a broad knowledge base on the issue of HPV vaccine hesitancy. Experts were selected if they satisfied the following criteria: (1) had been engaged in clinical or research work related to the field of vaccination or HPV for at least 3 years and, (2) were based in France or spoke French. There are no hard rules for the number of Delphi panel participants, however, a panel of 10 to 18 experts is generally recommended (30). Thus, we decided to invite at least twice the recommended number of

panellists, allowing for a minimum 50% participation rate. In May 2019, we e-mailed invitation letters, including the information on the aim of the study and a description of the Delphi study procedures to each potential panel member. Willing participants completed a brief form regarding their demographic and professional data.

Survey instrument

Following an extensive literature review, the scientific committee drafted a list of items, covering the three main thematic categories ((i) contextual, (ii) individual and group and (iii) vaccine/vaccination specific influences) and sub-categories of the Working Group Determinants of Vaccine Hesitancy Matrix.

All of the matrix sub-categories were covered in our instrument, except “Geographic barrier” (which may be best assessed by objective measures such as indicators of health care supply in the area of residence), “Mode of administration” (which is unlikely to be a sizable concern in teenagers as opposed to babies and very young children), “Risk/benefit of scientific and epidemiologic evidence” and “Influential leaders, gatekeepers and anti-vaccination lobbies” (whose related items could fit another matrix category; for example, an item about past issues regarding another vaccine could also fit the “Historical influences” category – a limit of the matrix which has been described previously (31)). The survey instrument was developed in French. In addition, 19 items were taken from the HPV Attitudes and Beliefs Scale (32) (HABS) and 19 from the HPV General Knowledge and HPV Vaccination Knowledge Scales (33), all of which have been validated in the French-Canadian setting. When drawing from this instrument, we paid particular attention to the need for transcultural adaptation, and so we slightly reworded/reformulated 12 of the French-Canadian items. One item on religion was taken from

the Vaccine Confidence Project™ (34). Five items were taken from the Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ) (35). As there is no version of the HCAMQ validated in French, translation was performed. An initial translation (English into French) was performed by two French native-speaking authors (FD and PC). Back-translation (French to English) was then independently performed by a third author (PM, non-English native speaker but a fluent-speaking researcher who has been working in the UK for almost three decades). The list of websites information was drawn from the Vaccine Confidence Project™ data (36). Items that did not reach consensus and have not either attracted specific suggestion for reformulation were recirculated without modification in the wording.

Round 1

In June 2019, we launched the first round of our modified reactive Delphi consultation by sending the structured questionnaire to the expert panellists. Different from the traditional first stage of Delphi procedure which requests participants to deliver new thoughts on their own, we asked the experts panel to react to the items that we had pre-generated, hence the "reactive" feature of our Delphi study (37). The items included the set of response options if the questions required modalities of responses other than a numeric rating scale, i.e., yes/no or true/false/I do not know. Experts were queried as to whether or not each of the items proposed by the scientific committee was essential to assess a specific factor on a 3-point Likert scale, in which 1 point meant "Essential"; 2 "Useful but not essential", and 3 "Not necessary". Besides, experts were also invited to comment on items clarity/comprehension and suggest items potentially missing. As per the experts' comments, the scientific committee reworded original items that did not reach consensus and generated new ones.

Round 2

Two months later, in August 2019, we e-emailed individualized questionnaires to those experts who had returned Round 1 responses. Only items upon which consensus was not reached in Round 1 were retained for re-assessment in Round 2 (38), thereby allowing experts to focus on the questionable items and consider changing their score (especially for those that have been reformulated) (39) while reducing participant dropouts due to a burdensome questionnaire. For each statement, participants were shown their initial individual evaluation (which could be confirmed or modified) and feedback from the Round 1: frequency distribution of the ratings (thereby showing the general extent of agreement in the experts' opinions) and a summary of anonymous comments made by the panel on Round 1. Participants were asked to re-rate the items using the same method as in Round 1. The possibility to amend previous scores, taking into consideration the overall picture is a fundamental part to reach consensus. Participants were also asked the rate the newly generated items, in line with the suggestions of Round 1. Participants were asked to return Round 2 responses within four weeks, with the help of e-mail reminders. The survey instrument was finalised by excluding the questions that did not reach consensus in Round 2.

Data analysis

Lawshe's Content-Validity Ratio (CVR) was computed after each round to assess the consensus level for each statement. The CVR measures agreement among raters regarding how a particular item is essential to a particular construct. It is a function of the number of participants and their ratings and ranges from -1 to 1. When fewer than half of the participants rate the item as "essential," the CVR is negative, when half rate the item as "essential" and half do not, the

CVR is 0 and when all rate “essential,” the CVR is 1. The formula for computing the CVR is CVR = (n-N/2)/(N/2), where n = the number of participants rating the item as “essential” and N = the total number of participants. Items with CVR values equal to or greater to a certain threshold (determined according to the number of respondents) were considered excellent in agreement evaluation (40). Traditionally, Lawshe’s method requires experts to provide their ratings just once, and items are immediately discarded if they fail to meet the minimum critical value. In this study, we decided to subject the items that did not reach the minimum critical value to further evaluation (whether as initially formulated or reformulated as per the experts’ comments). This conservative approach ensured no question would be missed out, given the complexity and multifaceted nature of HPV vaccine hesitancy.

Demographic data of the experts’ panel, the percentages of responses to each statement, and the CVR were analysed using SAS (version 9.4, SAS Institute Inc., Cary North Carolina).

Ethics statement

In France, ethics approval is not required for research that does not involve patients. The written invitations to the experts requesting them to participate in the study incorporated items conveying confidentiality procedures, and the prerogative to erase their data and thus revoke participation at any time. Data privacy and confidentiality of all participants were ensured, although total anonymity could not be achieved due to the need to directly e-mail participants. However, participant identities were known only to the main author, and participants were unaware of the identities of the other panel members.

RESULTS

Panel composition and response rates

Of the 40 potential panel members invited to participate in the study, 18 (45%) responded and sent their demographic data. Of them, 15 (6 health care professionals and 9 non-clinicians academics/researchers) sent back Rounds 1 and 2 questionnaires. Panel members were all based in France, except two, based in Canada and the UK (**Table 1**). For 15 participants, the minimum critical value of the content validity ratio (CVR) was calculated to be 0.6 (Round 1) at α = 5%.

Round 1

In Round 1, 83 items were evaluated by the expert panel, and participants gave comments on 66 items (79%). A total of 35 (42%) items reached or exceeded the CVR minimum critical value and were set aside for inclusion in the final questionnaire. The analysis of the CVR of the individual items is shown in **Table 2**. Items rated “essential” by all the experts pertained to “Knowledge/awareness”, “Communication and media environment”, "Immunisation as a social norm versus not needed/harmful” and “The strength of the recommendation and/or knowledge base and/or attitude of healthcare professionals” factors.

Round 2

In Round 2, 66 items were submitted to the expert panel. Of those, 48 were items that did not reach consensus at Round 1 and were recirculated either as initially worded (n=25, 52%) or after rewording (n=23, 48%), and 18 were new items. Among the new items, 9 were drawn from existing instruments (one item about “Knowledge/awareness” drawn from the HPV General Knowledge and HPV Vaccination Knowledge Scales (33) , 3 items about “Immunisation as a

social norm vs. not needed harmful" drawn from the HABS (32), and 5 items about "Risk/benefit (perceived/heuristic)" drawn from the HABS (n=3) and from the HPV General Knowledge and HPV Vaccination Knowledge Scales (n=2) (33)); the remaining were developed by the scientific committee (**Table 2, Figure 2**). In total, consensus was reached on 22 items (33%). The analysis of the CVR of the individual items is shown in **Table 2**.

The final version of the survey instrument will include 57 items (**Figure 2** and **Supplemental File 1**): 10 items in the category "Contextual influences", 37 items in the category "Individual and group influences", and 10 items in the category "Vaccine/vaccination-specific issues".

DISCUSSION

In this study, we developed a survey instrument specifically intended to evaluate HPV vaccine hesitancy among mothers of age-vaccination daughters in France. Within two rounds of a reactive Delphi methodology that took 12 weeks from preparation to conclusion, we generated a pool of items and consulted a panel of 15 experts who helped develop and validate a list of questions that reflect the many factors identified in the SAGE Working Group Determinants of Vaccine Hesitancy Matrix and that should now be applied to a survey of HPV vaccination vaccine hesitancy among mothers in France.

This study builds on the limited literature to date about how to measure the determinants of HPV vaccine hesitancy. Before starting this exercise, we had found only tools focusing on partial aspects of the factors contributing to vaccine hesitancy, e.g., the Carolina HPV immunization attitudes and beliefs scale (CHIAS) (41) and HABS (32), but none looking at determinants comprehensively. The domains covered by the FSQD-HPVH that the above-mentioned tools do

not include are essentially those that fall under “Contextual factors”, for example, “Historical influences”, “Politics/policies” and “Communication and media environment”. The other domains not covered by existing questionnaires include the “Strengths of the recommendations and/or knowledge base and/or attitudes of healthcare professionals” and “Design of vaccination program/mode of delivery”. This study is novel in considering using the SAGE Working Group Determinants of Vaccine Hesitancy Matrix. This matrix has been used to classify the data of the Annual WHO/UNICEF JRF (which are collected globally across WHO Member States to monitor vaccine hesitancy) (42), but not as a data collection tool. We hope the current study will stimulate further use of this matrix to investigate vaccine hesitancy related to other vaccines or settings.

We constructed a questionnaire with the most content-valid items. It appeared that only 42% of the items were deemed representative of the construct (factor) they intended to measure at Round 1. This finding emphasizes the relevance of including the perspectives of a multidisciplinary panel of experts**.** However, some of the items could be selected after rewording (n=8/23, 35%). Each factor is represented by at least one item, except “Reliability and/or source of supply of vaccine and/or vaccination equipment” and “Costs”, which ended up without any item.

The main strengths of our study include the composition of a multidisciplinary and multi-stakeholder panel of experts and the rigorous multistage quantitative analysis of their responses. As vaccine hesitancy is a complex, multifaceted phenomenon, the problem needs to be examined in a multidisciplinary manner. An excellent retention rate (100%) was achieved in Round 2, avoiding the risk of response bias. However, some limitations need to be

acknowledged. First, the length of the final questionnaire might be challenging from a practical point of view. In a subsequent study, we aim to propose a shortened version based on factor analysis of the data collected through this questionnaire. Second, the sample size of the panel of experts was small, although it falls within the range recommended in the literature, and the calculation of the consensus criterion was weighted by the number of respondents. Third, we only performed the a priori-planned two rounds of Delphi survey. There is a delicate trade-off between the number of rounds and the risk of attrition, and it turned out that no modification in terms of rewording was required following Round 2, since the experts did not suggest any reformulations for the items that did not meet consensus. In addition, three factors ("Communication and media environment", "Perception of the pharmaceutical industry", "Health system and providers-trust and personal experience") ended up with only one item. Although single-item measures for each facet of multifaceted constructs have been suggested in the literature (43), these are often considered to compromise on reliability. Finally, the questionnaire was designed to target only the mothers as they often have the main decision-making power with regard to the HPV vaccination (44-46). Adaptation of the item "Personally, I have already had abnormal pap smears for which treatment was needed (conization/surgery)" would be required it the questionnaire is to be administered to fathers. Finally, the FSQD-HPVH was designed to be administered to the French population, with reference to the French health system and culture. However, our approach could provide a reference for other settings. The FSQD-HPVH has not yet been pilot-tested, but it is intended to aid in the evaluation of HPV vaccine hesitancy in France through administration to a large sample of mothers, which will, in turn, allow further validation.

CONCLUSION

In conclusion, 57 items of FSQD-HPVH with good content validity were developed in this study in preparation of a thorough evaluation of HPV vaccine hesitancy in France. Unlike other existing tools, the FSQD-HPVH is the first to comprehensively consider all factors that may influence HPV vaccine hesitancy, the first step towards an evidence-based approach to curbing the low HPV vaccination rates in France.

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Author's contributions

FD has participated in the design of the study, the generation of Delphi items, the data analysis, the redaction of the manuscript, and the revision process. PC and OL have participated in the design of the study, the generation of Delphi items, and the revision process. PM has participated in the redaction of the manuscript and the revision process. All authors have approved the final manuscript. All members of the FSQD-HPVH study group have participated in the Delphi procedure.

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Conflict of interest

FD declares that MSD vaccines have covered registration fees, transport and accommodation costs for attendance to a conference. PM, OL and PC declare no conflict of interest.