Brazilian Society of Bioethics (SBB) RECOMMENDATION No. 01/2020

It addresses fundamentals and ethical aspects in coping with the COVID 19 pandemic in Brazil, including the allocation of resources and the equal use of health technologies. It advocates the protection of the most vulnerable and the indispensability of the Unified Health System (SUS), the right to access the best treatment for all and equal access to all ICU beds, public and private. It recommends principles for defining parameters to be followed in a situation of insufficiency of these.

The **BRAZILIAN SOCIETY OF BIOETHICS,** a civil association of national scope, founded in 1995, in accordance with its statute, which provides, among other purposes, the search to bring together people from different backgrounds, interested in fostering the discussion and dissemination of Bioethics, as well as providing subsidies for the implementation of policies, programs and normative production related to bioethical themes;

CONSIDERING that respect for human dignity must be the basis for decision-making and health conduct without any distinction that could devaluate and/or discriminate socially vulnerable persons, communities or groups;

CONSIDERING human rights, notably the right to life, health, privacy, equality, which stem from respect for human dignity;

CONSIDERING the necessary reflections on public health and the right to health in a context prior to the pandemic; on the right to access to diagnosis and health care; on the ethics of the indication and maintenance of self-confinement and the guarantee of access to sufficient financial resources for the citizen; on adequate public health funding to address emergencies; the need to establish measures to ensure access to intensive care for all who need them and to mitigate the causes that can lead to insufficient hospital beds; the need to respect the rights of patients and health

professionals; and on the essential role of Bioethics as a reflection applied to the dilemmas to be faced;

CONSIDERING the Universal Declaration on Bioethics and Human Rights (DUBDH) [1] which aims, among other aspects, "to provide a universal structure of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of Bioethics; guide the actions of individuals, groups, communities, institutions and corporations, public and private; to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms; to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole; to promote equitable access to medical, scientific and technological developments, as well as the greatest possible flow and the sharing of knowledge related concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries"; [2]

CONSIDERING the principles of DUBDH, which are Human Dignity and Human Rights; Sharing of Benefits; Autonomy and Individual Responsibility; Consent; Persons without the Capacity to Consent; Respect for Human Vulnerability and Personal Integrity; Privacy and Confidentiality; Equality, Justice and Equity; Non-Discrimination and Non-Stigmatization; Respect for Cultural Diversity and Pluralism; Solidarity and Cooperation; Social Responsibility and Health; Sharing of Benefits; Protecting Future Generations; and Protection of the Environment, Biosphere and Biodiversity;

CONSIDERING the recognition of the "right of every person to enjoy the highest possible level of physical and mental health", as provided by the International Covenant on Economic, Social and Cultural Rights of the United Nations - UN, 1966 and of which Brazil is signatory[3];

---

[1] Unesco. Universal Declaration on Bioethics and Human Law. Adopted by acclamation on October 19, 2005 by the 33rd session of the General Conference. Available in http://fs.unb.br/images/Pdfs/Bioetica/DUBDH.pdf Access in 11 Maio 2010.
[2] Ditto.
[3] Un. International Covenant on Economic, Social and Cultural Rights. Adopted by Assembl Resolution No. 2,200a (XXI)eGeneral Assembly of the United Nations on December 16, 1966 and ratified by Brazil on January 24, 1992. Available in https://www.oas.org/dil/port/1966%20Pacto%20Internacional%20sobre%20os%20 Rights%20Econ%C3%B3micos,%20Social%20e%20Culturais.pdf Access on May 11o 2010.

CONSIDERING that Brazil is a signatory country of DUBDH, which is included in its article 22, regarding the role of States, item (a), that "States shall take all appropriate legislative, administrative or other measures in order to implement the principles set out in this Declaration and in accordance with international law and human rights. Such measures should be supported by actions in the spheres of education, training and information to the public[4]";

CONSIDERING article 5 of the Brazilian Federal Constitution which states that "all are equal before the law, without distinction of any nature", that "no one shall be subjected to torture or inhuman or degrading treatment", that "intimacy, private life, honor and the image of persons are inviolable", that "property will meet its social function", and that "in the event of imminent public danger, the competent authority may use private property, insuring the owner indemnification, if there is damage", that "the law shall punish any discrimination affecting fundamental rights and freedoms" and that "the rights and guarantees expressed in this Constitution do not exclude others arising from the regimen and principles adopted by it, or from international treaties to which the Federative Republic is bound"; [5]

CONSIDERING article 6 of the Brazilian Constitution which states that "education, health, food, work, housing, transportation, leisure, security, social security, maternity and child protection, assistance to the helpless, are social rights in accordance with this Constitution[6],

CONSIDERING article 25 of the Universal Declaration of Human Rights (UDHR), [7] which states that every person has the right to personal safety and is entitled to a standard of living capable of ensuring himself/herself and family health and well-being, including food, clothing, housing, medical care, indispensable social services, and the right to security in situations of unemployment, illness, disability, widowhood, old age or other cases of loss of livelihood outside his/her control;

[4] Unesco. Universal Declaration on Bioethics and Human Law. Adopted by acclamation on October 19, 2005 by the 33rd session of the General Conference. Available in http://fs.unb.br/images/Pdfs/Bioetica/DUBDH.pdf Access at 11 Maio 2010.
[5] Brazil. Constitution of the Federative Republic of Brazil of 1988. Available in http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm Access on May 11o 2010.
[6] Ditto.
[7] Unesco. Universal Declaration of Human Rights. Adopted and proclaimed by Resolution 217 A (III) of the United Nations General Assembly on December 10, 1948. Available in http://unesdoc.unesco.org/images/0013/001394/139423por.pdf Access on May 11o 2020.

CONSIDERING that the infection by SARS-Cov-2 has already reached the entire Brazilian territory at different intensities, and that the increase in cases already overloaded the health care system;

CONSIDERING the lack of timely and adequate planning by several federal, state and municipal health managers for the provision of intensive care unit (ICU) beds, equipment (respirators, PPE) to cope with the spread of infection;

CONSIDERING that the increase in the number of severe cases and the lack of availability of resources may result in ethical and scientific dilemmas in decision-making on the distribution and occupation of beds and uses of technologies, if insufficient, to care for patients;

CONSIDERING that the rapid spread of SARS-CoV2 is capable of weakening the health system and the economy of each country, as well as its political system, in the event of possible unreasonable confrontation with scientific arguments;

CONSIDERING that the underfunding of Unified Health System (SUS), aggravated by Constitutional Amendment 95 of 2016, which prevents the increase of health funds for twenty years and has already withdrawn substantial resources from this system;

CONSIDERING that the increase in funding for the SUS, to guarantee its principles of universality, integrality and equity, is *a sine qua non* condition to accompany the growing financial needs, accentuated by the pandemic;

CONSIDERING the need to make resources available quickly to ensure the best for all communities and that this imperative is even more important at a time when the country is facing the biggest and most serious health crisis in the last 100 years;

CONSIDERING the apparent lack of ICU beds available in Brazil, mainly a consequence of the inequity in the distribution of the 45,848 beds currently existing, with 1.4/10,000 inhabitants in the public system *versus* 4.9/10,000 in the private system;[8]

[8] AMIB, New Year. Brazilian Association of Intensive Care Medicine. AMIB presents updated data on ICU beds in Brazil. Available in https://www.amib.org.br/fileadmin/user_upload/amib/2020/abril/28/dados_uti_amib.pdf Access on May 11o 2020.

CONSIDERING that the Brazilian Society of Bioethics understands to be fundamental the discussion of the various bioethical aspects in the context of the PANDEMIC of SARS-CoV2;

Recommends

In decision-making for the allocation of health resources and technologies at the current stage of the COVID-19 pandemic, the constitutional principles of human dignity and social solidarity, human rights and bioethical principles, especially those mentioned above, are respected, and must include that:

I. The decision on resource allocation ensures the right of all patients, including those not infected with SARS-CoV2, to receive care according to their needs, promoting the best scientifically recognized health care;
II. The financing of the Unified Health System (SUS) is effectively and urgently expanded to enable, among other aspects of the necessary supply, the immediate hiring of professionals from various health areas, for the proper care of patients and for working in intensive care units available or built specifically to cope with the pandemic;
III. The State uses available ethical and legal instruments to ensure price policy and conditions of access to medicines, supplies and equipment, in order to avoid the risk of exploitation of the economic vulnerability of the health system and society;
IV. Ample access to appropriate preventive measures, including social isolation, the provision of masks, access to quality water, and adequate financial support for the maintenance of those in self-confinement is ensured;
V. Patients' rights, including equal access, are guaranteed at all levels of care, from primary care to intermediate care, to intensive and palliative care, according to the best current scientific standards. If there is technical feasibility, the ICU patient will be guaranteed the possibility of establishing contact with their family members through virtual access;
VI. It must be ensured that all intensive care beds, private and public, are immediately regulated by the SUS and made available equally to all patients who need them. The insufficiency of ICU beds is often a consequence of inequity in their distribution;

VII. The principle of equity must be ensured, so that there is no distinction that implies in the devaluation and discrimination of socially vulnerable people, communities or groups in access to services;

VIII. In health management, all mechanisms are used to ensure secrecy and confidentiality in the relationship between professional and patient;

IX. The information provided to patients and society is correct, based on scientific evidence, transmitted in clear language and widely available, including the communication of bad news;

X. Health professionals and ancillary services are allocated in an appropriate number, that there is an effective increase in health security, which includes ensuring measures to mitigate exhaustion, making available and providing preparedness for the use of Personal Protective Equipment (PPE) and timely access to diagnostic tests for SARS-CoV-2;

XI. New drugs or *off-label* use may only be permitted in the course of research duly approved by the local Research Ethics Committee/National Research Ethics Committee (CEP-CONEP System) or in compassionate access situations, as defined in Resolution 466/2012 of the National Health Council (CNS), [9] and must be adequately justified and ethically evaluated;

XII. When, even after the allocation of all private and public ICU beds to SUS, they are insufficient, the establishment of a flowchart based on scientific knowledge for their occupation by patients who need them is evaluated;

XIII. Hospital Bioethics Commissions are strengthened and/or established in places where they do not yet exist, to participate in the triage process and contribute to reflections and proposals specific to local particularities, and in decisions related to complex choices, including to mitigate the emotional burden of the care team. That they are composed of professionals, with multidisciplinary training, with experience in bioethics, including at least one representative of civil society and odd number of members;

XIV. to ensure patient autonomy, advance directives of will, if any, will be taken into account and palliative care services are established or expanded, so that they are made available, in a timely manner, to patients not eligible for curative treatment, as well as in terminal situations;

XV. In decision-making and treatment of bioethical issues, including dilemmas in situations of bed insufficiency, these committees apply principles of the

[9] Brazil. National Health Council. Resolution CNS N#466of 12 December 2012. Available in http://www.conselho.saude.gov.br/resolucoes/2012/Reso466.pdf Access on May 11o 2020.

Universal Declaration on Bioethics and Human Rights, and consider that: "a) Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular in explaining all conflicts of interest and due knowledge sharing. Every effort must be made to use the best scientific knowledge and methodology available in treatment and for continuous review of bioethical issues"; "(b) the individuals and professionals involved and society as a whole shall be regularly included in a common process of dialogue"; and "c) opportunities should be promoted for pluralistic public debate, seeking to express all relevant opinions[10]";

XVI. Be assured that, at the end of the pandemic, there will be needed investment in the SUS, in applied research and training and in expansion of the number of professionals and researchers in all areas of activities in Brazil;

XVII. In decision-making allocation of needed health resources and technologies with the objective of establishing criteria for prioritization of access, depending on the evolution of the pandemic, the bioethical, dignity and human rights principles are respected;

XVIII. The flowchart for establishing ethical criteria for access to health technologies for all who need them is based on validated scientific knowledge, ensuring absolute respect to ethical principles, fundamental rights and human dignity, without discrimination of any nature or any other factor not related to the health condition, as described in ANNEX I and ANNEX II. This flowchart considers local, regional and cultural conditions, with updated information on the availability of beds, with extensive communication to the health professionals involved in the care and to the respective Hospital Bioethics Commissions.

Brasilia, May 15, 2020.

DIRCEU GRECO

President, Brazilian Society of Bioethics

[10] Unesco. Universal Declaration on Bioethics and Human Law. Adopted by acclamation on October 19, 2005 by the 33rd session of the General Conference. Available in http://fs.unb.br/images/Pdfs/Bioetica/DUBDH.pdf Access on May 11o 2010.

SBB RECOMMENDATION 01/2020

ANNEX I - POSSIBLE ETHICAL RISKS IN THE PHASES OF CARE IN THE COVID-19 PANDEMIC[11]

1. Prior to access to the health system

- Social vulnerability;
- Biological vulnerability;
- Discrimination and/or stigmatization;
- Disrespect for cultural and/or sexual diversity/pluralism.

2. In triage - access to clinical and etiological diagnosis

- Absence of vacancy for adequate primary care;
- Absence of a triage team properly protected with PPE and qualified for care;
- Stigmatization, disrespect for cultural and/or sexual diversity/pluralism;
- Lack of timely access;
- Lack of diagnostic testing (if necessary);
- Lack of information on hospital care vacancies, including ICU, in the city and the region.

3. In hospital care, absence of

- Adequate communication in case of socially vulnerable patient;
- Informed consent for non-emergency invasive conduct;
- Authorization of a legal representative in case of patients without the ability to consent;
- Respect for confidentiality and privacy;
- Provision of information to the legal representative, when authorized by the patient;
- Hospital Bioethics Commission in operation.

4. In the access to the Intensive Care Unit (technological support), absence of

- Hospital Bioethics Commission in operation;

[11] See flowchart in Annex II.

- Algorithm that considers local and cultural conditions, widely discussed and disseminated, containing: scientifically validated and ethical technical criteria, as well as absolute respect for dignity and human rights, without discrimination of any social nature - including issues of gender, age and people with disabilities - economic, cultural, ethnic/racial and any other factor not related to health condition;
- Flowchart that considers local, regional and cultural conditions, which apply to patients with COVID-19 or other pathologies, in situations of effective insufficiency of beds and technologies.

Therefore, as long as these risks are assessed and based on the SBB Recommendation 01/2020, the Brazilian Society of Bioethics endorses the step by step flowchart contained in Table 1 of AMIB (Brazilian Association of Intensive Care Medicine), ABRAMEDE (Brazilian Association of Emergency Medicine), SBGG (Brazilian Society of Geriatrics and Gerontology) and ANCP (National Academy of Palliative Care) Recommendations -Version 2, for the allocation of insufficient resources during the pandemic by COVID-19[12] :

Table 1 - Step by step triage model (AMIB/ABRAMEDE/SBGG/ANCP)

Steps	Criteria	Score				Total
		1	2	3	4	
1	Calculate SOFA (total:___) accordingly	= or <8	9-11	12-14	>14	
2	Severe morbidities, with life expectancy <1 year	---	---	Yes	---	
3	Apply ECOG and score accordingly					
4	Calculate total score adding criteria 1+2+3					
5.	The ICU bed or mechanical ventilation will be allocated to the patient with the lowest overall score, unless there is a tie					
6.	In the event of a tie, use the following criteria hierarchically: - Lower SOFA gross score - Clinical judgment of the screening team.					

[12] Recommendations of AMIB (Brazilian Association of Intensive Care Medicine), ABRAMEDE (Brazilian Association of Emergency Medicine, SBGG (Brazilian Society of Geriatrics and Gerontology) and ANCP (National Academy of Palliative Care) of allocation of insufficient resources during the pandemic by COVID-19. Available in https://www.amib.org.br/fileadmin/user_upload/amib/2020/abril/24/VJS01_maio_-_Versa__o_2_-_Protocolo_AMIB_de_alocac__a__o_de_recursos_em_esgotamento_durante_a_pandemia_por_COVID.pdf Access on May 11o 2020.

SBB | SOCIEDADE BRASILEIRA DE BIOÉTICA

SBB RECOMMENDATION 01/2020

ANNEX II - FLOWCHART