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COVID-19 vaccination in nursing homes: considerations on freedom to make decisions and legal protection measures

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In the most vulnerable people, especially among the elderly, the COVID-19 pandemic has brought to light complex ethical issues such as consent to receive health care, the relationship between risks and benefits of therapies, the choices to be made during the most serious phases of the disease and family relationships have been made extreme and heavily emphasized by the pandemic.

The article analyzes the ethical and legal aspects of the problem of reconciling respect for the individual's right to make their own decisions and the need to protect the most vulnerable and fragile sections of the population (the dilemma between the principle of charity and respect for autonomy), with all the related communication, procedural and legal problems relating to Informed Consent.

The exceptional circumstances of the pandemic have prompted lawmakers to tackle the complex and long-neglected issue of the consent of vulnerable, generally elderly, individuals.

In many contexts, from home to hospital to nursing home, patient involvement in decision making, the role of the family, and procedures for defining competencies above and beyond diagnostic categories, continue to be largely left behind. part in the hands of the health care workers or team. The methods chosen to obtain consent to vaccination, together with the provisions of the Law of 22 December 2017 on the role of the trustee, pave the way for more appropriate operating methods for daily clinical practice in the field.

Key words: COVID-19 vaccination, elderly, informed consent

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INTRODUCTION

Our society, its social and occupational organisation, our communities, and our healthcare systems were not prepared to deal with the COVID-19 epidemic. The most critical situations concerned the most vulnerable people: the elderly, affected by chronic medical conditions, mental impairments, or physical disabilities, were at greater risk of contracting the disease and suffering its most dramatic consequences [1].

In relation to this category of people, complex issues such as consent to receive healthcare treatments, the relationship between risks and benefits of therapies, the choices to be made during the most severe phases of the disease and family relationships have been made extreme and strongly emphasized by the pandemic.

Health emergency and vulnerable members of society: general considerations

"The term emergency indicates both the emergence or the manifestation of something already existing [...] and the appearance of the unanticipated, the uncalculated, the unexpected and the new" [2]. This definition is particularly suited to the COVID-19 pandemic, which has led to the unforeseen, unexpected emergence of critical factors and problems which had been swept under the rug for a long time, and which were thought to be manageable, if not resolvable, through the routine use of consolidated procedures. The paradox of the emergency is that the unforeseen is something already present and somehow known whereas the unexpected concerns its actual scale and the violence of its impact on society [3].

At the same time, this crisis has led to the emergence of surprising resources, potentials and reserves of humanity, while indicating directions where solutions should be sought within the healthcare sector [4]. Especially in this sector, the pandemic emergency has led to radical changes, in clinical and organisational terms and in the approach to certain ethical consequences linked to research and experimentation, relationships between doctors/healthcare professionals and patients as well as the nexus between *"private suffering and public health"* [5].

In healthcare, as in other sectors, alongside with the wish to return to normal and provide patients with the best possible care, the realisation has gradually emerged that *"nothing will ever be the same again"*.

Ethics and the vaccines: a subject of great complexity

One phenomenon, which was perhaps foreseeable, but which has been occurring on a scale and with consequences that were certainly unexpected, is "vaccine hesitancy". This euphemism covers a vast range of quite different attitudes: from mere indecision and reluctance and/or thoughtlessness through to a radical and sometimes even violent ideological opposition and refusal [6]. At a time when, in Italy as well as in many other developed countries, the campaign to administer the booster dose of the COVID-19 vaccine is under way, starting with the most vulnerable and/or those at the highest epidemiological risk, is under way, the heat of the debate on vaccination is showing no signs of abating, partly due to ever-present media coverage which tends to accentuate extreme positions. It is clear that this polarisation does not make it any easier to correctly consider these complex issues or to contemplate their ethical and bioethical implications constructively.

From the ethical and bioethical point of view, vaccination, especially in emergency contexts, seems to be a real "minefield," which comprises considerations in the fields of research, clinical practice, and public health, at several levels (individual, institutional, social, and global) [7-11].

In each of these contexts, questions arise concerning the problem of balancing respect for the individual's right to make their own decisions and the need to protect the most vulnerable and fragile segments of the population (the dilemma between the principle of beneficence and respect for autonomy), with all the related communicative, procedural, and legal issues relating to Informed Consent.

This initial point gives rise to major philosophical, legal, and political issues, such as the problem of balancing personal freedom/interest and the principle/duty of social solidarity, and the problem of applying the principle of justice and equality when setting priorities for the administration and distribution of vaccines, both within the various countries and globally. There then is the issue of defining ethical criteria with which these priorities are to be set. Also problematic is the production of suitable forms of communication and persuasion that encourage vaccine uptake and strengthen the trust on which the therapeutic alliance is based [12].

The importance of an ethical approach: information and/or communication?

At the end of 2020, when there were still many scientific and epidemiological unknowns surrounding the evolution of the pandemic and actual availability of vaccines over the short term, the Italian Comitato Nazionale per la Bioetica (CNB) [National Committee for Bioethics] already provided indications on the subject. In its Opinion "I vaccini COVID-19. Aspetti etici per la ricerca, il costo e la distribuzione" [COVID-19 vaccines, ethical aspects of research, cost, and distribution], dated November 27 2020, the Committee underlines the importance of an ethical approach to ensure that choices relating to vaccines were based "on the general moral, ethical and legal principle of the equal dignity of every human being and the avoidance of all forms of discrimination, as well as the additional principle of fair access, meaning careful consideration of vulnerability due to specific needs" [12]. The document further urges that every effort should be made to achieve optimal vaccine coverage, whilst not ruling out compulsory measures if the emergency persists it instead suggests to resort to forms of communication that could encourage voluntary uptake as the preferred path.

This issue is discussed in depth in point 4 of the Opinion, entitled "Distribution, compulsory vaccination and information", where the Committee reaffirms the need for "transparent, clear, comprehensible consistent and coherent information, based on scientific proof and data", while focusing on the essential requirements and strategies for winning the public's trust. Insistence on this question is justified by the conviction that only the right information and communication can enable people to make informed, responsible, public-spirited choices, and reinforce "the therapeutic alliance in which doctors, who have the skills and knowledge to provide adequate information about the risks and benefits of treatments and drugs, are those responsible for providing information regarding the health of their patients and of the community as a whole". This opinion touches on the central point of the foregoing ethical issues, i.e. the bond of trust that forms the therapeutic alliance, which is the "ethical core of medicine" as well as its relational and communicational dimensions, with its function of ensuring that patients and society as a whole are capable of making informed and free choices [5].

The therapeutic alliance: autonomy and trust

At this fundamental level, the pandemic and the vaccination campaign put at least two issues worthy of further consideration into focus: first, the ambiguity which often surrounds the matter of doctor-patient communication as the ethical foundation of the therapeutic relationship and the role of information, especially in the Informed Consent procedure, from this point of view. Closely linked to this outlook is a way of conceiving respect for the patient's autonomy and right to self-determination in sharp contrast with the principle of beneficence and the duties of solidarity.

The difficulties often encountered in obtaining consent in specific care contexts, especially in the case of minor, elderly, partially or totally incapacitated patients, are just the tip of the iceberg of a more general underlying problem. There has been a deliberate oversimplification of medical communication and care relationships, understood as pure, one-way transfer of information with all the formalistic and legalistic drifts that this approach entails.

This coincides with a doctrinal and practical orientation towards making Informed Consent the basis of the relationship of trust and the therapeutic alliance, which, instead, have their ethical foundation in the condition of need arising from the "patient's wounded humanity" as Edmund Pellegrino pointed out [13]. One of the main reasons for this tendency is an anthropological and ethical concept that interprets autonomy in a categorical, unconditional, and sometimes unrealistic manner. This stance introduces theoretical and practical obstacles into the therapeutic relationship, which is asymmetrical by its very nature, and therefore entails a series of ethical and professional obligations toward particularly vulnerable people that cannot be adequately represented by a contractual model.

In recent decades, the rigid, schematic interpretation of the Theory of Principles which absolutizes the principle of autonomy has been countered by many contributions based on a more realistic view of the human condition, its vulnerability, and the network of relationships of interdependency within which it develops. This outlook has generated alternative, more credible patterns for the therapeutic relationship and its ethical dimensions, which focus on the bond of trust and/or are founded on a relational conception of autonomy [14-16].

From this standpoint, it would be useful to consider the experience acquired in specific care contexts such as nursing homes, where the immediate impact of the pandemic was devastating, and where patients could only be protected through rapid reaction and high levels of flexibility, adaptation, integration, and collaboration. In these contexts, those same safety measures often conflicted painfully with the need to safeguard the residents' quality of life, and notwithstanding, despite or perhaps because of the restrictions, "the relational element became particularly important" [4].

Moreover, especially during the initial phases of the pandemic, institutional contexts, and nursing homes, suffered from a kind of isolation that accentuated management problems (lack of safety systems, clear operational guidelines as well as human and technological resources, isolation from families and breaks of ties with the community) as they were forced to rethink their residential care model [17]. Currently, in an almost "post-pandemic" phase, certain problems have still not been completely resolved.

The experience gained in these contexts may constitute a sort of "laboratory" where more flexible, suitable actions in the implementation of consolidated rules and procedures can be attempted, also in non-emergency situations.

Expression of consent to receive COVID-19 vaccination for the mentally impaired in nursing homes resident

With the legislation on "Expression of consent to receive COVID-19 vaccine for incompetent persons hospitalized in residential care facilities" (note no. 1) the Legislature addresses the expression of consent to be vaccinated against COVID-19 in a specific way in relation to situations of incapacity in which there are subjects hospitalized in residential care facilities, in the presence or absence of a legal representative or legal protection or a network of family members.

The aim was to speed up the achievement of vaccine cover in contexts with a high infection risk to safeguard the health of the incapacitated people resident there and their host communities, and to comply with the stated or presumed wishes of the individuals concerned.

It should be borne in mind that about 80% of Italian nursing homes residents are affected by cognitive impairment. In fifty percent of these cases the impairment is such that it precludes any real ability to express valid consent [18]. Despite this, only an extremely small proportion of these people have a support administrator, and thus the situation which the law envisages as applying only to exceptional circumstances could be considered the rule.

In this particular context, the Legislature has provided for a complex procedure, which assigns guarantor functions to subjects (physician, family members) who play a primary role in the treatment and care of an incompetent person resident in a nursing home. Although included in legislation issued to deal with an emergency situation, the indications provided should be able to harmonise with the law on ownership and the criteria which guide the decision-making process with regard to healthcare and treatment in situations of incompetence.

The note issued by the Ministry of Health on 24 December 2020 containing "Recommendations for the organisation of the SARS-CoV-2/COVID-19 vaccination campaign and vaccination procedures" (note no. 2), identified the categories of people to be prioritised in the vaccination process, including nursing home residents, and provided forms for the acquisition of consent to be vaccinated, to be signed by the subject or their legal representative, and the two professionals who administered the vaccine.

More specifically, the Legislature set out the procedures for acquiring the consent of incapacitated persons resident in nursing home, distinguishing between persons with formally appointed guardians or representatives and persons not covered by any measures, with a kind of presumption that the former was unable to decide autonomously.

In particular, the law requires that the incompetent persons, resident in nursing homes, should express their consent to be vaccinated through their guardian, curator or support administrator or trustee, in compliance with the provisions of Article 3 of Law 219/2017 and in accordance with any wishes already stated by the subject in the form of an advance directive, or the wishes they would presumably have expressed if in full possession of their faculties (note no. 3).

In situations of natural incapacity, i.e., if the representatives referred to above are not appointed or are unavailable for at least forty-eight hours, the law assigns the role of support administrator to the medical director or, in their absence, to the chief medical officer of the facility or, if neither is available, to the medical director of the local national health service trust with jurisdiction over the facility or their representative, for the sole purpose of providing consent to be vaccinated.

Having specified the subjects legally authorised to express consent to be vaccinated, the Legislature has provided precise guidance concerning the decision-making process, to protect the health of the person with cognitive impairment and enable the expression of a decision consistent with their previously expressed or presumable wishes, also through the involvement of their relatives.

In fact, for the purposes of expressing consent to be vaccinated, "having ascertained that the vaccination will provide the best protection of the health of the person in residential care", the legally authorised subjects are required, if the identity of these parties is already known, to consult "the spouse or civil or live-in partner, or otherwise the nearest relative up to the third degree" (note no. 4).

The person-centred nature of this approach clearly emerges in the statement that the consent must be given in compliance with the wishes of the person concerned expressed pursuant to Articles 3 and 4 of Law no. 219 of 22 December 2017 or, failing this, in accordance with the wishes of those people closest to the person involved, as specifically defined by the Legislature (note no. 5).

The Law then assigns the Court the role of validating decisions in the absence of a prior or current expression of their wishes by the cognitively impaired person, or if the persons close to the latter, as defined by the Legislature, cannot be contacted or are unavailable. In this case, the consent to the vaccination, signed by the person temporarily acting as support administrator *ad actum* under the law (medical director or chief medical officer of the nursing home, or medical director of the local health trust) shall be notified to the Court at once. This notification shall be accompanied by the documentation proving that the person in residential care is indeed incapacitated, the absence or unavailability for 48 hours of a legal representative, or of a formally appointed legal protection figure or trustee, the lack of people close to the person concerned to be involved in the decision-making process regarding the vaccine, the lack of an advance directive issued by the patient and, last, that the vaccine will ensure the best protection for that person's health.

Consent thus expressed shall be considered confirmed and definitively effective for the purposes of administration of the vaccine upon notification to the person concerned, and their representative, within 96 hours of submission of the approval request, of the Court's approval, or if no such notification is issued by the expiry of this deadline.

Within the complex web of measures issued by the Legislature, acknowledgement that the nursing home resident's physician and relatives function as guarantors of the patient's healthcare and of compliance with his or her wishes, which is in line with their actual roles of care and support for the patient, is significant [19].

Moreover, the Legislature must inevitably consider the far from secondary role of relatives among the various parties involved in the care and treatment process [20].

Although it raises some critical issues, the involvement of the people close to the patient is an important step in acknowledging the real situation in many cases, and is also envisaged in the cited Law 219/2017, containing "Provisions concerning informed consent and advance directives" (note no. 6).

With regard to use of the support administration system, with a view to personalising measures for the legal protection of persons incapable of defending their own interests, legal precedent has underlined the need to check whether support is available within the family and the health care system: the appointment of a support administrator may be considered unnecessary if safeguards are guaranteed by a family network attentive to the person's needs, and through targeted actions within the institutional social and healthcare context [21].

Moreover, relatives are often also involved in the cases of patients capable of autonomous decision-making, who "may still want other people to be consulted, or to be accompanied or represented by a "natural" support (a family member) or by a "designated" person, such as a person they trust" [22].This practice has been implemented by Law 219/2017, which grants significant decision-making power to third parties, on the request of the person concerned, with regard to both the communication of health information and to the expression of consent (note no. 7).

FROM EMERGENCY LEGISLATION TO THE OPPORTUNITY FOR TAKING AN APPROACH FREE OF FALSE PRECONCEPTIONS TO THE PROBLEM OF CONSENT OBTAINED FROM VULNERABLE PEOPLE

However, the provisions of the legislation run the risk of not streamlining the procedures intended to speed up the vaccination campaign [23], and of failing to cover circumstances as they occur in real life and the different situations regarding individual capacity, in which the clear distinction between autonomy and legal protection or legal representation is not necessarily appropriate.

The Associazione Italiana di Psicogeriatria (AIP) highlights the limitations of the distinction between people subject to Court protection and people not yet subject to any form of Court protection or legal representation, suggesting that it would be more reasonable to distinguish between "people capable of deciding for themselves and those unable to do so" and to differentiate, within the second category, between situations with legal representatives or trustees, situations with a well organised, cooperative and present family structure, and situations where the person is on their own, without relatives of the kind referred to in the legislation.

The document drawn up by the same Association [19] a few days after the issue of Decree-Law 1/2021, which contained operating instructions intended to provide guidelines on the practical level, stated that "A person is defined as naturally incapacitated if they are, in practice, suffering from an incapacity which reduces or limits their ability to understand and decide, even if their condition has not yet been formally recognised by a Court. For a clinical diagnosis, it is necessary to assess […] various cognitive domains, first and foremost the person's ability to state a choice, to understand information received, to appreciate the implications of a decision and to make rational use of information received. Without administration of the psychometric tests used in screening for dementia and without basing the relative clinical assessment on a numerical threshold, in the full awareness of the fact that there are many intermediate situations between capacity and natural incapacity which must be evaluated with great care and attention. If in doubt, always consulting the relevant family network, following the order of hierarchy confirmed by the Decree-Law" (fourth statement).

It also specified that "If the person to be vaccinated against COVID-19 is already the subject of legal protection measures, consent to be vaccinated must be given not only by the same person but also by the guardian and support administrator as required by Law 219/ 2017 (Art. 3)" (sixth statement) and that "If the person to be vaccinated against COVID-19 has already been legally incapacitated, consent to be vaccinated must be given by the same person and not by the curator, as required by Law 219/2017 (Art. 3), notwithstanding the erroneous instruction provided in Decree Law 1/2021" (seventh statement) [24].

After the enactment of Decree Law no. 1 of 5 january 2021, the Associazione autonoma aderente alla Società Italiana di Neurologia per le Demenze (SINdem), the Società Italiana di Medicina Generale e delle Cure Primarie (SIMG) and the Società Italiana di Neurologia (SIN) issued guidelines [25] on the subject of informed consent for COVID-19 vaccination of people with dementia, whether resident in nursing homes or at home. In particular, they provided the same guidance on the distinction between people with dementia considered capable of expressing a consent and people with dementia unable to do so: in fact the guidelines issued by the SINdem and SIMG together with the SIN envisage first and foremost the "signature of a person with dementia considered capable of issuing consent" (first statement) or the "signature of the legal representative of a person with dementia, if formally nominated with regard to health matters" (second statement). It is then specified that "In the case of a person with dementia incapable of giving consent, the physician shall consider the situation to be urgent and shall not allow for delay and shall proceed in compliance with Article 1(7) of Law 219/2017. The consent form will also be signed for acknowledgement, if possible, by a relative of the person with dementia or a support administrator who does not hold powers with regard to health procedures or necessary care". (third statement); "In the case of people with dementia who do not have a traceable living relative, the physician will proceed in accordance with Article 1(7) of Law 219/2017" (fourth statement) (note no. 8).

The situation created by the pandemic has highlighted the need to delineate ownership and decision-making criteria in care structures, whereas many patients in these facilities are in a situation of limited decision-making capacity due to disability. Consequently, the need arises to place alongside the person concerned legal protection figures that guarantee the making of choices in respect of the autonomy and dignity, in these situations where timely action is needed to protect the health of the patient.

Law No. 6 of 9 january 2004, establishing the Support Administration, provides that those responsible for health and social services, who are directly involved in the care and assistance of the person, are required to initiate procedures for requesting support administration, if they are aware of facts such as to make it appropriate to open the procedure.

The support administrator can perform "a very relevant guaranteed function, whose primary objective is respect for the self-determination of the person", being called to "to support the patient, even in the case of residents in socio-sanitary structures, with reference to their specific needs and to reconstruct their presumed wishes and desires" [26].

As pointed out by some authors [27], with particular reference to the current situation, as "certainly the pandemic is causing an emergency health crisis, but widely discussed is the qualification of vaccine treatment as an emergency intervention", whereas "if the vaccine treatment against COVID-19 were included in this hypothesis, the emergency legislation […] would be even superfluous", being able to intervene to ensure the necessary care, in accordance to art. 1 paragraph 7 of Law No. 219/2017 (note no. 9).

If "the requirement to assess the person's ability to express a valid informed consent reflects the need to strike a balance between the duty to "protect" the patient from potentially harmful choices on the one hand, and the need to respect his/ her individual choices on the other", the Recommendations for governance and clinical practice in the dementia sector underline that "another important issue to be emphasised is the dualism of autonomy and authenticity" since "if on the one hand autonomy presupposes a competent individual exercising his/ her right to self-determination, authenticity, on the other, is linked to the congruency between the person's values (beliefs, relationships, commitments) and his/ her decision, even if this decision is taken by a substitute" [28]. This trade-off is particularly complex in dementia, where the person may be incapable of self-determination but may still retain "ethically relevant capacities", such as the ability to state a preference, and some levels of decision-making. Moreover, "the ability to understand information and to process decision-making consent must not be understood as a 'all or nothing' phenomenon, but must be contextualized each time" [26].

The same Law 219/2017 establishes that "An underage or incompetent person has the right to the full consideration of their understanding and their decision-making capacities, in compliance with the rights under Article 1(1). They must receive information about choices concerning their health in a way appropriate to their capacities, to enable them to express their wishes", in order to guarantee respect for the rights even of people who are incapacitated.

As the AIP has also pointed out, one of the limitations of this law was the fact that it only referred to incompetent persons resident in nursing homes, with no guidance concerning incompetent individuals not institutionalised in facilities of this kind, such as people with psychogeriatric conditions cared for at home by a family or informal network.

With regard to people in this category in particular, in the view of the AIP it is important to assess the role of the primary care general practitioner, "who is often the physician who is caring for patients resident in nursing homes as well as those resident at home, especially with regard to the many incompetent people cared for at home by their families and informal networks", since not everyone suffering from dementia lives in a nursing home and "the medical director of the local healthcare service or their representative cannot be expected to undertake all the actions and checks required by the decree-law to arrive at a decision appropriate to the wishes of a person unknown to them".

The latest Decree-Law no. 44 of 1 April 2021 "Urgent measures to contain the COVID-19 epidemic, with regard to vaccination against SARS-CoV-2, justice and public employment selection procedures" Legislators have supplemented the legal provisions already examined with a reference to people in a state of natural incapacity who are not resident in nursing homes or similar facilities, assigning the medical director of the relevant local healthcare service or their representative to represent the person concerned with regard to their expressing consent for vaccination (note no. 10).

CONCLUSIONS

The exceptional circumstances that have forced legislators to deal quickly with a complex and long-neglected topic are an opportunity for taking an approach that is clear and free of false preconceptions to the problem of consent to be obtained from vulnerable, generally elderly, people.

In many settings, from home to hospital to nursing homes, the patient's involvement in the decision-making process, the role of the family, and the procedures for defining competence above and beyond diagnostic categories, continue to be left largely in the hands of the healthcare professionals or teams. The procedures chosen for obtaining consent to be vaccinated, together with the provisions of Law 22/12/2017 on the role of the trustee, open the way to operating procedures more appropriate to daily clinical practice on the ground.

Summary of the notes

1. Article 1-quinquies of Law no. 6 of 29 january 2021 (Conversion into law, with amendments, of Decree-Law no. 172 of 18 december 2020, containing urgent measures to deal with the health risks associated to the spread of the COVID-19 virus), published in the Italian Official Journal General Series no. 24 of 30 january 2021). The issue had already been addressed by Article 5 (Expression of consent to COVID-19 vaccination for incompetent persons resident in nursing homes) of Decree-Law no. 1 of 5 january 2021 (Further urgent measures to contain and manage the COVID-19 epidemic emergency), published in the Italian Official Journal, General series no. 3 of 5 january 2021.

2. With regard to "Target Categories", this the note specified that "since initially only a limited number of doses are available, in this first phase of the SARS-CoV-2/COVID-19 vaccination campaign the aim will be to maximise results by concentrating resources on the protection of the personnel dealing with the pandemic emergency and of the most vulnerable (social and healthcare workers and the staff and residents of nursing homes)". With regard to the "Informed Consent", it provided, as an annex, the documentation issued by the Working Group of the Observatory on Good Practices for Patient Safety (Age.Na.S. no. 2020/0007765 dated 23/12/2020): this document is to be signed by the person receiving/refusing the vaccine or their legal representative.

3. Therefore, the emergency legislation acknowledges a representational role - although only with regard to the expression of consent to COVID-19 vaccination, subject to verification via public medical documentation that the vaccine will provide the best safeguards for the nursing home resident's health – to the subjects indicated above, considering the roles of the person's trustee, curator or support administrator, this latter with no jurisdiction over health matters, as equivalent to that of the legal representative or guardian of a person with cognitive impairment, without making any distinction between legal incapacitation and forms of support administration with power to provide necessary care or with exclusive legal representation, and without issuing any specific provision stating whether proceedings are to be brought before the judge supervising a guardianship (hereinafter the "Court") to establish a support administration or to extend the powers of an existing support administrator to cover these circumstances. Law no. 219 of 22 december 2017, (Provisions covering informed consent and advance treatment directives) (Official Journal General Series no. 12 of 16 january 2018) states in Article 3(3) and 3(4) (Minors and incompetent persons) respectively, that "The informed consent of an interdected person as defined by Article 414 of the Italian Civil Code shall be expressed or refused by the guardian, after consulting the person concerned if possible, with the aim of protecting the person's physical and mental health and their life, with full respect for their dignity" and that "The informed consent of a legally incapacitated person is given by that same incapacitated person. If a support administrator whose powers include assistance (assistance administration), or exclusive representation (substitute administration) regarding health matters, has been appointed, informed consent is also expressed or refused by the support administrator, i.e., only by the latter, bearing in mind the wishes of the beneficiary, depending on their degree of capacity".

4. The provision of a procedure, which involves the relatives of the person in residential care, when known, in order to obtain information about the person's wishes and thus guide the decision accordingly, is envisaged for all subjects legally authorised to express consent to be vaccinated on the person's behalf. Therefore, it would appear to apply as well, also in the case of a support administrator who has been awarded decision-making powers about health matters in the form of exclusive legal representation of the beneficiary, to allay the risk of slowing down the vaccination procedure.

5. Moreover, the Law states that, "If the latter parties refuse consent, the medical director or chief medical officer of the facility where the person concerned is resident, or the medical director of the local health service or his delegate, may petition the Court under Article 3(5) of Law 219/2017 for authorisation to proceed with the vaccination notwithstanding said refusal" (Art. 1-quinquies(4)). Similarly, "In the event of refusal to have the vaccine administered or to express the relevant consent on the part of the medical director or chief medical officer, or the medical director of the local health service or his delegate, under the provisions of paragraph 5, the spouse, civil or live-in partner, and relatives up to the third degree, may apply to the Court […] for an order enforcing the administration of the vaccine".

6. After establishing, in Article 1, that "In compliance with the principles set forth in Articles 2, 13 and 32 of the Italian Constitution and in Articles 1, 2 and 3 of the Charter of Fundamental Rights of the European Union, this law safeguards people's right to life, health, dignity and self-determination […]", valorises the role of relatives (or a civil or live-in partner) by requiring their involvement in the treatment relationship, if the patient wishes, and by stating that they may be authorised by the patient to receive medical information and express consent on their behalf. If the patient withdraws from or refuses the medical treatment necessary for their survival, with the patient's consent the doctor shall also inform the relatives of the consequences of this decision and the possible alternatives, and within the joint planning of treatments, with the patient's consent their relatives or civil or live-in partner shall be properly informed regarding the possible evolution of the disease, the patient's realistic expectations in terms of quality of life, and the treatment and palliative care options available.

7. Article 1(3) (Informed Consent) of Law 219/2017 establishes that anyone "may totally or partially refuse to receive information or may designate relatives or another person of their choice to receive it, and to express consent on their behalf, if the patient so wishes".

8. On this point, Article 1(7) of Law 219/ 2017 establishes that "In emergency or urgent situations, the physician and the members of the health care team shall provide the necessary treatments, in accordance with the patient's wishes if their clinical condition and the circumstances enable these to be made clear".

9. The Authors (Fumagalli L. [27]) wonder if it might not have been more appropriate "simply refer to the existing legislation on informed consent and support measures in favours of fragility, introducing - rather - virtuous dynamics of bureaucratic simplification that can allow a rapid response of the Voluntary Jurisdiction, or, alternatively, to qualify – without any misunderstanding whatsoever – the vaccine treatment anti COVID-19 as a life-saving treatment of urgency, thus bringing the case back to institutes already precisely regulated".

10. In particular, Article 5(2-bis) (Expression of consent to SARS-CoV-2 vaccination for persons in conditions of natural incapacity) of Decree-Law 44/2021 supplements the legislation as follows: "When a person in a state of natural incapacity is not resident in a nursing home or similar facility, whatever it may be called, the functions of support administrator, for the purposes of expressing consent under paragraph 1, shall be performed by the medical director of the relevant local healthcare service or their representative".

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