10-1984

Determination of Brain Death

Senate Select Committee on Anatomical Transplants

REPORT OF THE

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ON

ANATOMICAL TRANSPLANTS

Senator Ollie Speraw, Chairman

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INTRODUCTION

Although the concept of human organ and tissue transplantation has been acknowledged by the medical profession for decades, technological advancements during the post-World War II era have moved at a pace rivalling even those of the spectacular space sciences.

Removal of an organ or tissue from the body of one person to save or enhance the life of another is no longer considered speculative medicine, but rather an accepted practice throughout the world.

Studies have illustrated the urgent need for organ and tissue transplantation. For example, in 1979 only slightly more than 3,000 of the 45,000 kidney patients on hemodialysis in the United States received transplanted kidneys, while an estimated 20,000 potential donor Americans died from brain injury, brain tumor, stroke or the like. It is estimated that by 1990, 80,000 to 100,000 end-stage kidney failure patients will be on dialysis, half awaiting transplantation.

Consent of family is required in the United States prior to removal of organs for transplantation. However SB 21 (Presley), recently enacted, allows coroners in California to authorize the release of eye tissue in the absence of dissent. Although there is no other "presumed consent" law in the 50 United States, 13 other countries now have presumed consent laws, which allow organs to be harvested in the absence of dissent of the donor or his/her family. Even those countries with presumed consent fail to meet their transplantation needs as they arise.

There is no question that an urgent need for transplantation exists, and therefore great promotional steps have been taken. As a special project of the Select Committee on Anatomical Transplants, a non-profit organization, the Anatomical Transplant Association of California, (ATAC) was encouraged and formed.

In existence for more than three years, ATAC has promoted the education of the lay public and medical professionals, established a transplant "hot line", and raised substantial funds, all for the sole purpose of promoting and facilitating organ and tissue transplantation.

Very recently, the California Department of Health and Welfare, through administrative channels, authorized Medi-Cal benefits for heart transplant recipients. Heart transplants no longer carry the "experimental" label with them.

BACKGROUND

Several questions and relative problems in the areas of a standard protocol for the determination of brain death and coroner involvement have developed as organ and tissue transplantation have increased. California has followed the UDDA, Uniform Determination of Death Act, California Health and Safety Code, Section 7180, since its adoption by the state in 1982, although different hospitals and doctors follow different procedures and protocol in the determination of brain death.

Recently, a DMV survey sent to 7 million Californians, revealed how uninformed the average California resident is about the determination of brain death. Those that replied indicating that they did not want to donate organs gave the reason that they were afraid that "perhaps they might prematurely take the donation".

In addition, the brain death issue was currently in the news due to a 5-year old child connected to life-support systems. Four medical physicians had diagnosed the child as brain dead, but the mother refused to consent to the withdrawal of the life support. The mother sought a mandatory injunction to keep her child on extraordinary support, which the court granted, despite the prior diagnoses of brain death by the four physicians.

The questions of jurisdiction and coroner involvement was brought into focus when another child, diagnosed as brain dead in Oregon and flown to California for the purpose of organ transplantation had two death certificates prepared and filed, one in Oregon and one in California. The potential problems created by this type of occurrence can involve state benefits, and probate proceedings, not to mention which state's coroner/medical examiner has responsibility for the body.

It is against this backdrop of these potential problems and questions that a public hearing was held on September 18, 1984, for the purpose of evaluating the possible need for a specific protocol in the determination of brain death, and the rights and responsibilities of the respective coroners or medical examiners. Involved, distinguished and knowledgeable witnesses shared impressive testimony on these extremely technical and sensitive subjects. It is from their testimony and related documents and personal inquiries that the following report is extracted.

CRITERIA FOR DETERMINATION OF BRAIN DEATH

Presently, there is no strict criteria followed by every hospital and doctor in diagnosing brain death. The UDDA is broadbased in scope and leaves the determination of death--somatic or brain death, which are across the board considered legal death in California--in the hands of the physician or physicians involved. The UDDA encompasses the case of brain death as well as somatic death, and includes the organ donor situation while a strict criteria for the determination of brain death would ideally give reliable results that could be accepted without question by the medical or lay public, special standards for organ donation situations may give rise to justifiable public concern that the practical and urgent concerns of the recipient may be allowed to outweigh the interests of the potential donor.

Recommended criteria for brain death diagnosis have been published by the Medical Consultants on the Diagnosis of Death to the President's Commission for the Study of Ethical Problems in Medicine & Biomedical and Behavioral Research, a Harvard University Faculty ad Hoc Committee appointed for this purpose, the American Association of Neurological Surgeons, and numerous individual neurological surgeons, including Lawrence H. Pitts, M.D., Chief of Surgery at San Francisco General Hospital, and Julius Yeomans, Professor of Neurosurgery at U.C. Davis Medical Center. The criteria all suggest the same basic procedures in the determination of Brain Death:

(1) Known mechanics of the injury

(2) Ruled out intoxicants

(3) Absence of brain function, cerebral non-responsivity

(4) Apnea, no breathing

Although the basic requirements may be relatively the same, there are nuances and variations that the involved physician must take into consideration. For example, some criteria suggests a "flat" electroencephalogram (EEG) as part of the protocol, while others require confirmation of the diagnosis of brain death after a period of 6, 24, or 48 hours.

However, the question of whether or not to standardize the criteria by codifying it was unanimously rejected by all the physicians and witnesses involved at the hearing. One reason cited was the rapidly changing and improving medical technology such as the nuclear magnetic resonance scanner. A strict protocol for determination of brain death would very probably restrict the capability of modern technology, in determining brain death, thereby causing undue delay and risking the loss of a potentially lifesaving organ suitable for donation. Also, physicians were in agreement that each patient and his or her particular set of circumstances differ so that strict criteria for determining brain death could not encompass all circumstances that arise, again possibly causing needless and risky delays. The general consensus of the witnesses was that no suggested criteria was intended to be "ironclad". In fact, one witness physician referred to the UDDA as a "masterpiece of brevity and clarity".

However, there were questions posed regarding the need for a 24-hour confirmation of brain death prior to harvesting of organs for transplantation. The physician witnesses were in agreement that once accepted criteria had been met and a patient was declared brain dead the chance of survival was zero--no one has ever survived after a diagnosis of brain death--and to require a 24-hour confirmation had "no relationship to the real world", and was impractical, or worse, detrimental, in most cases, possibly causing damage to the organs to be transplanted. Brain death is "irreversible".

With respect to the EEG portion of some criteria for diagnosing brain death, there has been in the past an erroneous assumption that the EEG is required by statutes. Actually, the EEG was instituted as a conservative and additional reaffirmation of the brain death diagnosis and not meant to be a determining factor in the diagnosis itself.

CORONER INVOLVEMENT
Authority and Responsibilities

Coroners and Medical Examiners in California are county agents, but subject to California Statutes as well. As a result, due to individual counties' interpretation of state law and differences in the county regulations, each county's coroner or medical examiner functions independently from his or her counterparts in the other California Counties.

The primary role of all coroners/medical examiners is that of law enforcement and the protection of public health. Their involvement in the area of anatomical transplants stems from the fact that the primary candidate for organ donor is an individual who is free of disease or significant aging process and has suffered a traumatic or sudden somatic or brain death, typically under the jurisdiction of the county coroner or medical examiner. There is a definite need for interaction between the coroner and the transplant programs, and the major problems encountered have been either the loss of a potential donor patient or the loss of evidence for the judicial system, or both. For instance, when a brain dead individual is connected to life support systems for the purpose of harvesting the organs, the coroner may lack control over the evidence of blood alcohol content as it dissipates. Also, clothing cut off the body may be discarded or lost in haste, rendering possibly valuable evidence lost forever.

The jurisdiction of the coroner typically remains in the county where a sudden and questionable death occurs. However, the county where an alleged crime is committed generally retains jurisdiction and responsibility for any criminal investigation involved. If a body on life support systems is transported across county lines, the responsibility of the body for purposes of medical autopsy transfers with the cadaver, but the examining coroner must testify, if necessary, in the county wherein the crime was committed. As a result some confusion and differences in procedure can cause additional problems.

One suggestion offered to solve the question of coroner jurisdiction in transporting a body on life support systems across county lines for the purpose of organ transplantation was to investigate the possibility of amending the rules and regulations applying to funeral directors and embalmers to encompass that situation.

CONFIRMATION OF BRAIN DEATH

It is not unusual for an individual to be declared brain dead by physicians and immediately transported across state lines to supply organs to awaiting recipients, and confirmation of brain death by additional physicians in the second states has been standard procedure. Witnesses were generally in agreement that such reaffirmation of a diagnosis of brain death should be omitted in the absence of doubt after review of doctor notes from the physician that originally declared the patient brain dead.

REMAINING ISSUES TO BE RESOLVED

Many questions were posed by witnesses that require the time and effort to research. These unanswered questions are indicative of the problems encountered and the confusion resulting from the rapid growth in the area of organ and tissue transplantation. The following is a list of such inquiries that urge the Legislature's response and the continuance of this committee on anatomical transplants:

- Can and should we do away with the requirement of a 24-hour-later confirmation of brain death?

- Should a second EEG 24 hours later be required, even in clearly and irreversibly injured patients (classic example: steamroller over the skull)?

- Should we legally distinguish between "life-support systems" and "organ function support systems"?

- What if a physician mistakenly or through some error, transfers a homicide victim across state lines?

- If a death initially thought to be an accident or suicide changes in its perception, how can we protect the people involved?

- In those cases where the coroner has jurisdiction with the legal proviso that jurisdiction starts at the moment of death, when does he assume physical and legal control?

- When does the coroner assume the responsibility for the body and the evidence that goes along with it?

- Who has the legal responsibility for collecting and maintaining in a legal chain of custody such evidence as paint fragments, fibers, foreign material, or blood in urine for toxicology or serology?

- Who has the responsibility for documenting pattern injuries that may be present on the patient initially, but will fade or disappear or be lost over the days or sometimes weeks?

- Who would pay costs of investigation by a coroner on admission of patient but prior to diagnosis of brain death?

- With our capabilities, is a patient who is being transported over a state or county line brain dead by definition somatically dead?

- Which coroner or medical examiner is responsible for the investigation and, therefore, which county incurs the costs and responsibilities of the investigation and potential court presentation?

- If brain death is somatic death, do you have to file a death certificate and get a transport permit to move a patient across county or state lines?

- If brain death is somatic death, what becomes of the brain dead patient on a respirator for weeks or possibly months?

- Do we file a death certificate at a required time even though that patient may technically have an EKG on a ventilator?

- Once a brain dead patient is taken across the state or county line with or without a death certificate or transport permit, what procedure do we go through to legally get them back to their loved ones?

- Is the coroner or medical examiner responsible for obtaining donation permission in harvesting tissue?

- And, does this interfere with his responsibility as a law enforcement officer and does it incur any reflection in the public's eye as to his impartiality to do such an investigation?

- Should an alleged homicide case be included or excluded from consideration in this program?

- Should date and time of death be when brain death is diagnosed or when circulation ceases (when organs are removed)?

- What time and date should go on the death certificate?

- Does the local coroner have jurisdiction when a body is transported from another county or state for organ transplantation?

- Should judicial panel or judge be able to override concurring opinions of physicians that patient is brain dead, and require that organ function support system be kept on patient?

- Should brain death information regarding criteria (and ethics) be required by law to be taught to medical students?

- Should there be law allowing family (or a conservator) to order the plug pulled prior to a decision to do so of physicians involved (physicians may be afraid of liability to them)?