PRELUDE

This Guideline complements, and should be read in conjunction with, the Code of Professional Conduct of the Malaysian Medical Council (MMC). Reference should be made to the Consensus Statement on Brain Death 2003, published jointly by the Ministry of Health, Academy of Medicine of Malaysia and the Malaysian Society of Neurosciences, for details on procedures and technical instructions.

In this Guideline, the words “doctor”, “physician”, “medical practitioner” and “practitioner” are used interchangeably, and refer to any person registered as a medical practitioner under the Medical Act 1971. The words “hospital” and “healthcare facility and service” are used interchangeably and refer to any premises in which members of the public receive healthcare services. Words denoting one gender shall include the other gender. Words denoting a singular number shall include the plural and vice versa.
FOREWORD

The Malaysian Medical Council, with the objective of ensuring that registered medical practitioners are fully aware of the codes of professional medical practice, issues directives and guidelines from time to time. The purpose of these codes, guidelines and directives is to safeguard the patient and members of the public, to ensure propriety in professional practice and to prevent abuse of professional privileges.

The Guidelines are designed to complement, and should be read in conjunction with, the Medical Act and Regulations, Code Of Professional Conduct of the Malaysian Medical Council and other Guidelines issued by the Council or any related organisation, as well as any statute or statutory provisions in force and all related statutory instruments or orders made pursuant thereto.

This Guideline on Brain Death has been prepared with careful attention to details, cognisant of the current international stand on the subject. The draft has been reviewed numerous times by the Malaysian Medical Council includes valuable from individuals, organisations and professional bodies in the country, before formal adoption by the Council.

The Guideline is available in the printed form as well as in the MMC website. Registered medical practitioners are advised to familiarise themselves with the contents, as they will serve as documents to refer to or to seek clarifications from, when they need guidance on matters of professional ethics, codes of professional conduct and medical practice in general.

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BRAIN DEATH

SUMMARY

Brain Death is a term which defines the clinical state by which a person is recognized as dead when the function of the brain as whole, including that of the brain stem, is irreversibly lost.

The certification of brain death is to be done only by specialist medical practitioners experienced in the diagnosis, and strict guidelines are used.

There are ethical, human, intellectual and utilitarian reasons to recognise brain death. There are aspects of the right to dignity and respects at death, the recognition of irreversible damages to the brain, the criteria for this recognition and certification, as well as ethical and economic considerations, which make brain death a complex clinical issue.

In these days of greater success in cardio-pulmonary resuscitation, efficient vital system support in intensive care units and of (cadaveric) organ transplantation from brain dead donors, the diagnosis and certification of brain death assumes critical importance.

This Guideline lays down the ethical considerations for doctors diagnosing and certifying brain death.
1. INTRODUCTION

The Brain Death Committee was formed by Ministry of Health in late 1992 to make recommendations regarding brain death and prepare guidelines for use in the country. Members comprised of specialist in relevant fields and representatives of medical organisations. The committee submitted its report to the Director General of Health and the Master of the Academy of Medicine in January 1993.

The Guidelines were then circulated to all major government and private hospitals and the three University medical faculties then in existence. Members of the committee also gave lectures nationwide and explained the guidelines on brain death.

The concept of brain death was accepted by the medical fraternity at a consensus meeting organized by the Ministry of Health and the Academy of Medicine of Malaysia on 12th December 1993. The consensus was reviewed in 2002 and published as Consensus Statement in 2003.

2. BACKGROUND

Traditionally, death is recognized by the permanent cessation of the cardiovascular and respiratory functions. Until a few decades ago, this had served well in all situations. However medical knowledge has advanced, enabling these two vital functions to be supported and taken over by drugs and machines. The traditional definition of death will be inappropriate in such situations, and a different method to ascertain death is therefore required.

In general terms, death is permanent cessation of the coordinated function of the organism as a whole. The use of circulation and respiration as markers of death is valid because permanent cessation of these two
functions will lead to the inevitable permanent loss of yet another vital function, that of the brain. In fact, the organ that determines whether the organism functions as a whole or not, is the brain. It receives stimuli which it processes, integrates and responds. As opposed to the functions of the heart and lung, these functions cannot be taken over by machines. The brain is also the centre for the respiration, vasomotor, neural, hormonal and neurotransmitter control and is therefore the ultimate organ that makes the difference between life and death.

The concept of the development of brain death as the second medical diagnosis and certification of death was developed as a necessity as successful resuscitation and vital system support in Intensive Care created the clinical dilemma of artificial ventilation of a dead person (necrotic body on a ventilator).

The ethical issues become relevant if one does not terminate artificial vital system support (prolonging the agony of relatives, misuse of crucial medical facilities, wrongful bed occupancy) after having diagnosed Brain Death.

3. VIEWS OF RELIGIOUS BODIES

The major religions of Malaysia, namely Islam, Buddhism, Hinduism and Christianity accept the concept of brain death. The National Fatwa Council accepted the concept and practice on brain death following representation by the Medical Faculty of the University of Malaya. In 1992, another representation was made by the Ministry of Health to the Syariah Investigation Panel regarding brain death, and the concepts were duly accepted. Unfortunately there was no formal statement of endorsement by the religious authorities.
Islamic jurists first discussed Brain Death at the Jeddah Conference in 1985, but sadly no conclusion was made. At another conference in Amman in 1986, there was a resolution recognising brain death as death. This was reaffirmed by the 10th Fiqh Academy Conference in Makkah in 1987.

Closer to home, the Singapore Islamic Council in its position statement of 1994, regarding the practice of Living Will, accepted the concept and recognition of brain death. In 1996 a meeting in Jakarta involving Indonesia Islamic Groups and Federation of Islamic Medical Association endorsed the concepts on brain death.

4. NEED FOR BRAIN DEATH CONCEPT

Brain death is a state when the function of the brain as a whole, including that of the brain stem, is irreversibly lost. A person certified to be brain dead is dead.

It follows that brain death is a term that simply means that a person is recognized as dead, based on the examination of the nervous system. This method of ascertaining death is only limited to patients in the Intensive Care Units (ICUs) who are deeply unconscious and whose cardiopulmonary functions are supported by machines. It accounts for less than 1% of all deaths. The certification is only done by doctors experienced in the diagnosis, and strict guidelines are used. The reasons for the need to recognise brain death can be divided into:

- Ethical
- Human
- Intellectual
- Utilitarian
4.1 Ethical

Brain death is a definite clinical state. Adults with brain death will develop asystole within a week, regardless of what treatments are given. Magnetic resonance imaging (MRI) of the brain shows diffuse swelling with tentorial and foraminal herniations while various angiographic studies show absent blood flow. In over 2,000 well documented cases of brain death, nobody has survived. At postmortem, there is widespread necrosis and the brain hemispheres and brain stem are swollen and soft, with fragments of brain lodged in the spinal cord, a situation totally incompatible with life.

It is therefore a matter of good medical practice to recognize brain death. In an era of rising medical cost, private health care and insurance, non-recognition either through ignorance or choice can be construed as unethical.

4.2 Human

Every human being has a right to dignity and respect at death, and the pronouncement of death should not be unduly delayed. To continue ventilating the body whose brain is dead and undergoing liquefaction is an affront to this dignity. The heart may take up to a week to stop, and during this time, the family waits in immense distress for the inevitable. Some may in fact be cruelly persuaded by the earnest attention of medical staff to believe the patient may still survive.
4.3 Intellectual

Certification of death by doctors has always been by brain death. To begin with, the patient is always unreceptive, unresponsive and not moving, and these are often taken for granted. The doctor examines the pulse, heart, respiration and may even do an ECG. Convinced of the absence of these two vital functions, he would then examine the pupils. Fixed unreactive pupils (usually dilated) confirm his diagnosis of death. Thus, some of the basis criteria for brain death have always been used by doctors to certify death. The absence of heart beat and respiration is actually a marker heralding the inevitable irreversible damage of the brain which is the ultimate organ that determines death. It is therefore a matter of intellectual progression to recognize brain death.

4.4 Utilitarian

Treating patients in an Intensive Care Unit (ICU) is costly. The number of ICU beds and ventilators is also limited. It is morally and economically unjustifiable to keep ventilating a brain dead patient in ICU, thereby denying these facilities for patients with better prognosis.

Medical progress has also made possible organ transplantation which is now an accepted mode of treatment for chronic organ failure. The demand for organs for transplantation is now a major issue worldwide, to which the profession has a duty to respond in the most appropriate manner. However, donor organ survival is only possible when it is taken from the brain of a dead patient prior to circulatory collapse. Acceptance of brain death therefore, will be an important step for cadaveric organ transplantation programme.
5. CRITERIA FOR DIAGNOSIS OF BRAIN DEATH

The criteria for diagnosis of brain death have evolved over the past 30 years. During this period refinements have been made. However, the basic core features have remained unchallenged. The crux of the criteria is deciding what signs need to be present or demonstrated when the brain is dead. These refinements include additional safeguards and exclusions which preclude a proportion of apnoeic coma patients in the ICU, while at the same time enabling an earlier diagnosis. The practices in various countries are also fairly similar, with minor variations only in details. This concurrence is indeed remarkable, bearing testimony to a definite clinical entity. These criteria are all very stringent so as not to allow any possible errors in diagnosis.

Based on these contemporary medical practices and the situation in the country, the committee drew up the guidelines on brain death. Essentially, it is a clinical diagnosis, but brain death can only be certified when the diagnosis of irreversible brain damage is absolutely certain, and metabolic factors are not the cause of the state the patient is in. The patient must be apnoeic and properly ventilated, be totally unreceptive and unresponsive and the brain stem reflexes absent. The loss of the inherent ability to breathe is further ascertained by the apnoea test.

If there is any doubt in the diagnosis, the patient should be re-examined according to the recommended criteria and the diagnosis deferred until the diagnostic criteria are fulfilled without any doubt. If there is any doubt at all about the diagnosis, brain death should not be certified.
6. **RECOMMENDATIONS**

The Committee made the following recommendations:

6.1 That the concept and entity of brain death be recognised and accepted; and that brain death means death.

6.2 The diagnosis of brain death is a clinical diagnosis and no confirmatory test is necessary. The exception to this is only for children because of the greater ability of the child’s brain to withstand damage.

6.3 Two specialists who are registered medical practitioners, and who are experienced in diagnosing brain death, are qualified to certify.

6.4 Doctors involved in organ transplantation are not allowed to certify brain death.

6.5 Hospitals where brain death is being certified, shall have a committee that functions as a coordinating body and is responsible for general policies, training and accrediting staff, counseling and overseeing the facilities available.

6.6 The brain death guideline shall be reviewed every 5-10 years to accommodate new knowledge and contemporary practice.
7. QUALIFICATIONS OF DOCTORS CERTIFYING BRAIN DEATH

7.1 Each hospital must have a subcommittee to appoint and review doctors authorised to certify brain death in that hospital.

7.2 Two specialists, with at least three (3) years of postgraduate clinical experience and trained in brain death assessment and in diagnosing brain death, are qualified to certify brain death. They should preferably be anesthesiologists, physicians, neurologists and neurosurgeons.

8. QUALIFICATIONS OF HOSPITALS

Brain death certification must be done in areas of the hospital with full facilities for intensive cardiopulmonary care of comatose patients.

9. DIAGNOSIS AND CERTIFICATION OF BRAIN DEATH

Details on Procedures and Technical Instructions on the diagnosis of brain death, including the assessment, pre-conditions, exclusions and pitfalls, and procedures for diagnosis of brain death in children, are outlined in the Consensus Statement on Brain Death 2003, published jointly by the Ministry of Health, The Academy of Medicine Malaysia and the Malaysian Society of Neurosciences. A list of References is also provided at the end of this Consensus Statement. Doctors, particularly those involved in diagnosing brain death, should familiarize themselves with this document.
REFERENCE


ANNEXURE

BRAIN DEATH GUIDELINES

DEFINITION

Brain death is a clinical diagnosis. It is a state when the function of the brain as a whole including the brain stem, is irrevocably lost.

RECOGNITION AND ACCEPTANCE

A person certified to be brain dead is dead.

DIAGNOSIS OF BRAIN DEATH

1. Preconditions (all to be fulfilled):

   - Patient in deep coma, apnoeic and on ventilation, for at least 24 hours.
   - Cause of coma fully established and sufficient to explain the status of the patient.
   - There is irremediable brain damage.

2. Exclusions

   - Coma due to metabolic or endocrine disturbance, drug intoxication and primary hypothermia (defined as a core temperature of 32 C (90 F0 or lower).
   - Certain neurological disorders, namely Guillian-Barre syndrome and locked-in syndrome.
   - Coma of undetermined cause.
   - Preterm neonates.
3. **Diagnostic criteria (all to be fulfilled)**\(^1\)

- Deep coma, unresponsive and unreceptive, Glasgow coma score (GCS) 3/15.
- Apnoea, confirmed by apnoea test.
- Absent brain stem reflexes confirmed by the following tests:
  - Pupillary light reflex
  - Oculo-cephalic reflex
  - Motor response in cranial nerve distribution
  - Corneal reflex
  - Vestibulo-ocular reflex (Caloric Test)
  - Oro-pharyngeal reflex
  - Tracheo-bronchial reflex

4. **Assessment and certification**

- The assessment of brain death is to be carried out by two specialists. A repeat assessment and certification must be carried out at least 6 hours after the first, not necessarily by the same pair of specialists.
- The brain death certification is for 2 tests to be done 6 hours apart. The repeat test should still be performed regardless of whether the patient will or will not continue to be an organ donor.
- The “Brain Death Certification” form is filled up by the first set of doctors (A and B) and completed by the second set of doctors (B and C); or
  - Doctors A and B if the same doctors are performing the repeat test. The time of death will then be declared by the doctors performing the repeat test.

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\(^1\) Consensus Statement on Brain Death, 2003 (Appendix I and II)
The time of death is at the time of the second testing. If for any reason, the second test is unable to be carried out 6 hours later, e.g. patient is unstable, then the time of death will be when the test is next repeated. Should the patient’s heart stops before the repeat test, that will be taken as the time of death.

OTHER CONSIDERATIONS

1. During the period of observation, the patient shall remain deeply comatose with no respiratory effort, no abnormal posture or movements in cranial nerve distribution.

2. Patients who do not meet all the above criteria shall not be considered for brain death certification.

3. For children, additional guidelines are required:
   - The interval between two examinations is lengthened depending on the age of the child.
   - An ancillary test (EEG) is recommended for those less than one year old.
   - No recommendations are made for newborns or preterm infants.

4. Pitfalls in diagnosis may occur, especially if certain aspects of the clinical tests cannot be reliably performed (or evaluated). Ancillary laboratory tests (not usually mandatory) may be useful in these situations and in certain instances where children are involved. (Appendix III and IV)

2. Consensus Statement on Brain Death, 2003 (Appendix III and IV)
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