Clinical Criteria for the Determination of Death

WHO Technical Expert Consultation

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Introduction

Death is an everyday medical occurrence that has social, legal, religious and cultural consequences requiring common clinical standards for its diagnosis and legal regulation, since death certification can vary quite widely among countries. The certification of death of an individual, namely the medical act which provides a written record of a person's death diagnosis, has been a clinical practice for centuries. This diagnosis generally leaves few or no doubts. However, despite scientific progress in the last few decades, including developments in life-support technology, there remain, at present, big variations in the diagnosis criteria applied in each country, and so in their legal regulations, which can result in misunderstandings of the public and even among health care professionals. Defining the moment of death is important to avoid the use of unnecessary medical interventions on patients who have already died. Furthermore, this is important to ensure that the process of organ donation is clear and transparent.

Death is a process involving cessation of physiological functions, and the determination of death is the final event in that process. For most people, death takes occurs with the confirmation of irreversible cessation of cardiorespiratory function.

In the second half of the twentieth century, the use of mechanical ventilation and cardiovascular support conducted in intensive care units, began to allow maintenance of the cardiac activity of patients with serious brain injuries who had cerebral circulatory arrest, no encephalic functions and an absence of spontaneous breathing. It has become scientifically evident that death was a result of the irreversible loss of the functions in the brain, either from an intra-cranial cause (devastating brain injury) or extra-cranial cause (absence of circulation).

To define the precise moment when death occurs can be difficult and should be based on the best available scientific evidence. This important medical occurrence has evolved over the last two decades in parallel with medical progress, the development of ancillary tests and the need for a certain and immediate diagnosis. There are numerous ways of dying but just one way to be dead. Therefore, the minimum determination of death criteria should be rigorous, global, and acceptable for medical practice worldwide, while remaining respectful of diversities. It is of central importance to achieve international consensus on the clinical criteria for the determination of death to maintain public trust and promote ethical practices which respect the fundamental rights of people and promote quality health services.

The aim of this technical expert consultation was to decipher this issue and reach universally accepted criteria.

Methodology

On 22-23 September 2014, the Department of Service Delivery and Safety at the World Health Organization organized a consultation which aimed to contribute to building a global agreement on the clinical criteria that should apply in the determination of death. This meeting built on previous consultations, as well as on a Cochrane literature review completed in 2014 (http://www.who.int/servicedeliverysafety/determination-death-review/en/) Twenty independent experts from all six WHO Regions were invited to attend, to formulate recommendations to define the procedures that should be in place to ensure the appropriate implementation of these clinical criteria in different settings. This meeting brought expertise and experience from the different regions of the world with the aim of harmonizing different practices. Participants were encouraged to focus on the algorithms that were distributed in advance of the meeting, in order to identify and resolve any areas of disagreement while keeping an adequate focus on the main targets of the subject.

General Discussion

Participants agreed on several general points, including the following:

- Although there are different ways to determine death, there is only one way of being dead; thus, the two classic algorithms of "brain death" and "circulatory death" initially presented should merge into a single end point identified as "death" and should not imply that "brain death" and "circulatory death" are two distinct phenomena.
- The same definition of death should apply everywhere, even if some of the tests used to confirm death may not be available in all settings.
- The process of determining death should not vary depending on whether the patient's organs will be retrieved or not.
- The algorithms should identify the tests that need to be conducted at each stage of the process, but they should not attempt to specify the details on how each test should be performed.
- The algorithms should be free-standing documents that do not require cross-references to other guidelines.
- The algorithms should apply to both adults and children.
- A checklist could be developed to facilitate the implementation of the different components described in the algorithms.

Algorithms distributed in advance were discussed in detail, in order to build new ones (annexes 1, 1A and 1B) based on the general consensus reached.

Algorithm on cardiocirculatory death (*see Annex 1A)*

Participants agreed on the following:

A. That the algorithm should begin by identifying the essential characteristics of cardiocirculatory arrest, but it should not attempt to provide detail on the process by which cardiocirculatory arrest is confirmed. Consistent with guidelines issued by the International Liaison Committee on Resuscitation (ILCOR), cardiocirculatory arrest should be defined by the following features*: (see algorithm box 4)*

(1) unresponsiveness
(2) absence of breathing or only occasional gasps, and
(3) absence of circulation.

If the patient is successfully resuscitated following cardiocirculatory arrest, the process of determining death does obviously not start. As such, in order for the practitioner to proceed with the algorithm, one of two things must occur:

(1) cardiopulmonary resuscitation (CPR) is not attempted; or
(2) CPR is attempted but fails.

B. The algorithm should identify these two circumstances but should not attempt to provide detail on all the factors that might lead practitioners to forego CPR or to determine that it has failed.

For the circumstance "CPR not attempted," the algorithm should provide a general description of the main reasons for foregoing CPR. These could include:

(1) the individual has a do-not-resuscitate (DNR) order or for other reasons does not meet the criteria for attempting CPR; or
(2) treatment aimed at sustaining life has been withdrawn, allowing death to occur.

C. It is not necessary for the algorithm to specify the circumstances in which life-sustaining treatment can legitimately be withdrawn. Instead, it is assumed that treatment will be withdrawn only for legitimate reasons (e.g., pursuant to an advance directive or based on a medical judgment that the treatment has become unnecessary).

D. Similarly, for the circumstance of "CPR failed," the algorithm should not attempt to provide details on the circumstances in which a CPR attempt should be stopped.
This issue lies outside the scope of the algorithm and is already the subject of other international guidelines, so was not investigated further.

Once either of the above two circumstances have occurred (no CPR attempted or CPR attempts failed), the next step in the process is to confirm the absence of circulation through clinical and, in some cases, instrumental tests. Participants agreed to eliminate the distinction in the draft algorithm between the tests to be used in primary care versus hospital settings. First, the distinction is misleading because the clinical tests that are used in primary care settings should also be used in the hospital context. Second, the fact that a patient is in a hospital does not necessarily mean that additional instrumental tests should be used. For example, an ECG might be used for a patient who arrests in an intensive care unit, but not for an elderly cancer patient in the general ward whose death is anticipated.

E. For all patients, regardless of setting, the absence of circulation should be confirmed by a clinical diagnosis that includes: *(algorithm box 5)*

(1) absence of a central pulse on palpation and
(2) absence of heart sound on auscultation
(3) absence of breathing and
(4) absence of pupillary responses to light.

The algorithm should then state that one or more of the following instrumental tests should be performed if indicated: *: (algorithm box 6)*

(1) asystole or pulseless electrical activity on a continuous ECG display; and/or
(2) absence of pulsatile flow during intra-arterial pressure monitoring; and/or
(3) absence of contractile activity using echocardiography.

Instrumental tests are not mandatory since diagnosis can be made without them. The instrumental tests would, however, be indicated for patients on advanced life support therapies or for whom life-sustaining treatment is withdrawn in a critical care setting. In critical care, the use of instrumental tests seems reasonable since all patients are monitored and it makes sense to use these monitors to perform the diagnosis.
Practitioners may choose to perform one, two, or three of the instrumental tests, depending on clinical judgment and situation.

Once the clinical and, if necessary, instrumental tests have been performed, it is then necessary to wait several minutes to ensure that there is no spontaneous return of cardiac or respiratory function. This period is particularly important with children. The

minimum waiting time should be five minutes, but countries can choose to require a longer waiting period. The determination of death should not be made until the waiting

period has elapsed, with the obvious exception of people whose body is discovered long after their death.

The initial draft algorithm presented a "Yes/No" option after the five-minute waiting period, and directed practitioners to wait a "further five minutes" if spontaneous cardiac or respiratory activity occurred during the initial five-minute wait. It was concluded that this section of the algorithm should be eliminated. If the patient has a spontaneous return of cardiac or respiratory activity during the five-minute waiting period, the process of determining death should stop. If the patient goes into cardiac arrest again, the determination should start again from the beginning of the algorithm.

The draft algorithm also specified certain clinical tests that would be performed after the five-minute waiting period. Participants agreed that this approach did not make sense, as a complete diagnosis of death should be made before the five-minute waiting period begins. They therefore agreed to move all of the clinical tests to earlier in the algorithm, during the process where absence of circulatory function is confirmed.

Algorithm on neurological arrest *(Annex 1B)*

Participants agreed on the following:

1.- The "brain death" algorithm should be reformulated to make clear that its purpose is not to identify a unique "type" of death, but rather to explain how death can be determined in cases of "neurological arrest", when the traditional cardiocirculatory criteria of death cannot be applied. Rather than providing a flow chart of specific steps to be performed in a particular sequence, the algorithm should identify the three general components of the process, which include:

(1) the basic requirements that must exist for triggering the algorithm;
(2) the clinical examination and diagnosis; and
(3) confirmatory testing to ensure irreversibility.

The first component *(algorithm box 1)*, namely the basic requirements, should include both the diagnosis of neurological arrest and the evaluations necessary to ensure that no confounding conditions are present. A diagnosis of neurological arrest can be made if the etiology of coma is known from a clinical assessment or neuroimaging, or if there is catastrophic structural injury to the central nervous system. In order to ensure the absence of confounding conditions, the practitioner must check for:

- hemodynamic stability

- adequate oxygenation and ventilation
- absence of severe hydroelectrolytic and acid-base equilibrium alterations

- absence of hypothermia (defined as temperature <32° C)
- absence of severe metabolic and endocrinological alterations
- absence of toxic substances and their effects, and
- absence of clinically significant neuromuscular blockers and neurodepressant drugs of the central nervous system.

Although not stated in the algorithm, it is implicit that there should be a waiting period before the clinical examination, to ensure that the preconditions described above have been met. The appropriate waiting period will be longer for children than for adults.

The second component of the algorithm*: (algorithm box 2)*, clinical diagnosis, consists of three parts:

- examination of coma;
- confirmation of absence of brain stem reflexes;
- apnoea test.

The algorithm should simply list these three elements. For the stem reflexes tests, the general preference is to use mechanical testing of the vesticulo-ocular reflex, but if the patient's condition makes performing the test dangerous or difficult, caloric testing can be used instead. Some participants suggested that it should not be compulsory to include the oculocephalic reflex or gap reflex tests.

The apnoea test should be the last test performed. Participants noted that this test is somewhat controversial because it is theoretically possible that if a patient is not dead before the test is performed, the test itself could be harmful. In exceptional cases, if it is not possible to accomplish the apnoea test safely, practitioners may choose to wait to perform it once confirmatory testing with instrumental tests has been performed.

Participants considered the usefulness of the atropine test from the algorithm, although this test was included in the draft algorithm it is not used in many countries because it is prone to both false positives and negatives. However some countries still use the atropine test and find it valuable.

The final component of the algorithm is confirmatory testing*: (algorithm box 3)*, which can include a second clinical examination and/or instrumental tests, depending on the circumstances. In cases where a primary supratentorial lesion or secondary brain damage has been confirmed, instrumental testing is usually not necessary. Instead, practitioners can either use instrumental testing, if it is available, or conduct a second clinical examination following an observation period. The length of the observation period should be based on clinical judgment, depending on the etiology of coma and the

patient's age. The second clinical examination should include all of the elements of the initial examination, including a second apnoea test.

There are, however, circumstances where using instrumental tests should be mandatory. First, in cases involving a primary infratentorial lesion, instrumental tests are needed to confirm an absence of function in the hemispheric regions. This is because the clinical examination focuses solely on the brain stem. In the absence of direct evidence of injury to the hemisphere, the clinical examination alone is insufficient to confirm that the standard of whole brain death (as opposed to merely brain stem death) has been met.

Second, instrumental tests may even be necessary in cases which do not involve primary infratentorial lesions. For example, in some situations, such as a patient whose eyes have been damaged, it may be impossible to perform the necessary clinical examinations. In other situations, it may not be possible to exclude all confounding conditions, such as when it is unclear whether there are drugs present that could suppress central nervous system function.

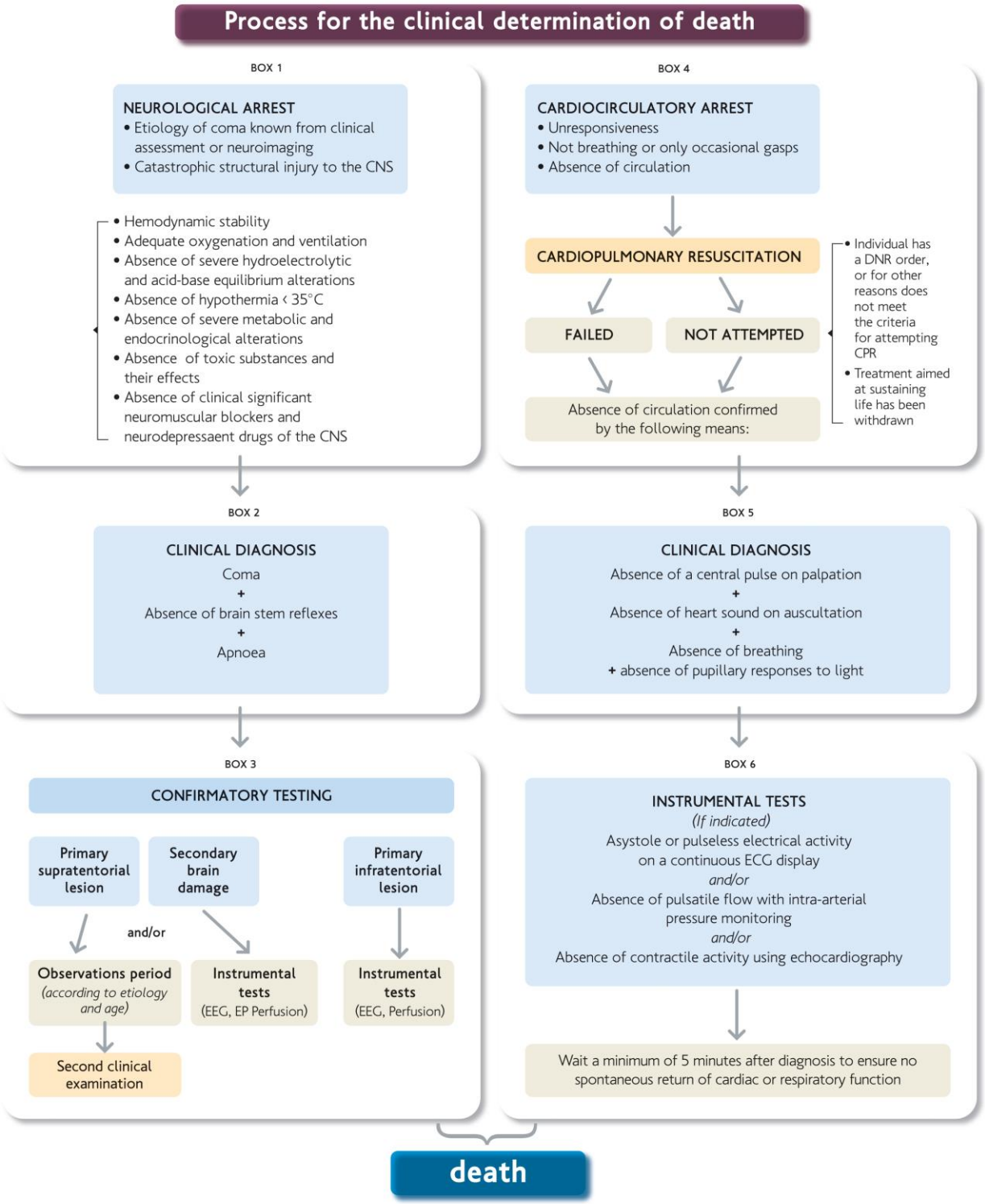
If it is impossible to determine whether the patient has suffered a primary infratentorial lesion or hemispheric damage, practitioners should err on the side of caution and proceed as if the patient has suffered an infratentorial lesion. Thus, in these situations, instrumental tests should be performed.

In the event that instrumental tests are used, only one test should be considered necessary. There is no single instrumental test appropriate to all situations; the choice of test should depend on the context, pathology, and resources available. The reliability of tests can be operator-dependent, so it is important to ensure that the test is administered by someone with the skills necessary to obtain reliable results.

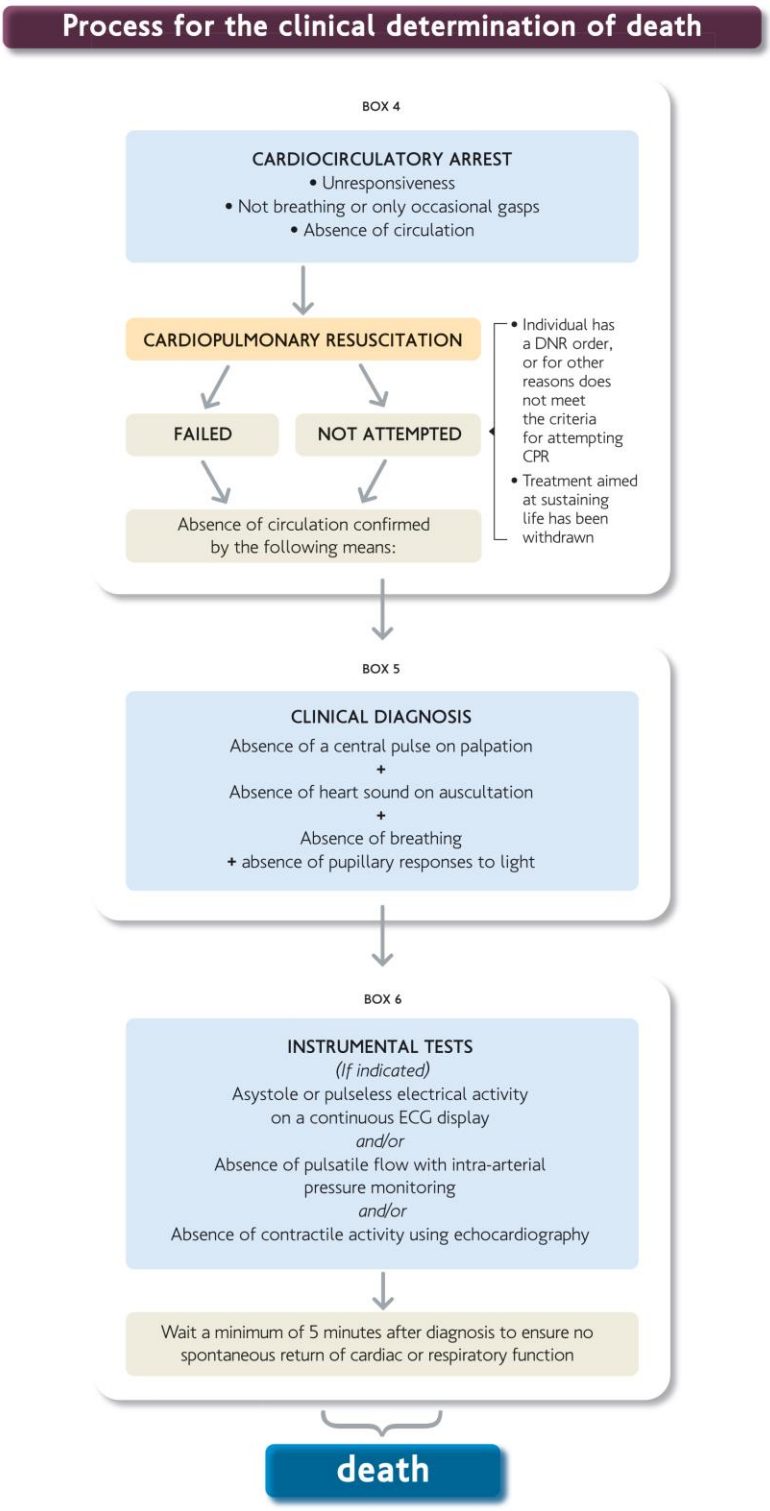
In exceptional situations, instrumental tests may be necessary but unavailable. In these cases, death cannot be determined based on neurological criteria, because there would be a small likelihood that the determination would be incorrect. Instead, determination of death should be postponed until the patient suffers cardiocirculatory arrest, at which point the determination would follow the cardiocirculatory arrest algorithm.

ANNEX 1

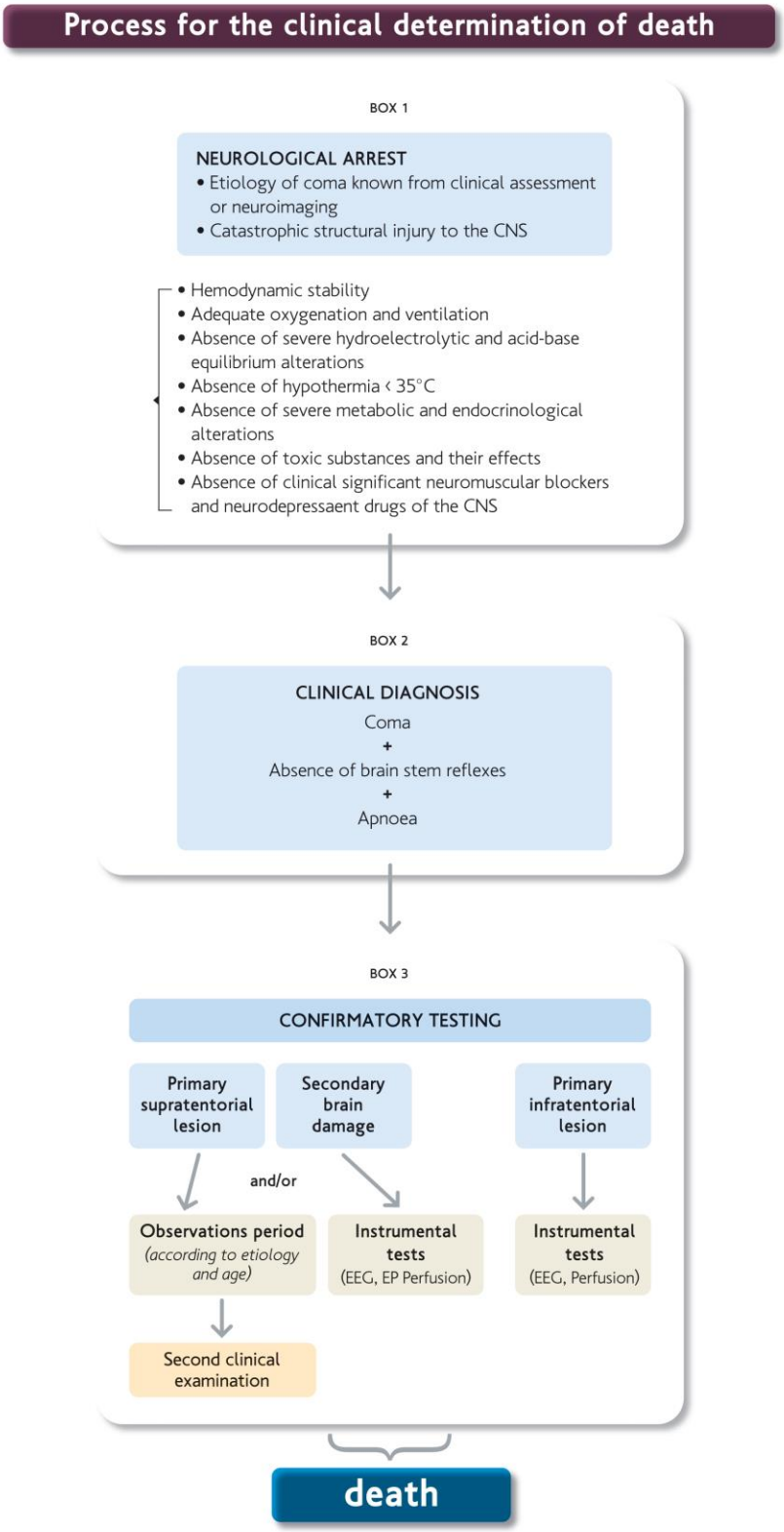
Clinical determination of death: two different workflows but a common end point - death



ANNEX 1A


Process for the clinical determination of death
BOX 4
CARDIOCIRCULATORY ARREST
• Unresponsiveness
• Not breathing or only occasional gasps
• Absence of circulation
CARDIOPULMONARY RESUSCITATION
FAILED
NOT ATTEMPTED
Absence of circulation confirmed by the following means:
• Individual has a DNR order, or for other reasons does not meet the criteria for attempting CPR
• Treatment aimed at sustaining life has been withdrawn
BOX 5
CLINICAL DIAGNOSIS
Absence of a central pulse on palpation
+
Absence of heart sound on auscultation
+
Absence of breathing
+ absence of pupillary responses to light
BOX 6
INSTRUMENTAL TESTS
(If indicated)
Asystole or pulseless electrical activity on a continuous ECG display
and/or
Absence of pulsatile flow with intra-arterial pressure monitoring
and/or
Absence of contractile activity using echocardiography
Wait a minimum of 5 minutes after diagnosis to ensure no spontaneous return of cardiac or respiratory function
death

ANNEX 1B


Process for the clinical determination of death
BOX 1
NEUROLOGICAL ARREST
• Etiology of coma known from clinical assessment or neuroimaging
• Catastrophic structural injury to the CNS
• Hemodynamic stability
• Adequate oxygenation and ventilation
• Absence of severe hydroelectrolytic and acid-base equilibrium alterations
• Absence of hypothermia < 35°C
• Absence of severe metabolic and endocrinological alterations
• Absence of toxic substances and their effects
• Absence of clinical significant neuromuscular blockers and neurodepressaent drugs of the CNS
BOX 2
CLINICAL DIAGNOSIS
Coma
+
Absence of brain stem reflexes
+
Apnoea
BOX 3
CONFIRMATORY TESTING
Primary supratentorial lesion
Secondary brain damage
Primary infratentorial lesion
and/or
Observations period
(according to etiology and age)
Instrumental tests
(EEG, EP Perfusion)
Instrumental tests
(EEG, Perfusion)
Second clinical examination
death

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