VACCINATION OF
PROFESSIONALS WORKING IN
THE HEALTH AND MEDICO-SOCIAL
SECTORS: PATIENT SAFETY,
PROFESSIONAL RESPONSIBILITY
AND THE SOCIAL CONTEXT



VACCINATION OF PROFESSIONALS WORKING IN THE HEALTH AND MEDICOSOCIAL SECTORS: PATIENT SAFETY, PROFESSIONAL RESPONSIBILITY AND THE SOCIAL CONTEXT

This opinion was voted on in the plenary committee on 6 July 2023.

Some CCNE members wanted the associated publication of a text entitled "Different Opinion".

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Some CCNE members wanted the associated publication of a text entitled "Different Opinion" on page 44.

SUMMARY

On 21 November 2022, the Minister for Health and Prevention referred the matter of compulsory vaccination for health professionals and professionals working in the health and medico-social sectors to the CCNE. This designation includes not only health professionals (caregivers) but also other categories of professionals (maintenance staff, care assistants, administrative staff, catering staff, entertainment staff, reception staff, security officers, etc.) working within medicosocial and health institutions¹. The referral states that it wants "to know the CCNE's opinion on defining criteria that can be used to justify, or not, the introduction of compulsory vaccination, in particular with regard to considering the values of individual freedom on the one hand and the collective benefit and public interest underlying the social contract brought about by vaccination on the other hand". Within the context of Covid-19 that still persists, the CCNE wished to broaden its thinking with a forward-looking vision.

At the same time, the Director General for Health asked the French National Authority for Health [Haute autorité de santé (HAS)] to conduct an assessment of all compulsory and recommended vaccinations for professionals in the health and medico-social sectors.

1. Protecting patients: a key requirement for caregivers

 Having considered the issues raised by compulsory vaccination in care and medico-social settings, the CCNE's position can be summarised as follows, given the further knowledge and expected progress with new types of vaccines:

The CCNE believes that against a backdrop that poses increased risks of exposure to infectious agents, the challenge of reducing the risk of transmission to patients and residents as much as possible should be among the key commitments of people working in the health and medico-social sectors.

Considering the duty to protect the fundamental rights of patients, especially the frailest whose protection depends on others, and the safety of care requirement, the CCNE considers that vaccinating health professionals against infectious diseases - when a vaccine is available that shows a positive benefit-risk ratio for the population - is a joint responsibility for the professions of the health and medico-social sectors, aiming to do everything to minimise the risk to patients.

2. A range of protective measures

¹ Within the meaning used in Part I of the Opinion.

• The CCNE points out, however, that vaccination should not be considered as the only prevention tool, especially in care settings. All the means currently available to limit the risks of infection in care settings as much as possible such as wearing a mask, ventilating premises, hand hygiene particularly with the wide use of hydroalcoholic solutions, screening tests and vaccination must be considered complementary and regularly reviewed based on collective benefits versus individual risk.

It is established that vaccines do not always fully guarantee non-transmission of an infectious agent but that they generally help to reduce the risk of infection and the risk of severe or serious forms of infection.

In view of these elements, the CCNE emphasises that vaccination is part of a range of tools that complement each other, none of which is fully effective. These tools make it possible to achieve the objectives of protecting against the risks of patient infection and the infection of people working in care settings or settings in which there are frail people.

3. A distinction between a health crisis and an everyday situation

 This opinion is part of a biomedical context revolutionised by new techniques for producing vaccines in much shorter time frames than before. The CCNE has focused its thinking on a forward-looking framework to apply in the event of possible future health crises due to one or more infectious agents.

In view of the issues raised by the vaccine strategy for professionals working in care settings, the CCNE notes that a **distinction between an everyday situation and a health crisis period** (as defined by the World Health Organization)² needs to be established in the decision-making processes involved.

The CCNE is thus committed to furthering thinking in order to distinguish a crisis period, which may in some cases justify compulsory vaccination, which is a political decision, from vaccination in an everyday situation, so that the tools available can be adapted to both these situations. This must be done by prioritising the practice of health democracy promoting the expression of all stakeholders, professionals, health system experts and users, including those belonging to the most vulnerable populations in the face of the pathogens concerned. This democratic practice is a necessity because it involves the most accurate assessment of the situation, based on shared knowledge that is explained to all stakeholders; it specifies the expected role of a vaccination and defines the legal framework that applies.

Taking into account the duty to protect the fundamental rights of patients and the safety of care requirement:

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² See II.4. of this Opinion.

- in an everyday situation, the CCNE encourages the provision of information and assuming responsibility aimed at doing everything possible to minimise risks for patients, prioritising the use of recommended vaccines; compulsory vaccination may apply when starting studies or a job in respect of vaccines that have demonstrated a very high benefit-risk ratio such as that against hepatitis B, for example³, and as recently mentioned by the National Authority for Health (HAS) in its recommendation of 14 June 2023⁴ on measles vaccination.
- in the event of a health crisis⁵ potentially endangering the healthcare system, and where there is a solid scientific body of material guaranteeing the effectiveness (even moderate) and safety of the vaccine concerned, the CCNE considers that the political decision to impose compulsory vaccination on professionals in the health and medico-social sectors, whose vaccination is a priority, may be legitimate, on a precautionary basis in view of a potential risk to patients or frail individuals and in order to maintain an operational healthcare system.

4. Promoting information and discussion with professionals

- To encourage the ethics of responsibility among professionals in the health and medico-social sectors as mentioned in its opinion drawn up with the National Conference of Regional Ethical Thinking Spaces [Conférence nationale des espaces de réflexion éthique régionaux (CNERER)] on "Ethical issues raised by vaccination against Covid-19" 6 published on 29 March 2021 the CCNE advocates that recommended and/or compulsory vaccinations, and in general all decisions involving measures likely to cause tension within teams, follow cobuilding processes with the target occupational groups and associations representing users, in particular those belonging to the most vulnerable populations in the face of the pathogens concerned.
- In view of the large amount of disinformation or conflicting information inherent in crisis situations and the furthering of knowledge, the health and medico-social sectors are required to adapt.

³ As the HAS noted in its opinion of 29 March 2023: HAS, "Compulsory and recommended vaccination for professionals. An update of the recommendations and obligations for students and professionals in health and medico-social sectors and those in close contact with young children. Part 1/2: diphtheria, tetanus, poliomyelitis, hepatitis B, Covid-19", 29 March 2023. https://www.has-sante.fr/upload/docs/application/pdf/2023-03/obligations-et-recommandations-vaccinales-des-professionnels-actualisation-des-reco-et-obligations-pour-les-etudiants-et-pr.pdf

⁴ HAS, "Compulsory and recommended vaccination for professionals. An update of the obligations and recommendations for students and professionals in health and medico-social sectors and those in close and repeated contact with young children. Part 2/2: whooping cough, seasonal flu, hepatitis A, measles, mumps, rubella, chicken pox", 14 June 2023. https://www.has-sante.fr/upload/docs/application/pdf/2023-06/recommandation-obligations-vaccinales-des-professionnels-volet-2-consultation-publique.pdf

⁵ Within the meaning used in Part II.4. of the Opinion.

⁶ CCNE, CNERER, "Ethical issues raised by vaccination against Covid-19", 29 March 2021, 10 p.; https://www.ccne-ethique.fr/sites/default/files/2021-07/CCNE-CNERER%20-%200pinion%2025.03.21.pdf

The CCNE encourages, on the one hand, **enhancing the scope of the initial and continuing training** of professionals – regardless of their position and whether they are caregivers or non-caregivers – in the area of vaccination and, more broadly, in terms of health-related **professional responsibilities**. This could be based on **raising awareness of the ethics of care**.

On the other hand, the appointment, in institutions, of a vaccination officer with a solid basis in vaccinology and ethics, who can be turned to in case of doubts, fears and questions about a vaccination could help to ease possible tensions. It is about increasing the number of contact points and having a structured and shared approach on thinking related to vaccinations which are subject to discussion.

At society level, there is the issue of the influence that hesitant professionals may
have on the patients they encounter with regard to certain vaccinations. Although
quantitatively low, the vaccine hesitancy of doctors and other caregivers has a
significant impact since the general public has a great deal of confidence in these
professionals.

5. The urgent need for research and evaluation tools

The CCNE notes, on the one hand, significant gaps in data on vaccination coverage and the level of vaccine hesitancy for professionals working in care settings. A better assessment of the vaccine hesitancy phenomenon, including through qualitative surveys and polls, would increase knowledge and help develop strategies for informing health professionals and the institutions that are responsible for them. Thus, the Committee recommends developing and approving tools that can be used to measure these elements on a regular basis.

On the other hand, and taking a macro-social view, as part of provisions aimed at easing tensions around compulsory vaccination, the CCNE considers it essential not to be limited to only clinical and epidemiological arguments and to take into account the social and political contexts both national and local in which these tensions arise.

- In summary, following on from its previous work and excluding the particular case
 of vaccines that have demonstrated a very high benefit-risk ratio such as, currently,
 the hepatitis B vaccine, the CCNE considers that the question of compulsory
 vaccination for professionals working in the health and medico-social sectors can
 only be raised as a last resort, i.e.:
 - in the face of a health situation that poses a major and serious threat to the population, and which may undermine the operation of the healthcare system;
 - even if there are scientific uncertainties about the effectiveness of the vaccine, once knowledge at the population level shows documented benefits and the individual risks appear to be low and closely monitored.

Such a decision, which belongs to the politicians, can only be taken following a process that has been clearly explained, debated and supported by health structures and professional organisations.

For the CCNE, the issue is not how to justify the obligation but whether it is acceptable under the main principles mentioned above.

The Committee stresses the importance of raising awareness of the decision-making processes leading to recommendations or obligations for professionals. In terms of compulsory vaccination more specifically, it is up to the institutions to provide information on how expertise is produced for newly introduced vaccines, including the independence of knowledge building.

PREAMBLE

"Vaccination of Caregivers, a Priority"⁷. Under this title of an editorial of the *Le Monde* newspaper published in March 2021, one year after the start of the Covid-19 pandemic, it is pointed out that "no health decision can be taken without dialogue or education, no discourse on the pandemic can be delivered without taking into account the tensions that are pervading society".

The publication of this editorial was at a particular point in the timeline of the health crisis in France: only one third of medical staff⁸ were vaccinated despite priority access to the SARS-CoV-2 vaccine since January 2021 due to their high exposure to the virus. The same proportion was observed in the EHPADs (residential homes for dependent elderly people) and USLDs (long-term care units) which accommodate particularly vulnerable people.

On 12 July 2021, the President of the Republic finally announced compulsory vaccination against Covid-19 for people working in the health and medico-social sectors⁹. The Law of 5 August 2021¹⁰ (Art. 12) defines the scope of compulsory vaccination by laying down three non-cumulative criteria: the place of practice, the profession of the individuals concerned and the conditions under which the work is carried out. Decree No. 2021-699 of 1 June 2021 amended by Decree No. 2021-1059 of 7 August 2021 specified the reasons for exceptions to the obligation¹¹.

Although the increase in vaccination coverage was noticeable between March and July 2021, the decision taken and framework thus set probably helped to increase the level of vaccination coverage for the first dose of the vaccine both among professionals working in EHPADs or USLDs, from 77.2% on 12 July 2021 to 92.6% on 15 September 2021 (+15.4%) and among medical staff in private practice whose vaccination coverage for the first dose increased from 81.2% to 95.1% between 12 July and 15 September 2021 (+13.9%)¹².

⁷ Editorial of *Le Monde*, "*Vacciner les soignants, une priorité*" [Vaccination of Caregivers, a Priority], 09/03/2021 (https://www.lemonde.fr/idees/article/2021/03/09/vacciner-les-soignants-une-priorite_6072468_3232.html).

⁸ According to Santé publique France, InfoCovidFrance, "Chiffres clés et évolution de la COVID-19 en France et dans [Key figures and evolution of COVID-19 in France https://www.santepubliquefrance.fr/dossiers/coronavirus-covid-19/coronavirus-chiffres-cles-et-evolution-de-lacovid-19-en-france-et-dans-le-monde. The definition used by Santé publique France includes "all health professionals regardless of their place of practice (private practice, private or public health institution, medicosocial institution, others, etc.) [...] outpatient, other health professionals: students, prevention practitioners)", in: Santé publique France, "Covid-19, Point épidémiologique hebdomadaire n° 64 du 20 mai 2021" [Covid-19, Weekly Epidemiological No. 64 20 of https://www.santepubliquefrance.fr/content/download/346156/document_file/COVID19-PE_20210520_signets.pdf?version=3.

⁹ Elysée, "Address to the French people - 12 July 2021"; https://www.elysee.fr/emmanuel-macron/2021/07/12/adresse-aux-francais-12-juillet-2021.

¹⁰ Law No. 2021-1040 of 5 August 2021 on the management of the health crisis (1); https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043909676.

¹¹Decree No. 2021-1059 of 7 August 2021 amending Decree No. 2021-699 of 1 June 2021 laying down the general measures necessary for managing the recovery from the health crisis; https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043915443.

¹² Santé publique France, InfoCovidFrance, Ibid.

More than two years have passed since this rule was rolled out from which certain tensions have emerged, both in care settings and the political arena.

Health professionals are already subject to special vaccination provisions, as has been the case since 1991 with the obligation to be protected against hepatitis B. However, for several years, France has been described as a country that is particularly hesitant over vaccines¹³. In 2019, the American polling institute Gallup revealed that one in three French respondents disagreed with the idea that "vaccines are safe", i.e. the highest proportion worldwide¹⁴. Nearly 20% of French respondents also disagreed with the statement "vaccines are effective", i.e. ranking in second place after Liberia¹⁵.

The same study points out that 73% of people surveyed (all countries combined) have more confidence in health professionals than any other source of health advice. Therefore, how can we understand the vaccine hesitancy of the general population without taking into account the medical professions' relationship with vaccinations? It was in this sensitive context that on 21 November 2022, the Minister for Health and

Prevention referred the matter¹⁶ of compulsory vaccination for health professionals and professionals working in the health and medico-social sectors to the CCNE. The referral states that it wants "to know the CCNE's opinion on defining criteria that can be used to justify, or not, the introduction of compulsory vaccination, in particular with regard to considering the values of individual freedom on the one hand and the collective benefit and public interest underlying the social contract brought about by vaccination on the other hand". The CCNE was asked to carry out an expanded analysis of all vaccinations likely to concern the professionals mentioned.

At the same time, the Director General for Health asked the French National Authority for Health [Haute autorité de santé (HAS)] to conduct an assessment of all compulsory and recommended vaccinations for professionals in the health and medico-social sectors. Following an initial opinion from the HAS dated 29 March 2023¹⁷ and in accordance with legislative provisions¹⁸, the Minister for Health and Prevention made the decision to reinstate staff not vaccinated against Covid-19 to health institutions, sparking heated public and political debate.

¹⁶ See the matter referred in Appendix 4.

<u>O3/obligations et recommandations vaccinales des professionnels actualisation des reco et obligations pou r les etudiants et pr.pdf</u>

¹³ This matter was already topical before the Covid-19 pandemic, see for example: Ward, J.K., Peretti-Watel, P., Bocquier, A. et *al.*, (2019), "Vaccine hesitancy and coercion: all eyes on France", *Nature Immunology*, 20, 1257–1259; https://doi.org/10.1038/s41590-019-0488-9.

¹⁴ Wellcome, "How does the world feel about science and health?", *Wellcome Global Monitor*, 2018; https://wellcome.org/reports/wellcome-global-monitor/2018.

¹⁵ See Box 2

¹⁷ HAS Opinion of 29 March 2023: HAS, "Compulsory and recommended vaccination for professionals. An update of the recommendations and obligations for students and professionals in health and medico-social sectors and those in close contact with young children. Part 1/2: diphtheria, tetanus, poliomyelitis, hepatitis B, Covid-19", 29 March 2023.

https://www.has-sante.fr/upload/docs/application/pdf/2023-

¹⁸ Article 12, Chapter II of Law No. 2021-1040 dated 5 August 2021; https://www.legifrance.gouv.fr/loda/article_Ic/LEGIARTI000046119263.

As part of their respective missions, covering for the CCNE the ethical aspects and for the HAS the medical and scientific elements relating to the scope of compulsory and recommended vaccination for professionals in the health and medico-social sectors, both institutions, while forming their opinions with complete independence, wanted to engage in discussion throughout the process of preparing their work.

The CCNE's previous stance on vaccination

Up to that point, the CCNE had given little consideration to the scope of the vaccine strategy, but the Committee invested heavily in this area during the Covid-19 pandemic during which it prepared four works on this topic:

- In its response to the matter referred by the Minister for Solidarity and Health on the "Ethical Issues of a SARS-COV-2 Vaccination Policy" 19 published on 18 December 2020 and therefore written in a context of vaccine uncertainty (availability, risks), the CCNE considered that, in the context of the Covid-19 pandemic, compulsory vaccination "can only be seen as a last resort, in the face of very serious danger created by an uncontrolled pandemic, with a supply of vaccines which are known to be effective and safe, and which have been tested with the objectiveness required. If the situation changes and compulsory vaccination is envisaged, this issue will have to give rise, in the light of the circumstances at the moment, to a consultation which will have to address ethical issues in particular.
- In its opinion on the "Ethical issues raised by vaccination against Covid-19" published on 29 March 2021, drawn up with the National Conference of Regional Ethical Thinking Spaces [Conférence nationale des espaces de réflexion éthique régionaux (CNERER), the CCNE updated its position in view of the changes in the pandemic's dynamics, in particular regarding the vaccination of health professionals. Considering the large proportion of unvaccinated caregivers, the CCNE and CNERER considered it "imperative to set themselves the objective of ensuring that all health professionals and medico-social workers working in institutions and in homes are vaccinated as soon as possible". This was based on an ethic of responsibility and solidarity, as well as the principle of non-malfeasance, and it stated that "vaccination, beyond its personal and collective impact, is a matter of professional ethics and meets an ethical requirement".
- The CCNE also addressed the issue of vaccinating minors during the pandemic. In its opinion of 8 June 2021 on the "Ethical issues related to Covid-19 vaccination

¹⁹ During the Covid-19 crisis, the CCNE decided to publish certain texts, responses and bulletins, which are not counted as numbered opinions. CCNE, "Enjeux éthiques d'une politique vaccinale contre le SARS-COV-2. Réponse du CCNE à la saisine du ministre des solidarités et de la santé" [Ethical Issues of a SARS-COV-2 Vaccination Policy. The CCNE's response to the matter referred by the Minister for Solidarity and Health,] 18 December 2020, 21 p.; https://www.ccne-ethique.fr/sites/default/files/2021-07/Saisine%20Vaccins.pdf

²⁰ CCNE, CNERER, "Enjeux éthiques soulevés par la vaccination contre la Covid-19" [Ethical issues raised by vaccination against Covid-19], 29 March 2021, 10 p.; https://www.ccne-ethique.fr/sites/default/files/2021-07/CCNE-CNERER%20-%200pinion%2025.03.21.pdf

for children and adolescents"²¹, in response to a referral from the Minister for Solidarity and Health, the CCNE questioned the direct individual benefit of COVID-19 vaccination for healthy children and adolescents (hardly affected by severe forms of Covid-19) in terms of infection-related risks. In view of the knowledge available at the time, the CCNE concluded that vaccinating children under the age of 12 did not appear "ethically and scientifically acceptable" because there was "no study assessing the safety of COVID-19 vaccines in this population". With regard to adolescents (12-16 years of age), the CCNE considered that the "very low" "individual benefit in connection with the infection [...] in the absence of comorbidity" did not seem sufficient to justify vaccination alone. The CCNE was in fact advocating an adolescent-specific pharmacovigilance follow-up and recommended that clear and appropriate information be provided to adolescents wishing to have the vaccine.

• Finally, the CCNE was asked to give a further opinion on the vaccination of children under 12 years of age in response to a referral from the Minister for Solidarity and Health, in its opinion of 16 December 2021, "Is it ethically acceptable to offer the Covid-19 vaccination to children aged 5-11 years old?»²². In this opinion written in a context of uncertainty, the CCNE considers that vaccinating children aged 5 to 11 without comorbidities, although ethically acceptable, must nevertheless meet several requirements: up-to-date knowledge of the benefits and risks of the vaccine, respecting the informed choice of parents and the absence of constraints, not rushing the preparation of a vaccine campaign, establishing a pharmacoepidemiologic follow-up for the 5 to 11 year-old age group and ensuring that the organisation of child vaccination does not interfere with the booster dose which is necessary and a priority for adults.

The CCNE's thinking on the Covid-19 vaccination strategy emphasised the uncertainty at the time regarding knowledge about the vaccines in question. The Committee attached particular importance to preparing these recommendations, taking into account the highly evolving nature of the available data. It should be noted that knowledge about vaccines evolved during this period, particularly as regards the duration of their effectiveness and their role in transmission. However, it is important to note that the CCNE had not hitherto been referred the matter of compulsory vaccination for health workers, outside the specific context of this pandemic. There

https://www.ccne-ethique.fr/sites/default/files/2021-

²¹ CCNE, "Enjeux éthiques relatifs à la vaccination contre la Covid-19 des enfants et des adolescents" [Ethical issues related to Covid-19 vaccination for children and adolescents], 29 March 2021, 19 p.;

^{07/}Enjeux%20%C3%A9thiques%20relatifs%20%C3%A0%20la%20vaccination%20Covid%2008.06.21.pdf

²² CCNE, "Proposer la vaccination contre la Covid-19 aux enfants de 5-11 ans est-il éthiquement acceptable ? Réponse du CCNE à la saisine du ministère des solidarités et de la santé" [Is it ethically acceptable to offer the Covid-19 vaccination to children aged 5-11 years old? The CCNE's response to the referral from the Ministry for Solidarity and Health], 16 December 2021, 15 p.; https://www.ccne-ethique.fr/sites/default/files/2022-02/ccne-vaccination_des_enfants_-15.12.pdf

has been a scientific debate on this topic for many years, especially on the flu vaccine²³.

INTRODUCTION: PROTECTING PATIENTS

1. Framework for ethical thinking on the issues of compulsory vaccination in care settings

The opposition of some health professionals, even a minority, observed after the introduction of the compulsory SARS-CoV-2 vaccination among these professions calls for reflection on the ethical issues of the vaccination strategy for people working in the health and medico-social sectors, taking into account the major crisis affecting the entire healthcare system.

Compulsory vaccination sets patients' rights against the safety of actions, health safety and the specific obligations of professionals carrying out a care or support role in contact with the people under their care.

The CCNE believes that in a care situation with increased risks of exposure to infectious agents, the challenge of reducing the risk of transmission to patients and residents as much as possible should be among the key commitments of people working in the health and medico-social sectors.

Considering the **duty to protect the fundamental rights of patients**, especially the frailest whose protection depends on others, and the **safety of care** requirement, the CCNE considers that **vaccinating health professionals** against infectious diseases – when a vaccine is available that shows a positive benefit-risk ratio for the population – **is the joint responsibility** for the professions of the health and medico-social sectors, aiming to do everything to minimise the risk to patients.

With regard to Covid-19 in particular, the benefit of vaccinating caregivers was twofold: it provided protection against the disease and its serious forms and also enabled the health system to remain operational.

2. Vaccination should not be considered as the only prevention tool

All the means currently available to limit the risks of infection in care settings as much as possible such as wearing a mask, ventilating premises, hand hygiene particularly with the wide use of hydro-alcoholic solutions, screening tests and vaccination must be considered complementary and regularly reviewed based on collective benefits versus individual risk. These tools are a joint responsibility for the professions of the health and medico-social sectors.

It is established that vaccines do not fully guarantee non-transmission of a pathogen but that they generally help to reduce the risk.

The CCNE emphasises that vaccination is part of a range of tools that complement each other, none of which is fully effective. These tools make it possible to achieve the objectives of protecting against the risks of patient infection and the infection of people working in care settings.

3. A distinction between an everyday situation and a health crisis period

The CCNE points out that this opinion is part of a biomedical context revolutionised by new vaccine production techniques. The Committee has focused its thinking on a forward-looking framework to apply in the event of possible future health crises due to one or more infectious agents.

In view of the issues raised by the vaccine strategy for professionals working in care settings or facilities for frail people, the CCNE notes that a **distinction between an everyday situation and a health crisis period** needs to be established in the decision-making processes involved.

The CCNE is thus committed to furthering thinking in order to distinguish a crisis period, which may in some cases justify compulsory vaccination, which is a political decision, from vaccination in an everyday situation, so that the tools available can be adapted to both these situations. This must be done by prioritising the practice of health democracy, promoting the expression of all stakeholders, professionals, health system experts and users, including those belonging to the most vulnerable populations in the face of the pathogens concerned. This democratic practice is a necessity because it involves the most accurate assessment of the situation, based on shared knowledge that is explained to all stakeholders; it specifies the expected role of a vaccination and defines the legal framework that applies.

Taking into account the duty to protect the fundamental rights of patients and the safety of care requirement:

- in an everyday situation, the CCNE encourages the provision of information to, and the joint responsibility of, the health and medico-social professions, in order to do everything possible to minimise risks for patients and residents, prioritising the use of recommended vaccines; compulsory vaccination may apply when starting studies or a job in respect of vaccines that have demonstrated a very high benefit-risk ratio such as that against hepatitis B, for example²⁴, and as recently mentioned by the National Authority for Health (HAS) in its recommendation of 14 June 2023²⁵ on measles vaccination:
- in the event of a health crisis potentially endangering the healthcare system, and where there is a solid scientific body of material guaranteeing the effectiveness (even moderate) and safety of the vaccine concerned, the CCNE considers that the political decision to impose compulsory vaccination on

²⁴ As the HAS noted in its opinion of 29 March 2023: HAS, "Compulsory and recommended vaccination for professionals. An update of the recommendations and obligations for students and professionals in health and medico-social sectors and those in close contact with young children. Part 1/2: diphtheria, tetanus, poliomyelitis, hepatitis B, Covid-19", 29 March 2023. https://www.has-sante.fr/upload/docs/application/pdf/2023-03/obligations-et-recommandations-vaccinales-des-professionnels-actualisation-des-reco-et-obligations-pour-les-et-udiants-et-pr.pdf

²⁵ HAS, "Obligatory and recommended vaccination for professionals. An update of the obligations and recommendations for students and professionals in health and medico-social sectors and those in close and repeated contact with young children. Part 2/2: whooping cough, seasonal flu, hepatitis A, measles, mumps, rubella, chicken pox", 14 June 2023. https://www.has-sante.fr/upload/docs/application/pdf/2023-06/recommandation_obligations_vaccinales_des_professionnels_volet_2_consultation_publique.pdf

professionals in the health and medico-social sectors, whose vaccination is a priority, **may be legitimate** on a precautionary basis **in view of a potential risk** to patients and residents and in order to maintain an operational healthcare system.

I. PROFESSIONALS IN THE HEALTH AND MEDICO-SOCIAL SECTORS AND COMPULSORY VACCINATION: BETWEEN SOLIDARITY AND AUTONOMY

The terms "professionals in the health and medico-social sectors" and "health professionals" used in this opinion cover a wide **range of stakeholders, places and conditions of practice**. In order to observe the scope of the referral, the CCNE relies on the definitions provided by the relevant legislation, i.e.:

- Law No. 91-73 of 18 January 1991 laying down provisions on public health and social insurance created Article L10 of the French Public Health Code, which, for the first time, provided for the compulsory vaccination of health professionals in France. The Decree of 31 March 1991 establishes the public or private institutions or bodies for prevention or care in which exposed personnel must be vaccinated regardless of the public or private nature of the institution²⁶.
- Today, it is Article L.3111-4 of the French Public Health Code that makes vaccinations against "hepatitis B, diphtheria, tetanus and poliomyelitis (27) compulsory" for individuals engaged in a professional activity "within a public or private institution or body for prevention or care or within those accommodating the elderly"28 exposing them or exposing the individuals for whom they are responsible to the risks of infection; the status of the professional (civil servant, salaried employee, private practitioner) is irrelevant, and it also applies to students in the medical and paramedical fields. This article gives a ministerial order the authority to determine, after an opinion from the HAS, the categories of institutions and bodies concerned.

Compulsory vaccination is required for the professionals concerned. They are subject to a termination of their contract or termination of their civil servant position in the event of non-vaccination (except in the case of a medical contraindication recognised by the occupational physician).

²⁶ Decree of 15 March 1991 establishing the list of public or private institutions or bodies for prevention or care in which exposed personnel are to be vaccinated.

²⁷ See however the HAS' opinion of 29 March 2023: HAS, "Compulsory and recommended vaccination for professionals. An update of the recommendations and obligations for students and professionals in health and medico-social sectors and those in close contact with young children. Part 1/2: diphtheria, tetanus, poliomyelitis, hepatitis B, Covid-19", 29 March 2023. https://www.has-sante.fr/upload/docs/application/pdf/2023-03/obligations-et-recommandations-vaccinales-des-professionnels-actualisation-des-reco-et-obligations-pour-les-etudiants-et-pr.pdf

²⁸ Article L3111-4 of the French Public Health Code, as amended by Law No. 2017-220 of 23 February 2017 - Art. 4 (V).

Furthermore, it is recommended that professionals in the health and medico-social sectors are vaccinated against seven diseases: whooping cough, flu, hepatitis A, measles, mumps, rubella and chicken pox²⁹.

In its 2016 opinion "on compulsory vaccination for health professionals" published in conjunction with the national consultation on compulsory vaccination, the French Public Health Council [Haut Conseil de la santé publique] recommended that any decision to introduce or maintain compulsory vaccination in care settings must concern situations where there is "a serious disease with a high risk of exposure for the professional, a risk of transmission to patients or the person in care and the existence of an effective vaccine of which the benefit-risk ratio is largely in favour of the vaccine"31. This means taking into account the evolution of the epidemiology of the diseases concerned in order to adapt compulsory vaccination to public health requirements.

Law No. 2021-1040 of 5 August 2021³² on managing the health crisis establishing compulsory vaccination for health and medico-social professionals against Covid-19 as of 15 September 2021 suddenly emerged within the specific context of a major crisis, requiring a series of collective measures.

Comparatively, in the general population, compulsory vaccination mainly concerns the vaccination of children³³ and has been extended from three to eleven diseases since Decree No. 2018-42 of 25 January 2018 on compulsory vaccination: previously limited to diphtheria, tetanus and polio (Articles L. 3111-2 and 3 and R. 3111-2 and 3 of the French Public Health Code), it now also applies to: whooping cough, Haemophilus influenzae type b, hepatitis B, meningococcus C, pneumococcal, measles, mumps and rubella.

1. International perspectives: different vaccine strategies

Developing vaccination as an individual preventive action to control or limit the effects of certain diseases is among the public health objectives of each country. The Covid-

²⁹ Santé publique France, VaccinationInfoService.fr, "Recommandations vaccinales spécifiques" [Specific vaccine recommendations], "professionnels de santé" ["Health Professionals" section]; volet https://professionnels.vaccination-info-service.fr/Recommandations-vaccinales-specifiques/Professionnelsexposes-a-des-risques-specifiques/Professionnels-de-sante

³⁰ Haut Conseil de la santé publique (HCSP), (2016), "Avis relatif aux obligations vaccinales des professionnels de santé" [Opinion on compulsory vaccination for health professionals], 10 p.

https://www.hcsp.fr/Explore.cgi/Telecharger?NomFichier=hcspa20160927_obligationsvaccinalesprosant%C3%A9. pdf

³¹ HCSP, (2016), Ibid, p. 6.

No. 2021-1040 of August 5 2021 the health crisis (1);on managing https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043909676

³³ Compulsory vaccination in the general population applies to any child born after 1 January 2018. Since 1 June 2018, it has been a requirement for any child entering the community (crèche, leisure centre, nursery school, care provided by a childminder, school, etc.) regardless of the status of the form of childcare, private or public. Article L.3111-2 French **Public** of the Health Code: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006687781/2016-01-28; Article 49 of Law No. 2017-1836 30 December ٥f 2017: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006687781

19 pandemic only reinforced the inequalities in access to vaccination across regions of the world, challenging the mechanisms of international solidarity, as was the case before, especially with access to HIV treatment.

The Covid-19 crisis also highlighted differences in vaccine strategies rolled out across countries with respect to a possible obligation. Since the increase in the number of compulsory vaccines in 2018, from three to eleven childhood vaccinations (see above, p. 17), France is among the countries with the largest number of compulsory vaccines for the general public ³⁴ along with Italy, Greece and several Eastern European countries.

Vaccination strategies for health professions follow almost the same model: out of 36 European countries, one third have implemented one or more compulsory vaccinations for health professionals ³⁵, including, in addition to France, several Eastern European countries, Portugal and Belgium. The Scandinavian and Anglo-Saxon countries as well as Switzerland stand out for vaccination policies, both in the general population and among health professionals, which are more focused on incentive than obligation.

However, the outbreak of the pandemic led many European countries to make COVID-19 vaccination mandatory for health professionals³⁶. Yet the difficulties encountered and the evolution of the virus as well as the pandemic have prompted the vast majority of countries to abandon or discontinue compulsory vaccination campaigns for this population.

This very contrasting situation leads to two questions: firstly, which strategy is best suited to obtaining the best vaccination coverage, and secondly, how do countries that do not impose compulsory vaccination implement an incentive policy?

Regarding the first point, the French strategy for childhood vaccines provides some explanations. The third annual review of the extension of compulsory infant vaccination shows a positive effect on vaccination coverage, adherence to the reform and vaccination in general³⁷. However, with regard to measles, mumps and rubella, France remains below the 95% vaccination coverage required to block the circulation

³⁴ According to a comparative study (Bozzola, E., Spina, G., Russo, R. et al., (2018), "Mandatory vaccinations in European countries, undocumented information, false news and the impact on vaccination uptake: the position of the Italian pediatric society", *Italian Journal of Pediatrics*, 44, 67; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6001041/. There is at least one compulsory vaccine in 35.4% of European countries.

³⁵ H.C. Maltezou et *al.*, (2019), "Vaccination Policies for, Vaccination of healthcare personnel in Europe: Update to current policies", *Vaccine*, Vol. 37, Issue 52, pp. 7576-7584 ;https://www.sciencedirect.com/science/article/abs/pii/S0264410X1931285X?via%3Dihub

³⁶ Italy, Hungary, Greece, Germany and Austria. See for example: Y. Bourdillon, "Vaccination obligatoire des soignants: ce que font les autres pays" [Compulsory vaccination of caregivers: what other countries do], Les Echos, 5 July 2021.

³⁷Ministry of Health and Prevention, (2022), *Troisième bilan annuel des obligations vaccinales du nourrisson* [Third annual review of compulsory infant vaccinations], 46 p. (https://sante.gouv.fr/IMG/pdf/bilan_3eme_annee_obligations_vaccinales.pdf).

of the measles virus; a rate that Portugal and Sweden have achieved without introducing any obligation³⁸.

With regard to the second point, it would be useful to examine the strategies put in place in different countries. The example of flu is noteworthy because no country in Europe has imposed compulsory vaccination against this disease. However, vaccination coverage among health professionals varies significantly from one country to another, from 15% in Italy to 80% in Finland between 2017 and 2020. In France, vaccination coverage for health professionals was just over 20% during the 2021-2022 campaign³⁹. In addition, several studies show that intensive actions, particularly on the ground, can significantly increase vaccination coverage ⁴⁰. Even if further studies are needed, it would be useful to draw inspiration from these actions that make it possible to *reach out to* professionals and use vaccination prevention campaigns within working groups. Although such an approach is to be prioritised outside a crisis period, it may not be completely appropriate in the event of a health crisis where time is of the essence, there are high expectations of protection, and the more sensitive pedagogy is to be implemented.

2. Coexistence of obligations and recommendations, a source of confusion

Compulsory vaccination for professionals in care settings has several objectives, depending on the transmission profile of each disease, how the vaccine works and its level of effectiveness: individual protection against the targeted diseases by limiting the risk of infection or that of developing a serious form, the protection of individuals cared for or being accommodated using an approach to reduce the risk of transmission by all possible safety measures, and contributing to herd immunity in the general population. Specifically with regard to Covid-19 vaccination, in this particular period of the pandemic, protection of the healthcare system by limiting the rate of absences related to sick leave⁴¹ was added. However, it should be noted that the flu vaccination meets each epidemic with the same objectives.

https://www.ecdc.europa.eu/sites/default/files/documents/Measles%20 Annual%20 Epidemiological%20 Report%20202%20 data.pdf

³⁸ Vaccination coverage of children of vaccine age being 86% (2 doses of vaccine) in France in 2022, see: ECDC, Measles surveillance report, Annual Epidemiological Report for 2022, 14 p. (https://www.ecdc.europa.eu/sites/default/files/documents/Measles%20Annual%20Epidemiological%20Report% 202022%20data.pdf).

³⁹ Haute autorité de santé, *Rapport : Développement d'un indicateur de qualité et de sécurité des soins sur la « Couverture vaccinale antigrippale du personnel hospitalier* [Developing a care quality and safety indicator for "Influenza vaccine coverage of hospital staff], 9 March 2023, 31 p. (https://www.hassante.fr/upload/docs/application/pdf/202304/rapport_experimentation_couverture_vaccinale_antigrippale_2023 .pdf).

⁴⁰ See, among others, a recently published study that shows this positive effect for influenza and Covid-19: Schumacher S., Salmanton-García J., Liekweg A. et al., (2023), "Increasing influenza vaccination coverage in healthcare workers: analysis of an intensified on-site vaccination campaign during the COVID-19 pandemic", *Infection* (https://doi.org/10.1007/s15010-023-02007-w).

⁴¹ Health professionals, due to their exposure to the virus, have been identified as the individuals having the highest priority access to the vaccine. CARE – COVID-19 Scientific Committee – COVID-19 Vaccine Committee.

Observation of contrasting and fragmented vaccine coverage data, in the absence of a national register and comprehensive vision, shows that caregivers⁴² are mostly well covered by compulsory vaccinations: in 2009, 91.7% were vaccinated against hepatitis B and 95.5% had the booster against diphtheria, tetanus and polio (dTP), according to the most recent survey to date⁴³. For Covid-19, there are lower rates (86.4% for professionals working in EHPADs or USLDs, 88.9% for medical professionals in private practice and 88.4% for medical professionals in health institutions)⁴⁴. The difference between these coverage rates and the 100% legitimately expected in the case of compulsory vaccination is explained by unvaccinated professionals who cannot be vaccinated for medical reasons or who are in a "nonoperational" role (e.g. temporary posting). That being said, it is observed that where vaccination is compulsory, coverage rates remain higher than those for recommended vaccinations: 11.4% for DTP 10-year booster combining the whooping cough valence, 49.7% for at least one dose of measles and rubella vaccine⁴⁵, 29.9% for chickenpox and 25.9%⁴⁶ for flu.⁴⁷

These variations in vaccination coverage can be explained by differing social perceptions, both among the general population and among professionals in the health and medico-social sectors, depending on whether vaccines are compulsory or recommended, the latter often mistakenly perceived as related to benign diseases. Studies⁴⁸ mentioning these different perceptions highlight misrepresentations of the

Opinion "Vaccines against SARS-CoV-2. A VACCINATION STRATEGY - 9 July 2020". "III. Populations considered as a top priority, in metropolitan areas and overseas. A. Populations at risk of occupational exposure: about 6.8 million people. a. Very high priority: around 1.8 million people. This category mainly concerns health workers." Faced with the pandemic. Opinions of the COVID-19 Scientific Committee 2020-2022 Presented by Paul Benkimoun. The French Documentation, (2023), p. 150.

 $^{^{42}}$ The term "health professionals" is assumed here because the known vaccination coverage data in care settings generally only covers medical staff (doctors, nurses).

⁴³For the CCNE, the compilation and analysis of data on vaccination coverage for professionals in the health and medico-social sectors is not sufficiently developed in France and would require updates at least every year. See the survey cited in the text: J-P. Guthmann, D. Abiteboul, (2011), "Vaccinations chez les soignants des établissements de soins de France, 2009. Couverture vaccinale, connaissances et perceptions vis-à-vis des vaccinations, rapport final", [Vaccination of caregivers in French care facilities, 2009. Vaccination coverage, knowledge and perceptions of vaccinations, final report], Saint Maurice: Institut de veille sanitaire, 76 p.; https://www.santepubliquefrance.fr/content/download/186533/document_file/34099_9831-ps.pdf?version=1

⁴⁴ Complete primo-vaccination and at least 1 booster dose, data as of 21 March 2023, according to Santé publique France, InfoCovidFrance, "Chiffres clés et évolution de la COVID-19 en France et dans le monde" [Key figures and evolution of COVID-19 in France and worldwide]; https://www.santepubliquefrance.fr/dossiers/coronavirus-covid-19/coronavirus-chiffres-cles-et-evolution-de-la-covid-19-en-france-et-dans-le-monde

⁴⁵ Rubella vaccination is not mentioned in the study cited because it was recommended later, but we can conclude that for the measles vaccine also containing mumps and rubella valences, the vaccination coverage against measles is similar to that of rubella.

⁴⁶ J-P. Guthmann, D. Abiteboul, (2011), *Ibid*.

⁴⁷ Santé publique France, (2022) *Quelle est la couverture vaccinale contre la grippe des professionnels exerçant dans les établissements de santé ? Le point sur* [What is the flu vaccination coverage for professionals working in health institutions? An update on], Saint-Maurice, 6 p. Director of publication: Pr Geneviève Chêne; https://www.santepubliquefrance.fr/content/download/440659/document_file/2022_LePointSur_ES_grippe_010622.pdf

⁴⁸ See for example: R. Sardy, R. Ecochard, E. Lasserre, J. Dubois, D. Floret, & L. Letrilliart, (2012), "Représentations sociales de la vaccination chez les patients et les médecins généralistes : une étude basée sur l'évocation hiérarchisée" [Social representations of vaccination in patients and general practitioners: a study based on hierarchised evocation], Santé Publique, 24, 547-560. https://doi.org/10.3917/spub.126.0547

relative importance of recommended vaccines, both to the general population⁴⁹ and to professionals in care settings ⁵⁰ and highlight a global lack of knowledge about recommended vaccinations. These perceptions are dependent on a labyrinth of determinants (epidemiological, immunological, social, economic and political⁵¹); in particular, they stem from the very principle of obligation establishing the duality, according to the legal system, of a vaccine and suggesting that there are priority vaccinations, as they are compulsory, and others are optional⁵².

For a long time, the distinction between recommendations and obligations has been frequently challenged but this has lessened since the 2016 Citizens' consultation on vaccination, which allowed for public debate on the issues of the vaccine strategy.

Box 1 - 2016 Citizen consultation on vaccination

The Citizens' consultation on vaccination organised in 2016, on the initiative of the Health Minister, consisted of hearings, opinion polls and two panels (citizens and health professionals) who gave an opinion on how to restore trust and improve vaccination coverage. The topic of making vaccination compulsory was therefore widely discussed.

On the citizens' panel, there were mixed opinions. They did not comment much on what justifies compulsory vaccination.

The panel of health professionals agreed that strengthening compulsory vaccination was counterproductive, stating that it would undermine the trust and accountability of citizens. The panel therefore concluded that compulsory vaccination was justified in serious epidemiological situations, but that outside this framework it was preferable to rely on the transparency of expertise, training of caregivers and public information about vaccines, access to which must be ensured.

The coexistence of obligations as well as recommendations is both a strength and a point of contention of French vaccination policy in the general population. On the one hand, from a moral point of view, compulsory vaccination, like many collective public health measures (the obligation to wear safety belts, ban on smoking in public places,

⁴⁹ E. Nicand, E. Debost, (2018), "Obligation vaccinale: pourquoi le changement de législation de la politique vaccinale chez le nourrisson en France en 2018?" [Compulsory vaccination: why the change in legislation in infant vaccination policy in France in 2018?] Actualité et dossier en santé publique, No. 105, pp.18-20; https://www.hcsp.fr/Explore.cgi/Telecharger?NomFichier=ad1051820.pdf

⁵⁰ J-P. Guthmann, D. Abiteboul, (2011), *Ibid*; R. Sardy et al., (2012), *Ibid*; F. Collange, L. Fressard, C. Pulcini, O. Launay, A. Gautier, P. Verger, (2016), "Opinions des médecins généralistes de la région Provence-Alpes-Côte d'azur sur le régime obligatoire ou recommandé des vaccins en population générale, 2015" [Opinions of general practitioners of the Provence-Alpes-Côte d'azur region on the compulsory or recommended vaccination system for the general population, 2015], *Bulletin Epidémiologique Hebdomadaire*, No. 24-25, p. 406-13.

⁵¹ D. Lévy-Bruhl, (2016), "*Politique vaccinale*" [Vaccine Policy], In: François Bourdillon ed., *Traité de santé publique* (pp. 311-322). Cachan: Lavoisier. https://doi.org/10.3917/lav.bourd.2016.01.0336.

⁵² F. Vié le Sage, Gelbert, N., Cohen, R. & Assathiany, R., (2018), "Le vaccinateur et la politique: être assis entre deux chaises n'est pas toujours confortable: Enquête sur la perception de la politique vaccinale par les pédiatres français" [The vaccinator and the politician: sitting between two chairs is not always comfortable: survey on the perception of vaccination policy by French paediatricians], Les Tribunes de la santé, 58, 81-89. https://doi.org/10.3917/seve1.058.0081.

ban on the sale of alcohol to minors, etc.) goes against the general rule of free and informed consent (although there are exceptions) which itself is based on the fundamental principle of respect for individuals' freedom of choice. Compulsory vaccination can be considered as undermining the individual liberty of each citizen.

On the other hand, this duality sends out conflicting messages: whereas the obligation indicates strong voluntary action by government, which undertakes in particular to assume any damage that could result from a compulsory vaccine⁵³, a recommended vaccine encourages individuals to assume responsibility and autonomy for their health. Each of these two methods is justified by ethical principles. While an obligation meets the principles of non-malfeasance (protection of vulnerable people) and distributive justice (by theoretically offering equal access to compulsory vaccination when vaccines are made available free of charge), a recommendation is based on respect for the individual's freedom to make decisions on their health and body and based on their ability to decide on the basis of supposedly existing, available and appropriate information.

The tension between these two regimes was heightened by the sudden outbreak of the Covid-19 pandemic, which forced rapid action to be taken within a context where scientific knowledge was incomplete and constantly evolving. The specific obligation for health and support professionals to observe as far as possible the right to health safety of those cared for was strongly challenged on this occasion.

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⁵³ The State's strict liability regime for the possible harmful consequences of compulsory vaccinations was established by Law No. 64-643 of 1 July 1964. It is replaced by Article L. 3111-9 of the French Public Health Code (https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000036393284), resulting from Law No. 2004-806 of 9 August 2004, which gives the ONIAM (*Office national d'indemnisation des accidents médicaux* [National Office for the Compensation of Medical Accidents]) the responsibility of compensating compulsory vaccination accidents.

II. THE VACCINE STRATEGY PUT TO THE TEST BY THE HEALTH CRISIS

When the principle of public health was developed in the 19th century, the organisation of care, which had hitherto been dependent on private initiatives and charitable works, became a major concern of the modern state. The latter then integrated health into the political sphere by defining intervention strategies to protect the population's health. Theorised by Michel Foucault using the concept of "biopower"⁵⁴, this profound transformation was based on the development of various sciences (biological, statistical, epidemiology, demography). The emergence of a certain "nationalisation of the biological"⁵⁵ assuming forms of body control based in particular on coercive measures, draws a relationship of interdependence between individual and collective health. In conjunction with the emergence of this new political issue, public health, the vaccine method spread in the 19th century and suggested the possibility of protecting or improving the immunity of the community against infectious diseases.

On 15 February 1902, vaccination became a pivot of the biopolitical system by being made compulsory⁵⁶ by the first public health law in France. This law took root in a period that saw progress, both politically and legally, in the concept of solidarity. In his book on this idea⁵⁷, the thinker Léon Bourgeois applied mechanisms of law to political philosophy⁵⁸ by developing in particular the idea that "freedom can generate positive obligations that preserve [it]".⁵⁹ The solidarity-based doctrine, which supports the appearance of our republican model, proposes a theoretical foundation legitimising the intervention of the state as an expression of the general will while respecting the individual freedom of everyone around the idea that "man is born a debtor to society", according to this author.

⁵⁴ M. Foucault, (1976), *Histoire de la sexualité*. *1. La volonté de savoir* [History of sexuality. The will to know], Paris: Gallimard, 224 p.

⁵⁵ M. Foucault, (1975), "Pouvoir et corps" [Power and Body], in Dits et Écrits vol. II (1970-1975), p. 757-758 (in Quel corps ?, No. 2,

September-October 1975, p. 2-5 (June 1975 interview), Gallimard, 1994.

⁵⁶ The Public Health Law of 15 February 1902 makes the smallpox vaccine compulsory from the child's first year.

⁵⁷ L. Bourgeois, (1896, 1902 edition), Solidarité, [Solidarity] Armand Colin, (p. 115-158).

⁵⁸ According to the philosopher Marie-Claude Blais, the conception of solidarity by Léon Bourgeois "is the transfer into political philosophy of two mechanisms of the civil law of obligations: solidarity and quasi-contract. The latter describes "the purely voluntary acts of man, from which results any commitment to a third party" (Art. 1371). Social solidarity becomes a kind of retroactively agreed contract that commits every man, because he lives in society and benefits from the shared assets, to help maintain this community and its progress. The fundamental contribution of the legal concept of "quasi-contract" is that it makes it possible to move away from the idea of a debt, which retains a character of moral duty (or broad duty in philosophy), towards a strict obligation with penalties"; see: M-C. Blais, (2018), "Solidarité: une idée politique?" [Solidarity: a political idea?], in Solidarité(s): Perspectives juridiques, M. Hecquard-Théron (ed.), (2018), pp. 35-48.

⁵⁹ L.Bourgeois, (1896, édition de 1902), Solidarité, Armand Colin, (p. 115-158).

As a public health strategy requiring the support of the community and considering the context of the emergence of compulsory vaccination, French vaccination policy has historically been built around the concept of solidarity. Nowadays, it can create tension within civil society between individual freedoms and collective interest, subjectivity and intersubjectivity, choices and constraints.

1. Vaccine hesitancy of medical professions: symptom of the deterioration of trust in institutional and political authorities within a context of tension over the healthcare system

Based on the data on SARS-CoV-2 vaccination coverage for health and medical-social professionals, after three years of pandemic, it appears that these main stakeholders in the healthcare system, in almost their entirety, complied with compulsory vaccination as the pandemic continued. However, the use of this strategy restricting individual freedoms demonstrates the difficulties encountered in convincing some professionals of the benefits of this vaccination for themselves, for the protection of vulnerable people under their care⁶⁰, for the protection of the healthcare system, but also for achieving the widest possible community vaccination coverage. This difficulty can be partly explained by the crisis situation, as mentioned above, resulting in incomplete and evolving knowledge of a virus that was constantly changing.

Beyond fears about the effectiveness or possible adverse effects of this vaccine, or support for disputed theories sometimes promoted by public figures, including those belonging to the medical profession, the reluctance expressed is part of a profound discomfort of healthcare and support stakeholders experienced due to an accumulation of crises (pressures on the healthcare system, Covid-19 pandemic, a crisis of skill recognition within care professions) creating tension in the relationship between caregivers and those being cared for, and disrupting the very meaning of care, as indicated by the CCNE in its Opinion 140⁶¹. Indeed, indifference to vaccination or even refusing vaccination preceded the health crisis, as evidenced every year by the low coverage rates for professionals' vaccination against seasonal flu⁶².

In 2019, the World Health Organization (WHO) referred to vaccine hesitancy on its list of the top ten threats to global health and stressed that health professionals represented the most reliable and influential advisers on vaccination decisions⁶³. As defined by the experts of the WHO's Strategic Advisory Group of Experts on

⁶⁰It should be noted that Law **No. 2016-41 of 26 January 2016 on the modernization of the health system** introduces the concept of "altruistic vaccination" adding to the individual benefit of vaccination for caregivers, the notion of a benefit for the people under their care (L. 3111-4 of the French Public Health Code).

⁶¹ CCNE, Opinion No. 140, "Repenser le système de soins sur un fondement éthique. Leçons de la crise sanitaire et hospitalière, diagnostic et perspectives" [Rethinking the healthcare system on an ethical basis. Lessons from the health and hospital crisis, diagnosis and perspectives], 20 October 2022, 53 p.; https://www.ccne-ethique.fr/sites/default/files/2022-11/Avis140 Final 0.pdf

⁶² This vaccine being recommended for certain health professions, including those in regular and prolonged contact with people at risk of severe influenza.

⁶³ WHO, (2019), Ten threats to global health in 2019: https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019

Immunization, this concept⁶⁴ "refers to delay in acceptance or refusal of safe vaccines despite availability of vaccination services"; it is "complex and context specific, varying across time, place and vaccines" particularly related to the level of confidence in the authorities. This concept is to be distinguished from anti-vaccine resistance and activism, rejecting the very principle of vaccination, although the line between the two may be blurred.

The care relationship is considered a special opportunity to respond to the general public's vaccine hesitancy, but to do so, health professionals managing this relationship must themselves be convinced of the merits of vaccination (effectiveness, safety, usefulness). However, the literature available in the field of vaccine hesitancy shows that a significant proportion of caregivers (with wide occupational disparities) show reluctance towards certain vaccines, and in particular against the Covid-19 vaccine 65, supported in this by the debatable discourse of some self-proclaimed medical authorities.

Like surveys in the general population, fear of adverse reactions⁶⁶, lack of confidence in the pharmaceutical industry, health authorities and experts⁶⁷, and preference for alternative medical practices ⁶⁸ are arguments frequently put forward by hesitant health professionals.

The Covid-19 episode appears to have provided favourable ground to amplify behaviours and feelings of mistrust towards the authorities, particularly among professionals working in care settings who were in great demand during the management of the health crisis. In the early stages of the pandemic, rationing or even

⁶⁴ WHO, (2014), Report of the Sage Working Group on Vaccine Hesitancy, 64 p.

⁶⁵ Dzieciolowska S., Hamel D., Gadio S., et al., (2021), "Covid-19 vaccine acceptance, hesitancy, and refusal among Canadian healthcare workers: a multicenter survey", American Journal of Infection Control, 2021;49 (9):1152-1157; https://www.sciencedirect.com/science/article/pii/S0196655321002741?via%3Dihub. Verger P., Scronias D., Dauby N., et al., (2021), "Attitudes of healthcare workers towards COVID-19 vaccination: a survey in France and French-speaking parts of Belgium and Canada, 2020", EuroSurveillance 2021;26(3):2002047; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7848677/. Gagneux-Brunon A., Detoc M., Bruel S., et al., (2021), "Intention to get vaccinations against COVID-19 in French healthcare workers during the first pandemic wave: a cross-sectional survey", The Journal of Hospital Infection, 2021;108:168-173; https://pubmed.ncbi.nlm.nih.gov/33259883/.

⁶⁶ Verger P., Collange F., Fressard L., et *al.*, (2014), "Prevalence and correlates of vaccine hesitancy among general practitioners: a cross-sectional telephone survey in France", *EuroSurveillance*, 2014 [Apr Jul]; 21 (47):30406; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5291145/. Thomire A, Raude J., (2021), "The role of alternative and complementary medical practices in vaccine hesitancy among nurses: a cross-sectional survey in Brittany", *Infectious Diseases Now*, 2021;51(2):159–163;

https://www.sciencedirect.com/science/article/pii/S0399077X20307198.

⁶⁷ See for example: Verger P., Fressard L., Collange F., et *al.*, (2015), "Vaccine hesitancy among general practitioners and its determinants during controversies: a national cross-sectional survey in France", *EBioMedicine*, 2(8): 891–897; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4563133/.

⁶⁸ Verger P., Collange F., Fressard L., et *al.*, (2014), "Prevalence and correlates of vaccine hesitancy among general practitioners: a cross-sectional telephone survey in France", *EuroSurveillance*, 2014 [Apr Jul]; 21 (47):30406; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5291145/. Thomire A., Raude J., "The role of alternative and complementary medical practices in vaccine hesitancy among nurses: a cross-sectional survey in Brittany", *Infectious Diseases Now*, 2021;51(2):159–163; https://www.sciencedirect.com/science/article/pii/S0399077X20307198.

the shortage of personal protective equipment (masks, gowns, caps, etc.) forced the teams to "make do with what was available" using non-regulatory equipment (bin bags, painters' coveralls, etc.), sometimes driving them to break the most basic hygiene rules (use of the same gown for several patients, washing paper gowns initially intended for single use, etc.)⁶⁹, under extreme pressure within hospitals and in a situation of uncertainty about the risks related to SARS-CoV-2 infection. These harsh and traumatic events have generated among health professionals a sense of misunderstanding or even abandonment by the political and health authorities, especially in the context of the healthcare system crisis already mentioned.

This situation in the first few months was marked by fluctuating positions concerning lockdowns, the obligation to wear masks and the ventilation of premises. Added to this, following the development of the vaccine in record time and according to a recent method (vaccines produced by **new vaccine production techniques, in particular mRNA-type platforms**⁷⁰), was the introduction of the health pass and then the vaccine pass and compulsory vaccination for professionals in the health and medico-social sectors. This was perceived by some as an infringement of individual freedoms that was not justified by a public health requirement, of the freedom to make decisions about our own body and of the right to consent or not to any kind of treatment. However, when these issues were referred to them, the French *Conseil d'État* and Constitutional Council repeatedly noted that self-protection and public health justified proportionate measures to restrict these freedoms⁷¹.

As the CCNE already pointed out in its Opinion 140^{72} , the crisis of confidence that we are currently going through is a symptom of previous imbalances; it has been encouraged by health cases that have marked French society for several decades (Chlordecone in Guadeloupe and Martinique, growth hormones, contaminated blood, Isomeride or Mediator), but also by the increasing use of the Internet as the main

⁶⁹ Le Monde, "Coronavirus: masques, surblouses... Du matériel manque toujours dans les hôpitaux" [Coronavirus: masks, gowns... Equipment still missing in hospitals], 2 April 2020; https://www.lemonde.fr/planete/article/2020/04/02/coronavirus-masques-surblouses-du-materiel-manque-toujours-dans-les-hopitaux 6035257 3244.html.

⁷⁰ The properties of mRNA vaccines enables numerous applications to many pathogens and can provide quick and effective solutions in future health crises, see: COVARS, "Avis du Comité de Veille et d'Anticipation des Risques Sanitaires (COVARS) du 9 Février 2023 sur le futur des vaccins a ARNm dans l'anticipation et la gestion des crises sanitaires" [Notice of the Committee on Health Risk Monitoring and Anticipation (COVARS) of 9 February 2023 on the future of mRNA vaccines in the anticipation and management of health crises], 49 p.; https://www.enseignementsup-recherche.gouv.fr/sites/default/files/2023-02/avis-du-covars-sur-le-futur-des-vaccins-arnm--13-f-vrier-2023-26444.pdf

⁷¹ CE, 8 April 2020, Syndicat national pénitentiaire Force ouvrière, No. 439821, cons.3, https://www.conseiletat.fr/arianeweb/#/view-document/?storage=true and Cons.Cons, DC No. 2020-800 of 11 May 2020, https://www.conseileconstitutionnel.fr/decision/2020/2020800DC.htm

⁷² CCNE, Opinion No. 140, "*Repenser le système de soins sur un fondement éthique. Leçons de la crise sanitaire et hospitalière, diagnostic et perspectives*" [Rethinking the healthcare system on an ethical basis. Lessons from the health and hospital crisis, diagnosis and perspectives], 20 October 2022, 53 p.; https://www.ccne-ethique.fr/sites/default/files/2022-11/Avis140 Final 0.pdf

source of information (dissemination of unvalidated content, misinformation, unfounded rumours) 73 .

Box 2 - French and international controversies that have fuelled vaccine hesitancy for 20 years

The past 20 years have been marked by several vaccine controversies that have fuelled doubts about the safety and usefulness of this preventive measure. The first began in 1998 when the Ministry of Health interrupted a massive vaccination campaign of school pupils against hepatitis B because of suspected possible links between the vaccine and the onset of demyelinating diseases (mainly multiple sclerosis). However, the association between the administration of this vaccine and the occurrence of demyelinating diseases has been invalidated by numerous epidemiological studies⁷⁴. It should be noted that hepatitis B is among one of the first diseases for which vaccination has been made mandatory for professionals in the health and medico-social sectors since 1991. In the same year, a study published in The Lancet on an alleged association between MMR vaccination and autism shook up the British public authorities. It took 12 years to prove that this study was fraudulent and for this journal to retract this publication 75. While other controversies have followed (challenging aluminium adjuvants, vaccine against papillomavirus infections accused of causing autoimmune diseases), the controversial management of the influenza A (H1N1) pandemic in 2009-2010 has particularly contributed to the increase in distrust of vaccinations76.

The legitimate scientific uncertainties in the face of an emerging virus and an innovative vaccine developed in an extremely reactive manner, the sometimes contradictory medical, scientific and political discourse, as well as the scientifically unfounded positions of some public figures, the lack of educational and coherent communications (difficult to implement in critical times) on the need to restrict individual freedoms to protect the community have all contributed to a crisis of

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⁷³ See: Comité pilote d'éthique du numérique, Bulletin de veille No. 2, "Réflexions et points d'alerte sur les enjeux d'éthique du numérique en situation de crise sanitaire aiguë" [Reflection and warning points on digital ethics issues in acute health crises], 21 July 2020, 24 p.; https://www.ccne-ethique.fr/sites/default/files/2021-07/CNPEN-desinformation-2020-07-21-CP.pdf

⁷⁴ Mouchet J., Salvo F., Raschi E., Poluzzi E., Antonazzo IC., De Ponti F., et *al.*, (2018), "Hepatitis B vaccination and the putative risk of central demyelinating diseases – A systematic review and meta-analysis", *Vaccine*, 14;36(12):1548–55; https://pubmed.ncbi.nlm.nih.gov/29454521/.

⁷⁵ Dyer C., (2010), "Lancet retracts Wakefield's MMR paper", British Medical Journal, 340; https://www.bmj.com/content/340/bmj.c696

⁷⁶ According to Santé publique France: "The percentage of people who were "very" or "rather favourable" was 61% between October 2009 and June 2010, while it exceeded 90% in the early 2000s; see: Gautier A., Chemlal K., Jestin C. et le groupe Baromètre santé 2016, (2017), "Adhésion à la vaccination en France: résultats du Baromètre santé 2016" [Support for vaccination in France: results of the 2016 Health Barometer], Bulletin Epidémiologique Hebdomadaire, (Vaccination special edition): 21-7; https://www.santepubliquefrance.fr/content/download/183070/document_file/41099_13510-ps.pdf?version=1

confidence, creating doubt about the state of knowledge and suspicion where there was a need for rationality and caution, as the CCNE points out in its Opinion 140^{77} .

2. Social and regional inequalities: what lessons can be learned?

In France, the vaccination campaign against Covid-19 sparked major protests including citizens opposing the health pass (established in June 2021 and extended on 9 August 2021 for access to public places)⁷⁸ and active but a minority of health workers denouncing the government's decision to make vaccines mandatory for the practice of their profession. From July 2021 and for about six months, dozens of demonstrations were organised in France in the name of defending individual freedoms.

During this significant episode of the health crisis, the geographic distribution of demonstrations was inversely proportional to that of vaccination rates against Covid-19, in other words, there were more demonstrations in regions with lower levels of vaccination (except Paris)⁷⁹. This phenomenon of geographic disparity as regards support for vaccinations was already known to public health authorities since the levels of vaccination coverage against hepatitis B - of which we have discussed the important controversy in the mid 1990s - and against measles, mumps and rubella (MMR), had, for around 20 years, already drawn a line between North and South with less coverage in southern France⁸⁰.

This divide between northern France which is generally well vaccinated and Southern France - particularly the South East – as well as the overseas departments and regions (DROMs) with Covid-19 vaccination levels below the national average is the result of a labyrinth of determining factors. Thus, in areas far from urban centres, isolation may suggest that populations are less exposed to infectious risk – which was the case in the early stages of the pandemic – and in the case of pandemic vaccination, it is also accompanied by the difficulty of doing so because of the distance of vaccination

⁷⁷ CCNE, Opinion No. 140, "Repenser le système de soins sur un fondement éthique. Leçons de la crise sanitaire et hospitalière, diagnostic et perspectives", [Rethinking the healthcare system on an ethical basis. Lessons from the health and hospital crisis, analysis and perspectives], 20 October 2022, 53 p.; https://www.ccne-ethique.fr/sites/default/files/2022-11/Avis140_Final_0.pdf

⁷⁸ Law No. 2021-689 of 31 May 2021 on managing the recovery from the health crisis, https://www.legifrance.gouv.fr/loda/id/JORFTEXT000043567200/ and Law No. 2021-1040 of 5 August 2021 on managing the health crisis, https://www.legifrance.gouv.fr/loda/id/JORFTEXT000043909676/2021-08-09/

⁷⁹ See in particular: C. Stromboni, "Covid-19: en France, une triple fracture vaccinale" [Covid-19: in France, a triple vaccine divide], lemonde.fr, 25 July 2021; https://www.lemonde.fr/planete/article/2021/07/25/covid-19-enfrance-une-triple-fracture-vaccinale 6089451 3244.html. J-F. Fernandez, "Manifestations contre le pass sanitaire : la mobilisation est plus importante là où le taux de vaccination est plus bas, selon Santé Publique France" [Demonstrations against the health pass: there are more gatherings where the vaccination rate is lower, according Santé Publique francetvinfo.fr, 28 to Francel. August 2021: https://www.francetvinfo.fr/sante/maladie/coronavirus/pass-sanitaire/manifestations-contre-le-pass-sanitaire-lamobilisation-est-plus-importante-la-ou-le-taux-de-vaccination-est-plus-bas-selon-sante-publiquefrance_4750775.html.

⁸⁰ L. Guimier, (2021), "Les résistances françaises aux vaccinations : continuité et ruptures à la lumière de la pandémie de Covid-19" [French resistance to vaccinations: continuity and divides in the light of the Covid-19 pandemic], Hérodote, vol. 183, No. 4, pp. 227-250; https://www.cairn.info/revue-herodote-2021-4-page-227.htm

centres. More generally, the geographic distance from central Parisian authority and a sense of belonging to a local community with a strong cultural identity – Marseille, Cévennes, DROMs etc. – influence the indifference to or mistrust of the recommendations of institutions, perceived as distant bodies⁸¹.

In the DROMs, scepticism towards the vaccine has exacerbated a particularly unstable health and social situation, weakened by the muddle of the healthcare system crisis and pandemic. In September 2021, while the percentage of 65-74 year olds who had received at least one dose of Covid-19 vaccine was 93% nationwide, the vaccination rate for this same age group was between 40 and 45% in Guyana, Martinique and Guadeloupe82. During the same period, both these regions experienced a very severe deterioration in their health situation with the arrival of the fourth epidemic wave which spread very rapidly and on a much larger scale than previous epidemics. While elsewhere in France, expanding vaccination coverage made it possible to keep the fourth wave under control despite the spread of the more contagious delta variant, Guadeloupe and Martinique experienced a catastrophic situation: mortality during this period⁸³ reached 78% in Guadeloupe and 69% in Martinique⁸⁴ where there is a high prevalence of comorbidity in the population (obesity, diabetes, high blood pressure, kidney failure). Hospital services were then forced to switch to "disaster medicine"85. In Guadeloupe, an island that went back into lockdown from 30 July 2021, the incidence rate among young people was nearing 4,000 cases per 100,000 inhabitants, an unprecedented rate in France since the start of the pandemic. As for Martinique, the situation was just as critical; during this fourth wave, the island recorded more than 220% hospital overload, and the army was sent in as reinforcements to increase the capacity of resuscitation beds. By mid-August, 240 health workers had left France for Guadeloupe and Martinique to help overcome a situation that seemed out of control. The overwhelming majority of patients admitted for resuscitation due to Covid-19 during this fourth wave in the overseas territories were not vaccinated. More significantly, Martinique and Guadeloupe were and still are the two French departments with the most unvaccinated health workers.

Various reasons explain the barriers to Covid-19 vaccination in the DROMs⁸⁶, starting with the population's feeling of being removed from the epidemic that had hitherto

⁸¹ L. Guimier, Ibid; C. Stromboni, Ibid.

⁸² INSEE, (25 November 2021), "France, portrait social" [France, a social portrait], 2021 edition (available at the following link: https://www.insee.fr/fr/statistiques/fichier/5435421/FPS2021.pdf).

⁸³ Period from 1 June to 20 September 2021.

⁸⁴ INSEE, (25 November 2021), "France, portrait social" [France, a social portrait], 2021 edition; https://www.insee.fr/fr/statistiques/fichier/5435421/FPS2021.pdf

^{85 &}quot;Covid-19 en Guadeloupe : on a basculé dans la médecine de catastrophe" [Covid-19 in Guadeloupe: we've moved into disaster medicine], FranceInfo.fr, 07/08/2021; https://www.francetvinfo.fr/sante/maladie/coronavirus/covid-19-en-guadeloupe-on-a-bascule-dans-la-medecine-decatastrophe 4730783.html

⁸⁶ J.M. Arnaud, R. Karoutchi, (2021), "Rapport d'information fait au nom de la mission commune d'information destinée à évaluer les effets des mesures prises ou envisagées en matière de confinement ou de restrictions d'activités (1) relatif aux enseignements de la quatrième vague épidémique outre-mer en matière sanitaire et

relatively spared these territories. In addition, the low uptake of the vaccine, both within the population and among professionals in the health and medico-social sectors, results from strong distrust of the state for historical reasons related to the colonial issue, which has been fuelled more recently by the health and political issue of Chlordecone⁸⁷. In general, loss of trust is a serious and lasting phenomenon while building trust is a long process.

However, explaining the scepticism towards the COVID-19 vaccination in Guadeloupe and Martinique by these factors alone would be simplistic. As the sociologist Stéphanie Mulot points out, the promotion of stances advocating resistance and autonomy that could be observed during the health crisis, particularly in Guadeloupe, has also been fuelled by strong socio-economic inequalities, the extremely tense situation in hospitals and inequalities in access to information, the quality of which is sometimes poor⁸⁸.

Although the situation of both the population and health professionals challenging compulsory vaccination in the overseas territories is distinctive in many different ways, the key element of the social unrest that has marked these territories lies in the crisis of public services (access to drinking water, inadequate public transport, barriers to continuing education, medical shortages, digital divide, access to law and justice, etc.⁸⁹) which were made worse by the Covid-19 health crisis. Therefore, as part of provisions aimed at easing tensions around compulsory vaccination, the CCNE considers it essential not to be limited to only clinical and epidemiological arguments and to take into account the social and political contexts, both national and local, in which these tensions arise.

3. Issues raised by vaccine hesitancy in care settings

When the use of vaccination is scientifically justified for individual but also collective protection, vaccine hesitancy can affect public health. This hesitancy becomes critical when it occurs at the very heart of the healthcare system, when caregivers question the justification of medical treatment applied by institutions with rules on validation, authorisation and legitimacy. These doubts increased, or for some came to light, at the heart of the pandemic, in an urgent situation with very rapid scientific advances. The

économique" [Information report made on behalf of the joint information mission to assess the effects of measures taken or envisaged with regard to lockdown or activity restrictions (1) relating to learning from the fourth epidemic wave overseas in health and economic matters], 18 November 2021,, Sénat, No. 177, 116 p.; https://www.senat.fr/rap/r21-177/r21-1771.pdf

⁸⁷ See: Anses, "Chlordécone aux Antilles : les risques liés à l'exposition alimentaire" [Chlordecone in the West Indies: the risks related to dietary exposure], 9 December 2022; https://www.anses.fr/fr/content/chlordecone-aux-antilles-les-risques-lies-a-lexposition-alimentaire

⁸⁸ S. Mulot, (2021), "Sur le refus de la vaccination contre le Covid-19 en Guadeloupe" [On the refusal of Covid-19 vaccination in Guadeloupe], AOC.media; https://aoc.media/analyse/2021/11/02/sur-le-refus-de-la-vaccination-contre-le-covid-19-en-guadeloupe/

⁸⁹ These elements are highlighted in the following document: Défenseure des droits, (2023), "Services publics aux Antilles: garantir l'accès aux droits" [Public services in the West Indies: guaranteeing access to rights], 60 p.; https://www.defenseurdesdroits.fr/sites/default/files/atoms/files/ddd rapport-antilles 20230317.pdf

crisis of trust in institutions and within institutions such as hospitals and EHPADs has played a part in weakening the whole of an already vulnerable system. The vaccine hesitancy of healthcare professionals must thus be considered as a symptom as profound as resignations, or the moral crisis of caregivers already described by the CCNE in Opinion 14090.

The literature available on the vaccine hesitancy of caregivers⁹¹ highlights that their positions vary according to occupation, type of activity and level of study. Vaccine hesitancy is thus higher among nurses than doctors⁹² and it appears that confidence in vaccines positively correlates with the number of years of medical studies⁹³.

The professional gradient regarding vaccine hesitancy is specifically reflected by vaccination rates varying according to occupational activity. The example of seasonal flu vaccination coverage in health institutions is particularly revealing: in 2019, 67% of doctors were vaccinated (75% in EHPADs), followed by 48% of midwives, 36% of nurses (43% in EHPADs) and 21% of nursing auxiliaries (27% in EHPADs)⁹⁴. An Italian study shows the same with higher flu vaccination among doctors than in other professions within health and medico-social sectors⁹⁵.

The observation of vaccine hesitancy that is less easy to understand in professions whose vaccination rights are more restricted (nurses, midwives) or even absent (nursing auxiliaries) gives us cause to examine the stakeholders who shape the healthcare system on a daily basis. The promotion of self-esteem and personal achievement are important issues to be taken into account when responding to

⁹⁰ CCNE, Opinion No. 140, "Repenser le système de soins sur un fondement éthique. Leçons de la crise sanitaire et hospitalière, diagnostic et perspectives" [Rethinking the healthcare system on an ethical basis. Lessons from the health and hospital crisis, diagnosis and perspectives], 20 October 2022, 53 p.; https://www.ccne-ethique.fr/sites/default/files/2022-11/Avis140 Final_0.pdf

⁹¹See an important review of existing literature: Verger P., Botelho-Nevers E., Garrison A., Gagnon D., Gagneur A., Gagneux-Brunon A., Dubé E., (2022), "Vaccine hesitancy in health-care providers in Western countries: a narrative review", *Expert Review of Vaccines*, 21:7, 909-927; https://www.tandfonline.com/doi/full/10.1080/14760584.2022.2056026

⁹² Karlsson LC., Lewandowsky S., Antfolk J., et *al.*, (2019), "The association between vaccination confidence, vaccination behavior, and willingness to recommend vaccines among Finnish healthcare workers", *PloS One*, 14(10); https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0224330. Tomljenovic M., Petrovic G., Antoljak N., et *al.*, (2021), "Vaccination attitudes, beliefs and behaviours among primary health care workers in northern Croatia", *Vaccine*, 2021;39(4):738–745; https://pubmed.ncbi.nlm.nih.gov/33386176/

⁹³ Rostkowska OM., Peters A., Montvidas J., et *al.*, (2021), "Attitudes and knowledge of European medical students and early graduates about vaccination and self-reported vaccination coverage-Multinational cross sectional survey", *International Journal of Environmental Research and Public Health*, 2021; 18 (7): 3595; https://pubmed.ncbi.nlm.nih.gov/33808446/

⁹⁴ Santé publique France, (October 2019), "Couverture vaccinale antigrippale chez les professionnels de santé" [Flu vaccination coverage in health professionals], Bulletin de santé publique, 8 p.; https://www.santepubliquefrance.fr/content/download/198638/document_file/BSP_Nat_Vaccination_211019.pdf

⁹⁵ Di Martino G., Di Giovanni P., Di Girolamo A., Scampoli P., Cedrone F., D'Addezio M., Meo F., Romano F., Di Sciascio MB., Staniscia T., (2020), "Knowledge and Attitude towards Vaccination among Healthcare Workers: A Multicenter Cross-Sectional Study in a Southern Italian Region", *Vaccines* (Basel), 2020 May 24;8(2):248; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7350011/

vaccine hesitancy among professionals working in the health and medico-social sectors.

Like the factors determining vaccine hesitancy in the general population, vaccine hesitancy among health professionals may reflect a lack of confidence in institutions and political authorities, as a result of past or recent health cases and due to the fear of conflicts of interest between health authorities and the pharmaceutical industry⁹⁶.

Understanding the factors determining vaccine hesitancy within the health and social professions cannot ignore the social context in which these professionals evolve, the perception of a deterioration in working conditions⁹⁷, their perception of their place within the healthcare system and how they perceive their actions or hierarchical position and how their actions or hierarchical position are perceived. Refusal of compulsory vaccination can thus result in the expression of social or structural tensions within the health system⁹⁸.

The influence that professionals, who are hesitant about certain vaccinations, may have on patients they encounter is an issue that particularly stands out to the CCNE. Although quantitatively low, the vaccine hesitancy of doctors and other caregivers has a significant impact since the general public has a great deal of confidence in these professionals.

In the absence of accurate data on vaccination coverage and the level of vaccine hesitancy among professionals working in care settings, the CCNE recommends developing and approving tools to regularly measure these elements. A better assessment of the vaccine hesitancy phenomenon, including through qualitative surveys and polls, would increase knowledge and help develop strategies for informing health professionals and the institutions that are responsible for them.

4. Adapting to the situation: making decisions in crisis situations is not the same as making decisions in everyday situations

The promotion of vaccination against a disease in a controlled temporal situation requires a sufficient level of evidence through well organised review processes and the assessment of the collective benefits and potential individual risks of this preventive medical procedure. Once this process has been completed, it also requires all the necessary means to enable health professionals to identify the individual and

⁹⁷ CCNE, Opinion No. 140, "Repenser le système de soins sur un fondement éthique. Leçons de la crise sanitaire et hospitalière, diagnostic et perspectives", [Rethinking the healthcare system on an ethical basis. Lessons from the health and hospital crisis, analysis and perspectives], 20 October 2022, 53 p.; https://www.ccne-ethique.fr/sites/default/files/2022-11/Avis140 Final O.pdf

⁹⁶ Verger P. et al., (2022), Ibid.

⁹⁸ Verger P., Botelho-Nevers E., Garrison A., Gagnon D., Gagneur A., Gagneux-Brunon A., Dubé E., (2022), "Vaccine hesitancy in health-care providers in Western countries: a narrative review", *Expert Review of Vaccines*, 21:7, 909-927; https://pubmed.ncbi.nlm.nih.gov/35315308/

collective benefits of these preventive measures and to participate in its promotion in an informed manner to the population.

When an infection risk emerges, it can lead to a health crisis impacting the health of populations, the operation of the healthcare system or even the balance between societies. The case of the Covid-19 pandemic demonstrates this: it has caused not only a major disruption to the global economy, but in terms of health, it has overwhelmed many countries' health systems overrun by the combination of a massive influx of patients with severe forms of a poorly known disease, the scarcity of protective equipment and staff shortages.

Describing the concept of crisis is a complex exercise as the scope of this term is vast. Taking a well-known specialist in these situations, Patrick Lagadec, some authors define it at the intersection of three words: surge, disruption and breakdown. "The crisis fiercely overwhelms, breaks up and suddenly introduces a crack in the habits and operating methods of multiple stakeholders" 99. Olivier Borraz favours three concepts: loss of meaning, de-sectorisation (the erasure of organisational boundaries) and the complex, urgent and dynamic nature of the situation 100. Therefore, in such a situation, a two-dimensional paradox is established. On the one hand, public authorities are called upon to act and make decisions. On the other hand, the knowledge is incomplete and there is much scientific uncertainty.

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⁹⁹ Combalbert L., Delbeque É., "Chapitre premier. *La crise ou l'exception permanente*" [Chapter one. The crisis or permanent exception], in: Laurent Combalbert éd., *La gestion de crise,* Presses Universitaires de France, "Que saisje ?" [What do I know?], 2018, p. 11-52. https://www.cairn.info/la-gestion-de-crise-9782130812616-page-11.htm ¹⁰⁰ Borraz O., "Qu'est-ce qu'une crise?" [What is a crisis?], 20 April 2020. https://www.sciencespo.fr/cso/fr/content/qu-est-ce-qu-une-crise.html.

Box 3: Definition of a public health emergency of international concern

If reference is made to the framework defined by the World Health Organization (WHO) in order to respond to the risks of spreading pandemic diseases, a "public health emergency of international concern" means an "extraordinary event which is determined ... i) to constitute a public health risk to other States through the international spread of disease; and ii) to potentially require a coordinated international response" 101. This definition entails an event with the following criteria:

- serious, unusual or unexpected;
- high potential for international spread;
- a significant risk of international restrictions 102.

In the context of public health emergencies, public authorities are required to take rapid and proportionate measures to protect the population without waiting for the consolidation of scientific knowledge: pressure is at a maximum and the public authorities' responsibility is subject to a major order to act.

Exercising political responsibility in these uncertain situations must take into account the possibility of anticipating interventions most likely to limit risks to populations, but also the ability to protect it through effective prevention tools¹⁰³. It is in this context that it is important to maintain the public authorities' capacity to assess how compulsory vaccination for health professionals may be necessary in the face of a health situation that poses a major and serious threat to the population, and which may undermine the operation of the healthcare system.

The CCNE is therefore committed to furthering thinking in order to distinguish a crisis period, for which compulsory vaccination may, in some cases, be justified, from vaccination in everyday periods. This must be done by prioritising the practice of health democracy, promoting the expression of all stakeholders, professionals, experts and users of the health system, including those belonging to the most vulnerable populations in the face of the pathogens concerned. This democratic practice is a necessity because it requires the most accurate assessment of the situation, based on shared knowledge that is explained to all stakeholders; it specifies the expected role of a vaccination and points out the legal framework that applies.

Taking into account the duty to protect the fundamental rights of patients and the safety of care requirement:

- in an everyday situation, the CCNE encourages the provision of information to, and responsibility of, health professionals, to be vaccinated, by prioritising the use of recommended vaccinations;

¹⁰¹ WHO, (2005), International Health Regulations, p. 10.

¹⁰² WHO, (2005), International Health Regulations, pp. 56-59.

¹⁰³ In this regard, it is important to note that the arrival of Covid-19 vaccines using a new technology (mRNA) has been accompanied by enhanced surveillance of adverse reactions (pharmacovigilance) at national, European and international levels, which has made it possible to give reassurance about these adverse reactions, while quickly and transparently identifying certain side effects. Overall, the collective benefit to individual risk ratio was largely positive.

in the event of a health crisis potentially endangering the healthcare system, and where there is a solid scientific body of material guaranteeing the effectiveness (even moderate) and safety of the vaccine concerned, the CCNE considers that the political decision to impose compulsory vaccination on professionals in the health and medico-social sectors may be legitimate on a precautionary basis in view of a potential risk and in order to maintain an operational healthcare system.

III. ENCOURAGING THE ETHICS OF RESPONSIBILITY AMONG PROFESSIONALS IN THE HEALTH AND MEDICO-SOCIAL SECTORS

Innovative vaccines targeting emerging or re-emerging diseases are being developed to prevent the spread of possible epidemics or pandemics. The principle of compulsory vaccination applicable to professionals exposed and exposing third parties to the risk of infection in future health crises is a possibility to be taken into account when developing public health policies, especially when managing epidemic risks.

Compulsory vaccination is more easily accepted at the start of professional training because it is a condition of accessing a profession and because its primary objective is to protect the caregivers themselves. However, its acceptance may not be so straightforward in the course of a career if a new compulsory vaccine is introduced to respond to a particular or evolving epidemiological situation.

For the CCNE, examining tensions between the public interest and individual freedoms raised by the compulsory vaccination of professionals in the health and medico-social sectors develops thinking focused on the ethical responsibility of people working in care settings.

1. Trust at the heart of care

The combination of current crises (Covid-19, healthcare system) and changes in people's health needs are testing health professionals, disrupting their daily practices and ultimately raising questions about what the very essence of the care profession is today.

Working in a profession that involves taking care of others' health is not simply a qualification, the implementation of skills or compliance with procedures; it is above all assuming responsibility in an asymmetrical relationship between caregiver and patient in which the patient entrusts their health to the caregiver. The care cannot simply come down to the treatment (cure) alone. It is a relationship between people who are complex and ambivalent (care).

If the technical and medical aspects of the knowledge and the relationship to science are part of a "moral contract" between caregiver and patient, uncertainty and doubt are feelings which are completely legitimate and which accompany scientific reasoning; they lay the foundations for trust, a fundamental concept in both the caregiver-patient relationship and in the relationship between professionals in the care professions and the institutions that produce scientific and clinical knowledge.

In situations of uncertainty, emergencies or crises, patient protection must be a factor guiding caregivers by combining the various means and tools available to achieve the objective with least risk (social distancing measures, screening tests, masks, ventilation, vaccination, etc.).

However, if the care professions expose patients to infection from medical staff, this exposure also applies to caregivers, who are therefore subject to specific obligations. Some legitimate obligations and expectations are an integral part of caregivers' commitments. Compulsory vaccination deemed necessary by health authorities does not result from the use of force but from the caregiver's agreement to the professional contract, and a specific ethical requirement which is an intrinsic part of the obligation incurred by working in a profession that involves caring for others.

2. The need for a reciprocal requirement to lead by example

For the CCNE, vaccine hesitancy in care settings should be understood in a way that first questions the basis from which it stems and what it entails, not only for the community and vulnerable patients, especially immunocompromised individuals, but for health professionals themselves. As previously mentioned, there are many reasons for vaccine hesitancy, and they are not only due to insufficient knowledge about the bases of vaccination; among other things, this hesitancy is linked to inter-professional tensions, how the professionals concerned perceive their place within the healthcare system and how they perceive their actions and how these actions are perceived. Suffering at work, social logics and systemic reasons - as evidenced by the healthcare system crisis – lead people to doubt vaccination to the point of refusing it. Such situations call for reassuring responses prompting the trust needed as well as the awareness of the responsibility to do everything to minimise the risk to patients, an integral part of health sectors professions.

When introduced in care settings, compulsory vaccination binds health professionals, their employers and the institutions responsible for managing the health system as a whole. Examining compulsory vaccination must therefore be thought about from an ethical point of view in relation to, firstly, all the means implemented and efforts made by health professionals to protect patients and, secondly, all the resources made available to these health professionals by their employers for this purpose, and to protect their health.

Institutions' lack of resources, limited human resources, excessive workload and encouraging presenteeism (working despite illness) to maintain teams' productive capacity, are all factors that have adverse effects on the health of professionals working in care settings, as well as on the care provided to patients. According to the work of Rachel Gur-Arie, an ethical researcher¹⁰⁴, these failings play a part in eroding the legitimacy of institutional arguments justifying the compulsory vaccination of caregivers by the need to protect professionals and patients since the fact that these arguments are not applied to other aspects of hospital care raises the question of the strength of commitment to these values.

¹⁰⁴ Gur-Arie R., Hutler B., Bernstein J., (2023), "The ethics of COVID-19 vaccine mandates for healthcare workers: Public health and clinical perspectives", *Bioethics*, 37(4):331-342; https://pubmed.ncbi.nlm.nih.gov/36710589/

These working conditions and the extremely variable use of these arguments are partly responsible for health professionals' distrust of their hierarchy and the health authorities.

At the workplace level, a caregiver who doubts their colleagues, what has been approved by the scientific authorities and assessed by the institutions responsible can help weaken their institution from within. The inherent risk of an institution's own employees losing confidence in its recommendations or obligations is that some will be led to doubt the legitimacy of their profession, the knowledge, and intentions of their colleagues, which will weaken the link within these professions.

The issues of vaccine hesitancy in care settings thus pose significant challenges that are central to contemporary ethical thinking: how to introduce acceptable compromises by not sacrificing the individual for the community, nor the community for the individual? The answer is related to finding what connects individuals to each other in a community.

Compulsory vaccination raises questions about the difficult balance of creating ethical justice that aims to bring about "a good life, with and for others, in just institutions" according to Ricœur's formula, which is based on normative values of which the primary pursuit must be that of combatting injustice. The risk of ethics that disregard these standards exposes society to arbitrary danger, as Philippe Svandra highlights 106. That is why this author writes: "these procedures must be able to be developed during public and democratic debate. In this respect, the conditions for developing these standards are more important than the standards produced" 107.

The perception by some professionals in the health and medico-social sectors that compulsory Covid-19 vaccination was a harsh decision has resulted in resentment building up towards political and health institutions, the roots of which originated long before the health crisis.

This does not justify the refusal of compulsory Covid-19 vaccination by some professionals but helps to shed light on the landscape in which it took place. In a situation where vaccination does not ensure zero risk of virus transmission, the focus on compulsory vaccination has been able to reduce the recommendations regarding other tools in the range of methods to protect patients (wearing a mask, hygiene measures, hydro-alcoholic solutions, gowns, ventilation of premises, screening tests, etc.) by establishing a hierarchy of effectiveness between these various complementary means to reduce risks.

This analysis leads us to question the conditions of support for standards set by institutions as they fail to develop policies jointly with target groups. The requirement

¹⁰⁵ P. Ricœur, (1990 re-ed. 2015), *Soi-même comme un autre*, Paris, Seuil, coll. "*Points Essais*" [Test Points]. ¹⁰⁶ Philippe Svandra is a Healthcare Executive and Doctor of Philosophy. P. Svandra, (2016), "*Repenser l'éthique avec Paul Ricœur. Le soin : entre responsabilité, sollicitude et justice*" [Rethinking Ethics with Paul Ricœur. Care: between responsibility, concern and justice], *Recherche en soins infirmiers*, 2016/1 (No. 124), pp. 19-27; https://www.cairn.info/load pdf.php?ID ARTICLE=RSI 124 0019&download=1

¹⁰⁷ P. Svandra, *Ibid*.

to lead by example, which has been widely used to legitimise compulsory vaccination for health professions, must be conceived reciprocally: the political and health authorities must be exemplary in the manner in which they make, justify and implement vaccination policies, especially when it concerns compulsory vaccination. In times of crisis justifying compulsory or highly recommended vaccination, and in the absence of any contraindication to vaccination, it is important to remember that patients, when they can do so, also have a duty to get vaccinated for reasons beyond their mere individual interest (protecting themselves from a potentially serious disease): to protect the healthcare system and health professionals they may encounter during a consultation or hospitalisation.

The CCNE recommends, as far as possible, that compulsory and/or recommended vaccination, and in general all decisions involving measures likely to cause dissension within teams, follow processes that involve co-building with the target occupational groups and associations representing users, in particular those belonging to the populations who are most vulnerable to the pathogens concerned.

In the face of the large amount of **disinformation** or **conflicting information** inherent in crisis situations, and the furthering of knowledge, **the health and medico-social sectors are required to adapt**.

The CCNE encourages, on the one hand, **enhancing the scope of the initial and continuing training** of professionals – regardless of their position and whether they are caregivers or non-caregivers – in the area of vaccination and, more broadly, in terms of health-related **professional responsibilities**. This could be based on **raising awareness of the ethics of care**.

On the other hand, the appointment, in institutions, of a vaccination officer with a solid basis in vaccinology and ethics, who can be turned to in case of doubts, fears and questions about a vaccination could help to ease possible situations of tension within services. It is about increasing the number of contact points and having a structured and shared approach on thinking related to vaccinations which are subject to discussion.

Occupational medicine, infectious disease specialists, members of an operational hygiene team, pharmacists, etc. could be among the stakeholders asked on the ground by management teams to provide information on vaccinations that raise questions. These professionals share a daily life and a common sense of belonging to a community. The action or presence of peers allows professionals to attach themselves to familiar reference points. Discussions may take place both in a collective setting and as part of a special doctor-patient meeting. In both cases, this environment is conducive to trust.

It is about increasing the number of contact points and having a structured and shared approach on thinking related to vaccinations which are subject to discussion.

The CCNE wishes to draw attention to the current state of occupational medicine in France, which represents a discipline that is nearing extinction. Few medical students go into this field and many organisations have been without occupational medicine for several years or without enough time to properly support professionals. However, Article L.3111-1 of the French Public Health Code makes occupational medicine responsible for helping to implement the vaccination policy. In addition, occupational health, as a multi-professional field, also has a major role in helping to solve the crisis in our country's health institutions. The lack of support for this discipline potentially undermines the process of disseminating prevention within institutions.

This section is devoted mainly to the health sector. The CCNE considers, however, that a closer look should be given to this in the medico-social sector.

CONCLUSION

In summary, following on from its previous work and excluding the particular case of vaccines that have demonstrated a very high benefit-risk ratio such as, currently, the hepatitis B vaccine, the CCNE considers that the question of compulsory vaccination for professionals working in the health and medico-social sectors can only be raised as a **last resort**, i.e.:

- in the face of a health situation that poses a major and serious threat to the population, and which may undermine the operation of the healthcare system;
- even if there are scientific uncertainties about the effectiveness of the vaccine, once knowledge at the population level shows documented benefits and the individual risks appear to be low and closely monitored.

Such a decision, which belongs to the politicians, can only be taken following a process that has been clearly explained, debated and supported by health structures and professional organisations.

For the CCNE, the issue is not how to justify the obligation but whether it is acceptable under the main principles mentioned above.

The Committee stresses the importance of raising awareness of the decision-making processes leading to recommendations or obligations aimed at care stakeholders. In terms of compulsory vaccination more specifically, it is up to the institutions to provide information on how expertise is produced for newly introduced vaccines.

DIFFERENT OPINION

Some CCNE members wanted the associated publication of the following text:

Different opinion proposed by several CCNE members

In this text, we wish to express a different view not with regard to the benefit of vaccination, but with regard to its compulsory nature in certain situations (particularly a health crisis with a great deal of uncertainty), which, in our view, raises important ethical questions.

We note, in the introduction, the differences in vaccination strategy between European countries, identified by the CCNE's Opinion in particular for "the Scandinavian and Anglo-Saxon countries as well as Switzerland" which "stand out for vaccination policies, both in the general population and among health professionals, which are more focused on incentive than obligation"; and although the outbreak of the pandemic led many European countries to make COVID-19 vaccination mandatory for health professionals¹, "the difficulties encountered, and the evolution of the virus as well as the epidemic have prompted the vast majority of countries to abandon or discontinue compulsory vaccination campaigns for this population". The wide range of positions adopted within Europe shows that there is no consensus on this issue.

It also seems essential to clarify beforehand that vaccination has made enormous progress and remains the best weapon to protect children and adults from a large number of infectious diseases: it has made it possible to eradicate serious diseases, such as smallpox, and will certainly help to eradicate others, such as polio in the near future².

In its reply dated 18 December 2020³ to the Minister of Solidarity and Health's referral on the "Ethical Issues of a SARS-COV-2 Vaccination Policy", the CCNE indicated that "vaccination is above all a public health issue and illustrates, more than other fields of medicine, an ethical conflict between the interests of society and those of the individual. Because it is not only protecting the individual being vaccinated. Vaccination also protects others, which highlights the altruistic nature and social value of vaccination" (page 4), and "inasmuch as it undermines individual freedom, compulsory vaccination examines the circumstances that may justify it. In the context of the Covid-19 pandemic, it can only be seen as a last resort, in the face of very serious danger created by an uncontrolled pandemic, with a supply of vaccines which are widely known to be effective and safe, and which have been tested with the objectiveness required" (page 9). Finally, the CCNE suggested complying with a few

¹ Yves Bourdillon, "Vaccination obligatoire des soignants : ce que font les autres pays" [Compulsory vaccination of caregivers: what other countries do], Les Echos, 5 July 2021.

² Gilles Pison, "Rougeole, coqueluche, tétanos...Les vaccins restent la meilleure arme mondiale pour protéger les enfants" [Measles, whooping cough, tetanus...Vaccines remain the best weapon worldwide to protect children], The Conversation, 2023

³ https://www.ccne-ethique.fr/sites/default/files/2021-07/Saisine%20Vaccins.pdf

rules for the establishment of an ethical framework, in particular "demonstrating vigilance when collecting consent to the vaccination of vulnerable individuals; the time given to provide information and for its use by the individual in deciding whether or not to be vaccinated must be observed regardless of the emergency situation, and it must be possible to trace the effectiveness of this process" (page 16).

Our main point of disagreement with the recommendations proposed in the CCNE's opinion does therefore not concern the need for and importance of vaccination, nor the fact that compulsory vaccination is only considered as a strategy of last resort, but the legitimisation a priori of mandatory vaccination imposed by the public authorities in a health crisis situation, for certain vaccines and for a category of individuals. This obligation, if it is to be imposed, can only be assessed by taking into account the whole context; the crisis situation does not justify this obligation alone. It also needs to be assessed with regard to everyone's freedom to make decisions about their own body according to the principle of the inviolability of the human body. In this respect, the question arises about the limit of the government's right to impose a vaccination on the citizen's body which, without that citizen's consent, is likely to be only a constraint.

The different opinion expressed here opposes three reasons for this justification.

The first reason is that, while this type of health crisis situation requires a specific response, it is not necessarily the suspension of citizens' freedom to make decisions about their own body. The alternative, in this case, would be to seize this crisis situation as an opportunity to decisively raise citizens' awareness of their duty of solidarity, which entails appealing to their responsibility through a recommendation instead of subjecting them politically by constraint. However, if this opportunity is not seized, the political risk of constraint results in realising "biopower". How can we not worry about this governmental choice of constraint, which is contrary to the pursuit of the democratic ideal of emancipation of an increasingly active and responsible citizenship?

The second, more specific reason, is related to the **professional status of health workers**. What right does government have to impose compulsory vaccination on these professionals, who have some expertise and field experience on the means to be implemented to avoid possible transmission of an infectious agent? Does a government which imposes vaccination not take the risk here of dismissing the professional expertise acquired? Moreover, as the Opinion shows however that the lower the level of medical expertise, the higher the rate of vaccine hesitancy, it can be questioned whether this argument may be underlying the introduction of compulsory vaccination. If that were the case, would this mean that caregivers' freedom of choice would be a right differentiated according to their level of qualification?

The third reason concerns the specific characteristics of the vaccine. Indeed, in the light of the recent experience of the Covid-19 health crisis, it seems to us that, even if vaccination must be recommended and that everything must be done to encourage health workers to be vaccinated, the compulsory vaccination of these staff could only be ethically acceptable, including in times of health crisis, if preclinical and clinical trials have demonstrated that, in addition to its safety, the vaccine:

- effectively blocks the transmission of the infectious agent (thus having a proven collective benefit). If this is not the case, the obligation to wear a mask, combined with hand hygiene, ventilation of premises, regular screening tests, etc. will ensure safe care;
- provides effective immunity against the disease, and not just against serious forms, so that the healthcare system remains operational. If this is not the case, then any health professional whether vaccinated or not who may be infected, even if they are showing few symptoms, or are even asymptomatic, will have to isolate themselves in order not to infect anyone else.

If these two conditions are not met, the health consequences could be significant. Thus, vaccination may:

- **not have the collective benefit expected** (protection of the rest of the population and in particular the most vulnerable); an essential benefit in view of the individual constraint imposed by the mandatory nature of vaccination;
- build confidence that leads vaccinated people to feel protected and be less vigilant with less respect for preventive measures, including towards vulnerable people and to neglect mild symptoms (without being tested to determine whether or not they are carrying the infectious agent). As a result, vaccinated individuals carrying the infectious agent, and therefore potentially contagious, may access various living and care environments without being aware of the risk they pose to vulnerable people.

Furthermore, in order to protect ourselves from the potential opportunistic instinct of certain pharmaceutical companies, particularly in times of health crises, we wish to note, as stated in the CCNE's Opinion 135⁴, that it is necessary to reflect on "the issues relating to the legal qualification of certain innovative medicines as "global public goods" (page 37).

In conclusion, compulsory vaccination for professionals working in the health and medico-social sectors would be **an individual constraint that would only be ethically conceivable after a rigorous review of the situation**, numerous recommendations, and

⁴ L'accès aux innovations thérapeutiques : enjeux éthiques [Access to therapeutic innovations: ethical issues] – https://www.ccne-ethique.fr/sites/default/files/2021-07/Avis%20135.pdf

in any event only if it is considered that the collective benefit is greater, especially for the most vulnerable, i.e. if it has been scientifically demonstrated that vaccination is effective in preventing the transmission of the disease.

Gilles Adda Mounira Amor-Guéret Abdennour Bidar Sophie Crozier Marion Muller-Colard

APPENDICES

Appendix 1. Members of the working group:

Régis Aubry

Jean-François Bach

Alexandra Benachi (Rapporteur)

Yvanie Caillé

Anne Caron-Déglise

Laurent Chambaud (Rapporteur)

Alain Claeys

Christophe Delacourt (External participant)

Didier Dreyfuss

Jean-Louis Haurie

Florence Jusot

Séverine Laboue (Rapporteur)

François Stasse

With the organisational and editorial support of Manon Brûlé (trainee), Capucine Garnier-Muller (trainee), Lucie Guimier (editor) and Clara Ruault (trainee).

Appendix 2. External members from other institutions

Emmanuelle Ripoche (HAS)

Jeremy Ward (INSERM, Technical Committee on Vaccinations at HAS)

Appendix 3. List of people heard:

François Arnault, President of the Conseil national de l'ordre des médecins;

Brigitte Autran, physician, professor of immunology, President of the French Committee for monitoring and anticipating health risks (Covars);

Marc Bourquin, strategy advisor to the Fédération Hospitalière de France;

Eric Buleux Osmann, President of Transhépate;

Patrick Chamboredon, President of the Ordre national des infirmiers;

Jan-Marc Charrel. President of France Rein:

Marie-Charlotte Dalle, AP-HP's Director of Legal Affairs and Patient Rights;

David Fiant, President of Vaincre la Mucoviscidose;

Alain Fischer, physician, professor of paediatric immunology, coordinator of the Covid-19 vaccine strategy in France;

Pascal Forcioli, Director of the Public Mental Health Institution of Vendée;

Carmen Hadey, administrator for SOS Hépatite et maladies du foie:

Quentin Henaff, Deputy Manager of the Human Resources Unit, Fédération Hospitalière de France (FHF);

Marylin Lackmy, genetics physician at Guadeloupe CHRU and Director of the Espace de Réflexion Ethique Régional de Guadeloupe;

Odile Launay, physician, professor of infectious diseases;

Magali Leo, Renaloo's Advocacy Manager;

Daniel Lévy-Bruhl, epidemiologist and Head of the respiratory infections unit at Santé publique France;

Sylvie Mercier, President of Renaloo;

Frédéric Pierru, researcher in social and political sciences at the CNRS and EHESP (Ecole des Hautes Etudes en Santé Publique);

Didier Pittet, Chief Medical Officer of the Infection Control Programme and Director of the World Health Organization (WHO) Collaborating Centre on Patient Safety, University Hospitals of Geneva;

Vincent Prévoteau, President of the Association of Hospital Directors;

Zaynab Riet, Delegate-General of the Fédération Hospitalière de France;

Charlotte Roffiaen, Ellye's Advocacy Manager;

Ivan Sainsaulieu, researcher in sociology and political sciences, professor of universities:

Nathalie Senecal, Director of the Care Quality and Health Policy Unit, Vaincre la mucoviscidose:

Ruddy Valentino, resuscitation physician at the CHU of Martinique and Director of the Espace de Réflexion Ethique Régional de Martinique;

Frédéric Worms, Professor of Philosophy, Director of the Ecole Normale Supérieure, PSL.

Appendix 4. Referral to the CCNE by the Minister for Health and Prevention



The Minister

Paris, 21 November 2022

Our Ref.: D-22-025071

The Minister

to

Mr Jean-François Delfraissy, President National Ethics Advisory Committee (CCNE)

Re: Referral on the compulsory vaccination of health professionals and professionals working in the health and medico-social sectors

Dear Jean-François,

Vaccination is an effective way of preventing many infectious diseases. Professionals working in the health and medico-social sectors have a vital role in caring for frail people, but also in protecting them. The list of mandatory vaccines, as well as the professions concerned, has thus evolved over the years, and following epidemics.

The compulsory vaccination of health workers has thus led to infrequent cases of hepatitis B stemming from health professionals, although they were very common in the 1970s.

With the Covid-19 epidemic, the issue of compulsory vaccination has again arisen for individuals with a high risk of exposure to the virus and who support frail and vulnerable people on a daily basis.

In order to protect both professionals and patients, the first booster dose was incorporated into compulsory vaccination applicable to staff working in health and medico-social institutions on 30 January 2022, in accordance with Law No. 2021-1040 of 5 August 2021 on managing the health crisis.

In addition, the annual vaccination against seasonal flu was mandatory for health professionals until 2006 when it was suspended by the Decree of 14 October 2006. This vaccination has been recommended since that date.

In March 2022, Santé publique France estimated that flu vaccination coverage was 22% among these same professionals. However, these professionals in the health and medico-social sectors are in close contact with the frailest individuals who are at risk of severe forms of influenza and Covid-19.

.../...

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It is necessary to process your data in order to manage your request and it is part of the tasks entrusted to the social ministries. In accordance with the General Data Protection Regulation (GDPR), you can exercise your rights at dgs-rgpd@sante.qouv.ff or by post. For more information: https://solidarites-sante.gouv fr/ministere/article/donnees-personnelles-et-cookies

In this context, I would like to know the opinion of the National Ethics Advisory Committee on defining criteria that can be used to justify, or not, the introduction of compulsory vaccination, in particular with regard to considering the values of individual freedom on the one hand and the collective benefit and public interest underlying the social contract prompted by vaccination on the other hand. This consideration will also take into account the issues attached for the public authorities to the protection of professionals who are among the most exposed to the risks of illness, especially with the spread of an epidemic.

Your consideration will therefore take into account the compulsory vaccination of vaccine-preventable diseases at high risk of transmission such as, for example, measles or pneumococcal infections.

To give you a complete picture, the Haute Autorité de Santé was asked in October 2019 to review all recommended vaccines

101	professional	s working in	the nealth	and medico-social	sector. II	was s	supplemented	to integrate	the subject	OI C	: Ovia-i
vaccination. Its recommendations are expected in January 2023.											

I would like to have your opinion during April.

Yours sincerely,

[signature]

François Braun

