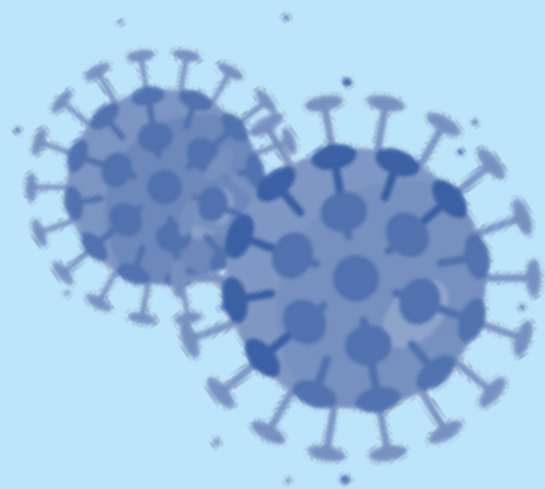
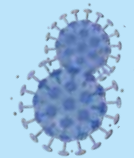
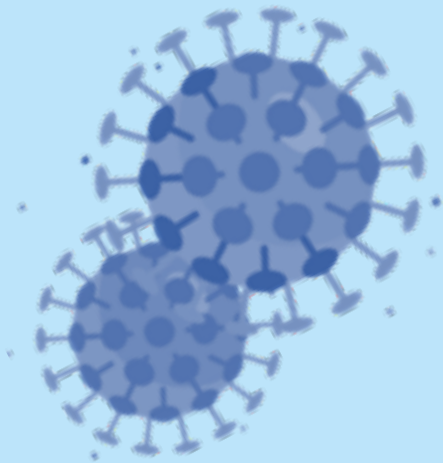
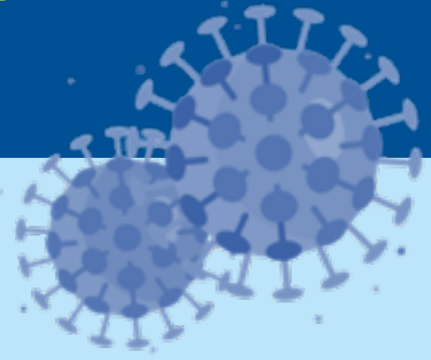
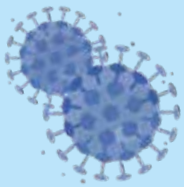


MINISTRY OF HEALTH REPORT ON ETHICAL ISSUES IN PANDEMIC SITUATIONS: SARS-CoV-2

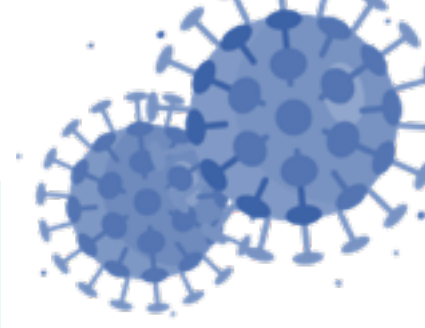


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MINISTRY OF HEALTH REPORT ON ETHICAL ISSUES IN PANDEMIC SITUATIONS: SARS-CoV-2

CONTENTS

EXECUTIVE SUMMARY	2
CONCLUSIONS.....	2
RECOMMENDATIONS.....	3
1. INTRODUCTION	5
2. VIRAL INFECTION TESTING: RIGHTS AND DUTIES	5
3. PRIORITIES IN THE ADMISSION AND TREATMENT OF PATIENTS AND SUSPECTED CARRIERS	6
4. CRITERIA REGARDING ICU ADMISSION AND USE OF MECHANICAL VENTILATION FOR PATIENTS WITH SEVERE SYMPTOMS	6
5. DECISIONS ON INTENSIVE CARE IN VULNERABLE PATIENTS	8
6. AVAILABILITY AND RECRUITMENT OF HEALTHCARE STAFF	9



EXECUTIVE SUMMARY

The Task Force under the aegis of Spain's Ministry of Health that has drafted the present report on ethical issues involved in pandemic situations due to SARS-CoV-2 considers that this pandemic -the magnitude of which is as yet unmeasurable, given how quickly and easily it is being spread- is putting the healthcare systems of every country to the test, and is posing a considerable number of extremely complex ethical problems, **which in many cases cannot be addressed decisively and definitively**. There also seem to be significant difficulties in obtaining the necessary resources, both material (essential infrastructure and medical devices) and human.

Our aim in presenting this document is to offer a series of conclusions and recommendations to help decision-making in applying treatment and care measures to patients affected by Covid-19 (the disease caused by SARS-CoV-2), within a pandemic situation marked by limited resources.

Bearing in mind that these recommendations may be revised as necessary or advisable in view of ongoing developments (and aware that the criteria are not set in stone), the purpose of these recommendations is for the competent authorities to disseminate them and support them in the manner they deem most appropriate.

CONCLUSIONS

- 1st The SARS-CoV-2 pandemic is causing a large-scale **health crisis** due to the number of people infected, who pose a risk to the rest of the population, and due to the large number of people who are falling ill and need healthcare—and very often, hospitalization and critical care. This **requires** a variety of **extraordinary measures** aimed at the entire population, and in particular, at those affected by the virus.
- 2nd Under Spain's current state of emergency, general interests involving public health and the common good may clash with individual interests, and require **restrictions** on the latter interests in favour of the former -even if such restrictions may have a varying impact on fundamental rights and public freedoms- provided that, as per our Constitutional Court, such restrictions do not compromise the essential content of those rights and freedoms. Protecting the fundamental rights and public freedoms of each citizen is a *prima facie* duty, which may clash with the *prima facie* duty to protect the same rights and freedoms of all other citizens; therefore, in specific cases there is a need to **prioritize**.
- 3rd Any measures adopted will be governed by the **principles of equity, non-discrimination, solidarity, justice, proportionality and transparency**, among others. In this regard, it is also essential to continually (re)evaluate the criteria adopted -whether guidelines or instructions- in light of any changes that may take place in the evolution of the pandemic.
- 4th Resource shortages, whether temporary or long-lasting, may require **establishing criteria for prioritizing** access to the resources available. Prioritization will be based on criteria that are objective, generalizable, transparent, public and consensus-based, notwithstanding the possibility of also assessing the unique and individual characteristics of each person who has fallen ill with the virus.
- 5th There can be no delay in **designing a post-lockdown healthcare scenario, as well as the gradual return to the situation of social normalcy** that existed before the outbreak of the SARS-CoV-2 pandemic, taking all necessary precautions to prevent a second wave of infections.



6th As a consequence of declaring the state of emergency, the Government of Spain, through its Ministry of Health, has the political responsibility, with full democratic legitimacy, to adopt unifying and constructive -and, as the case may be, reassuring- criteria, guidelines, recommendations and decisions aimed at healthcare and non-healthcare professionals, at patients, and, in short, at society as a whole.

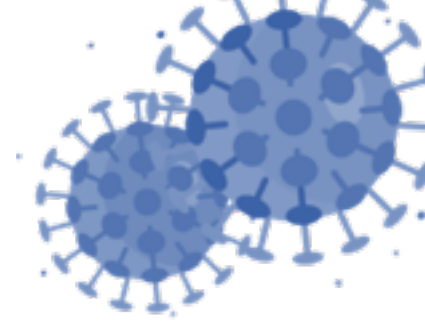
RECOMMENDATIONS

- 1st** Imposing the prevalence of general interests over individual interests in a pandemic situation, which could involve restricting or suspending different fundamental rights, must not impinge upon the essential content of said rights, and is subject to the principles of equity, non-discrimination, solidarity, justice and proportionality.
- 2nd** In the framework of the constitutional right to the protection of health (article 43 of the Spanish Constitution), access must be guaranteed to diagnostic tests, in particular for potentially infected persons, and if sufficient test units are available, said tests will be mandatory for potentially infected persons, in the overriding interest of public health.
- 3rd** It is a moral imperative to provide medical professionals with clear and simple guidelines, which will not become a trap for decision-makers, leading them to mistakenly suggest or promote automatic, routine or depersonalized decisions.
- 4th** These guiding principles will have to follow criteria that are objective, generalizable, transparent and public. But at the same time, it will be necessary to combine the general framework for such criteria with a thorough reflection on the situation and circumstances of each particular patient, and assessing -within that general framework of guiding principles- the uniqueness and individuality of each person affected.
- 5th** As general applicable criteria, without going into their technical and clinical implications, we have considered the following:
 - 1st** Non-discrimination for any reason beyond the patient's clinical situation and their objective, evidence-based expectations of survival.
 - 2nd** The principle of maximum benefit in saving human lives, which must be made compatible with continuing the treatment initiated with each individual patient.
 - 3rd** Severity of the patient's condition, providing evidence of the need for intensive care, e.g. treatment in intensive care units (ICUs) and access to mechanical ventilation.
 - 4th** Objective expectations of the patient's return, in the short term, to their previous state of health, taking into account the existence or absence of any serious concomitant pathologies that would point to a fatal prognosis (such as terminal illness with a prognosis of irreversibility, or irreversible coma), even though this could involve additional clinical care.
 - 5th** Order in which patients come into contact with the healthcare system; namely, the date on which they were admitted to the centre in order to objectify the starting point of the patients for whom the health care system is responsible. However, this criterion must never prevail over the others, because it could lead to preference for patients whose condition is less severe and therefore less urgent, or for patients with no favourable prognosis for recovery.
- 6th** Resorting to such prioritization criteria will only be legitimate when health professionals have exhausted all the existing possibilities for accessing the necessary healthcare resources and for optimizing the use of those available.



- 7th** The medical team responsible for the patient will be responsible for weighing the implications of their decisions; therefore, it is not appropriate for a third party to impose their own criteria, unless said third party is also involved in caring for that patient. It is recommendable to request or obtain guidelines, for example, from the hospital's healthcare ethics committee, whenever possible in the time available, or from other medical staff with greater experience and maturity, maybe even as part of an ad hoc committee.
- 8th** The care and dedication that must be given to patients who are seriously ill due to SARS-CoV-2 should not lead to any neglect of other patients with similarly serious diseases not caused by the virus.
- 9th** Public authorities have the obligation to ensure to the utmost the planning of healthcare resources. Not providing care to a patient due to a lack of said resources at a given healthcare centre will be unacceptable if there are vital medical devices idle at other centres. In line with the principles of institutional solidarity and of justice, optimized planning regarding the use of these healthcare resources must be guaranteed at the local, regional and national levels.
- 10th** What must be underscored here is the absolute proscription on using discrimination-based criteria for any reason when prioritizing patients in these kinds of situations. In this regard, excluding patients from access to certain healthcare resources or to certain treatments—for example, exclusively on the grounds that they are elderly—is discriminatory and, therefore, contrary to the very essence of our rule of law (article 14 of the Spanish Constitution). That is to say, in the event of extreme shortages of healthcare resources, elderly people must be treated under the same conditions as the rest of the population, i.e. following the clinical criteria for each particular case. Accepting discrimination of this kind would mean giving less value to certain human lives due to their life-cycle stage, contradicting the very foundations of our rule of law, in particular our recognition of the equal intrinsic dignity of every human being.
- 11th** Arguments like these are applicable for the purpose of proscribing any kind of discrimination for reasons such as any form of disability, or discrimination that may be suffered by certain groups of children.
- 12th** The public administrations must seek to make housing solutions available to healthcare professionals for the duration of the pandemic, to address the needs of those professionals who have gone to work at other healthcare centres due to the pandemic, and of those professionals who, because they live with people from vulnerable groups, may prefer such an option to prevent the risk of infecting their loved ones.
- 13th** The availability of certified personal protective equipment (PPE) must be guaranteed to all professionals on the front lines of the fight against the SARS-CoV-2 pandemic (e.g. professionals at healthcare centres, law enforcement agents and the military).
- 14th** Healthcare service managers must plan healthcare professionals' working hours in the current context of the SARS-CoV-2 pandemic so that, while guaranteeing the best possible care for patients, these professionals are allowed appropriate levels of rest, thus ensuring the continuity of care.
- 15^a** Appropriate psychological support must be guaranteed for healthcare professionals in this context, to prevent or minimize the consequences of burnout in the short and medium term.

As may be required by healthcare needs or by the possible existence of healthcare staff on sick leave (basically due to the impact of the SARS-Cov-2 pandemic on the healthcare professionals themselves), there must be a policy for recruiting healthcare professionals among groups such as retired staff, medical residents, unemployed health professionals, or non-EU professionals awaiting recognition of their qualifications. In particular, the option of taking on retired staff must be considered with the utmost caution, to prevent the risk of infection for people who, given their age, may belong to a vulnerable group.



All staff must be guaranteed appropriate training for the healthcare duties they are to carry out. In many cases this will require certain specific prior training.

1. INTRODUCTION

The emergency situations stemming from the pandemic caused by the SARS-CoV-2 virus encompass a wide range of what in some cases are highly serious individual and collective problems affecting society as a whole. These problems concern many areas—such as healthcare (individual health and life vs. public health), mobility, employment, the economy and finance—and are, in turn, triggering secondary negative impacts.

Our starting point is that ethics cannot be set aside during a public health catastrophe such as the SARS-CoV-2 pandemic. On the contrary, in a crisis it is more important than ever to articulate ethical guidelines for extraordinary circumstances and to prevent decision-makers from failing to consider professional standards when under pressure. Similarly, in this tension between general and individual interests, **the possible imposition of some restrictions on citizens' fundamental rights and public freedoms** must be accepted, but only when subject to the **principle of proportionality**, and without jeopardizing the core or essential content of such rights and freedoms, as has been underscored by Spain's Constitutional Court.

Furthermore, we consider it a given that resolving the severe, difficult, and problematic, even conflictive, situations that arise during pandemics—and in particular those situations caused by the SARS-CoV-2 virus—is a task that **must not be left exclusively in the hands of individuals, or of professional or scientific groups or bodies**. Rather, it is a task that requires the **involvement and commitment of society as a whole**, through an interdisciplinary assessment that incorporates, moderates and completes the views of different sectors, while continuing to take their formal positions into account. For this reason, we have consulted a variety of reports and opinions from within Spain, such as those of the Spanish Society of Intensive and Critical Care Medicine and Coronary Units (SEMICYUC), the General Council of Official Medical Colleges (CGCOM), and Spain's Bioethics Committee; as well as other European and international advisory bodies, and other national and international scientific societies.

In our case, in this current state of emergency, it is the Government of Spain, through its Ministry of Health, which has the political responsibility, with full democratic legitimacy, to adopt unifying and constructive —and, as the case may be, reassuring— criteria, recommendations and decisions aimed at the affected healthcare and non-healthcare professionals, at patients, and, in short, at society as a whole.

In this Report we address the problematic implications for healthcare, in particular in the fields of prevention and clinical care. We also tackle the issue of how to safeguard fundamental rights, with a particular focus on the **most vulnerable groups**, taking into account such aspects as justice, duty of care, and the administration of resources.

2. VIRAL INFECTION TESTING: RIGHTS AND DUTIES

As regards access to diagnostic tests for the SARS-CoV-2 virus, **there is still an insufficient number of these tests**.

This is the situation faced by the health professionals caring for infected patients, as well as other professionals and employees who may also have had contact with such patients (members of the different national, regional and local police corps, and armed forces personnel) or with individuals at greater risk (e.g. care home staff and staff at other centres providing services to older people and dependent adults, staff at children's homes, and



those in prisons), and by those who may have been in close contact with other people identified as asymptomatic carriers infected with the virus. **It is not easy to establish a hierarchy of priority for these groups while test kits remain in short supply, but the order in which they have been listed above could serve as a guideline,** with all remaining members of the general public wishing to be tested coming last.

Going further still, from the moment at which these tests become widely available, the civil right to health protection could become a duty, given the crucial general interest at stake in protecting public health, provided that the limits defined by adherence to the principle of proportionality are respected.

In the light of a positive test result (and its confirmation, in the event of any doubt), home isolation, or admission to a health centre or another secured place, could be imposed, as applicable.

3. PRIORITIES IN THE ADMISSION AND TREATMENT OF PATIENTS AND SUSPECTED CARRIERS

The duty of care incumbent upon health professionals flows from the constitutional right to health protection (article 43 of the Spanish Constitution) corresponding to all Spanish nationals and to all foreign nationals resident in Spain (article 1.2 of General Health Act 14/1986 of 25 April). However, mass demand and the scarcity of resources with which to meet it, however provisional this may be, entails a reduction in the effective enjoyment of that right, and calls for priority to be given to those individuals who are potentially at the greatest risk of exposure to infection, as well as those already infected.

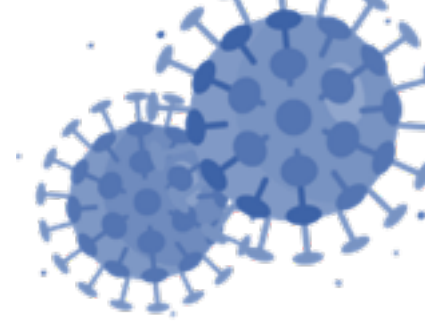
In an overwhelming public health emergency, many patients could require the use of the available ventilators, but in a disaster on the scale of the SARS-CoV-2 pandemic, there may not be enough ventilators to meet existing demand, even when health centres have been equipped with them. And even where the necessary ventilators are available, there may be a shortage of staff trained in their use and thus able to provide care to the most seriously ill patients.

Consequently, if the **rapid spread of a disease causes certain hospital services to be overwhelmed** (or demand for certain medicines or medical devices outstrips the available supply) and there is a shortage of staff to care for all those affected, **a hierarchy of priorities must be established.**

4. CRITERIA REGARDING ICU ADMISSION AND USE OF MECHANICAL VENTILATION FOR PATIENTS WITH SEVERE SYMPTOMS

Health professionals directly involved in the care of these patients—already under considerable strain due to the excessive workload caused by the extreme seriousness of the situation and the shortage of vital resources—are faced with conflicts placing them under extraordinary additional pressure. In such situations, the conflict of interests is not, primarily, between public health and fundamental rights, but between the health and, most probably, the life of different patients waiting to receive vital care. It is a true conflict or collision of duties (the duty of care owed to different patients awaiting treatment when it is not possible to provide treatment to them all), in principle of the same or similar importance.

Therefore, these health professionals cannot, and must not be required to, take sole responsibility for identifying the appropriate criteria for making decisions that could lead to the postponement of or exclusion from vital treatment for certain patients, whose prognosis would then foreseeably be fatal. Once again, there is a **tension**



between utilitarianism (obtaining the maximum benefit for those patients who receive treatment and recover, to the detriment of those whose care is postponed) **and humanitarianism** (every critically ill person deserves to receive the vital care that they need). Therefore, it is a moral imperative to **provide clear and simple guidelines, which should not become a trap for decision-makers** that could lead them to mistakenly suggest or promote automatic (or even purely arithmetic), routine or depersonalized decisions.

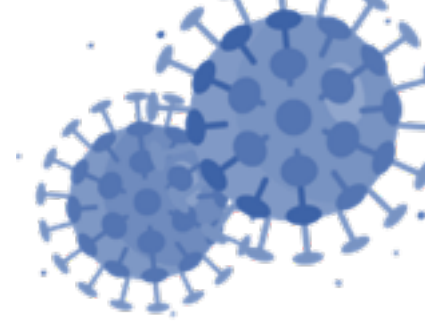
These guiding principles must respond to **criteria that are objective, generalizable, transparent, public, and consensus-based**. But at the same time, it will be necessary to combine the general framework for such criteria with a thorough reflection on the situation and circumstances of each particular patient, and to assess—within that general framework of guiding principles—the uniqueness and individuality of each person.

We consider the **following general criteria to be applicable**:

- 1st Non-discrimination for any reason beyond the patient's clinical situation and their objective expectations of survival.**
- 2nd The principle of maximum benefit in saving human lives, which must be made compatible with continuing the treatment initiated with each individual patient.**
- 3rd Severity of the patient's condition which evinces the need for intensive care**, e.g. treatment in ICUs with access to ventilators (or, at the very least, access to ventilators).
- 4th Objective expectations of the patient's return, in the short term, to their previous state of health**, taking into account the existence or absence of any serious concomitant pathologies that would point to a fatal prognosis (such as terminal illness with a prognosis of irreversibility, or irreversible coma), even though this could involve additional clinical care.
- 5th Order in which patients come into contact with the healthcare system; namely, the date on which they were admitted to the centre**, in order to objectify the starting point of the patients for whom the health care system is responsible. However, **this criterion must never prevail over the others**, because it could lead to preference for patients whose condition is less severe and therefore less urgent, or for patients with no favourable prognosis for recovery.

Moreover, we consider that these criteria for deciding which patients with severe symptoms should be placed in ICUs or be put on ventilators (which, in practice, entails excluding certain people from the treatment they need) can only legitimately be used when all possible options for obtaining the necessary healthcare resources and optimizing the use of those available have been exhausted. In this regard it must be stressed that there are **alternative treatments to the invasive mechanical ventilation** provided in ICUs, even in cases in which this does not appear to be indicated (e.g. admission to hospital in a non-ICU ward, delivering oxygen through nasal cannula, positioning the patient face down, adjuvant medications).

This means that the public authorities are obliged to **ensure the utmost planning of healthcare resources** (including vital care, the need for hospitalization for treatment and observation, as well as outpatient healthcare resources such as those located at primary care centres, where it is also possible for situations to arise in which treatment cannot be provided due to a lack of planning). It is therefore not admissible for there to be a failure to provide care to patients due to a lack of resources at certain health centres when these same resources are standing idle at other centres. Optimization in the planning of these healthcare resources must be guaranteed at the local, regional and national levels; institutional solidarity is also of key relevance in this area.



In situations as serious as the current pandemic crisis, it is fundamental not to forget that the entire process has a highly significant emotional impact which will probably not surface immediately, but after a period of time, which may vary from person to person. From an ethical perspective, health professionals must take this into account throughout the process, providing and adapting the necessary information as the case may be without emotionally overwhelming the patient, and without minimizing or overstating the relevance of the clinical circumstances.

When it may be applicable to exclude a patient from intensive care, including access to mechanical ventilation, **there is no clear consensus as to whether this decision should be made solely by the physician or physicians responsible for the patient's care, or whether it must be a collective decision, made by an ad hoc medical committee.** The involvement of **healthcare ethics committees at hospitals** in making decisions of this nature, or to provide guidelines on how to act in this specific scenario, has also been proposed.

The **medical team responsible for the patient** will be faced with the implications of their decision, and therefore it is not appropriate for a third party to impose their own criteria on the team, unless they are also involved in that patient's care. It is advisable that guidelines be requested and received, for example, from the **healthcare ethics committee of the same hospital**, provided that this is possible in the time available, or from **other physicians with greater experience and maturity, perhaps even forming an ad hoc committee.**

Finally, we would like to underscore that the care and dedication owed to those patients who are seriously ill due to SARS-CoV-2 should not lead to any neglect of other patients with similarly serious diseases not caused by the virus, which adds a further element of conflict to the situation. In such cases, infectious patients are usually kept separate from other patients requiring intensive care.

5. DECISIONS ON INTENSIVE CARE IN VULNERABLE PATIENTS

Within the debate regarding criteria on the allocation of scarce treatment resources during a health emergency situation, both in the media and in different scientific documents and forums, one issue has been the possibility of resorting to criteria such as **the patient's age to discriminate against certain population groups** when deciding on access to these resources in extreme situations of obvious shortages. This is particularly relevant in the SARS-CoV-2 pandemic, given the lack of ICU beds (and particularly of ventilators) to cover the total existing need in the entire population.

Highly relevant here is the **absolute proscription on using discrimination-based criteria** for any reason in order to prioritize patients in such contexts. In this situation, excluding patients from access to certain care resources or certain treatments (e.g. applying such a limitation to everyone over 80 years old) is contrary—due to being discriminatory—to the very foundation of our system of rule of law (article 14 of the Spanish Constitution). Therefore, in a situation of extreme scarcity of treatment resources, older patients must be treated under the same conditions as the rest of the population, i.e. following clinical criteria on a case-by-case basis. This means that, hypothetically and to the extent that the scarcity of basic resources makes it impossible to cover the needs of the entire population, the criteria specified above for ICU admission and for the use of ventilators in patients with severe symptoms will be applied to older patients under the exact same conditions as for any other patient. **What is not acceptable under any circumstances is to rule out access to such resources to everyone over a certain age *ex ante*.**

Accepting discrimination of this kind would mean giving less value to certain human lives due to their life-cycle stage, contradicting the very foundations of our rule of law, in particular our recognition of the equal intrinsic dignity of every human being.



The same line of reasoning should be applied to **proscribing any other kind of discrimination** in access to scarce treatment resources during a pandemic due to such motives as **disability of any kind**. Moreover, special attention must be devoted to avoiding discrimination in this context with regard to the **children in the most vulnerable situations** (e.g. children who have been abandoned by their families, unaccompanied foreign minors). As regards children, the medium-term impact on their physical and mental health, due to forced confinement during the state of emergency, must also be underscored.

6. AVAILABILITY AND RECRUITMENT OF HEALTHCARE STAFF

The situation described above, of maximum stress on the resources of many hospitals across Spain due to the SARS-CoV-2 pandemic, together with the fact that there is a large proportion of infected health professionals who must be separated from their units for a certain period of time, forces the consideration of **recruiting additional health staff**.

As much as possible, such a measure—despite its exceptional nature, given the conditions of extreme urgency and need in which it is carried out—must be provided with **maximum guarantees regarding the qualifications of the staff hired in this manner** with regard to taking on the care duties that they will have to perform.

Here, documents such as the *Contingency Plan for Intensive Care Services during the COVID-19 Pandemic* stipulate relevant measures for optimizing staffing and ensuring the maximum suitability of professionals being hired to address these new healthcare needs and the fact that staff are on sick leave due to having been infected. These measures include creating a **list of staff specialized in critical care** (which could include those who are unemployed, recently retired, working in a different area, non-EU professionals awaiting the recognition of their qualifications, etc.), and creating **lists at each hospital of other health staff or residents from other specialities who could be able to provide care for less severe patients**. Similar measures could apply to the possible recruitment of new **nurses and auxiliary nurses**. These provisions must also be set forth within the different Autonomous Communities (which in Spain are responsible for their own regional health systems) and the National Health System.

One of the options that has been repeatedly proposed is that of hiring **retired health professionals** to address the scarcity of staff that could occur in the course of the SARS-CoV-2 pandemic. As regards this option, which could be the most appropriate from the viewpoint of training and performance, a possible objection is that the existing studies seem to indicate an increase in the risk of infection (as well as lethality) from SARS-CoV-2 as people get older. Based on the above, **it is not advisable to expose such retired personnel to front-line care duties that involve a high risk of contagion**. It could be acceptable for them to carry out different duties, in order to free up staff resources for other treatment areas.

Moreover, guarantees must be put into place for the staff specifically recruited due to the SARS-CoV-2 pandemic to receive appropriate training for taking on the professional duties to be assigned to them.

Finally, it is crucial to **ensure adequate planning at the regional level of the recruitment processes for health professionals**, proceeding to an equitable distribution of human resources based on the needs of each region. Quality healthcare must be guaranteed across the entire country.

We cannot end these reflections and recommendations without acknowledging that the pandemic we are currently suffering has contributed to reaffirming **core values of the people of Spain: solidarity, altruism, empathy, and responsibility**, reflected in the professionals who are taking care of our health, our safety, and ensuring the maintenance of basic services and the availability of essential products, values complemented by the self-discipline of the entire population.



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