Supplementary File

Bocquier A, *et al. BMJ Open* 2022; 12:e057943. doi: 10.1136/bmjopen-2021-057943

Supplemental table 1 Teams conducting the PrevHPV programme (The PrevHPV Consortium)

Team n°	Contact/scientific leader	Field of expertise
1	EA 4360 APEMAC - Université de Lorraine 9 av. de la Forêt de Haye - BP 20199 - 54505 VANDOEUVRE LES NANCY Cedex Scientific leader, principal investigator: Pr THILLY Nathalie (email: n.thilly@chru-nancy.fr)	Epidemiology and Public health
2	Département de Médecine Générale - Université Paris - 24 rue du Faubourg Saint-Jacques -75679 PARIS Cedex 14 Scientific leader: Pr GILBERG Serge (email: sergegilberg@gmail.com)	Primary Care
3	Laboratoire Interuniversitaire de Psychologie - UFR Sciences de l'Homme et de la Société - Université Grenoble Alpes BP 47 - 38040 GRENOBLE Cedex 9 Scientific leader: Dr GAUCHET Aurélie (email: aurelie.gauchet@univ-grenoble-alpes.fr)	Health Psychology
4	CRCDC Pays de la Loire 5 rue des Basses Fouassières - 49000 ANGERS Scientific leader: Dr LE DUC-BANASZUK Anne-Sophie (email: as.banaszuk@depistagecancers.fr)	Public Health, Cancer prevention
5	Campus Santé Innovations - Faculté de Médecine Jacques Lisfranc 10 rue de la Marandière - 42270 SAINT-PRIEST-EN-JAREZ Scientific leader: Dr GAGNEUX-BRUNON Amandine (email: amandine.gagneux-brunon@chu-st-etienne.fr)	Infection Diseases
6	INSERM UMR 1123 ECEVE, Université de Paris,75010 PARIS Scientific leader: Pr CHEVREUL Karine (email: karine.chevreul@inserm.fr)	Health Economics
7	Institut Pasteur - 25 rue du Dr Roux - 75724 Paris cedex 15 Scientific leader: Dr MUELLER Judith (email: judith.mueller@ehesp.fr)	Epidemiology and Public health
8	CHRU de Tours - Centre d'investigation Clinique Bretonneau - 37044 Tours cedex 9 Scientific leader: Pr GIRAUDEAU Bruno (email: bruno.giraudeau@univ-tours.fr)	Biostatistics

Supplemental table 2 SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed in section
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Title page
	2b	All items from the World Health Organization Trial Registration Data Set	See Clinicaltrials.gov, NCT04945655
Protocol version	3	Date and version identifier	Title page
Funding	4	Sources and types of financial, material, and other support	Funding section
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page
	5b	Name and contact information for the trial sponsor	See Clinicaltrials.gov, NCT04945655
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Funding section
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Study organisation

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Introduction
	6b	Explanation for choice of comparators	Introduction
Objectives	7	Specific objectives or hypotheses	Study objectives and endpoints
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Study design and setting
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Study design and setting
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Eligibility and allocation of municipalities & Target populations
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	The three components of the intervention & Table 2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA (public health research)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA (public health research)

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA (public health research)
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Study objectives and endpoints & Table 1
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Sample size
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Data collection
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Eligibility and allocation of municipalities
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Eligibility and allocation of municipalities
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Eligibility and allocation of municipalities
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Data collection
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Details on the study's e-case report form and data management available on request.
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Statistical analyses
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Statistical analyses
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Primary endpoints: no missing data (health insurance database)

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Not required (in accordance with the French law regarding this type of research, and with the ethics committee's agreement)
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA (organisational intervention)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics and dissemination
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Ethics and dissemination
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	See Item 32
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA

Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Data collection
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Competing interests
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Data collection
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Ethics and dissemination
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	No individual consent required for this type of research (information sheets available in Supplemental text 2)
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license. NA: not applicable.

Supplemental table 3 Populations included in the statistical analyses

Endpoints	**Population included in analyses**	**Groups**
Vaccine coverage	Inhabitants of the municipality aged 11-14 years	1-6
KABP-6C	Adolescents attending the secondary school of the municipality	1-6
	Parents of adolescents attending the secondary school of the municipality	1-6
	GPs practicing in the municipality	1, 3, 5
Satisfaction regarding the intervention(s)/tool(s)	Adolescents attending the secondary school of the municipality	1-4
	Staff of the secondary school of the municipality	1-4
	GPs practicing in the municipality	1, 3, 5

GPs: general practitioners; KABP-6C: Knowledge, attitude, behaviours, practices and six psychological determinants of vaccination intention (Confidence, Complacency, Constraints, Calculation, Collective responsibility and social Conformism).

Supplemental text 1 Random sampling design

As part of the recruitment procedure, 351 municipalities were randomly selected from 1,205 eligible ones. Sampling was stratified for the school district and the French deprivation index [1] of the municipality. Due to feasibility constraints, municipalities located in schools districts/regions of the PrevHPV consortium were oversampled, using the following sampling ratios:

(i) Municipalities of school districts where one team of the consortium is located: 1/2;

(ii) Municipalities of school districts where no team of the consortium is located, but belonging to a region where a team is located: 1/5;

(iii) Municipalities of other selected school districts: 1/8.

The French deprivation index was dichotomised according to the median in the school district. This index is available by municipality in the French health insurance database (Système National des Données de Santé, SNDS). It is defined as the first component of a principal component analysis (PCA) of four variables coming from census data: the median household income, the percentage of high school graduates in the population aged 15 years and older, the percentage blue-collar workers in the active population, and the unemployment rate.

Reference

1. Rey G, Jougla E, Fouillet A, Hémon D. Ecological association between a deprivation index and mortality in France over the period 1997 – 2001: variations with spatial scale, degree of urbanicity, age, gender and cause of death. BMC Public Health. 2009;9:33.

Supplemental text 2 Information sheets (translated in English by the authors for the purpose of the publication)

Bocquier A, *et al. BMJ Open* 2022; 12:e057943. doi: 10.1136/bmjopen-2021-057943

A) Parents' information sheet (for groups 1 and 3)

PARENTS' INFORMATION SHEET

Version N°**4.0 07/10/2021**

N° Inserm	N°IDRCB	N° CPP	N°CNIL
C20-76	2020-A02031-38	AU 1655	921334

Dear Madam, Sir,

Your child's secondary school participates in the PrevHPV project ("Evaluation of a multicomponent intervention aiming at improving the acceptability of Human Papillomavirus (HPV) vaccination in France") coordinated by Pr Nathalie THILLY, investigator-coordinator[1] of this project.

The PrevHPV project is conducted by 8 research teams with expertise in Epidemiology, Social and Human Sciences and Primary Care. It is a multicentre study, i.e., conducted in several secondary schools in France.

This project is also supported by the Direction Générale de l'Enseignement Scolaire (DGESCO).

The purpose of this document is to give you written information to help you decide whether or not you and your child will participate in this project. You are free to participate or not. During the course of the project, if you need additional information, do not hesitate to ask questions to the head of your child's school or to the project referent (whose name appears on the project label stuck in your child's home-school liaison booklet). Persons under judicial protection are not eligible to participate in this study.

The Inserm, Institut National de la Santé et de la Recherche Médicale, is the sponsor[2] of this project (*Inserm - Pôle Clinique – Biopark, Bâtiment A 8 rue de la Croix Jarry 75013 Paris*).

1. CONTEXT, OBJECTIVES AND JUSTIFICATION

HPV infection is the most common viral infection of the reproductive tract worldwide.

It is associated with an increased risk of some cancers (cervix, vagina, vulva, penis, anus and oropharynx) among women and men.

Vaccination against HPV has been available for more than 10 years. It is effective against 90% of the HPV infections responsible for cancers and also protects against anogenital warts (also called condylomas).

Until 2019, vaccination was mainly recommended for young girls, but despite many reassuring data on the effectiveness and safety of the vaccine, less than 30% of girls aged 11 to 14 years are vaccinated in France.

In order to better fight this virus, as of December 16, 2019, it was decided to recommend the vaccine for boys aged 11 to 14 years too.

The aim of the PrevHPV project is to propose the implementation of different actions within secondary schools and to observe whether these actions allow increasing the number of vaccinated adolescents (girls and boys aged 11-14).

[1] The investigator is the person responsible for the conduct of the research at a trial site. If the research involves several investigators, one investigator-coordinator is appointed among them.

[2] The sponsor is an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a trial.

2. DESCRIPTION OF THE PROJECT

As part of the PrevHPV project, the intervention includes different actions that will be carried out within your child's school:

- **Some questionnaires will be completed online**, twice, by you and your child (if he/she is in 9th or 10th grade). The first questionnaire will be sent to you shortly and the second questionnaire will be completed in a few months. This step will take 15 minutes per questionnaire.

  These questionnaires aim at assessing your and your child's knowledge and perceptions about HPV infection and vaccination. Your child will complete the questionnaires during class hours and you will soon receive a web link to fill out the questionnaires yourself.

- Then, your child (if he/she is in 9th or 10th grade), will participate in educational sessions on HPV infections and vaccination as part of the school curriculum (sessions entitled "Education, Motivation and Mobilisation").

  During these sessions, specific tools developed as part of this project will be used (serious game, videos...). At the same time, **information meetings will be offered to you, the parents, whatever your child's grade (from 7th to 10th).** During these meetings, information on HPV infections and vaccination will be provided and you will be able to ask questions on this subject.

Then, if your child has not yet been vaccinated, he/she will be able to get vaccinated against HPV directly at school, subject to your agreement, during a day dedicated to vaccination. During this day, a physician and a nurse, working in a vaccination centre and used to vaccinate, will be present to vaccinate the teenagers whose parents (holders of the parental authority) have given their written consent. The project referent of your child's school will give you additional information on this intervention conducted by the vaccination centre soon. You are free to accept or refuse your child's vaccination. And, if you wish to refer to your general practitioner (or any other health professional of your choice) for this vaccination, this remains also possible.

For all participating municipalities, the number of vaccinated and unvaccinated adolescents aged 11-14 years will be collected using data from the Système National des Données de Santé (anonymous data on vaccines delivered in community pharmacies) and from vaccination and family planning centres (also anonymous data). These data will be collected before the intervention and then 2 months, 6 months and 12 months after the end of the intervention. These data will allow us to measure the impact of our project on the percentage of adolescents vaccinated against HPV.

Duration of your participation: 6 months
Total duration of the project: 6 years

3. EXPECTED BENEFITS, CONSTRAINTS, RISKS AND SPECIFIC PROJECT PROCEDURES

There is no risk associated with participating in this project.

Your and your child's participation is voluntary. You and your child are free not to answer the questionnaires. And if you agree to participate, you can stop your participation at any time for you and/or your child, without incurring any liability or prejudice as a result. Finally, if you do not want your child to answer the questionnaires during school hours, you just have to inform the head of the school or the project referent, whose name appears on the project label stuck in your child's home-school liaison booklet.

The results of this project will allow a better understanding of vaccination preferences from a scientific research perspective. These data can then help increase vaccination coverage in France and decrease the number of HPV-related infections in the population.

For more information or to discuss about vaccination, you can contact your general practitioner or visit the website https://vaccination-info-service.fr/

4. CONFIDENTIALITY AND PROCESSING OF YOUR AND YOUR CHILD'S PERSONAL DATA

As part of this project, the processing of your personal data and those of your child (in particular your age, sex, school municipality) will be performed to enable the analysis of the research's results. The execution of the public interest mission entrusted to Inserm justifies the processing of your personal data and that of your child for scientific research purposes. The collected data will not be directly identifying. These data will be identified by a non-identifying confidential number (participant code) which you will receive and be the only one able to enter. There will be no correspondence between this participant code and your child's identity.

How long your and your child's data will be retained and archived as part of this project:

The data collected through the questionnaires will be analysed by the PrevHPV teams under the responsibility of the investigator-coordinator.

Your and your child's data will be kept in the secure information systems of the PrevHPV consortium's data controller for a maximum of 7 years (duration of the project + 1 year necessary for the writing of the final report). Then, the data will be archived for 15 years.

Your rights

In accordance with the provisions of the Règlement Général sur la Protection des Données (Règlement (UE) 2016/679)) and of the law "n°78-17 relative à l'informatique, aux fichiers et aux libertés", you have the following rights:

- The right to object: the right to object at any time to the transmission of your and your child's data. You can exercise this right to object to the data collected (i.e., you can refuse to answer the project questionnaires). To do so, you just have to inform the head of the school or the project referent.

- The right to withdraw, at any time, your agreement regarding the collection of your and your child's data. To do so, you will have to communicate the participant code to the head of the school or to the project referent; this is the only way to make the link between your data, you and your child. If during the course of the project you no longer wish to participate, your and your child's data collected before your withdrawal will nevertheless be used by the

investigator-coordinator in accordance with the public health code. Indeed, their deletion would compromise the achievement of the project's objectives.

- The right of access to information about you and your child, in order to verify their accuracy and, if necessary, to rectify, complete or update them.
- The right to restrict processing: right to block the use of your data and those of your child, no action can be performed on them.

You will be able to exercise your rights and those of your child by contacting the head of the school or the project referent and by providing them with your child's participant code.
In case of difficulty in exercising your rights or those of your child, you can also contact the Inserm Data Protection Officer by email (dpo@inserm.fr) or postal mail (Délégué à la Protection des Données de l'Inserm, 101 rue de Tolbiac, 75 013 Paris).
If you are unable to exercise your rights "Informatique et Libertés" as mentioned above or if you feel that your personal data has been violated, we inform you that you also have the right to file a complaint with the "Commission Nationale de l'Informatique et des Libertés - CNIL- l'autorité française de protection des données personnelles", 3 Place de Fontenoy - TSA 80715, 75334 PARIS CEDEX 07 or online at https://www.cnil.fr.

Below is a summary table.

Data controller	**Data processor**	**Data Protection Officer**	**Supervisory authority**
Who is responsible for the project?	*Who to contact to exercise your rights?*	*In case of difficulties to exercise your rights*	*To file a complaint*
Institut National de la Santé et de la Recherche Médicale (Inserm)	Head of your child's school, project referent	DPO Inserm	CNIL
101 rue de Tolbiac, 75 013 Paris	Project referent's name appears on the project label stuck in your child's home-school liaison booklet	101 rue de Tolbiac, 75 013 Paris dpo@inserm.fr	3 Place de Fontenoy, TSA 80715, 75 334 PARIS CEDEX 07 https://www.cnil.fr

5. INFORMATION ON THE OVERALL RESULTS

You have the right to be informed of the overall results of this project. To do so, you can contact the head of the school or the project referent.
The results of this project can be presented during conferences or in scientific publications.
As no information allowing you to be identified is collected, your child's name and surname or your own will not be published.

6. LEGISLATIVE AND REGULATORY PROVISIONS

This project is carried out in accordance with the applicable regulations[3]. It was approved by the Comité de Protection des Personnes « SUD-EST VI » on 22/12/2020.

It was approved by the Commission Nationale de l'Informatique et des Libertés (CNIL) (reference 921334) on 26/10/2021.

Thank you for taking the time to read this information sheet.

[3]Articles L.1121-1 and following of the public health code, relating to research involving the human person.

Bocquier A, *et al. BMJ Open* 2022; 12:e057943. doi: 10.1136/bmjopen-2021-057943

B) Adolescents' information sheet (for groups 1 and 3)

ADOLESCENTS' INFORMATION SHEET

Version N°**4.0 07/10/2021**

N° Inserm	N°IDRCB	N° CPP	N°CNIL
C20-76	2020-A02031-38	AU 1655	921334

Your secondary school participates in the PrevHPV project ("Evaluation of a multicomponent intervention aiming at improving the acceptability of Human Papillomavirus (HPV) vaccination in France") coordinated by Pr Nathalie THILLY, investigator-coordinator[4] of this project.

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This project is also supported by the Direction Générale de l'Enseignement Scolaire (DGESCO).

The purpose of this document is to give you written information to help you decide whether or not you will participate in this project. You are free to participate or not. During the course of the project, if you need additional information, do not hesitate to ask questions to the head of your school or to the project referent (whose name appears on the project label stuck in your home-school liaison booklet).

The Inserm, Institut National de la Santé et de la Recherche Médicale, is the sponsor[5] of this project (*Inserm - Pôle Clinique – Biopark, Bâtiment A 8 rue de la Croix Jarry 75013 Paris*).

1. CONTEXT, OBJECTIVES AND JUSTIFICATION

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It is associated with an increased risk of some cancers (cervix, vagina, vulva, penis, anus and oropharynx) among women and men.

Vaccination against HPV has been available for more than 10 years. It is effective against 90% of the HPV infections responsible for cancers and also protects against anogenital warts (also called condylomas).

Until 2019, vaccination was mainly recommended for young girls, but despite many reassuring data on the effectiveness and safety of the vaccine, less than 30% of girls aged 11 to 14 years are vaccinated in France.

In order to better fight this virus, as of December 16, 2019, it was decided to recommend the vaccine for boys aged 11 to 14 years too.

The aim of the PrevHPV project is to propose the implementation of different actions within secondary schools and to observe whether these actions allow increasing the number of vaccinated adolescents (girls and boys aged 11-14).

[4] The investigator is the person responsible for the conduct of the research at a trial site. If the research involves several investigators, one investigator-coordinator is appointed among them.

[5] The sponsor is an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a trial.

2. DESCRIPTION OF THE PROJECT

As part of the PrevHPV project, the intervention includes different actions that will be carried out within your school:

- First, you will be asked to **complete an online questionnaire during class hours**. This step will take 15 minutes. This questionnaire aims at assessing your knowledge and perceptions about HPV infection and vaccination. *(This first questionnaire will be provided soon.)*

- Then, some educational sessions on HPV infections and vaccination (entitled "Education, Motivation and Mobilisation") will be proposed as part of the school curriculum. These sessions will be performed during class hours, specifically for pupils in grades 9th and 10th). **During these sessions, some specific tools developed as part of this project (serious game, videos…) will be used. You will be asked whether or not you found these tools appropriate.**
  (Your parents will also be invited to information meetings on this topic and will be able to ask questions on it).

Then, if you have not yet been vaccinated, you will be able to get vaccinated against HPV directly at school during a day dedicated to vaccination. During this day, a physician and a nurse, working in a vaccination centre and used to vaccinate, will be present to vaccinate the teenagers whose parents (holders of the parental authority) have given their written consent. The project referent of your school will give you additional information on this intervention conducted by the vaccination centre soon. You and your parents are free to accept or refuse this vaccination. And, if you want to get vaccinated but not at school, you and your parents can refer to your general practitioner (or any other health professional of your choice). After the vaccination at school, we will ask you to complete a questionnaire of satisfaction about the action performed by the vaccination centre.

- Lastly, you will be asked to **complete another online questionnaire during class hours**. This step will take 15 minutes. This questionnaire aims at assessing whether your knowledge and perceptions about HPV infection and vaccination have changed since the beginning of the intervention.

For all participating municipalities, the number of vaccinated and unvaccinated adolescents aged 11-14 years will be collected using data from the Système National des Données de Santé (anonymous data on vaccines delivered in community pharmacies) and from vaccination and family planning centres (also anonymous data). These data will be collected before the intervention and then 2 months, 6 months and 12 months after the end of the intervention. These data will allow us to measure the impact of our project on the percentage of adolescents vaccinated against HPV.

Duration of your participation: 6 months
Total duration of the project: 6 years

3. EXPECTED BENEFITS, CONSTRAINTS, RISKS AND SPECIFIC PROJECT PROCEDURES

There is no risk associated with participating in this project.

Your participation is voluntary. If you do not want to answer the questionnaires during school hours, you just have to inform the head of the school or the project referent, whose name appears on the project label stuck in your home-school liaison booklet.

The results of this project will allow a better understanding of vaccination preferences from a scientific research perspective. These data can then help increase vaccination coverage in France and decrease the number of HPV-related infections in the population.

For more information on HPV and/or HPV vaccination you can contact your general practitioner or visit the website https://vaccination-info-service.fr/

4. CONFIDENTIALITY AND PROCESSING OF YOUR PERSONAL DATA

As part of this project, the processing of your personal data (in particular your age, sex, school municipality) will be performed to enable the analysis of the research's results. The execution of the public interest mission entrusted to Inserm justifies the processing of your personal data for scientific research purposes. The collected data will not be directly identifying. These data will be identified by a non-identifying confidential number (participant code) which you will receive and be the only one able to enter. There will be no correspondence between this participant code and your identity.

How long your data will be retained and archived as part of this project:

The data collected through the questionnaires will be analysed by the PrevHPV teams under the responsibility of the investigator-coordinator.

Your data will be kept in the secure information systems of the PrevHPV consortium's data controller for a maximum of 7 years (duration of the project + 1 year necessary for the writing of the final report). Then, the data will be archived for 15 years.

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In accordance with the provisions of the Règlement Général sur la Protection des Données (Règlement (UE) 2016/679)) and of the law "n°78-17 relative à l'informatique, aux fichiers et aux libertés", you have the following rights:

- The right to object: the right to object at any time to the transmission of your data. You can exercise this right to object to the data collected (i.e., you can refuse to answer the project questionnaires). To do so, you just have to inform the head of the school or the project referent.
- The right to withdraw, at any time, your agreement regarding the collection of your data. To do so, you will have to communicate the participant code to the head of the school or to the project referent; this is the only way to make the link between your data and you. If during the course of the project you no longer wish to participate, your data collected before your withdrawal will nevertheless be used by the investigator-coordinator in accordance with the public health code. Indeed, their deletion would compromise the achievement of the project's objectives.
- The right of access to information about you, in order to verify their accuracy and, if necessary, to rectify, complete or update them.

- The right to restrict processing: right to block the use of your data, no action can be performed on them.

Your parents will be able to exercise your rights by contacting the head of the school or the project referent and by providing them with your participant code.

In case of difficulty in exercising your rights, your parents can also contact the Inserm Data Protection Officer by email (dpo@inserm.fr) or postal mail (Délégué à la Protection des Données de l'Inserm, 101 rue de Tolbiac, 75 013 Paris).

If you are unable to exercise your rights "Informatique et Libertés" as mentioned above or if you feel that your personal data has been violated, we inform you that you also have the right to file a complaint with the "Commission Nationale de l'Informatique et des Libertés - CNIL- l'autorité française de protection des données personnelles", 3 Place de Fontenoy - TSA 80715, 75334 PARIS CEDEX 07 or online at https://www.cnil.fr.

Below is a summary table.

Data controller	**Data processor**	**Data Protection Officer**	**Supervisory authority**
Who is responsible for the project?	*Who to contact to exercise your rights?*	*In case of difficulties to exercise your rights*	*To file a complaint*
Institut National de la Santé et de la Recherche Médicale (Inserm)	Head of the school, project referent	DPO Inserm	CNIL
101 rue de Tolbiac, 75 013 Paris	Project referent's name appears on the project label stuck in your home-school liaison booklet	101 rue de Tolbiac, 75 013 Paris dpo@inserm.fr	3 Place de Fontenoy, TSA 80715, 75334 PARIS CEDEX 07 https://www.cnil.fr

5. INFORMATION ON THE OVERALL RESULTS

You have the right to be informed of the overall results of this project. To do so, you can contact the head of the school or the project referent.

The results of this project can be presented during conferences or in scientific publications.

As no information allowing you to be identified is collected, your child's name and surname or your own will not be published.

6. LEGISLATIVE AND REGULATORY PROVISIONS

This project is carried out in accordance with the applicable regulations[6]. It was approved by the Comité de Protection des Personnes « SUD-EST VI » on 22/12/2020.

It was approved by the Commission Nationale de l'Informatique et des Libertés (CNIL) (reference 921334) on 26/10/2021.

Thank you for taking the time to read this information sheet.

[6]Articles L.1121-1 and following of the public health code, relating to research involving the human person.

C) General practitioners' information sheet

GENERAL PRACTITIONNERS' INFORMATION SHEET

Version N°**5.0 07/10/2021**

N° Inserm	N°IDRCB	N° CPP	N°CNIL
C20-76	2020-A02031-38	AU 1655	921334

Dear colleague,

The "Département de Médecine Générale" of the Université de Paris (Pr Serge Gilberg) participates in the PrevHPV project ("Evaluation of a multicomponent intervention aiming at improving the acceptability of Human Papillomavirus (HPV) vaccination in France") coordinated by Pr Nathalie THILLY, investigator-coordinator[7] of this project.

The PrevHPV project is conducted by 8 research teams with expertise in Epidemiology, Social and Human Sciences and Primary Care. It is a multicentre study, i.e., conducted in several secondary schools in France.

This project is also supported by the Direction Générale de l'Enseignement Scolaire (DGESCO).

The purpose of this document is to give you written information to help you understand the project and decide whether or not you will participate in this project. You are free to participate or not.

The Inserm, Institut National de la Santé et de la Recherche Médicale, is the sponsor[8] of this project (*Inserm - Pôle Clinique – Biopark, Bâtiment A 8 rue de la Croix Jarry 75013 Paris*).

1. CONTEXT, OBJECTIVES AND JUSTIFICATION

HPV infection is the most common viral infection of the reproductive tract worldwide.

It is associated with an increased risk of some cancers (cervix, vagina, vulva, penis, anus and oropharynx) among women and men.

Vaccination against HPV has been available for more than 10 years. It is effective against 90% of the HPV infections responsible for cancers and also protects against anogenital warts.

Until 2019, vaccination was mainly recommended for young girls, but despite many reassuring data on the effectiveness and safety of the vaccine, the vaccine coverage in France remains one of the lowest in Europe; it is lower than 30% among girls aged 11 to 14 years.

Since December 16, 2019, the Haute Autorité de Santé (HAS) has recommended the expansion of the vaccination to boys aged 11-14 years (universal vaccination).

This project aims at improving the acceptability of HPV vaccination in France. To that purpose, the PrevHPV teams will perform actions in secondary schools and one action among general practitioners.

[7] The investigator is the person responsible for the conduct of the research at a trial site. If the research involves several investigators, one investigator-coordinator is appointed among them.

[8] The sponsor is an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a trial.

These actions are the following:

1. **'Education, Motivation, Mobilisation'** targeting adolescents and their parents and aiming at information/educating on HPV infections and vaccination;
2. **'HPV vaccination at school'** which consists of a vaccination day on school premises where health professionals from local vaccination centres initiate HPV vaccination;
3. **'General practitioners' training'** with a training on the use of motivational interviewing techniques in the field of vaccination and provision of an educational tool to support the dialogue necessary for parents to make an informed decision to vaccinate an adolescent.

Indeed, in the context of vaccination in general, general practitioners play a key role, but to date have only been rarely targeted in actions aimed at improving vaccination coverage. Every day, we, general practitioners, face vaccine hesitancy and because of our proximity to young people and their parents, we are a significant source of information and can help them in their decision making.

2. DESCRIPTION OF THE PROJECT

You are located in a municipality where we are evaluating the effect on vaccination coverage of training for general practitioners and in order to be able to invite you to participate in the PrevHPV project, we have used the public contact information available in the "pages jaunes" and the "Conseil National de l'Ordre des Médecins" directories.

We offer you, if you wish, access to our training modules on HPV and its vaccination, the technique of motivational interviewing in the field of vaccination and the use of a decision aid tool that will be made available to you and that you can use afterwards.

This is an **online training which lasted about 3 hours** and **composed of 4 modules that you can follow according to your availability (and by stopping and starting again at any time)**.

If you agree to follow the proposed training, **we will also ask you to complete 2 online questionnaires, one at the beginning of the training and the second at the end of the training (about 5 minutes per questionnaire) on your activity and your practices regarding PrevHPV vaccination. A compensation of 350€ is available for the general practitioners who have followed the training and completed the 2 questionnaires.**

If you do not wish to participate, we simply ask you to inform us.

If you agree to participate, you may withdraw at any time without incurring any liability or prejudice. We will simply ask you to inform us.

From now on and throughout the duration of your participation, if you need additional information, you can contact the team of **Pr Gilberg Serge by contacting the PrevHPV Project Manager**:

Mme Minghui ZUO

07 81 92 47 23 - minghui.zuo@parisdescartes.fr

For all participating municipalities, the number of vaccinated and unvaccinated adolescents aged 11-14 years will be collected using data from the Système National des Données de Santé (anonymous data on vaccines delivered in community pharmacies) and from vaccination and family planning centres (also anonymous data). These data will be collected before the intervention and then 2 months, 6 months and 12 months after the end

of the intervention. These data will allow us to measure the impact of our project on the percentage of adolescents vaccinated against HPV.

Duration of your participation: 6 months
Total duration of the project: 6 years

3. EXPECTED BENEFICES, CONSTRAINTS, RISKS AND SPECIFIC PROJECT PROCEDURES

There is no risk associated with participating in this project.
The results of this research will help identify potentially effective actions to increase the acceptability of HPV vaccination, from a scientific research perspective. These data can then help increase vaccination coverage in France and decrease the number of HPV-related infections in the population.

4. CONFIDENTIALITY AND PROCESSING OF YOUR PERSONAL DATA

As part of this project, the processing of your personal data will be performed to monitor the progress of the project and enable the analysis of the research's results. The execution of the public interest mission entrusted to Inserm justifies the processing of your personal data for scientific research purposes.

The project manager of Pr Gilberg's team will provide you with a confidential non-identifying code to use when you complete the online questionnaire. The PrevHPV team in charge of analysing the questionnaires will not know your identity and will only know the confidential code.

How long your data will be retained and archived as part of this project:
The data collected through the questionnaires will be analysed by the PrevHPV teams under the responsibility of the investigator-coordinator.
Your data will be kept in the secure information systems of the PrevHPV consortium's data controller for a maximum of 7 years (duration of the project + 1 year necessary for the writing of the final report). Then, the data will be archived for 15 years.
Once the data has been collected and checked, the table of correspondence between your confidential code and your identity held by the "Université Paris - Département de Médecine Générale" during contacts with general practitioners throughout the project will be deleted (i.e., at the end of two years following the start of the intervention).

Your rights
In accordance with the provisions of the Règlement Général sur la Protection des Données (Règlement (UE) 2016/679)) and of the law "n°78-17 relative à l'informatique, aux fichiers et aux libertés", you have the following rights:

- The right to object: the right to object at any time to the transmission of your data and to the collection of your data in the future. You can exercice this right to object to data collected. For that, you just have to inform the Pr Gilberg's team (address above).
- The right to withdraw, at any time, your agreement regarding the collection of your data. If during the course of the project you no longer wish to participate, your data collected before your withdrawal will nevertheless be used by the investigator-coordinator or her representative

in accordance with the public health code. Indeed, their deletion would compromise the achievement of the project's objectives. For that, you just have to inform the Pr Gilberg's team.

- The right of access to information about you, in order to verify their accuracy and, if necessary, to rectify, complete or update them.
- The right to restrict processing: right to block the use of your data, no action can be performed on them.

You will be able to exercise your rights for 24 months after the start of the intervention. After that, the correspondence table between your participant code and your identity will be deleted. You will then have to communicate your participant code to exercise your rights, please keep it.

In case of difficulty in exercising your rights, you can also contact the Inserm Data Protection Officer by email (dpo@inserm.fr) or postal mail (Délégué à la Protection des Données de l'Inserm, 101 rue de Tolbiac, 75 013 Paris).

If you are unable to exercise your rights "Informatique et Libertés" as mentioned above or if you feel that your personal data has been violated, we inform you that you also have the right to file a complaint with the "Commission Nationale de l'Informatique et des Libertés - CNIL- l'autorité française de protection des données personnelles", 3 Place de Fontenoy - TSA 80715, 75334 PARIS CEDEX 07 or online at https://www.cnil.fr.

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Institut National de la Santé et de la Recherche Médicale (Inserm)	Pr Gilberg's team	DPO Inserm	CNIL
101 rue de Tolbiac, 75 013 Paris	Département de Médecine Générale - Université Paris - 24 rue du Faubourg Saint-Jacques -75679 PARIS Cedex 14 01.44.41.23.63 sergegilberg@gmail.com	101 rue de Tolbiac, 75 013 Paris dpo@inserm.fr	3 Place de Fontenoy, TSA 80715, 75334 PARIS CEDEX 07 https://www.cnil.fr

5. INFORMATION ON THE OVERALL RESULTS

You have the right to be informed of the overall results of this project by contacting the Pr Gilberg's team.

The results of this project can be presented during conferences or in scientific publications.

Your data will be completely anonymous and you will not be identified. Your data will generally be aggregated with that of other participants in order to reach overall scientific conclusions.

6. LEGISLATIVES AND REGULATORY PROVISIONS

This project is carried out in accordance with the applicable regulations[9]. It was approved by the Comité de Protection des Personnes « SUD-EST VI » on 22/12/2020.

It was approved by the Commission Nationale de l'Informatique et des Libertés (CNIL) (reference 921334) on 26/10/2021.

Thank you for taking the time to read this information sheet.

[9]Articles L.1121-1 and following of the public health code, relating to research involving the human person.