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Italian Committee for Bioethics

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Motion

Medical futility or
unreasonable prolongation of
treatments in young children
with low expectations of life

30th January 2020



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Presidenza del Consiglio dei Ministri



MOTION

**CLINICAL PERSISTENCE OR UNREASONABLE
PROLONGATION OF TREATMENTS IN YOUNG
CHILDREN WITH LOW EXPECTATIONS OF LIFE**

30 January 2020

Premise

The expression "therapeutic persistence", often used in medical, ethical and legal literature, highlights a sort of contradiction between the two terms: "therapy" has a positive connotation, while "persistence" indicates a negative excess that does not accord with the preceding positivity; it follows that if a practice is defined as persistence, it is very unlikely that it can be considered therapy.

Therefore, the Committee preferred the expression "clinical persistence"¹ to indicate the initiation of treatments that are presumed to be ineffective or the continuation of treatments which have become documentedly ineffective in relation to the objective of care or the improvement of the quality of life (understood as well-being) of the sick person or such treatments likely to cause further suffering to the patient and a precarious and painful prolongation of life without conferring further benefits.

Bioethical reflection, as well as ethical and legal reflection, has matured respect on the one hand for the patient's expressed and conscious will to refuse or discontinue medical treatment and on the other the belief that it is the doctor's primary duty to refrain from initiating or prolonging unnecessary and disproportionate² care, especially with regard to patients with poor short-term prognosis and/or imminent death.³

It is generally believed that the identification of clinical persistence comprises scientific elements and elements given by the way in which the treatments are experienced and autonomously desired by the patient.

Conversely, the identification of clinical persistence is more complex in the case of young children who cannot autonomously express themselves and are not able to fully communicate the subjective perception of pain and suffering. These situations become even more problematic when it involves very young patients with a certain poor diagnosis and/or prognosis with limited life expectancy and who also require burdensome treatments. It is precisely these latter cases involving the complex and sometimes tragic assessment of the "overall benefit" of care which lies with the doctor and parents⁴, that is the subject of reflection of this motion.

As regards young children, it must be acknowledged that in practice clinical persistence is often practiced because almost instinctively, even at the request of parents, we are inclined to do everything possible, without leaving any stone unturned, to preserve the child's life, without considering the negative effects that this can have on the existence of the child in terms of outcomes and further suffering. At other times, however, clinical persistence is consciously practiced as a defence against possible accusations of failure to provide medical assistance or active interruption of care or life-sustaining treatments. Therefore, these clinical practices are mainly performed not to ensure the patient's health and good, but as a form of protection and safeguard of personal medical-legal responsibility pertaining to the activity carried out.

Clinical persistence has various modalities of implementation and on occasion it can even be minimally invasive. However, in the majority of cases clinical persistence is accompanied by the use of often sophisticated technologies. For this reason, more and more frequently, the term "clinical persistence" is also associated with "technological obstinacy". Clinical persistence can also lead to "experimental obstinacy", when the experimentation is

¹ The Italian Committee for Bioethics (ICB) proposed the expression "clinical persistence" in the Opinion *Refusal and conscious renunciation of health treatments in the patient-doctor relationship*, 24 October 2008.

² Hence art. 16 of the *Code of Medical Ethics*.

³ Hence art. 2 of Law 219/2017.

⁴ In the motion, reference will be made to parents, as the primary exercisers of parental responsibility, although informed consent to medical treatment of minors may involve other people such as a guardian or legal representative.

not scientifically and ethically justified by adequate and rational research hypotheses, submitted previously to the attention of the scientific community and recognized by it as legitimate and evaluated by independent ethics committees.

Moreover, pediatric medicine is now facing new critical issues, represented by the complexity of the healthcare scenario, which is mainly characterized by the increasing incidence of chronic and rare diseases, often associated with permanent disabilities and, sometimes, resulting in the loss of life in a short period of time. It follows that the traditional, analytical-linear model, based on predictable cause-effect sequences, appears inadequate today. The model that adapts to the actual needs, the individual needs of the particular case, represents a greater degree of appropriateness, as long as global welfare responses are created, capable of answering even to the psychological and relational sphere.

All this makes it even more complex to reflect on what is to be done in these situations and when and how to identify the circumstances that lead to consider a certain way of intervening on a child as clinical persistence, contrary to the child's interests.

For the abovementioned reasons the Italian Committee for Bioethics (ICB) is aware that the issues involving clinical persistence in young children are largely to be addressed based on an individualized analysis which takes into account the specific circumstances prevailing in the different concrete realities: any precise solutions can be given only by those who have direct knowledge of the clinical case in question.

The Committee, is well aware of both the foreseeable increase in these situations in the pediatric environment following the rapid developments in science and technology, and the need for a case-by-case assessment, nevertheless, it believes it is important to provide recommendations on this issue which, although it already appears consolidated in bioethics, it is actually (consciously or unconsciously) in practice still very uncertain. Recommendations that take into account the conditions and guidelines regarding the identification of clinical persistence; the roles played by the doctor and parents in the decisions to be taken in the interest of the child; the need for palliative care in the pediatric field; the role of clinical ethics committees.

The ICB recommends the following:

1. Identification of clinical persistence through scientific and clinical data that are as objective as possible, guaranteeing the best quality of available treatments and preferably making use of shared planning between the medical team and the parents in the best interests of the child. The best interest of the child is the inspiring criterion in the situation and must be defined starting from the contingent clinical condition, together with the consideration of pain and suffering (as far as measurably possible), and respect for the child's dignity, excluding any evaluation in terms of the economic costs. Doctors must avoid implementing ineffective and disproportionate clinical pathways only in order to comply with parental requests and/or to meet defensive medicine criteria.

2. Establish by national law and render effectively operational the clinical ethics committees⁵ in pediatric hospitals, having an advisory and formative role, so as to facilitate evaluation of the complexity of these decisions and provide mediation of disputes emerging between doctors and parents. These ethics committees should be interdisciplinary, composed of pediatric doctors, specialists from the medical fields under analysis, nurses, and non-healthcare figures such as bioethicists and biojurists. The committees should not replace professionals in the taking of appropriate decisions, but help them exercise their autonomy responsibly.

3. Integrate the decision-making processes of doctors and ethics committees, with the participation of parents and people they trust, ensuring the space and time of communication

⁵ See the ICB opinion on *Clinical Ethics Committees*, 31 March 2017.

and reflection, involving them in the care plan of the young patient, adequately informing them about the possible evolution of the pathology in progress and to identify the limits of the therapeutic interventions and the legitimacy to initiate care treatments or to maintain or suspend them and resort to palliative care.

4. Allow for a possible second opinion to that of the team that first took charge of the child, if requested by the parents or the treating medical team, guaranteeing, in conditions of scientific authoritativeness, the freedom of choice of the parents, taking into account the primary interest of the child. The ICB hopes that the two opinions can give greater certainty in the identification of clinical persistence and greater sharing in the decision to initiate, continue or suspend ongoing treatments. To this end, the full clinical records of the patient (medical record and electronic health record) should be easily accessible so as to be able to evaluate the scientific and ethical judgment regarding deemed clinical persistence.

5. Provide for recourse to judges, in the event of an irreconcilable disagreement between the medical team and family members, as *extrema ratio* and in compliance with Law 219/2017; this solution should be taken into consideration only after seeking mediation through adequate communication with parents or family, taking into account correct clinical documentation and the request to the clinical ethics committee.

6. Avoid the prohibition of unreasonable obstinacy of treatments transmuting into abandonment of the child in respect of whom the absolute duty of doctors stands firm in the provision of appropriate treatments and support, be they technological or pharmacological aids, and palliative care with accompaniment in dying, also through continuous deep sedation in association with pain therapy.

7. Ensure homogeneous access to palliative, hospital and home care throughout the territory.

8. Strengthen research on pain and suffering in children, in order to implement and improve the validation of objective measurement scales of pain and suffering, which can guide - together with other parameters - clinical decisions.

9. Avoid the child being considered a mere object of experimentation and research by doctors,⁶ especially in the case of poor short-term prognosis.

10. Implement the training of doctors, health personnel and psychologists, to create a core group of professionals (social workers, psychologists, bioethics experts, family associations, voluntary associations) able to support parents on an emotional and practical level and accompany them in the difficult path given by the conditions of illness of the child.

11. Facilitate the closeness of parents to children in extremely precarious clinical conditions (e.g. palliative care carried out in their own home; provision of leave from work, etc.).

12. Recognize the important role of the Associations of the parents of sick children and consolidate the networks for joint support from parents and also from society itself.

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The text was drawn up by Profs. Lorenzo d'Avack and Laura Palazzani. Valuable contributions to supplement the discussion were made by the auditions of: Prof. Mario De Curtis, full professor of Pediatrics University of Rome "La Sapienza" (internal audition); Prof. Gianpaolo Donzelli, former full professor of Pediatrics University of Florence, President of Meyer Foundation (internal audition); Prof. Franca Benini, Head of the Palliative Care and Pediatric Antalgic Therapy Unit of the Department of Women's and Children's Health of the University of Padua; Prof. Alberto Giannini, Director of the Pediatric Anesthesia and

⁶ See the ICB opinion, *Single patient care and non-validated treatments (the so-called "compassionate use")*, Accompanied by a Juridical note, 25 February 2015.

Resuscitation Unit - Civil Hospital of Brescia; Dr. Andrea Messeri, Director of palliative care and pain therapy - Meyer University Hospital; Dr. Sergio Picardo, Director of Anesthesia and Resuscitation Service - Bambino Gesù Pediatric Hospital.

The motion was approved in the plenary session on January 30, 2020 by Profs: Salvatore Amato, Luisella Battaglia, Carlo Casonato, Antonio Da Re, Lorenzo d'Avack, Mario De Curtis, Riccardo Di Segni, Gianpaolo Donzelli, Mariapia Garavaglia, Silvio Garattini, Assunta Morresi, Maurizio Mori, Laura Palazzani, Tamar Pitch, Lucio Romano, Luca Savarino, Monica Toraldo di Francia, Grazia Zuffa. Prof. Francesco D'Agostino abstained.

Despite their not having the right to vote assent was given by: Prof. Carlo Petrini, the delegate for the President of the National Institute of Health; Dr. Maurizio Benato, the delegate for the President of the National Federation of MDs and Dentists Colleges; Dr. Carla Bernasconi, the delegate for the President of the National Federation of the Orders of Italian Veterinarian

Profs: Bruno Dallapiccola, Stefano Canestrari, Carlo Caltagirone, Cinzia Caporale, Marianna Gensabella, Massimo Sargiacomo, Lucetta Scaraffia and the advisory members: Prof. Paola Di Giulio, the delegate for the President of the Superior Health Council, and Dr. Amedeo Cesta, the delegate for the President of the National Research Council, absent from the session, subsequently assented.



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