

SUMMARY OF THE PROTOCOL FOR RESEARCH MENTIONED IN 30 OF ARTICLE L. 1121-1 OF THE PUBLIC HEALTH CODE INVOLVING ONLY QUESTIONNAIRES OR INTERVIEWS

Research title	Evaluation of healthcare workers knowledge regarding their vaccination status and their relationship to vaccination at Melun Hospital
Acronym	Statuvax Pro
Registration number (ID-RCB)	2023-A00923-42
Date and version number of abstract :	Version 6 of 31/07/2023
Date and version number of information and consent form :	Version 4 of 31/07/2023
Date and version number of questionnaires / Interview:	Version 4 of 31/07/2023

Compliance of this request with the procedure planned in II of article R. 1123-20 of the French Public Health Code (a negative response to one of the four criteria below means that you are not qualify for this procedure) :

This research involves only data collected by questionnaire(s) or interview(s) :

☒ YES

☐ NO

This research hasn't consequences for the participants, either in terms of safety or in terms of modifying their usual care

☒ YES

☐ NO

This research is risk-free and the disadvantages for the research participants are negligible:

☒ YES

☐ NO

The collection and processing of data used in this research complies with the reference methodology MR003 approved by the CNIL :

☒ YES

☐ NO

Administrative informations

Last name, first name (individual sponsor) or legal form, name (corporate promoter) :	Groupe Hospitalier Sud Ile de France
E-mail address :	drc.promotion@ghsif.fr
Adress :	270 avenue Marc Jacquet 77000 Melun
Telephone :	01 81 74 17 17
Head of Clinical Research Unit	M. Arezki AGHER
E-mail	arezki.agher@ghsif.fr
Phone/Fax	Tel : 01 81 74 22 28 Fax : 01 81 74 25 59

Investigator or, if applicable, coordinating investigator

Last name, First name and Function :	Dr Pierre Leroy, MD
E-mail address :	pierre.leroy@ghsif.fr
Address of main research location :	270 avenue Marc Jacquet 77000 Melun
Phone :	01 81 74 20 62
Nombre de centre si recherche multicentrique :	Monocentric research

Background and rationale

Research background	<p>Vaccination coverage for adults in France is mediocre: only 44% of people aged 65 and over are up to date with diphtheria, tetanus and infectious polio vaccinations (1), and in an earlier study in 2002, among people aged 16 and over, 71.2% against tetanus, 41.9% against infectious polio and 33.7% against diphtheria (2). Other vaccinations, such as pneumococcal, may be recommended depending on the individual's co-morbidities, and vaccination coverage is sometimes very low, depending on the pathology (less than 2% of people living with diabetes mellitus are correctly immunized against pneumococcus) (3), whereas vaccination coverage against SARS-CoV-2 is much better (over 90% among diabetics, for example), according to French health insurance data (4), under the influence of a proactive, even coercive vaccination policy.</p> <p>Healthcare professionals in France are subject to a number of vaccination obligations, and following successive anti-SARS-CoV2 vaccination campaigns, these obligations are under discussion. Even healthcare professionals are reluctant to be vaccinated (5-7), particularly in view of</p>
----------------------------	---

annual vaccination rates against seasonal influenza: 22% were vaccinated against seasonal influenza in 2022, and 25.9% knew their general vaccination status (8).

As part of the national "European Vaccination Week" event organized by the French Ministry of Health and Prevention, we propose a questionnaire designed for hospital healthcare workers to assess their knowledge of their own vaccination status, and evaluate their attitude with vaccination.

1. National Institute of health monitoring (InVS). National survey of vaccine coverage, France, January 2011. Vaccination coverage against seasonal influenza in target groups and measure of vaccine efficacy. Vaccination coverage with diphtheria-tetanus-polio vaccines (dTP) and... [Internet]. 2011 [cited 11 Apr 2023] p. 21. Available from : <https://www.santepubliquefrance.fr/content/download/181715/2304769?version=1>
2. Guthmann JP, Fonteneau L, Antona D, Lévy-Bruhl D. Vaccination coverage against diphtérie, tétanos, poliomyélite among adults in France : results of the health and social protection survey, 2002. Bull Epidemiol Hebd. déc 2007;(51-52):441-5.
3. Wyplosz B, Fernandes J, Sultan A, Roche N, Roubille F, Loubet P, et al. Pneumococcal and influenza vaccination coverage among at-risk adults: A 5-year French national observational study. Vaccine. 5 août 2022; 40(33):4911-21.
4. Data Vaccin Covid (Assurance Maladie) [Internet]. [cité 11 avr 2023]. Disponible sur: <https://datavaccin-covid.ameli.fr/pages/home/>
5. Haviari S, Bénet T, Saadatian-Elahi M, André P, Loulergue P, Vanhems P. Vaccination of healthcare workers: A review. Human Vaccines & Immunotherapeutics. 2 nov 2015;11(11):2522-37.
6. Paterson P, Meurice F, Stanberry LR, Glismann S, Rosenthal SL, Larson HJ. Vaccine hesitancy and healthcare providers. Vaccine. 20 déc 2016;34(52):6700-6.
7. Napolitano F, Bianco A, D'Alessandro A, Papadopoli R, Angelillo IF. Healthcare workers' knowledge, beliefs, and coverage regarding vaccinations in critical care units in Italy. Vaccine. 31 oct 2019;37(46):6900-6.
8. Santé Publique France. Quelle est la couverture vaccinale contre la grippe des professionnels exerçant dans les établissements de santé ? [Internet]. Santé

	Publique France; 2022 juin p. 6. (Le point sur.). Disponible sur: https://www.santepubliquefrance.fr/maladies-et-traumatismes/maladies-et-infections-respiratoires/grippe/documents/enquetes-etudes/quelle-est-la-couverture-vaccinale-contre-la-grippe-des-professionnels-exercant-dans-les-etablissements-de-sante-point-au-1er-juin-2022
Research hypotheses	Knowledge of own vaccination status is less than 50% among healthcare workers working at Groupe Hospitalier Sud Ile de France.
Objectives and evaluation criteria	
Primary research objective and primary endpoint (maximum 750 characters)	Evaluation of the rate of knowledge of own vaccination status among healthcare workers working at Groupe Hospitalier Sud Ile de France.
Secondary objective(s) and potential secondary endpoint(s) (maximum 1500 characters)	Assessment of the relationship between healthcare workers of Groupe Hospitalier Sud Ile de France and vaccination in general.
Study Organization	
A. Summary description of the study plan (maximum 750 characters)	<p>Questionnaire : Hetero-randomized, anonymous, online questionnaire proposed as a recommendation during the "European Vaccination Week" event.</p> <p>Link to questionnaire : https://redcap.ghsif.fr/surveys/?s=JEWWTMCMFEDNN9FD</p>
B. Questionnaire/interview methodology	
- Questionnaire (s) Yes	

Terms and conditions :

Questionnaire administered by:

- ☐ E-mail
☒ internet
☐ phone
☐ face to face
☐ other (specify)

Questionnaire administered in :

- ☒ one go
☐ several times (specify number of times)

Questionnaire type:

- ☒ if validated, indicate origin of validation: The questionnaire was tested on a sample of the target population and experts.
☐ if not validated, justify :

Free comments (if necessary, to clarify the above answers, especially when more than one questionnaire is passed) :

Free comments (if necessary, to clarify the above answers, especially when several interviews are held) :

C. Statistical analysis framework and/or biostatistician's references :

Descriptive statistics (frequencies, means, standard deviations). Analysis of independent variables using the Chi-2 test.

Information on research implementation

A. Type of research location (e.g. hospital department, doctor's surgery, school, etc.)

Hospital department

B. Estimated duration of research :

1 week

C. Estimated duration of participation per person :

10 minutes

D. Does the research also involve retrospective data collection :

- ☐ YES
☒ NO

E. Personnes incluses dans la recherche	
Number of participants :	At least 100
Inclusion criteria :	Anyone working at GHSIF
Non-inclusion criteria :	Any person refusing to participate
Secondary exclusion criteria :	Demonstration of the right to withdraw from the study
Does the research include people with no affection?	Yes
Method of recruiting survey participants :	Healthcare executives, department heads
Information and traceability procedures for non-opposition :	Signed non-opposition form
F. Disadvantages for research participants	
Estimated duration of data collection by interview or questionnaire for one participant :	10 min
Anticipated total duration of research participation for a participant if data collection is carried out in several stages (duration between inclusion and last data collection) :	10 min
Maximum transport time estimated for participants if applicable :	N/A