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# 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

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## 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

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

23 Twelve years after its introduction, HPV vaccine uptake in France remains low, despite the  
24 extensive safety data accumulated for this vaccine both nationally and internationally (5–8). In  
25 2018, the estimated coverage rate for full (two-dose) HPV vaccination was estimated at 23.7%  
26 in girls aged 16 years (9), well below the objective of a 60% coverage for a two-dose vaccination  
27 set by the National Cancer Control Plan (NCCP) 2014-2019 (10), and the coverage reached in  
28 other European countries, which ranged from less than 40% in Germany (11) to more than 85%  
29 in the United Kingdom (12).

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

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

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

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

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

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

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

## 82 **MATERIALS AND METHODS**

### 83 **Study Design**

84 A two-round modified electronic Delphi methodology was implemented using an instrument  
85 developed in the online Research Electronic Data Capture (REDCap) survey system hosted at the  
86 Pierre Louis Institute of Epidemiology and Public Health (IPLESP), Paris Sorbonne University.  
87 REDCap is a secure, web-based software platform designed to support data capture for research  
88 studies (25). We used a Delphi approach since it is a universally recognized scientific technique  
89 for tapping individual judgments among experts from varying practices to build consensus  
90 (26,27). The Delphi methodology, developed by the Rand Corporation, is a structured approach  
91 to group interaction using self-completed questionnaires. Through an iterative process of  
92 consultation rounds, the members of the group (the “experts”) can reconsider their responses  
93 to the questionnaire after receiving feedback about how their responses compare to those from  
94 the rest of the group. The numbers of iterations of experts review and consensus criteria were  
95 established before starting the study (28,29). Each panel member responded to the  
96 questionnaire individually and independently, unbiased by the identity and opinions of other  
97 panellists.

### 98 **Delphi panel selection**

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

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

## 110 **Survey instrument**

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

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

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

### 137 **Round 1**

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



## 150 **Round 2**

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

## 166 **Data analysis**

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

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

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

#### 184 **Ethics statement**

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

## 192 **RESULTS**

### 193 **Panel composition and response rates**

194 Of the 40 potential panel members invited to participate in the study, 18 (45%) responded and  
195 sent their demographic data. Of them, 15 (6 health care professionals and 9 non-clinicians  
196 academics/researchers) sent back Rounds 1 and 2 questionnaires. Panel members were all  
197 based in France, except two, based in Canada and the UK (**Table 1**). For 15 participants, the  
198 minimum critical value of the content validity ratio (CVR) was calculated to be 0.6 (Round 1) at  $\alpha$   
199 = 5%.

### 200 **Round 1**

201 In Round 1, 83 items were evaluated by the expert panel, and participants gave comments on  
202 66 items (79%). A total of 35 (42%) items reached or exceeded the CVR minimum critical value  
203 and were set aside for inclusion in the final questionnaire. The analysis of the CVR of the  
204 individual items is shown in **Table 2**. Items rated “essential” by all the experts pertained to  
205 “Knowledge/awareness”, “Communication and media environment”, “Immunisation as a social  
206 norm versus not needed/harmful” and “The strength of the recommendation and/or knowledge  
207 base and/or attitude of healthcare professionals” factors.

### 208 **Round 2**

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

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

219 The final version of the survey instrument will include 57 items (**Figure 2 and Supplemental File**  
220 **1**): 10 items in the category “Contextual influences”, 37 items in the category “Individual and  
221 group influences”, and 10 items in the category “Vaccine/vaccination-specific issues”.

## 222 **DISCUSSION**

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

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

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

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

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

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

279 **CONCLUSION**

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

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424 **Author's contributions**

425 FD has participated in the design of the study, the generation of Delphi items, the data analysis,  
426 the redaction of the manuscript, and the revision process. PC and OL have participated in the  
427 design of the study, the generation of Delphi items, and the revision process. PM has  
428 participated in the redaction of the manuscript and the revision process. All authors have  
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435 **Conflict of interest**

436 FD declares that MSD vaccines have covered registration fees, transport and accommodation  
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