

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 α
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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423

424 **Author's contributions**

425 FD has participated in the design of the study, the generation of Delphi items, the data analysis,
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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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