# **OPINION 142**

CONSENT AND RESPECT FOR INDIVIDUALS IN CASE OF GYNAECOLOGICAL OR INTIMATE EXAMINATIONS



NATIONAL CONSULTATIVE ETHICS COMMITTEE FOR HEALTH AND LIFE SCIENCES





# Consent and respect for individuals in case of gynaecological or intimate examinations

This Opinion was adopted unanimously by the committee members during the CCNE plenary assembly on 16 February 2023.



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## SUMMARY

In its Opinion 136 of July 2021 on the "Changes in the ethical issues surrounding consent in healthcare", the CCNE drew renewed attention to every patient's fundamental right to take part in the decisions relating to their health, as well as the dynamic and evolving nature of the consent process, which is not only based on a relationship of mutual trust, but also adapts to the person's journey and choices.

On 4 July 2022, in light of the specific importance and sensitivity of examinations involving physical and psychological intimacy, the Prime Minister, Elisabeth Borne, referred the matter to the CCNE for an in-depth review of the concept of consent in cases of gynaecological and intimate examinations.

This Opinion 142, entitled "Consent and respect for individuals in case of gynaecological or intimate examinations", analyses the ethical issues relating to the practice of gynaecological and/or medical examinations involving the urogenital and anorectal areas, which patients may experience as an "extremely intimate" procedure. These examinations, which are performed by different healthcare professionals (HCPs), are classed as screening, diagnostic and monitoring procedures; they may be scheduled or unscheduled, and may take place in a clinical and/or teaching setting.

This Opinion is being issued at a time when a number of patients are filing complaints against HCPs and amidst the backdrop of high tensions between patient associations and HCPs, which has prompted learned societies to take action and produce guidelines and recommended best practices.

At the end of its 33 hearings and eight months of work, the CCNE notes that the conditions for performing intimate examinations and the procedures for obtaining consent are currently being discussed in several countries. It highlights the major risks associated with a loss of trust between patients and HCPs, such as the risk of patients losing out if they decide to abandon the idea of seeking treatment, the risk of some medical specialities losing interest as a result of the trend of shaming HCPs and launching targeted attacks against their reputation over social media, and the risk of medical practices evolving in a way that fails to meet patients' real needs.

Given this situation, the CCNE stresses the need for appeasement, for mutual consideration between patients and HCPs, and for mutual understanding when it comes to intimate examinations, such as the difficulty for patients undergoing this type of examination and the complexity for HCPs in carrying out these procedures.

The CCNE emphasises the need to build a framework that is respectful and reassuring for both patients and HCPs. On the one hand, the framework must ensure that intimate examinations do not elicit a feeling of ill-treatment or intrusion among patients, and on the other hand, it must enable HCPs, the vast majority of whom are concerned about their patients' well-being, to carry out their work without any fear of seeing their clinical practices illegitimately challenged.

Firstly, the CCNE points out that intimate examinations require extra care, interpersonal



skills, precautions and tact at every stage of the procedure. HCPs must listen to their patients and consider what they are feeling and saying, while taking account of their modesty and need for privacy, as well as due consideration to the pain or discomfort that the examination might cause. In this respect, the CCNE stresses that care must be taken about the equipment used, the time allocated and the way in which the examination is organised. The CCNE also points out that the relevance for performing examinations must be constantly reviewed against the principles of necessity, subsidiarity and proportionality.

Secondly, when it comes to consent for the examination and unlike what may happen in certain countries, the CCNE does not consider that it is appropriate to collect consent in writing or require a third party to always be present during the examination. However, the CCNE insists that consent must no longer be implied or presumed, but instead must be explicit and differentiated for each examination carried out during a consultation. In some circumstances, HCPs or patients may wish to have a third party of their choosing present during all or part of the consultation. This possibility should be maintained, especially for minors, bearing in mind that the presence of a third party can be reassuring, but may also sometimes interfere with the care relationship.

The CCNE also emphasises the following points:

- The importance of providing information prior to seeking consent: patients should understand why they are being offered an examination, the information that it will provide, what it will actually involve, whether it is likely to cause pain or discomfort, and whether other options are available.
- The need to consider any reluctance or refusal: the patient's decision to refuse an examination should never lead to an abrupt end to the consultation or a breakdown in the care relationship.

Thirdly, the CCNE considers that additional precautions must be taken when:

- Pupils or students are performing or attending intimate examinations.
- Patients are in a particularly vulnerable situation, such as minors, people with disabilities, people in psychological distress, people with cognitive difficulties and victims of violence.

Generally speaking, the CCNE also considers that it is vitally important to give patients' grievances, complaints and claims the attention that they deserve and deal with them in an appropriate manner.



Finally, because participatory democracy in healthcare is a key driver for strengthening trust, the CCNE recommends that patients should be involved in HCP training programmes, and that guidelines and recommended best practices should be developed jointly by professional organisations and patient associations.

Finally, the CCNE wishes to make two specific recommendations for the authorities:

- The Ministry of Health and Prevention must ensure that the conditions for organising care allow examinations to be carried out as effectively as possible, particularly with regard to information and consent.

- The Ministry of Higher Education & Research and the Conference of Medical Deans must take greater account of the issues for providing training on humanities and the ethics of care, and consistently reinforce these issues when developing teaching programmes.

In its Opinion, the CCNE analysed how an act towards the body can become an intrusion, although it is ultimately intended to restore, soothe and heal. This can happen if we forget that the mind must always give consent before the body can be touched. The particular sensitivity surrounding intimate examinations is a reminder that giving due consideration to subjectivity is key to gaining patients' agreement to nudity and the examination. Subject to the pressures of an intense work rate and challenging conditions, healthcare facilities may make patients feel as though they are required to submit their bodies to examination, whereas patients should instead be invited to entrust their most valuable asset, i.e. their body, which is inseparable from their psyche, to someone who welcomes, respects and then cares for them.



## INTRODUCTION

On 4 July 2022, Prime Minister Elisabeth Borne asked the CCNE to "conduct an in-depth review into the concept of consent in cases of gynaecological examinations and, more broadly, all intimate examinations" for the purpose of "guiding HCPs with their essential duties, while responding to patients' expectations and legitimate concerns regarding respect for their wishes and integrity."

This referral takes place amidst a specific context marked by:

- The development of gender studies, which analyse the roles assigned to individuals according to their gender and, in the field of gynaecology and obstetrics, the control over women that may result from certain medical practices in the areas of sexuality and fertility.
- Awareness of the prevalence of sexual and gender-based violence in society in general<sup>1</sup> and in the healthcare system in particular.<sup>2</sup>
- The rejection of authoritarianism and paternalism in medicine and the rise of a more general movement spearheaded by user associations and certain HCPs in favour of promoting participatory democracy in healthcare and giving greater value to patients' role in the care pathway.

The creation of the #PayeTonUtérus hashtag in 2014 to raise greater public awareness of the complex relationship that some women have with the medical profession, particularly gynaecologists, the controversy that broke out in 2015 about vaginal and rectal examinations performed under general anaesthesia without consent in certain establishments, the recent media coverage of legal proceedings against doctors, cases brought by associations after patients' complaints of painful experiences or even gynaecological and obstetric violence during medical examinations were not sufficiently investigated, and the growing number of public statements issued by HCPs who fear that their profession as a whole will be unfairly stigmatised reveal the extreme sensitivity of this particular issue.

<sup>&</sup>lt;sup>1</sup> Report by the Independent Commission on Sexual Abuse in *the Catholic Church (CIASE)*. Sexual violence in the Catholic Church, France 1950-2020. October 2021. Available on the CIASE website: <u>https://www.ciase.fr/medias/Ciase-Final-Report-5-october-2021-english-version.pdf</u>; Report by the Independent Commission on Incest and Sexual Violence against Children (CIIVISE), Sexual violence: *Protecting children. Intermediate conclusions.* March 2022. Available on the CIIVISE website: <u>https://www.ciivise.fr/wp-content/uploads/2022/03/CCI-inter 2803 compressed.pdf</u>

<sup>&</sup>lt;sup>2</sup> Report by the High Council for Gender Equality (HCE), Sexist acts during gynaecological and obstetric care: recognising and ending violence that has long been ignored. June 2018. Available on the HCE website: https://www.haut-conseil-egalite.gouv.fr/sante-droits-sexuels-et-reproductifs/actualites/article/actes-sexistes-durant-le-suivi-gynecologique-et-obstetrical-reconnaitre-et.

Report by the National Health Conference (CNS). *Health democracy: a public health emergency,* April 2022. Available on the CNS website: <u>https://sante.gouv.fr/ministere/acteurs/instances-rattachees/conference-nationale-de-sante/avis-rapports-et-recommandations/mandature-2020-2025/article/la-democratie-en-sante-une-urgence-de-sante-publique-rapport-de-la-cns-du-06-04</u>



The upsurge in complaints, the indictment of a gynaecologist for deliberate violence, and accusations of rape made against doctors by several patients who considered that they had been subjected to rough vaginal and rectal examinations without their prior consent, have galvanised the learned societies into action. In particular, they have produced guidelines and recommended best practices<sup>3</sup> in an effort to rebuild and maintain trust between patients and HCPs, including initiatives to raise awareness of the issues surrounding consent for intimate examinations, and risk prevention initiatives. They are truly committed to gaining greater awareness of the discomfort and unease affecting the care relationship for a number of patients receiving gynaecological and intimate treatment, listening to their testimonies, improving the quality of the care relationship and abandoning inappropriate practices. These steps are likely to contribute to the much-needed appeasement of the relationship between patients and all HCPs involved in intimate procedures and examinations.

The CCNE's review reflects the same desire for bringing long-lasting peace to the relationship between patients and HCPs. Appointing two rapporteurs<sup>4</sup> and setting up a working group allowed the CCNE to conduct around 30 hearings between September 2022 and January 2023 with the aim of gathering feedback from representatives of user associations, including in the field of disabilities, as well as from HCPs, legal professionals, junior doctors and students<sup>5</sup>.

This work extends and builds on Opinion 136 on "*Changes in the ethical issues surrounding consent in healthcare*", published by the CCNE in July 2021. It also has the advantage of exploring the issue of intimacy in greater detail.

<sup>&</sup>lt;sup>3</sup> Examples of professional guidelines and recommendations:

*Guidelines for gynaecological and obstetric consultations* (2021): http://www.cngof.fr/actualites/758-chartre-examen-gynecologie.

Recommendations for the clinical practice of pelvic examinations (2023), presented at the Pari(s) santé Femmes conference in Lille on 25 January 2023. To be published in the Gynécologie Obstétrique Fertilité et Sénologie journal.

Guidelines for gynaecological and obstetric consultations, 2021: http://www.cngof.fr/actualites/758-chartre-examen-gynecologie.

*Guidelines for radiology consultations,* French National Council for Radiology and Medical Imaging Professionals (2022): http://www.cnpg4-radiologie.fr/wp-content/uploads/sites/26/2022/07/Charte-Consultation-en-Radiologie-Finale.pdf;

In addition to the obvious value of producing and publishing guidelines and recommendations, which are also displayed in doctors' surgeries and hospital departments, there remains the question of their effective uptake by HCPs and patients alike.

<sup>&</sup>lt;sup>4</sup> Rapporteurs: Fabrice Gzil and Karine Lefeuvre

<sup>&</sup>lt;sup>5</sup> Refer to the list of people interviewed in the appendix.



**Scope of the opinion:** this opinion analyses the ethical issues relating to the practice of gynaecological examinations and/or intimate procedures - and which are even experienced as "extremely intimate" in the case of examinations involving the urogenital and anorectal areas. Such examinations and procedures may require patients to partially reveal their inner selves (discussions about psychologically sensitive subjects) and remove all or part of their clothing, entail visual or tactile contact with the external genital organs (vulva, vagina, penis, testicles, etc.), breasts or anus, and even penetration of the urogenital tract and/or anorectal canal with an instrument or finger (e.g. a speculum for smear tests, inserting an intrauterine device or a urinary catheter, and introducing an endovaginal ultrasound probe or an instrument for anoscopies and rectoscopies). All these procedures are classed as intimate examinations. They may be used for screening, establishing a diagnosis or providing follow-up care, whether scheduled or otherwise (emergencies), in a purely clinical and/or teaching setting (in the presence of future medical or paramedical professionals in training), under anaesthesia or not, painful or not, uncomfortable or not.

The issues discussed in this opinion do not include an analysis of the medical procedures involved in obstetric emergencies where the functional or life-threatening risk for the mother or unborn child substantially modifies the way in which the ethical issues relating to the patient's consent are understood. Obstetric emergencies merit studies that are specifically devoted to these situations.

This opinion does not take account of all the intimate acts during the care pathway (intimate grooming carried out by a HCP or nurse, intimate questions asked in a questionnaire or during discussions, shared hospital rooms, doors opened during care, patient gowns open at the back, etc.). These acts call for a review of the conditions for respecting privacy in the French healthcare culture.

Therefore, this opinion mainly concerns women, who attend an average of 50 to 80 gynaecological consultations during their lifetime, but not exclusively. It is also aimed at those men whose decision not to complain does not mean that they are not suffering, and also HCPs from a wide range of specialities, including gynaecology, obstetrics, urology, proctology and gastroenterology, radiology, emergency medicine, dermatology and general medicine, as well as midwives, physiotherapists<sup>6</sup> and osteopaths, nurses and caregivers, whether in private practices, public or private hospitals or social and medical care facilities.

<sup>&</sup>lt;sup>6</sup> Physiotherapists are authorised to carry out pelvic exams (vaginal and rectal) for diagnostic and therapyrelated purposes.



Similar discussions are currently taking place in other countries, as illustrated in the United States by the 2022 publication of a study in the Hastings Center Report on unconsented intimate medical exams<sup>7</sup> and in the United Kingdom with the decision by the General Medical Council in 2020 to update its ethical recommendations entitled *Intimate examinations and chaperones*<sup>8</sup> and the publication in 2020 of the book edited by Camilla Pickles and Jonathan Herring, entitled *Women's Birthing Bodies and the Law. Unauthorised Intimate Examinations, Power and Vulnerability*<sup>9</sup>.

<sup>&</sup>lt;sup>7</sup> Bruce, L., Hannikainen, I.R. and Earp, B.D. (2022), New Findings on Unconsented Intimate Exams Suggest Racial Bias and Gender Parity. *Hastings Center Report*, 52: 7-9. <u>https://doi.org/10.1002/hast.1349</u>

<sup>&</sup>lt;sup>8</sup> General Medical Council (2013, updated in 2020) *Intimate examinations and chaperones,* https://www.gmc-uk.org/-/media/documents/maintaining-boundaries-intimate-examinations-and-chaperones\_pdf-58835231.pdf

<sup>&</sup>lt;sup>9</sup> Camilla Pickles & Jonathan Herring (2020) Women's birthing bodies and the law. Unauthorised intimate examinations, power and vulnerability, Bloomsbury Publishing



## I. SPECIFIC FEATURES AND COMPLEXITIES OF THE CARE RELATIONSHIP WHEN PERFORMING INTIMATE EXAMINATIONS

### A. SPECIFIC FEATURES OF CARE BORDERING ON INTIMACY

While any medical examination or procedure, by its very nature, involves contact between HCPs and their patients' physical or mental bodies, which may therefore infringe on their intimacy and undermine their modesty or even endanger their integrity, gynaecological and urogenital/anorectal examinations can amplify the level of discomfort felt both by those undergoing the examination and those performing it.

#### 1. Definitions of intimacy, modesty and integrity10

**Intimacy:** can be defined as a strictly personal physical (external) or mental (internal) space - involving thoughts, beliefs, dreams, plans, actions, body zones and images - from which others are excluded unless invited, which is generally secret and protected from disclosure by silence, cover or concealment. Therefore, it is fundamentally private and specific to the individual or a chosen group (family, couple, etc.). The different aspects of intimacy create an *absolutely original place*<sup>11</sup> where the most original solitude reigns and the most profound and certain identity unfolds - that explains why negating intimacy is so objectifying and destructive. The contours of privacy are blurred, subjective and evolving, depending on changing social, cultural and religious norms, the times and the geography, but the need to preserve privacy is universal. It is a need and a right guaranteed by the right to privacy<sup>12</sup>.

**Modesty**: refers to discretion, restraint or the propensity to feel embarrassed when faced with speech or actions that may offend decency, penetrate the individual's physical or mental space, undermine the right distance from others, or be classed as sexual in nature. It is partly related to susceptibility, and its intensity varies according to each person's subjectivity, age, experience, culture and any weaknesses. An individual's

<sup>&</sup>lt;sup>10</sup> For the purposes of this opinion, the CCNE working group defined the concepts of intimacy, modesty and integrity.

<sup>&</sup>lt;sup>11</sup>Alain Cugno, "The Intimate", *Études*, 2003/12 (Vol. 399), p. 621-631. DOI: 10.3917/etu.996.0621. URL : https://www.cairn.info/revue-etudes-2003-12-page-621.htm

<sup>&</sup>lt;sup>12</sup> The right to privacy encompasses the right to effective respect for the individual's physical and moral integrity and is enshrined in Article 12 of the United Nations Universal Declaration of Human Rights, 1948, https://www.un.org/en/about-us/universal-declaration-of-human-rights; Article 8 of the European Convention on Human Rights, https://www.echr.coe.int/documents/d/echr/guide\_art\_8\_eng; and Article 9 of the French Civil Code. United Nations Universal Declaration of Human Rights, 1948, Art. 12 https://www.un.org/en/about-us/universal-declaration-of-human-rights; European Convention on Human Rights, Art. 8 https://www.echr.coe.int/documents/d/echr/guide\_art\_8\_eng; French Civil Code, Art. 9



modesty is especially challenged during gynaecological or intimate examinations.

**Integrity:** refers to the state of a thing or being that has remained intact, has not undergone any alteration in its body or mind, and from which nothing is missing. Physical, psychological and moral integrity is also a right that is protected by the legislator<sup>13</sup>.

#### 2. Type of unlawful and disproportionate infringements

Due to the principle of the inviolability of the human body, invasions of privacy and/or integrity during predefined medical examinations or procedures are authorised by law only in exceptional circumstances (French Civil Code, Article 16-3; French Criminal Code, Article 1224; French Public Health Code, Article L.1111-4). The exception lies in medical situations, where such acts are subject to consent and must be warranted on medical grounds. Therefore, the law attempts to seek a balance between the least invasion of privacy and/or integrity and the greatest medical benefit for patients<sup>14</sup>. In this sense, only necessary and proportionate examinations and procedures are legal.

As pointed out by the High Council for Gender Equality (HCE)<sup>15</sup>, in gynaecology-obstetrics and in all medical disciplines involving intimate procedures (urogenital and anorectal), the acts or attitudes that constitute an infringement of an individual's intimacy include:

- Failure to take account of patients' physical or psychological discomfort and modesty, associated with the intimate nature of the consultation<sup>16</sup>.

<sup>&</sup>lt;sup>13</sup> Civil and criminal provisions protect the individual's physical and moral integrity (Articles 16 to 16-9 of the Civil Code; Articles 222-1 to 222-67 of the Criminal Code)

<sup>&</sup>lt;sup>14</sup> Medical acts that are likely to undermine a person's integrity are, by exception, permitted when they correspond to a medical need and are strictly proportionate to that need.

<sup>&</sup>lt;sup>15</sup> Report by the High Council for Gender Equality (HCE), Sexist acts during gynaecological and obstetric care: recognising and ending violence that has long been ignored, 2018. Available on the HCE website: <u>https://www.haut-conseil-egalite.gouv.fr/sante-droits-sexuels-et-reproductifs/actualites/article/actes-sexistes-durant-le-suivi-gynecologique-et-obstetrical-reconnaitre-et</u>. Page 4.

<sup>&</sup>lt;sup>16</sup> An evidence report by the American College of Physicians confirms that vaginal and pelvic examinations may cause pain, discomfort, fear, anxiety or embarrassment in about 30% of women. Hanna E. Bloomfield, Andrew Olson, Nancy Greer, et al. <u>Screening Pelvic Examinations in Asymptomatic. Average-Risk Adult</u> <u>Women: An Evidence Report for a Clinical Practice Guideline from the American College of Physicians</u>. Ann Intern Med.2014;161:46-53. [Epub 1 July 2014]. DOI:<u>10.7326/M13-2881</u>



- Derogatory remarks and/or judgmental comments about sexuality, appearance, weight, and the desire to have or not have a child, which reflect sexist conduct and a lack of empathy.
- Sexist insults.

In the medical fields covered by this opinion, there may also be various types of infringements of physical and moral integrity:

- Carrying out examinations without obtaining consent or respecting the patient's choices or wishes.17
- Carrying out examinations that are not medically justified or fail to comply with the latest scientific data and rules of practice<sup>18</sup>.
- All forms of sexual violence, such as sexual harassment, sexual assault and rape.

Criminal penalties are tiered according to the acts described above, and cases where an individual's integrity has been undermined are considered to be the most serious offenses and subject to the harshest penalties. Such unlawful and disproportionate infringements can result in lasting damage (after-effects) associated with the reduction of the person's physical, psychosensory or intellectual potential, including lower self-esteem.

The lack of reliable statistical data is an obstacle to rigorous objectification and quantification. For information purposes, reference may be made to the few studies focused on analysing patients' experiences during gynaecological or obstetric care:

- In October 2015, the Conference of Medical Deans submitted a report to the French Minister of Health, which indicated that between 20% and 33% of vaginal or rectal examinations performed on patients under general anaesthesia by medical students as part of their training were carried out without the patients' prior explicit consent<sup>19</sup>.

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https://dumas.ccsd.cnrs.fr/dumas-01194852/document
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<sup>&</sup>lt;sup>17</sup> A report on women's experiences of vaginal examinations during antenatal consultations shows that the lack of consent intensifies the psychological and physical discomfort of such examinations. Pauline Morvan. Women's experience of vaginal examinations during antenatal consultations. *Gynaecology and obstetrics*. 2015. dumas-01194852 Available at the following address:

<sup>&</sup>lt;sup>18</sup> For example, consistently performing vaginal examinations during medical check-ups on young girls, and women with low-risk pregnancies has sparked debates within the profession itself (Romain Lorioux. Is there any point in performing routine vaginal examinations when monitoring low-risk pregnancies? *Gynaecology and obstetrics.* 2010). An evidence report by the American College of Physicians claims that it is useless for detecting serious illnesses, and even counter-productive, a source of errors during the diagnostic process, and recommends it only when certain symptoms are present. Amir Qaseem, <sup>19</sup> Survey conducted by the Conference of Medical Deans in October 2015 and disseminated over several media channels, including Europe 1, See: <a href="https://www.europe1.fr/societe/touchers-vaginaux-sans-consentement-comment-mettre-fin-a-ces-pratigues-inacceptables-2538273">https://www.europe1.fr/societe/touchers-vaginaux-sans-consentement-comment-mettre-fin-a-ces-pratigues-inacceptables-2538273</a>



- Sociologist Aurore Koechlin, who conducted five surveys between 2015 and 2018 based on interviews and observations, states in her book, *The gynaecological norm*, that she "witnessed moments during the consultations where tensions were abnormally *high*." In her view, these situations where "patients often reveal their distress by screaming and crying" are "paroxysmal cases" that "remain (...) the exception" (p. 226). However, the fact that only partial data are available causes a problem, and Aurore Koechlin believes that we are constantly navigating our way between two pitfalls; i.e. covering up what really goes on during clinical examinations that are improperly performed, or "falling into media sensationalism" (2022, p. 226), by wrongly considering that these exceptional situations are representative of most practices.<sup>20</sup>

- In 2018, the AP-HP Clinical Ethics Centre carried out a survey among 216 patients in 16 different departments<sup>21</sup>. The first part of the questionnaire addressed respect for privacy in hospitals, which was defined as "*the way in which HCPs treat the body during examinations, care and grooming.*" 88% of respondents said that the HCPs paid great attention to their privacy, even though they were aware that their modesty could have been undermined by being treated in hospital; the other patients (12%) did not share this view.

- In the major national perinatal survey<sup>22</sup> conducted in March 2021 among 12,723 women, over 90% of respondents said that they were satisfied or very satisfied with the medical care that they received during their pregnancy and the care that they received from HCPs in the delivery room. However, 4% of them claimed that HCPs had never asked for their consent before performing a vaginal examination during their pregnancy.

- In the survey carried out in 2022 by the National Association of Medical Students in France (ANEMF)<sup>23</sup> in anticipation of its hearing with the CCNE, 19% of the 480 student respondents claimed that they had already attended an intimate examination (all specialities included) without the patient's consent.

<sup>&</sup>lt;sup>20</sup> Aurore Koechlin, The gynaecological norm, What medicine does to women's bodies; Editions Amsterdam, 16 September 2022. ISBN 9782354802530 See: http://www.editionsamsterdam.fr/la-norme-gynecologique/

<sup>&</sup>lt;sup>21</sup> See: <u>https://www.aphp.fr/contenu/ap-hp-realisation-dune-enquete-sur-le-respect-de-lintimite-de-la-confidentialite-et-de-la</u>

<sup>&</sup>lt;sup>22</sup> See: <u>https://www.santepubliquefrance.fr/les-actualites/2022/sante-publique-france-partenaire-de-la-6e-edition-de-l-enquete-nationale-perinatale</u>

<sup>&</sup>lt;sup>23</sup> The findings of this survey were disclosed internally during the hearing. Unpublished.



- In France, questions about "gynaecological violence" have been included in the survey entitled "*Context of sexuality in France*"<sup>24</sup>, conducted jointly by INSERM and INED. The initial findings will be available early 2024.

- The Stop VOG association says that it receives an average of 200 reports a month of obstetric or gynaecological violence<sup>25</sup>. These complaints appear to relate more to scheduled consultations than emergency examinations, where women are more tolerant. Complaints are often lodged in response to the medical profession's failure to provide satisfactory answers when patients attempt to discuss the reasons why the consultation went wrong.

# B.COMPLEXITY AND RISKS ASSOCIATED WITH INTIMATE EXAMINATIONS

#### 1. Complexity of gynaecological or intimate examinations

We believe that the complexity can be attributed to six major difficulties:

- The difficulty in getting HCPs to respect a patient's decision to refuse consent to an intimate examination: this difficultly may be reflected in a lack of consideration towards the patient or negative judgements from HCPs. It represents the clash in views between HCPs who believe that the need for the procedure is obvious and patients who believe that the procedure is anything but obvious, which can lead to misunderstandings, tensions and even suffering, as well as eroding trust in the care relationship.

- The difficulty in undergoing examinations while students are present: the presence of interns, medical students, midwifery students and paramedical students during consultations and examinations is an integral part of their practical training, essential for learning how to properly perform such acts and procedures, and key to the future quality of the care that they will provide. However, while HCPs see this approach as a traditional part of the health studies curriculum, and as a legitimate and standard process in university teaching hospitals, the perception among patients who are forced to undergo these practices, without always taking care to inform them beforehand and obtain their consent, is different and sometimes painful.

<sup>24</sup> This edition of the survey is still in progress, but it is consistent with the approach outlined in

the book by Nathalie Bajos and Michel Bozon, *Survey on sexuality in France. Practices, gender and health.* La Découverte, Hors Collection Social, 2008, ISBN: 9782707154293. URL: https://www.cairn.info/enquete-sur-la-sexualite-en-france-9782707154293.htm

<sup>&</sup>lt;sup>25</sup> According to Sonia Bisch, founder and spokesperson for the Stop VOG collective, who was interviewed by the CCNE on 20 September 2022.



- The difficulty in undergoing examinations for women who have been victims of sexual violence: some examinations can rekindle memories of significant and painful events. A number of patients would like HCPs to question them more consistently about any previous violence (sexual or other) of which they may have been a victim. The utmost care needs to be taken in these situations, even if victims cannot always bring themselves to mention it, and the subject remains difficult to understand because it is so sensitive in the limited time available for the examination. These women are especially vulnerable and often have difficulty in coping with their gynaecological care. Their experience can range from simple discomfort to the profound trauma of reliving previous violence.

- The difficulty in undergoing examinations for people in vulnerable situations: people in precarious situations, people with disabilities<sup>26</sup>, migrants, minors (particularly young teenagers, for whom a clinical examination is not recommended during the first consultation for contraception where there are no symptoms<sup>27</sup>), the elderly, and patients suffering from psychological distress, psychological and/or cognitive disorders whose ability to discern may be impaired. Their access to care may be limited or non-existent, their understanding of the medical information provided may be very limited or non-existent, and it may sometimes be hard or impossible to obtain their free and informed consent.

- The difficulties associated with practical constraints, particularly the lack of time available for the consultation: all the HCPs interviewed explained that the process of educating and paying attention requires time, but sufficient time is not available. The current rate of hospital consultations arising from the pressure to generate activity and the difficulties in organising care due to the lack of staff and resources, which are exacerbated by the crisis facing public hospitals, are difficult to reconcile with the time required for dialogue<sup>28</sup>.

- The difficulties associated with inadequate training for HCPs on the ethical issues and patients' rights: the initial training programme for doctors and other HCPs required to perform urogenital or anorectal examinations fails to sufficiently address the issues relating to patients' suffering when their intimacy, modesty and integrity are violated, or how to build a care relationship between the HCP and the patient with real mutual trust.

<sup>&</sup>lt;sup>26</sup> According to the *Handidactique* association and the surveys that it conducts every year among 100,000 respondents, the rate of access to gynaecology consultations among people with disabilities remains 50% lower than that for the general population.

<sup>&</sup>lt;sup>27</sup> See: Guidelines for gynaecological and obstetric consultations (2021): http://www.cngof.fr/actualites/758-chartre-examen-gynecologie.

<sup>&</sup>lt;sup>28</sup> CCNE Opinion 140: "Rethinking the healthcare system on an ethical basis. Lessons from the health and hospital crisis, diagnosis and prospects," November 2022. Available at the following address: <u>https://www.ccne-ethique.fr/node/530</u>



#### 2. Risks inherent in the loss of trust between patients and HCPs

We consider that there are various types of risks:

- The risk of a significant loss of opportunity for patients: The loss of confidence and the suspicion towards gynaecology and, more generally, all the specialities where HCPs perform urogenital or anorectal examinations, are likely to create a climate of mistrust and even fear, and consequently result in fewer patients attending consultations. Since many of these procedures are preventive (particularly for cancer), the decision to refuse means that the risks are under-assessed, which represents a significant loss of opportunity.

- The risk that some medical specialities will lose interest, especially gynaecology and other specialities that carry out intimate examinations<sup>29</sup>: the HCPs who feel as though their profession is being challenged by the surge in complaints, even though they only concern a minority of practitioners, mention the risk that the HCPs concerned will abandon their speciality and that future specialists will lose interest. However, the medical students interviewed remain fairly confident. In today's day and age when waiting times may already be long and HCP shortages are affecting access to preventive and diagnostic care, patients would experience a significant loss of opportunity if HCPs decide to walk away from their chosen speciality.

- The risk of overestimating the frequency of professional practices that could be classified as criminal offences or abuse: HCPs emphasise the feeling of unease created by the use of certain terms from criminal law (which can go as far as rape) in medical specialities where diagnosis, screening and follow-up care require intimate examinations within their field of expertise.

- The risk of stigmatising all HCPs performing intimate examinations and launching targeted attacks against their reputation over social media: representatives of the gynaecologists interviewed fear that, following the intense media coverage of current court cases, the inappropriate behaviour and practices by a minority of practitioners could cause patients' distrust to be projected onto the entire profession. They also criticise the level of violence aimed at HCPs, especially on social media and in the press (personal humiliation, attacks on their reputation, etc.).

- The risk of medical practices evolving in a way that fails to meet patients' real needs: the certain amount of reluctance to consistently feel and palpate the breasts during gynaecological consultations, even though this is recommended as part of a preventive

<sup>&</sup>lt;sup>29</sup> Long-term prospects for teams: what future for continuity of care in obstetrics and gynaecology? CEGO and CNGOF (national college of gynaecologists and obstetricians). Report of the Demographic Commission. November 2022 Available at the following address: <u>http://coordination-defense-sante.org/wp-content/uploads/2023/02/CNOG-rapport-CD-2022-v2.pdf</u>



healthcare approach, and auscultate by placing a stethoscope on the bare skin (replaced by auscultating through the clothing) should be seen as the warning signs of a deterioration in the quality of patient care in the wake of the crisis of confidence undermining the care relationship.



## II. THE NEED FOR AN ETHICAL REVIEW

Irrespective of the action taken by the courts, updates to legislation and essential changes in professional practices, an in-depth ethical review is required into the issues of consent and respect during intimate examinations.

#### A. THE NEED TO LISTEN TO PATIENTS AND THE HCP

The need to banish any form of indifference towards an individual's suffering, as already mentioned by the CCNE in its Opinion 139 on the ethical issues relating to end-of-life situations<sup>30</sup>, generally applies to all HCPs and means that due consideration must be given to the grievances expressed by patients, while taking account of the concerns expressed by HCPs.

#### 1) Consideration for patients' feelings and complaints

Ethics can be defined as a form of resistance to indifference. When patients report a painful experience during or relating to intimate examinations, their account must be listened to without suspicion, without downplaying and without judgement, and with respect for difference, subjectivity and others. The suffering that they express is real and warrants a change in intimate medical practices in response to the growing number of movements lobbying for patients' emancipation, rejecting medical authoritarianism and consolidating women's rights. Patients are sending out a clear signal of their determination to stop accepting pain and are calling for extra efforts in the fight against pain. Their grievances should pave the way for an innovative approach within the care relationship and help improve the way in which care is provided.

#### 2) Addressing HCPs' concerns

HCPs are currently going through a major institutional and vocational crisis, both in hospitals and in the community. They regularly explain in the media how certain ethical issues are causing suffering within their profession, and they repeated their claims during the interviews with the CCNE. This is compounded by the unease that occasionally arises in the care relationship when the patient's intimacy is involved. The vast majority of HCPs respect patients' rights and do their utmost to act with every consideration and provide professional care, but they feel undermined and a sense of injustice in light of the attacks from patients. They fear that the profession as a whole will be affected by the

<sup>&</sup>lt;sup>30</sup> CCNE Opinion 139, Ethical issues relating to end-of-life situations: autonomy and solidarity, June 2022. Available at the following address: <u>https://www.ccne-ethique.fr/sites/default/files/2023-01/Opinion%20139\_0.pdf</u>



accusations levelled against certain practitioners. They say that they are ready to adapt their practices in a bid to meet patients' changing needs and expectations.

Note that medicine is one of the three professions that Freud described as "impossible", namely educating / governing / caring: "These three professions are actually linked by a common power that underlies their action, by their potential to abuse that power, and they come up against powerlessness when the other thwarts their intention."<sup>31</sup> Medical practices involving intimacy also touch upon complex and fundamental aspects of the human being (intimacy, gender identity and sexuality) that are largely outside the scope of representation. Therefore, fostering a relationship of mutual trust appears to be a prerequisite for the effective and seamless provision of care, and HCPs who are committed to strengthening the relationship hope that efforts will be made on both sides.

#### B. THE ESSENTIAL ALLIANCE IN THE CARE RELATIONSHIP

#### 1. Ethical principles for respectful interactions

Performing intimate medical examinations without any medical justification, in a brutal manner, without prior information, without obtaining consent and/or without respecting the patient's refusal constitutes a violation of the Code of Medical Ethics and the laws protecting patients' rights. Depending on the case, such acts may be punishable by the medical council, civil law and/or criminal law. In addition to imposing these sanctions, ethical discussions are required and can help restore peace in the relationship between HCPs and patients.

What conditions are required to ensure that examinations are seen by patients as respectful and not construed as a disproportionate invasion of their privacy and integrity? On the other hand, how can we ensure that HCPs can perform examinations with the patients' trust and without seeing their intentions or skills being unduly challenged? Several ethical principles are fundamentally important in these situations:

- Respect for the inviolability of the human body and for physical and psychological integrity: such respect is key to guaranteeing appropriate and humane care. Medical consultations are already asymmetrical by nature and are even more so when it comes to exploring intimacy, and the patients' vulnerability brings an element of complexity and sensitivity to the care relationship. These conditions are fertile for inflicting or reopening wounds that HCPs struggle to understand, especially as the social context behind medical consultations is constantly changing, i.e. gynaecology is used to treat desire and risk, and not just a given condition. Understanding the psychological issues surrounding intimate examinations is an integral part of professional practice and the skills required to practise in a considerate and truly caring way. Minimising these issues prevents examinations from being carried out properly and reduces the effectiveness of the

<sup>&</sup>lt;sup>31</sup> Mireille Cifali, "Impossible profession? An inexhaustible outburst", *Le Portique* [Online], 4 | 1999, published on 11 March 2005, viewed on 14 February 2023. URL: http://journals.openedition.org/leportique/271; DOI: https://doi.org/10.4000/leportique.271



medical approach.

- **Respect for personal autonomy**: this means safeguarding patients' freedom to consent or refuse, or to provide gradual or partial consent. As stated in CCNE Opinion 136<sup>32</sup>, respect for consent is based on the idea that everyone not only has the right but also the capacity to take part in the decisions concerning them. Consent allows everyone to play a part in the choices affecting their health. A person's will would be invisible without their inherent expression of consent, whatever its form. Patients' consent must be free and informed, i.e. it must be given when they receive fair and clear information adapted to their level of understanding, while being free of any pressure or constraints. Seeking consent is a medical skill and should become second nature for HCPs. The culture of consent must make greater inroads into the medical environment, especially since patients, as a result of their illness and potential suffering, are in a state of "wounded humanity", to paraphrase physician and philosopher Edmund Pellegrino<sup>33</sup>. This culture of consent is based on displaying ethical behaviour through our regard of others, our encounters and our touch.

Respecting patients' autonomy helps them develop a comfortable and nonconfrontational relationship with their body. It plays a part in helping each person take or regain ownership of their own privacy. In addition: "When patients feel involved in the medical decision-making process, they are more likely to adhere to the care strategy. By listening to what patients have to say, doctors can refine or add to the information through a game of questions and answers which, over time, creates trust."<sup>34</sup>

<sup>&</sup>lt;sup>32</sup> CCNE Opinion 136, Changes in the ethical issues relating to consent in healthcare. April 2021.

Available at the following address: https://www.ccne-ethique.fr/sites/default/files/2021-07/Avis%20136.pdf

<sup>&</sup>lt;sup>33</sup> Patrick Verspieren, "Patient and doctor, partners", *Études*, 2005/1 (Vol. 402), p. 27-38. DOI: 10.3917/etu.021.0027. URL: https://www.cairn.info/revue-etudes-2005-1-page-27.htm

<sup>&</sup>lt;sup>34</sup> Pierre Le Coz, "Ethics: why respect patient autonomy?" *Cancer(s) et psy(s),* 2020/1 (no. 5), p. 147-158. DOI: 10.3917/crpsy.005.0147. URL: https://www.cairn.info/revue-cancers-et- psys-2020-1-page-147.htm



- **Respect for patients' dignity**: safeguarding physical and psychological integrity and respecting personal autonomy are the real conditions for respecting patients' dignity by protecting them from medical objectification, which introduces a form of inhumanity into the care pathway by reducing people to their bodies and making it harder to restore their "*ability to be* in the world", which seems to be the ultimate aim of the medical act.

#### 2. Benefits of an alliance between patients and HCPs

An agreement of mutual trust: this agreement calls on HCPs to accept patients' requests for care, and on patients to accept the clinical methodology, technical skills and knowledge offered by HCPs. These are two distinct paths, but they must be followed in the same way with the same intentions and goals, i.e. cure or improve, stabilise and ensure better quality of life for patients suffering from chronic illnesses.

A dialogue-based relationship of trust: dialogue must be ensured between both sides in the event of a misunderstanding or disagreement, and the medical decision must be established and shared by the HCP and patient - especially since the growing amount of information available to patients has given everyone chance to improve their knowledge on health matters or at least given them easier access to such information, and has accelerated the change from what was once a paternalistic medical model to an informative, interpretative and deliberative model. The decision-making process must be in line with people's values and preferences.

This relationship of trust must also be beneficial to HCPs. They are protected from abusive or unfounded accusations by prohibiting defamation, and they have the right - except in emergencies - to refuse care when the relationship with the patient appears to have deteriorated to such an extent that they cannot offer reassuring and satisfactory care<sup>35</sup>. When conditions are conducive, students should be able to take part in consultations, which is essential for acquiring the necessary medical and healthcare knowledge, and vitally important for their proper training. Ultimately, this benefits all the parties. During consultations, students must obviously abide by the ethical principles set out above and respect patients as much as their tutors.

<sup>&</sup>lt;sup>35</sup> In this sense, Article R.4127-47 of the Public Health Code enshrines the right for HCPs to refuse care for personal or professional reasons, except in emergencies.



## III. ETHICAL GUIDELINES FOR MAINTAINING A RESPECTFUL AND SAFE ENVIRONMENT FOR PATIENTS AND THE HCP

#### A. A MUTUAL NEED FOR CONSIDERATION

#### 1. Acknowledging the mutual need for soft skills

- Patients may sometimes express their grievances in a particularly violent way. HCPs are sometimes attacked as a whole, outside of any institutional framework, as if any breakdowns in the process were systematic or representative of the majority. In some cases, these attitudes are caused by the frustration of not being listened to or not getting the answer that they were looking for. However, such generalisations run the risk of weakening the absolutely essential trust that must exist between the public and HCPs. We need to be careful about the dangers inherent in generalisations.

- The presence of students during consultations or examinations must be strictly supervised and respectful towards patients<sup>36</sup>.

- Care necessarily involves a moment of objectification, insofar as it requires the HCP to temporarily focus on a condition or an organ. In addition to such moments of objectification, providing overall care for patients as subjects and according to their individual profiles requires specific attention to the quality of the care relationship, establishing a relationship of trust and proposing a consultation schedule or rhythm that respects the time that patients need to agree to reveal their intimacy.

- Taking modesty and the need for privacy into account is an integral part of providing effective care and respecting patients. Patients must be given the opportunity to get undressed and put their clothes back on out of the HCP's view and in a gradual manner depending on the parts of the body being examined.

- HCPs must be attentive to any verbal or non-verbal signs of pain or discomfort during the examination. The feeling of violence experienced during uncomfortable or painful examinations should never be denied or minimised.

<sup>&</sup>lt;sup>36</sup> See p.20 above.



- HCPs must allow patients to express their expectations and feelings. Before examinations are carried out, this type of dialogue can provide a clearer idea of the extent of what patients know about their bodies and the planned examinations, and sometimes detect whether they have been victims of any kinds of violence in the past. After the examination, a debriefing session can give patients an opportunity to express how they felt, while allowing HCPs to explain the purpose of the examination.

- Arrangements must be made to ensure that conditions are conducive for treating people in particularly vulnerable situations (people in precarious situations, people with disabilities, migrants, minors and young teenagers, the elderly, patients suffering from psychological distress, psychological and/or cognitive disorders, etc.), such as providing an interpreter (or a digital translation system), appropriate equipment and dedicated consultations, and allowing enough time.

- When patients talk about bad experiences with intimate examinations, some say that their words have been devalued or disqualified out of sheer principle. In addition, complaints, disclosures or reports do not always receive the attention that they deserve, or are not dealt with appropriately<sup>37</sup>. In case of a bad experience with an intimate examination, it is important for patients to be able to talk about it with the HCPs concerned, either immediately after the examination or at a later date, if necessary with support from a mediator. Finally, when people who believe that they are victims or witnesses of violence or abuse, or who have questions about what they have experienced or seen, do not wish to discuss the matter directly with the HCP concerned, it is essential to give them the opportunity to discuss the matter confidentially with a trusted third party and report any worrying situations through this process. Even if mechanisms are available for this purpose, there is an urgent need for improvement and reinforcement.

<sup>&</sup>lt;sup>37</sup> According to several media: https://www.nouvelobs.com/societe/20211014.obs49856/ungynecologue-du-val-d-oise-vise-par-118-plaintes-pour-violences-sexuelles.html; https://lesjours.fr/obsessions/gynecologue-viols/ep1-victimes-domont/; https://www.liberation.fr/societe/un-gynecologue-du-val-doise-vise-par-118-plaintes-pour-violencessexuelles-20211013 3YAPFGIEGRDAFABERIAN7QY7I4/



#### 2. Reinforce precautions during the dynamic process of collecting consent

- Obtaining consent for the examination by asking patients to sign a form would not protect patients from procedures that they do not wish to undergo, or HCPs from legal proceedings after the event. As emphasised in CCNE Opinion 136<sup>38</sup>, consent is a dynamic, evolving process that can be withdrawn at any time. Therefore, it would seem preferable for consent to be obtained orally and accurately transcribed in the patient's medical records.

- Consent to the examination will only be valid where given freely and preceded by accurate, fair and appropriate information. Many complaints are caused by poor initial information, which prevents patients from understanding what they are being subjected to<sup>39</sup>. Prior information about the examinations that HCPs are proposing to carry out enables patients to make informed decisions. This information covers the objectives pursued (the purpose of the examination), the practical procedures for performing it and any associated risks. It helps patients understand why an examination is necessary, whether there is any risk of discomfort or pain, and whether other (potentially less invasive or painful) examinations are available.

- Consent to the examination should be explicit and differentiated. In the past, it was considered that consent could be presumed as soon as patients attended a consultation, basically as soon as they sat down on the examination table. The CCNE considers that consent can no longer be presumed and that explicit consent is required for intimate examinations. This consent must also be differentiated, i.e. obtained for each procedure performed.

- A patient's refusal and reluctance to undergo an examination must be taken into consideration. In this respect, Article L. 1111-4 of the French Public Health Code on the patient's refusal to consent should make explicit reference to "examinations" in order to be complete and clear, i.e. a medical act whose specific nature deserves to be emphasised<sup>40</sup>.

<sup>&</sup>lt;sup>38</sup> CCNE Opinion 136, Changes in the ethical issues relating to consent in healthcare. April 2021.

Available at the following address: https://www.ccne-ethique.fr/sites/default/files/2021-07/Avis%20136.pdf

<sup>&</sup>lt;sup>39</sup> According to the HCPs interviewed.

<sup>&</sup>lt;sup>40</sup> Article L 1111-4(2) of the French Public Health Code currently states that "every person has the right to refuse or not receive treatment", but it should be amended to include the words "or a medical procedure, including an examination". Similarly, Article L 1111-4(4) states that "no medical procedure or treatment may be carried out without the person's free and informed consent (...)", but the words "including an examination" should be added after "no medical procedure".



HCPs may struggle to understand why patients object to undergoing an examination. However, a refusal to undergo an examination does not necessarily mean that patients do not understand the situation or have no confidence in the HCP's recommendations. It is vitally important to ascertain and try to understand the reasons for their refusal, without presuming that such refusal is permanent or necessarily the result of the patient's ignorance, lack of understanding or some form of irrationality. Whatever the case, refusing an examination should never lead to an abrupt end to the consultation or a breakdown in the care relationship.

- Particular care is required in case of people whose capacity to discern has been impaired. Where genuine consent cannot be obtained, assent may be sought, i.e. an agreement based on a partial understanding of the situation and the options. The presence of a third party, legal representative or trusted person (French Public Health Code, Article L.1111-6) can also help patients express their wishes.

- Failure to comply with the requirement to obtain consent for examinations must be sanctioned. From this point of view, it would be useful to introduce into the Public Health Code a reference to Article L119-1 of the French Social Action and Family Code, which provides a definition of abuse.<sup>41</sup>

# B. A MUTUAL EFFORT TO UNDERSTAND THE CONSTRAINTS INHERENT IN PERFORMING INTIMATE EXAMINATIONS

## 1. Systematically question the relevance, context and environment for examinations

- Some invasive and uncomfortable examinations are required for prevention, diagnosis or treatment. It is essential to explain the reasons and warn patients beforehand of the risk of discomfort or pain.

<sup>&</sup>lt;sup>41</sup> Article L.119-1 of the French Social Action and Family Code introduced a definition of abuse in Law 2022-140 of 7 February 2022 on child protection: "Abuse within the meaning of this Code refers to any person in a vulnerable situation when a gesture, word, action or failure to act compromises or adversely affects their development, rights, fundamental needs or health, and when this occurs in a relationship of trust, dependence, care or support. Abuse may be occasional or sustained, intentional or unintentional. The origins of abuse can be individual, collective or institutional. Abuse and neglect can take many forms and be associated with these situations." »



- HCPs are not obliged to accede to all the patient's requests. They have the right, and even the duty, to refuse examinations that would contradict current scientific knowledge, or whose benefit-cost ratio would be clearly unfavourable, such as expensive complementary examinations that would provide less reliable information than a clinical examination without any major disadvantages for the patient.

- Health students need to learn how to carry out intimate examinations. Simulations and the use of mannequins may contribute to their training, but they are not a complete substitute for real-life learning. To allow future HCPs to gradually become proficient in the procedures that will form a core part of their professional practice, patients are invited, when permitted by their emotional state, to accept students' presence and understand the reasons and what is at stake. Individual participation in the training for the HCPs of the future is part of a civic commitment that is essential for preserving public health, which is a common good.

Patients' prior consent to the presence of students or examinations performed by students must be obtained after appropriate information has been provided<sup>42</sup>. Consent must be explicit and cannot be presumed simply because the patient is in a university teaching hospital. Patients should be free to accept or refuse, and any refusal must be respected.

- Intimate examinations are used to detect illnesses or the risk of illness, confirm or exclude diagnoses and guide treatment. They produce information that other complementary examinations do not necessarily provide. However, the relevance in carrying out such examinations must be consistently reviewed. In addition to the necessary discussions led by learned societies on the cases where intimate examinations are warranted, their relevance must be assessed on a case-by-case basis, while taking account of the specific profile of each patient.

HCPs can use two principles to ensure that examinations are not proposed as a matter of habit or routine:

- The principle of subsidiarity: is a less invasive or less painful examination available that could provide the same information at the same cost to society?
- **The principle of proportionality**: does the information sought justify an examination that affects privacy and integrity?

On the other hand, constantly reviewing examinations for relevance also means not assuming that some people would not need an examination due to their particular situation or that they would not benefit. From an ethical point of view, deciding not to carry out an indicated and justified examination raises just as many problems as conducting an examination that is not really necessary. Stereotypes, especially relating to disabilities or mental illness, can wrongly lead to some patients being under-examined.

- Special attention must be paid to the equipment, the allotted time and the

<sup>&</sup>lt;sup>42</sup> French Public Health Code, Article L1111-14 10.



organisational aspects of the examination. The physical and architectural environment can affect the confidentiality of discussions, respect for privacy, and patients' sense of security and comfort. It is also important to allow sufficient time for patients to reveal their feelings and for HCPs to obtain genuinely free and informed consent. As the CCNE pointed out in Opinion 140<sup>43</sup>, it is an "essential resource for providing treatment that respects the individual", but it is now being dramatically jeopardised by the conditions in which HCPs are forced to work, which encourages HCPs to develop automatic habits that make it difficult to accurately analyse their interactions with patients and identify any signs of reluctance.

- Special care should also be taken over the organisational conditions in which examinations are carried out, since some types of organisational arrangements (e.g. examinations performed in adjoining examination rooms) prevent HCPs from giving patients the consideration that they are legitimately entitled to expect.

- In some countries, the systematic presence of an impartial observer ("chaperone") is recommended during intimate examinations<sup>44</sup>. Two practices have been observed in France<sup>45</sup>: in some situations, HCPs ask a third party (e.g. a care assistant or nurse) to be present during the examination to ensure that it has been carried out in accordance with the rules. In addition, patients (particularly minors) may request the presence of a trusted third party (family member or otherwise) of their choosing<sup>46</sup>. It seems that these two possibilities should be maintained, but without making a chaperone an obligation, bearing in mind that their presence can reassure patients, but may also sometimes create tension, prevent the patient from speaking freely and interfere in the care relationship.

#### 2. Strengthening training for HCPs and raising awareness among patients and HCPs as part of a greater approach to promote participatory democracy in healthcare

Improving training for HCPs

<sup>&</sup>lt;sup>43</sup> CCNE Opinion 140: "Rethinking the healthcare system on an ethical basis. Lessons from the health and hospital crisis, diagnosis and prospects," November 2022. Available at the following address: <u>https://www.ccne-ethique.fr/node/530</u>

<sup>&</sup>lt;sup>44</sup> They tend to be qualified HCPs or administrative staff who have received specific training to attend the examination, reassure patients if necessary, observe the doctor's actions and report any problems.

Refer to the following examples: (Quebec) <u>https://www.cmq.org/en/pdf/banque-info/binfo4.pdf;</u> (USA) <u>https://www.uofmhealth.org/patient-visitor-guide/patients/use-chaperones-during-sensitive-</u>

examinations-and-procedures; https://yalehealth.yale.edu/topic/medical-chaperones-sensitiveexaminations-treatments-and-procedures; Ehrenthal DB, Farber NJ, Collier VU, Aboff BM. Chaperone use by residents during pelvic, breast, testicular, and rectal exams. J Gen Intern Med. 2000 Aug;15(8):573-6. DOI: 10.1046/j.1525-1497.2000.10006.x. PMID: 10940150; PMCID: PMC1495582.; https://www.aafp.org/pubs/fpm/issues/2018/0900/p6.html ; Croft M. Chaperones for genital examination. Chaperones should always be present. BMJ. 1999 Nov 6;319(7219):1266. DOI: 10.1136/bmj.319.7219.1266. PMID: 10550103; PMCID: PMC1117032. <sup>45</sup> According to the people interviewed.

<sup>&</sup>lt;sup>46</sup> This option is mentioned in the guidelines produced by AP-HP. See: https://robertdebre.aphp.fr/wp-content/blogs.dir/114/files/2022/12/Charte-GO-janv-22.pdf



- Performing intimate examinations requires medical knowledge and technical expertise, as well as soft and ethical skills. These skills are taught during HCPs' initial and ongoing training, at conferences and when shadowing experienced clinicians. In addition to training on the necessary technical skills, most future HCPs now learn about the Law of 4 March 2002 on patients' rights, the characteristics of the doctor-patient relationship, the importance of effective treatment, users' rights, gender-based and sexual violence, and gynaecological and obstetric violence. HCPs are also made aware of the importance of communication and empathy by their peers. Specific training on how to carry out intimate examinations should be developed due to their particular complexity. Similarly, in an effort to develop a true culture of consent, the medical students interviewed by the CCNE advised that they would like to gain a clearer understanding of the interpersonal aspects of their profession through practical training sessions, especially to learn how they should communicate in a non-violent manner and listen to patients with all the necessary empathy.

#### > Strengthening participatory democracy in healthcare

- Strengthening participatory democracy in healthcare and empowering users, whether collectively through associations or individually, is essential for developing satisfactory care relationships and a true alliance in care. In this respect, patients' knowledge and understanding of their bodies and the examinations that may be performed, as well as their rights and the mechanisms for expressing their grievances, are important drivers for action. Involving patients in the initial and ongoing training for HCPs to address the many issues involved in intimate examinations should be strongly encouraged wherever possible. Finally, every effort should be made to ensure that guidelines and recommended best practices are consistently developed by professional organisations together with patient associations.



In light of these considerations, the CCNE wishes to make two specific recommendations for the authorities:

- The Ministry of Health and Prevention must ensure that the conditions for organising care improve the process for implementing revised and adapted consent.
- The Ministry of Higher Education & Research and the Conference of Medical Deans must take greater account of the issues for providing training on humanities and the ethics of care when developing teaching programmes.



## CONCLUSION

Special attention must be paid to cases of gender-based and sexual violence committed in the healthcare system. They should be considered in light of the changes sweeping the different care professions. Increasingly high-tech and fragmented, and ever at risk of becoming more impersonal, care practices are in the firing line as questions are raised about how an act towards the body can become an intrusion, although it is ultimately intended to restore, soothe and heal. How can violence erupt when the very act of caring involves paying attention to the other person's body?

The sensitivity of intimate examinations, especially in the "extremely intimate" cases addressed in this opinion, serves as a reminder of the risk when health care forgets that "any contact must be through touch, otherwise it becomes an act of violence". Whereas contact is the manifestation of a technical act, touch is what a patient can accept, i.e. contact consented to by the *mind*. HCPs can only come into contact with a body if they respect its sovereign will and the patient's expressly formulated consent. The body can never be separated from the mind and can never be detached from the inner self. Giving due consideration to subjectivity is key to gaining patients' agreement to nudity and the examination.

Healthcare facilities are subject to work rates and conditions that can cause HCPs to neutralise their emotions at the risk of becoming completely impersonal. As such, they may unintentionally make patients feel as though they are required to submit their bodies to facilitate the HCP's task of performing a medical act, whereas patients should instead be invited to entrust their most valuable asset, i.e. their body, which is inseparable from their psyche, to someone who welcomes, respects and then cares for them.

The challenge with intimate examinations is maintaining awareness of the humanity shared between the patient and the HCP. This does not imply abdication on one side and technical efficiency on the other, but a profound alliance and mutual consideration, thereby restoring medical practice's status as an art, a status that it should never lose.



## **APPENDICES**

#### **APPENDIX 1 - LETTER OF REFERRAL FROM THE PRIME MINISTER**

The Prime Minister

4 July 2022

Dear Sir,

As the National Ethics Advisory Committee stated a few months ago in its Opinion 136 on the new ethical issues relating to consent in healthcare, the concept of consent has changed in recent years, especially due to the new situations created by advances in medicine and technology, and also the new forms of vulnerability facing health and social care professionals.

All patients must have the fundamental right to take part in the healthcare decisions affecting them. This right should be enforced, irrespective of whether patients are at home, in hospital, in a private practice or a social care facility. As specified in your aforementioned opinion, consent must be seen as an evolving and dynamic process, which is based on a relationship of mutual trust and adapts to the individual's journey and choices. This process allows patients to change their mind and withdraw their consent over time.

In matters of gynaecological care, the concept of consent is especially important and sensitive, because examinations touch upon women's psychological and physical intimacy.

In addition to the recommendations and work carried out by the learned societies in this medical speciality, I would like your Committee to conduct an in-depth review into the concept of consent in cases of gynaecological examinations and, more broadly, all intimate examinations. The purpose of such a review is to guide professionals with their essential duties, while responding to patients' expectations and legitimate concerns regarding respect for their wishes and integrity.

I would like to thank you in advance for your Committee's work on this issue, and I hope to benefit from your recommendations by the end of the year

Yours faithfully,

Elisabeth Borne [illegible signature]

Mr Jean-François Delfraissy President of the National Ethics Advisory Committee 66 rue de Bellechasse 75007 PARIS, FRANCE



#### **APPENDIX 2 - COMPOSITION OF THE WORKING GROUP**

Alexandra Benachi Yvanie Caillé Anne Caron-Déglise Alain Claeys Sophie Crozier Annabelle Desgrées du Loû Didier Dreyfuss Cécile Duflot **Fabrice Gzil (rapporteur) Karine Lefeuvre (rapporteur)** Séverine Laboue Noémie Nauleau

With organisational and editorial support from Louise Bacquet (editor) and Camille Roué (legal intern)



#### APPENDIX 3: LIST OF PEOPLE INTERVIEWED

Users:

- **Sonia Bisch**, founder and spokesperson of the "Stop VOG" collective aimed at stopping obstetric and gynaecological violence

- July Bouhallier, Co-President of IRASF (Institute for Research and Action on Women's Health)

- Marie Citrini, AP-HP User Representative, and Jean-Luc Diehl, AP-HP Central Medical Mediator

- **Mélanie Déchalotte**, freelance journalist and documentary filmmaker at France Culture, author of several documentaries on the doctor-patient relationship and *Livre noir de la gynécologie (Black Book of Gynaecology)* 

- Anne Evrard, Co-President of CIANE (network of childbirth associations)

- Pascal Jacob, President of the Handidactique association

- The Health Committee of CNCPH (National Advisory Council for People with Disabilities): Florian Deygas, President of the committee, Marie-Jeanne Richard, assessor, and Odile Antoine, member

- <u>Physicians representing colleges, orders, councils and/or unions:</u>

- **Catherine Adamsbaum**, Emeritus Professor of Radiology and General Secretary of CERF (College of Radiology Lecturers of France), and **Romain Pommier**, radiologist and member of CERF's medical research radiology ethics committee

- Joëlle Belaisch-Allart, President of CNGOF (National College of French Gynaecologists and Obstetricians)

- Isabelle Derrendinger, President of CNOSF (National Midwifery Council)

- Adrien Gantois, President of CNSF (National College of Midwives of France)

• Physicians involved in training HCPs:

- **Frédéric Glicenstein**, President of AGOF (Association of Junior Gynaecologists and Obstetricians), and **Mila Laffond**, President of AIGM (National Association of Gynaecology Interns)

- Philippe Ruszniewski, Dean of the School of Medicine, Université Paris Cité

- Yaël Thomas, President of ANEMF (National Association of Medical Students of France), and Clémence Chabrier, Vice-President of ANEMF and Head of Ethical Issues



<u>Gynaecologists-Obstetricians:</u>

- Frédéric Chiche, gynaecologist-obstetrician at the American Hospital of Paris

- Ghada Hatem-Gantzer, gynaecologist-obstetrician and founder of the Maison des Femmes de Saint-Denis women's support centre

- **Perrine Millet**, obstetrician-gynaecologist at Montélimar Hospital, coordinator of the inter-university diploma on "Care and effective treatment for female victims of violence", set up at the University of Grenoble-Alpes and Paris Descartes University, and **Pascale Hoffmann-Cucuz**, obstetrician-gynaecologist at Grenoble University Teaching Hospital, who is in charge of overseeing teaching for the same diploma

- Amina Yamgnane, gynaecologist-obstetrician, founder of La Clinique des Femmes and former head of the CNGOF's "Commission ProBité" (**Pro**moting Effective Treatment in Maternity Wards)

<u>Physicians from other specialties involved in intimacy</u>:

- **François Ansermet**, psychiatrist and psychoanalyst, specialising in support for women with traumatic experiences of pregnancy, MAR, abortion, termination of pregnancy, and obstetric violence ;

- **François Blot**, intensive care physician and President of the Ethics Committee of the Gustave Roussy hospital

- **Philippe Godeberge**, gastroenterologist, hepatologist and proctologist, specialising in digestive endoscopy, and President Emeritus of SNFCP (French National Society of Coloproctology) and SNFGE (French National Society of Gastroenterology)

- **Pierre Mongiat-Artus**, urological surgeon at Saint-Louis Hospital and Head of the Ethics Committee of the French Urology Association

- Martin Winckler, former general practitioner, blogger and author of several essays and books on gynaecological care and medical negligence

Legal experts:

- Marie-Charlotte Dalle, Magistrate and Director of Legal Affairs and Patients' Rights (DAJDP) at AP-HP

- Diane Roman, Professor of Public Law at the Sorbonne Law School

Anne Simon and Elsa Supiot, Professors of Private Law, and heads of the GIP project on "Gynaecological and obstetric violence under the law" at the Institute of Legal and Philosophical Sciences of the Sorbonne

• Regional health agency and private health insurance directors:

- **Clara de Bort**, Managing Director of the French Guiana Regional Health Agency, former hospital director and author of the blog "En jupe!" »;

- **Nicolas Gombault,** Deputy Managing Director of the Mutuelle d'Assurance du Corps Sanitaire Français (MACSF)

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NATIONAL CONSULTATIVE ETHICS COMMITTEE FOR HEALTH AND LIFE SCIENCES