OPINION 136

CHANGES IN THE ETHICAL ISSUES RELATING TO CONSENT IN HEALTHCARE

NATIONAL CONSULTATIVE ETHICS COMMITTEE
FOR HEALTH AND LIFE SCIENCES

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This Opinion was adopted unanimously by the committee members during the plenary assembly on 15 April 2021.

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SUMMARY

While consent has a clear legal framework and is enshrined as a fundamental right and freedom for all people, irrespective of the context (homes, hospitals, medical facilities, social care centres, etc.), question marks often arise over the effectiveness of obtaining informed consent in everyday life. In addition, several major reasons have led to changes in the ethical issues surrounding consent in healthcare. Advances in health technology may have pushed back the boundaries and increased the number of possibilities for screening, analysing, diagnosing and treating various conditions, but they have brought a new layer of complexity to the very purpose of consent, its scope and the prospects for the medical sector.
How can people consent to something that they understand only partially or not at all? To what extent is consent compatible with people in highly vulnerable situations? How can decisions be taken for another person when their ability to give consent has been impaired?

Against the backdrop of this highly complex situation, the CCNE wanted to address the issue of consent by going beyond the traditional concept of binary consent (yes or no).

- Consent must be seen as **an evolving and dynamic process**: it is not given once and for all, but evolves and may change as part of a relationship based on mutual trust. Consent adapts to the individual's journey, choices and health, and may ultimately be withdrawn. Such refusal must be respected.
- For people who struggle to express their wishes, impaired psychological autonomy does not mean that they have lost all autonomy. Therefore, it should not prevent their **consent from being sought**. On the contrary, it is all the more important to obtain their consent as part of a permanent process. When individuals are no longer fully able to give their clear consent, other more subtle and less formal ways may still be used to express their wishes. As such, **obtaining "assent" is essential** for people who are partially or totally unable to consent. Healthcare professionals (HCPs) must therefore learn how to recognise, observe, describe, interpret and respect a patient's assent and give real, indisputable and binding value to their assent in the care relationship to respect the autonomy of the person receiving support or treatment.
- For people who are unable to decide for themselves, the **decisive question arises about the capacity to decide for others**. Providing an answer to this question is clearly facilitated where a relationship of great trust has already been initiated or established. The CCNE believes that it is vitally important to increase and prioritise the role played by trusted people to adopt a more ethical approach for respecting the wishes of vulnerable people through their "extended consent".

At the end of this opinion, the CCNE makes the following recommendations

Consent should be construed as a dynamic and evolving process that facilitates the person's care pathway and includes the possibility for withdrawing consent.

Strengthen initial and ongoing training for health and social care professionals on informing and communicating with individuals to ensure that consent is effective.

Use several tools to aid understanding when complex explanations are involved: seek the opinion of an outside person, use new information media and solutions, and harness digital technology to help people express their wishes and remember the consent mechanism.

Ensure that the prior information and pathway leading to the person's consent or refusal constitutes evidence that takes precedence over their signature on a pre-formatted consent form.

Recognise and value information and support for obtaining consent (a process to guide patients) as an act of care in its own right. Increased training on these issues, and full recognition of the information and support process for guiding people receiving care, should contribute to greater use of the advance healthcare directives that the law recommends for all citizens.

When making decisions on behalf of others, **restrict subjectivity to an absolute minimum by basing the decision on several different arguments**. It must incorporate feedback from different HCPs and the views of the trusted person, which must override the opinion of the patient's legal representative or carer.

Reinforcing the role of the trusted person, by giving them greater awareness of their role, and promoting other non-written forms of advance healthcare directives would now seem to be essential.

Strengthen the role of consent in health and social care facilities and services, and transform consent into a major institutional and ethical issue in professional practice.

Finally, set up initiatives aimed at the general public: alert citizens of all ages and across every region to the ethical and legal issues surrounding consent with a helping hand from France's network of regional ethical forums (ERER) (public debates, ethics workshops, etc.), especially by organising a national day for trusted people across various towns and cities, as well as in each establishment and service (hospitals, medical facilities, social care centres and patients' homes).

INTRODUCTION

Definitions

The word "**consent**" means "*accept*" or "*approve*". The term comes from the Latin word *consentire*, which translates as "*agree with*". It refers to the possibility of *adhering to* or *not objecting to* something. Therefore, it has both a positive and negative meaning between approval and permission.
These two nuances are reflected in Greek, which has two verbs (εθελημοσ and βουλει) to describe the attitude of the person consenting. These verbs respectively mean that the "*subject is ready, willing and consenting without having taken a specific decision*" and that the subject "*expresses a wish, a preference for a given object, or a choice taken after deliberation*"[1].

The term **autonomy** comes from the word *autonomos* (Greek: αὐτόνομος), meaning "*self-governing*" or "*acting of its own accord*". It refers to the ability to *freely self-direct* or *self-determine*.
It is important not to confuse *functional* autonomy[2], which is generally understood as a person's ability to carry out the various tasks required in daily life[3], with *psychological* autonomy, which refers to people's ability to determine for themselves, self-govern and lead a life in accordance with their own principles, values and beliefs. People may experience a significant loss of functional autonomy (e.g. a severe disability) yet still be perfectly capable of making their own decisions and choices based on their own concept of what is good[4].

The concept of autonomy developed in this opinion is not considered to be "**absolute**". In other words, the CCNE believes that there is no way to be totally and individually autonomous, especially when suffering from an illness or condition that alters people's relationship with themselves and their environment. Therefore, autonomy is never considered to be absolute. Medical relationships tend to be **asymmetrical**, so autonomy can only develop where **trust** has been established. In other words, patients can only formulate a reasoned opinion if they trust and understand the information that they have been given. Paradoxically, autonomy depends on others and the relationship with others**. Consent and trust do not imply a loss of autonomy.** This idea is expressed in Article 1111-4 of the French Public Health Code, which states that "*every person, together with the healthcare professional and taking account of the information provided, makes decisions concerning his or her health*" (Appendix 3). It is about making a decision *with* someone, rather than alone. At the same time, we need to avoid developing an "absolute" and radical view of consent. As revealed by anthropologist Sylvie Fainzang in her work[5], consent is always only relatively free

[1] Laetitia Monteils-Laeng, "Ancient Perspectives on the Philosophy of Consent", *Tracés. Revue de Sciences humaines* [online], 14 | 2008, published on 30 May 2009. URL: http://journals.openedition.org/traces/369 ; DOI: https://doi.org/10.4000/traces.369

[2] Or independence.

[3] This capacity may be reduced in cases of disability or dependency.

[4] Fabrice Gzil, Alzheimer's disease. Philosophical disorders. PUF, 2009.

[5] Sylvie Fainzang is an anthropologist, Research Director at Inserm and a member of Cermes (centre for research on medicine, science, health and society). She specialises in medical anthropology and has been accredited to direct research from the EHESS (School for Advanced Studies in the Social Sciences)

and partially informed - for any individual - and expertise can only be shared up to a certain extent.

Consequently, consent is the expression of a person's autonomy. It cannot be an order, a writ or an instruction[6]**.** It is based on the idea that everyone not only has the ***right*** but also the ***capacity*** to take part in the decisions concerning them. Therefore, 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. Consent is both the "action of consenting" and the "result of that action"[7].

Free and informed consent means that "*the patient must receive **fair and clear information adapted to their level of understanding** from the health and medical teams, **while being free of any pressure or constraints, whether real or subjective**. Providing informed consent implies being aware of the potential alternative therapies, i.e. other ways of treating the health problem(s) in question, along with their advantages and disadvantages*."[8]

Although **choosing** and **consenting** may seem to involve a similar process, consent is a form of choice. When consent is sought, the individual is given the opportunity to choose, i.e. consent or refuse to consent, or refuse the proposal to choose.
This nuance between choosing and consenting is therefore fundamental. In other words, it specifically relates to the **relativity and elasticity of the space reserved for free will in matters of consent**. It questions the real value of consent.
Finally, *assent* can be seen as an agreement based on only a partial understanding of the issues. The Declaration of Helsinki[9] clearly sets out this concept within the field of research. It is also highly important in situations where the person's capacity to discern is neither totally present nor totally absent, weakened but not abolished, such that the person in question might not be able to give genuine consent, but the decision cannot be taken on his or her behalf.

Why did the CCNE begin taking a closer look at changes in the ethical issues surrounding consent in healthcare in 2021?
This is not the first time that the CCNE has taken a head-on approach to tackling the ethical issues relating to consent in healthcare. Its endeavours have culminated in

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See in particular: Sophia Rosman, "Sylvie Fainzang, *The doctor-patient relationship: information and lies*", *L'Homme* [online], 184 | 2007, published on 21 November 2007. URL: http://journals.openedition.org/lhomme/13042 ; DOI: https://doi.org/10.4000/lhomme.13042

[6] Marie Ménoret, "The recommendation for autonomy in medicine",*Anthropologie & Santé* [Online], 10 | 2015, published on 27 May 2015. URL: http://journals.openedition.org/anthropologiesante/1665 ; DOI: https://doi.org/10.4000/anthropologiesante.1665

[7] Consent and legal subjectivity - Contribution to a rational emotive theory of law - Thesis presented and publicly defended by Mr Maxence Christelle on 18 September 2014.

[8] https://www.france-assos-sante.org/66-millions-dimpatients/patients-vous-avez-des-droits/consentement-aux-soins/

[9] https://www.espace-ethique.org/sites/default/files/Entretiens%20croise%CC%81s%20-%20de%CC%81claration%20d%27Helsinki.pdf

several opinions, such as in 1998 (Opinion 58)[10] on "*Informed consent of and information to persons taking part in treatment or research*", in 2005 (Opinion 87)[11] on the issues relating to "*Refusal of treatment and personal autonomy*", and in 2019 (Opinion no. 130)[12] during a debate on the "Ethical issues in connection with big data in the health sector" (consent to the use of personal data in healthcare or research protocols).
Early 2020 just before the Covid-19 pandemic struck, the CCNE once again believed that it was important to address this issue for **several major reasons** which, although unrelated to the health crisis, were undoubtedly **brought to the fore and into sharper focus by the unprecedented situation**.
Since advances in health technology have pushed back the boundaries and increased the number of possibilities for screening, analysing, diagnosing and treating various conditions, the development of the consent process must now take account of the short-term and/or medium-term consequences arising from the use of such new medical procedures, not only on patients' health, **but also on the life plans of any people who may be indirectly involved** in the consent process. By way of example, this applies to prenatal diagnostic testing, preimplantation genetic diagnosis (consequences for children) and genome analysis.

Paradoxically, technological and scientific developments in medicine are spawning new forms of vulnerability, especially an alteration in vulnerable people's capacity to discern (comorbidity and cognitive disorders linked to old age, neurological consequences such as vegetative and minimally conscious states, severe disabilities, and sometimes the consequences of performing resuscitation where the outcome is uncertain, which leads to critical life situations). In these cases, legal assistance or representation is required to help obtain consent or take the most beneficial medical decision.

The advent of the concept of "free and informed consent" in the field of medicine
"Informed consent" is a relatively recent concept in medicine. Although it had undoubtedly been used before in the doctor-patient relationship, it came to light for the first time when used opportunistically during the Nuremberg Trials (1945-1946). According to Paul Julian Weindling (2004, cited by Marie Ménoret[13]), the counsel for the Nazi doctors came up with a defence strategy of deliberately placing the issue of medical war crimes (see the "Doctors' Trial") into the field of medical research ethics in an attempt to "blur the otherwise political issue of war crimes[14]." Subsequently, a combination of factors helped cement this concept in the healthcare sector. Eve Bureau-Point and Judith Hermann-Mesfen have identified four concomitant movements that have undermined the paternalistic medical model[15]. These movements include

[10] Opinion No. 58 - 12 June 1998. Informed consent of and information to persons taking part in treatment or research; https://www.ccne-ethique.fr/fr/publications/consentement-eclaire-et-information-des-personnes-qui-se-pretent-des-actes-de-soin-ou
[11] Opinion no. 87 - 14 April 2005. Refusal of treatment and personal autonomy - available at the following addresses: and https://www.ccne-ethique.fr/sites/default/files/publications/avis087.pdf
[12] https://www.ccne-ethique.fr/sites/default/files/publications/avis_130.pdf
[13] Ibid.7.
[14] Ibid.7.
[15] Eve Bureau-Point and Judith Hermann-Mesfen, "Contemporary patients vs health democracy",*Anthropologie & Santé* [online], 8 | 2014, published on 6 April 2021. URL: http://journals.openedition.org/anthropologiesante/1342;

"the development of an extensive approach to illness and the resulting breakdown in scientific silos, the questions raised about biomedicine, the institutionalisation of patient-centred medicine, and finally the reinforcement of values associated with contemporary individualism." The development of health education from the 1940s onwards, the emergence of various self-help social movements (AFM[16] in France in the 1950s, breast cancer associations in the United States, the US self-help trend at the beginning of the 20th century as a variation of the "self-made" model, and actions by people living with HIV from the 1990s onwards), and the growing circulation of medical information, particularly over the Internet from the 2000s onwards, have helped redefine the patient's place in medical practice from patient-object to patient-subject. Patient empowerment has also been strengthened by the spread of democratic and neo-liberal values throughout the healthcare system[17].

Consent enshrined in law

French Law no. 2002-303 of 4 March 2002, known as the "Kouchner Law", relating to patients' rights and the quality of the healthcare system, and the Law of 2 January 2002 reforming health and social care had the effect of consolidating patients' rights, emphasising the need to seek their consent and binding HCPs with an obligation to obtain consent.

Therefore, consent is covered by a specific legal framework, as set out in Article L1111-4 of the French Public Health Code and clarified by the Regulation of 11 March 2020[18]. This is a fundamental right and freedom as part of the individual's personal autonomy, which must remain a priority in all circumstances[19]. Consent is available to anyone, irrespective of their condition or status, including protected persons[20].

These laws and regulations have strengthened patients' rights and bear testament to the legislator's determination to **rebalance dialogue between the doctor's duties and the patient's rights in the decision-making process**. This means that patients are no longer simply giving their consent, but also participating in the HCP's decision. Therefore, doctors must encourage patients to express their wishes by providing fair, explicit and appropriate information so that informed consent or refusal can be given. Even in law, consent cannot be reduced to the signature on a form due to the fear of incurring legal liability amidst the growing number of medical cases being brought before the courts.

Finally, it should be noted that the bioethics bill currently being discussed in Parliament contains dozens of references to consent or the consent process.

From theory to practice

"Contemporary patients" (Fainzang, 2006) are encouraged to embrace their autonomy and take part in healthcare decisions, but they are still experiencing difficulties in this process due to the sheer complexity inherent in medicine and the supporting

DOI: https://doi.org/10.4000/anthropologiesante.1342

[16] French Muscular Dystrophy Association

[17] Ibid. 18.

[18] French Regulation no. 2020-232 of 11 March 2020 relating to the decision-making system in matters of health and social care with regard to adults subject to legal protection measures.

[19] Except in emergencies.

[20] In addition to legal representation measures between spouses, the legal protection system includes the following civil protection measures: judicial protection, supervision, guardianship, legal family-member guardianship and springing power of attorney.

technologies, as well as the severity of certain situations featuring a high level of vulnerability.

In practice, it has to be said that effective compliance with the principle of consent raises so many questions, particularly in cases of vulnerability, that it might be wondered whether applying the right to consent has instead become an illusion in certain circumstances[21].

Although legislation is clear and explicit, the hearings that were conducted when preparing this opinion nonetheless reveal just how much **regulations are sometimes at odds with what is happening on the ground**. In an article published in *Le Monde* in July 2020, doctor and bioethicist Samia Hurst-Majno, who is Director of the Institute of Ethics, History and Humanities at the Faculty of Medicine, University of Geneva, spoke of the "misunderstandings that can arise" on the issue of consent and the importance of preventing such misunderstandings, while regretting that "many doctors do not fully understand the issues involved in informed consent."[22] A flash survey carried out by France Assos Santé at the end of 2020 revealed that only 20% of respondents considered that the information provided by doctors to patients was fair, clear and appropriate[23]. A survey conducted by the regional health agency for Hauts-de-France among healthcare establishments and published in July 2018 as part of a report into the rights of people using the healthcare system acknowledges that "for many establishments, consent amounts to a signature at the bottom of a form and does not include any attempt to ensure that patients understand."[24]

Respect for consent: a fundamental ethical requirement

Although the effectiveness of "free and informed" consent in new situations of vulnerability sometimes requires a **difficult process of prioritising the principles that structure the doctor-patient relationship**, namely respect for autonomy, consideration, non-maleficence and justice, **respect for individuals** and their **dignity** remains the fundamental ethical requirement that must govern how such principles are prioritised. This places a duty upon HCPs to inform patients about the choices available to them concerning their health in a clear and fair manner as part of the aim to build a true relationship of trust while avoiding the pitfall of adopting a paternalistic or contractual model[25].

*After considering WHO's take on the concept of health[26], the CCNE wishes to use this opinion to draw attention to the **critical considerations** that must be taken into account to not only create a consent process that is as free and informed as possible, irrespective of how care is provided (hospitals, medical facilities, social care centres

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[21] Obtaining consent to enter a residential care home is a frequently mentioned example.

[22] https://www.lemonde.fr/sciences/article/2020/07/12/samia-hurst-majno-de-nombreux-medecins-ne-comprennent-pas-entierement-les-enjeux-du-consentement-eclaire_6046006_1650684.html

[23] https://www.france-assos-sante.org/2021/05/03/enquete-flash-1-delivrance-de-linformation-au-patient/

[24] https://www.hauts-de-france.ars.sante.fr/system/files/2018-09/RA%20Droit%20des%20usagers%20%202017.pdf

[25] The rights to free choice, consent and participation were simultaneously granted the same recognition in the field of health and social care when the Law of 2 January 2002 was enacted. Each subsequent text in the health sector has constantly strengthened the right to consent and, more broadly, the possibility for citizens to express their health-related wishes by bringing greater democracy to the healthcare system.

[26] Health is a "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." It represents "one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition" (Constitution of the World Health Organisation: https://www.who.int/en/about/who-we-are/constitution).

or patients' homes), but also foster a true relationship of trust with the HCP. Therefore, the CCNE has given due thought to the **practical ways for incorporating the ethical principles that govern the creation of a free and informed consent process** and the aspects that guarantee whether or not they are ethical, depending on whether they manage to combine the times, wishes, demands, responsibilities and capacities of individuals and HCPs.

The need to collectively reform practices

Since situations of vulnerability complicate the process of sharing information and obtaining consent, while also making it harder for individuals to understand its aims, scope and prospects for the medical sector, the CCNE has decided to focus on **consent in the field of healthcare, especially care for vulnerable people**. The other aspects of consent, especially in the field of research, will be covered in later opinions (therefore, this opinion does not address specific healthcare situations, such as consent for genetic investigations in paediatrics, gynaecology, and so on, genetic screening or the use of digital health data).
Judith Hermann-Mesfen and Eve Bureau-Point assert that "promoting the contemporary patient concept also means promoting values and sometimes reforming morals."

Paradoxically, "without real involvement and participation from doctors, patients cannot embrace their new role as expert patients[27]."[28]
While achieving greater individualisation involves a process of voluntary disaffiliation[29], gradually building autonomy involves striking the right balance between the disengagements and commitments, detachments and attachments that individuals consent to. Such arbitration must help forge social ties that are "capable of uniting but not smothering". In the real world, true autonomy is a question of "belonging". Do individuals see it as a freedom or constraint?" [30] In other words, we need a clearer insight into why some relationships create dependence while others lead to autonomy in order to bring a more human face to the medical relationship, especially where personalised medicine is concerned. Precision medicine will need to offer a personalised approach to both the medical side (genome medicine and data medicine) and human side of the medical relationship. It must respect and welcome each patient's distinctive qualities to ensure an effective interaction between doctors and patients, and provide what can truly be described as "bespoke" care.

Following the emergence of the concept of free and informed consent, as well as its legitimisation and incorporation into law, the CCNE is calling for collective action to further what it considers to be a vital "moral reform". It suggests a number of avenues that can be investigated further to ensure the harmonious and practical application of the **rules on consent, which it considers to be an integral part of respecting human dignity**.

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[27] Lorig, 2002, cited by Eve Bureau-Point and Judith Hermann-Mesfen, Ibid.15.

[28] Ibid. 18.

[29] Biljana Zaric-Mongin, François de Singly. "*With each other. When individualism creates ties*", *L'orientation scolaire et professionnelle* [Online], 35/1 | 2006, URL: http://journals.openedition.org/osp/949; DOI: https://doi.org/10.4000/osp.949

[30] Ibid. 29.

The aim of taking a long, hard look at the ethical issues of consent is to describe an ideal that we should strive to achieve. Everyone is responsible for using their best efforts to attain or come as close as possible to that goal.
Ultimately incorporating consent into the healthcare profession's practices is not only a challenge but an objective that must be reached. The CCNE is aware of the need to integrate the recommendations put forward in this opinion into wider-ranging discussions about the prospect of overhauling the healthcare system so that humanity, which is an essential part of supporting and caring for the sick, can regain the place that it has lost. The healthcare system is currently organised in such a way that the process of seeking consent, which is a highly humanistic aspect of the medical relationship, does not appear to be a priority in contemporary healthcare thinking. Yet the relationship of trust between HCPs and patients is really what brings a sense of meaning to the medical profession.
It should also be remembered that adequate time, resources and staff are the first keys to guaranteeing proper treatment. While HCPs need to maintain an ethical attitude, regardless of the deterioration in their working environment, it is clearly essential to acquire the necessary long-term resources to carry out an in-depth reform of the healthcare system.

The list of members who took part in the working group that launched these discussions is presented in Appendix 1, and the list of people interviewed is available in Appendix 2.

I. DIFFICULTIES ARISING FROM THE INCREASINGLY COMPLEX CONSENT PROCESS

1. PRACTICAL DIFFICULTIES IN EFFECTIVELY IMPLEMENTING THE PRINCIPLE OF CONSENT AMONG THE GENERAL POPULATION

1.1 Complex information hindering informed consent

- *The complexity in providing information, associated with predicting the risks*

People looking for information legitimately ask questions about the **balance between the expected benefits and the risks involved in their decision** (consent or refuse to consent to treatment). **Risk prediction can be reliable**: this first case is highly widespread. Many "standard" clinical procedures (biological tests, routine surgical procedures, etc.) are now performed while reliably predicting the risks for the future. **Risk prediction is relative**: the process of predicting risks may be more complex and require an overview of a range of potentially conflicting information and an individual ability to formulate a reasoned prediction while weighting certain factors and incorporating uncertainties. **Risk prediction may also result in a suspected but undefined risk for the future**: in other words, the risk is suspected, but cannot be objectified. Genomic analysis and prenatal diagnostic testing are iconic examples that combine the present moment with an uncertain future that may affect an individual's life, but also the life of their relatives and/or children.
Other effective treatments, such as implanting deep electrodes to treat Parkinson's disease, can lead to **progressive and very significant changes in the patient's personality that are unpredictable but just as critical as the actual disease (or even more so) for patients and their friends and family**. Successful treatment can destroy the social side of the patient's life context.

- *The complexity in receiving information, associated with biases in its transmission*

Information generally comes from a wide range of sources. It is important to determine whether that information has been-properly received and understood. However, there may be major biases when sending information that can have an impact on obtaining informed consent: There are five types of bias as follows.**Emotional and relational biases**: a purely technical relationship lacking any real human warmth can cause patients to reject information, however relevant that information might be, and skew the decision-making process. **Informational biases**: although the trend of citizens doing their own research, especially on the Internet, is a positive development, all the information needs to be sorted and summarised, while discarding any incorrect or irrelevant information, and educational efforts are required to avoid drawing the wrong conclusions. **External biases**: it cannot be ruled out that the contact person or HCP might abandon their benevolent and neutral position and instead adopt a form of activism, a self-interested stance or an attitude compelled by external situa-

tions, or even exert a form of control, such as through persuasion or lying by omission[31]. **Organisational biases**: sometimes, the means used to transmit information amounts to giving the patient an information form during a medical examination that then needs to be signed, largely due to staff shortages in the healthcare profession[32]. **Religious and/or political institutional biases**: national or international institutions sometimes play with the accuracy or uncertainty of the facts to promote a given objective. Crisis communication aimed at garnering public support for health or preventive measures can run the risk, even temporarily, of overriding the true facts. Assessing the trustworthiness and/or independence of the person or entity sending the information may support, distort or, in extreme cases, discredit the information received, regardless of the quality of the objective information.

- *The complexity of accepting information, associated with the individual's irrationality or aspirations*

The non-rational way in which evidence is formed may undermine or even replace any rational and scientific information. Humans are not always rational beings. Sometimes they create a personal set of ideas that may be confused with objective information or eliminate such objective information from the decision-making process prior to consent. Subjectivity and its series of representations and beliefs can compete with reason, and this non-rational dimension of humans must be respected.

1.2 How can a relationship of trust be established and maintained between HCPs and patients?

- *The characteristics of the medical relationship*

Isabelle Moley-Massol, a psycho-oncologist and psychoanalyst[33], describes the medical relationship as the "foundation of medical practice", a "distinctive and unpredictable encounter built on body language, symptoms and the spoken word." She points out that the medical relationship has "**real strategic power**". Under no circumstances can it be considered to be a business relationship.
Nowadays, it is more like a therapeutic alliance than a power relation[34]. Communication must no longer be one-sided, top-down or condescending. The term "assertiveness" is used to describe all the interpersonal skills of HCPs and bring together the various elements involved in building a relationship of trust, such as "representations, norms, values, loyalties, alliances, interactions, emotions and languages."[35]

[31] The constraints facing doctors in light of staff shortages or the very high cost of certain drugs, the constraints facing those rare doctors who are opposed to certain mandatory vaccinations, and the conflicts of interest that other doctors may have with pharmaceutical laboratories or corporations in the health sector are just some of the examples.
[32] Due to their complexity and multifactorial implications (long lead-times, uncertainties, influences on family members, etc.), genetic analyses require an integrative pre-analysis and consultation with professionals, when the request or proposal is made by a doctor and also when the results are delivered.
[33] Sessional practitioner at Cochin Hospital.
[34] https://www.profilmedecin.fr/contenu/nouveau-visage-de-relation-patient-medecin/
[35] Favre, A., V., Rossi, I., Ruiz, J., Izzo, F., Bodenmann, P., Gianinazzi, F. (2010). "The quest for informed consent in medicine as a social construct", *Rev Med Suisse* 2010; volume -4. no. 252, 1205 - 1208 DOI:

The balance in this relationship partly determines adherence to therapy, compliance and persistence, i.e. overall patient care. Consent is one of the tools used to support adherence[36].

- *Trust: a prerequisite for patient autonomy and shared medical decisions*

It **is important to consider the paradox that we need others in order to be autonomous when we are ill, and this requires *trust***, the "enigma that links individuals to society" (Georg Simmel)[37]. Niklas Luhmann (German sociologist) defines it as *"anticipating the future based on prior experience and which aims to reduce the complexity of the future world."*[38] Empathy (both verbal and behavioural), fairness and confidentiality during discussions allow both sides to express their opinions and sometimes their disagreements. These are the foundations for building a relationship of trust in medicine. As explained by Carl Rogers[39] in On Becoming a Person (1998)[40], establishing a relationship of trust can foster a climate of security and active listening, thereby helping patients to express their views and conquer their autonomy. It excludes "any preconceived notion of judgement, support or control" and is based on "optimism and confidence in each individual's ability to change, despite psychological suffering."[41] Therefore, it gradually leads to a **process of empowering patients, easing their personal journey and even creating resilience**[42]. The experience of counselling[43], particularly in providing psychological support to people suffering from AIDS, has shown that respecting the patient's values, personal resources and decision-making abilities lowers "their anxiety to a more controllable level", reduces their range of fears and helps them "explore their own reactions and take their own decisions" (Jean-Louis Pedinielli, cited by Monique Formarier[44]). A genuine relationship between HCPs and patients, and the trust that it gradually nurtures over time, facilitates the process of imparting information, gives patients a positive image of themselves, makes them feel valued and, if necessary, strips away any feelings of guilt. It allows them to analyse situations objectively and therefore make decisions, i.e. consent (or refuse). It is a prerequisite for ensuring a constructive encounter between the patient's lay knowledge and the HCP's expertise, for taking shared medical decisions, and encouraging their acceptance by stimulating the real creativity that patients need to develop resilience against changes in their living conditions.

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[36] Schneider, M., P., Herzig, L., Hampai, D., H., Bugnon, O. (2013). "Adherence to therapy in chronic patients: from concepts to outpatient care", *Rev Med Suisse* 2013; volume -1. no. 386, 1032 - 1036 DOI: .

[37] Lagarde-Piron, Laurence. "Chapter 13. Trust in nursing care. A vulnerable requirement. A communication-driven approach to care relationships", Richard Delaye ed., *Trust. Relationships, organisations and human capital.* EMS Editions, 2016, pp. 242-256.

[38] Karsenty, L. (2011). Interpersonal trust and work communications: The case of shift handover. Le Travail Humain, 2(2), 131-155. https://doi.org/10.3917/th.742.0131

[39] American psychologist, born on 8 January 1902 in Oak Park, and died on 4 February 1987 in La Jolla. Counselling and psychotherapy (1942), ESF Editeur, 2008, 135 p. On Becoming a Person (1961), Dunod, 2005, 270 p.

[40] *On Becoming a Person, Carl Rogers, 1951-1961, Dunod, "Social Psychology" collection, 1998.*

[41] *Counselling and psychotherapy, Carl Rogers. ESF Sciences Humaines. 11 April 2019.*

[42] Vasseur, Annie, and Marie-Christine Cabié. "Relationships of trust as a foundation for resilience in psychiatry", Recherche en Soins Infirmiers, vol. 82, no.3, 2005, pp. 43-49.

[43] "*In Anglo-Saxon culture, the term "counselling" is used to refer to a set of practices as varied as guiding, helping, informing, supporting and treating.* It is *"a relationship where one person tries to help another understand and solve the problems that they are facing*." See: https://en.wikipedia.org/wiki/Counseling_psychology

[44] Formarier, Monique. "The care relationship, concepts and aims", Recherche en Soins Infirmiers, vol. 89, no. 2, 2007, pp. 33-42.

- *The complexity of creating and maintaining trust in the care relationship*

There are many reasons why it is **hard to create and maintain trust in the care relationship**: uncertainty in medical practice[45], the lack of time or urgency, constantly changing doctors[46] (locums or intern turnover) due to the increasing number of professionals in certain care pathways, the lack of a conducive place for quality communication, the "risk of obscuring the patient's subjective experience" as a result of specialised disciplines, fragmented follow-ups, the complex and changing organisation of the healthcare system, the risk of an identity crisis caused by physical injury and suffering[47], and the list goes on.

Nevertheless, it is essential to find **ways of avoiding mistrust**. A number of lessons can be learned from on-the-ground experience:

- It would seem essential to consider education as an integral part of therapy[48] - medicine is not only curative, and the care relationship should not be "confiscated by the medical procedure". Care and taking care are one and the same. HCPs need to take account of the psychological aspects and the suffering caused by experiencing something that may not make any sense to the patient. The care relationship is "complex and fragile, straddling the dividing line between the subjective and the objective, the affective and the rational, the intimate and the political."[49]
- It is beneficial to help patients understand that they are not the same as their body or their illness, and to avoid confusing care with grief. In addition, nobody can be considered as a passive object of care.
- "Overcoming structural constraints and economic shackles to return to a relationship that is as little perverted as possible by agents that are external to what it should be and what it is."[50]
- Finally, it should not be forgotten that trust, which is a fundamental part of all care-related interactions, is both trust *in oneself* and trust *in the other person*. It is experienced in this dual movement which creates reciprocity and leads to a commitment from both the patient and HCP. Therefore, it is collaborative development process. Depending on the degree of trust generated by the care relationship, patients can "attribute trust" - this is a decision at this stage -, "feel trust" - this state of security is based more on intuition than certainty, and "have trust" - this is the peace of mind that "commits to the promise of attentive care and enables care to be carried out under the best possible conditions."[51]

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[45] Aubry, Régis. "Uncertainty in medical practice", Jusqu'à la mort accompagner la vie, vol. 109, no. 2, 2012, pp. 41-49

[46] https://www.voixdespatients.fr/retablir-la-relation-de-confiance-patient-medecin.html/amp

[47] These points were especially discussed during a conference organised by the Ecole Normale Supérieure, entitled "The Philosophy of Care - Ethics, Medicine and Society". Paris, 10-11-12 June 2009. See: https://philosophie.ens.fr/La-philosophie-du-soin.html, particularly: Céline Lefeve, lecturer in philosophy, Paris Diderot University, REHSEIS/Centre Georges Canguilhem, and Philippe Barrier, philosopher, CNED, Health Science Teaching Laboratory, University Paris 13.

[48] Barrier, Philippe. "The normal and the educational", Injury and strength. Illness and care relationships against self-normativity, edited by Philippe Barrier. Presses Universitaires de France, 2010, pp. 89-192.

[49] Ibid. 42.

[50] https://www.espace-ethique.org/ressources/editorial/la-relation-de-soin-une-question-de-confiance

[51] Lagarde-Piron, Laurence. "Chapter 13. Trust in nursing care. A vulnerable requirement. A communication-driven approach to care relationships", Richard Delaye ed., Trust. Relationships, organisations and human capital. EMS Editions, 2016, pp. 242-256.

2. ADDITIONAL PRACTICAL DIFFICULTIES IN EFFECTIVELY IMPLEMENTING THE PRINCIPLE OF CONSENT AMONG VULNERABLE PEOPLE

2.1 How can people consent to something that they understand only partially or not at all?

- *Seeking consent is a fundamental requirement, whatever the individual's cognitive abilities:*

A state of dependence in no way contradicts the notion of a person's autonomy, and altered physiological autonomy in no way precludes the need to systematically seek consent; on the contrary, it is even more necessary**.** As such, a comprehension deficit does not obviate the duty to inform patients and obtain their consent. Autonomy is not monolithic, and consent may require assistance from a third party. It is vital to identify the reason for the patient's misunderstanding (causes/consequences, pros/cons, benefits/risks) and make a distinction between the reasons that rule out any possibility of obtaining consent and the reasons that do not prevent consent from being given.

- *An "evolving and dynamic" process for people who can only partially understand.*

Consent can still be obtained from people with a partial or imperfect understanding of what they can or cannot consent to. However, their consent should not be considered to be absolute. Their consent **is "evolving", i.e. not set in stone, and dynamic**, because it requires regularly updated knowledge and information. This is already the case for anyone in full possession of their mental faculties. With people whose cognitive functions have been impaired, **the moving, evolving nature of consent** is simply heightened, and special care must be taken to ensure that they are able to update and review their consent quickly - if necessary, to prevent their consent from lapsing. **Respect for consent as an evolving and dynamic process is subject to a number of factors**, i.e. the use of **language that is appropriate to the person's abilities** when presenting the information, the presence of a HCP who can **repeatedly present the information** when the person feels the need or is more psychologically available, the need to **allow enough time depending on the person's subjectivity,** the possibility of discussing with someone close to them to offer **several different perspectives**, provide different types of explanations, and increase the quality of the person's presence or attention.

The possibility of not giving, withdrawing or revising consent must be reminded and explained to the person, and updated over time. In this sense, HCPs must be on the lookout for any **tell-tale signs of the patient's regret** about giving their consent, whether at the time of consenting or subsequently during care and treatment.

Unlike other countries, France has yet to reach a consensus about the methods for rigorously assessing a person's ability to discern or give consent in healthcare matters[52]. This raises problems, especially faced with the rising prevalence rate of neurocognitive disorders. It would be desirable to see a number of multi-disciplinary studies address this particular subject, since the ability to consent is a specific capacity that can only be approximated with existing cognitive scales. Therefore, we could draw inspiration from international literature and propose[53] some simple criteria to assess a person's ability to discern, such as after duly informing them of their situation and the alternative therapies. The aim would be to check that:
(1) The person has a broad understanding of their situation (i.e. that they have an illness).
(2) The person understands that they have a choice (that they can accept or refuse the proposed treatment).
(3) The person understands the foreseeable consequences of the different options (what is likely to happen if they choose option A, what is likely to happen if they choose option B, and so on).
(4) The person expresses a relatively consistent choice over time (they do not change their mind for no apparent reason).
(5) The person is able to explain why they have chosen a particular option if applicable[54].

- *An accessible process for minors*

Doctors need to seek the consent of minors on a case-by-case basis, depending on an assessment of their maturity, their family situation and the degree of urgency.
Evaluating a child's maturity means assessing their emerging self-awareness, developing beliefs and values, maturing cognitive skills, spiritual and social identity, and emerging capacity for autonomy. Consequently, HCPs should adopt a gradual approach based on transparency and process in the event of a disagreement with the child and endeavour to establish a relationship of trust[55].
Note that as part of this drive to bring the process of consistently seeking consent into widespread use, the Council of Europe and its associated Committee on Bioethics are currently leading a Europe-wide survey with support from TEDDY (European Network of Excellence for Paediatric Clinical Research) with the aim of preparing a good practice guide on children's **participation in decisions about their health**. The CoE rightly felt that it was essential to identify considerations and define common positions on the recognition to be given to children's ability to take part in decisions about their health (particularly transgender and intersex children).

[52] Hearing with philosopher Fabrice Gzil at the CCNE's offices on 24/4/2020.
[53] Fabrice Gzil, Alzheimer's disease. Philosophical disorders. PUF, 2009
[54] It is important to stress that the ability to consent must always be assessed in light of the specific therapy-related decision and not from a general perspective, since the person may be capable of making some decisions and not others. In addition, if a person does not appear to possess the necessary discernment to take a decision, then determine whether they could demonstrate the necessary ability with appropriate help before concluding that they are unfit to decide.
[55] See: Coughlin KW. Medical decision-making in paediatrics: infancy to adolescence. Paediatr Child Health. 2018 May; 23(2):138-146. DOI: 10.1093/pch/pxx127. Epub 2018 Apr 12. PMCID: PMC5905440.

2.2 To what extent is consent compatible with people in highly vulnerable situations?

The process of seeking consent faces a challenge in cases of institutionalisation (1), multimorbidity (2), end-of-life care (3) and organ donations (4).

- *Vulnerable people entering residential care*

Some care pathways, the limited possibilities for providing home care, and exhausted or lacking carers lead elderly people with a loss of independence or autonomy, or people with disabilities, to enter specialised care facilities, even though they did not necessarily choose to do so. These people give a form of consent that is more akin to an agreement or assent "**by default**". As explained in a recent opinion by the CCNE[56], the lack of alternatives to remaining at home is often what drives people to agree to institutionalisation. Therefore, entering a residential care home, which is intended to protect people by ensuring their personal safety, may paradoxically be experienced as an act of mistreatment by depriving them of their freedom to choose. Whatever the situation, the greatest care and attention must be taken over the meaning of **consent and the procedures for obtaining it. Does consent mean resigning oneself through necessity or freely assenting?**[57] In these situations, seeking consent first involves clarifying the boundaries of what is possible and then providing patients with the best support in coming to terms with their own vulnerability.

- *The inherent complexity of multimorbidity*

Obtaining consent is a complex issue when it comes to people with delicate medical or social conditions (synchronous multiple illnesses that are invariably associated with age, people with chronic illnesses or suffering from what will become a long-term condition due to the technological and scientific possibilities of contemporary medicine, etc.). Seeking consent in these cases implies making it easier for patients to understand what is at stake by harmonising and coordinating the messages from the different specialities and HCPs involved and by **striking a balance between telling "the reality" with tact and moderation, and revealing "the whole truth"**. The difficulty in providing information involves finding the right moment, using the right language[58] and determining the right perspective for sharing it - to maximise the likelihood of the information being understood, retained and "digested" by the patient[59]. **The duty to tell the truth coincides with the duty to avoid causing the other person pain and suffering.**

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[56] "Ethical challenges of ageing. What is the point of concentrating elderly people together in residential care homes? What incentives for a more age-inclusive society?" CCNE Opinion 128. 16 May 2018. This opinion can be viewed at the following address: ccne_avis_128.pdf (ccne-ethique.fr)

[57] Merlier, P. (2013). *Philosophy and ethics in social work: Manual* (pp. 55-61). Rennes, France: Presses de l'EHESP. *"Consenting may amount to resigning oneself through necessity, on the strict condition that it is the actual subjects who accept a possibility based on what they consider to be a necessity. In this respect, people can freely assent to what seems necessary."*

[58] Refer to the collection of fact sheets written using understandable and easy-to-read language: https://www.unapei.org/article/de-nouvelles-fiches-en-facile-a-lire-et-a-comprendre-falc-realisees-par-la-cnsa/

[59] Refers to F. Nietzsche's question in Ecce Homo, 1888. "How much truth does a spirit endure, how much truth does it dare?"

- *The inherent complexity of end-of-life situations*

In case of end-of-life patients, their choices and consent, as well as their refusal to consent, can potentially be anticipated through their advance healthcare directives. Consent is built up over time as their health changes, in line with their suffering or, on the contrary, the peace of mind that people in vulnerable situations may experience. **Anticipating what may happen can help exercise a degree of control over the uncertainty, prevent the images and anxieties** that may affect vulnerable people, and ease the burden on their friends and family. The legal mechanism for advance healthcare directives should be seen as a valuable tool for offering and anticipating the future, and helping people make their own decisions, even if they are no longer in a position to explicitly express their wishes at the given time. **Therefore, advance healthcare directives must be open to a potential review.**

- *Consent and organ donations*

People can donate organs or tissue during their lifetime or after their death. 92% of organ and tissue donations come from deceased people. According to the Caillavet Law that was implemented in France on 22 December 1976, everyone is presumed to be a donor unless they express their refusal during their lifetime[60]. Organ and tissue donation coordinators are responsible for interviewing one or more relatives and checking that **brain-dead patients did not object during their lifetime to their organs being removed**. If the relatives reply "*I don't know*", "*No*" or "*He/she never mentioned it*", the donation process may go ahead unless one or more relatives strongly object during the interview. If this happens, it is rare for coordinators to pursue the donation process to avoid exacerbating what is already a painful situation, combined with the shock of hearing the double announcement that the patient is irreversibly brain dead (i.e. death is inevitable) and that there is a request for a donation for a patient awaiting a transplant.

Under French law, organ donations are based on the individual's presumed consent or their refusal recorded directly in the national organ donor register. Organ donations raise a number of major ethical issues: **How can the "migration" from proven consent to presumed consent be analysed on an ethical level?**[61]
Can organ donations be seen as a new form of social contract or a way of living together?[62]
Does silence indicate an individual's will? (the legislator is responsible for regulating the scope of silence, since the rule of law dictates that silence can never constitute consent to a donation. The French Bioethics Law specifies the scope of silence, which in this case is equivalent to consent).

In practice, it must be recognised that **the relatives' acceptance or refusal of such an approach is almost always decisive**. Is it fair that access to life-giving treatment

[60] https://solidarites-sante.gouv.fr/systeme-de-sante-et-medico-social/parcours-de-sante-vos-droits/respect-de-la-personne-et-vie-privee/article/les-modalites-du-don-d-organes-ou-de-tissus
[61] Dumitru Speranta, "Presumed consent: family and equity in organ donation", Revue de métaphysique et de morale, 2010/3 (no. 67), p. 341-354. DOI: 10.3917/rmm.103.0341. URL: https://www.cairn-int.info/revue-de-metaphysique-et-de-morale-2010-3-page-341.htm
[62] Lepresle Élisabeth, "Presumed consent from the donor: a paradox of language", *Essaim*, 2006/2 (no. 17), pp. 179-188. DOI: 10.3917/ess.017.0179. URL: https://www.cairn.info/revue-essaim-2006-2-page-179.htm

should be *so* dependent on the family institution?[63] The issue of consent to organ donations is unique insofar as it raises the question of balancing the interests at stake, namely those of the family, those of the person awaiting the transplant, and those of society, by putting them into perspective with the wishes of the deceased person. The ethical challenge might be to respond to an **altruistic duty** by ensuring that all the stakeholders' interests are taken into account as far as possible in the decision-making process, without any one interest taking precedence over any other moral consideration.

2.3 How can decisions be taken for another person when their ability to give consent has been impaired?

When people become incapable of making decisions for themselves, whether temporarily or permanently, a third party (such as a relative or HCP) must take responsibility for making choices that will have a direct effect on their health or life[64].

- *The trusted person: how to help that person make a decision and/or express the wishes of someone who is no longer able to consent or refuse to consent*

The Kouchner Law of March 2002 gave patients the right to designate a trusted person, whose role was strengthened and extended by the Law of December 2015 on adapting society to ageing and the Law of February 2016 on the end of life[65]. A trusted person's primary duty is to **assist and support** the patient in understanding the medical information provided and reaching a decision. Their second duty is to bear witness to the wishes of the person who is no longer able to express their own wishes. **This clearly involves testifying and acting as a "messenger" of the person's past will and not taking a decision**.

However, current legislation does not adequately explain what is meant by "testifying to another person's wishes", especially when the person in question has never expressed their opinion on the matter.
What rationale should be used to testify to a person's wishes and what testimony should be given in that person's interests?
These **ambiguities raise a number of problems**, firstly because it is a pity to leave the people concerned in a state of helplessness without providing them with the clarifications and support that they need to fulfil their role properly, and secondly because **appointing a trusted person should become second nature for the general population**.

The role played by trusted people is clouded by many different questions and issues:
If trusted people are to bear witness to **someone else's will, they should not allow their own will and/or representations to intrude**, since "*I am mistaken if I judge others by myself.*"[66] Being a trusted person undoubtedly means removing any psychological

[63] Ibid. 57.
[64] "Over 900,000 people in France are subject to legal protection measures (guardianship, supervision, etc.), but many more are disqualified from deciding for themselves, whether temporarily or permanently, while others (whether family members or HCPs) are required to decide for them." See: Béliard, Aude, et al. "It's for their own good". Decisions for others as a micro-political issue", Sciences sociales et santé, vol. 33, no. 3, 2015, pp. 5-14.
[65] Reference texts: Article L 1111-6 of the French Public Health Code and xxx French Social Action and Family Code.
[66] Malebranche, The Search after Truth, III, 7, Paris, Vrin, 1965, t. 1, pp. 259.

thoughts or emotions from the difficulties facing the affected person in order to be as objective as possible. Have any studies been carried out into the quality of the actions performed by trusted people, depending on their relationship with the patient and the nature of their relationship? "*One who knows them cannot be other than a friend,*" wrote Saint Augustine in the Confessions. Without judging, how can we identify the honesty of the person who has been designated as best capable of bearing witness to a patient's presumed wishes, while maintaining a balance between the emotional attachment to that patient and respecting the presumed choices based on the knowledge of that patient? Does this mean that sincere testimony is lucid? What is the best way of accessing the truth about others? What type of psychological support should be given to the trusted person, depending on whether they have a romantic, family, platonic or other relationship with the patient?

It would seem necessary to **question the nature of the evidence that must be given** to testify to a patient's presumed will. Should an attempt be made to recount a certain number of memories and moments spent together, and interpret them through an intellectual or intuitive analysis? What reflects a person's relationship with life? Which words? Which habits? Which attachments (literary, cultural, political, religious, spiritual, ideological, geographical, etc.)? Which fears, doubts and certainties? A person's representations and wishes can always be overturned in extremis in their twilight years or following an accident. In that case, how can we remain faithful to the other person's wishes while bearing the risk of misunderstanding, transgressing or even betraying them? HCPs need to take a look at their practices and role, understand how to distinguish between assisted reflection and interference, avoid conflicts between relatives when the trusted person is expressing a choice of priority, etc. It would seem feasible for HCPs to think collectively about the ways in which they can support trusted people and reduce the ambiguities and ambivalence that sometimes plague their lives?
The most important step is not providing definitive, fixed and universal answers to these questions, but creating the conditions (time, resources, framework, etc.) for those answers to emerge within the relationship between the patient, trusted person and HCP, and allow the questions to be considered and explored on a case-by-case basis, so that the trusted person's role is to look for their own intimate conviction and dare to give a unique response in front of witnesses.

- *How can the expression of the wishes of a person subject to legal protection measures be preserved?*

Some adults under legal protection (judicial protection, supervision, guardianship, legal family-member guardianship and springing power of attorney) retain their ability to discern and therefore their potential to give consent, whatever the protective measures. **For each adult, the question of respecting and implementing their right to express a choice relating to their health should always be raised, even in case of the most restrictive protection measures**[67]**.** This ethical requirement, which is reiterated

[67] Thouvenin D. "Consent in medical practice subject to bioethics: protection or decoy?", Consentement et Santé, AFDS, Dalloz, 2014, 359-369

in Article 12 of the International Convention on the Rights of Persons with Disabilities[68], has led to renewed questions about the conditions and effectiveness of systematically seeking consent and expressing the wishes and preferences of these people.
In France, the Law of 5 March 2007 reforming legal protection for adults heralded a step in this direction by proclaiming the principle of autonomy for all protected persons, who "*make their own personal decisions to the extent permitted by their condition.*"[69] This principle whereby respect for the protected person's wishes overrides their protector's decision was confirmed by the Regulation of 11 March 2020 in the field of health[70]. The challenge now is for HCPs to take ownership of these new regulations, since they still tend to automatically seek the guardian's authorisation before asking questions about the protected person's capacity to consent.

When the protected person is still capable of making a decision: seeking consent clearly highlights the **ethical tensions between the desire to respect the person's autonomy and the need to protect that person**. Similarly, when a protected person has validly appointed a trusted person other than their protector, it is the trusted person's testimony that should take precedence out of respect for the choices expressed by the protected person[71].
Presuming the capacity to consent does not give the protected person back that capacity if already lost, but encourages the HCP to think about that person's freedom, however intangible, [72] and thereby incorporate it into a **form of dialogue that respects their dignity**.

When protected persons are unable to express a choice relating to their health, authorisation can only be requested from their legal representative (guardian, person authorised by the judge, etc.), who will seek the judge's authorisation for the most serious acts. Representation is used only as a last resort, and assistance is preferred wherever possible. When the will has not been clearly formulated, seeking consent does not appear to be an end in itself, but a **means**, i.e. **to initiate the process of establishing autonomy and protection, and never one without the other**[73]. The care taken to maintain a balance between autonomy and protection, without reinstating the person's capacity to consent, guarantees respect for a private space.

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[68] Available at the following address: https://www.un.org/development/desa/disabilities-fr/la-convention-en-bref-2/texte-integral-de-la-convention-relative-aux-droits-des-personnes-handicapees-13.html#:~:text=Article%2012&text=Les%20%C3%89tats%20Parties%20r%C3%A9affirment%20que,l'%C3%A9galit%C3%A9%20avec%20les%20autres.
[69] Article 459 of the French Civil Code, resulting from the Law of 5 March 2007 as amended by the Law of 23 March 2019
[70] See attached Article L 1111-4 of the French Public Health Code, as amended by French Regulation no. 2020-232 of 11 March 2020 - Article 2 relating to the decision-making system in matters of health and social care with regard to adults subject to legal protection measures.
[71] On this particular point, refer to the CCNE's response of 18 November 2020 on the "ethical issues of a vaccination policy against SARS-CoV-2."
[72] Benoît Eyraud and Pierre A. Vidal-Naquet, "Consent and guardianship. Consent for adults subject to protection measures", *Tracés. Revue de Sciences humaines*, 14 | 2008, URL: http://journals.openedition.org/traces/378 ; DOI: https://doi.org/10.4000/traces.378
[73] Ibid. 71.

- *The paradoxes of consent and coercion in mental health*

The risk involved in assessing the true nature of consent is even greater in psychiatry, since the patient's "yes" sometimes means "no" and vice versa, and consent tends to be more **volatile** over time. The role of the third party, who is often called upon in general medicine when the patient's consent can no longer be obtained, is more **delicate** in psychiatry. Family members, who may actually **initiate the patient's hospitalisation** at the request of a third party, often bring out **distinct and multiple visions of the patient**, and one of the members may also be acting as the **legal protector** (guardianship, supervision or family-member guardianship). Finally, a trusted person is not often appointed. Therefore, HCPs need to take special care to ensure that the trusted person (if applicable) or otherwise the legal protector consistently attempts to obtain an **expression of the patient's will**. In some situations, however, it is hard to get patients to **express their choices, wishes and preferences,** in which case the decision taken by another person "in the patient's best interests" takes precedence.

In addition, a certain amount of care is administered without consent in a way that is strictly regulated by law[74]. When a person's condition requires treatment[75], they may be automatically hospitalised in an authorised psychiatric establishment by decision of the prefect[76] .

From an ethical point of view, involuntary hospitalisation obviously begs the question as to whether the person's freedom of movement has been infringed, which also includes other forms of coercion (isolation rooms, restraints, drug treatments, transfers between hospitals[77], etc.). However, the question of the **patient's capacity to consent** and the degree of freedom that they can exercise despite the coercion **may continue to be raised**, not about the actual principle of care (which is required in such a context) but the way in which it is administered.

What remains of consent when care is ordered under criminal law in a place that may or may not be custodial, i.e. when the obligation to provide care is a binding legal measure and may form part of the judgment[78]?
How can the requirement to respect consent be reconciled with the indisputable need to treat these patients?[79]
When looking to **reconcile** consent with the need to treat, coercion must be considered in light of its **many uses "in the name of care"**: "*calming-containing, maintaining*

[74]Law no. 2011-803 of 5 July 2011 on the rights and protection of persons under psychiatric treatment and the terms for their care.
[75] The person may be found to be irresponsible, dangerous or even criminal in the case of an inmate, and their mental state may be likely to undermine public order or jeopardise personal safety.
[76] In pursuance of Article D. 398 of the French Code of Criminal Procedure, the prefect is responsible for ensuring the best possible medical care for the individual while protecting society.
[77] Over 92,000 people received involuntary psychiatric treatment on at least one occasion in 2015 in France. https://www.irdes.fr/recherche/questions-d-economie-de-la-sante/222-les-soins-sans-consentement-en-psychiatrie.pdf; https://tel.archives-ouvertes.fr/tel-02151955v1
[78] This includes involuntary psychiatric treatment, which is authorised under certain conditions by the Law of 5 July 2011, as reformed by the Law of 27 September 2013, as well as legal protection measures for vulnerable adults (Law of 5 March 2007) and care ordered by the judge in the case of criminal offences (Law of 17 June 1998). See also: Article 132-45 of the French Criminal Code: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000033460112/2016-11-20
[79] Berthon Georges, "The paradox of respecting consent in involuntary care: between the rule of law and psychiatric ethics", L'information psychiatrique, 2011/6 (Volume 87), p. 459-465. DOI: 10.3917/inpsy.8706.0459. URL: https://www.cairn-int.info/revue-l-information-psychiatrique-2011-6-page-459.htm

order-supervising and preventing patients from running away"[80], and determining the **point of balance in terms of the individual benefits for the patient, between breaking off their care and posing a life-threatening risk, and also in terms of the collective benefit between protecting the patient and protecting society in case of a real risk of violence towards others**.

The principles of **autonomy** and **consent** mean that - even in the context of coercion - a degree of freedom and choice must always been sought and protected.
The relationship with coercion can also change, and sometimes a space can be maintained where autonomy can nevertheless be exercised. Medically speaking, the fact that a person is forced into treatment cannot justify withholding information about their care and preventing them from understanding or consenting. The conditions for providing treatment must safeguard the prospect of the patient suddenly accepting or even lucidly agreeing during the relationship with the HCP. As patients recover their abilities, they must be given the information that they need to understand their situation. Coercion must not prevent clear information from being given to the patient (Appendix 4).
However, the term "**adherence**" may sometimes seem more appropriate than "free and informed consent" (the Law of 26 January 2016 also uses the term "**decision**" for seclusion or restraint, and not "prescription"[81].)
Changes in vocabulary highlight the **efforts** among legislators and HCPs to adapt as much as possible to the people undergoing treatment, reflect what is actually happening in the real world, and provide accurate wording for what constitutes genuine consent and what deserves to be described in another way. **Preserving the space of consent also means circumscribing the space of its flip side, such as injunctions, coercion and loss of freedom**, and dispelling any misunderstandings with the aim of delivering care that is proportionate to the benefits expected by the individual. In this respect, it is vitally important to move the doctor-patient relationship in a direction where patients are more involved in the choices shaping their care pathway.
The psychiatric exceptions where care is provided without consent (which is sometimes necessary) - it should be acknowledged that there are borderline cases where consent is irrelevant and the margin for autonomy non-existent -[82] must **give back people, as quickly and extensively as possible, the autonomy** that they have lost through their illness and the resulting imbalances[83]. Providing support and promoting uptake must be considered in light of the very purposes of psychiatry: "*Ideally, hospitality is the primary function of a psychiatric ward. Welcoming symbolises a movement towards the other. It involves welcoming patients, but also seeking to welcome their "inner self."*[84]

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[80] Delphine Moreau. Forced into treatment? The prescriptive tensions of psychiatric treatment after granting asylum. Sociology. Advanced School of Public Health Studies (EHESS), 2015. French. ⟨tel-02151955⟩

[81] Pechillon Éric, David Michel, "Decision or prescription of the psychiatrist: what difference does it make legally?" L'information psychiatrique, 2017/4 (Volume 93), p. 349-350. DOI: 10.1684/ipe.2017.1633. URL: https://www.cairn-int.info/revue-l-information-psychiatrique-2017-4-page-349.htm

[82] *See in particular: Information report no. 420 (2005-2006) by Messrs Philippe Goujon and Charles Gautier (Senate) , produced on behalf of the Law Commission and its information mission, submitted on 22 June 2006: Dangerous offenders with psychiatric disorders: how can society be protected while providing better medical care? https://www.senat.fr/rap/r05-420/r05-420_mono.html*

[83] David Michel, "Psychiatry under constraints", L'information psychiatrique, 2017/7 (Volume 93), p. 535-542. DOI: 10.1684/ipe.2017.1667. URL: https://www.cairn-int.info/revue-l-information-psychiatrique-2017-7-page-535.htm

[84] Baillon G., 1998 Les urgences de la folie. L'accueil en santé mentale, Montréal, Gaëtan Morin.

OPINION 136

II. WORKING TOGETHER TO ADDRESS THE ETHICAL CHALLENGES OF CONSENT

1. MOVING BEYOND THE TRADITIONAL CONCEPT OF BINARY CONSENT

1.1 Consistently seeking consent should be second nature

The law might not be capable of preventing bad habits from continuing. Legislation is clear on the matter, and consistently obtaining consent is a legal requirement, but the difficulty now is putting what the law says into practice (see also Appendix 5). **The challenge here is taking action to enforce a right that already exists, but which is not (sufficiently) implemented in the real world.**

Standards are essential, but there is a need to build a real consent culture. Current discussions about consent clearly reveal that it is not an "intimate matter". Geneviève Fraisse writes in "Du consentement"[85] how she long believed that *"the act of consent was a matter of the greatest intimacy, a mixture of desire and will, whose truth lay deep down inside of me. When I heard the word "consent" used in political forums, the European Parliament, televised debates and community discussions, I realised that the term was entering the public domain as a powerful argument"* (2017). The consent culture needs to make deep inroads into the medical world, especially since patients, due to their illness and potential suffering, are "*in a state of wounded humanity*" (Edmund Pellegrino, philosopher and doctor)[86]. In addition to its legal construction, consent must become a relational and social construction with the aim of improving how relationships and communication are managed, and thereby "(...) *promoting a culture of humanism in health care."*[87] **Seeking consent for care must be one of the mandatory professional skills for HCPs, since it represents an integral part of the care pathway.**

- *Consent from minors*

The Law of 4 March 2002 grants minors the right to object to HCPs consulting with the person possessing parental responsibility (father, mother, guardian, etc.) about a medical decision and the right to refuse that person from being informed about their state of health. This is known as the "right to secrecy"[88]. The child's consent must be obtained (Article L 1111.4 of the French Public Health Code, as amended by the Regulation of 11 March 2020), even though people with parental responsibility are required to give their consent to any treatment (doctors may have that responsibility if they feel that the parents' wishes conflict with the child's best interests). However, doctors are the legal decision-makers in neonatology and paediatrics. Although doc-

[85] *Du consentement, Geneviève Fraisse, new expanded edition, 19/10/2017, Seuil.*

[86] Verspieren, Patrick. "Partnership between doctors and their patients", Études, Vol 402, Issue no. 1, 2005, pp. 27-38.

[87] Anne-Christine Voeffray Favre, Ilario Rossi, Juan Ruiz, Filomena Izzo, Patrick Bodenmann, Francesco Gianinazzi Rev Med Suisse 2010; volume 6. 1205-1208

[88] https://solidarites-sante.gouv.fr/systeme-de-sante-et-medico-social/parcours-de-sante-vos-droits/modeles-et-documents/guide-usagers-votre-sante-vos-droits/article/fiche-13-les-soins-aux-personnes-mineures

tors submit their decision to parental consent, they may decide to overrule if warranted by the situation. The grounds and justification for their decision are stated in the medical record. The final decision is taken solely by the HCP[89].

- *Consent from adults subject to legal protection measures*

The principle governing decisions relating to protected persons is now clearly set out in legislation: "The consent of an adult who is subject to a legal protection measure with personal representation (guardianship or family-member guardianship with representation) must be obtained if he or she is capable of expressing his or her wishes, if necessary with assistance from the person responsible for his or her protection."[90] **Only in exceptional circumstances, such as if adults are totally incapable of expressing their wishes, will the guardian or court-appointed person represent them, i.e. take the decision on their behalf.** Changes in legislation and recognising the capabilities of the most vulnerable people, under the influence of Anglo-Saxon law and the International Convention on the Rights of Persons with Disabilities (Article 12 in particular), reflect this paradigm shift. **Agreeing to change attitudes towards protected people** involves adopting the ethical approach of asking questions about vulnerable people's real abilities beforehand. **Specifically, all HCPs are now responsible for giving priority to seeking and ensuring that vulnerable people express their wishes, regardless of their protective measures. This means eliminating the automatic habit that some HCPs have of first resorting to the guardian, whether a court-appointed non-family guardian or a family guardian, for fear of the consequences of being held legally liable[91].**

- *Consent from mental health inpatients or inmates*

The principle of consistently seeking consent must be prioritised wherever possible, irrespective of whether the initial constraint was imposed for health and personal protection reasons, or following a court conviction. This applies to people who have been involuntarily hospitalised for psychiatric care or deprived of their freedom of movement as a result of a prison sentence**.** This freedom to express choices, participate, consent and refuse to consent must continue to be exercised in healthcare matters or the activities of everyday life, to the extent permitted by the operation of the mental health facilities or prisons. Such limits should be strictly proportionate, appropriate and regularly re-assessed, and are subject to judicial review.

The CCNE recommends consistently seeking consent from minors or adults, regardless of the parental responsibility, legal protection measures or coercive situations to which they may be subject, and reinforcing the place of consent in social and health care

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[89] In the event of a conflict with the parents, especially due to religious reasons, doctors may decide to go against their wishes and limit or stop treatment if they consider that doing otherwise would constitute unreasonable obstinacy, where such decision is taken in the child's interests and takes precedence over the parents' wishes. However, doctors must have tried to obtain their consent after informing them accordingly and allow them, if time permits, to file an appeal with the administrative court before implementing the decision. In fact, the Council of State specified that "responsibility for assessing the appropriateness of implementing the decision lay with the doctor", which was upheld by the European Court of Human Rights on 23 January 2018 in the case of Afiri and Biddarri v. France. In the specific case of neonatology and paediatrics, concern for the child's welfare and best interests overrides the principle of benevolence towards the parents.

[90] Article L 1111-4 of the French Public Health Code, as amended by Regulation 2020-232 of 11 March 2020 (see Appendix 3), in line with Article 459 of the French Civil Code.

[91] When protected persons are capable of expressing a choice, it is important to trace the information provided and the efforts made at seeking their consent, even in the presence of a third party. This does not mean that guardians should be kept out of the loop, but they will not be asked to provide authorisation.

facilities and services to ensure that it becomes a major institutional and ethical issue in professional practices. Listening to and obtaining the consent of people in hospitals or residential care homes should be one of the cornerstones of the facilities' core principles and the patient's personalised support plan. The CCNE also recommends raising awareness among family caregivers of the priority given by all HCPs to the patients' or residents' word from the outset, and ensuring that the patients' or residents' consent is taken into account in all professional decisions as soon as they are able to express it, and using the process of seeking consent and its traceability as a specific indicator in the HAS (French National Authority for Health) certification and assessment manual applicable to social and health care facilities.

1.2 Seeking assent where consent is no longer possible

As indicated above, when individuals are no longer fully able to give their clear consent, other more subtle and less formal ways may still be used to express their wishes. **Assent "offers a recognised space for expression and fills the gap between all or nothing", because "incapacity often has varying degrees, moments and forms."**[92] It is a less perceptible indicator of the person's truth and preferences than consent, but no less accurate. Assent is often associated with the term murmur. For example, the New York Times regularly uses the expression "*a murmur of assent*". It refers to giving an agreement in a low voice or in the infra-verbal dimension of communication.[93] Assent should be sought when patients only have partial or altered awareness, psychological disorders (denial or anosognosia), cognitive disorders or fluctuating points of view.[94] **Assent is more a matter of *feeling* and *sensing* than of intellectual judgement**. It is a progression, a pathway or a process. It is more than a term or an acquired certainty. That is why it is less official and less ritualised. It does not necessarily have to be verbalised, but it can "use signs", such as "*nodding, flashing a smile and making a gesture of welcome, however fleeting*. *Sometimes, all it takes is a moment's awareness, a glance or a sudden display of vigilance. On the other hand, a tense face and averted gaze are more indicative of refusal than a signature extracted from a "capable" patient. While giving consent is sometimes tantamount to submitting in complete defiance, assent is given quietly and confidently.*"[95] HCPs must therefore learn how to recognise, observe, describe, interpret and respect a patient's assent and give real, indisputable and binding value to their assent in the care relationship to respect the autonomy of the person receiving support or treatment. It sidesteps the pitfalls of "forcing everything through in the name of following prescribed procedures and the need to do the right thing" and "giving up on care because no agreement has been reached". **The main aspect that distinguishes assent from consent is the difference in the level of communication that HCPs require when seeking assent or consent. HCPs require less assurance, formality and intensity from patients when expressing their preferences and choices.** Considering that assent is a form of "attenuated consent" means recognising that attenuating evidence,

[92]Armelle Debru, Professor of the History of Medicine, Paris Descartes University, Espace Éthique / Îlede France; see: https://www.espace-ethique.org/ressources/article/lassentiment-fait-son-entree-dans-le-langage-de-la-bio-ethique

[93] Georges Lambert is a hospital practitioner in geriatrics and long-term care. He is also the co-founder and chairman of the Aveyron Alzheimer association: https://www.geriatrie-albi.com/Assentiment_2021.pdf

[94] Ibid. 66.

[95]Ibid. 87.

traceability and expression does not detract from the sincerity of sharing assent or the clear-sightedness surrounding the decision to give consent. In any case, such clear-sightedness is never complete, even for people who are fully capable of giving formal consent[96].

The CCNE believes that action must be taken to tackle the tendencies, habits and traditions that sometimes continue to permeate the medical system, whereby HCPs stop seeking a patient's agreement when that patient is no longer capable of consenting, and they also no longer explain the reasons for their actions or the medical rationale for treatment. This attitude tends to discredit the patient and runs counter to respecting their dignity, which is a fundamental ethical requirement *(see also Appendix 6).*

1.3 Considering consent as an evolving process

Consent is not - or is not only - a procedure that should simply be applied before getting people to agree to that procedure. It is increasingly seen as a relationship based on mutual trust that can evolve as the patient's choices and medical condition change. When it comes to the complex issues, the notion of a process should be understood as both a **process that evolves over time** and as a **discursive process**, such as between the doctor and the patient. Consent or refusal may develop over time[97]. **Ultimately, consent is not given, it is developed. It is more of a process than an act.**
Is there an appropriate way to interpret or account for its ability to evolve over time? How can it be used and exploited when it is no longer fixed in time? Finally, how can HCPs deal with the prospect of patients revoking their consent and the ensuing risks?

- *Accepting the person's right to refuse consent, and ensuring that the refusal is free and informed*

Seeking free and informed consent includes accepting the possibility of adults refusing to consent[98], as long as it is free and informed. The right to turn down care, treatment or investigations goes hand-in-hand with a number of ethical issues. In particular, medical ethics must allow HCPs to fundamentally respect such refusals and raise profound questions when techniques are used in an attempt to get patients to go back on their decision. The perception of care depends on the recipient. What a HCP considers to be care may be perceived as violence by the patient, for whom the act then loses its very status as care. How can HCPs ensure that refusal

[96] However, caution is required with this approach to interpreting the situation. For example, it is not unusual for patients with a disorder of consciousness (mental confusion) or cognitive impairment (such as Alzheimer's disease) to oppose care, because they construe or feel such care to be akin to an attack. In these specific situations, their opposition should not be taken to mean refusal. In other words, a distinction needs to be made between a patient's opposition (which needs to be questioned and overcome) and a patient's disagreement (which needs to be respected and acknowledged).
[97] In an article published in the Canadian Journal of Psychiatry in 2015, Grainne Neilson and Gary Chaimowitz justify this concept of consent and explain its consequences: "Physicians must not conflate the procedure of consent with the process of consent. Informed consent is not necessarily formed (the signed consent form) consent. (...) The process of consent is the dialogue that facilitates adequate disclosure of relevant information, and promotes appropriate understanding of the relative merits of, and reasonable alternatives to, the treatments proposed. Express consent requires a meaningful exchange of information that starts at the moment of first contact between doctor and patient, and continues during the course of the treatment relationship."
[98] Law of 4 March 2002 (French Health Code, Article L1111-4 as amended by Regulationno. 2020-232 of 11 March 2020 - Art. 2.

is free and informed? The concept of refusal must be clearly distinguished from the concept of opposition. Whereas refusal implies "informed", opposition tends to concern people with a cognitive impairment who may perceive care or treatment as a form of aggression. This is a legitimate reaction to what is perceived as aggression, but it does not mean refusal. That is why information is especially important and also tricky when passing onto those people whose ability to understand has been impaired. Could it be that the very long amount of time that is sometimes needed to provide information is too restrictive in today's world, where performance requirements are gaining ground in the healthcare system? The risk is that people are not given sufficient explanations about what they are entitled to know, simply because they do not understand or fail to comprehend everything, or do not understand quickly enough. Another risk is considering that their refusal is not informed when it does not appear to be rational or logical, or when it is contrary to the HCP's proposal. Accepting the refusal does not mean abandoning the patient and ruling out the prospect of care, far from it. The HCP should listen to the patient.

- *Accepting patients' right to change their mind at any time, i.e. confirm the right to withdraw consent*

The whole issue of consent cannot be reduced to a binary choice (consent or refuse), and HCPs must accept that people have the right to change their mind, i.e. withdraw their consent or give their consent after initially refusing at the different stages in their health and life. The reasons may relate to changes in their quality of life or the sense of meaning that they give to their life. Once again, it can be seen that consent is a process rather than a procedure, and that the relationship of trust between the HCP and patient is essential. Like any other citizen, people subject to legal protection measures have the same right to change their mind, and their decision and choices may not be systematically belittled or denied as a result of their altered mental faculties. They are entitled to take risks like any other person. However, they must be duly informed of the consequences, especially the health-related risks, of their refusal or change of mind.

- *Exploring digital technology as part of the consent process*

When the consent process has been sufficiently formalised, it can benefit from an **algorithmic description**.
The idea is not to digitise the process to the extreme and out of all proportion, but instead create a **parallel approach** to the human relationship that is more accurate in terms of the information provided, more flexible in the ability to modulate consent, more formal about accessing information and more educational through the use of appropriate digital interfaces. Digitising the process for developing and representing consent could help support patients if the digital solutions for collecting consent (benefiting from human oversight of digital health) are developed in compliance with current legislation (see also Appendix 7).

The CCNE recommends that initial and ongoing training programmes for health and social care professionals should include lessons on fostering dialogue and developing a relationship of trust, and that when complex explanations are involved, the advice of an outside person should be sought, and new information media and tools should be used. Finally, digital technology can be harnessed to help people express their wishes and remember the consent mechanism. It can help promote a narrative

and personalised expression that is not reduced to a binary choice and which leaves an objective record of the narrative and consent process. Information traceability and the collection of consent by HCPs must constitute evidence that takes precedence over the patient's signature on a consent form.

2. RATIFYING THE USE OF SUBSTITUTE DECISION-MAKING: A MATTER OF TRUST WHERE CONSENT IS IMPOSSIBLE

2.1 Trust as a necessary basis for providing ethical support to patients who are unable to express their wishes

What remains of trust when patients can no longer express their wishes? How can their wishes be respected when there seems to be no way to guess their intentions at the *present time*?
First of all, it is important to emphasise the need to use **anticipatory tools** where possible, such as appointing a trusted person, preparing advance healthcare directives or granting a springing power of attorney[99]. These tools can help secure patients' trust insofar as they convey their choices and bear testament to a proactive approach for expressing their wishes in advance, thereby giving them a proper and official existence that persists even after they have lost their speech, free will or consciousness. When deciding to use these methods, patients know that they will accompany them in the future when they lose their ability to express themselves, and will protect them from any decisions against their intimate desires and choices. In the same way that we are required to respect a person's last wishes, and that respect and loyalty to their choices continue after their death, trust and respect for a patient's wishes do not stop when they lose their capacity for expression and understanding. The idea is to respect their previous guidelines and the preferences that emerged more or less informally over time during the care relationship. **Respecting a person's previous wishes is still consistent with respecting the person.**
Furthermore, trust can be granted due to the **collective aspect of medical practice**. People can rest assured that their case will be discussed by HCPs from a broad range of specialities and benefit from different perspectives, and that involving many different subjective opinions will ensure that their dignity is respected and will probably lead to fair, informed, unhurried and considerate decisions. Extending trust in this case means placing trust in the people, ethical principles and procedures inherent in medical practice. Gaining trust and respecting patients means strictly respecting the many different and complementary people, principles and procedures.

This person-centred relationship[100] is not innate. Trust is not given, but earned. It results from the alchemy between the persons communicating and the environment for dialogue. HCPs must be attentive, respectful and available to others, and know how to combine rigour with humility, while basing decisions on scientific data. What

[99] See Art. 477 et seq. of the French Civil Code at https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000031345528/. As amended by Regulation no. 2015-1288 of 15 October 2015 - Art. 13
[100] In relation to the person-centred approach developed by US psychologist Carl Rogers.

HCPs know must be balanced with what they do not know, due to the fact that patients are unique, whereas scientific data are often reduced to statistics. Therefore, it is important not to confuse science with knowledge, and acknowledge that fact with humility, which also helps bring a more human touch to the relationship with that person. HCPs must adapt to the person, depending on their ability to listen and understand, their limits, their psychological resistance and their subjectivity (fears, beliefs, representations, etc.). Finally, the physical and geographical environment for communication is especially important and must be appropriate. It is key for communication to take place in a calm and undisturbed setting with an atmosphere of confidentiality and simplicity. Whether face-to-face or remotely if required by prevailing health conditions, creating this relationship of trust must be seen as the foundation and starting point of a process that can lead to an informed opinion.

A certain degree of expertise and an acute awareness of the importance of verbal communication, as well as paraverbal and non-verbal communication, are essential for building a quality relationship with patients. The way in which the body, the voice and its prosody[101], the senses and movement are used is essential. It is fundamentally important to choose the right words and explicit terms that are appropriate to what the person can hear and understand. Proficiency in sign language or foreign languages may prove useful, depending on the patient's profile. HCPs must do everything in their power to restrict their own subjectivity, strive to ensure that the information provided is neutral or objective, and allow for two-way communication. Listening is crucial. Knowing how to listen to other people and interpret what they are saying or not saying is essential. Knowing how to respect moments of silence and consider how time is such an invaluable tool is another important factor, so that patients can progress at their own pace, according to their own difficulties, defence mechanisms, and psychological and emotional barriers. Finally, care must be taken during the conversation to check not only what the patient seems to have understood, but also what the information given elicits on an emotional level. It is exactly this type of process and interaction that will help clarify the patient's opinion, hence the expression of free and "informed" consent.

2.2 Trusted people: establishing their primacy among HCPs and reinforcing their role

The role of trusted people[102], who have been exclusively appointed by patients when able to do so (which means that any self-appointed person or any person appointed by a close relative has no legal value), is to share a message or intent expressed by the patient[103]. These "third parties" relate the discussions that they may have had about the patient's healthcare choices in general, or more specifically about a given medical procedure. As such, they **assist patients in thinking about those choices until the decision is taken**. It creates a climate of trust and conveys a certain **promise**[104],

[101] Vocal range, intensity, accent, rhythm, rate of speech, intonation and volume.
[102] In pursuance of Article L 1111.6 of the French Public Health Code
[103] The trusted person may also assist the patient during medical interviews if so desired.
[104] Consent to care and designation of a trusted person. Trust or promise? Benoît Pain, Philosophy of Medicine and Ethics of Care, UFR Medicine and Pharmacy, University of Poitiers. 2012. Espace éthique Nouvelle Aquitaine. See: https://www.espace-ethique-na.fr/obj/original_120621-consentement-aux-soins-et-designation-de-la-personne-de-confiance.pdf

namely the promise to avoid rushing into a decision, to prevent a lack of lucidity or to avoid blindly following an ideology with the aim of ultimately reflecting the patient's preferences as faithfully as possible. In the eyes of the law, conveying an intention is not the same as consenting and therefore deciding. Could this be a form of quasi-consent, i.e. consent that carries greater weight than a close relative's opinion and which could be similar to the legal scope of the authorisation provided by a legal representative, when considering that the trusted person embodies the "extended consent" of the "incapable person"?

The trusted person's testimony must "**carry weight**" in the positive sense of the term. In other words, it must have a dominant influence on the decision-making process in line with the very philosophy embodied by the legal anticipation mechanisms and democracy in healthcare (in the same way as advance healthcare directives or the springing power of attorney). Taking account of the patients' initial decision to express their choices in advance means continuing to give those patients all the consideration to which they are entitled, and preserving their dignity regardless of their level of dependence[105].

In cities, hospitals and the medical and social care sector, there must be a record of the trusted person's **appointment**. The process of identifying such a trusted person must not only be effective but also second nature **for everyone**, because their testimony will take precedence over all others, even in the presence of a guardian, supervisor or court-appointed person.

To increase the role of the trusted person in the interests of promoting a more ethical approach to respecting patients' wishes, information must be consistently provided to patients by HCPs, starting with general practitioners, and all HCPs need to be given more training to ensure that procedures are effectively put into practice in healthcare facilities.

As specified in the latest law on end-of-life care (2016), their testimony must take precedence over any other third parties involved in the decision. Their testimony must be considered to be decisive by providing key information for the substitute decision-making process, especially when medical arguments are not the most decisive[106],[107], and recognised as "quasi-consent", i.e. stronger than a simple opinion (caregivers) and which would be similar to the legal scope of the authorisation provided by a legal representative (guardian, count-appointed person, person designated in a springing power of attorney, etc.).

Since the advance healthcare directives expressed by patients are now binding and must be followed by HCPs unless there are arguments to the contrary, it would be logical and legitimate in the name of the patient's "extended consent" for the words of the trusted person to carry the same legal value as the words expressed by the patient in the advance healthcare directives.

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[105] It should not be forgotten that Article L 1111-4 of the French Public Health Code stipulates that the doctor may override the legal representative's refusal in exceptional cases, which may be extended to the trusted person (footnote): "In the event where treatment is refused (..) by the person responsible for the legal protection measure in the case of an adult subject to a legal protection measure with personal representation, and such refusal is likely to entail serious consequences for the health of the protected adult or minor, the doctor shall provide the life-essential treatment."

[106] Such as a decision to stop treatment for people who are unable to decide... Biographical and systemic elements (reported words, etc.) are likely to guide a collective decision.

[107] Unlike a trusted person, the legal representative does not give an opinion, but may be asked to take a decision on someone else's behalf if that protected person is unable to do so, which is very different.

The CCNE recommends that the trusted person's testimony should be given greater weight in healthcare decisions. It should be considered as more than just a simple opinion, and instead as the "extended consent" of the "person prevented from making the decision", while only resorting to taking a decision on behalf of another person in exceptional circumstances and in the alternative, so that the expression of the patient's wishes takes precedence. The CCNE suggests promoting the use of advance healthcare directives other than just in writing. Testimonies corroborated by records other than the written word, such as sound or video recordings, can be deemed to constitute advance healthcare directives, provided that they form a body of converging evidence.
Finally, organising a special national day for trusted persons every year could be beneficial in raising greater public awareness of the importance of anticipating situations where people may be prevented from expressing their wishes on a one-off or long-term basis. The regional ethical forums (ERER) could take part in this annual event by organising public debates.

2.3 Trust through the controlled use of expertise from other third parties, namely legal representatives and family members

In practice, all stakeholders must be fully aware that the involvement of a third party is subject to the **following order of priority**: trusted person, then legal representative, and finally caregiver, who are prioritised according to their proximity to the patient and their presumed ability to convey the patient's preferences or wishes.
The legal representative is the guardian or person who has been granted legal family power of attorney with representation. If a trusted person has not been appointed, the legal representative will only make a decision if the person concerned is no longer able to do so. If the patient's capacity is simply restricted[108], the role of the legal protector is limited to providing assistance. In all cases, the legal protector must always endeavour to ensure that the vulnerable person's wishes and preferences take precedence.
Caregivers, whether family members or friends, are only entitled to give an opinion, but giving an opinion is not the same as giving consent and therefore making a decision. However, this opinion is part of the collective decision-making process.
HCPs bound by professional secrecy are not allowed to disclose medical information to anyone other than the patient without the patient's permission. This fundamental principle of medical practice is part of the right to privacy[109]. However, the law does provide an exemption for close relatives, especially in the event of a serious diagnosis or prognosis, where disclosure lies in the strict interest of the person concerned. At the doctor's discretion and in consultation with the healthcare team, family members

[108] Article L 1111-4 of the French Public Health Code refers to an authorisation issued by the guardian, and states, as an exemption to this principle, that in the event of refusal, doctors may override the authorisation if they consider that it contravenes the person's interests.

[109] Law no. 2002-303 of 4 March 2002 on patients' rights and the quality of the healthcare system states that: "Any person treated by a professional, a facility, a health network or any other organisation involved in prevention and care has the right to respect for his or her privacy and the confidentiality of the information concerning him or her [...]" (Article L1110-4(1) of the French Public Health Code).

may be given certain information, especially information that helps support the patient[110]. The Code of Medical Ethics is even more explicit: "[...] a fatal prognosis should only be disclosed with caution, but close relatives must be informed, unless in exceptional circumstances or if the patient has previously forbidden such disclosure or designated the third parties to whom such information should be disclosed" (Article 35 "Information of the patient").

[110] "In the event of a serious diagnosis or prognosis, medical confidentiality does not prevent family members, close friends or the trusted person (...) from receiving the necessary information to provide direct support to the patient, unless the patient objects" (Article L1110-4(6) of the French Public Health Code).

Consent is an integral part of the time taken to administer care. The contiguous and inseparable nature of these two aspects of the patient's existence must be endured, i.e. autonomy and vulnerability. It allows patients to express a form of autonomy despite their vulnerability, and it is binding on the caregiver - while at the same time indicating the limits of their own autonomy. It involves displaying ethical behaviour through our regard of others, our encounters and our presence. However, improving care for vulnerable people cannot be reduced solely to respecting their consent. It is fundamentally important to bring about a wider change in our relationship with vulnerability[111] *and the associated responsibility. The CCNE will take a closer look at the contemporary understanding of vulnerability in subsequent studies.*

[111] Frédéric Boyer suggests (La Croix, 24/4/2021) looking at old age and vulnerability in general as a "different intensity of existence", and asks: "What kind of humanity would it be if presence only extended the realm of its kingdom to the limits of force?" »

APPENDICES

Appendix 1: Composition of the working group

Régis Aubry (rapporteur)
Gilles Adda
Claude Delpuech
Florence Gruat
Claude Kirchner
Karine Lefeuvre (rapporteur)
Martine Le Friant
Florian Maltis (guest)
Francis Puech
Hubert Stéphan (guest)

Editorial support: Louise Bacquet

Appendix 2: List of people interviewed

Anne Caron-Deglise, Assistant Public Prosecutor at the Court of Appeal, author of the interministerial mission report on "changes in legal protection for individuals: recognising, supporting and protecting the most vulnerable people".[112]
Dr Michel David, psychiatrist, President of the French Psychiatric Federation.
Emmanuel Didier, sociologist, CNRS research fellow, member of the Maurice Halbwachs Centre, member of the CCNE.
Pierre Gouabault, Director of public residential care homes in Loire-et-Cher.
Fabrice Gzil, philosopher, Head of Networks at the Île-de-France regional ethical forum, national centre for ethical consideration of neurodegenerative diseases, member of the CCNE.
Muriel Fabre-Magnan, Professor of Private Law, University of Paris 1 Panthéon-Sorbonne, Paris joint research unit on comparative law.
Séverine Laboue, Managing Director of Loos-Haubourdin Hospital, Haut-de-France.
Lionel Naccache, neurologist at the Pitié-Salpêtrière Hospital (APHP), researcher at the Paris Brain Institute, member of the CCNE.
Dr Marie-Jeanne Richard, President of UNAFAM.
Trainee directors at the EHESP (School of Advanced Studies in Public Health) as part of a study on "the consent of vulnerable elderly people in 2020 in light of the Covid-19 crisis: Ethical and legal issues in medical and social care facilities" (inter-professional module): **Antoine Bolmont (coordinator), Barbara Bourgès, Chrystèle Dalby, Wendy Eriana, Hélène Freuchet, Loïs Giraud, Géraldine Hézard, Morgan Morel, Basile Rousseau and Christine Saugis.**

112 https://www.espace-ethique.org/ressources/etuderapport/rapport-de-mission-interministerielle-levolution-de-la-protection-juridique

Appendix 3: Article L. 1111-4 of the French Public Health Code

(Amended by French Regulation no. 2020-232 of 11 March 2020 - Article 2 relating to the decision-making system in matters of health and social care with regard to adults subject to legal protection measures)

Every person, together with the healthcare professional and taking account of the information provided, **makes decisions concerning his or her health**. Everyone has the **right to refuse** or **not receive treatment**. However, the doctor will continue to monitor the patient's condition, especially in case of palliative care.

The doctor is required to respect patients' wishes after informing them of the consequences of their choices and their severity. If a person's decision to refuse or withdraw from treatment endangers their life, they must repeat their decision within a reasonable period of time. That person may call on another member of the medical profession. The entire procedure is noted in the patient's medical records. The doctor safeguards the dignity of the terminally ill patient and ensures the quality of their end of life by providing the palliative care mentioned in Article L. 1110-10.

No medical procedure or treatment may be carried out without the person's free and informed consent, which may be withdrawn at any time.

Where the person is incapable of expressing their wishes, no procedures or investigations may be carried out, except in cases of urgency or impossibility, without consulting the trusted person provided for in Article L. 1111-6, or the family, or otherwise a close relative.

Where patients are incapable of expressing their wishes, the decision to limit or stop treatment, which is likely to result in their death, may not be carried out without following the collective procedure stipulated in Article L. 1110-5-1 and the advance healthcare directives, or otherwise consulting the trusted person provided for in Article L. 1111-6 or otherwise the family or a close relative. The reasoned decision to limit or stop treatment is noted in the medical records.

The consent referred to in the fourth paragraph must be consistently sought from minors, who may be under guardianship, if they are capable of expressing their wishes and participating in the decision.

The consent of an adult (mentioned in the fourth paragraph) who is subject to a legal protection measure with personal representation must be obtained if he or she is capable of expressing his or her wishes, if necessary with assistance from the person responsible for his or her protection. Where this condition is not fulfilled, the person responsible for the legal protection measure with personal representation must give their authorisation, while taking account of the opinion expressed by the protected person. Except in emergencies, in the event of a disagreement between the protected adult and the person responsible for their protection, the judge will authorise either one to make the decision.

In the event where **treatment is refused** by the person with parental responsibility or by the guardian if the patient is a minor, or by the **person responsible for the legal protection measure in the case of an adult subject to a legal protection measure with personal representation**, and such refusal is likely to entail serious consequences for the health of the protected adult or minor, the doctor shall provide the life-essential treatment.

Examining a patient as part of a clinical teaching exercise requires the patient's prior consent. Students taking part in the teaching exercise must first be informed of the need to respect patients' rights as set out in this section.

The provisions of this article apply, notwithstanding any special provisions relating to the person's consent, for certain categories of care or procedures.

Appendix 4: Constrained freedom hindering free consent

Consent marks the point when information, beliefs and discussions converge at a given moment in time and in the uncertainty of life. Expressing free consent is not always easy, since freedom can be constrained by five major factors.

- **Freedom constrained by the existence of cognitive or psychiatric disorders**

People suffering from cognitive disorders or psychiatric conditions have a limited ability to understand what is essential and provide free consent. The four aspects of establishing consent are wholly or partly lacking (understand, assess and weigh up, reason and communicate).

- **Freedom constrained by the emotional complexity of life situations**

Emotional relationships within the family may raise the issue of consent given for oneself or in the interests of friends and family, and of the freedom of choice, particularly in the context of genetic testing or organ donations among families[113]. Emotional attachment, moral feelings, the perception of risk and the weight of the gaze from family and friends (particularly in case of refusal) create a tense situation that adds extra complexity to the decision-making process. Unlike other forms of consent, this type of consent is strictly regulated and requires **mandatory and explicit approval by a judge**.

- **Freedom constrained by a controlling relationship**

The principle of non-maleficence is not always respected, and human and interpersonal relationships can sometimes be malicious. The **pressure exerted by some professions or lobby groups**, whether for economic or ideological reasons[114], can lead to a form of **coercive consent** that is devoid of any reason or freedom. Its consequences can have a major impact on daily life. Analysing the information available, being able to "think critically for oneself again" and comparing one's beliefs with the opinions of friends and family, or trusted and various HCPs, are all fundamental to breaking free from manipulation or a type of conditioning that is detrimental to making free and informed personal or collective choices in the field of medicine.

- **Freedom constrained by organisational or economic factors**

There are situations where the process of obtaining consent takes place within a **restricted framework**, when the equipment and treatment available are limited, particularly due to costs or the difficulty in obtaining such equipment or treatment[115]. Therefore, admission to a residential care home is a very common case of reduced or non-existent freedom of choice, an "imposed" choice with only one outcome, because it is often influenced by economic considerations, such as when the family environment can no longer provide dignified living conditions, and the possibility of remaining at home is limited.

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[113] Kidney donations are a prime example.

[114] In particular, encouraging the sale and consumption of food products that are harmful to health, and praising thin models in the fashion world despite the spread of anorexic behaviour.

[115] The very high cost of certain innovative therapies and shortages during crises or natural disasters are just a few examples.

- **Freedom constrained by changes in medical practice**

Finally, it is essential to draw attention to the highly complex process of making **choices that involve the life of a being in the making** through preimplantation genetic diagnosis (PGD), prenatal diagnostic testing and genomic analyses. The use of these techniques, which are partly influenced by choices in national public health policies, undermines the unpredictable nature of life, not only for a person and their descendants, but also for their family members, who sometimes have no choice but to bear the resulting knowledge without having given their prior consent.

Appendix 5: What are the remaining exceptions to the principle of consent?

The concepts of "general interest", "public health order" or "common good" are likely to undermine or challenge our freedom to consent.

In some circumstances, consent is no longer expressly required. This applies to certain vaccinations or where hospitalisation is requested by a third party[116]. On this particular subject, the French National Medical Council writes that *"the doctor may override the refusal to consent where the patient presents a life-threatening risk, such as the final phase of a hunger strike or suicidal behaviour*."[117] In a summary judgment on 16 August 2002, the Council of State ruled that "*doctors do not commit a serious and clearly unlawful infringement of this fundamental freedom (to refuse treatment) when, after using their best efforts to persuade a patient to accept essential treatment, they perform an act that is essential to the patient's survival and proportionate to the condition in an effort to save the patient's life; that the use of such an act in these conditions is not manifestly incompatible with the requirements arising from the European Convention for the Protection of Human Rights and Fundamental Freedoms, particularly Article 9 therein*."

Finally, **the State may override any person's individual consent when imposing containment and quarantine measures to deal with an epidemic**. While it is easy to understand that the common good or general interest may be based on solidarity, security or health, great care must always be taken to avoid any excessive or inappropriate use of these concepts. **The ethical tensions in these situations are especially strong between an "open" attitude based on trust and "living together in harmony", and a more authoritarian attitude to protect the collective against the excesses of certain individuals.**
Therefore, introducing one or more exceptions to the consent of a group of people to measures that deprive them of their freedom or which run counter to their individual wishes requires prior information and transparent, accessible and proportionate justification of the position adopted. Information combined with greater democracy in the healthcare system (especially through citizens' groups and public debates) are likely to encourage the necessary level of acceptance in society,-without which consent (the social contract in liberal democracy) is nothing more than a **pipe-dream**[118].

[116] Due to attempted suicide or hunger strikes.
[117] Art. 35, Code of Medical Ethics.
[118] Refer to the CCNE Opinion on the "Ethical issues in the face of a pandemic", published on 13 March 2020: https://www.ccne-ethique.fr/sites/default/files/publications/reponse_ccne_-_covid-19_def.pdf

Appendix 6: Strengthen the role of consent in health and social care facilities and services: a major institutional and ethical issue

- **Listening to and obtaining the consent of people in hospitals or residential care homes should be one of the cornerstones of the facilities' core principles and the patient's personalised support plan.** Consistently involve the patient or otherwise the trusted person (or otherwise the legal representative or caregiver) in preparing and monitoring the patient's personalised support plan.
- **Ensure that the key focus areas of the facility's annual training plan** for all its HCPs, irrespective of their position, includes the following: (1) users' rights, particularly the issues of ethics and democracy in the healthcare system (freedom of choice, right to informed consent and right to participate), and the meaning of consenting and refusing to consent; (2) legal protection for individuals, especially the principle of consistently seeking the consent of protected individuals, including those under guardianship measures.
- **Raise awareness among family caregivers** of the priority given by all HCPs to the patients' or residents' word (respecting their consent or refusal to consent) as soon as they are able to express it, including when they are under legal protection measures.
- **Appoint two "Health Democracy" officers in each facility, comprising a user and a HCP**, who are trained on such issues and appointed by management. The role of this two-person team is not to exercise control, but ensure that users' consent and participation are respected. They can proactively issue proposals and suggestions to the facility in liaison with the user and patient support bodies. Their role would not be to interfere or intrude in the HCPs' practices, but instead support them in the process of seeking and obtaining consent or assent from patients.
- **Set up an ethical review body in each facility**, which could evolve into an inter-facility ethics review committee, for discussing such issues as consent or substitute decision-making. Garner the support of the regional ethical forums (ERER) to drive this approach.
- **In the event of a crisis, especially a health pandemic, involve the facility's users from the outset as fully fledged stakeholders in the decision-making process.** Users can be involved through representative bodies, such as user and patient support bodies, but also through other means, such as the two-person team of "health democracy" officers, discussion groups, or an outside person belonging to an ethics support group or regional ethical forum (ERER).
- Where consent is conceived as a process, **include the search for consent and its traceability as a specific indicator in the HAS certification and assessment manual** applicable to health and social care facilities.

Appendix 7: Consent to the use of health data

The processing of personal health data (genetic data, biometric data, data concerning a natural person's sex life or data concerning health) is prohibited in principle, but Article 9 of the General Data Protection Regulation (GDPR) provides for a number of **exemptions**, including[119][120]:

- The data subject has given explicit consent to the processing of those personal data for one or more specified purposes.
- Processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent.
- Processing is necessary for reasons of public interest in the area of public health.

What about consenting to the processing of health data? What do patients agree to when they authorise their data to be used? : As stated by the–Article 29 Working Party[121]: *"Consent can only be valid if the data subject is able to exercise a real choice, and there is no risk of deception, intimidation, coercion or significant negative consequences (e.g. significant additional costs) if he/she does not consent. Consent will not be free in cases where there is any element of compulsion, pressure or inability to exercise free will."* » [122] **.** In addition, according to Article 5(2) of Council of Europe Convention 108, data processing may only be carried out on the basis of "*free, specific, informed and unambiguous*" consent of the data subject or of some other legitimate basis laid down by law.

How do patients give free, specific, informed and unambiguous consent to the processing of their health data? : In the case of the personal data involved in big data-type processing, "*the protective nature of the requirement for free, specific and informed consent is liable to be less effective when the consent to the collection and processing of these data is presented in what are often standard form contracts as a precondition for using certain devices, services or applications[123], or when certain connected devices are offered free of charge provided their users agree to the personal data captured by these devices being collected and processed. The issue then becomes one not so much of informed consent as of whether it is acceptable to relinquish the right to personal data protection, a right that is recognised as being fundamental*." [124]

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[119] The other exemptions can be viewed on the CNIL website at the following address: https://www.cnil.fr/fr/reglement-europeen-protection-donnees/chapitre2

[120] Where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject.

[121] The EU's independent advisory body on data protection and privacy, established by Article 29 of Directive 95/46/EC. Its tasks are defined in Article 30 of Directive 95/46/EC and Article 15 of Directive 2002/58/EC. See: https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2007/wp136_fr.pdf

[122] Article 29 Working Party. Guidelines on consent under Regulation 2016/679, Adopted on 28 November 2017. As last Revised and Adopted on 10 April 2018

[123] Often presented as membership contracts.

[124] Antoinette Rouvroy, Report for the Council of Europe by the Bureau of the Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, "Of Data and Men", Fundamental Rights and Freedoms in a World of Big Data, 11 January 2016.

Relinquishing the right to personal data protection is in line with a very Stoic conception of consent, as seen in Antiquity. It is then an "*act of acceptance directed towards something that is beyond us, against which we can do nothing, but which we paradoxically make our own by acquiescing to its presence*."[125]
To ensure that consent is free and informed, it must be preceded by an exploration into the **personal balance sought between "the convenience of immediacy, the perceived benefits of interaction and personal exposure" and "the loss of privacy**".

[125]Laetitia Monteils-Laeng, "Ancient Perspectives on the Philosophy of Consent", Tracés. Revue de Sciences humaines [online], 14 | 2008, published on 30 November 2009, viewed on 19 March 2020. URL: http://journals.openedition.org/traces/369; DOI: https://doi.org/10.4000/traces.369

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