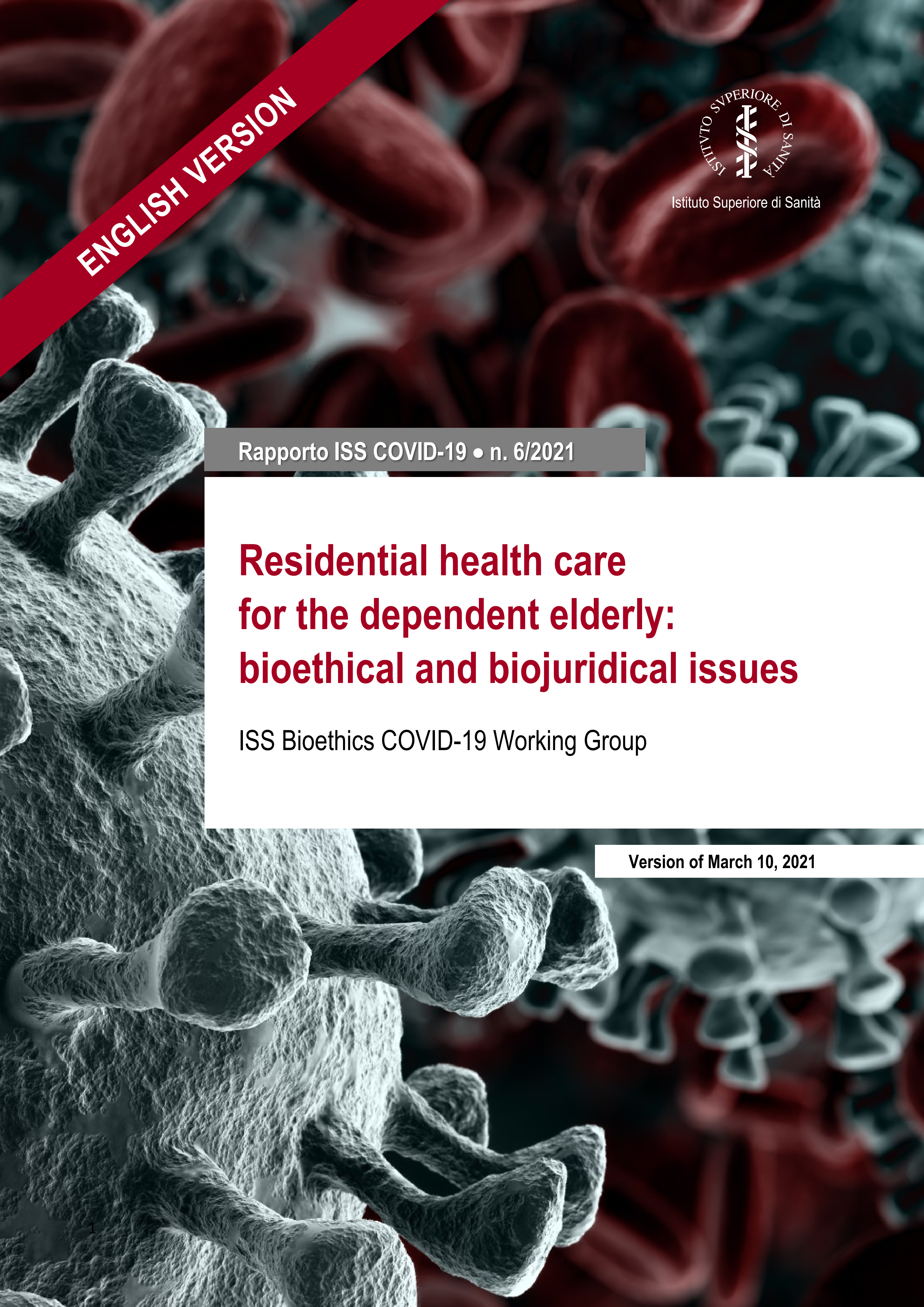

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Residential health care for the dependent elderly: bioethical and biojuridical issues

ISS Bioethics COVID-19 Working Group

Version of March 10, 2021

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ISS Bioethics COVID-19 Working Group

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The devastating events documented during the SARS-CoV-2 epidemic have resulted in a renewed focus on the issue of care of the elderly in need of long-term care. The health promotion and protection system of the aging population is a relevant issue for Italy and involves, at different levels, health authorities and institutions, professionals and society as a whole. This document, produced with the collaboration of the National Guarantor of the Rights of Persons Deprived of Liberty, proposes an ethical-legal reflection on the protection of residents in social-health structures, especially in emergency conditions. Any form of institutionalization, because of the total nature of care, may jeopardize the safeguarding of essential goods and the respect for the fundamental rights of the persons being cared for.

The original Italian version of ISS COVID-19 Reports are available from: **https://www.iss.it/rapporti-COVID-19**

The reports translated in English are available from: **https://www.iss.it/rapporti-iss-COVID-19-in-english**

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Preface

The Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy) is the technical and scientific body of the National Health Service; it is responsible for the promotion and protection of public health and carries out research, surveillance, regulation, control, prevention, communication, consultancy and training activities.

Since the beginning of the outbreak of SARS-CoV-2 in Italy, the ISS has played a crucial role in addressing the spread of the disease, and has been the national point of reference for data collection and analysis, health surveillance, definition of public health actions, biomedical research and many other activities related to the management of the emergency.

Thematic Working Groups dedicated to COVID-19 were set up, made up of experts both internal and external to the ISS, with the task of developing analyses, providing information and formulating proposals. The “COVID-19 Bioethics” Working Group covers several disciplinary areas: clinical medicine, epidemiology, public health, law, philosophy, palliative care, paediatrics, nursing science, as well as bioethics: the interdisciplinary nature of the Group makes it suitable for producing analyses and proposals, many of which have already been published in the series “ISS COVID-19 Reports” which are available on the ISS website.

Various issues dealt with in this report (the elderly, disability, assistance, rights, and others) have been addressed from different points of view also in other documents produced by the ISS COVID-19 Working Groups and published in the same series. This text, therefore, is in continuity with previous documents, integrating them with an analysis from a different perspective.

The text was drafted with the contribution of experts from the internal sections of the ISS and from outside institutions operating in the areas covered by the report: the Department of Cardiovascular, Endocrine Metabolic and Aging Diseases of the ISS; the National Centre for Disease Prevention and Health Promotion of the ISS; National Guarantor of the rights of persons persons detained or deprived of personal liberty.

The Committee for the Reform of the Welfare and Healthcare of the Elderly of the Ministry of Health also contributed to the paper. Cooperation with the Ministerial Committee, of which the ISS is a member, was possible thanks to His Exc. Mons. Vincenzo Paglia, President of the Committee itself and of the Pontifical Academy for Life: special thanks are due to the two bodies, their President and the Secretary of the Committee, Prof. Leonardo Palombi.

Carlo Petrini, Luciana Riva

Introduction

The tragic events that occurred during the SARS-CoV-2 epidemic in Italian facilities providing medical and social care have called renewed attention to the issue of care models for the elderly in need of long-term care. The epidemic has shown the structural fragility of many sectors of the Italian health system and, on a global level, the residences that have the function of protecting and caring for vulnerable older people actually became hotbeds of the epidemic and, in some cases, places where people were abandoned. The discussion on the characteristics of nursing homes for the elderly, considering the needs of a progressively ageing population, comprises several interrelated levels. There is the political and social level, the clinical level that concerns the quality and appropriateness of the healthcare services provided by the National Health Service and the ethical-legal level that refers to the pursuit of wellbeing and the recognition and protection of rights. Based on their historic and cultural characteristics, the various European countries have chosen and experimented with different solutions in taking care of the elderly, sometimes abandoning institutionalization in favour of home-based models conceived to be "open" and closely intertwined with the community, since for many of the residents these homes are their world for the remaining months or years of their lives. Regardless of which solution is preferable, the objectives of protecting the rights and improving the quality of life of dependent elderly people constitute a major issue for public health. The responsibility of governing bodies appears to be decisive at every level of governance, especially with regard to ensuring adequate and homogeneous conditions of care across the national territory.

Through specific working groups set up during the SARS-CoV-2 epidemic, the ISS has produced a series of operational documents on the subject of long-term care facilities (RSA) to help tackle the main critical issues that emerged at the local level. These include, in particular, a report on the prevention and control of SARS-CoV-2 infection in residential and health care facilities (1) and a report on appropriate support for people with dementia (2). **In addition, the COVID-19 Bioethics working group has chosen to focus on the bioethical and biolegal aspects of care for dependent and disabled people and to formulate some ethical-welfare considerations on specific issues, with the aim of encouraging, even in emergency conditions, uniform practices where the focus is on the individual and his/her needs. The COVID-19 epidemic has shown that it is the vulnerable elderly who are most affected by the lack of material and organizational resources during a crisis. Therefore, in the future, general preparation plans must also include adequate tools and strategies to guarantee the protection of all individuals, including those in a condition of non-self-sufficiency, albeit with a possible temporary compression and limitation of rights generated by the circumstances of the emergency.**

There are different categories of dependent residents: the elderly, people with disabilities (both physical and mental), and people affected by terminal illnesses (3). For the purposes of this Report reference is made specifically to elderly people, with the awareness that according to the official statistics, even disabled individuals above the age of 65 fall within the classification of elderly people. As is specified in the document, however, some general considerations also refer to other categories of dependent individuals who live in social-health care facilities.

The monitoring of residential facilities for the disabled or the elderly through unannounced visits falls within the remit of the National Guarantor of the rights of persons persons detained or deprived of personal liberty. These facilities are part of the fourth operational area "Deprivation of liberty in health, social-health and welfare facilities" which are visited by the Authority as part of its supervisory obligations and in the exercise of the powers entrusted to the Authority by law (the other three areas are criminal detention, detention and / or arrest of individuals by the Police Forces and the detention, for the purpose of repatriation, of foreign individuals present in the Country without papers) since these are situations where the limitation of fundamental freedoms may occur .

These facilities have been placed within the remit of the Authority, in consideration of the fact that for the individuals living in such facilities, *de facto* situations are likely to occur where the exercise of their rights and the implementation of their self-determination may be impossible or limited.

In general, every residential facility should enhance the residual capacities of its residents and their right of choice, through personalized interventions that promote autonomy within the bounds of the residents' physical and mental abilities. The risk of residents being exposed to violations of the integrity of their rights should not be underestimated, especially in the cases where institutionalization and isolation are the result of a *de facto* situation, albeit after voluntary entry into a facility, as a consequence of the loss of capacity for self-determination or the absence of family support, and when the network of community services is not very effective.

The points of reflection proposed in this document cannot in and of themselves represent an exhaustive response to the complexity of the delivery of care to a population characterized by a major demographic revolution. As has been pointed out, on a global level there is a strong "urgency for renewed attention to the elderly". Within the framework of the activities of the Committee on the reform of health and social-health care for the elderly set up by the Ministry of Health, a wide-ranging synergy of all the institutions involved is required in rethinking entirely how society is to cater to the needs of the elderly (4).

1. Description and aims of the report

This document has been drawn up within the cultural context of a debate which is taking place at different levels in our Country on the reform of the welfare system for dependent individuals and patients requiring long-term care. A crucial aspect of the issue, forcibly brought to the fore by the events of the pandemic, is the undeniable need to build adequate monitoring systems and indicators for assessing the quality of social-health care facilities.

Setting aside the analysis of the multiple aspects of a very complex and highly heterogeneous situation at the local level, the authors of this paper propose an ethical-legal reflection on the protection of people living in health care facilities, especially from the standpoint of fundamental rights. The basic assumption is that any form of institutionalization, where all the aspects of an individual's life are managed by the facility, may put at risk both the adequate safeguarding of essential goods and respect for the fundamental rights of the person who is institutionalized. Such violations may be due to many causes and may sometimes be very difficult to detect and measure.

In the first part of this report, after describing the national health care system for dependent elderly people, their rights will be examined with reference to the Italian legal system. The situation of dependency of older people will also be described and analysed from a bioethical point of view, in light of the principles and priorities outlined in 2006 by the National Bioethics Committee (5).

In the second part of the report, some clinical bioethics issues related to the context of medical and nursing care in residential health care facilities will be addressed. Indeed, as has been pointed out by some authors (6), in such contexts certain ethical problems may prove to be more difficult to deal with and in addition, studies and literature of reference on the matter are still rather scarce at the present time.

Both "daily ethical issues" such as respect for autonomy, informed consent, the use of physical and pharmacological restraint, pain management, communication with family members, etc., and "major ethical issues" such as end-of-life decisions, are very important elements in the general framework of the protection of the wellbeing and rights of the residents of healthcare facilities. Some indications are provided here that are meant to make sure that the individual is always at the centre of the care process and that the right attention is paid to the enhancement of his/her autonomy (or residual autonomy) and independence. A Charter of the rights of the elderly is therefore proposed with special reference to the work carried out at European level by the AGE Platform Europe, which has led to the definition of the "European Charter of the rights and responsibilities of older people in need of long-term care and assistance" (7).

A specific paragraph will be dedicated to the analysis of the main critical issues that long-term care facilities have had to face in the context of the SARS-CoV-2 pandemic, underlining how the protection of rights and the care of people must be guaranteed in a manner that is as transparent as possible in these places where people live also during a state of emergency.

2. Definitions: elderly adults, oldest-old adult, fragile person, dependent elderly

As life expectancy becomes longer the less relevant it is in the medical field to establish a threshold beyond which we should talk about **old age**. However, a demographic and nosographic classification of the population is still necessary due to the multiple implications of efforts aimed at improving the quality and appropriateness of care in the different care settings. The perception of old age, on the other hand, often appears to be linked to the social context in which one lives and to personal history, factors that may anticipate or postpone the age at which one becomes 'old'. The definition of old age must therefore be based on a dynamic concept, and we must take into account an irrefutable observation, namely that, however much biomedicine can slow down aging and postpone the end of life, there is, in any case, a physiological limit to physical and mental performance.

According to the definitions officially adopted to date, a person who has reached the age of 65 is considered to be an elderly adult. In Western countries, the average extension of life expectancy (Italy 85.2 years for women and 80.8 for men) (8) has led to an update of the concept of old age raising it to 75 years, and suggests that the elderly be broken down into individuals belonging respectively to the third age (good health conditions, social inclusion, availability of resources) and the fourth age (dependence on others, decrepitude). Another classification is more analytical and considers four subgroups: youngest-old (64-74 years), middle-old (75-84 years), oldest-old (85-99 years) and centenarians.

A similar line of reasoning in the social and scientific health care field is proposed for the so-called **oldest-old**. In fact, the overwhelming increase in the number of adults over the age of 85 in all industrialized countries demands that the phenomenon be quantitatively evaluated to consider its impact on welfare systems and to understand the problems that these adults face in everyday life. Old age is strongly marked by the emergence of various kinds of limitations that are responsible for radical changes in every-day life: worsening of physical health, reduction of vital energy, contraction of social life and getting closer to the end of one's life. The onset of deafness, the appreciable loss of vision and longer reaction times, all combine to reduce the physical and social space of older people and to fuel the feeling of being distanced from the world which is often experienced as inhospitable and hostile even within the family.

Fragility is a physiological state of greater vulnerability associated with aging and is due to the body's reduced ability to cope with stressful situations such as acute diseases. The fragility of old people is configured as a syndrome with a high risk of unfavourable clinical outcomes that constitute a significant deterioration in the quality of life and are leading factors in bringing about disability and adverse events. Fragility is a complex condition that goes beyond the concepts of senescence and disease. The definition of fragility applies to those individuals who are affected by multiple chronic disorders and with more or less disabling handicaps. These conditions may be complicated by socio-economic problems which as a whole, especially in the case of the elderly, involve a high risk of rapid deterioration of psychophysical well-being and of functional conditions, accompanied by the consumption of huge amounts of resources to cope with such conditions. The assessment of fragility is an activity of prevention and of promotion of quality of life. The identification of fragile individuals was proposed by Kenneth Rockwood through the Frailty Index, a score based on the idea that fragility is a state of chaotic disorganization of physiological systems which can be estimated by evaluating functional status, the presence of diseases, physical and cognitive impairments, psychosocial risk factors and geriatric syndromes. The identification of the fragile population is essential for establishing the priorities of public health policy where people at greatest risk need to be identified (e.g. vaccinations).

It is important to emphasize that the difficulties encountered in relating to fragile old people does not justify, in any way, compromising or discounting the ethical value of the care services that they require, nor failure to protect their rights. Entering data on fragility into a computer system means storing a wealth of information that is useful from an epidemiological and preventive point of view, especially in the event of an epidemic.

However, fragility should not be considered as a dimension of the human being that is explained exclusively from a clinical point of view; on the contrary, it is also strongly influenced by economic and social variables. Loneliness and social isolation are conditions that, especially in older people, may undermine their capacity for self-management and self-defence and may affect their capacity to maintain their functional skills, cognitive status and the ability to seek medical care. In the general approach to the system for protecting the rights of older people, these aspects must therefore be carefully considered. Social and relational needs are essential needs for the people living in residential facilities which must always open and encourage relational exchanges with the surrounding community.

The distinction between a self-sufficient and a **dependent** older person is of great importance for the organization of social and health care which should always be tailored to the needs of the individual. In general, group homes, hotel homes, assisted living facilities and day care centres are more suitable for self-sufficient elderly people, while long-term care facilities and nursing homes are more suitable for dependent elderly people (9). However, people with dementia live in many retirement homes today, although these are not the places where appropriate care can be provided to them. Another important fact concerns the presence of a conspicuous number of self-sufficient people living in long-term care facilities; these are elderly people whose fragility is predominantly of a social, relational or economic nature and for whom it would be reasonable and desirable to propose home-based solutions. This, together with other general findings, that are also presented in this document, clearly suggests that the system that governs and modulates care for providing assistance to dependent people requires thorough rethinking at the public health level.

There is no official estimate of how many dependent adults there are in Italy today. Now, since the loss of self-sufficiency is a dynamic process which occurs with the onset or worsening of a variety of organic and functional disorders, it should be tackled at first by seeking to respond to the new needs of the person in the place where he/she resides, bearing in mind as well that institutionalization, as a result of which ties with one's home, family and friends are severed, constitutes an important risk factor which hastens the general decay of the elderly. Furthermore, it is of fundamental importance to promote the recovery of autonomy and self-sufficiency, where possible.

It is not a simple task, from a conceptual standpoint, to define the characteristics of dependency of an elderly person. There are no doubts that the inability to take care of oneself independently and the need for coaching in daily activities are effective indicators of dependency. The definition of non-self-sufficiency identifies people with physical, psychic, sensory or confirmed relational disability on the basis of the criteria laid down in the *International Classification of Functioning Disability and Health-ICF* of the World Health Organization (WHO) and on the basis of the multidimensional assessment of functional and social conditions.

Our legal system provides for the payment of an allowance for conditions of dependency once such conditions have been ascertained. The assessment is made by a number of interdisciplinary units belonging to the social-health services that comprise such figures as medical specialists in the clinical disciplines involved in the disability being examined, health personnel from the nursing and rehabilitation area, and social workers designated by the municipalities, as well as the general practitioner of the person being assessed. Upon completion of the assessment, an Individualized Care Plan (PAI) is drawn up which is the document that describes the clinical condition of the patient.

The characteristics on the basis of which the legislator declares that an individual is not self-sufficient are the person’s inability to independently provide for housekeeping, shopping for groceries, preparing meals, providing personal-care and carrying out the functions of daily life (washing, dressing, eating, going to the toilet, moving around, going out) and the person’s inability to maintain external relationships, especially in the presence of mobility problems and clinical instability. In addition to these functions there is also the loss of cognitive skills arising from the deterioration or loss of intellectual faculties (memory, space-time orientation, reasoning).

3. Organization of the system catering to the needs of elderly people in italy: social context and regulatory framework

In Italy, the current network of services that cater to the needs of the elderly dates back to the early Nineties of last century, that started with the implementation of the “Project for the protection of the health of the elderly 1991-1995 (POA)” and subsequent implementation guidelines. The POA envisaged the establishment of the geriatric assessment unit with the function of providing care to the elderly through the drafting of a comprehensive personalized treatment plan.

For dependent people who need long-term care, rehabilitation and functional maintenance treatments and who do not have the possibility of being taken care of at home, the National Health System guarantees the provision of care in non-hospital residential and semi-residential facilities (Article 29 and Article 30 of the Decree of the President of the Council of Ministers-DPCM of 12 January 2017), designed to provide different levels of care to patients who are frequently affected by complex diseases and, in some cases, need support for their vital functions (respirator, artificial nutrition, etc.). These services are regulated by the Regions and local Bodies which, also on the basis of ministerial guidelines, plan the local network of care delivery services including the provision of home care (see in particular Law 178/2020 which, in Article 1 (406), amends Legislative Decree 502/1992). There is considerable regional variability as regards the classification and names of the individual facilities providing care, ranging from long-term care facilities, to retirement homes, nursing homes, institutes of geriatric rehabilitation, long-term rehabilitation institutions, etc. so much so that, according to the individual region, we can speak of long-term care facilities, nursing homes, assisted living facilities, protected residences, geriatric rehabilitation institutes, long-term rehabilitation facilities, etc. which may have even different meanings from one Region to another.

In Italy, approximately 21 elderly people per 1,000 live in a social-health care facility and approximately 210,000 are not self-sufficient (16 per 1,000 elderly residents). The residential care facilities for the elderly that host dependent people are currently 7,829 (10). The population living in health care facilities is increasingly made up of very elderly and clinically fragile people, the vast majority of whom have some type of cognitive impairment that affects their ability to participate fully in making decisions about their health. A survey conducted by the ISS in the 2015-2019 period on a sample of 330 long-term care facilities revealed that 26% of their residents suffered from dementia and it was also pointed out that the diagnosis of dementia is frequently underestimated in residential facilities for the elderly (11).

With reference to the services provided in these facilities, there are currently no integrated quality assessment systems at national level, although many Regions have started trials at the local level for the implementation of indicators as a monitoring and management tool. At ministerial level, an instrument is being used, the FAR (Information on healthcare homes for the elderly) (12), to gather information on the services provided by the institutions for the elderly.

Defining the elements that indicate a good quality of life in health care facilities and the appropriate measurement indicators to make the assessment is a complex issue that goes beyond the scope of this report. However, it is worth pointing out that the management processes of these data and the possibility of having access to such data, together with systems for sharing and monitoring the data, are an essential prerogative of public health management, since each health care facility must always be configured as an open place, integrated with the local community and in constant dialogue with the institutions, and should never be inaccessible or impermeable and surrounded by physical or symbolic walls of indifference and inattention.

It is also important to emphasize that, at the time of the drafting of this analysis, the organizational system of health care as a whole is articulated in a multidisciplinary and multiprofessional way and includes the complementary activities of various professional profiles: doctors (with single or multidisciplinary specialties), nursing staff and social workers. Considering that all the different professional profiles are indispensable, team work is absolutely necessary in healthcare to make the care delivery system efficient and functional. When it comes to autonomy, the latter cannot be considered as an absolute element, synonymous with independence, but is part of an integrated organization where different professional skills coexist with specific areas of action and autonomy and with related responsibilities.

4. Protection of the health of the elderly in residential social-health care facilities

Some ethical-legal issues that arise in the context of homes for dependent people can be extremely difficult to address in comparison, for example, to the hospital context where they are more easily recognized and studied. Doctors and health care staff come up against a multitude of problems in providing care to the elderly in residential homes and some of these problems can become true ethical dilemmas at times due to the conflict between the assets at stake and the principles of reference.

As has been highlighted, the most difficult balance to strike is the balance between respecting the autonomy (or residual autonomy) of the patient, on the one hand, and the duty of the healthcare staff to protect the patient, on the other (13, 14). In fact, all the residents of healthcare facilities need assistance in varying degrees and their right to act autonomously is balanced against the responsibility of the healthcare staff to protect them against possible risks. Many residents of healthcare facilities are limited in their ability to make personal and medical decisions due to cognitive impairment or communication difficulties. However, their limited decision-making capacity does not necessarily mean that they are completely unable to make decisions or that they should not be involved and consulted in decisions concerning their health and their daily life. There is no denying that people who find themselves in these conditions are defined as belonging to one of the ‘special vulnerability’ groups mentioned in Article 8 of the UNESCO Bioethics and Human Rights Declaration, adopted on October 19, 2005: “Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected” (Article 8, paragraph 2) (15).

Healthcare should recognize that dependent elderly individuals have a restricted possibility of choice and less control over their life and privacy and that the transition from a family environment to a completely extraneous setting confirms and adds a new dimension to their loss of autonomy and self-determination. Most decisions in the context of health care facilities are taken by someone other than the resident / patient. Healthcare professionals not only prescribe treatment and therapies, but also recreational activities, diet and they make decisions also about other aspects of daily life. Therefore “targeted efforts are needed to help residents feel more in control of their lives, through, for example, adequate emotional support, effective counselling, adequate information, an optimal treatment regimen, and opportunities for involving their family and friends” (13).

In this regard, it should be noted that the action of the National Authority – being the National Prevention Mechanism (NPM) [1] – in its supervisory obligations and in the exercise of the powers entrusted to it by law[2] within the area of competence concerning health and the monitoring of facilities for elderly people or people with disabilities, takes the concrete form of safeguarding the values contained in Article 3 of the UN Convention on the Rights of Individuals with Disabilities[3] (16). Such values include: respect for inherent dignity, individual autonomy, including the freedom to make one’s own choices, and the independence of persons (17). This supervision appears necessary in order to avoid *de facto* situations where people find it impossible to directly exercise their rights and self-determination.

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[1] The Optional Protocol to the UN Convention against Torture and other Cruel, Inhuman or Degrading Treatment or Punishment (OPCAT) ratified by Italy, Law no 195 of 9 November 2012 defines the National Authority as a national prevention mechanism (NPM).

[2] *See* Law Decree no. 146 of 23 December 2013 converted into Law no. 10 of 21 February 2014 and Law Decree no. 130 of 21 October 2020.

[3] With Law no. 18 of 3 March 2009, Parliament authorized the ratification of the United Nations Convention on the Rights of Individuals with Disabilities and its Optional Protocol signed by Italy on 30 March 2007.

However, the introduction of an oversight and monitoring body is not in and of itself sufficient to prevent possible situations where the dignity of the person is not respected, and it is for this reason that the National Authority is committed to promoting training and collaboration initiatives with numerous Italian and foreign Institutions, Research Bodies, Universities and Associations (18).

In this sense, the collaboration with the ISS is also part of the initiatives launched by the National Authority in support of its preventive action aimed at reducing possible criticalities through the production of recommendations for the various Administrations, in the form of standards to be achieved. This is necessary also to avoid that Italy be condemned by international human rights protection bodies.

4.1. Elder abuse

Elder abuse is defined by the WHO as a single or repeated act, or a lack of appropriate action, occurring within any relationship where there is an expectation of trust, which causes harm or distress to an older person and constitutes a public health problem.

Worldwide, it is believed that the available data on the occurrence of elder abuse is underestimated, also considering that violent conduct in these settings is often subtle and difficult to recognize and report. The phenomenon is not yet fully defined neither in terms of the number of victims but also in terms of the effectiveness of prevention and control actions.

In Italy, data and information on the prevalence and characteristics of elder abuse are very limited and there is no specific legal framework nor are there enforcement strategies. Some articles of the Criminal Code refer to the wider context of violence against disadvantaged groups, and the general services providing support which, however, are not specifically targeted to this group of people, are mainly managed at the local level. More empirical research would be useful for disseminating information and promoting best practices. It could also produce a database on which to build public education activities and the training of professionals on the issues of prevention, detection and treatment of abusive practices (19).

In the context of institutionalization, neglect on the part of employees and the lack of adequate hygienic conditions are the most common forms of reported abuse, discovered with the help of police inspections or authorized video recordings for investigation purposes. Even the arbitrary or abusive use of physical constraint is gradually emerging and becoming an area of concern. Without prejudice to the inadmissibility of undue generalization, available data does suggest that the phenomenon of elder abuse is widespread, also in Italy.

More in-depth research will provide accurate data to increase general awareness of the phenomenon – which is currently limited – both of public opinion and of the professionals in charge. Some authors have suggested that it would be necessary to implement a legal framework and a dedicated protocol to address and prevent the phenomenon, as well as *ad hoc* support services for the victims (20).

In the United States, the “Nursing Home Reform Act (NHRA)” of 1987 provided some guidelines for regulating care for the elderly. The law was passed with the aim of strengthening the protection of the rights of residents of retirement homes. In 1986, Congress asked the Institute of Medicine (now the National Academy of Medicine) to analyse the state of nursing homes in the United States. Congress suspected that many of these facilities did not provide care of sufficient quality for the elderly. The study showed that many residents were not receiving adequate care and that neglect and abuse were widespread. After this analysis, the Institute of Medicine recommended the intervention of the authority and the initiation of reforms. Congress used the recommendations provided by the Institute to draft the nursing home reform act. The NHRA was approved in 1987 as part of the “Omnibus Budget Reconciliation Act”. A Residents’ Bill of Rights is also included in the NHRA: this part of the law formally defines the fundamental rights of the residents of nursing homes. The NHRA requires that nursing homes protect and promote the rights of all their residents.

5. Guidance on care and ethical aspects

5.1. Social and healthcare needs: multidimensional assessment and tailored care plans

The Multi Dimensional Geriatric Assessment (MGA) is a useful and indispensable procedure for identifying the needs of each patient and of his/her family and for defining a tailored care plan. It includes clinical, psychic, social-health, nutritional and possibly spiritual dimensions. For each dimension there are several evaluation tools, both quantitative and qualitative, both objective and subjective, which explore different symptomatic domains. In the area of residential care, the NHS envisages extensive treatment, functional recovery and long-term care to dependent individuals, after a MultiDimensional Assessment (Article 30, DPCM 12 January 2017).

The Multidimensional Geriatric Assessment of the elderly is an activity that requires adequate time and organization and through which elderly patients who are particularly fragile or at risk of becoming fragile can be identified among the elderly population. The problems of each individual who is assessed are identified, described and explained: functional capacities are identified, the need for care services is established, and a management plan is set up in which the different interventions are tailored to the real needs and problems of the patient through the preparation of an individualized healthcare intervention plan. The minimum network of healthcare services that guarantees continuous assistance is also described.

The heterogeneity of the tools adopted by the individual regions, which measure different areas with highly variable and often not validated methodologies, is a major weak point. The MGA explores the different factors that contribute to creating conditions of fragility through the juxtaposition of different measuring instruments which, although validated, are created in most cases for other purposes or for general applications and which, above all, never constitute a comprehensive and internally consistent system.

Furthermore, also in the context of Integrated Home Care, there is a lack of tools for assessing the environmental factor which is mostly explored through the stress of caregivers and the perception of the quality of life, while information is not collected about the more general context of resources and policies that may aggravate or alleviate the fragility of older people.

The Tailored Care Plan (TCP) is one of the minimum organizational requirements that long-term care facilities need to have and is provided for in the health regulations of the various Regions as indicated by the Presidential Decree of 14 January 1997. It is a document that summarizes the conditions of the dependent person and defines a tailored approach aimed at promoting dignified living, health and well-being conditions. Since the MGA can identify a wide variety of clinical, social, functional, cognitive, and environmental deficits and problems, the tailored care plan represents a very complex and multidisciplinary document, precisely because the areas in which action is necessary are a great many. The definition of the TCP is based on the involvement of various professionals who contribute to the treatment process (nurses, doctors, psychologists, social workers, healthcare workers, sometimes the nutritionist), and sets out the interventions to be carried out for each individual patient.

The TCP is therefore a summary document that is applied for a pre-established period and subjected to periodical checks to monitor the progress of the resident's state of well-being and his/her comprehensive care plan with respect to the objectives. During these checks, the plan can be reconfirmed or revised based on the results obtained and on the dynamic evolution of the patient's general conditions, in order to achieve as much as possible personalized assistance tailored to the actual needs of the person receiving care.

5.2. Decision-making autonomy, informed consent and advance medical directives

Informed consent pertains to the doctor-patient relationship and is a prerequisite for health care activities[4]. It is the enactment of the principle of patient autonomy and represents the voluntary and conscious adherence to the proposed medical act. It must take place within a balanced relationship between the two figures in the relationship of care, where even the autonomy of the doctor retains its value and does not turn into heteronomy or into a sort of paternalism towards the patient[5]. Compliance with informed consent is a legal requirement enshrined in Article 32 of the Constitution of the Italian Republic, which states that "no one can be obliged to undergo any specific health treatment except under the provisions of the law". This responds to the fundamental principle of the inviolability of personal freedom, affirmed in Articles 2 and 13 of the Constitution.

The need for informed consent is reaffirmed also by Law no. 833 of 23 December 1978 (21), establishing the NHS, in Article 33 ("Medical examinations and treatments are normally voluntary. In the cases referred to in this Law and in those expressly provided for by the laws of the State, compulsory health examinations and treatments may be ordered by the health authority, in pursuance of Article 32 of the Constitution, respecting the dignity of the person and his/her civil and political rights, including, as far as possible, the right to freely choose the doctor and the place of treatment ").

Law no 219 of 22 December 2017 (22) sets out the "Rules on informed consent and advance directives regarding medical treatment". Currently this law is the main national regulation of reference for informed consent in healthcare workup and treatment. For the purposes of a brief overview on the discipline of informed consent, it is worthwhile summarizing the parts most directly related to the subject matter of this report.

Article 1 ("Informed consent") states that:

- No medical treatment can be started or continued without the free and informed consent of the person concerned, except in cases expressly provided for by the legislation.
- A relationship of care and trust between patient and doctor, based on informed consent, is to be promoted and valued.
- Everyone has the right to know what their health conditions are and to be informed in a thorough, updated and understandable way about the diagnosis, prognosis, benefits and risks of diagnostic tests and health treatments, and to receive indications about possible alternatives, and about the consequences entailed in refusing medical treatment and diagnostic assessment.
- Patients have the right to refuse any diagnostic assessment, as well as to revoke, at any time, the consent given previously, even when the revocation involves the interruption of treatment, including artificial nutrition and hydration.
- The doctor is required to respect the patient's will to refuse medical treatment or to renounce it and as a result of this obligation he/she is exempt from any civil or criminal liability.

Article 2 ("Pain therapy, prohibition of unreasonable obstinacy in care and dignity in the final phase of life") states that:

- Appropriate pain therapy must always be provided.

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[4] Article 35 Code of Medical Ethics (CDM), Informed Consent and Dissent.

[5] *See* Andrea Nicolussi, in Professione e quadri di riferimento legislativo, Padova, 7 aprile 2019.

- In the presence of suffering that does not respond to medical treatment, the doctor may resort to continuous deep palliative sedation in association with pain therapy, with the patient's consent.

With regard to incompetent individuals Article 3 ("Minors and incompetent individuals"), states that:

- In the case of interdicted/legally restrained persons, consent shall be expressed or refused by the guardian, after hearing the interdicted person, where possible; in the case of an incapacitated person, consent shall be expressed or refused by the incapacitated person him/herself and by the curator; in the event that a support administrator has been appointed whose task involves providing assistance or exclusive representation in health matters, informed consent shall also be expressed or refused by the support administrator or only by the latter, taking into account the will of the beneficiary.
- In the absence of advance medical directions, if the legal representative of the interdicted or incapacitated person or the support administrator refuses the proposed treatments, thus going against the opinion of the doctor who deems them to be appropriate and necessary, the decision shall be left to the judge supervising guardianship cases.

Article 4 ("Advance medical directives") states that:

- The "Advance medical directive" is a legal document in which a person of age and competent leaves instructions, in case of being incapable in a possible future of making his/her wishes known, concerning beliefs and preferences regarding health care treatment, as well as consent or refusal with respect to diagnostic or therapeutic choices and individual health treatments, including artificial nutrition and hydration.
- The writer of the advance medical directive can designate another person to make healthcare decisions and represent him/her in the interactions with the doctor and with the healthcare facilities.
- The doctor is required to comply with the advance medical directive, which may be disregarded, in whole or in part, by the doctor himself, in agreement with the patient's representative, if the contents appear to be clearly incongruous or do not correspond to the current clinical condition of the patient or if there were no therapies at the time when the directive was written but now there are concrete possibilities that the patient's living conditions can be improved.
- In the event of a conflict between the patient's representative and the doctor, the judge supervising cases concerning guardianship shall decide.
- The advance medical directive can be expressed in a video recording or through devices that enable people with disabilities to communicate.

Article 5 ("Shared planning of care"). With regard to the evolution of the consequences of a chronic and disabling disease or a progressive disease with a poor prognosis, Article 5 provides for and regulates the possibility of defining and stating in writing a treatment plan drawn up jointly by the patient with the doctor that the doctor is required to comply with if the patient finds him/herself in the condition of not being able to express his/her consent or in a condition of incompetence.

From an ethical point of view, Law no 219 of 22 December 2017 has obtained broad consensus with regard to the general discipline of informed consent, the attribution of legal value to advance medical directives, the recognition of the importance of communication between patient and healthcare professionals, the shared planning of care and the stigmatization of disproportionate therapeutic interventions. Other aspects of the legislation, on the other hand, have sparked significant discussions, such as those concerning the suspension of clinically assisted nutrition and hydration, the binding value attributed to advance medical directives and failure to provide legal space for conscientious objection by the healthcare personnel (23). The analysis of this debate, however, is beyond the scope of this report.

In the “Code of medical practice” (24), the information and the time dedicated to the patient are of fundamental importance in the relationship of care (as stated in Article 20 the time dedicated to communication is part of the treatment), and the duties of the doctor towards fragile individuals are also of fundamental importance (Article 32). The sections dedicated to “Information, communication, consent and dissent”, contain elements that were later transposed into Law 219/2017 regarding advance medical directives and care provided to patients with a poor prognosis or with irreversible impairment of their state of consciousness. In particular[6], the essential importance of acquiring consent / dissent is confirmed and considered to be a medical act that cannot be delegated and for which the doctor has direct responsibility. The doctor must obtain the patient’s consent / dissent in an objective manner and will preserve it adequately with the means available and with “documentary effectiveness”.

Both the legal and the professional regulations, therefore, defend the importance of the patient’s autonomy, without admitting exceptions associated with his conditions and they reject not only any paternalistic attitude by the healthcare staff, but also any possibility of abuse or excesses towards fragile patients.

Great importance is attached to the concepts of caring (care pact) and advocacy (protection of rights and values) in the relationship between nurse / healthcare worker and the patient, because they are considered to be critical for establishing a relationship of trust between people needing care and assistance and those who provide the care and assistance.

With regard to the multiprofessional relationship and the specific competences, roles and responsibilities of the staff, the Professional Code of the Nursing Professions[7] outlines the importance of the nursing staff who, in the context of the team relationship, does not have a direct role in giving information on the state of health and on the clinical evolution of the patient - prerogatives that belong exclusively to the doctor - but participates in the communication process, interacting effectively in order to make clear the doctor’s communication with the patient.

5.3. Use of restraint

Restraint is a non-therapeutic act that makes use of manual, chemical, physical or environmental means applied directly to the individual or to their surrounding space to limit their movements.

Manual restraint is obtained by direct intervention by the healthcare staff, in order to manually “block” the person and overcome resistance.

Physical restraint is achieved by applying devices to the person to limit or obstruct his/her freedom of movement. The means of restraint can be applied by means of the bed or chair, on body segments or by means of devices that force the patient to remain in a given posture.

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[6] Article 35 (“Informed Consent and Dissent”) of the Italian Code of Medical Ethics (CDM) states that: “Obtaining consent or dissent is an act of specific and exclusive competence of the doctor, which cannot be delegated. The doctor shall not undertake nor shall he continue a diagnostic procedure and / or therapeutic intervention without the prior acquisition of informed consent or in the presence of informed dissent. The doctor shall obtain, in writing and signed, or with other methods of equal documentary effectiveness, the consent or dissent of the patient, in the cases provided for by the law and by the Code and in those where the mortality risk is high or where outcomes may heavily affect the patient’s psycho-physical integrity. The doctor shall take into due account the opinions expressed by a minor in all the decisions concerning his/her health.

[7] Article 15 about information on the state of health, specifies: “The Nurse shall make sure that the person concerned or the person indicated by the latter as a reference, receives accurate, complete and timely information on his state of health, shared with the care team, in full respect of his needs and in a culturally appropriate manner. The Nurse shall provide the information falling within his/her remit and shall not replace any other professional figure”.

Chemical restraint (pharmacological) is achieved through the administration of drugs, in some cases even forcibly, that modify behavior, such as psychotropic drugs.

Environmental restraint is achieved through changes made to the environment in which the person lives in order to control or limit their movements.

In specific contexts, mechanical restraint can also be achieved by using medical devices, and thus becomes part of a therapeutic activity (some examples are placing a plaster cast device in orthopaedics or immobilizing a trauma patient on a stretcher). The action of pharmacological restraint, on the other hand, is difficult to define clearly with respect to the general category of drug sedation treatment. The exhaustive analysis of this issue on which there is a debate involving professional ethics and the law is beyond the scope of this work; however, it is important to point out that restraining patients in a healthcare context is legitimate only in cases of absolute and mandatory clinical need, and is never admissible for "precaution" purposes and cannot be left to the autonomous decision of the healthcare and/or nursing staff.

In the hospital context, the legitimacy of physical or mechanical constraint by the healthcare professionals is conditioned by the duty to protect the health of patients. Therefore, among the tasks of healthcare workers there is the duty to protect and control the patients' aggressive gestures against themselves or others by adopting measures to prevent aggressive actions or in any case reduce their harmful consequences.

However, since restraint is not a rational instrument of assistance and care, in the absence of any legislation of reference, this practice cannot be justified except in the presence of a "state of real necessity", once all the possible alternative intervention measures suitable for solving or at least mitigating the problem have all been applied and found to be ineffective. All the adopted measures that failed are to be documented in detail.

The practices of restraint raise important questions from an ethical-legal point of view, since categories of offences have been defined such as: abuse of means of correction or discipline (Article 571 of the Criminal Code); abuse (Article 572 of the Italian Criminal Code); kidnapping (Article 605 of the Italian Criminal Code); private violence (Article 610 of the criminal code); negligent personal injury (Article 589 of the Criminal Code); involuntary manslaughter (Article 590 of the Criminal Code).

The restraint can cause: **physical damage** (e.g., strangulation, asphyxiation, injuries to muscles, bones, nerves, vessels); **psychosocial damage** (e.g., stress, mood changes, fear, discouragement, humiliation); **organic and functional disorders** (e.g., infections, incontinence, bedsores).

There is a general orientation, supported by national and international institutions, according to which restraint as a healthcare practice is to be abolished. In a document on the subject, the National Bioethics Committee (NBC) (25) states: "Restraint in itself is a violation of the fundamental rights of the person. The fact that in absolutely exceptional situations healthcare workers can resort to justifications to apply restraint does not diminish the force of the rule of non-restraint and does not change the fundamentals of ethics".

According to the National Bioethics Committee, "we can do without restraining people: the existence of facilities that have chosen not to apply restraint and the success of the programs aimed at monitoring and reducing this practice confirm this indication". In fact, the data show that restraint is used not so much because of the seriousness of the patients' clinical conditions, but because of shortcomings in the organization of the services and because of the unacceptable attitudes of the staff.

The National Bioethics Committee observes that restraint is admissible only "in situations of real necessity and urgency, and in a way that is proportionate to the concrete needs, using the least invasive methods and only for the time necessary to eliminate the conditions that required its use". In particular, it is not sufficient for the patient to be in a state of mere agitation, but in order for the restraint to be "justified", there needs to be a serious and current danger that the patient may injure or cause harm to him/herself or to third parties. As soon as this danger disappears, the containment treatment must be discontinued, since it would no longer be justified by necessity and would constitute a criminally relevant conduct".

Therefore "eliminating restraint is a fundamental step in the advancement of the culture of care – in psychiatric services and in providing care for the elderly – in line with generally recognized ethical criteria applied to all other social and healthcare fields". There may be alternative measures to restraint aimed at improving pain control and motor performance, and at providing more effective supervision thanks also to the possibility of providing the healthcare staff with counselling support. In addition to a friendlier environment, attention is paid to the need for adequate training for the staff on alternatives to restraint. The NBC recommends, among other things: research and monitoring, at national and regional level, in particular of the daily practices in the units; detailed programs on providing alternatives to restraint; quality standards that are conducive to "no-restraint" services and facilities; dissemination of services that can be addressed by vulnerable people, such as the elderly, "exposed to inhuman and degrading practices".

Given the potential for abuse and mistreatment, the use of restraint remains a field of major concern for the National Guarantor for the Rights of Persons Detained or Deprived of Liberty.

According to this National Authority, the use of restraint, in all its forms, in residential, social, health and welfare facilities, must not be among the staff's routine management methods, nor the result of saving on human resources, and even less so a solution for managing organizational emergencies as occurred in many facilities, during Phase 1 of the SARS-CoV-2 pandemic[8].

In any situation, even in contingencies, the facilities entrusted with the task of providing care and assistance to people need to be safe places for both residents and staff. Everyone must be treated with respect and dignity, in a protected and humane environment that respects choices and self-determination; therefore, the use of mechanical or chemical restraint cannot be justified in cases where it would not be needed if there were an adequate number of staff proportionate to the number of patients requiring care.

In line with the indications of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), the National Guarantor believes that the application of any form of restraint considered to be indispensable, whether it be mechanical or pharmacological, must be subject to the procedural obligations set out in the operational protocols defined by the local health authorities[9] and must be implemented by all healthcare facilities. At the same time, the restraint must be subject to constant monitoring and accurately recorded in a special register established for this purpose (and recorded also in the patients' personal files). [10]

The time when the measure started and ended are to be entered into the register, as well as the circumstances that made it necessary, the name of the doctor who ordered or approved it and any injuries to the patient or staff (26). Monitoring and recording the use of restraint is expected to limit the risk that restraint may become ordinary practice in the management of patients and, in the same way, it protects the staff responsible for the monitoring because they have the duty of protecting the patients. In fact, in the opinion of the National Authority, the monitoring of the use of restraint measures, where they are used,

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[8] National Guarantor for the Protection of the Rights of Person detained or deprived of Liberty. Report to Parliament 2020, p. 61.

[9] *See* Conference of Regions and Autonomous Provinces 10/081/CR07/C7 "Physical restraint in Psychiatry: a possible prevention strategy". As at December 6, 2017, not all Regions had taken steps to adapt to the Recommendations of the aforementioned document. See Conference of Regions and Autonomous Provinces 17/178 / CR06a / C7 "Document to be presented to the Select Committee on the protection and promotion of human rights in the context of the fact-finding investigation on the levels and mechanisms of protection of human rights in force in Italy and internationally, and on mechanical restraint"

[10] *See* Report to the Italian Government on the visit to Italy by the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) from 8 to 21 April 2016. CPT/Inf (2017) 23.

cannot be entrusted exclusively to remote surveillance via video cameras, nor can it be replaced by invasive forms of chemical restraint.

With the clear objective of reducing the use of all forms of restraint, it would be appropriate for the issue to be dealt with in the continuous education courses for healthcare workers with the aim of consolidating an operational model that is person-centred and with full respect for his/her dignity and not a model where the individual is a “sick person” without guarantees and with no capacity of self-determination. Training should be aimed at ensuring greater awareness of the responsibilities of operators who practice restraint, of the risks in its application and the impact it has on the person who who entrusts him/herself or is entrusted to receive care and treatment by the staff of the facility. At national level, it could be a good idea to set up an “observatory” for research and surveillance purposes on the abuse of restraints or of other methods, with a view to reducing the use of such measures significantly.

5.4. Principle of therapeutic proportionality

With regard to the bioethically crucial problem of assessing whether a treatment is proportionate or not, the recent pandemic experience has generated situations in which doctors have had to decide, often in a dramatically short time, whether a given diagnostic or therapeutic intervention was to be considered proportionate or not.

In general, in the ethical-clinical context, there may be a difference between the doctor’s and the patient’s point of view regarding the complex choices to be made in a specific case (27). This diversity should not cause a clash between different intentions and views but should be used to arrive at an adequate decision, promoting the therapeutic alliance (28) which is the foundation on which even difficult choices can be made.

Proportionate treatment is to be defined on the basis of an evaluation of both the clinical condition and the personal history of the patient, seeking a balance between objective (clinical) and subjective (existential) data such as the patient’s clinical history, objective health conditions, needs, psychological aspects and personal and existential values (ascertained through careful listening, open dialogue and sufficient time) (29).

The term *disproportionate* or *futile* treatment indicates any intervention that is not adequate for the real clinical and existential situation of the patient because it is too risky compared to expected benefits. In other words, this term indicates any treatment that in a rather generic way is defined as “futile care” or “unreasonable obstinacy”.

The concepts of *proportionate means* and *disproportionate means* are related to the ancient concepts of ordinary and extraordinary means. The latter developed in the philosophical and theological debate from the sixteenth century to the second half of the twentieth century. Since 1980 the concepts of ordinary and extraordinary means have been replaced by the terms “proportionate and disproportionate means”, where greater importance is attached to the assessment made by all the professionals involved in the treatment of a clinical case (30).

Some clinical scenarios are outlined below with the sole intention of providing examples to better specify the concepts mentioned above.

A classical example is that of cardiopulmonary resuscitation for a patient in the terminal phase of an oncological disease who is also affected by acute pulmonary oedema: in this case any resuscitation attempt could cause more suffering than benefit since death is imminent and inevitable, and could be postponed by only a few hours or days in the face of further suffering. A patient of this type will probably not be sent to an intensive care unit and resuscitation practices will not be attempted but rather palliative care will be offered which will ensure an optimal control of symptoms for the remaining time the patient has to live.

Another possible clinical situation is when the proposed amputation of a limb, for severe diabetic necrosis, is rejected by the patient. In extreme cases, the clinical appropriateness of the operation is out of the question, but the patient does not always accept the burden of the operation. In the latter circumstance, the intervention is to be considered too burdensome and therefore, even if only subjectively, disproportionate. Another example of disproportion is that of the possibility of yet another line of chemotherapy offered to a patient suffering from an advanced stage multimetastatic neoplasm, a stage of the disease in which a strictly palliative approach could guarantee adequate accompaniment and good symptom control.

Artificial nutrition and hydration are considered therapeutic treatments (Law 219/2017, "Rules on informed consent and advance medical directives") and therefore subject to the criterion of proportionality. If artificial nutrition and hydration can be considered proportionate in an earlier stage of the disease, they could prove to be "disproportionate" when the expected benefits do not occur or when the patient does not want them.

Artificial nutrition could be considered proportionate when "there is a reasonable clinical hypothesis that the expected survival for the natural evolution of the disease would be reduced by concomitant malnutrition due to the patient's inability to swallow" (31), or when maintaining oral feeding exposes the patient to serious risks (e.g. aspiration pneumonia).

Artificial hydration can be considered proportionate in all the cases in which the patient's body can take it: in the last hours or in the last days of life, a careful hemodynamic evaluation is required to avoid overloading the circulation and the pulmonary oedema. In cases where artificial hydration must be suspended or not started, the decision must be communicated to the patient and, if he/she agrees, to his family (where possible), presenting also the actions that will be taken to reduce the discomfort caused by disturbing symptoms such as thirst and dry mouth. Law 219/2017 establishes that in order to be considered "proportionate", hydration and nutrition must have the consent of the patient: otherwise they will be "disproportionate".

In the rehabilitation / palliative field we may find patients suffering from degenerative neurological diseases such as amyotrophic lateral sclerosis, who, in anticipation of an acute respiratory crisis due to the paralysis of the respiratory muscles, refuse tracheotomy, mechanical ventilation support and the positioning of an enteral feeding tube (e.g., a PEG, percutaneous endoscopic gastrostomy). The task of the doctor and more generally of the treatment team is always to explain to the patient in a precise and detailed manner also the consequences of any refusals ("withholding").

In urgent or emergency situations where the patient cannot express his/her consent or dissent or in which DATs are not present, or the latter are not clear, the doctor will abide by his/her judgment of proportionality according to his experience, the available means and the guidelines of best clinical practice and of Evidence Based Medicine.

In the specific context of homes for the elderly, which is the focus of this document, the pandemic has certainly increased in number and complexity the problems that the staff must face in providing the necessary attention to all the residents. In particular, very complex situations may arise associated with the delivery of care that may sometimes involve the delicate ethical-legal problem of hospitalization of an elderly resident. In some cases, on the other hand, problems and decisions may arise that directly and exclusively concern the staff of the residential structure with regard to food issues, for example.

In a recent article by the European Society for Clinical Nutrition and Metabolism (ESPEN), some clinically and ethically relevant aspects are highlighted regarding the nutrition of patients affected by COVID-19 (32). Considering the evidence that prolonged periods of hospitalization in resuscitation, co-morbidities and advanced age are conditions associated with a high risk of malnutrition and a high mortality rate in the case of chronic and acute diseases, as shown by the clinical experience gained during flu epidemics (33) and taking into account that the outcomes of such conditions are very often observable in long-term healthcare facilities, even for residents who return after more or less long periods spent in intensive care, the authors propose some recommendations, that are summarized here. Diagnosis and treatment of malnutrition must be routinely included in the management of COVID-19 patients and therefore constitute proportionate procedures. Nausea, vomiting and diarrhoea, that are often present in cases of infection, lead to reduced calorie intake and decreased absorption of nutrients and hence require assessments to be made by experienced professionals not only in the case of malnutrition but also in the case of obesity. Finally, in patients with a "reasonable" prognosis and who cannot feed themselves orally, ESPEN indicates the need to resort to enteral feeding or, if impossible, parenteral nutrition, considered as "proportionate" also in this case.

It is not among the purposes of this paper to draw up precise indications to support decisions that, in critical circumstances, will always be taken by doctors on the basis of an accurate assessment of all the specific characteristics of each case. However, it is dutiful, both on an ethical and a legal level, to strongly recommend that inappropriate behaviours be avoided, both in the direction of overtreatment and of abandonment.

In evaluating the decision-making process and the choices regarding treatment in critical situations, in relation to the pandemic contingency, the provisions established by the Italian National Federation of Medical Doctors, Surgeons and Dentists N (Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri, FNOMCeO) in the joint document with the Italian Scientific Society of Anaesthesiologists, Intensivists, and Pain Therapists (Scientific Society of Resuscitator Anaesthetists (Società Italiana Anestesia, Analgesia, Rianimazione e Terapia Intensiva, SIAARTI) on the way in which therapeutic choices should be made are presented here. Therapeutic choices must be made on a case-by-case basis, defining the efficacy criteria of a treatment for each individual patient, on the basis of competing clinical criteria that are to be considered jointly such as, for example, the severity of the clinical presentation, the comorbidities, the previous functional status, the impact on the person of the potential side effects of intensive care, and biological age.[11]

5.5. Training of healthcare staff

In the social-health facilities there are many professional figures in the medical and health field (family doctors, specialists, physiotherapists, professional educators, nurses, social workers and social-health workers) who are part of what is defined as a multidimensional and multi-professional approach, coordinated in a team that responds to the clinical and care needs of fragile older people.

The assisted person, considered subjectively and globally, even more so if in the context of residential institutions, needs not only specific medical treatment for his/her disease, but also all the daily care that ensures that quality of life is maintained and developed through the recognition of his/her problems and needs. All this falls within the broad definition of "to care", to take care of, care that is provided by all the professional figures present in the facility without ever losing respect for the person being taken care of.

In the relationship of assistance and care, special importance is attached to the ethical concept of caring, and caring-oriented behaviours are considered fundamental aspects of the role of the nurse because of the direct relationship they have with the patient's health. Caring can be explained as a form of engagement with others that creates an interest in how other people experience the world around them. All this requires

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[11] *See* the FNOMCeO-SIAARTI document of 22 October 2020 approved and adopted by the Central Committee of FNOMCeO on 29 October 2020.

sensitivity and social skills - knowing how to relate to others - but also the ability to give support, share knowledge and put to use one's skills (34).

Due to the complexity of the work, they carry out, not only the medical staff, but also all the other professions involved in providing care and assistance to the elderly need continuous support in a complementary relationship in which there are different skills, roles and responsibilities. Training therefore represents a particularly critical aspect. There are international studies that have explored the significance of the role of healthcare professionals working in residential facilities and have analysed how this role has changed over the years (35). In Italy, an in-depth reflection has not yet been developed that can indicate to what extent the skills currently present within residential care facilities are adequate in responding to the multifaceted needs of dependent people and to identify any obstacles that may prevent the full delivery of care, understood in its broadest sense. A deep understanding of the needs, together with an analysis of the changes taking place within residential facilities, could enable the healthcare sector to change its strategies and address the lack of adequate skills, if any. It therefore appears to be necessary to thoroughly explore the role of healthcare workers in the context of social-health residential care and identify possible areas requiring improvement.

Nursing education now provides specialized university training courses[12] on the management, assistance and care of fragile older persons. Continuous education is a moral duty for professionals who intend to continue to provide targeted responses to social-health needs.

Also, the training courses for Nursing Aides, although diversified at regional level, all tend to provide their trainees with social skills in order for them to be able to respond to transversal needs in the various care and assistance contexts. Recently, the Italian Society of Geriatrics and Gerontology (Società Italiana di Geriatria e Gerontologia, SIGG) proposed that updates for doctors, nurses and nursing aides on relevant and specific topics is mandatory in the context of facilities for the elderly (36).

5.6. Communication between healthcare staff and residents or their families

Communication is the fundamental pillar of any relationship of care and is naturally characterized by a fundamental asymmetry of knowledge between the healthcare staff and the person in need of care. The asymmetrical nature of the relationship is also influenced by the context, hospital or residential, in which it is established, both for the patient and for his/her family. Care delivery and communication occur within the healthcare staff-patient relationship and requires that a balanced and transparent language be used. It follows that communication is always measured by the "why" and "how" it is done (37). The "why" of communication, in particular, also includes the ability to recognize and know about the personal stories behind people's faces, their relations and emotions and it is indispensable in order for every relationship to take place under the banner of trust.

Each person who arrives in a residential facility brings with them their past life, regardless of whether they are able to talk about it or express it, a life which deserves to be known and respected so that their dignity is protected and also in order to create a tailored care and assistance plan. Often the patient's life

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[12] Following the document that was drafted by the FNOPI in 2002 in pursuance of Ministerial Decree no. 739/94 and which identifies 5 areas of specialized training (public health, pediatrics, mental health / psychiatry, geriatrics and critical area), and having recognized the need for well-trained professionals to provide care for an aging population, the 1st level master's degree in Geriatrics has been designed to provide advanced and specific nursing skills in the geriatric area to improve the quality of care for the elderly and their families in different care settings and for different types of intervention, such as the prevention and promotion of health, therapeutic education, counselling and research.

becomes known through the stories told by family members or friends and it is with the latter that the relationship of the healthcare professionals is fundamental in order to recognize the needs of the residents and be able to take care of them in the best of ways, also by allowing them to keep contact with the life they had prior to entering the facility. Time must be filled with meaning so as not to let it simply go by, threads of meaning are to be woven no matter how short a time they have (38).

The way of communicating, the "how to communicate", also affects the outcome of the process. A communication that is not attentive to content and to what it can generate in terms of interpretation and behaviour, risks having a negative and harmful effect both on the nurse-patient relationship and on the person who is the recipient of the care. Communication must always be commensurate with the person's request and in order for it to be characterized by respect and effectiveness it must not only be accurate but also properly contextualized. Awareness and responsibility in making choices risk being lost if undermined by ineffective communication.

5.7. Palliative care

The recent definition of palliative care by the *International Association for Hospice and Palliative Care*[13] points out that the palliative approach, especially for elderly people, does not consist merely in controlling symptoms but also includes aspects of communication, social and spiritual support and enhancement of the person that can and must be implemented at home, in the hospice and obviously also in social-health residential facilities. For this to happen, however, it is necessary to deeply rethink the way care is delivered to the elderly in residential facilities, ensuring that they are given full access to professional care and human attention that in many cases is still absent. It would be a mistake to believe that palliative care is reduced to end-of-life care: in patients suffering from multiple diseases, the palliative approach goes hand in hand with the etiological treatment of morbid conditions, including viral diseases. For example, the administration of antiviral drugs or antibiotics in the elderly affected by coronavirus or in some degenerative neurological pathologies in an advanced stage, does not exclude the palliation of dyspnoea with adequate drugs, the control of anxiety or sessions with a physiotherapist based on a rehabilitation program drawn up by the physiatrist with breathing exercises and postures aimed at improving lung ventilation; the presence of a spiritual assistant must also be envisaged to strengthen the human bonds that often contribute to improving quality of life.

A FIRST RECOMMENDATION is therefore to make an early assessment to decide whether palliative care is required, alongside the treatment and care for chronic degenerative diseases because palliative care is not restricted only to the end-of-life phase.

In recent years, a model called *simultaneous care* has come to the fore. In this model, the adoption of palliative care is proposed to the patient at an early stage of his/her disease through a collaboration involving palliativists, general practitioners and other professional figures depending on the patient's needs. This integrated care approach ensures that patient needs are met more effectively and that there is also a progressive, gradual and less traumatic transition to palliative care when the progression of the disease cannot be stopped. This model of care has been shown to provide the patient with a better quality of life, better symptom control, and reduction in anxiety and depressive symptoms (39). This model can also help

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[13] https://hospicecare.com/what-we-do/projects/consensus-based-definition-of-palliative-care/definition/ .

overcome the widespread belief that palliative care is limited to the end of life, a belief that can make it difficult for the doctor to suggest it to the patient.

A SECOND RECOMMENDATION involves making a careful assessment of symptoms and monitoring them using validated assessment scales administered by adequately trained medical and nursing staff.

A factor that makes the pharmacological approach to the elderly patient more delicate is the change that occurs in pharmacokinetics as a result of age. The volume of water- and lipid-soluble drugs that is distributed is different and the heart, liver and kidney functions are decreased. Malnutrition, which is frequent especially when the patient is cared for at home, exposes the elderly to the risk of drug overdose even when standard doses of drugs are being taken and hypoalbuminemia may cause very high blood levels of some active ingredients, such as benzodiazepines, that can circulate thanks to their strong bond with albumin. Great attention must therefore be paid to adjusting the usual pharmacological dosages, also by using tools that help monitor drug interactions. Even greater caution must then be taken to reduce as far as possible the use of drugs such as NSAIDs, as widespread as they are harmful, and in evaluating an appropriate deprescribing (43).

A THIRD RECOMMENDATION is to carefully monitor the pharmacological treatment the patient is on and pay special attention to any new drugs that are prescribed using tools that help identify dangerous drug interactions. Deprescribing must be applied with care in older patients especially for effective quaternary prevention (i.e., prevention of overmedicalization)

In daily practice there is a growing desire to be treated at home, even until the end of life. However, most elderly patients in Western countries die in hospitals, hospices or in social-health residences. The lifestyle changes of today's society, the increasing involvement in work, the loss of family unity, the lower birth rate, all contribute to the isolation of the elderly and to their hospitalization. In this regard, in France, the Observatoire National de la Fin de la Vie (ONFV) published, in 2013, an in-depth report on the end of life of elderly patients (44), highlighting three possible end-of-life scenarios: slow decline, typical of cognitive disorders such as Alzheimer's disease, gradual decline, as seen in organ failure, and rapid decline, as in the case of oncological diseases. For each scenario, the report highlights the main problems that were found in residential social-health facilities which further worsened during the days of the Coronavirus pandemic like the late identification of palliative care needs, the lack of prevention of complications typical of the end of life, the management of the emergency that did not take into account the reality and priorities of needs, the disproportion or the extraordinary nature of some treatments (refer to the specific ethical reflections made earlier), and difficulties in making clinical and ethical decisions that are typical of end of life conditions, which are even more difficult in patients rendered fragile by age.

A FOURTH RECOMMENDATION concerns the need to enhance home care services, thus meeting the widespread wish of elderly patients to be cared for at home. This policy will have to provide concrete aid to families who, in the absence of family caregivers, will have to rely on external caregivers.

A separate discussion is required by deep palliative sedation, a practice implemented in a limited number of cases, when treatments aimed at controlling symptoms prove to be insufficient. In the case of advanced respiratory insufficiency, deep and continuous sedation is to be reserved to the cases with refractory symptoms, cases that is which, despite the administration of opioids and benzodiazepines, do not respond. As highlighted in 2016 by the NBC (45), however, this practice is reserved to patients with refractory symptoms and illnesses with a fatal outcome and whose death is imminent, i.e. expected to occur in a matter of hours or a few days. The use of continuous deep sedation is totally unjustified in any other condition, even more so when it is offered almost as an alternative to resuscitation in potentially reversible situations.

A FIFTH RECOMMENDATION provides for the application of deep and continuous pharmacological sedation protocols only in the presence of the three basic requirements provided by the main scientific societies of palliative medicine: chronic disease with a fatal outcome, one or more refractory symptoms, death expected in a matter of hours or a few days. Apart from these situations, pharmacological sedation runs the risk of being a life-shortening practice.

The personal experience of the palliative care physicians who participated in the drafting of this Report and who are palliative care consultants in nursing homes, but also make home visits to activate home care or to transfer patients to hospices, constitutes direct proof of the following reality: in some long-term care facilities the staff do not have the skills and specific competences required to provide the highly complex care that some end-of-life situations require. The COVID-19 pandemic has brought to the fore some critical issues that cannot remain unresolved, not even from the standpoint of palliative medicine, and this is probably a unique opportunity for re-examining at least some of our healthcare models, also with a view to being prepared for any future health emergency scenarios.

The Italian Society of Palliative Care gives recognition to Palliative Doctors and Palliative Nurses after evaluating their core curriculum in palliative care and, considering the principle of cooperation which is necessary in order to respond to the needs of the persons needing care, has defined the palliative care team that provides assistance and care to patients and their families. Palliative care professionals are to be present in all public and private health facilities and in non-profit organizations operating in the Palliative Care Network. Emphasis is placed on the role of the nurses whose functions are characterized by the skills they have acquired.[14]

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[14] The skills are based on five fundamental levels of skills that are intertwined: ethical skills, aimed at understanding the difficult and controversial clinical situations involving Palliative Care; clinical skills: required to make appropriate and effective assessments of the symptoms of the advanced stages of any developmental disorder and administration of the therapy prescribed by the Palliative Physician; communication and relational skills: aimed at providing care and support that respect the uniqueness, dignity and will of the patient and his/her family; psychosocial skills: for attentive and effective support of the overall needs expressed; team work skills: for an integrated approach to the management of care.

6. Service Charter and charter of the rights of older people

The Service Charter is the document in which a Service Provider sets forth the commitments he makes towards his users, the quality standards that his services comply with and the forms of protection he ensures. The Service Charter has been introduced in Italy also in the health sector and not only as a mere formal recognition of guarantees for users, but also as an instrument attributing direct control over the quality of services. The service provider is required to meet the quality standards he has communicated and to verify that they are complied with.

In line with the principles expressed by the Service Charter, Legislative Decree 502/1992, amended by Legislative Decree 517/1993, states that:

“the main characteristics that define the quality of health services are tailored treatment, humanization, the right to information, accommodation services and the implementation of prevention activities”.

This standard also provides for the definition of a national system of indicators for measuring quality and ensures consultation of citizens and the organizations that monitor the organization of services and assurance of quality. The Service Charter is therefore an important document that reflects the general degree of organizational maturity of a welfare service. However, it is important to underline that, as specified in the DPCM of 19 May 2005 (46), the technical quality of healthcare services goes beyond the issue of service quality. The dimensions of the quality of the service concern, in fact, variables such as, for example, promptness of the service or the shortness of waiting lists; simplicity of the paper work; information about treatment (intelligibility, clarity, completeness), qualities of the physical facilities such as comfort and cleanliness and also the quality of the social and human relationships involving the tailoring and humanization of treatment, providing reassurance, courtesy and respect for dignity.

To date, there are no studies at national level on the characteristics of the Service Charters of social-health facilities; some data available on a non-representative sample seem to indicate that almost all the facilities have a service charter (88%). The quantity and quality of information, on the other hand, differs from one facility to another (as regards, for example, references to the Public Protection Office, information on privacy protection, informed consent, individualized care plans, etc.) and some also include a charter of the rights of the elderly (47).

In 2010, with the support of the European Community, a network of non-profit organizations providing services to the elderly or working in the field of aging, ***Age Platform Europe*, proposed a European Charter “of rights and responsibilities of older people in need of long-term care and assistance” to open a discussion in Member States on how to better recognize and affirm the rights of the most vulnerable among elderly people. The Charter aims at facilitating the access of older people to their fundamental rights hence increasing their awareness.**[15]

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[15] Unabridged version available at: https://www.age-platform.eu/sites/default/files/European%20Charter_IT.pdf .

The document, which is addressed directly to older people, indicates, among others, the following rights:

- **Right to dignity, physical and mental well-being, freedom and security**

  In particular you have the right to:
  - respect for and protection of your physical well-being and safeguarding from any form of physical abuse, which includes: maltreatment and neglect, malnutrition and dehydration, exhaustion, excessive cold or heat, and any preventable physical illness.
  - Resepct and protection of your psychological and emotional welfare and protection from any form of psychological or emotional abuse or mistreatment.
  - Be protected from any attempt to separate you from another person whom you wish to be with.
  - Protection from all medical and pharmaceutical abuse, including inappropriate, unnecessary or excessive medical treatment.

- **Right to self determination**

  In particular:
  - You have the right to lead a life which is as self-determined and independent as your physical and mental capacities permit, and to receive advice and support in order to do so.
  - You have the right to expect that your opinions, wishes and choices are respected even if you are not able to communicate eloquently. You have the right to be consulted and participate in any decision-making processes that affect you.
  - You have the right to be given sufficient time to consider your decisions carefully, to access relevant documents, and to make your choices, having received independent information, advice and guidance.
  - In the event that you are unable to take decisions for yourself or express yourself at a later date, you have the right to leave in advance instructions on decisions relating to your care, to be carried out by an appropriate third-party.
  - You may not be subject to any form of physical or mental restraint unless it is a proportionate response to a risk of potential harm. In which case, it must be determined to be in your best interest through a transparent and independently verifiable process that can be reversed. Assessments of your level of mental capacity to make decisions are neither absolute nor enduring and must be re-evaluated regularly.

- **Right to privacy**

  In particular:
  - You are entitled to respect for your need for privacy. You should have the opportunity for time and space alone, or with persons of your choice, if you so wish.
  - Respect for your privacy is also reflected in the consideration given to your feelings of modesty. You have the right to be treated by caregivers with sensitivity and discretion.
  - Your right to privacy must also be reflected in the confidential handling of your data and documents. Your personal data are protected by law.
  - You have the right to expect that discussions about your condition, care and treatment, whether held with you or not, are handled with sensitivity and discretion, and with respect for your privacy.

- **Right to high quality and tailored care**

  In particular:

  - You have the right to receive high quality, timely and affordable health and long-term care services that are adapted to your individual needs and wishes and without discrimination of any kind.
  - You have the right to be attended to by people who have the skills required and adequate support to respond to your need for assistance, care and treatment.
  - You are entitled to benefit from measures to prevent any deterioration of – or to bring about an improvement in – your condition, and to promote your independence to the greatest extent.
  - You have the right to expect that all individuals, institutions and professional bodies involved in your care, support and treatment should communicate and cooperate with one another and closely align the services they provide to ensure that they are in your best interest.
  - You have the right to receive timely support for your daily needs.
  - You have the right to move freely within your surroundings. You have the right to be given support and encouragement for your mobility.
  - You are entitled to expect that aspects of your background and past lifestyle that are important to you are taken into consideration.

- **Right to personalized information, advice and informed consent**

  In particular:

  - You have the right to be informed about your state of health and the available treatment and care options.
  - Your informed consent or that of the appropriate third-person of your choice must be sought on decisions relating to all of your care and treatment, as well as to any participation in research projects and medical trials.
  - You and a third-party of your choice continue to have the right to access your personal medical data and to request the opportunity to inspect all documents relevant to your health.
  - Your right to refuse to be informed should also be respected.

- **Right to continued communication, participation in society and cultural activity**

  In particular:

  - You have the right to all the support necessary to enable you to communicate. You are entitled to have your communication needs taken into consideration, in whatever way these are expressed.
  - You have the right to continue to exercise your civil rights, including the right to participate in political elections and, if required, to receive impartial assistance to do so. Your right to freedom of choice must be respected and confidentiality concerning your vote must be maintained by anyone assisting you.

- **Right to freedom of expression and freedom of thought/conscience: beliefs, culture and religion**

  In particular:

  - You have the right to be respected for your values and beliefs, your philosophy of life and religious freedom regardless of whether or not these values are shared by those who are supporting you.
  - You have the right to practice and observe your religion or spiritual beliefs. You also have the right to obtain spiritual or religious care and guidance from representatives of your faith or spiritual beliefs when you wish. You have the right to refuse to paritcipate in religious activity and to reject approaches by representatives of religions or faiths.

- **Right to palliative care and support, and respect and dignity in dying and in death**

  In particular:

  - You have the right to compassionate help and palliative care when you reach the end of your life and until you die. You have the right to measures to relieve pain and other distressing symptoms.
  - You have the right to expect that the medical and care professionals involved in your end-of-life care should include and offer support to those close to you or other trusted persons, acording to your wishes.
  - In the event that you are not able to express yourself, your advance instructions concerning decisions about your end-of-life care must be fulfilled within the limits of the national legislation of your country of residence.

- **Right to redress**

  In particular:

  - You are entitled to expect care professionals to be trained to recognize signs of abuse and mistreatment and act appropriately in order to safeguard you from any further mistreatment.
  - You have the right to be informed of the channels through which you can report abuse. You have the right to report abuse or mistreatment without fear of any negative reprecussions, and to expect that the authorities will respond appropriately when you make a report. This right extends to those around you, particularly people who are responsibel for your care and support.

7. SARS-CoV-2 epidemic and protection of the rights of the elderly in healthcare facilities in an emergency situation

On 8 May 2020, almost at the end in Europe of what was called the "first wave" of the SARS-CoV-2 pandemic, the newspaper *Le Monde* headlined "Coronavirus: the residents of the EHPAD (Etablissement d'Hébergement pour Personnes Agées Dépendantes, i.e., facilities for dependent elderly people) account for half of the deaths reported in France". In our Country, as at September 13 of the same year, 85.4% of deaths with Coronavirus were people aged 70 and over. Numbers are the most effective way to have a bird's eye-view of a dramatic reality: elderly people living in residential healthcare facilities have paid a very high toll to the pandemic.

The pandemic has highlighted some characteristics of elderly patients that increase their fragility. In many cases the viral infection hastened the evolution of chronic degenerative diseases that were already present: neoplasms, heart disease, chronic kidney failure, diabetes, chronic obstructive pulmonary disease and metabolic diseases. The National Dementia Observatory-ISS in collaboration with the National Authority for the Protection of the Rights of Individuals deprived of Personal Liberty conducted a survey in Italian long-term healthcare facilities from 24 March to 5 May 2020. The data obtained show that in 1,356 long-term care facilities that voluntarily participated in the survey for a total of 100,806 residents, 9,154 people died from 1 February to the time the questionnaire was completed. Of these, 7.4% had COVID-19 and 33.8% had flu-like symptoms (11). The main factors associated with the presence of COVID-19 in long-term care facilities have been identified in the lack of staff, difficulties in transferring patients to hospitals or other facilities, and difficulty in isolating residents with COVID-19; in addition, long-term healthcare facilities are the facilities with the highest number of beds and are located in the geographical area where the spread of the infection was greatest, at least during the first wave (Northern Italy vs. Central, Southern Italy and the Islands).

Specific legislative interventions have been prepared to prevent the spread of the virus in semi-residential and residential facilities, in particular Law no. 77 of 17 July 2020, that converted Law Decree no. 34 of 19 May 2020, which provided for the activation in all Regions of a system to monitor COVID-19 in all types of residential facilities, and the DPCM of 13 October 2020 which, among other things, provides for the drafting of local plans by the Regions to ensure, through specific protocols, compliance with the provisions for the prevention of contagion and the protection of the health of residents and workers.

The ISS has produced a number of reports: ISS COVID-19 Report no. 4 / 2020 Rev 2. "Interim Guidance for the Prevention and Control of SARS-CoV-2 infection in Long-term Healthcare Facilities" (1), ISS COVID-19 Report no. 61/2020 "Interim Guidance for appropriate Support for People with Dementia in the Current Scenario of the COVID-19 Pandemic" (2) and ISS COVID-19 Report no. 8/2020 Rev. 2 "Interim Guidance for appropriate Support for People on the Autism Spectrum and / or with Intellectual Disabilities in the current SARS-CoV-2 Emergency Scenario" (48).

7.1. Some recommendations for the management of residents in long-term healthcare facilities in emergency situations

In emergency situations, the control measures implemented by the competent authorities for the protection of public health may impose restrictions on the individual, limiting even significantly, but in any case, for limited periods of time, certain fundamental freedoms (49). When establishing individual interventions and undertaking to ensure effective compliance, it is necessary to comply with the criteria of reasonableness and proportionality, and to limit the restrictions to the time strictly needed to achieve the goal being pursued. These criteria also apply to the measures taken in relation to people living in long-term care facilities that this report deals with. Whoever has responsibility for such facilities must, in fact, put in place organizational measures consistent with the indications of the local and national health authorities, in order to protect the well-being of the residents and their rights, including their health-related rights.

The DPCM of 8 March 2020 providing "Further implementing provisions of Law Decree no. 6 of 23 February 2020 establishing urgent measures regarding the containment and management of the COVID-19 epidemiological emergency ", stated in Article 2 (1) letter q) that:

> "Access of relatives and visitors to nursing homes and long-term care facilities, assisted living facilities, hospices, rehabilitation facilities and retirement homes for both self-sufficient and dependent elderly, is allowed only in the cases indicated by the Health Director of the facility, who is required to take the necessary measures to prevent the possible transmission of the infection".

This provision was also confirmed by the DPCM of November 3, 2020. On November 30, 2020, the Ministry of Health, in accordance with the provisions of the ISS report "Interim Guidance for the Prevention and Control of SARS-CoV-2 Infection in Residential, Social, and Healthcare facilities", version of 24 August 2020, issued the circular entitled" Recommendations for the access of visitors to nursing homes, social-healthcare facilities and hospices and indications for the admission of new patients in the event of COVID-19 positive residents in the facility", which provides further indications to ensure full access to relatives and visitors in safe conditions. And the ISS COVID-19 Report no. 62/2020 "Guidance for the Prevention of SARS-CoV-2 Infections in Hospices and Home Palliative Care" was published on December 15, 2020, (50).

The admission of new patients represents a dilemma between operational complexity and the need to protect both the fragile residents and the new patients being admitted. Based on the experience gained in the early months of the epidemic, one of the fundamental measures to prevent the virus from entering the residences was to put a stop on new admissions. Apart from the particularly critical phase being referred to, the measures for new admissions to the residential facilities are, at least at first sight, simple on a technical level, since they require that the newly admitted be kept in isolation in a one-bedded room.

However, the concrete implementation of this measure must take into account the special bio-psycho-social fragility of the elderly, especially those suffering from major neurocognitive disorders. From this standpoint, isolation risks causing serious damage to their psycho-emotional integrity, since, in addition to the trauma of the change in their living environment, these patients must also face the trauma of a two-week solitary confinement, with the intermittent presence of only unrecognizable operators wearing full personal protection gear. Indeed, it seems unlikely that a dependent, highly fragile elderly person with multiple disorders would have the resilience to adapt to this disruptive change; and something similar also applies to cognitively unimpaired elderly people to whom, in any case, it is not easy to explain, nor for them to understand, the reasons for such procedures. Therefore, there is a high risk that the isolation procedures upon admission to a facility may trigger the classical example of a "cascade of functional decline", whereby the elderly discount (due to the continuous loss of their self-esteem) the value of their life and let themselves "go", thus speeding up the onset of fatal terminal events: paradoxically, therefore, being admitted to a residence determines the opposite effect to that desired.

The SARS-CoV-2 epidemic has made it clear that in order to ensure that patients in residential facilities receive adequate care even in complex emergency circumstances, the integrated management of clinical care and other support services needs to be optimized, and processes are to be monitored in order to make sure that, where the organizational and / or structural resources are not adequate, the more vulnerable people are not abandoned or neglected, or find it difficult to gain access to care services. In Italy, the analysis of a sample of 2,621 clinical records of deaths with SARS-CoV-2 positive swabs representative by age, residence and period of the approximately 35,000 deaths in the general population in early May 2020, has shown that patients with dementia had reduced access to ICUs (OR = 0.31; 95% CI 0.17-0.59, p <0.001) compared to patients with other diagnoses (34). The same phenomenon has also been documented in other countries. "Alzheimer Europe", a non-profit organization, intervened, stressing that the triage procedures for access to sub-intensive and intensive care should be based on the individual prognosis of a patient and not on isolated criteria such as age, diagnosis or even the place the patient comes from (e.g. a social-health facility). The general ethical issue of triage for access to intensive care in conditions of insufficient availability has also been debated in the bioethical literature (51, 52).[16]

The last part of this report intends to provide some useful information for the management of some problems with ethical implications in the social-health care facilities in the current pandemic context, to guarantee, despite the complexity and difficulty of the operational solutions, the best possible protection of the dignity of the residents and full respect for their rights.

7.1.1. Communication and access of relatives/visitors to the health care facilities

In general, the involvement of family members should always be part of the life of the residents in the social-health care facilities, institutions that must always be open and accessible to the outside world and with which there must always be a vital exchange. During Phase 1 of the SARS-CoV-2 epidemic, the measures adopted to contain the spread of the contagion imposed the closure of the long-term care facilities to external visitors. This caused tensions and reactions of despair of family members who were denied the possibility of seeing and comforting their loved ones and, sometimes, they could not even get information about them. Many long-term care facilities throughout the country have managed to organize themselves to enable contact and feelings of closeness, albeit always in compliance with the distancing rules (e.g. by encouraging and facilitating telephone calls, video calls or even visits through windows or plexiglass screens or transparent plastic curtains (cuddle curtains) designed to allow protected contact of the hands or simple gestures such as a caress). Under the current legislation, each health facility decides independently which is the best method to protect their residents and operators and prevent the spread of the virus, according to the epidemiological situation and in accordance with the operational protocols of the health authorities. However, the measures should always be proportionate to the epidemiological situation and modifiable as the external and internal conditions change.

To date, there are no studies or data that can clearly be of guidance in making these choices and **the total suspension of visits by way of precaution to protect the health of residents and healthcare workers, should only be imposed if strictly necessary and also only for the duration of the critical circumstances**. As indicated in the aforementioned Circular of the Ministry of Health of 30 November 2020, **the facilities should always provide solutions for allowing visits to take place, albeit with safety precautions, in order not to weaken the emotional ties between the patients and their families and not cause additional suffering besides the isolation by preventing contact with family members; in order to facilitate safe access by visitors, it is recommended to adopt screening strategies by performing rapid antigen tests.**

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[16] In Italy, the Italian Society of Anesthesia, Analgesia, Resuscitation and Intensive Care (SIAARTI) contributed to the issue of tragic choices in providing access to Intensive Care Units (ICU) with its policy document on March 6, 2020 "Recommendations of clinical ethics for admission to intensive care treatments and their suspension, in exceptional conditions of imbalance between needs and available resources", which was followed on 22 October 2020 by a document, mentioned earlier, which was the result of the work of a joint committee of the Medical Federation (FNOMCeO) and SIAARTI set up with the aim of jointly starting a debate within the framework of medical ethics and evaluating the desirability of envisaging changes to the Code of Medical Ethics. The National Bioethics Committee, on its part, published on 8 April 2020 the opinion "COVID-19: clinical decision-making in conditions of resource shortage and the pandemic emergency "triage" criterion".

By exacerbating the separation between the inside and the outside of the facility, physical and social distancing exposes people with disabilities and also the elderly to a greater risk of perceiving such isolation as an abandonment by family members, acquaintances or friends. It is known that this situation can also have an impact on the effect of medical treatment, making it less effective or leading the patient to refuse medication which, in some cases, causes a sudden worsening of the prognosis. It is also worth pointing out that in some types of facilities there are people with specific forms of disability for whom contact with family members has a therapeutic effect, and it also motivates them to continue their rehabilitation process.

The adoption of general restrictive measures in residential healthcare and welfare facilities and above all when such measures led to the prohibition of visits by relatives and other external figures of reference, inevitably restricted individual freedom which the National Authority for the Protection of the Rights of Persons Deprived of Liberty monitors both as regards its formal legitimacy and concrete implementation, as well as for the impact they may have on the irrepressible scope of freedom of each person.

Monitoring through the reports received from family members and social actors, highlighted, in some cases, the fact that these restrictive measures were applied rigidly and extensively also after Phase 1 of the pandemic. The situations most frequently reported to the National Authority range from the refusal to allow visits by relatives, even where specific precautions could be used, to cases where access to the facility was allowed only exceptionally, e.g., for end-of-life cases, authorized exclusively by the internal health director. In some cases, such restrictive measures had to be applied because of the impossibility of implementing health safety protocols.

In some cases, delays in adapting the facilities to comply with the health safety protocols interrupted patient discharge even for the patients for whom leaving the facility was part of cognitive rehabilitation treatment and of a plan for the maintenance of self-determination skills. The National Guarantor deems it necessary to draw attention to the fact that these provisions - prohibition of visits by relatives as well as postponing patient discharge in a generalized and preordained manner - may have detrimental effects on the protection of the rights of the residents in these facilities. Consequently, the National Guarantor expressed its concerns to the Regions, that have exclusive competence over the matter, regarding the fact that respect for the rights of residents in these facilities was being disregarded and that it was necessary to take action in ways that would not undermine the protection of health. Extending confinement of the residents of long-term healthcare facilities when there are spaces that can be equipped for the prevention of contagion and when visit schedules can be arranged to ensure visits by relatives in full safety can be construed as a situation of *de facto* deprivation of freedom of the residents.

In this regard, it should be remembered that, in the acute phase of the emergency, both the DPCM of 3/11/2020 and the indications of the ISS contained in particular in the Report “Ad Interim Guidance for appropriate Support for People with Dementia” (2) promoted the possibility of allowing visits by family members, friends and other figures of reference to ensure continuity in emotional relationships albeit with the appropriate limitations associated with the adoption of anti-contagion measures. These provisions clearly pointed to a prudential attitude and not to a generalized prohibition.

On the other hand, in the opinion of the National Guarantor the restrictive measures adopted in a non-uniform manner by individual facilities, have not allowed family visits and have even hindered patient discharge. The adoption of prescriptions that were not previously assessed, and applied in a generalized way or to make up for organizational deficiencies, without a verifiable analysis of the possibility of other options such as the adoption of preventive devices and procedures, can undermine the freedom of residents, exposing them to the risk of a form of isolation that is not in line with the provisions of the national guidelines.

The communication of information about the clinical situation of a resident to relatives or friends of reference, especially when the person is SARS-CoV-2 positive, should be done in a timely manner and if possible daily, and should include information about all the actions that are necessary to prevent contagion, for example isolation of the patient, or hospitalization where necessary.

7.1.2. Information and consent to treatment

The ability to understand information and process it to reach the decision to express consent must not be understood as an "all or nothing" phenomenon, but needs to be contextualized every time. Unless proven otherwise, an elderly patient retains his capacity for self-determination which must be protected at all times, with the sole exception of cases of proven necessity.

Generally, it is the person involved who signs the contract for admission to a social health facility and accepts, even with implicit consent, that he/she accepts the care treatments being offered. For the more invasive procedures, on the other hand, the explicit consent of the interested party is always required although, as is known, in clinical situations in which the patient is temporarily unable to express his will, the doctor can provide indispensable and undeferrable care independently even in the absence of the express consent of the interested party, given the emergency of the situation. In the event of a decree appointing a support administrator, pursuant to Law no. 6 of 9 January 2004, the latter has the task of assisting the person also in health care decisions, in accordance with the powers conferred on him in the decree.

In such cases, family members are not recognized as having real decision-making power, nevertheless they should always be adequately informed on the evolution of the clinical conditions of the patients, of the choices that need to be made, even with regard to the measures to be adopted in order to prevent the spread and / or the treatment of the COVID-19 disease. **As a general principle, the rule enshrined in paragraph 8 of Article 1 of Law no. 219 of 22 December 2017: "Communication between doctor and patient is part of the treatment". It is therefore necessary, even in the course of a pandemic, to communicate information in a clear and understandable manner and to make provision, where possible, for moments when the professionals of the facility can meet the residents / family members for an exchange of information and to draw up treatment plans that are accepted and agreed.** The presence of nurses in the care delivery system is important because of the function they have of providing support and enabling the patient to understand the therapeutic decisions included in the treatment plan.[17]

Article 5 of Decree-Law no 1 of 5 January 2021 introduces provisions regarding the "manifestation of consent to vaccination against the COVID-19 virus by incompetent individuals admitted to healthcare facilities" particularly in the cases in which the person receiving care is unable to express his/her free and informed consent and does not have legal guardians for protection and representation, or when the latter are unavailable in a short time (53).

7.1.3. Legal protection

Due to the residents' psychophysical conditions, it is not infrequent that not only are they supported at the emotional and operational level, but also at the legal level by support figures. In particular, the guardian in cases of incompetence (Article 414 of the civil code), the custodian, for people whose incompetence is less serious and less undermined (Article 415 of the civil code) and, in pursuance of the aforementioned Law no. 6 of 9 January 2004, the support administrator (Ads) (Articles 404 *et seq*. of the Civil Code). While the powers of the guardian and custodian, also over matters of personality rights such as the right to health,

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[17] *See* Code of Ethics for Nurses, Article 17.

are established by law, the powers of the support administrator are from time to time established by the decree appointing the judge supervising cases concerning guardianship.

All these figures are envisaged, as protectors of the rights of the patients, even for the residents of social and healthcare facilities within which there are additional figures that protect the rights of the elderly: their involvement in decision-making processes, as well as their being constantly informed, must be guaranteed by the organization of the facility, and they must be ensured the visiting and communication rights mentioned above. **Communication between the resident of a healthcare facility and his/her representative (guardian, and especially the custodian and the support administrator, since they assist elderly people who have not totally lost their ability to take care of their interests), must be appropriately and effectively ensured.**

It is important to underline that the support administrator (Ads), in particular, does not only take care of bureaucratic issues but performs a very important function, whose primary objective is to ensure respect for the person's self-determination. The support administrator is in fact called upon to support his/her client, even in the case of residents in social-health facilities, with reference to their specific needs and to reconstruct their alleged wishes and desires.

On the basis of Article 406 of the Italian Civil Code, the health and social services, directly involved in the providing care and assistance have the responsibility of putting in place procedures for requesting a support administrator should this be deemed necessary. The process of appointing a support administrator can, however, also entail very long waiting lists. To overcome this criticality, during the first phase of the pandemic, several Italian courts took action to streamline procedures by working in close connection with the social and health services, in order to ensure legal protection also in health emergencies.

The implementation of simplified procedures, in cases of urgency and of the undeferrable protection of the beneficiary, should be made possible throughout the national territory. In the cases where support administrators have already been appointed, they must be regularly informed about the general conditions of their clients residing in the facilities and be put in a position to interact regularly without prejudice to the will of their clients.

7.1.4. Isolation and quarantine measures

Many social and health facilities do not have the appropriate spaces to ensure that patients be put in isolation and this has certainly been a critical issue particularly during the acute phases of the pandemic. The ISS has issued specific organizational guidelines which include, among other things, the need to isolate positive SARS-CoV-2 patients in order to prevent the spread of the infection. As already pointed out above, the vulnerability of older people could be aggravated by sudden isolation and deprivation of all forms of relationship. **It is therefore necessary that, especially in cases of isolation, in addition to ensuring the continuity of high standards of care, adequate daily communication time with both family members and care-givers be guaranteed, adopting all the relevant measures that are reasonably feasible to make such contact possible because it is absolutely crucial at the human and also at the health level.**

Family members, legal representatives and / or support administrators should be promptly informed of the measures put in place to prevent contagion, and at least daily communications with the residents of the facilities should be guaranteed for the entire duration of the isolation period.

7.1.5. Performing swabs and other diagnostic tests

Taking swabs of the residents of the social-healthcare facilities and other diagnostic tests may be obligatory in pursuance of regional provisions and are to be performed in accordance with the prescriptions of the health authorities. Even though this is not a risky or particularly invasive treatment, it can nevertheless be disturbing and even traumatizing for people with certain disabilities. Some residents may not tolerate the test or be scared and uncooperative.

It is necessary to pay particular attention to these situations, carrying out, where possible, all the procedures in a reassuring environment, through known personnel, taking care of the communication and information aspects in such a way as to reassure the uncooperative person, avoiding the use of force and / or traumatizing behaviour, opting for the use of simulations and explanations, and where possible even postponing the execution of the test. In no case should restraint be used to carry out these procedures.

7.1.6. Hospitalization and access to intensive care

During the first pandemic wave, various social-health facilities found it difficult to transfer COVID-19 patients to hospitals, and it was not possible for them to bring in specialized doctors to make up for the impossibility of hospitalizing the patients in need.

The patients in long-term care facilities have the full right, like everybody else, to be transferred to the hospital if they need emergency or intensive care. If this is not immediately possible, or is considered not possible to avoid aggravating the risk of spreading the infection, it is important that family members be promptly informed and that the decision not to transfer the patients is communicated and documented in their medical records. **With reference to access to Intensive Care, it is ethically relevant that the criteria for allocating health resources in conditions of scarcity are made explicit and disclosed. Transparency implies that family members are promptly informed about the criteria that are followed.** As underlined by the SIAARTI-FNOMCeO document of 30 October 2020, it is necessary to resort to “rigorous, explicit, concurrent and integrated criteria, assessed always on a case-by-case basis, such as: the severity of the clinical presentation, presence of comorbidities, previous functional conditions, the impact of the potential side effects of intensive care, knowledge about previous expressions of will as well as biological age, which must never be a prevailing factor”.

7.1.7. Approach to a SARS-CoV-2 patient with behavioural changes

Social-health facilities should have standard operating procedures for the isolation of residents who have behavioural changes (e.g., “wandering”) as a result of cognitive impairment. Even where it is necessary to isolate the residents to prevent the spread of the virus, in accordance with the provisions and indications of the health authorities, behavioural interventions can be adopted, but physical restraint must not be used (36).

7.1.8. Palliative care and end of life

Under no circumstances should sick people be abandoned: even when they are approaching the end of their life, they must always be accompanied by having recourse, where clinically indicated, to palliative care which was officially introduced by Law no. 38 of 15 March 2010 in the Essential Levels of Care (LEA) that everyone in our Country is entitled to, together with pain therapy (Article 1). The same principle must also inspire the ethical and professional behaviour of doctors in accordance with the Code of Ethics mentioned several times above.[18] An adequate treatment approach combines therapeutic treatment with relational care provided uninterruptedly and started as early as possible. According to the WHO, palliative treatment is an approach that improves the quality of life of the patients and of families who are at grips with the problems

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[18] *See* Article 39 Code of Medical Ethics, 2014.

associated with life-threatening diseases, through the prevention and treatment of suffering and through the timely identification and treatment of other physical, psychological and spiritual problems.

Both in the case of simultaneous care[19] and of palliative care, the palliative care team operating at home should also be able to collaborate with the medical and nursing staff of the long-term care facilities for the management of COVID-19 positive patients who require palliative care. To this end, however, it is necessary to rethink some of the aspects of home palliative care models, providing the teams operating at community level with adequate training, organization and the necessary Personal Protective Equipment (PPE) that is required. In particular, it is recommended to create teams dedicated to infected patients, in order to protect non-COVID-19 patients and their families from any risk of infection transmitted by the healthcare workers.

Particularly in the long-term healthcare facilities, it is recommended that palliative care and a careful evaluation of physical, mental and spiritual symptoms and constant monitoring be provided as early as possible and that therapeutic reviews be carried out frequently.

In the presence of one or more refractory symptoms, deep and continuous sedation must be provided when death is expected to occur within a few hours or a few days and when patients are affected by chronic diseases with a fatal outcome. In such circumstances it is recommended that the professionals involved in delivering treatment cooperate closely with the doctor and that the nurse provide moral support to family members.[20]

7.1.9. IT systems and data flow

Law no. 77 of 17 July 2020 provides for the adoption of the “Guidance for the management of the epidemiological emergency in facilities for elderly people with disabilities and other subjects in fragile conditions” by the Technical-Scientific Committee, provided for in ordinance no. 630 of February 3, 2020 issued by the Head of the Civil Protection Department.

In addition, it is emphasized that the implementation of adequate systems for managing and monitoring data flows in residential care facilities constitutes a primary objective to be pursued by the national system, with the awareness that epidemiological knowledge represents the fundamental prerequisite for any strategy drawn up to respond to an emergency situation. Furthermore, transparency is an ethical criterion of reference in relation to the production and dissemination of scientific data which, also in the health sector, must always be as truthful, complete and up-to-date as possible.

As part of the reflection on the problems of Italian long-term care facilities during and after the COVID-19 pandemic, the Italian Society of Geriatrics and Gerontology (SIGG) has underlined the importance of carrying out, on a regular basis, a computerized multidimensional geriatric assessment (MGA) and to use a uniform documentation system that is compatible with the system used in hospitals and at home; in this way it is possible to have a single medical record that facilitates the continuity of care and allows the collection of data that are useful for applied research in the sector (38).

The adoption of the Electronic Medical Record (CCE) can promote greater quality and security of medical information and ensure that structured information can be rapidly shared among authorized health professionals even outside the facilities. The use of these systems, however, unquestionably requires compliance with all the principles and guarantees designed to protect patients’ data protection rights.

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[19] Early palliative care, when administered in an integrated manner with other treatment, constitutes a model called “simultaneous care”.

[20] *See* Article 24 of the Code of Ethics of Nurses, 2019.

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Rapporti ISS COVID-19 (ISS COVID-19 Reports)

ISS COVID-19 Reports are mainly addressed to healthcare professionals to cope with different aspects of the COVID pandemic. They provide essential and urgent directions for emergency management and are subject to updates. All reports have an English abstract.

The complete list is available at https://www.iss.it/rapporti-COVID-19.

Some reports (highlighted below) are also translated in English and are available at
https://www.iss.it/rapporti-iss-COVID-19-in-english

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