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ISSN: 1642-5758

e-ISSN: 1731-2515

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Authors: Andrzej Kübler, Jacek Siewiera, Grażyna Durek, Krzysztof Kusza, Mariusz Piechota, Zbigniew Szkulmowski

DOI: 10.5603/AIT.2014.038

Article type: Special articles

Submitted: 2014-08-15

Accepted: 2014-08-15

Published online: 2014-08-17

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Articles in "Anaesthesiology Intensive Therapy" are listed in PubMed.

Guidelines regarding the ineffective maintenance of organ functions (futile therapy) in ICU patients incapable of giving informed statements of will

Andrzej Kübler¹, Jacek Siewiera², Grażyna Durek³, Krzysztof Kusza⁴, Mariusz Piechota⁵,
Zbigniew Szkulmowski⁶

¹ National Consultant in intensive therapy, Chair and 1st Department of Anaesthesiology and Intensive Therapy, Wrocław Medical University, Poland

² Department of Medical Law, Chair of Forensic Medicine, Wrocław Medical University, Poland

³ Chair and 2nd Department of Anaesthesiology and Intensive Therapy, Wrocław Medical University, Poland

⁴ National Consultant in anaesthesiology and intensive therapy, Chair and Department of Anaesthesiology and Intensive Therapy, Collegium Medicum, Nicolaus Copernicus University (NCU) in Toruń, Poland

⁵ Department of Anaesthesiology and Intensive Therapy, Regional Specialist Hospital in Łódź, Poland

⁶ Department of Respiratory Physiopathology and Home Ventilation, Chair of Anaesthesiology and Intensive Therapy, Collegium Medicum, NCU in Toruń, Poland

Key words: intensive care, maintenance of organ functions, futile therapy, de-escalation of treatment

Short title: Guidelines regarding de-escalation of futile therapy

Introduction

Intensive care involves medical interventions aimed at maintaining bodily functions and treating patients in life-threatening conditions caused by potentially reversible failure of one or more major organs, particularly the lungs, heart, central nervous system, kidneys, liver and coagulation system. Intensive care services are provided in hospital intensive care stations where the functions are continuously monitored and therapeutic methods and techniques are used to maintain the functions of major body organs. Intensive care management mainly involves cardiopulmonary resuscitation, mechanical ventilation, cardiac electrotherapy, renal replacement therapy, extracorporeal techniques for the support of circulatory, respiratory and liver functions, administration of drugs maintaining proper function of the cardiovascular system (e.g. infusions of catecholamines), parenteral nutrition and antibiotic therapy. Intensive care has created new possibilities for the effective treatment of severe diseases and traumas. The intensive care stations have become the required sections of modern hospitals. However, intensive care is associated with a new therapeutic problem, i.e. the prolonged maintenance of organ functions, which does not lead to therapeutic benefits, i.e. survival and discharge from the intensive care unit (ICU). The maintenance of organ functions can be the precondition for a patient's recovery yet can also prolong the process of dying and be of no benefit to patients. In many patients, multiple organ failure cannot be permanently cured. In such cases, futile therapy can intensify the patient's complaints and cause suffering as well as moral dilemmas for his/her family and friends. The vast majority of patients treated in ICUs (over 80%) are not capable of making their statements of will regarding treatment due to their severe clinical conditions or effects of the sedatives, analgesics, and/or hypnotics they are administered.

De-escalation of treatment can involve its withholding, i.e. no new treatment methods instituted or no further increase in the intensity of the treatment method already applied, or withdrawing, i.e. discontinuation of the treatment method used.

Withholding or withdrawing of treatment that is maintaining organ functions that are not beneficial to patients does not mean that patients are not provided with care; only the aim of treatment is different. Since the therapy is of no benefit to the patient, the further maintenance of organ functions is no longer its goal. The crucial therapeutic objective is to provide the patient with optimal comfort, which involves specialist nursing care, the elimination of adverse symptoms, such as pain, anxiety, dyspnoea, seizures, fever, etc., nutrition and hydration as

required. The above measures are collectively called ‘palliative treatment’ and are continued even when the treatment supporting organ functions is no longer effective and justified. In such cases, the principles of palliative medicine are applied during ICU management.

There are different terms to define the treatment-limiting decisions, which are mainly based on English literature. ‘Futile therapy’ defines accurately management which is of no therapeutic benefit. The term ‘persistent therapy’ is used mostly in Polish literature and can be found in the Code of Medical Ethics, definitions regarding palliative medicine (consensus of the Polish Group on End-of-Life Ethical Problems), and numerous publications in the field of medicine and law. The term ‘futile therapy’ is more accurate and suitable to define the decision of withholding or withdrawing treatment maintaining organ functions in ICU patients.

Futile therapy can be considered the term generally accepted in ICUs to define interventions aimed at maintaining organ functions which are of no benefit to patients.

The principles of withholding or withdrawing the treatment maintaining organ functions in ICUs should be standardised to enable their assessment, control and optimisation. They cannot be inconsistent with the legal regulations and generally accepted ethical principles of autonomy, beneficence and justice¹.

The principles in question are drawn up by different scientific organisations and societies in various countries to serve as medical practice guidelines. They reflect current medical knowledge and define the rules of due healthcare for purposes of judicial proceedings, if need be. In Poland, the need to regulate the medical measures regarding futile therapy is recognised by all those dealing professionally with intensive therapy of severely ill patients.

Aim

The guidelines aim to define the best clinical practice for ICU patients whose therapy maintaining organ functions has become futile. Moreover, the guidelines aim to provide optimal comfort to patients and to determine one formal and uniform procedure of withholding or withdrawing medically futile therapy when the process of dying cannot be stopped.

¹*Beauchamp TL, Childress JF: Principles of Biomedical Ethics, 7th Ed, Oxford, Oxford University Press, New York 2013.*

Guidelines

1. Patients are admitted to the intensive care unit according to the well-defined indications (failure of one or many vital systems or organs, the need for continuous monitoring of vital functions, other life-threatening conditions). The fundamental indication is the potential reversibility of body dysfunctions resulting in the patient’s survival and discharge from the

ICU. The admission of the patient to the intensive care station for dying is medically and ethically ungrounded.

2. After admission, the management plan should be designed considering the aims and limits of treatment. The plan should be systematically evaluated and revised. The aim of therapy should depend on whether the therapeutic benefit, i.e. survival and discharge from the ICU, can be achieved. Once the method used to maintain organ functions is found ineffective, the treatment measures applied can be limited, i.e. withheld (no new methods introduced or no intensification of the treatment method already used), or withdrawn.
3. Maintenance of organ functions which is of no benefit to patients and does not enable the achievement of the therapeutic goals is defined as futile therapy, and is considered medical malpractice.
4. The decision to withhold or withdraw the interventions maintaining organ functions is a formal procedure of management in the intensive care stations. It should be recorded in medical records (preferably in the form of a separate protocol), with a detailed description justifying the above-mentioned decision.
5. Withholding or withdrawing the maintenance of organ functions particularly regards the following methods: cardiopulmonary resuscitation, mechanical ventilation, cardiac electrotherapy, mechanical circulatory support, and pharmacological liver support. Improper use of the above methods of management only prolongs the process of dying.
6. The decisions to de-escalate futile therapy are taken by two physicians of the attending team, specialists in anaesthesiology and intensive therapy or intensive therapy, with the approval of the physician in charge of the department. They can additionally contact some other specialists, if they find this is reasonable.
7. The decision to limit the use of certain methods maintaining organ functions does not lesser the significance of palliative treatment, which is to eliminate the patient's suffering and provide them with optimal comfort (including nursing care, hydration, nutrition, access to family members and those supporting the patient, relieving adverse symptoms); it in fact makes this aspect of therapy the top priority. The limitations imposed on maintaining organ functions do not remove the need for palliative treatment.
8. The provision of palliative treatment is to relieve suffering by making the most effective use of analgesics, sedatives or hypnotics. Palliative treatment should not hasten the natural process of dying.
9. Proper communication with the patient and his/her relatives is essential for the appropriate therapeutic process during the period of dying, and for de-escalation of futile therapy. The

patient's family should be fully aware of medical and ethical grounds of withholding or withdrawing treatment maintaining organ functions, yet should not be burdened with the responsibility for this decision.

10. Each decision regarding de-escalation of futile therapy should have its clear written justification and cannot be conditioned by treatment costs or organisational aspects (e.g. making the intensive care station available for another patient).
11. Having decided to limit the maintenance of organ functions, the attending team adjusts to the management plan accepted, which can be modified in well-grounded cases.
12. All actions purposefully aimed at causing or hastening death are medically, ethically and legally impermissible.

Protocol

Management regarding ineffective maintenance of organ functions (futile therapy) in ICU patients
incapable of giving informed statements of will

First name and surname of the patient:

Personal identity number.....

Due to the current clinical condition, the patient is incapable of consciously expressing his/her will regarding therapeutic management.

In accordance with the current state of medical knowledge, it should be stated that organ failure is irreversible and permanent. Therefore, use or further use of the specific methods maintaining organ functions becomes futile therapy harmful to the patient.

Considering the current clinical condition of the patient, and having been fully familiarised with his/her medical records, as well as having presented the patient's family with the current health situation of the patient, the decision is made that from this moment on the administration of palliative therapy will be most beneficial for the patient. From this moment on, the institution or continuation of the definite forms of treatment aimed at maintaining organ functions will be unfavourable as it will be medically futile, hence will not serve the patient's needs.

This decision has been taken considering clinical, ethical and social aspects; moreover, the therapeutic procedures designed to maintain organ functions, which will be withheld or withdrawn, have been listed.

Clinical aspects:

Underlying diagnosis:

Current clinical condition and therapeutic problems:

Opinions of consultants (if need be):

Ethical and social aspects:

Although the therapy maintaining organ functions will be limited, palliative treatment will be administered to provide best comfort. The specialist nursing care will be continued and symptoms such as pain, anxiety, dyspnoea, seizures, and fever will be relieved. The patient will be hydrated and nourished, suitably to his/her needs. Contact with relatives and those of support will be ensured, depending on the patient's needs and organisational capacity.

To determine the best interests of the patient, the following individuals were talked to:

Family members/close friends: (first name, surname, kinship):

- 1)
- 2)
- 3)
- 4)
- 5)

The following issues have been discussed:

1. Possible previously expressed statements of will regarding the continuation of procedures maintaining organ functions in a situation comparable to the current one;
2. possible previously expressed wishes of the patient as to management of life-threatening/end-of-life situations that the patient's family or other close friends are aware of;
3. moral and ethical beliefs accepted by the patient;
4. patient's current state of awareness and prognosis regarding survival, clinical improvement, recovery and rehabilitation after leaving the intensive care unit;
5. methods of treatment currently applied, including their effectiveness and invasiveness;
6. further management planned.

Therapeutic procedures which will be withheld or withdrawn

Procedure	withheld	withdrawn
Cardiopulmonary resuscitation		
Cardiac electrotherapy		
Renal replacement therapy		
Mechanical circulatory support		
Pharmacological circulatory support		
Mechanical ventilation		
Antibiotic therapy		
Surgical procedures and other invasive procedures		
Parenteral nutrition		
Extracorporeal respiratory support		
Extracorporeal liver support		
Transfusion of blood preparations		

Statement

Withholding or withdrawing of the above-mentioned procedures is fully grounded. Their initiation or continuation will be medically futile and harmful to the patient.

1. Physician - specialist in anaesthesiology and intensive therapy or intensive therapy

First name and surname:

Speciality:

Signature: Date.....

2. Physician - specialist in anaesthesiology and intensive therapy or intensive therapy

First name and surname:

Speciality:

Signature: Date.....

3. Physician in charge of the department

First name and surname:

Speciality:

Signature: Date

Reviewers of guidelines:

Prof. Janusz Andres, MD, PhD

President of the Polish Resuscitation Council

Chair of Anaesthesiology and Intensive Therapy, Collegium Medicum, Jagiellonian University in Krakow

Prof. Piotr Knapik, MD, PhD

President elect of the Polish Society of Anaesthesiology and Intensive Therapy

Department of Cardiac Anaesthesia and Intensive Therapy, Medical University of Silesia in Katowice

Associate Professor Lidia Łysenko, MD, PhD

Chair and 2nd Department of Anaesthesiology and Intensive Therapy, Wrocław Medical University

Associate Professor Dariusz Maciejewski, MD, PhD

Department of Anaesthesiology and Intensive Therapy, Regional Hospital in Bielsko-Biała, Faculty of Health Sciences, Technical-Humanistic Academy in Bielsko-Biała

Associate Professor Lesław Niebrój, PhD

Chair of Philosophy and Humanistic Sciences, Medical University of Silesia in Katowice

Prof. Rafał Nizankowski, MD, PhD

President of the Polish Society of Interdisciplinary Intensive Therapy

Department of Angiology, 2nd Chair of Internal Diseases, Prof. Andrzej Szczeklik Collegium Medicum, Jagiellonian University in Krakow

Małgorzata Seroczyńska, PhD

Regional Prosecutor's Office, central Warsaw

Prof. Barbara Świątek, MD, PhD

National Consultant in forensic medicine

Chair of Forensic Medicine, Wrocław Medical University

Prof. Maria Wujtewicz, MD, PhD

President of the Polish Society of Anaesthesiology and Intensive Therapy,

Chair of Anaesthesiology and Intensive Therapy, Medical University of Gdańsk