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Criteria For Brain Death

Senate Select Committee on Anatomical Transplants

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CALIFORNIA LEGISLATURE
SENATE SELECT COMMITTEE ON
ANATOMICAL TRANSPLANTS
Senator Ollie Speraw, Chairman

CRITERIA FOR BRAIN DEATH

Hearing
September 18, 1984
University of California at Davis
Medical Center
2315 Stockton Boulevard
Auditorium, Room 1107
10:00 a.m.

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California Legislature

SENATE SELECT COMMITTEE
ON
ANATOMICAL TRANSPLANTS

OLLIE SPERAW

CHAIRMAN

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ANATOMICAL TRANSPLANT COMMITTEE HEARING

Tuesday, September 18, 1984
University of California at Davis
Medical Center
2315 Stockton Boulevard
Sacramento, California
Auditorium, Room 1107
10:00 a.m.

WITNESSES

Boyd Stevens, M.D.
Chief Medical Examiner/
Coroner

City and County of San Francisco

Phyllis Weber, R.N.
Program Director

No. California Transplant Bank at
Pacific Medical Center

Lawrence H. Pitts, M.D.
Chief of Neurosurgery

San Francisco General Hospital

Julius Yeomans, M.D.
Professor of Neurosurgery

U.C. Davis Medical Center

Davis Drinkwater, M.D.
Asst. Professor of
Cardiothoracic Surgery

U.C.L.A. Medical Center

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of Driver Safety and Licensing

Jay N. Hartz, Esq.
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J. E. "Skip" Muir
Asst. Vice President
for Legislative Relations

California Hospital Association

IN ATTENDANCE

Senator Ollie Speraw
Assemblyman Nolan Frizzelle
Senator Robert Presley
Senator John Doolittle

STAFF IN ATTENDANCE

Kathleen A. Norris, Associate Consultant

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CHAIRMAN OLLIE SPERAW: We're about ready to start. We had a letter from Senator Diane Watson that said she would be attending. I was delaying to see if she would make it, but I know that everyone here to testify has a busy schedule and time is important, so we won't delay any further.

I am Senator Ollie Speraw, Chairman of the Select Committee on Anatomical Transplants. With me is Senator Robert Presley. I might add that Senator Presley has been a supporter of this committee and carried the bill last year that changed the law so that coroners were able to authorize the release of eye tissue in the absence of dissent on the part of any next of kin, which was just a reversal of the role -- instead of having to obtain consent, if there wasn't any dissent there, they were able to release it.

That bill, at this point in time, has accommodated about half of the people who were awaiting cornea transplants -- about 1,000 people. There was a waiting list of about 2,000 at that time. Hopefully, within the next few months, the entire backlog will be cleared up and all these people will have a normal quality of life restored. Of course, this means not only has joy been brought to their lives, but also to the lives of the taxpayers since most of these people have to rely on some social assistance.

Senator Diane Watson is Chairman of the Health and Human Services Committee so that you will know when she arrives what her interest in this is.

With regard to some of the past work of this committee, we generated a bill which was to place heart transplant benefits under Medi-Cal. Since there would be about a \$7 million expense connected with that, and the Legislature has been very cost-conscious of late, we explored possible sources of revenue to offset this cost. We discovered that when people who have been using wheelchairs, pacemakers, etc., and all the other types of equipment, pass away, this equipment just becomes part of their estate; it does not revert back to the State of California. As a result, there is approximately a \$10 million expense per year for these types of health aids. So we included in the bill a provision that at time of death this equipment would revert back to the state.

~~The Health and Human Services Department felt that part of the bill was cumbersome~~ and they wouldn't be able to implement it; however, they dropped their active opposition at the last moment and the bill was passed and is in front of the Governor now.

I have been informed by Secretary Swoap of the Health and Human Services Department that they have the administrative capability to authorize payment of heart transplants under Medi-Cal without SB 1967 and they are asking the Governor to veto the bill because they feel it is an administrative nightmare trying to keep track of all the health aids and equipment that are dispersed around the state. In any case, they are

authorizing heart transplants for Medi-Cal, irrespective of whether the bill is vetoed.

This is the fifth hearing that this committee will have held in the past year. It is also the last one. We will deal exclusively today with the question of brain death. I might add that our first witness is responsible for this hearing being held on this subject.

Dr. Boyd Stevens is the Chief Medical Examiner and Coroner of the County and City of San Francisco. I have worked with him for three years through a nonprofit group called the Anatomical Transplant Association of California in which he and other coroners have been quite active.

I am not going to spend a lot of time addressing a subject on which I am certainly not an expert as are few other lay people. I will leave it to Dr. Stevens to set the ground for why we are here today and what his concerns are, including the fact that determination of brain death is not uniform throughout our fifty states and the problems generated when brain-dead bodies cross state lines. Dr. Stevens, if you would please start the testimony.

While he's coming up, I would like to announce that we have additions to the agenda. First, Dr. Lawrence Pitts will be represented by Dr. John Wagner of UC, Davis, and attorney Jay Hartz of Weissburg and Aronson, Inc., of Los Angeles. We also have received letters from Brian Broznick, Organ Procurement Coordinator of the University of Pittsburgh; Dr. Albert Jonsen, Professor of Ethics at the University of California, San Francisco; Dr. Thomas Raffin, Assistant Chief of Medicine at Stanford University Medical Center; Dr. Philip Calanchini of the Pacific Medical Center; and Dr. David Ogden of the National Kidney Foundation, that will be included as part of the record.

One additional introduction is the chief counsel to this committee, Kathleen Norris, on my right.

Doctor, It's all yours.

DR. BOYD G. STEVENS: Thank you, Senator. Good morning, Senator Presley and Miss Norris and ladies and gentlemen.

I won't go back into the history, since I know you've already done this, of transplantation and the benefits that can be reaped by that. But I would like to just simply ~~address one thing and that is the aspects of the issue of medical examiners/coroners~~ and their involvement in sudden unexpected death.

As you know, the primary purpose of the medical examiner/coroner is that of law enforcement and protection of public health. It's also well known to you, however, that the ideal candidate for a tissue donation is a healthy young individual who is both free of disease or significant aging processes and is either somatically or brain dead suddenly and unexpectedly. By definition this is a case that is typically death under the coroner or medical examiner's jurisdiction with relatively few exceptions.

Since we must obviously be an interrelation between any transplant program and those responsible for the investigation of sudden or unexpected death, there must obviously be support and interaction between the two. In point of fact, that has not always been the case up and down the state; and there have been conflicts and problems on both sides including those that cause the loss of potential donor patients from the system as well as those cases that have cost the loss of evidence for the judicial system.

The problem, then, that I want to discuss here today deals primarily with the resolution of those difficulties so that tissue and organ transplantation can continue to advance the welfare of mankind smoothly and unimpededly. Principal to tissue harvesting is the assurance of death or that death is totally assurable. No family should have to fear the potential of error in the diagnosis of death. That anatomic death is assured beyond any reasonable doubt must be an unquestionable principal for any of our donor programs.

Although all of our states have adopted a Uniform Anatomic Gift Act, principal to which is the concept of brain death, there is considerable variation by which that critical decision is made. Not only do the minimum criteria vary, but the quality of the evaluation and the training of those making the diagnosis of somatic or brain death vary tremendously.

Currently, all of the cases that I am personally aware of in the United States where a person was declared dead but in fact wasn't were patients pronounced dead by physicians. In some situations death was so very near that the difference was a mere technicality; but nevertheless, the basis for cures is such that doctors will act in a selfless or self-serving manner, taking lives to aid their own purpose. This evokes the movie writers and, of course, stirs the press.

The most significant problem of concern to myself and others, however, is the judicial aspect. Since many of these patients are victims of accidents or violence, there is an increased probability of a court proceeding either in the criminal or civil system. Such proceedings are extremely expensive to the taxpayers and depend heavily on evidence and facts for proper adjudication. More and more, patients are being removed from the scene of the death or injury and, more and more, they are being placed on life support equipment while the issue of tissue harvesting is considered. Without the scene of the injury or the accident or the event, careful investigation becomes difficult. While the patient is in the hospital, vital real and biologic evidence is being lost.

Recently we had the experience of a young lady who had taken an overdose in another state who was determined to be brain dead largely by physical examination and an EEG. The medication she had ingested was a classic, a very strong respiratory and mid-brain depressant. She was transported across several state lines to my particular jurisdiction.

On investigation, having heard of the case, I determined that she was not legally brain dead. Brain death was redetermined in our state and she was used as a donor successfully.

I performed an autopsy and examination. The drug in question was still detectable in her body. However, afterwards, the county jurisdiction issued a death certificate. This death certificate then raises a tremendous difficulty, because the lady had two death certificates, two separate times and dates of death. And as you can well imagine, her death has left a conflict typical of what we are seeking to avoid.

What if a physician, mistakenly or through some error, transfers a homicide across several state lines? Or if a death initially thought to be an accident or suicide changes in its perception, how can we protect the people involved?

Principal to this purpose is the issue of jurisdiction, reporting to the legal authority, and some degree of investigation, supporting the manner of death prior to the intercounty or interstate transport of those cases where the entire patient must be moved. And I know well that this committee is familiar with the differences.

Similarly, this should be true where patients of unnatural death are being maintained for potential harvesting. The same policy should be enforced nationally as well as within the state.

Secondly, there must be a uniform brain death protocol, one that will reasonably protect patients and physicians alike from error. I personally believe that the protocol proposed by Dr. Pitts, which you are familiar with and will be discussing, will reasonably preclude the potential for medical error that a patient who in fact still has brain stem function will be inappropriately or mistakenly pronounced brain dead.

Under the concept of the Uniform Anatomic Gift Act, brain death is in fact somatic death. All life forces have irreversibly left the patient, never to return in any form; and as such, the following problems become significant to the medical examiner/coroners responsible for the investigation of that death.

First, when is a brain-dead individual legally dead? What date and time should go on the death certificate? On those cases where the coroner has jurisdiction with the legal proviso that that jurisdiction starts at the moment of death, when does he assume ~~physical and legal control? When does he 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? Since these patients on a respirator to facilitate harvesting for hours or even days continue to metabolize chemicals, many times that evidence is lost. Since the potential for a legal

motion or a trial misdirected is enormous against what would have been proven by appropriate investigation -- or, I should say, could have been proven -- there is little doubt that prolonging the patient's life interferes with or affects, at least, potential for a proper adjudication.

Many of the facilities, for example, have protocols where wounds are debrided if a patient appears to be capable of surviving for 24 hours. As such the issue of a wound such as a gunshot wound may become clouded in the aspects of the distance from which the weapon was fired; and therefore, the issue of homicide, accident, or suicide becomes forever clouded.

To me, this type of question would require the examination of the patient on admission by a criminalist or forensic pathologist when trained in collecting and recognizing that evidence as well as the appropriate photography, collection of blood and urine, other specimens for proper examination. Who will pay for these costs?

Currently, we know who pays the costs when they aren't done properly because in the judicial system, these questions become major questions and with the advent of Hitch and Nations and several other decisions regarding evidence, such issues are commonly major difficulties.

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, and mention the issue of what time and hour go on the certificate? Additionally, if brain death is somatic death, do you have to file a death certificate and get a transport permit to move a patient across the county or state line? If indeed brain death is somatic death, then 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 ~~part of that answer is currently in the works, as you're well aware. Does this inter-~~ fere 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 a homicide case be included or excluded from consideration in this program?

Obviously, I suggest and believe that these are not minor or trivial questions, but the very foundation of which any transplantation program must be based. They go to the root also of our American judicial system and the health of our community.

We've recently seen a coroner accused of contributing to a recipient's death by

failing to make certain patients available for harvest. As a result, these questions not only in our state but nationally take on potentially more and more consideration.

If we make appropriate legislation to evaluate a patient and determine brain death appropriately throughout the nation, that alone would help solve many of these problems. The uniform brain death policy is one that must be followed ... in order to mean a meaningful transplant program.

Additionally, we need to recognize the few problems involving certain tissues, at this time, that require intercounty or interstate transplantation or transport of the patient in its entirety. As you well know, many organs and tissues do not have that unusual situation.

Since many of these patients represent civil or criminal issues, the transplant program must not advance at the expense of the judicial system. In my opinion, to attempt to do so would be a critical error, because in that struggle the transplant program could only lose.

Finally, the coroner system in the State of California is extremely vulnerable as we've recently seen. The system is generally not well-established or supported in the U.S. in its entirety so that problems in methods of handling them vary widely as they do even within the 58 counties of this state. Since the changes we are discussing could be national, or should be national, in their scope, inappropriate and poorly made laws could literally destroy the medical legal investigation system as it exists in the United States. That would be a major injury to the legal and health programs in America and, in short, could make every suspicious death investigation as poor and as suspect as that of President Kennedy.

There is no reason that reasonable laws cannot be enacted to benefit all. With appropriate safeguards, no rights would be violated and both health and law would grow. To reach this goal, we need reasonable, well-thought-out state and national laws that fit the needs of all involved and don't sacrifice one aspect of patients' care.

One of the additional things that we may well consider is adding appropriate courses in medical school on death determination and the legal responsibilities of physicians. Generally we find that neither of those subjects are included formally in medical school programs; and if they are, they're given only very casual treatment.

That's my prepared statement. Can I answer any questions?

CHAIRMAN SPERAW: First of all, do we have a copy of your statement?

DR. STEVENS: I will see that you get one.

CHAIRMAN SPERAW: Thank you. Could you explain, Dr. Stevens, because the question has been asked me several times by reporters who are interested in this hearing, whether or not this has anything to do with pulling the plug on live patients?

DR. STEVENS: Yes, it does. As you well know, there is a great deal of controversy

about who has that authority or who should take that authority or who wants that authority. It's an extremely tough decision many times to make. We do not have well-prepared programs for handling just that issue, as you pointed out in the literature that Miss Norris prepared.

A classic example of exactly such a problem exists in the state now. These are not totally unheard of. This one has caught a lot of attention. But these are major issues because the issue on this particular case reference is whether or not the step is a factor if a patient dies of homicide. The longer the patient lives on a respirator, the more difficult those questions become to answer. Actually pulling the respirator plug or turning off the ventilator or life support equipment is tough. Legally there is a precedence. Legally the law sets forth those criteria. However, a court order has been issued not to turn off the respirator.

So yes, it does go to exactly that definition of when and how and who should do it.

CHAIRMAN SPERAW: But then, in fact, you're raising a second question. One, we have a person who is still legally alive and there has to be a decision made whether or not to pull the body function systems. Is that correct?

DR. STEVENS: Yes. On the brain death, the criteria should be absolute. The brain-death individual cannot survive without mechanical support. That should be an absolute criteria. But a patient who is injured severely and who is unquestionably not going to survive but who is not brain dead, that's another and totally separate issue.

CHAIRMAN SPERAW: All right, thank you.

All right, first of all, before we get into other questions, I'd like to introduce Assemblyman Nolan Frizzelle, representing the Fountain Valley area of Southern California.

Are there questions of the witness?

SENATOR ROBERT PRESLEY: Only a question of jurisdiction, Doctor. I always thought that the jurisdiction rested with where the---I guess in this case in your discussion, involved with crime--where it initially was committed. For example, if it occurred, say, in Phoenix and the person was transported to the Eisenhower Medical Center in Palm Springs, I thought the jurisdiction would remain with Phoenix. Is that clouded?

DR. STEVENS: Well, it is clouded, Senator. The investigative responsibility is ~~ordinarily where the crime was committed. The responsibility for the body is where the~~ body lies. So under the laws that exist now, if somebody murdered an individual in another county, transported the body to my county, I am the responsible medical examiner, even though the investigation for that case may be handled by another agency. It ordinarily means then that I would have to prepare my report and go to that other place for the actual court presentation. But yes, there is a dichotomy.

SENATOR PRESLEY: But within the State of California that law would be applicable statewide, so county to county wouldn't create the problem that state to state does.

DR. STEVENS: Well, no, that is the existing law in the county as you are well aware that coroner/medical examiner is a county agency, not a state agency. So we're limited by our county boundaries. Within the states, it becomes even more confusing because some states have a state medical examiner system and some have a coroner system that varies from what we use.

SENATOR PRESLEY: I think you're saying that the longer a person is in a hospital on life support systems, the less viable--I guess is the word--the organs that may be potentially transplantable.

DR. STEVENS: No, not necessarily. That really goes to the quality of their condition at the time they're actually pronounced brain dead. If the patient is not labile, in other words, very difficult to maintain, does not become infected or septic, then the organs may be fully transplantable for quite a period of time.

SENATOR PRESLEY: But it does cause a deterioration on some very important evidence, I guess.

DR. STEVENS: Well, it does. Just as a very quick example, if a person was in an auto accident and had a very high level of, say, alcohol, even though they are technically on a respirator and unquestionably brain dead, they're still metabolizing the alcohol at the rate of about one ounce per hour or very nearly so, as long as the liver is oxygenated. Therefore, the body continues to eliminate that drug as long as they're on the respirator. If the question asked of me, then, as a medical examiner after 24 hours is, was this person legally drunk, I have no data on which to give an opinion. And that's true for many drugs. And I had mentioned fibers and other evidence. In most of our trauma centers, one of the first things that's done to examine a patient is to cut the clothing off. With that clothing goes so much vital evidence.

Obviously, if the patient survives, that's an entirely separate matter and certainly that's the primary responsibility. But if the patient is not survivable in the beginning, once that evidence is lost, it's gone forever -- the clothing are lost or thrown away or discarded and the issues of distance of gunshots, the movement of particular automobiles, so much of that trace evidence is just simply lost forever.

SENATOR PRESLEY: Is there any prohibition against a doctor, or maybe not a doctor, ~~any kind of an evidence expert, coming into the hospital and securing that evidence---~~ immediately flown in to the hospital and while the person is under a life support system?

DR. STEVENS: No, there is no prohibition against doing that as long as it is a crime or a crime being investigated. Some cases would not ordinarily be investigated by the police in the same aspect. It really goes to protocol, what's commonly done, legal jurisdiction, and even reporting a case. Many times cases are simply not reported.

We recently had a man walk into the hospital with a fractured neck who indicated that he had been robbed and during the robbery his neck had been broken. But he was

still able to walk into the hospital. The patient died, essentially, two days later. There was never a police report made because it was expected by the hospital staff the patient would survive.

So there are many factors that do cause difficulty, but technically, there's no law that would prohibit someone from the police department or agency going there. There is an increased cost, of course, because some of these cases would never be adjudicated. But that's not the basis on which law enforcement works.

SENATOR PRESLEY: Since the Legislature is in the business of trying to clarify law or laws, have the coroners met and are they able to with one voice make a recommendation to the Legislature in areas where these kinds of confusion or cloudiness of the law could be clarified?

DR. STEVENS: Well, they do within our jurisdiction, Senator. The California Coroners Association represents the vast majority of county coroners, and they do have information that they've prepared and are certainly willing to submit and have done so in the past for the use of the Legislature.

SENATOR PRESLEY: So those recommendations have been made and it's up to us to try to sort those out and then, hopefully, they'll gain passage of some changes ...

DR. STEVENS: Yes, sir.

SENATOR PRESLEY: ... where we generally are at the moment.

DR. STEVENS: Yes.

SENATOR PRESLEY: Thank you, Mr. Chairman.

CHAIRMAN SPERAW: Nolan? Care to ask a question?

ASSEMBLYMAN NOLAN FRIZZELLE: I might take a stab at one ... I carried a bill last year, 3378, that I dropped in the Judiciary Committee before the legality problems in many circumstances confronted by physicians and attorneys. It has to do with the ethics, I suppose, and morality of making a final determination of when an individual is dead. And I consulted Leslie Steven Rothenberg. You may know of him through his efforts with the Los Angeles County Medical and Bar Association. They have a joint committee trying to deal with this very critical problem.

If I may, Mr. Chairman, I'd like to read just one little segment of this letter now ~~because I think it bears---it kind of goes to the heart of an issue. He says:~~

Finally, I am not so certain that eliminating any fear of liability is good for the patients. I have not been sued or prosecuted to date for the dozens of situations in which I have recommended the withdrawal of treatment and have stood by while treatment was withdrawn and the patient died. I certainly hope that I will never be found to have acted in violation of any civil or criminal legal standard. But if I should in the future, that is a risk that I must be willing to face as long as I do the type of work I do. I must approach each patient with humility and extremely conscientious concern, carefully learning and documenting each element of the factual situation on which I base my recommendation or consultation. I don't want people to be casually

strolling down the hall, deciding who shall live or who shall die. I know that is your opinion as well, but if we make this task too risk-free [that is, by defining to tightly all the different elements that comprise death], there are those who may succumb to laziness or indifference or worse motives. The concern about unknown liability may keep some people "on their toes"; it may also prevent patients from having their rights respected, but the solution to that may be to encourage them to find another physician or hospital, if possible [if there's a doubt].

I think that this gentleman has been dealing with this problem for many years. I know you have a board or some kind of a device, I understand you have, that makes or accepts some kinds of recommendations regarding death, when it occurs, who should be allowed to expire and who shan't and so forth. If we're going to transplant organs, I think it's very important that there be some definable way of ascertaining whether or not this individual body or structure could sustain life if it weren't on life support systems which you can't find out until you take the life support systems away. Then you get into the area of legal liability.

I'm not sure that we can solve the issue of transplants, Mr. Chairman, until we get to the business of solving legal liability, who makes these kinds of decisions. My bill spoke simply to having the family or nearest relatives have a hand in making that decision. If the patient does not activate themselves prior to being in the hospital, that legal document that they can activate, as I understand it, currently, which directs at what point, by the patient, at what point life support systems would be withdrawn.

I don't know that I have a specific question except to frame an issue that is sort of a bottom-line context for deciding how organs or when organs might be lifted or transferred from one individual to another. It's all related. And this gentleman, after much consideration, seems to say, let's not make the decision, let's decide not to decide in order to provide an ongoing risk to physicians so that they will not treat too lightly this concept of withdrawing life support systems or recommending that they be withdrawn.

DR. STEVENS: Well, my comment is that generally physicians take on inherent risk when they take their license, and almost everything they do is a decision-making process. Under our current system, risk is certainly entailed in many of the decisions they make.

~~I haven't really discussed or talked about ethics, because I know that's been a~~
subject this committee has handled before. But the ethics of dying and of no-code policies of how an individual hospital or medical group is going to handle the terminally ill or dying patient is another totally different subject. Ethics are extremely important here, and I think many times that the public is very concerned about just that factor. That's a subject that's commonly mentioned to me by next of kin when an issue of turning off a respirator or the fact that a no-code policy has been written by a physician, has occurred. And certainly one of the important ethic considerations is

the family itself. The right to die policy that you described is a very important document. But it's human nature for all of us not to expect to die; and therefore, few people are really that farsighted to really take the time to sit down and fill that very simple document out or even to discuss it with their next of kin as to what they want to happen in the event of a severe illness.

Those are important considerations and certainly just as the old issue of transplantation, discussing that with your family and loved ones, making your wishes one way or the other known is very important, because among other things it helps take some of the pressure off the family at that moment, a tremendous situation of grieving and the grieving process.

So I think the person who wrote the letter to you was certainly---has firsthand understanding of the ethics issues involved. I hadn't really gone into them because of what I believe the committee has done in the past.

CHAIRMAN SPERAW: I would---first of all, do you have a question? Well, thank you very much, Doctor.

DR. STEVENS: Thank you so much. Thank you for holding the hearing.

CHAIRMAN SPERAW: You're most welcome. For the succeeding witnesses, I'd like to ask that because the question has also been raised---or the issue has also been raised of the removing of life support systems for living patients as opposed to brain-dead patients, that if when they refer to life support or support systems that they clarify that they're talking about a life support system of a live person or whether they're talking of a support system for---we can refer to it as an organ function support where there is brain death. If you could clarify in your statements which it is you're referring to. Because without that, some of these lay people here may get a little confused about the issue you are addressing.

All right, our next witness is Phyllis Weber, the Program Director for the Northern California Transplant Bank at Pacific Medical Center in San Francisco.

MS. PHYLLIS WEBER: Good morning, concerned ...

My testimony is basically directed to the questions that you asked us in your letter of invitation, Senator Speraw. And I would like to comment on some things that ~~were discussed with Dr. Stevens after my~~

CHAIRMAN SPERAW: Could you briefly explain, first, exactly what it is that you do and why you're involved?

MS. WEBER: Sure. I'm the Program Director of the Northern California Transplant Bank. Our activities involve coordinating organ donation with the transplant centers in Northern California. We also operate a tissue bank including an eye bank which Senator Presley was ... [Inaudible.]

A couple of things: What criteria should be accepted in determining brain death?

Because of rapidly changing medical technology, we feel that it is very important not to incorporate medical criteria into the brain death statute that is already in existence in the State of California. While the State of California has a legal standard for the determination of brain function or brain death, the medical criteria must remain the prerogative and the responsibility of individuals involved.

We would recommend a uniform agreement among physician groups, however, to adopt certain criteria, such as those described by Dr. Pitts in his recent article in the Western Journal of Medicine. This would eliminate confusion regarding acceptable medical standards in the determination of death.

To give you an example, there is still a lot of confusion in hospitals as to what actually is the legal standard of death. Many hospitals have written their policies and procedures years before the California brain death statute went into effect in 1974. They require, for instance, on some occasions, two isoelectric EEGs 24 hours apart. Some hospitals even require three. Since this is not the legal standard in the state, there still is some confusion though as to how hospitals should approach this. And because the medical criteria are under the responsibility of the physician that it assumes that the physician will adhere to the standards in the community and that often is what the hospital's policy has already been dictated to be.

This has also been a problem on occasions with some of our county coroners who when we contact them about getting consent for organ donation, they will say well, do you have the results of the three EEGs. And again, since that's not legally required, we would like any attempt that you could make to eliminate the confusion in that area.

This conservative approach to declaring a patient brain dead can also result in a circulatory demise of the patient which would mean that even if the family was very committed to organ donation, the process or the delay in declaring brain death may mean that the patient will no longer be suitable for organ donation. This has been a very devastating impact to some family members who have really wanted to make some sense out of a terrible tragedy.

CHAIRMAN SPERAW: A question on that point: Aren't these patients on life support systems at that time and doesn't that preserve the organs and tissue?

~~MS. WEBER: Perhaps we should really clarify what we're looking for in the brain-~~
dead individual who is to be an organ donor. These patients have to be without any--- they cannot make any attempt to breathe without the aid of a ventilator support. The patients are in a deep coma. They're unresponsive to any type of painful stimuli. That's really the basic medical assessment that the physician will make of the patient.

Now there are other promontory tests that can be done to support this assessment of the physician. If you will read Dr. Pitts' criterion, I'm sure that Dr. Wagner will address this later on, these other supporting laboratory tests are not always necessary.

CHAIRMAN SPERAW: But my question---it's still not clear to me. If the person has lost the ability to perform his own body functions, and there still hasn't been a determination of brain death, doesn't the person go on life support systems at that time until brain death is determined?

MS. WEBER: I think it would depend on the situation of the individual patient -- what diagnosis the patient has, what disease the patient has. If we're talking about a patient who's involved in a car accident comes to the emergency room and it looks like that patient is not going to be able to maintain his vital functions, then yes, that patient resuscitated, is put on life support systems until some time can elapse where the determination of brain death can properly be made.

CHAIRMAN SPERAW: But you're saying that there are some cases where the determination will be made that the person is dead and therefore ... on life support systems even before a brain death is determined?

MS. WEBER: No, brain death can't really be determined unless the patient is maintained on life support. I think, you know, if the patient is not on life support systems, then the patient dies a circulatory death or a somatic death as Dr. Stevens often refers to it.

CHAIRMAN SPERAW: My question was based on the statement you made that sometimes procuring the organs is defeated by the waiting for the determination for the brain death. And I just thought they would be on support systems during that period of time.

MS. WEBER: Yes, the patients would be. However, as a result of the injury that the patient has sustained, the patient may become very unstable. And many studies that have been done, retrospective studies evaluating patients that have been declared brain dead, very few patients will survive more than about 48 hours once it's very apparent that the patient meets the clinical criteria for brain death, even if they are maximally supported on ventilator support.

Another question that you had was, Should "brain" death be accepted as legal "death"? The Uniform Brain Death Act establishes that irreversible cessation of brain function as death. This policy has become a legal standard in the State of California; therefore, we believe that there should be no question as to brain death being accepted as legal death. ~~We operate under the premise that the legal time of death is the time~~ when the second physician documents brain death in the patient's chart.

Just to give you, again, an example of some of the common problems that we run into when our teams are often out in the hospitals doing an organ recovery, the nursing supervisor will call the operating room nurses and say, "Well, make sure to call me when the patient has died." Well, the patient already is dead. If the patient were not dead, the transplant programs really have no business being there. What the nursing supervisor really means to say is "Please contact me when the surgical procedure is over."

However, her leading statement is misleading and at times the O.R. nurses will then write on an O.R. sheet a different time of death; i.e., when the organs were removed or when circulation ceased. And that has become very confusing to many people.

Does the local coroner have jurisdiction when a body is transported from another county or state for organ donation? If the determination of brain death is, in fact, legal death, then jurisdiction should remain with the county coroner where brain death occurs. Arrangements for post-mortem examination must be made in advance with the originating county coroner's office by the transplant program. Provisions for the transfer of an unembalmed donor body across county or state lines by common carrier should be made by amending rules and regulations relating to funeral directors and embalmers.

Again, this is a problem that Dr. Stevens initially addressed. What do you do when a patient has been declared brain dead at the legal standard of one state is transported to another state for organ recovery? You know, there are rules and regulations against transporting unembalmed bodies via common carrier. Now, we certainly don't use common carriers to transport these donors. We have a medical team that does the transportation. However, once the organ recovery has taken place in a state where the donation has taken place and the body is transferred back to the originating state, the body at that point, of course, is still unembalmed, so it doesn't interfere with the other coroner's duties. Often those bodies are shipped via common carrier; and you know, it's something that we've not really looked into very closely and we've just gone ahead and done it. But it is against the rules and regulations of the funeral directors/embalmers.

Does brain death need to be reaffirmed in California, when the determination has been certified in another state? And again, I think that Dr. Stevens really addressed this. There are different criteria in different states. Not every state has adopted the model statute that California has. And to determine a time of death in one state and then to determine it again in a second state makes the issue even more complex than it already is, and Dr. Stevens gave you a good example of the difficulties that he has run into in one occasion already.

~~The issue of discontinuing life support when a patient has become brain dead,~~
where the families are not going to donate the organs for transplantation, is an area out of my realm since I'm really involved simply in transplantation. I think that this is really a very, very difficult moral and ethical dilemma.

Not too long ago -- again to give you an example of how difficult this becomes to the family -- I was asked to speak to a family about the possibility of donation. Their young son who was 17 years old had been playing basketball; he had fallen and cracked his skull on a cement playground and was taken to a hospital where he underwent many

hours of surgery; and he simply did not recover from that. Two days after the accident he was pronounced brain dead by the physicians in the morning. And the family was informed of how serious this event was and that their son would not be with them for much longer. The physicians considered the fact that the patient might be an ideal organ donor and they did ask me to come and talk to the family since they had not had much experience in doing that in the past. I went to the hospital where the extended family was waiting in the waiting room. And I went in and sat down with them and asked them exactly what they understood about the gravity of the situation. The family told me that they understood that their son was really very ill; however, he had never ever been sick for a day in his life and that he had a very, very strong heart. And they felt very strongly that if they just waited long enough he would get better.

Now clearly in those situations, that family will never give consent for organ donation. But how, you know, if the family feels like that, can the physicians sensitively remove the patient from life support even though the patient has been declared brain dead. It's a very, very difficult situation. Another example has been included in your handout. Again, I can't really answer those questions.

The other thing that I would, finally, recommend is that the coroners, at least in the State of California, provide the transplant programs with guidelines. I know that individual counties have done that. Dr. Stevens has done that in his office. Other county coroners have done that. But a lot of the counties want different things from the transplant programs. Some want more information, more detailed information than others. And, you know, it gets very difficult when you're dealing with so many counties about OK, well, this person is---you know, this donation is occurring in this county, now let's make sure that this coroner has everything that he needs, which might be different than the adjacent county.

Senator Speraw, I really want to thank you once again for holding these hearings and dealing with some very, very sensitive issues.

CHAIRMAN SPERAW: Well, I want to thank you for your interest and participation on a statewide basis also. Are there questions of the witness?

ASSEMBLYMAN FRIZZELLE: May I ask a question? Is it true that some of the organs ~~of the body do not---the donation of them or the use of them have the successful use of~~ them does not necessarily depend on the brain death or absence of brain death, but rather, maybe, the circulatory death is more significant than brain death?

MS. WEBER: Yes, you're absolutely correct. When we're talking about patients being organ donors and needing to meet the criteria of brain death, we're talking about really solid organ transplants -- the heart, heart-lung combinations, liver, pancreas, and kidney. There are many tissues; again, as Senator Presley is very familiar with. The cornea can be used in transplantation. The cornea can be removed within six hours

after the patient's circulation ceases. And there are other tissues, like bone, skin, middle ear tissue, cartilage, many, many tissues. And those donors are certainly many, many more than we see than we see organ donors.

ASSEMBLYMAN FRIZZELLE: Do you have in addition the ability to remove organs that have been donated by a given patient prior to any criteria of death, like brain death or circulatory death, if I wanted to donate something, I could donate it in a live condition, right now?

MS. WEBER: The only time when transplants are removed or donations are taken from living persons is in the situation of kidney transplants where you can easily give up one of your kidneys and continue to live a normal existence and where the chance of the outcome of the recipient is very, very good. And right now, that's really restricted to family situations.

There is also a question now of being able to donate bone marrow to unrelated donors. That's not being done now in the State of California although bone marrow transplant programs are considering that.

But they're really the only tissues or organs that we're limited to in living situations. You could always donate your blood. That's included as tissue through transplantation.

CHAIRMAN SPERAW: Senator Presley? Thank you very much.

I'm going to make a quick change in the sequence here. I am most pleased to be able to announce that Dr. Lawrence Pitts, Chief of Neurosurgery at San Francisco General Hospital, has arrived, has made it. And we appreciate very much the fact that he made this effort. I know he had some problems this morning.

And I'd also like to add that in our request---our letter that we sent out to possible witnesses, we asked them to name anyone else they thought should testify as well. And in most cases, Dr. Pitts's name was included in the response; and he seems to be an authority on brain death. So we're most happy to have him here with us today.

DR. LAWRENCE H. PITTS: I'm not sure I'm entirely happy to be an expert on brain death, but that is the situation I'm afraid.

A particular point that I would like---several points I'd like to make at the outset and then I'd be happy to respond to any questions that you may have.

CHAIRMAN SPERAW: I might add that we have your summary here and your paper on brain death too.

DR. PITTS: Thank you. The points that I would make, and I believe these are fairly universally accepted among physicians, and that is the fact that it is possible to determine brain death and that insofar as there are any reasonably documented cases, there are no survivors of individuals who have had proper application of brain death criteria.

I think these facts have allowed the legislation in a number of states including California under the general rubric of the Uniform Determination of Death Act to be enacted. And I think that the UDDA is an excellent piece of legislation.

A couple points about the brain death law in California, at least in my judgment, reside in the fact that it's a very general statement of the concept of brain death without undue reliance on legislative determination of what goes into the determination of brain death; that is, it merely states that two physicians need to certify brain death by acceptable medical standards and that is the limit of the legislative language. Now in my judgment that's the proper way for such legislation to be written because technology is changing fairly rapidly. What was necessary for the proof of brain death at some point in the past is no longer necessary. The advent of new technologies including widespread availability of CT scanning, for instance, to measure the degree of brain injury. All of these things have changed our ability to diagnose brain death.

You referred to an article that I wrote and was published recently in the Western Journal of Medicine, and I was a little surprised to see a query come from one of the California Medical Association committees dealing with brain death and transplantation talking about the Pitts' criteria. That's a little shocking; it was clearly not written to be any set of criteria, but rather an interpretation of the elements necessary to diagnose brain death. They were not set up to be ironclad criteria or be the basis for any protocol determination of brain death, because from patient to patient, there are minor differences and so what necessarily must be used in one patient may not necessarily be required in another patient. So I think the general language as stated is very important. I think that trying to tighten it up more than that would be detrimental to technologic change in medicine. But the application of that portion of the law that is applying brain death to an individual, I guess, is still not universally or readily accepted or easily done.

I was just shown a copy of an article in the Sacramento Bee from, I guess, yesterday or the day before where a problem still remains with the application of an interpretation of brain death and the actual carrying through what the law allows us to do.

So, with those very general comments, I'd be happy to explore any further questions that you may have.

CHAIRMAN SPERAW: Doctor, you mentioned that you felt rather than the state attempting to set up by statute standards for determining brain death, or criteria, that it should be left to acceptable medical standards. Who in your opinion would determine those? Should they be uniform within our 58 counties? Should they be uniform within the 50 states? That's a relatively simple question I understand.

[Chuckles.]

DR. PITTS: Right. I think that since patients vary and clinical situations vary

from case to case that it would not be trivial to write a set of protocol guidelines that could then be applied across the board throughout this state or among states, for instance.

For instance, if one---at one point in time, electroencephalography was, if not required, was strongly recommended. And at one point with respect to the Harvard criteria where EEGs were not formally required but alluded to and then shortly after the Harvard criteria someone came up with the idea that you had to have two flat EEGs 24 hours apart. Well, that's a suggestion for the application of technology to confirm brain death and the irreversible nature of brain death, which is the other feature of the law.

The problem with that is there are a number of patients who are so clearly irreversibly injured from the moment of impact -- steamroller over the skull, for instance -- that a flat EEG 24 hours apart really bears no relationship to the real world. And so to set up technologic standards or time periods of standards would be impractical in some instances, would be detrimental in some instances. If a patient were having a rapid deterioration of their organ systems and one were waiting for the second EEG tomorrow, and in the process despite the fact the patient may have wanted to give organs for transplantation, the family may want to do that, and yet if you're constrained by some set of rules, then you may lose those organs which everyone agrees--- everyone in that clinical situation would have agreed would have been appropriate.

So, I think that an article such as mine or other general guidelines that might be proposed by some of the nervous system associations -- either one of the neurosurgery associations or one of the neurology associations -- would provide enough specific material for physicians to apply the concept of brain death in individual cases. And I think the matter of an individual physician judgment should still be left in the equation. I think that there are times when for family reasons you may know that a patient is brain dead, but for a variety of reasons choose not quite yet to say that because some family member is on their way to town or something and you don't want to quite quit at that point. There are a lot of judgment matters that would be very difficult, I think, to write into any specific set of guidelines in the interest of uniformity.

ASSEMBLYMAN FRIZZELLE: Before you go past that point, I want to point out one particular dilemma that we consistently run across. In the absence of some kind of definition, even if we define in flexibility or define in physician participation and so forth, ultimately the court makes a decision. And they seem to exercise jurisdiction as a matter of public policy rather than the Legislature that probably ought to be doing it. The public is more and more conscious of these kinds of problems, both the desire to donate organs, the concern about death and who determines it and who ought to have

the right to make judgments regarding it. And in the absence of legislative determination to some specific end, if we leave that void into which, for one reason or another or one set of criteria or another, this court may decide one thing, another court may decide another, other types of decisions may be made that really establish by precedent public policy that may not be valid across the board at all, may not allow for participation by physicians in general. It may indeed make physicians involved liable in some circumstances. Maybe it's the absence or the void that needs to be addressed. I don't know how to construct that type of thing. I think the committee is seeking, as much as anything else this type of addressing of the issue, some kinds of guidelines. And you struck a very common thesis, I believe, an important thesis, that physicians ought to be involved in the equation. But to what degree should public policy be actually an identifiable factor and could we even construct it? If we're going to take an organ out of a body, we can't allow the tissue structure to be dead. We can't allow the courts to go through their decision-making process to the point of the death of a tissue structure that you may need to use. You may lose the very motive for transplant or the very capacity to transplant if you allow that kind of complication in procedure. So could you address that a little bit?

DR. PITTS: It's a very thorny problem, as you have very clearly stated. But I'm fearful that even fairly specific language may not necessarily prevent a court from ruling otherwise. For instance, this article that I just reviewed or just read before I came up to the stand indicated that at least several physicians in the instance of this child who, I guess, is still on a ventilator or was when the article was written several days ago, the child had been pronounced brain dead by several physicians and it's clear in current California law that that is an allowable situation in which to call the patient dead and stop support. And yet the court, as I understand the article very briefly, decided to at least have to allow or require the hospital to continue to support the child with a ventilator for the present time. Now that's a situation where the law is reasonably clear and has been complied with and yet the court still chose to take a different course than it was my belief that the law intended.

So even if you write down a careful set of rules, the best rules that someone can construct, and I'm worried about how well they can be constructed, but even if you do that, I don't feel certain that that would forestall the legal process from stretching out from changing what the initial intent of legislation was.

ASSEMBLYMAN FRIZZELLE: ... by the court.

DR. PITTS: Sir?

ASSEMBLYMAN FRIZZELLE: That's a general problem we have with the court.

CHAIRMAN SPERAW: Doctor, you do have some suggestions though, I believe, that certain things be in place to determine brain death. Could you state what those

minimums---what you think those minimums ought to be? Like, for instance, should there be at least a second determination by a second physician?

DR. PITTS: The law currently calls for that, and I think that that's very reasonable. This is an emotional-laden situation in many instances, particularly in my area of specialty which is head injury. It's an unexpected event. All of a sudden someone has gone from very healthy to basically dead or indeed dead. And so that time course is such that it's hard for families to deal with the information and so forth. And I think that under those circumstances one wants to be very certain of the ground on which you're standing in calling brain death. So I think the opinion of the second physician would be entirely appropriate. I think that the individuals who are joining in the decision or in the diagnosis of brain death should feel comfortable in their ability to diagnose brain death.

And the purpose of the article that I wrote was to enumerate a number of things which must indeed be present before diagnosis of brain death could be entertained. I've tried to be as---since wishy-washy within the article or to allow as many interpretations of the data as are appropriate clinically. And the example of the steamroller over an individual's head is clear without a lot of technology that that's a pretty dead individual. So that needs to be tolerated or allowed within the criteria as well as the much more complex patient in whom a diagnosis is not certain, a CT scan doesn't necessarily show overwhelming brain injury. And in those individuals a much greater deal of caution needs to be applied and more data needs to be gathered. That's the spectrum in which we're trying to operate.

However, I did state a number of elements which must be present in order to be certain that brain death is present. They are enumerated in the article: the absolute absence of all brain function. That is clearly definable and testable and must be done. Making sure insofar as possible and as far as the clinical situation will allow that there are no toxic---intoxicated states -- barbiturate overdose, alcohol intoxication -- that would complicate the exam. Those need to be considered. And a known cause for brain injury, and the fact that it is overwhelming. Those are the essential elements.

When circumstances are uncertain, then one needs to allow a bit more time to pass ~~to make sure of the diagnosis and the accuracy of the diagnosis. I don't know if I can~~ enumerate any more closely than that.

CHAIRMAN SPERAW: Dr. Stevens, who testified prior to you, mentioned the possible need for something on brain death as part of the curricula for medical students, for doctors. And what brought that to mind was your statement that many doctors are not familiar with determining brain death. In your opinion, should it be part of the general education of the doctor to have some knowledge of brain death or how to determine brain death?

DR. PITTS: I think it certainly should be part of the medical curriculum to go over the key features of brain death. I think the interest in the process and the need for making the diagnosis is clear today, but was not perhaps so clear ten or fifteen years ago. So now would be an appropriate time to consider making it a formal presentation in some fashion to medical students because they indeed may be called on to make such determinations in the future and do need to feel comfortable with how the diagnosis is made accurate.

CHAIRMAN SPERAW: I'd like to introduce Senator John Doolittle who has joined us. Are there further questions of the witness? Senator Presley.

SENATOR PRESLEY: Doctor, on the last point, I guess that could be included -- medical training -- without any legislation though, right?

DR. PITTS: I think so. I'm not sure. I'm not aware that there are other legislative features ...

SENATOR PRESLEY: ... down there, there's a bill introduced that says in medical school you have to teach this and that you have a heretofore policy. I guess that's to force people to teach something maybe they don't want to. But nothing is said that they can't go ahead with it.

I was trying to listen very closely to your testimony and that of Mr. Frizzelle. I think what I hear you saying is that you think the law, as you've set forth in your article, the existing law, is adequate and that if you try to build on that, you may build more complications than you're asking or we'd like to have. With the 58 counties and different interpretations, I guess with the courts available if somebody has a dispute to resolve that, you think that's probably the best we can do -- I think, is what you're saying.

DR. PITTS: Insofar as physicians need to be educated as to how to make a diagnosis of brain death and what the applicable law is, it would suit me very well if the courts could come to some agreement that they understood these same interpretations and would take a common approach from the legal side.

SENATOR PRESLEY: I think Mr. Frizzelle's point is one that certainly is valid and that is that courts aren't supposed to be making public policy. They're supposed to be interpreting. ~~And I think his point is that we ought to somehow build on this law with~~ some rules and regulations that will be applicable statewide, but I don't hear any answer to those few concerns. And I guess maybe that your opinion is let's leave it like it is, and I think Mr. Frizzelle's opinion isn't all that strong. He just raised the question more than anything else. So we have a great big unresolved ...

CHAIRMAN SPERAW: Perhaps what we need is that something be included in the education of the attorneys who eventually become judges. That would help clarify the situation.

ASSEMBLYMAN FRIZZELLE: It needs to be pointed out also the fact that we have a

situation that bleeds the treasury or the money facilities of individuals, families, insurance companies, the state, and all kinds of people who put up the money to keep people alive which, technologically, in the future, potentially, would happen to everybody that you could keep the tissue structure somehow alive with technology at however much cost with cost not even considered. We may get to the point where we have to keep them alive at any cost and people not be allowed to die in a normal way. And it's to, maybe, at some point or other, be stated who gets the right to make that decision when an individual be allowed to die in the face of all this technology and the dollars involved.

DR. PITTS: There is a very major issue that to my knowledge no one has approached and that's the care of the clearly terminal patient but not, for instance, a brain-dead patient -- a patient who has irreversible brain damage and will not resume consciousness but who is not brain dead. That's a very sticky problem and a lot of legal, economic, ethical considerations are yet to be unraveled. But in the brain-dead patient, it really is a fairly straight-forward matter in terms of there are no survivors. No matter how much money you choose to spend in the person who is brain dead, there are no survivors. And given that fact, that's a fairly straight-forward question that I'm intrigued continues to generate so much discussion. That's a resolvable issue. And I think the law has resolved it and yet, periodically, it gets overridden by well-meaning legal systems.

There certainly is an element that needs to be passed on to the courts; and that is, when physicians seek---when a clinical situation seeks legal input, it needs to be extremely speedy. And I don't know how quickly court systems can move. But the point that you make while the legal wheels are turning, certain transplantable organs are deteriorating. And here again, I'm not trying to market the concept of harvesting more organs. I'm just saying, to allow the possibility when the patient wanted his organs to be transplanted should he die and his family wants it, everybody wants it, and yet the system can't quite deal with, that's very detrimental, I think, to the system. And so, there needs to be a speedier response from the courts in order for their decisions to have much meaning.

CHAIRMAN SPERAW: You used the statement that no brain death patient survived. ~~Would you explain how that takes place? How would---you just pull the plug and if~~ they don't start reviving themselves, the proof that they were brain dead ...

DR. PITTS: The technique that I have found useful is that one goes through the motions of confirming brain death by what is outlined in the article, leaving in a sense the breathing test as the last test. That is sort of one of the most robust brain functions that lasts longer than almost any other and may be present when no other brain function is present, for instance. Leave that test for last. One knows by the time you get around to having made all the other determinations except this breathing

test that the patient is a transplant candidate or is not a transplant candidate.

If the patient is a transplant candidate, then a breathing test that is outlined in the article, and it's a fairly straight-forward, well-accepted test, is conducted. If the patient fails to breathe, that is, has now shown in the last test to have no brain function, then the patient is put back on a ventilator and the process is started promptly for harvesting transplant organs, usually within a matter of hours, because everything has been lined up at that point.

If the patient is not a transplant candidate for a variety of reasons, then one simply does not reinstitute the ventilator and the patient then without a ventilator goes on to a lack of oxygen and the heart stops within a matter of half an hour or an hour. So that is---so when you pull the plug, you are doing so in the setting of the last test. Then if the patient fails that test, then the patient is indeed brain dead and there is no purpose in continuing artificial support in that setting. In the transplant setting, they have to go back on the ventilator to preserve the organs for the short time necessary to harvest the organs.

CHAIRMAN SPERAW: So when you do in fact terminate the life support---the body support systems, you do continue to check them and in fact that your diagnosis that there is brain death that it is confirmed?

DR. PITTS: Absolutely. I mean that is---discontinuing the ventilator is an absolutely critical feature of the brain stem death of the dead brain examination. And so one terminates the life support systems under a very specific circumstance where you're watching carefully to see if the patient has any brain function.

CHAIRMAN SPERAW: Are there any other questions of the witness? Doctor, thank you so much for the trouble you took this morning. We appreciate it.

We'll return to the agenda. Our next witness is E. L.---Mr. Twilley, would you like to wait until the rest have testified before you make your comments?

MR. E. L. TWILLEY: Yes, ...

CHAIRMAN SPERAW: Very good. Then we'll move to Dr. Julius Yeomans. Is he here yet? He was to arrive at 11:00. Good. Professor of Neurosurgery at UC Davis Medical Center, our host.

~~DR. JULIUS YEOMANS: Thank you. Senators, ladies and gentlemen, my testimony will~~
be very brief because I was going to say, almost word for word, what Dr. Pitts was saying. I guess it's because I'm a neurosurgeon also, we see the same type of problems on a daily basis.

I think the law as written is a masterpiece of brevity and clarity in the sense that it has to be where it can be broadly used. It has to be a physician's judgment. And although we use the same basic criteria of brain stem function being gone and some various chemical and ancillary laboratory tests, there are differences and it's a medical

judgment as to when brain death has occurred, just as you would make the medical judgment using various things if you were going to decide to do an appendectomy. It has to be left without the encumbrance of a tightly structured technologically defined area because, as was mentioned by the previous gentlemen, today we declare brain death differently than ten years ago. For instance, coming on the horizon now is a nuclear magnetic resonance scanner, which probably will tell us even more. So I think it's---in essence, I'll just stop to say the law as written I think is appropriate.

CHAIRMAN SPERAW: You mentioned a magnetic---I didn't catch all of it.

DR. YEOMANS: Nuclear magnetic resonance -- NMR -- scanner. It's a new type of scanner that, as opposed to the CT scan, which can show tumors or serious injury to the brain, it shows function of the brain; and we're basically judging functions. So we may be just on the horizon of having even a better technology. But this does bring up one point: it's expensive; it will be only in the larger medical centers. And it's necessary that brain deaths be---people to be declared in the smaller medical centers even if there's not going to be a transplant because, as one of the Senators mentioned, you can keep many patients going day after day and at \$500 to \$1,000 a day, it's rapidly draining the family when there will never be any good out of it whatsoever.

CHAIRMAN SPERAW: Question? Thank you very much, Doctor, for your testimony.

Our next witness, Dr. Davis Drinkwater, Assistant Professor of Cardiothoracic Surgery. That's a new one now. I haven't stumbled over that before. University of California, Los Angeles.

DR. DAVIS DRINKWATER: Good morning. I thank you for letting me speak. I just have a few thoughts as a physician and as a participant in the transplant program and some technical aspects I think which pertain to both which may be---should be uncovered a bit.

The question of brain death and what is defined has taken new meaning in the recent years with organ transplantation which is now a medically accepted practice. At issue is protecting the rights and dignity of the living as well as of the dead and to see or to be thought of as premature about the establishment of this diagnosis of death both in a legal and a medical term is an anathema to a transplant surgeon or to a transplant program.

~~Most of the victims that are potential donors are young, in prior good health, and participants in the senseless accidents of the type that we're all familiar with, with massive injuries involving a motor vehicle, gunshot wound, alcohol, drug, and suicide. The families are in some sense vulnerable to the aspect of the organ donation as a gift of life, which indeed it may be. And most families, therefore, are willing and supportive of a transplant program when educated properly.~~

However, if organs are perceived to be harvested, as it were, without a full diagnostic and therapeutic action being taken, and without full and informed consent,

a well-deserved sentiment against the organ procurement will severely and justifiably curtail transplantation programs. A judicious and efficacious arrival of the diagnosis of brain death prior to a program's involvement is essential.

Now as a brief background, I'll summarize what is involved in a transplantation. Since the introduction of cyclosporin A, I know that a transplantation era has begun. Briefly, it involves the kidney, the bone marrow and, more recently, the heart, heart-lung, and liver transplantation. Now the last two are very important in distinction to the earlier ones as one can easily see.

The constraints on a heart and liver transplantation are obvious; and they are two, primarily: one is---the first is financial, and the second is suitable donors. The question of cost effectiveness for social and personal good is a large one and one which we'll have to deal with with some more time and more results as we indeed have decreasing resources to deal with.

The issue of suitable donors is an important constraint as well. . And strict criteria and guidelines are needed to achieve the best results for the recipient in the sense to make the gift of an organ or organs as meaningful and justified as possible. We have strict criteria in the cardiac field for transplantation donors. Some of the criteria have been alluded to: less than 35, no infection, no major chest problems, etc., etc. And these have to be very strictly adhered to.

Now, a significant delay in the diagnosis and transplantation program involvement is crucial in some cases to the outcome. This equality of brain death, secondary to closed head injury, intercranial hemorrhage, gunshot wounds, respiratory rest, has a number of very important results. The first and most important is less vasomotor tone, resulting in hypertension of the individual. A second one is diabetes insipidus, resulting in hypovolemia. A third one is the homeostatic temperature regulator, which results in hypothermia. And neurogenic pulmonary edema may as well be present. And the ultimate, of course, is renal failure where acid-base regulation is deficient.

Now, an expeditious resolution of the question of death medicolegally then is certainly warranted. Whether or not a body may be released too presently has consequences to the transplantation program.

~~Now, in order to mobilize, in our experience, recipient and a donor involves the regional organ program, which then involves the doctors at the location of transplantation, special O.R. nursing, special pump teams, and transportation. It's a great deal of financial and logistic headaches, but it's one which is very worthy.~~

Now it takes two forms. The body itself may be supported with inotropes, keeping the organs and body in homeostatic balance; and this is probably presently preferable to the individual organ procurement from the standpoint of the coordination of these various teams. Now, if not allowed as in some instances of crossing state lines or

county coroner situations or any question of legal problem, the individual organ procurement time is an even greater issue.

Now with respect to the heart, approximately three hours to six hours from removal to implantation, kept in a cold environment, is the continentally accepted time period. Research is going on; and in some cases, certainly, this can be extended.

Liver transplantation has even larger constraints on time because of the mobilization of a large amount of blood.

Now I've presented two sides of the issue that are joined by the primary physician to make diagnosis of brain stem---brain death is at issue. A diagnosis which must be based on straight-forward guidelines and principals and government by "commonly accepted medical knowledge and practice."

Now, the Harvard Ad Hoc Committee of 1983 update of the earlier results, particularly relating to children, and as a participant at that time, I want to point out some of the important highlights of that which are workable. And that is, that the primary diagnosis of brain death is a clinical diagnosis and is based on clinical examination.

Now, all medical schools currently have neurology and neurosurgery rotations; and I think the diagnoses of brain death can easily be covered in their rotations and indeed are.

Now, the question of whether a death---the diagnosis of a death the individual suffered either, first, "irreversible cessation of circulatory respiratory function," and two, "irreversible cessation of all functions of the entire brain regardless of the cardiopulmonary status." And I think at issue here is the second one which is the diagnosis of brain death. Clinical examination is the absence of ... responsiveness to external stimuli, heartbeat, respiratory effort, in the absence of two very important factors: Hypothermia, which can result; and circulatory assist devices. Confirmatory tests only should be the EEG and other tests such as an NMR and other more advanced laboratory techniques which, I think, should be used as supporting if there is a question---any doubt in anyone's mind, particularly the two physicians making the diagnosis.

If there is a coma involved, the physician has to be absolutely or sufficiently certain that he can or she can account for the loss of brain function on the basis of ~~the injury and not on other causes external such as drugs or alcohol.~~

The strict adherence to a policy of establishing brain death prior to the involvement of the transplantation program is vital to the protecting of the individual rights and to preserve life when at all possible. This adherence is integral and essential for the success of transplantation programs by maintaining the high standards of human compassion and care at all levels that the public deserves and expects of the physicians.

This is some prepared remarks that I had, Senator. I'd be glad to answer any questions ...

CHAIRMAN SPERAW: Are there questions of the witness?

ASSEMBLYMAN FRIZZELLE: Through mechanical devices of one kind or another or chemical devices, you can keep the circulation going long enough to extend the time period, I imagine, for the surgery necessary to remove organs, transplant them in good repair from the donor to a recipient. Is a lot of the complication you mentioned chemical? I mean, you mentioned a number of different things that happen such that it occurred to me that there's no way you can measure what the response would be in a normal or a more vital individual. If an organ was transplanted from a donor to the other individual---in the other individual, you don't really know what kind of chemical reaction is going to occur under the nonartificial circumstances that you've created keeping this person alive. I begin to wonder whether or not there's a point at which we cannot really consider a donor however willing to be really a legitimate effective donor of an organ. Is there a way we can derive criteria that would establish not just is a tissue alive, but is the tissue credible tissue?

DR. DRINKWATER: Experience probably is the greatest test of that, the time that we're gaining with a number of cases that we do is increasing daily, but using strict selection criteria as always. The degeneration of the organs within the body, using the body as a support system, as it were, to create a whole new static environment is not without its problems. It cannot be done as some people alluded to, to 48 hours. In our cases, we've seen the effects at an earlier time period. And the heart, using so much oxygen, is very vulnerable to any type of oxygenation defect which can result -- acid-base problems; the use of inotropes -- these are drugs that support the cardiovascular system. Once we get over a certain level, which most physicians would consider a medium dose, we found the heart doesn't function as well, that it has a very grave input as to the result of that recipient's results of the heart.

ASSEMBLYMAN FRIZZELLE: And the fantastic cost of the whole procedure ...

DR. DRINKWATER: Exactly.

ASSEMBLYMAN FRIZZELLE: ... involves---

DR. DRINKWATER: Is an emotional---

ASSEMBLYMAN FRIZZELLE: If you have actually taken an organ from a donor that is ~~not as credible as it ought to be, you are not giving the appropriate chance to the~~ recipient.

DR. DRINKWATER: True. Then on the same regard, you are not giving the, as I had mentioned, I think the donor the benefit of giving the best in a sense as it were. When we obtain organs, we approach the families and they are very willing, because it is a gift that oftentimes makes their suffering a bit more palatable as it were. It's a difficult situation all told.

ASSEMBLYMAN FRIZZELLE: I think, Mr. Chairman, that where we're possibly heading

with this kind of a question is, is there a point at which, whether the brain is dead or not, there ought to be as a public policy a capacity for a donor to donate anyway? I'm not sure that we can take that quantum leap. Physicians don't want to potentially create the vulnerability or liability to themselves unless they have some definable criteria for when they can take the organs. And yet, on the other hand, I'm wondering if maybe under some circumstances with some kinds of organs, we ought not to establish a freedom to take from the donor the organ at an earlier point in time than when brain death has been established. Especially if it's a voluntary donor.

DR. DRINKWATER: I would think, Senator, that a very concise and flexible law relating to the criteria of brain death would facilitate its diagnosis at an earlier time without having to wait for the 48 hours or the 24-hour EEG, second one, which we don't feel is necessary in most cases. And if we could avoid that delay, I think we'd probably still be within a very acceptable period of time for organ procurement with good results, without having to bypass the family involvement, the issue of law, etc., which I think is a big one.

CHAIRMAN SPERAW: Are there other questions? Doctor, thank you so much for your testimony.

DR. DRINKWATER: You're welcome.

CHAIRMAN SPERAW: Our last scheduled witness, and I might add if there is anyone in the room who wishes to testify, you may have the opportunity to do so after Mr. Twilley. Mr. Twilley, Manager of Licensing and Identification Policies and Procedures with the Department of Motor Vehicles, Division of Driver Safety and Licensing.

MR. E. L. TWILLEY: Thank you, Senator Speraw. As you know, since the Legislature directed us to begin providing the donor cards with drivers licenses and identification cards in 1976, we have been one of the behind-the-scene instrumentalities of creating public awareness of this important program. Although our program doesn't involve these awesome issues on a day-to-day basis that are the topic of this hearing, we have a little survey that I believe you were aware of; and one of the responses that was given to one inquiry -- if you do not wish to become a donor, what are some of the reasons? And one of those was, candidly enough, that "I'm afraid that perhaps they might prematurely take the donation." ~~And it wasn't given facetiously or in humor, but it was a candid~~ response that kept appearing in the responses that we received.

As a point of information, we provide approximately 7 million of these cards to individuals and organizations each year. And we feel that it is a valuable function that we play for the benefit of the people in California.

CHAIRMAN SPERAW: Well, it most certainly is. We've been working closely with you, as you know, for the past two years; and the Department has been most supportive of a function that really had nothing to do with drivers licenses or licensing people

to drive. But they've been more than cooperative in assisting in this vital area of organ donations.

Are there questions of the witness?

I might add, I made a statement that I want to retract. I said this was the last witness. I'm sorry I didn't have---we also have Jay Hartz and Jon Wagner. I didn't mean to overlook you. Go ahead, Senator Presley.

MR. TWILLEY: We acquire 7 million and we make an effort. In addition to mailing it with each renewal by mail notice and each driver's license and identification card that we send out, we make them available to individuals upon request and to organizations who wish them. For the last two years, the round figure purchase of these for distribution has been 7 million.

SENATOR PRESLEY: Do you have any way of knowing what the return is on those 7 million in terms of a donored ...?

MR. TWILLEY: No, unfortunately, we don't have any way of determining that. Based upon these questionnaires, 5000 questionnaires, approximately 62 percent of the individuals responded favorably -- yes, we look upon this favorably.

SENATOR PRESLEY: There's no way to measure, though, what the actual return is on that ...

MR. TWILLEY: No, we have no way of knowing whether people use them or not.

CHAIRMAN SPERAW: I might add that the Governor signed into law a bill that generated from this committee which eliminated the need for the witnesses on the pink slip that goes on back of the license which seemed to be one of the stumbling blocks in people using it.

In addition, it will be included in the mailings for those who are able now to renew their license by mail -- the pink slip will be included so that they may attach it to their new license when they get it.

And one other item, there will be a small sticker issued that a donor may place on the face of their driver's license so that if someone forgets to turn their license over to look at the back, that they will be notified, it will appear on the front that they are donors. We thank the Department for their help in that.

~~MR. TWILLEY: Thank you ...~~

CHAIRMAN SPERAW: You bet. All right, Mr. Jay Hartz.

MR. JAY N. HARTZ: Yes, thank you, Senator. Good morning. My name is Jay Hartz. I'm an attorney with the firm Weissburg and Aronson in Los Angeles. We represent the United Hospital Association, and I'm appearing on behalf of the association.

CHAIRMAN SPERAW: I'm sorry, can we hold up? I don't believe the P.A. -- something has happened, we're not ... hear the witness.

MR. HARTZ: Is that better?

CHAIRMAN SPERAW: Yes, fine. Oh-oh, you just lost it again.

MR. HARTZ: [Faintly.] Does this do it?

CHAIRMAN SPERAW: I don't know. Just a moment, the Sergeant will help you.

MR. HARTZ: Is that working now?

CHAIRMAN SPERAW: Yes, that's all right. Continue.

MR. HARTZ: Thank you. I'm here on behalf of the United Hospital Association. It's an association comprised of over 170 hospitals in the State of California with about 17,000 beds.

We came in response to a letter invitation addressing this issue which I think is an important issue. I'd like to start by focusing, I think, attention on the critical distinction that I think exists, that I think has come up already in some of the testimony that has been given between this issue of brain death and the issue of terminating life support with respect to persons who do not satisfy criteria of brain death. I think you might visualize this issue as being the extreme end of one spectrum, because there are a whole host of decisions that must be made along the way as to when and under what circumstances to withhold treatment. The decision to terminate care for a patient who is brain dead is only the very extreme end of that spectrum, one where it is most clear that the patient is irreversibly gone and that brain function is gone and will not return.

It is, or at least has been, until very recently with one or two court intrusions into the area what I think all have viewed as the one fairly fixed point in the spectrum of decisions about terminating life support. Brain death, I think, has, as I think all the witnesses have acknowledged, come to be a necessary concept in our society as the technology improves and we can keep organs functioning longer and longer. It's necessary to facilitate transplants. It's necessary to answer some thorny problems that have arisen in the areas of criminal laws to when one dies. It's been necessary to relieve concerns about liability by physicians who are charged with the responsibility of care and decisions about when to terminate care. In some states, in fact, where there is no statute authorizing brain death, the courts have gone so far as to create it because of the necessity for it.

In our view, however, it is a mistake to go beyond the statute that presently exists, which says "~~Brain death is the loss of function of the entire brain which must be confirmed by two physicians.~~" I think it's the view of the Association and its members that to try and legislate on a specific protocol about how one goes about measuring the absence of brain function would be unworkable since technology changes, will continue to change, and since there is some clinical judgment involved in that determination. I think the statute as it exists now is workable and it is, I think, the proper function of the statute to define the concept generally and to permit the physicians to make the precise measurement.

Although I am not a physician, I have been consulted on a number of occasions by hospitals and physicians about these issues. From what I've seen, physicians tend to err, if at all, on the side of conservatism. Particularly in the climate of fear of liability that now exists, with the criminal prosecution that we saw in Los Angeles, most physicians are walking very carefully on these decisions and if anything, as I say, err on the side of conservatism. Every once in a while you find one who absolutely won't terminate care for fear of liability no matter what the statute says; and that exists out there right now -- not on a large scale, but a certain degree.

The accepted medical standards which I think the statute points to as the basis for determinations have evolved and will evolve over time. There have been study groups such as that which published the Harvard criteria, which most physicians, I believe, have looked to. There have been updates of those criteria. The President's commission recently published, I think, some suggested criteria. And I think these things will continue to change over time and must be left flexible to accommodate changes in the technology.

I might point out that all of the groups that I'm aware of that have studied this issue have also recommended that there not be a precise protocol written into law. That includes the President's commission, the Commission on the Uniform State Laws, and some of the courts even who have gone so far as to create these standards such as the Supreme Court of the State of Washington in the Bowman case.

To my knowledge, I've been unaware of any actual disputes about the validity of the diagnosis of brain death. The few cases that I've seen that have gone into the courts have not really focused on a dispute as to how one determined brain death or whether it was properly found. If I might take a moment to address the two cases that I think have been referenced here in testimony, the one that's currently underway in Eureka and another case in Riverside -- it was decided within the last six to eight months, which spawned this case in Eureka. What has happened in each of these cases is that there have been some unusual circumstances in the Riverside case, known as the Dority case, were these: A child came into a hospital as a result, apparently, of a severe beating. The child was in a coma over a period of time, was on a respirator, and was finally ~~determined by physicians to be brain dead. When the physicians sought the family's per-~~ mission to terminate care, as hospital guideline required within that hospital, the family refused to consent because of the pending child abuse charges against them. The hospital was uncertain what to do, so it went to court and asked that a conservator be appointed for the child and given the authority of consent to terminating care. That's conceptually a strange situation since conceptually the child was already declared dead and they were asking a court to appoint a conservator for a dead person, which is theoretically very strange and not what the conservatorship is designed to do.

The court did it, however, I think, as a matter of practicality to try to resolve the situation. And the child, in fact, died of natural circulatory cessation even prior to the court's decision. It went up on appeal, and on appeal the Court of Appeals said that was the proper way to deal with it, that hospitals ought to consult with family members before they terminate care, and if there's a dispute, the courts are available. That I think is what's happened up here in Eureka, as I read the newspaper article and from some information I've received about the case.

What's happening there is there are, once again, four physicians who have certified the condition of brain death. You have family members -- and I've seen two different issues raised in the news article: One is the possibility that there is some child abuse behind the incident, and the other is simply a mother who says, "I'm not prepared to accept that; I think a miracle will happen." And what's happened there is the physicians, because of all the litigation that they've seen including the criminal case in Los Angeles, are, as I understand it, simply afraid to terminate care until there's been an adjudication of whether or not they can do it in the face of opposition by the mother. Now, as I understand it, there has not been an order precluding them from stopping care, but rather they have voluntarily not stopped care until the issue has been decided. Yes.

ASSEMBLYMAN FRIZZELLE: I'd like to ask you, you've taken the issue on a basis of a protection of the patient or the protection of this odd case you've stated---protection against the legal situation. To take them from the other side, is there any protective device available to people who are required to support the individual who is on life support systems? Is there a petition device by means of which they can petition the court to terminate life?

MR. HARTZ: Prior to the determination of brain death, for example?

ASSEMBLYMAN FRIZZELLE: Yes.

MR. HARTZ: OK. There is not really a formal mechanism to do that. Theoretically, you can do it through the conservatorship proceedings, but as I think some of the physicians have referenced, that's long and cumbersome in terms of the time frames that medical care---or medical practitioners must act within particularly with respect, for example, to transplant issues. So it's difficult. One can sign---there is, for example, ~~a natural death act directive which can say, terminate the use of life supports under~~ certain circumstances. There is a document known as the "Durable Power of Attorney for Health Care" which someone can sign to appoint someone else to make decisions for them and then someone else might assist in directing care in an appropriate fashion.

There are conservatorship proceedings; but as I say, they're long and cumbersome. So there is not really a direct mechanism by which that can occur unless you have a mentally competent patient who can sit there and tell you, this is what I want you to do, this is what I don't want you to do.

Have I addressed your question? I'm not sure that I---

ASSEMBLYMAN FRIZZELLE: You've addressed the question, I guess, but you haven't addressed the issue fully. And of course, that's not the subject of this hearing -- we're basically involved in the transplant procedure and so forth so I'm not going to extend the question. But it is a consideration all the same in the determination at which point an individual can be determined to be dead and where life is not supportable. And I'm concerned about, to some extent, the liability that we place people under. Are hospitals always willing to terminate a life or to allow it to come to a conclusion in the face of the fact that they can extend life and collect \$1000 a day?

MR. HARTZ: Yeah, I think that they're not, and not necessarily for that reason. But I think many of them are simply concerned of legal liabilities as well, And I think there are two sides of the coin, which I think you're bringing out here, which is that many times families would like to have life support terminated prior to the time that physicians in hospitals are willing to do that. And individuals who are the recipients of care in some cases want that too. And that's the area where it's most difficult and most muddled because there are interests on both sides of that.

ASSEMBLYMAN FRIZZELLE: And nothing addresses it.

MR. HARTZ: Right. That's an unresolved problem, I think, at the present point in time.

But getting back one moment again to the court situation. The courts, from what I've seen, have intervened in cases like the two I've described, where there are unusual circumstances. In most cases, the determination of brain death has not resulted in legal problems and I'm not aware of any outside these two cases. In most cases where physicians determine that the patient is brain dead, the families, the loved ones, or the individual simply accept that and there is no incident. In some cases, they have a difficult time dealing with that emotionally. Typically what happens is the hospitals simply wait until they've had an opportunity to digest the situation and deal with it emotionally and then some resolution is achieved. In the rare and unusual cases, this kind of court proceeding may resolve the issues in the end. But that's what we've seen of the issues as they've gone through the court system.

~~That's really the end of my prepared statement. If anybody has any questions, I'd be happy to answer them.~~

CHAIRMAN SPERAW: Questions? [Inaudible.]

MR. HARTZ: Thank you.

CHAIRMAN SPERAW: Thank you very much, Mr. Hartz.

Dr. Jon Wagner was here to testify for Dr. Pitts. Is he still here? All right, are there other witnesses that wish to testify? One is J. E. "Skip" Muir of the California Hospital Association.

MR. J. E. "SKIP" MUIR: Senator and Members, we have prepared a statement for you answering the questions posed in your original letter setting up the hearing. And I have also included for your information and background portions of a document from the Consent Manual, which our legal staff prepares for the various hospitals; and it does describe the protocol used in determining brain death and also the obligations of a hospital in informing the family and all of the necessary requirements. And I think that will answer some of the questions that have been posed by the committee; and really, I have nothing further to add.

CHAIRMAN SPERAW: Any questions? All right, thank you very much.

Are there any other witnesses? Then we thank you for your interest and your attendance, and we'll conclude this hearing.

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Nothing easy in case of a brain-dead child

By Tom Coakley
Bee Staff Writer
and Bill Israel
Bee Correspondent

EUREKA — Kathy Williams fought to keep breath in her lifeless child's lungs Friday and won, just as gloomy clouds broke up to show patches of blue sky outside the Humboldt County courthouse.

But her temporary victory in court failed to scatter the clouds of uncertainty, legal entanglement and suspicion surrounding William's attempt to keep her 5-year-old daughter on life support.

This week, even more legal maneuvering is expected as the case shifts to Juvenile Court, following a decision by Humboldt County Superior Court Judge J. Michael Brown that Juvenile Court is where the matter belongs.

The court decision Friday also has meant that St. Joseph Hospital, this town's Catholic health care provider, operating on a medical landscape fraught with the fear of lawsuits, is treating a child — diagnosed as brain-dead by four doctors — in an intensive care unit where only a bed or two has been open in recent weeks.

"If your daughter was run over by a car," asked Jerry White, assistant administrator at the hospital, "and our ICU was full, and all we could do is stabilize and transport, and something happened to her in transit, how would you feel?"

In this Northern California coastal town of 25,000, Williams and her attorney, Bruce Watson, went to court last week to stop the hospital from turning off a ventilator pumping oxygen into the body of Slobhan Lynn Larkin, Williams' child.

For the past three weeks, Williams, her live-in boyfriend Darrell Sherman, hospital officials, doctors, lawyers, the district attorney and county social workers have been players in an intense, tragic drama offering an unusual public airing of the medical and legal issues surrounding the concepts of life and death.

This drama involves two perceptions of death: that of doctors and a hospital clinically examining a patient and finding the brain is dead, and that of a mother seeing that the child's color is better, watching the child "breathe" on a machine, talking to the unconscious youngster, spending the night with her and waiting for a miracle.

"There is clear law on the matter," said Sister Corrine Bayley, vice president for bio-ethics of the St. Joseph Health System. "If there is irreversible cessation of all functions of the brain, they're dead. The confusing thing is that technology gives the appearance that a person is really alive when they're dead."

Williams and Sherman, who have lived together for more than two years, have decided not to talk to the press.

But, Watson, Williams' attorney, observed: "If, on day one, Slobhan had died and that was the beginning and the end, (it would have been) easier for (Williams) to deal with the finality. (But) with the life support system . . . she, as a parent, to withdraw the breath from the child. She can't bring herself to do it. She sees it as causing death to her child."

The drama unfolding here has been made even more tragic by law enforcement suspicions that child abuse may have played a role in Slobhan's fate. It is a drama raising questions about what protection was provided to the child by the public agency charged with her welfare.

This drama has not caused sparks of anger or communal grief to ignite in this conservative community. But it has made life tougher for people working at the hospital that is em-

It began Aug. 25 when the child was taken by her mother to the St. Joseph emergency room, unconscious and in cardiac and respiratory arrest, according to the hospital's petition filed in the case. The child was resuscitated, but has been unconscious ever since. The hospital sought a court order Sept. 6 to permit the shutting off of her life support system after two electroencephalograms showed Slobhan to be brain-dead.

Clearly, if this story had occurred in years past, when technology was less sophisticated, Kathy Williams might have already buried her daughter. Nor should this drama be confused with the life and death scenarios of Karen Ann Quinlan or Elizabeth Bouvia, in which the issue was a living person's right to die.

In this drama, a hospital is not fighting to keep a patient alive, but to obtain the legal go-ahead to stop treatment after death, even though hospital officials feel that such a go-ahead may not be legally necessary to pull the plug, but is a prudent approach.

Money, hospital officials have insisted, has no bearing in the case, although one local doctor's estimate of the cost of caring for Slobhan — a Medi-Cal patient — is roughly \$1,100 to \$1,200 a day.

In this drama, as the court hearing Friday pointed out, key legal questions include "what rights does the parent of brain-dead patient possess when life support is being ceased" and "how long should a hospital wait to pull the plug when a survivor is having difficulty adjusting to a patient's death?"

In its original petition, the hospital cited the Dority case, a Southern California Appeals Court decision in which the court asserted the right of a hospital to cease life support to a brain-dead patient, but also emphasized parental rights to consultation on that decision. The court also suggested that it might be advisable for a hospital to consider keeping a brain-dead patient on life support, if relatives were not prepared for the shock of the person's death.

Sister Corrine, the health systems vice-president, said she believes that the only ethical dilemma in the case concerns the family's rights to insist on continuing medical treatment. But, in brain-death cases, she said, "I think there's no such right."

Watson, argued in court Friday that his client has a right to veto a decision to shut off life support to her child. And, he suggested that the hospital's request for legal sanction to turn off the ventilator was premature.

Meanwhile, as Slobhan lay in her intensive care bed, law enforcement officials began investigating how she was so badly injured. And both police and prosecutors conceded a sad fact: any successful investigation would require an autopsy on the child's body and a coroner's report.

"No charges are filed on anybody," said Eureka Police Department Capt. Muri Harpham. "There's

not much you can do unless you have a body."

Still, late last week the Humboldt County District Attorney's office began fighting Child Protective Services of Humboldt County for records prosecutors want for their investigation of child abuse in this case, District Attorney Terry Farmer said Friday.

Slobhan came under the jurisdiction of protective services in April after Darrell Sherman was charged in a misdemeanor warrant with abusing the child.

Last June, Farmer's office placed Sherman on a diversion program, approved by protective services, after learning that the agency's plan for the child included permitting her to live with her mother and with Sherman, the district attorney said.

But the agency has refused to comment publicly on any aspect of the case, and, according to Farmer, has claimed that it's records are confidential — even to a district attorney investigating child abuse.

So the drama goes on, against the backdrop of this conservative town, where timber is king but the government is the largest employer. Residents have read about the court developments in the local newspaper and seen stories on television.

But in this most pragmatic of towns, there has been no rush to judgement. Humboldt County Clerk Don Michael, a longtime resident, observed that people in Eureka get excited over expansion of Redwood National Park or spraying of pesticides. But this drama is a private one.

"The guy in the street really hasn't become that involved in it," said Michael, a Catholic, "I really don't think they know what it's all about."

At the hospital, and especially in the second-floor intensive care unit, however, the tragedy has had a significant impact.

Hospital spokesman Robin Crown said that nurses in ICU have been instructed to use all available means to sustain a child, ruled dead by doctors. The nurses have even been told to attempt resuscitation. If the child's heart gives out even though she's on the machine.

"Can you imagine resuscitating a dead person?" Crown asked.

"I was in Vietnam," he said. "I've seen a lot of kinds of death. This is the worst."

Compliments
S H Pitts

Critical Issues in Medicine

COMPLIMENTS OF: LAWRENCE H. PITTS
M.D.

Determination of Brain Death

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With the careful application of the principles outlined herein, brain death can be determined with certainty. There have been no documented reports of survivors when these guidelines have been followed. The triad of a known mechanism of brain injury, absence of contributing metabolic or toxic central nervous system depression and absence of demonstrable brain function is sufficient to determine brain death clinically and, in most states, legally. The use of apneic oxygenation protects cadaver organs for transplantation during the period needed to prove that a patient cannot breathe.

Very little can ameliorate the tragedy of sudden and unexpected fatal cerebral injury. Nonetheless, the concept of brain death is well established, and there is no longer a medical or an ethical reason to prolong unnecessary support of these patients.

(Pitts LH: Determination of brain death [Critical Issues in Medicine]. West J Med 1984 Apr; 140:628-631)

The recent report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research devoted considerable attention to the questions of defining death generally¹ and brain death specifically.² The concept of brain death, defined as the irreversible loss of all function of the cerebrum, the cerebellum, the midbrain, the pons and the medulla, is no longer very controversial among clinicians in the United States. However, during a recent nationally televised debate in Great Britain, claims were made that some patients had survived termination of life-support systems despite a diagnosis of brain death.³ A review of the cases in question showed that no patient who survived termination of life support had been declared brain dead. Additionally, a review of published instances of brain death³ and a review of data banks that have extensive information on central nervous system (CNS) disease^{1,3} did *not* identify a single instance of patient survival, for even brief periods, after brain death had been determined using the proper criteria. Conversely, none of more than 1,000 patients with severe head injuries who survived ever were suspected of being brain dead, even during their worst clinical states.³

Medical professionals must be able to accurately determine if a patient is brain dead so that life-support

systems can be withdrawn in a timely manner to prevent unjustified use of precious critical care facilities and to provide donor organs for transplantation. The success of renal transplantation and continuing attempts to transplant other vital organs require that appropriate donor candidates be identified and that their neurologic status be defined carefully to assure that they are indeed "beating heart cadavers" before organs are harvested. Transplant surgeons are extremely cautious and insist that candidates cannot be considered for organ donation until after they are declared to be brain dead. Because incorrect or questionable criteria have sometimes been used to evaluate brain death, occasionally incorrect diagnoses of brain death have been made. Rarely, organs have been harvested from patients who were not brain dead at the time of organ removal; patients have survived for short periods after organs were removed. Such errors invariably can and must be avoided by applying proper criteria for determining brain death.

Laws regarding brain death vary from state to state. California has an excellent law that requires only that brain death be certified by two physicians and does not require undue and unnecessary technologic verification of brain death. (Pertinent sections of the statute are reprinted in Figure 1). I believe that this law is

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ABBREVIATIONS USED IN TEXT

CNS = central nervous system
 CT = computed tomography
 EEG = electroencephalography

appropriate, expedient and correct and rightly places responsibility on physicians who are called on to determine if a patient is brain dead. Although a diagnosis of brain death does not have to be made by neurologists or neurosurgeons only, it is imperative that other physicians who may be in a position to make this diagnosis are confident of their knowledge of the criteria with which brain death can be determined and of their ability to apply them properly. I hope that the following discussion of these criteria will make this process easier for all clinicians.

Criteria for Determining Brain Death

Criteria to determine brain death described below are used at the San Francisco General Hospital Medical Center, a regional trauma center that treats a large number of patients who ultimately die of head injury. It should be emphasized that most patients who die after head injury typically are not brain dead until the time of terminal cardiopulmonary failure and arrest. The clinical course of these patients is characterized by coma with spontaneous ventilation and other brain-stem function for some days or weeks after severe head injury; patients usually die of infection or ventilatory complications of protracted unconsciousness. Thus, criteria for the diagnosis of brain death can be applied properly to only a relatively few of these patients.¹

The diagnosis of brain death requires that the cause of CNS dysfunction be known, that no toxic or metabolic factors that could depress neurologic function be present and that there be no demonstrable brain function (Table 1). While a number of electrophysiologic, radiologic or nuclear medicine studies may provide additional proof of brain death, generally these studies need not be done in typical patients. However, it is necessary occasionally to do one or more of these tests in patients whose clinical course is complicated, or who have a myriad of apparently unrelated clinical signs or results of laboratory tests (or both) that can make a diagnosis extremely difficult. An example of such a patient might be one with prolonged unconsciousness, no evidence of brain function, negative toxicologic studies and a nondiagnostic computed tomographic (CT) scan for whom no definitive cause for apparent brain death has been established.

The Cause of Brain Damage Must Be Known

A diagnosis must be established. This can be done clinically in instances of severe open head injury, gunshot wounds of the brain, prolonged cardiac arrest, drowning with recorded long periods under water or other *very obvious* causes of brain damage. Without such convincing clinical evidence, diagnostic studies

should be done to determine the nature and extent of the brain lesion; a CT scan provides the most readily available and definitive documentation of structural damage such as unilateral or bilateral cerebral infarction, massive intracerebral hemorrhage or other cerebral mass lesions that would account for failure of cerebral and brain-stem function. In a few patients with basilar artery occlusion that leads to brain death, early CT scans may show no abnormalities and cerebral angiography will be necessary to delineate the pathologic features. In the absence of clear clinical or radiographic evidence of overwhelming brain damage, a clinician must be extremely cautious in diagnosing brain death; patients should be supported for one or more days, during which time appropriate additional diagnostic information can be obtained.

Metabolic and Toxic CNS Depression Must Be Excluded

Many systemic abnormalities will depress central nervous system function and should be corrected as completely as possible before the diagnosis of brain

Article I

§ 7180. **Determination of death; irreversible cessation of circulatory and respiratory or brain functions**
 (a) An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards

Article II

§ 7181. **Independent confirmation of brain function cessation**
 When an individual is pronounced dead by determining that the individual has sustained an irreversible cessation of all functions of the entire brain, including the brain stem, there shall be independent confirmation by another physician

§ 7182. **Independent confirmation when part of donor used for direct transplantation**
 When a part of the donor is used for direct transplantation . . . and the death of the donor is determined by determining that the individual has suffered an irreversible cessation of all functions of the entire brain, including the brain stem, there shall be an independent confirmation of the death by another physician. Neither the physician making the determination of death . . . nor the physician making the independent confirmation shall participate in the procedures for removing or transplanting a part.

Figure 1.—Pertinent sections of the Uniform Determination of Death Act of the State of California (Chapter 3.7 of the California Health and Safety Code).

TABLE 1.—Criteria for Determining Brain Death

- Known mechanism of injury
- Absence of toxic or metabolic central nervous system depression
- Absence of brain function

DETERMINATION OF BRAIN DEATH

death is considered. Systemic hypotension or intracranial hypertension, singly or in combination, can lower cerebral perfusion and depress CNS function. Hypothermia lowers cerebral metabolism and can depress brain function, though coma as a result of hypothermia alone does not occur if core body temperatures are above 32°C (90°F). Temperatures between 27°C (80°F) and 32°C can cause coma and temperatures below 27°C virtually always cause coma.⁴ Severe hyponatremia may increase brain water content profoundly and cause severe cerebral edema, thereby depressing brain function. Hyponatremia also may cause focal or generalized seizures, the presence of which excludes a diagnosis of brain death. Poor ventilatory function with hypoxemia or hypercarbia can depress cerebral function and should be corrected. While it is unlikely that any of these metabolic disorders can cause cessation of cerebral function, any might depress minimal brain function to the point that an incorrect diagnosis of brain death could be made.

Systemic toxins alone *can* produce apparent brain death in patients who can recover with absolutely normal neurologic function if they are supported during the period of intoxication. Thus, it is *imperative to exclude an intoxicated state*, either by reliable history (for example, the patient being normal immediately before trauma or having a dramatic and abrupt neurologic ictus consistent with intracranial hemorrhage) or by appropriate toxicologic screening before the diagnosis of brain death is made. Barbiturate overdose can abolish all clinically detectable brain function, though brain-stem evoked potentials often are present even in the absence of other demonstrable brain function. Other hypnotic or sedative agents can greatly depress CNS function to the point that brain-stem reflexes are lost. Ethanol intoxication also can depress CNS function, though it is exceedingly unlikely that the effects of ethanol intoxication alone can mimic brain death.

An appropriate toxicologic screen for CNS depressants should be carried out on blood and urine specimens. Even in patients known to have structural brain lesions, toxins must be excluded before the diagnosis of brain death can be made reliably.

There Must Be No Demonstrable Brain Function

Neurologic testing must show that there is no *brain-generated* response to any neural stimulus (Table 2). Some brain dead patients retain spinal cord reflexes. Thus, minor flexion of upper or lower extremities with local extremity pain need not preclude the diagnosis of brain death. With medullary failure, however, spinal shock generally intervenes and deep tendon reflexes and segmental withdrawal reflexes are absent.

A patient would have no response to supraorbital pain stimulus because sensory input to the brain is via the trigeminal nerve into the brain-stem trigeminal nuclei. Pupils will be mid-dilated (5 to 6 mm in size), with loss of neuronal response of both hypothalamic sympathetic cells and of parasympathetic cells in the Edinger-Westphal nucleus located in the rostral mid-

TABLE 2.—Absence of Brain Function

No pupillary response to light
No corneal reflex
No eye movement with doll's eyes maneuver or caloric testing
No response to supraorbital pain
No gag reflex
No cough reflex
Apnea

brain. Pupillary response to light is absent because death of the upper midbrain causes loss of optic nerve input and parasympathetic nerve output from that region. No eye movement can be elicited either by the doll's eyes maneuver or by cold water caloric testing because pontine vestibular nuclei are without function, as are the pathways for coordination of eye movement in the medial longitudinal fasciculus that extends from the third nerve nucleus in the upper midbrain down to upper cervical spinal cord segments, where joint-position sensation of the cervical spine enters the medial longitudinal fasciculus for coordinating eye movement. Corneal reflexes in both eyes are absent with loss of trigeminal sensation input and facial nerve output to the orbicularis oculi. There is no gag response to firm tongue blade pressure against the oropharyngeal wall. There is no cough reflex with tracheal suctioning via an endotracheal tube. Finally, a patient must be apneic in the presence of an *adequate* carbon dioxide stimulus.

Because hypoxemia with prolonged apnea can cause cardiac arrest and complicate possible organ removal for transplantation, proper apnea testing⁵ is necessary and is summarized here. A patient should be ventilated for five minutes with 100% oxygen at normal tidal volumes so that arterial levels of oxygen are greatly elevated and levels of arterial carbon dioxide are normal (about 40 mm of mercury) at the time that ventilation is discontinued. The ventilator then is replaced by a T-piece delivering pure oxygen to replace oxygen removed from the alveoli by circulating blood. The patient is observed carefully for evidence of respiratory efforts; if none occur within 10 to 15 minutes, during which time the partial arterial carbon dioxide pressure usually will increase 30 to 45 mm of mercury, then apnea will have persisted despite an intense respiratory stimulus. This method of apneic oxygenation ensures that a patient has no response to apnea, a *sine qua non* of brain death, but will maintain an adequate partial arterial oxygen pressure for 15 minutes or more (in the absence of lung diffusion abnormalities) and protect organs that are potentially available for transplantation.

In a few instances, patients being ventilated mechanically are given muscle relaxants during treatment and the ability of a patient to respond to neurologic testing might be questioned. Most paralyzing agents used in this setting are metabolized within a few hours of administration. Even in unusual circumstances such as the use of aminoglycoside antibiotics in patients with renal failure or in rare instances of prolonged paralysis

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TABLE 3.—Supporting Examinations to Confirm Brain Death

Electroencephalography	Radionuclide brain scan
Brain-stem evoked responses	Intracranial pressure
Cerebral angiography	monitoring

from the use of a single injection of succinylcholine chloride, paralysis can be assessed using a nerve stimulator and observing an appropriate muscle twitch response. If possible paralysis is a concern, the issue should be resolved through consultation with an anesthesiologist.

There are no special precautions for pronouncing brain death in infants and children. Even very young infants have well-developed brain-stem reflexes, and absence of these reflexes is the cornerstone of a diagnosis of brain death. The usual precautions must be followed, including an accurate diagnosis for destructive brain lesions and the absence of CNS depression. Because it is often difficult for families to accept the death of a child, to allow the family time to adjust to the tragedy, some delay—perhaps up to a day—might be justified before ventilation is discontinued.

Additional Examinations That Can Be Made to Verify Brain Death

Results of several electrophysiologic, radiologic and other tests can be used when necessary to confirm a clinical diagnosis of brain death (Table 3). Since publication in 1968 of the Harvard Brain Death Criteria,⁶ electroencephalography (EEG) has been used frequently to confirm brain death. It has been suggested that two EEGs that record electrocerebral silence⁷—a “flat” EEG—must be obtained 6 to 24 hours apart before brain death can be diagnosed with certainty. The use of EEG is not required in California, though it is sometimes reassuring to clinicians, especially in difficult or uncertain cases, to prove the absence of electrocerebral function. If there is a known cause of brain destruction, absence of contributing metabolic or toxic CNS depression and absence of demonstrable brain function, we do not do an EEG. In patients for whom the diagnosis is uncertain, or if one of our clinicians desires support of the clinical diagnosis, an EEG may be done. However, a single flat EEG is enough to confirm brain death.

Cessation of cerebral circulation also invariably produces brain death. The absence of cerebral blood flow can be shown by arteriography,⁸ during which a carotid

injection of iodinated contrast material will fill the cervical carotid artery but will not enter the intracranial space, producing what is referred to as a “carotid stop.” If brain death is strongly suggested in a patient known to have barbiturate intoxication, absence of intracranial flow will allow a diagnosis of brain death regardless of the *degree* of intoxication. Radioisotopes injected intravenously will not enter the cranial space, and a brain scan will show no intracranial flow.⁹ Care must be taken with radioisotope studies to ensure that extracranial circulation is not misinterpreted as intracranial flow.

Both auditory and somatosensory evoked potentials of the brain stem can be used to prove brain death.¹⁰ They may be particularly valuable in *excluding* brain death in cases of barbiturate coma, which can produce absence of demonstrable brain function and a flat EEG, by showing that there are brain-stem evoked responses. In brain dead patients, all components of the brain-stem auditory evoked response will be absent except for wave I, which arises from the cochlea in the ear and may be present despite brain death.

Monitoring intracranial pressure may show the presence of intracranial hypertension that equals or exceeds arterial pressure. This lack of cerebral perfusion will produce complete cerebral ischemia and death within five to ten minutes.

None of these procedures is required for proof of brain death in many states, including California, and in my opinion should be reserved for those patients for whom there is considerable uncertainty about the clinical picture or some reason to doubt the reliability of the clinical examination.

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BRAIN DEATH LAWS AND PATTERNS OF CONSENT TO REMOVE ORGANS FOR TRANSPLANTATION FROM CADAVERS IN THE UNITED STATES AND 28 OTHER COUNTRIES¹

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Patterns of practice were analyzed for the United States and 28 other countries with respect to consent to remove cadaveric organs for transplantation and the legal status of brain death as a basis for declaring death. The Uniform Anatomical Gift Act, adopted throughout the United States, allows either the donor or the family to give consent to remove cadaveric organs. In no state is consent presumed. The legal status of brain death as a basis for declaring death is established by statute in 25 states and by court decision in 7 more. Model brain death laws have been proposed recently by the American Medical Association and by the National Conference of Commissioners on Uniform State Laws. Both models are brief. They recognize the equivalence of brain death and death of a person without prescribing the medical criteria and tests used to establish the diagnosis of brain death.

Seventeen of the 28 countries surveyed provide for donor cards similar to those used in the United States. In 15 countries consent to remove organs must be obtained from the donor or a family member. In thirteen, consent is presumed by law, but in 6 of the 13, the family is notified before proceeding with organ salvage. Brain death is recognized by statute or administrative law in 13 of 28 countries. In several of them, medical details and procedures for diagnosing brain death are incorporated into the laws and regulations. The number of cadaver organs salvaged fails to meet the needs of potential recipients in any of the countries. Possible modifications of attitudes, laws, and practice with respect to transplantation of cadaver organs are discussed.

In 1979, the survival of approximately 45,000 Americans with end stage renal disease depended on hemodialysis treatments three times a week (1). The number of patients on dialysis has increased dramatically from about 3,000 in 1972 when an amendment to the Medicare program of the Social Security Administration provided coverage for 95% of the patients with end stage renal disease in the United States. How many patients will be maintained by dialysis in 1990? No one knows, but the estimates range from 80,000 to 100,000.

Until the causes of renal failure can be prevented, only death and successful kidney transplantation act to reduce the numbers on dialysis. One-half of the patients on dialysis are suitable

candidates for kidney transplantation. As immunosuppressive techniques become more specific and much safer during the next decade, considerably more than one-half of them might benefit from transplantation. Yet, in 1979, only slightly more than 3,000 of the 45,000 patients on hemodialysis received cadaver kidney transplants (1). One major factor that limits the availability of kidney transplantation is a lack of cadaver kidneys. Transplant programs throughout the country have long waiting lists.

It is estimated that at least 20,000 Americans die from brain injury, brain tumor, or stroke each year under circumstances that could permit removal of viable organs for transplantation (2, 3). That number is easily large enough to meet the needs of patients who might benefit from transplantation. The public is increasingly aware of present and potential benefits from organ transplantation and can be expected to cooperate with a variety of statutory and social efforts toward facilitating salvage of cadaver organs. As long ago as 1968, a Gallup poll indicated that 70% of Americans were willing to donate organs for transplantation upon their deaths (4). Subsequently, all 50 states have passed the Uniform Anatomical Gift Act and 28 states recognize brain death through statute or Supreme Court decisions by the end of 1979. Yet, the availability of cadaver kidneys does not meet the demand. The remainder of this article reviews the evolution and current status of laws and practice related to declaration of death and consent to remove organs from cadavers for transplantation in the United States and 28 other countries. It considers new strategies that might facilitate retrieval of cadaver organs while maintaining scrupulous regard for the interests and wishes of the dead person and his family.

THE UNIFORM ANATOMICAL GIFT ACT

In 1968, the National Conference of Commissioners on Uniform State Laws proposed the Uniform Anatomical Gift Act. Its purpose was to standardize and simplify various state laws on donation of all cadaveric tissues and organs. Most statutes prior to 1968 required complex legal rituals to arrange for anatomical gifts and were too cumbersome to permit urgent postmortem removal of organs for transplantation. Under the Uniform Gift Act, which by 1970 had been adopted in all 50 states, the donor's wishes are binding after death in that the rights of the recipient created by the gift are paramount to the rights of others (5). The legal instrument is a simple wallet-sized card which requires the signatures of the donor and two witnesses (all at least 18 years of age). Many states have placed the donor card format on the back of vehicle drivers' licenses as a convenience to encourage organ gifts.

Those who drafted the Uniform Anatomical Gift Act ex-

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pected that the public's altruism and stated willingness to donate organs would be translated into widespread use of donor cards. Certainly, the National and many State Kidney Foundations as well as large employers have mounted campaigns to encourage organ gifts. Yet, a recent survey in Maryland, where the donor card is on the back side of the driver's license, indicated only 1.5% participation (G. M. Williams, personal communications). The remaining 98.5% simply avoided dealing with the completely voluntary donor card. Dukeminier (6) anticipated many of the weaknesses in the Uniform Gift Act and predicted that few would bother to sign the cards. The greatest weakness is the psychological difficulty in actually getting down to the task of giving one's own organs away. The signing of a donor card is a much more significant event than responding in the affirmative to a pollster's question about willingness to donate organs after death. Dukeminier (6) notes that less than 20% of all decedents leave wills. The fraction is even lower for the young and middle-aged whose organs would be most suitable for transplantation. In analyzing attitudes toward death, he quotes Freud:

Our own death is indeed unimaginable, and whenever we make the attempt to imagine it, we can perceive that we really survive as spectators. Hence, at bottom no one believes in his own death, or to put the same thing in another way, in the unconscious every one of us is convinced of his own immortality.

Dukeminier (6) maintains that society must find an alternative to the voluntary gift acts to meet the needs for transplantable organs and suggests that laws be modified to provide for routine salvaging of cadaver organs unless there is objection. In light of the Gallup poll result, he thinks a carefully drawn statute could be acceptable to a majority of people in the United States. Seventy-one per cent of the physicians in a 1969 survey supported the concept of routine organ salvage from cadavers (7). Presumed consent would also be in keeping with traditional humanist values by making the basic presumption one that favors life and by putting the burden of objecting upon those who would deny life to another. The policy of saving human life would be given first priority, yet the wishes of persons to preserve a corpse inviolate would also be accommodated. Objections could be entered in a nationwide computer registry such as the Medical Information System of the End Stage Renal Disease Program already funded by the Social Security Administration. In addition, the next of kin could register objections with the attending physicians before or at the time of death. Before proceeding further with analysis of the Uniform Gift Act and its possible modifications or alternatives, it may be helpful to review the practices of other countries with respect to consent for cadaver organ donation.

CONSENT TO REMOVE CADAVER ORGANS FOR TRANSPLANTATION IN 28 COUNTRIES

In late 1979, a questionnaire was mailed to renal transplant programs in 40 countries. Responses were obtained from 28 countries. Eighteen used some form of donor card that could be signed while a person was in good health (Table 1). Thirteen countries used presumed consent as the basis for removing organs for transplantation (Table 2). A crosscheck of Tables 1 and 2 indicates that several countries provided for both donor cards and presumed consent unless an objection had been entered by the decedent or his relatives. In about one-half of the countries where presumed consent prevails, physicians ap-

TABLE 1. Donor cards

Yes	No
Argentina	Australia
Belgium	Austria
Canada	Czechoslovakia
Denmark	India
Finland	Israel
France	New Zealand
Germany	Poland
Great Britain	Spain
Greece	Sweden
Ireland	
Italy	
Japan	
Norway	
Puerto Rico	
South Africa	
South Korea	
Switzerland	
Thailand	

proached the families to be certain that they had no objection (Finland, Greece, Italy, Norway, Spain, and Sweden); in the remaining one-half physicians simply proceeded with organ salvage in the absence of prior objection by the decedent or his family (Austria, Czechoslovakia, Denmark, France, Israel, Poland, and Switzerland).

In 15 of the 28 responding countries, consent was not presumed. Rather, as in the United States, consent was obtained through donor cards or requested from the next of kin. It should be noted that all of the English-speaking countries were in this category. In the absence of family, all but three countries (India, Japan, and South Korea) allowed hospital officials or medical examiners to authorize removal of organs. European countries are expected to gradually modify their consent laws toward presumed consent to remove cadaver organs. This has been the position of the European Committee on Legal Cooperation of the Council of Europe since 1975 (8). The Committee on Legal Cooperation is the European equivalent of the National Conference of Commissioners on Uniform State Laws in the United States.

Even those countries with presumed consent statutes fail to meet their needs for cadaver organs. All have sizable waiting lists for renal transplantation. Presumed consent laws increase the likelihood of kidney salvage after a potential donor has been identified, but they do little or nothing to stimulate hospital-based nurses and physicians to aid in that identification. Most of the kidneys come from large hospitals where transplantation and dialysis programs ensure heightened awareness of the need. The medical staff there are more likely to "go the extra mile" required after brain death has occurred to support the cardiovascular system until the transplant team has been notified and a decision has been made about the dead person's suitability as an organ donor. The problem of enlisting the interest and support of hospitals distant from or unfamiliar with transplant centers is a serious one for countries with and without presumed consent laws, but countries with presumed consent seem to come closer to meeting their needs for transplant kidneys.

Salvage of cadaver organs in countries without presumed consent laws depends more heavily on an informed, altruistic citizenry. The initiative must come from the dying patient via

TABLE 2. Basis for consent to remove cadaver organs

Countries with presumed consent	Family agreement sought		Countries where family consent or donor card are required	Hospital official or coroner can consent if family not available	
	Yes	No		Yes	No
Austria		X	Argentina	X	
Czechoslovakia		X	Australia	X	
Denmark		X	Belgium	X	
Finland	X		Canada	X	
France		X	Germany	X	
Greece	X		Great Britain	X	
Israel*		X	India		X
Italy	X		Ireland	X	
Norway	X		Japan		X
Poland		X	The Netherlands	X	
Spain	X		New Zealand	X	
Sweden	X		Puerto Rico	X	
Switzerland		X	South Africa	X	
			South Korea		X
			Thailand	X	

*Hospital Committee decides each case.

a signed donor card, or from the attending physician and the family at a time when the family is preoccupied with grief. The chief causes of brain death appear suddenly and give the family little time to prepare for loss of their loved one. It is natural, even in seemingly hopeless situations, for the family to hope and pray for recovery right up until the time that death of the brain occurs and the patient's death is declared. In some cases, it may not be appropriate to discuss organ donation before death has been declared unless it is initiated by the family. To do so might raise the possibility in the minds of the relatives that nurses and physicians would limit their effort on behalf of the patient. Nor should the announcement of death (on the basis of brain death) to the family be equivocal. It must be direct and clear and accompanied by a statement that the ventilator will be left in place until the family can make a decision about consent to remove organs for transplantation.

The attending physician is frequently reluctant to introduce the request to consider organ donation. From his own perspective he has failed, albeit against great odds, to restore the dead person's health. Insofar as he has been unable to "deliver" on the family's implied request for restored health, he may avoid making the request that they consider organ donation. Moreover, he may not wish to interrupt a busy schedule to make the contacts and arrangements for organ donation. Yet, retrospective sociological studies indicate that those families who consent to organ donation come to view it in a very positive way as their grief subsides (9). They draw comfort from knowing that a part of their relative survives and frequently relate that they are confident he would have wanted it that way. Thus, organ donation and transplantation actually offer some solace to the grieving family.

On the rare occasion when the potential donor has signed a donor card or when his family has requested organ salvage, the attending physician and hospital staff usually go to great lengths to contact a transplant team and are eager to facilitate organ donation. It is a request that can usually be met. However, in the usual situation where neither a donor card nor the family initiates consideration of organ donation, the attending physician must see beyond his own perspective and possible feelings of failure in order to bring the benefit of organ donation to the donor's family and to the potential recipients. Nurses who

helped to care for the patient in the intensive care unit, and hospital chaplains and social workers can be immensely helpful to both the attending physicians and the family in dealing concurrently with their loss and the opportunity to give. Members of transplant teams are also quite skilled in discussing organ donation and are usually available to answer questions for the family.

APPROACHES TO INCREASE THE SUPPLY OF ORGANS FOR TRANSPLANTATION IN THE UNITED STATES

Identification of potential organ donors and initiation of contact with a transplant center to arrange for organ salvage is a problem in all of the countries surveyed regardless of whether consent for removal is presumed or must be obtained from the family. But, the need to obtain specific family consent compounds the problem. In the United States, not more than 40% of suitable donors come to the attention of transplant teams according to studies made in several regions of the country by the United States Public Health Service Center for Disease Control (CDC) in Atlanta (3, 10). The CDC finds that consent to remove organs is obtained only 47% of the time, and actual organ salvage occurs in only 81% of cases with consent (because of logistics problems or sudden deterioration of the cardiovascular system). Thus, the CDC finds that kidneys are salvaged from only 16% of suitable potential cadaver donors. In addition, the CDC studies indicate that suitable donors comprise 2% of hospital deaths and could provide 110 kidneys per million population (about 25,000 kidneys each year). An actual retrieval rate of 16% would provide 4,000 kidneys. Subtraction of a final 20% for kidneys retrieved but not used because of damage, poor storage characteristics, or logistics problems leaves an estimate of 3,200 usable kidneys; a figure very close to the number actually transplanted in 1979.

An ideal combination of laws and practices would stimulate attending physicians and hospital personnel to notify transplant teams about potential donors, and also ensure a high likelihood of consent to remove organs. How might this combination be achieved? Perhaps one key is the positive response that attending physicians make to signed donor cards and requests from the family. Both situations remove the initiative for organ donation from the physician and place him in a much more

comfortable, familiar role, namely, one of attempting to meet the requests of patients and their families. Such requests serve as a maximal stimulus to contact the nearest transplant team.

Initiatives from the family should increase as the public becomes more aware of transplant recipients whose health has been restored. It will be a slow process and alone will probably not yield a sufficient supply of donor organs. However, the number of people carrying signed donor cards could probably be increased dramatically simply by requiring that every adult respond to the donor card provision of the Uniform Gift Act by either signing it or indicating that he is opposed to organ donation. Perhaps the current option of avoiding the issue altogether should be denied. If the polls are correct, at least 70% of the adult population could be expected to sign the cards. Yet, the mere act of requiring a response might decrease the number of people willing to sign the cards rather than register an objection. Before embarking on a nationwide program, it would be important to use polls or sample populations to anticipate the effect of requiring a response to the donor card option.

THE OPTION OF PRESUMED CONSENT LAWS IN THE UNITED STATES

Laws that presume consent to remove organs would require interpretation under the Fifth and First Amendments of the United States Constitution (6, 11). The Fifth Amendment gives government the right of eminent domain over property. It is likely that organs of the deceased would be considered property and could be claimed by the state with or without compensating the donor's estate. The First Amendment which provides for free exercise of religion would require that an "objection clause" be added to any presumed consent laws. There appear to be no other constitutional problems with such laws. However, legislation would remain the prerogative of each of the 50 states. Perhaps the National Conference of Commissioners on Uniform State Laws should be asked to consider proposing a "presumed consent" amendment to the Uniform Anatomical Gift Act, already enacted by all states. In the absence of a model amendment endorsed by the Conference, it is unlikely that many states would enact presumed consent laws.

Presumed consent laws would recognize the humanist mood of the country and relieve the family of deliberating on the physician's request for organ donation at a time when their grief is most intense. Such laws would almost certainly increase the number of organs salvaged. But, as discussed already, they would in no way direct a physician to initiate organ salvage. Rather, physicians would be free to initiate or to avoid organ salvage inquiries.

The team studying cadaver donor problems at the CDC in Atlanta seems to have found a way to increase identification of potential donors in hospitals that are not involved directly with organ transplantation (10). The plan was accepted by all but one hospital in the Atlanta metropolitan area. Initially, permission was obtained for a nurse coordinator from the nearest transplant program to work with the local hospital's medical record librarian to survey the incidence of deaths that might have been followed by organ salvage. Next, permission was obtained from the hospital administration and the medical staff for the nurse coordinator to visit the intensive care units on a regular basis and to approach the attending physicians about patients whose brain death was imminent. Then, with the physician's permission, and only after he had informed the

family of his declaration or intent to declare death on the basis of brain death, the transplant nurse coordinator was allowed to talk with the family about organ donation. In the event of family consent, the nurse, rather than the attending physician, made all of the arrangements for organ salvage. In several participating hospitals, identification of potential donors and contact with the family to consider donation approached 100%. However, consent was obtained only half of the time. The combination of increased use of donor cards, improved donor identification through the assistance of nurses from the transplant team, and adoption of laws that presume consent to salvage organs (in the absence of specific objection) would certainly ensure an increased supply of cadaver organs probably sufficient to meet society's needs.

Dukeminier (6) has noted that continued short supply of cadaver organs will inevitably increase the pressures to buy spare organs, such as a kidney or a segment of intestine, from willing, living, unrelated persons. Although the sale of organs by live donors or by the next of kin after the donor's death is repugnant to most people, it is not dealt with by the Uniform Anatomical Gift Act. Sale of organs by unrelated live donors is not forbidden by any state. Only Georgia specifically forbids the sale of cadaver organs. At present it is only the unwritten code of ethics of transplantation surgeons that prevents the sale of live, unrelated, and cadaver organs. Specific manipulation of the immune response will soon allow better control of graft rejection. Increasing success in transplantation will place tremendous pressure on transplant surgeons to modify their opposition, at least to the willing, live, unrelated donor. We are at the point where, as Dukeminier (6) states, "Society must face the fact that cadaver organs can be used to save human life and that a hard choice must now be made. It must decide whether to advance the policy of preserving life or to stand paralyzed by its taboos."

BASIS FOR EQUATING BRAIN DEATH WITH DEATH

Brain death (irreversible loss of all brain functions) is now widely recognized as a medically definable state and a basis for declaring a person's death (12, 13). Moreover, there are valid reasons why it is appropriate to recognize brain death when it occurs and to not leave a mechanical ventilator in place until hypotension or pneumonia and hypoxia finally cause the heart to stop (13). It is unreasonable to subject the patients' family to additional days or weeks of false hope, grief, and medical expense beyond the point of brain death. Society should also be spared the useless costs that it covers as a third party. Prolonged support of respiratory and cardiac function after brain death has occurred is demoralizing to nurses and other medical staff in intensive care units. Their attention is needed urgently by the living, yet they must take part in a charade involving the brain-dead patient for the sake of his relatives who are not yet aware that death has occurred. Finally, the only practical source of viable cadaveric organs for transplantation is from patients whose cardiac function and ventilation are maintained briefly after brain death has occurred. None of the organs will be viable and transplantable if the declaration of death is delayed until agonal hypotension, hypoxia, and cardiac arrest have occurred in spite of mechanical ventilatory support.

The American Medical Association has long maintained that physicians have had the prerogative of declaring death on the basis of brain death. Many physicians have exercised that

prerogative during the past two decades. Other physicians are afraid to declare death on the basis of brain death if it is not specifically allowed by state law. If they are unwilling to risk lawsuit, such physicians have little choice other than to leave the ventilator in place for as long as it takes until cardiac arrest occurs. Despite its medical and scientific validity and despite its considerable legal and social acceptance, use of the brain death concept has been hampered in some areas by the absence of legal recognition. This reluctance to make death pronouncements on the basis of total and irreversible cessation of brain functions has been documented by letters from neurologists or neurosurgeons in 13 of the 50 states. Because of these letters, the American Medical Association recently reversed its position that specific legislation to recognize brain death as a basis for declaring death was neither necessary nor helpful.

LEGAL STATUS OF BRAIN DEATH IN THE UNITED STATES

Twenty-five states adopted laws from 1970 through 1979 that specifically recognize brain death as a basis for declaring death (Table 3). As indicated in Table 3, the laws are patterned after several models that have been thoroughly reviewed elsewhere (13). In three additional states, Massachusetts (14), Colorado (15), and Arizona (16), the legality of a pronouncement of death based on total and irreversible cessation of brain functions has been considered before the highest state court. In all three of these states, brain death pronouncements have been held to be valid and legal. In four other states, New York, Minnesota, Florida, and Ohio, lower court decisions have made similar judgments. However, the decisions were not appealed to higher courts.

RECENT DEVELOPMENTS INDICATING THAT THE BRAIN DEATH CONCEPT WILL GAIN WIDER LEGAL RECOGNITION WITHIN THE UNITED STATES

In addition to the more widespread statutory and judicial recognition afforded brain death pronouncements over the past several years, several other recent developments indicate that still wider legal recognition is likely. The first is the adoption in August 1978 of a model Uniform Brain Death Act by the

National Conference of Commissioners on Uniform State Laws in the United States (17). This act specifies that:

For legal and medical purposes, an individual who has sustained irreversible cessation of all functioning of the brain, including the brain stem, is dead. A determination under this section must be made in accordance with reasonable medical standards.

In a comment on the Uniform Brain Death Act, the Commissioners stated that "the act does not preclude a determination of death under other legal and medical criteria, including the traditional criteria of cessation of respiration and circulation."

Another important development has been a change in the position of the American Medical Association away from opposition to statutory definitions of death. This opposition was based on a belief that there was no need for such laws. In 1977, this opposition softened and in December 1979, largely as a result of added pressure from organizations representing neurologists and neurosurgeons, this opposition was entirely reversed, and a Model Act to provide for the determination of death was adopted by the American Medical Association House of Delegates (18). The important sections of this act read:

An individual who has sustained either 1) irreversible cessation of circulatory or respiratory functions, or 2) irreversible cessation of all functions of the entire brain, shall be considered dead. A determination of death shall be made in accordance with accepted medical standards. A physician or any other person authorized by law to determine death who makes such determination in accordance with (the above) is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his acts or the acts of others based on that determination.

In May 1980, representatives of the American Medical Association, American Bar Association, and the National Conference of Commissioners of Uniform State Laws reached agreement on a Uniform Determination of Death Act. This new uniform determination reads:

An individual who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brain stem, is

TABLE 3. Models adopted by 25 states for statutory definition of death

Kansas model: alternative means for determining death ^a	Capron-Kass model: death is pronounced while heart and lung functions are artificially maintained	American Bar Association model: irreversible cessation of total brain functions equals death	Uniform Brain Death model: Similar to American Bar Association model but emphasizes irreversible cessation of brain stem function
Kansas 1970	Alaska 1974	California ^b 1974	Nevada 1979
Maryland 1972	Michigan 1975	Georgia ^b 1975	Wyoming ^d 1979
New Mexico 1973	West Virginia ^c 1975	Oklahoma 1975	
Virginia ^b 1973	Louisiana ^c 1976	Illinois ^c 1975	
Oregon 1975	Iowa ^b 1976	Tennessee 1976	
North Carolina ^c 1977	Hawaii ^{b,c} 1978	Idaho ^b 1977	
	Texas 1979	Montana 1977	
	Alabama ^c 1979	Arkansas ^c 1979	
		Connecticut ^{b,c} 1979	

^a Specifically allows death declaration on basis of cardiorespiratory failure or brain death.

^b Use of brain-related criteria to pronounce death requires opinion of two physicians. In some instances (Virginia and Hawaii), one of these must be a specialist in neurology or neurosurgery.

^c Physician who makes the determination of death may not participate in removal or transplantation of organs from the deceased.

^d Total brain function is defined as purposeful activities of the brain as distinguished from random activity.

^e Use of brain-related criteria only to be used for purposes of the Anatomical Gift Act, i.e., for purposes of organ donation.

^f Also requires absence of spontaneous breathing.

^g As amended in 1979; Capron-Kass like in some regards.

dead. A determination of death must be made in accordance with accepted medical standards.

This new model law has been officially endorsed by the Ethics Committee of the American Academy of Neurology, the National Conference of Commissioners of Uniform State Laws, and the Legislative Council of the American Medical Association. It is expected that the Board of Trustees of the American Medical Association and the House of Delegates of the American Bar Association will endorse the model law at meetings scheduled in late 1980 and early 1981. A newly appointed Presidential Commission on the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research is also considering the issue of brain death and the need for legislation to recognize it.

LEGAL STATUS OF BRAIN DEATH OUTSIDE THE UNITED STATES

Responses from 13 of the 28 countries reported that there was specific statutory recognition of brain death as a basis for declaring death: Argentina, Australia, Austria, Canada, Czechoslovakia, Finland, France, Great Britain, Greece, Italy, Norway, Puerto Rico, and Spain (Table 4). Two of the 13 countries (Australia and Canada) have several provinces or states that have not yet enacted brain death laws. Britain uses a code of practice that has quasi-legal status. The code was drawn up in October 1979, by a Working Party under the auspices of the United Kingdom Health Departments.

Although the remaining 15 countries have no specific laws that recognize brain death, in 10 of them the condition of brain death is accepted medically and used as a basis to declare death: Belgium, Germany, India, Ireland, The Netherlands, New Zealand, South Africa, South Korea, Switzerland, and Thailand. In the remaining five, it is the practice to wait for cardiac arrest before declaring death and proceeding with removal of organs for transplantation: Denmark, Israel, Japan, Poland, and Sweden.

BASIS FOR DECLARATION OF BRAIN DEATH

A consensus has evolved in the United States that brain death is a clinical diagnosis which can usually be established by

TABLE 4. Specific legal recognition of brain death

Yes	No
Argentina	Belgium ^a
Australia ^b	Denmark
Austria	Germany ^a
Canada ^b	India ^a
Czechoslovakia	Ireland ^a
Finland	Israel
France	Japan
Great Britain ^c	The Netherlands ^a
Greece	New Zealand ^a
Italy	Poland
Norway	South Africa ^a
Puerto Rico	South Korea ^a
Spain	Sweden
	Switzerland ^a
	Thailand ^a

^a Brain death is accepted medically even in absence of specific brain death statute

^b Varies with state or province.

^c Code of practice with quasi-legal status.

physical examination alone (19, 20). Electroencephalography, computerized axial tomography, and cerebral arteriography are procedures that may be used at the discretion of the physician to confirm the diagnosis of brain death. All of the state laws as well as the model laws proposed by the American Medical Association and the National Conference of Commissioners on Uniform State Laws require only that the physician use reasonable, accepted, or prevailing medical standards in pronouncing death. The statutes are brief and avoid details of the medical examination and testing that might be used to diagnose brain death. The laws simply recognize that brain death can be diagnosed and that it is equivalent to the death of a person. Other countries that follow this approach to the diagnosis of brain death are listed in Table 5. All of the English-speaking countries that responded to the questionnaire are in this group.

Ten countries require either electroencephalography and/or cerebral arteriography to confirm the diagnosis of brain death before proceeding with organ removal (Table 5). In these countries the medical criteria and tests required to diagnose brain death are either part of a statute or part of a nationwide regulation with legal status: Argentina, Austria, Czechoslovakia, France, Greece, Italy, Norway, Poland, Switzerland, and Thailand.

SOURCES AND REASONS FOR PRESENT OPPOSITION TO STATUTORY RECOGNITION OF BRAIN DEATH PRONOUNCEMENTS IN THE UNITED STATES

In the last several years, bills that recognize the legality of brain death pronouncements have been introduced in several state legislatures in the United States and have been defeated. The basis for most opposition to statutory definitions of death is that such laws are perceived as being related to laws that will facilitate active or passive euthanasia, so-called "death-with-

TABLE 5. Basis for declaration of brain death

	Clinical	Electroencephalogram required	Cerebral angiogram
Argentina	X	X	
Australia	X		
Austria	X	X	
Belgium	X		
Canada	X		
Czechoslovakia	X	X	or X
Finland	X		
France	X	X	
Germany	X		
Great Britain	X		
Greece	X	X	
India	X		
Ireland	X		
Italy	X	X	
New Zealand	X		
Norway	X		X
Poland ^a	X	X	X
Puerto Rico	X		
South Africa	X		
South Korea	X		
Spain	X		
Sweden ^a	X		
Switzerland	X	X	or X
Thailand	X	X	

^a Ventilatory support is stopped and cardiac arrest must occur before removing organs.

dignity" or "right-to-die" laws. Statutory definitions of death are regarded as "foot-in-the-door" legislation for bills which will permit euthanasia (21). Although this has rarely, if ever, been the case, this reasoning has prompted the strong and effective opposition of some groups.

Some opposition to the concept of brain death also exists (22, 23). Although a concept of death based on total and irreversible cessation of brain functions is consistent with the traditions, ethics, and theological writings of all three major Western religions (13), there are splinter groups within these religions which oppose this concept in principle. Most of these minority groups within major religions have failed to publish their opposition or the reasons that prompted it. Some members of the Right-to-Life or Pro-Life Movement have recently begun to recognize that statutory definitions of death and so-called right-to-die laws or laws that permit euthanasia deal with quite separate issues. This recognition has, in part, been stimulated by the realization that the existence of a statutory definition of death makes an inadequate death pronouncement and euthanasia more, not less, difficult. Awareness of these points has prompted the prestigious Pro-Life Catholic ethicists Germain Grisez and Joseph M. Boyle to write in support of statutory definitions of death (24).

Meanwhile, court cases over the issue of exactly what constitutes death continue to arise and attract public interest in those jurisdictions without statutory definitions of death. These cases more than anything else clearly emphasize to society the need for a statutory definition of death to keep the law consistent with present day science and medicine. These court cases are, therefore, a strong and continuing impetus to the more widespread legal recognition of the brain death concept.

DISCUSSION AND CONCLUSIONS

The need for cadaver organs will increase as the clinical outcome of organ transplantation continues to improve. Society is increasingly aware of the remarkable rehabilitation that transplants offer. The shortage of organs is not because of a lack of potential donors. Enough people die under conditions that would allow removal of transplantable organs to meet the needs of all potential transplant recipients. The shortage results from failure to identify potential donors and from frequent lack of consent to remove organs after death. Continued efforts to inform the medical community and the general public about transplantation will help to identify potential donors and increase the likelihood of obtaining family consent to remove organs. But, many doubt that these steps will be sufficient.

The Center for Disease Control of the United States Public Health Service has proposed that a surveillance system be established to identify suitable potential donors in hospitals with more than 100 deaths each year. The surveillance group would interface between attending physicians and transplant centers. Widespread use of the CDC proposal should identify more potential donors, and might also increase the likelihood of obtaining family consent as better informed hospital personnel learn to handle the issue in a sincere, sensitive manner.

Some suggest that only presumed consent to remove organs will yield sufficient numbers. The countries surveyed were equally divided among those that require family or donor consent and those that presume consent. Consent is not presumed in any of the English-speaking countries and attempts to introduce it would probably meet much resistance. Hope-

fully, other approaches than presumed consent will provide adequate numbers of organs for transplantation.

Finally, a consensus is evolving both in the United States and elsewhere that brain death can be diagnosed with reasonable certainty and should be recognized by law as a basis for declaring a person's death. Elimination of uncertainty about the legal equivalence of brain death and death of a person should increase the salvage of cadaver organs and reduce the amount of ischemic injury that they sustain before removal.

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DECLARATION OF CEREBRAL DEATH

A person may be pronounced dead if it is determined by a physician that the person has suffered a total and irreversible cessation of brain function. There shall be an independent confirmation of the death by another physician.

Factors to be considered in declaring brain death include:

1. Cerebral unresponsivity. There should be no evidence of a cerebral type of response to intensely painful stimulus, noise or visual stimulation. Spinal cord reflexes may be present.
 2. Absence of brain stem reflexes, including the pupillary and oculocephalic reflexes.
 3. Apnea. Trials of the first five and then ten minutes without respiration should produce no efforts at spontaneous breathing.
 4. The patient should have a brain lesion that is not unamenable to treatment. Primary hypothermia and significant abnormalities of the metabolic and endocrine factor should be excluded.
 5. Chemical screening for drug levels should be done in all cases except those with a firm diagnosis of a major cerebral lesion that is clearly capable of causing brain death and there is no history of ingestion of drugs.
 6. Confirmatory tests that may be used in making the diagnosis of brain death include the absence of blood flow as shown by angiogram, isotope studies or absence of midline echo pulsations, persistent intracranial pressure measurements sufficiently over systemic blood pressure to preclude intracranial flow; and electrocerebral silence on the electroencephalogram.
-
7. Factors supporting the diagnosis of cerebral death should be present for six hours with a known structural untreatable brain lesion of the type that can produce cerebral death. If such a lesion is not present, or the patient is under one year of age the factors supporting the diagnosis of cerebral death should be death should be present at least 24 hours.

JRY:b1

CEREBRAL DEATH

For ancient and medieval man, death was an experience cloaked in mystery and fear. Because of its universal and irreversible nature, the subject has been treated extensively in the literature of philosophy, theology, and science from ancient times to the present. The role of the physician in this drama was to prevent death through treatment and, if this was not possible, then to determine when death had occurred. Thus, various criteria for the determination of death arose, including cessation of respirations and heart beat, lack of pupillary action, rigor mortis, hypostasis, and relaxation of the anal sphincter. However, since even deep coma might be reversible in the rare case, the only incontrovertible sign of death for the ancients was the onset of tissue decay.

The lack of a reliable criterion for distinguishing actual from apparent death caused a universal concern that it might be pronounced prematurely. Indeed, in previous centuries this fear was not unfounded. Numerous instances of individuals who were thought to be dead but had cataplexy, trance states, hysteria, hypothermia, and coma from a variety of causes were reported even in the late nineteenth century.⁶⁶ Writing in 1896, Montgomery reported on the condition of bodies removed from a military cemetery. He states:

We found among these remains two that bore every evidence of having been buried alive. The first case was that of a soldier that had been struck by lightning. Upon opening the lid of the coffin we found that the arms and legs had been drawn up as far as the confines of the coffin would permit. The other was a case of death resulting from alcoholism. The body was slightly turned, the legs were drawn up a trifle and the hands were clutching the clothes.⁵²

He concluded his report by saying

Nearly two percent of those exhumed were, no doubt, victims of suspended animation.⁵²

Pamphlets with such titles as "Burying Alive, a Frequent Peril" kept the public concerned by citing cases like that of a 35-year-old man who was supposed to have died of scarlet fever and was buried 48 hours later. The pamphlet stated

The coffin was moved two months later and the glass front was found to be shattered, the bottom kicked out and the sides sprung. The body was reported to lay face downward with the arms bent and in the clenched fist were handfuls of hair.⁷⁴

Such reports gained wide circulation and fueled the universal fear of premature interment. As a result many individuals throughout the world left instructions that their bodies were to be mutilated by such actions as having a sword put through the heart after death was thought to have occurred. According to Walker, as late as 1918 the law in France was that death could be declared only after temporal or radial arteriotomy produced no hemorrhage.⁷² This widespread attitude changed little until a more scientific one developed later in this century. Despite the scientific progress, incidents still happen that support the fear of an incorrect diagnosis of death. For instance, in 1967 an American soldier who had failed to respond to the efforts of a resuscitation team for nearly an hour was left for dead and later showed signs of life as he was about to be embalmed.⁵⁴ In view of the centuries-old universal fear of incorrect diagnosis of death and premature burial, it is remarkable that during a mere two decades the world's society could accept such

sweeping sociological, philosophical, and legal changes as to even consider the diagnosis of death of the organism by death of a single organ, i.e., the brain.⁴

The background for acceptance of cerebral death as an entity was developed during the last few decades with the gradual acceptance of the idea that death encompasses many factors and evolves in stages rather than being one simple finite cataclysmic event. The definition of death as a cessation of all vital functions in a living organism was enlarged as insight and diverse connotations were applied to it by individuals of various professions and backgrounds. Many amplifying terms were used. They included such terms as "biological death," "brain death," "cardiac death," "cerebral death," "clinical death," "cortical death," "cytological death," "irreversible death," "legal death," "psychological death," "psychosocial death," and "spiritual death."² Against this background, the development of modern techniques that permitted prolonged artificial ventilation of apneic patients gave urgency to the quest for criteria for death that recognized the legal, social, medical, and ethical implications of declaring death in a patient who had lost certain vital functions but not all others.

These discussions have led to many definitions of death. One that has been well accepted defines death as ". . . a point at which the deterioration of functions becomes irreversible so that the organism can never again function as an integrated, rational organ."¹⁰ Perhaps, in the statement attributed to him, Justice Holmes best summarized the problem when he said "to live is to function; that is all there is to living."²⁷

The question has arisen whether destruction of the cerebral hemispheres or cerebral cortex in a person with preserved respiratory and vasomotor functions could be considered to be adequate evidence to declare that person clinically or legally brain dead. Some writers have argued that cortical death alone is not sufficient to deprive a person of his right to live.¹⁰ The justification for this argument is that some psychic activity may be present in the brain stem. Others have argued that if the cerebrum is irreversibly destroyed bilaterally, the infratentorial portions of the brain do not have psychic activity and make no significant contribution to the continuing function of

the total human organism.⁴³ The issue in this controversy is whether vegetative functions of the body without accompanying cerebral function constitute an adequate basis for declaring the person to be alive. Some authors have qualified the term "cerebral death" and have subdivided it into "neocortical death," which means the destruction of the cerebral mantle, and "brain death," which has been reserved to mean the total destruction of all the intracranial nervous tissue.⁴⁴ Although physicians well-informed in neurology can reliably diagnose brain death even with some lower brain stem reflexes present, at present it would seem that a holistic designation is appropriate and that a subdivision of the diagnosis should not be attempted.

A problem arises when the terms "cerebral death" or "brain death" and "irreversible coma" are used loosely. Cerebral death implies total and permanent abolition of brain function so that both volitional and higher-level reflex activity and responsivity are lost. In contrast "irreversible coma" refers to a state in which all functions attributed to the cerebrum that identify the human essence—mind, personality, behavior, and in theological terms, the soul—are lost, but certain functions that regulate respiration, temperature, blood pressure, and lower-level central nervous system activity remain. Patients with irreversible coma fit the so-called appallic state described by Ingvar and Brun, which implies loss of the pallium, the cortical gray matter that covers the cerebral cortex.³⁶ These patients are in the broad category that includes the persistent vegetative states, coma vigil, and akinetic mutism.⁴² In them a variety of vegetative functions including respiration may be preserved so that survival for years is possible.

The well-publicized case of Karen Quinlan fits the category of irreversible coma.²⁷ For reasons that are unclear, this 21-year-old girl ceased breathing for two 15-minute periods. On her admission to the hospital her temperature was 100°, her pupils were unreactive, and she was unresponsive to deep pain. She was given respiratory assistance via a respirator. When examined by a neurologist three days later she was found to be comatose with evidence of decortication. The respiratory assistance was continued. Tests of the urine disclosed traces of

quinine, barbiturates, and diazepam. A brain scan, an angiogram, and a lumbar puncture were normal. Her electroencephalogram was characterized as "abnormal, but it showed some activity and was consistent with her clinical state." The clinical state was a sleeplike unresponsive condition at first, but later she developed sleep-wake cycles. In the waking state she would blink and cry out. She was "totally unaware of anyone or anything around her," and was characterized as being in a "chronic, persistent, vegetative state, and no longer had any cognitive function."²⁷

LEGAL ASPECTS

Prior to the evolution of the concept of cerebral death before death of the entire body, the courts of the United States were applying the definition of death from Black's law dictionary, which was

... the cessation of life; the ceasing to exist; defined by physicians as a total stoppage of the circulation of the blood, and a cessation of the animal and vital functions consequent thereupon such as respirations, pulsations, etc.¹⁴

Typical of the legal rulings based on that definition was that of an appeals court, which said in a case determining which of two men had died first,

... death occurs precisely when life ceases and does not occur until the heart stops beating and respirations end. Death is not a continuous event and is an event that takes place at a precise time.⁶⁷

As a result of this type of approach by the courts, the physicians making a diagnosis of cerebral death and stopping respiratory assistance to the patient or removing organs for transplantation before cessation of heart beat were at risk of prosecution for malpractice by omission or criminal prosecution for permitting removal of an organ prior to the patient's death. Gradually over several years the concept of cerebral or brain death as representing the actual death of the individual came to be supported in a number of courts and judicial forums.^{35,51,59} For example, one early court ruling that supported the new concept of brain death was that

Death is the cessation of life. A person may be pronounced dead if, based on the usual and cus-

tomary standards of medical practice, it has been determined that the person has suffered an irreversible cessation of brain function. . . .¹⁸

The legal ramifications of defining death are far-ranging. For instance, the situation may exist in which a person is considered dead for one purpose such as transplantation of organs, and alive for another such as inheritance or predecease of another individual or resolution of problems involving estate taxes. The legal complexities have led legislative bodies to vary widely in the degree of specificity that they enjoin in giving legal sanction to the concept of cerebral death. Some states in the United States have been quite specific and others have followed the advice of the House of Delegates of the American Medical Association, which supported the concept of cerebral death but opposed statutory definitions. In the December 1974 meeting of the House of Delegates, the following resolution was passed.

Resolved, That the American Medical Association reaffirm established policies that: "At first statutory definition of death is neither desirable or necessary"; "that state medical associations urge their respective legislatures to postpone enactment of legislation defining death by statute"; "that death shall be determined by the clinical judgment of the physicians using the necessary available and current accepted criteria"; and "permanent and irreversible cessation of function of the brain constitutes one of the various criteria which can be used in the medical diagnosis of death."⁷²

MORAL ASPECTS

The potential for error and laxity causes troublesome ethical and moral questions. The remote possibility of error mandates caution and concern in every aspect of making the diagnosis. When appropriate caution and concern have been used, current theological teachings would support the concept of diagnosing cerebral death and taking appropriate action. For example, Pope Pius XII discussed the obligation to use elaborate and expensive means of resuscitation by saying

It is incumbent on the physician to take all reasonable, ordinary means of restoring the spontaneous vital functions and consciousness, and to employ such extraordinary means as are available to him to this end. It is not obligatory, how-

ever, to continue to use extraordinary means indefinitely in hopeless cases.³⁵

In this regard the definition of extraordinary means has been interpreted as

... whatever ... is very costly or very unusual, or very painful, or very difficult, or very dangerous, or if the good effects that can be expected from it are not proportionate to the difficulties and inconveniences that are entailed.²⁰

WORLD ACCEPTANCE

The acceptance of the concept of cerebral death varies in different countries of the world (Table 21-1). The difference in philosophies of the various nations and societies was shown at the 1976 meetings of the Neurotraumatology Committee of the World Federation of Neurological Societies.⁷² Two major views were put forth. One was that the criteria for brain death should be based upon clinical considerations with

little or no laboratory confirmation. Those holding that view thought that, with a confirmed diagnosis of an untreatable and soon to be fatal brain lesion, the absence of responsiveness and spontaneous respirations and cephalic reflexes for a period of 12 to 48 hours was a simple and satisfactory means of determining the death of the brain that could be used by all physicians regardless of their neurological expertise. The other view was that clinical criteria were inadequate and laboratory tests such as electroencephalographic or metabolic studies were needed to confirm the diagnosis. Implied in this second view is the constraint that the diagnosis of cerebral death could be made only in centers equipped for these laboratory studies and by individuals who were adequately trained to interpret and correlate them with the patient's neurological status. This latter approach would not be a significant impediment to organ transplantation, since organs are transplanted in well-equipped hospitals where the instru-

TABLE 21-1 MEDICAL AND LEGAL STATUS OF CEREBRAL DEATH*

COUNTRY OR REGION	CONCEPT OF CEREBRAL DEATH ACCEPTED		CRITERIA OF CEREBRAL DEATH
	Medically	Legally	
Argentina	Yes	Yes	Yes
Australia	Yes	No	Yes
Bolivia	Yes	No	Local
Brazil	Yes	No	Local
Canada	Yes	No	Yes
Chile	Yes	No	Local
Colombia	Yes	No	Local
Czechoslovakia	Yes	Yes	National
Egypt	No	No	No
France	Yes	No	Local
India	No	No	Local
Israel	Yes	No	Local
Italy	No	Yes	Yes
Japan	No	No	Local
Korea	Yes	No	Local
Mexico	Yes	Yes	Yes
Netherlands	Yes	No	National
Pan African	No	No	No
Peru	Yes	No	Local
Scandinavia	No(?)	No	Yes
Spain	No	No	Local
Switzerland	Yes	No	National
Turkey	Yes	No	Local
United Kingdom	Yes	No	National
Uruguay	Yes	No	Local
U.S.A	Yes	20 States	No
Venezuela	Yes	No	Local
Totals	Yes, 20; No, 7	Yes, 5; No, 22	Local 14 National 10 None 3

* From Walker, A. E. Cerebral Death. Dallas, Texas, Professional Information Library, 1977. Reprinted by permission.

mentation for making the various studies is available. However, the question of whether to continue costly and needless support of a hopelessly ill patient arises in smaller and less well-equipped hospitals also. Indeed, the need for the decision to be made for economic and humanitarian reasons involving only the patient and his family will arise much more often than it will for organ transplantation.

CHARACTERISTICS OF BRAIN DEATH

Physical Signs

A patient with brain death will have no respirations but may have a pulse and blood pressure. The blood pressure may be normal or unstable, and pressor agents may be required to maintain it. The pulse rate shows no distinctive pattern with cerebral death. If the blood pressure is unstable, shock should be ruled out. The use of pressor agents may cause characteristic arrhythmias, but these are related to cardiac irritability and not to cerebral responsiveness.

Cranial Nerves

A variety of reflex arcs subserved by the cranial nerves or cephalic reflexes are available to evaluate the viability and function of the brain stem. All these reflexes must be absent for the criterion of absence of cephalic reflexes to be met.

The pupillary light reflex is produced by flashing a bright light into one eye and then the other. Subsequent constriction of the pupil that is stimulated constitutes the direct response, and constriction of the other pupil, the consensual response. The light should be directed into the eye for several seconds while the pupillary response is observed closely. Rapid flashing of the light may cause slow or minimal responses of the pupil to be missed. Small pupillary size may make evaluation of the light reflex difficult. With pontine lesions that interrupt the brain stem sympathetic pathways the pupils will be small. In this situation, reactivity is best assessed by using a magnifying glass or the plus 20 lens on the ophthalmoscope. In as-

sessing this reflex, one must remember that damage to the optic nerves, chiasm, or radiation, and a variety of pharmacological agents, can result in nonreactivity of the pupils.

The corneal reflex is mediated through the pons with the trigeminal nerve as the afferent arc and the facial nerve as the efferent arc. It is elicited by drawing a wisp of cotton over the cornea and noting a blink response of the eye. Bell's phenomenon, the bilaterally responsive eyelid closure and upward deviation of the eyes, will be absent also when the corneal reflex is absent. Corneal hyposensitivity due to drying, edema, or corneal anesthetics reduces the validity of the test.

The oculoccephalic reflexes are tested by the doll's head maneuver. The head is briskly turned from side to side to evaluate horizontal eye movements, and the neck is flexed and extended to test vertical eye movements.³⁴ The normal response, turning of the eyes in the direction opposite to that in which the head is moved, reflects function of the vestibular mechanisms. Absence of vertical and horizontal movements implies dysfunction of the midbrain pretectal area and the pontine conjugate gaze centers respectively. In patients who have suffered trauma, the stability of the cervical spine should be assessed before this maneuver is attempted. The test should be done in conjunction with that of the oculovestibular reflex, since similar pathways are being evaluated. The latter test should not be performed until it has been established that the tympanic membrane is intact. Then 200 ml of ice water may be introduced slowly into the external auditory canal until nystagmus or ocular deviation occurs. An induced conduction current is set up in the labyrinthine endolymph of the lateral semicircular canal that alters the balance of the paired vestibular systems and produces tonic conjugate eye deviation toward the same side with cold stimuli or toward the opposite side with warm stimuli.

The pharyngeal, or gag, reflex is a contraction of the constrictor muscle elicited when the posterior part of the pharynx is touched. It may be unreliable in the apneic patient supported by a respirator owing to the presence of an endotracheal tube. The same may be said for the swallow and cough reflexes.

Sensory and Motor Responses

There are no cerebrally mediated sensory reactions or motor movements in patients with brain death. Decorticate or decerebrate movements may be present as long as lower parts of the brain survive, but usually these will be lost by the time that apnea occurs. If not, they will disappear soon thereafter. Muscle tone may be present in the extremities; in the majority of cases, however, it is absent.

Spinal Reflexes

Movements induced by noxious stimuli applied to the extremities after brain death are due to spinal reflexes. In the lower extremity the response is usually a partial flexor reflex, although other spinal reflexes such as the crossed extensor may be present. In the upper extremities, extensor responses such as those characterizing a high spinal cord transection may be induced.

The spinal reflexes manifested by tendon jerks of the arms and legs are poor indicators of the state of the brain. Since the spinal cord may still be viable in the presence of cerebral death, it is not surprising that the tendon reflexes may persist. Pathological reflexes such as the extensor plantar re-

sponse will be seen more often than the superficial tendon reflexes.

Laboratory Tests

Unfortunately, the clinical findings are not invariably reliable in making the diagnosis of brain death. Indeed, in the 503 patients who had coma and apnea for 15 minutes and were admitted to the Collaborative Study on Cerebral Death, 41 (9 per cent) survived for longer than three months.³ As would be expected, many of them had various forms of intoxication. A number of laboratory and pathological correlates may be used to corroborate the diagnosis of brain death.

Cerebral Blood Flow

To perform normally, the brain requires a constant supply of oxygen and glucose. Delivery of these substances requires approximately 15 per cent of the cardiac output.²⁶ Interruption of this blood flow in the human for only 5 to 10 minutes will begin to cause brain damage, and an interruption of 20 to 30 minutes will cause irreversible damage. As a result, the demonstration of an absence of cerebral circulation can be used to diagnose cerebral death.

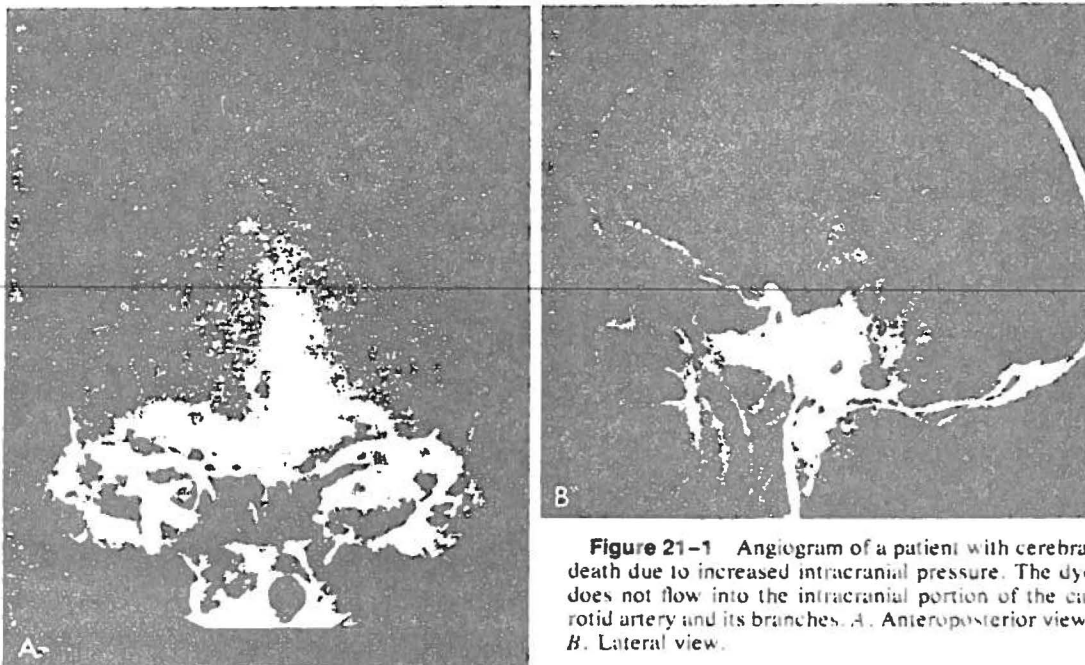


Figure 21-1 Angiogram of a patient with cerebral death due to increased intracranial pressure. The dye does not flow into the intracranial portion of the carotid artery and its branches. *A*, Anteroposterior view. *B*, Lateral view.

Cerebral angiography was the earliest standard technique to assess the status of the cerebral circulation (Fig. 21-1). Mitchell and associates noted the absence of cerebral blood flow in patients with severe intracranial hypertension. The contrast material stopped at the internal carotid artery at the level of the carotid siphon while the external carotid artery and its branches filled normally. At autopsy, patency of carotid vessels was demonstrated, thus confirming that the lack of flow was due to increased intracranial pressure.⁵⁰ Greitz and co-workers used aortocranial and carotid angiography in 42 patients with brain death. In them, the contrast media stopped at one of several sites—in the neck close to the carotid bifurcation, in the intradural parasellar part of the internal carotid artery, or intracranially either just distal to the carotid siphon or in the bifurcation of the middle cerebral artery.³¹ Angiographic evidence of absence of blood flow is not a *sine qua non* for the diagnosis of cerebral death, however, because of rare instances in which a therapeutic measure such as ventricular puncture has been successful in relieving the increased intracranial pressure and restoring the cerebral blood flow.⁵⁶ Of course, if the elevated intracranial pressure cannot be relieved in a short time, it may be assumed that cerebral infarction and death have occurred.

A noninvasive technique for assessing the cerebral circulation is to inject an isotope such as 2 mc of 99m technetium pertechnetate into an antecubital vein and then to place radioisotope detectors over the head and over the femoral artery. Patients with normal cerebral blood flow show a relatively sharp rise and fall of radioactivity in both cephalic and femoral leads. Patients with hypoperfusion have a small gradual linear increase in activity over the head and normal activity over the femoral artery. This latter pattern occurred in all of Korein and associates' 80 patients who were comatose and apneic.⁴⁵ Goodman and co-workers studied more than 500 patients by isotope angiography with the scintillation camera. The cerebral arteries and venous sinuses were visualized in all patients except three who had brain death.³⁰

Another technique for evaluating the presence of a cerebral circulation is recording of the pulsatile midline echo of the brain. These recordings are made by using

an ultrasonic reflectoscope or echoencephalograph coupled with a device that gives additional processing of the scope's electrical signal so as to show the pulsations of the midline of the brain with each heart beat. This system was tested in 46 patients by Uematsu and colleagues. Three of the patients were in stupor, fifteen in coma, and twenty-eight suspected of having cerebral death on the basis of unresponsiveness, apnea, and electrocerebral silence. One of those who were thought to have brain death and yet had a midline echo pulsation had had a large decompressive craniotomy with removal of the bone flap. It was thought that the persistent midline pulsation might have been transmitted from the external carotid pulsation to the intracranial cavity because of the large decompressive cranial defect.⁶⁹ The cause of the midline echopulsations in the other case with presumed brain death is less clear. Perhaps the function of the cortex and electrical activity were lost prior to the total cessation of cerebral flow. In any event, these findings lend credence to the *absence* of the pulsatile midline echo as clear evidence of lack of cerebral flow. Further, when this finding is present for 30 minutes or more, the diagnosis of brain death can be made with confidence.

Electrocardiogram

Electrocardiographic findings may be normal in patients with brain death, but ST-T changes usually are seen in the terminal stages. At necropsy, the heart often has minimal abnormalities such as subendocardial and subepicardial hemorrhages of a nonspecific nature. These changes may be related to anoxia.²⁵

CT Scan

CT scans of patients with brain death show no definitive characteristics in spite of the arrest of intracranial circulation as shown by the angiogram.⁵⁸ It appears that CT scanning cannot be used to diagnose cerebral death.

Biochemical Changes

As the cerebral function fails in brain death a variety of biochemical changes occur in the brain. It loses the ability to utilize nutrient sources of glucose and oxygen

to produce energy through production of high-energy phosphate bonds. Thus, the lack of oxygen consumption is manifest by the diminution in cerebral blood flow and the decrease in the arteriovenous difference of oxygen content across the brain.⁶¹ As less oxygen is used, anaerobic glycolysis begins, and it produces lactic acid. With loss of the brain's normal metabolic integrity there is a depletion of phosphocreatinine, adenosine triphosphate, and adenosine diphosphate in the neurons. They cease to function and become progressively edematous, and the oxidized respiratory enzymes are destroyed.

A variety of tests is available to assess the cerebral metabolic parameters, but they are too complex for routine clinical use.

Electroencephalogram

The electroencephalogram is a valuable aid in evaluating patients who may have brain death. Vestiges of cerebral cortical function may be detected with this test even though the patient is profoundly comatose as judged by the conventional neurological examination. The reliability of the electroencephalogram is shown by the study of the American Electroencephalographic Society's ad hoc committee on electroencephalographic criteria for the determination of cerebral death. They reviewed 2650 cases of coma with presumably isoelectric recordings.² Only three patients whose records satisfied the committee's criteria showed any recovery of cerebral function. These three had suffered from massive overdoses of nervous system depressants, two from barbiturates and one from meprobamate. The reported "isoelectric" records of these patients either were, on review, low-voltage records or had been made with techniques inadequate to bring out low-voltage activities.

The distinction should be made between a flat electroencephalogram, an isoelectric electroencephalogram, and electrocerebral silence. The flat electroencephalogram is one that shows no spontaneous activity of higher voltage than 20 μ v.¹ The majority of these studies consist of irregular bursts of activity of varying frequency that merge with each other and do not show any constant frequency even during hyperventilation. In rare instances there is almost no spontaneous activity. The flat study is

therefore fundamentally one with low voltage and fluctuating frequency. It may be seen in as many as 10 to 13 per cent of healthy persons.³⁶⁻⁴⁶ Further, it is thought that conditions such as advanced age, fatigue, drowsiness, and sleep, and anesthesia increase the number of flat studies.^{6,23,29} Diseases such as encephalitis may cause a flat electroencephalogram. Bental and Leibowitz reported the case of a 44-year-old woman with encephalitis who had a flat electroencephalogram for 28 days.⁹ Although in their report they speak of her as having "complete absence of electrical activity," it is apparent from review of their publications that she merely had a flat recording and not one that meets the requirements of electrocerebral silence. This patient made a complete clinical recovery, and her electroencephalogram returned to normal.

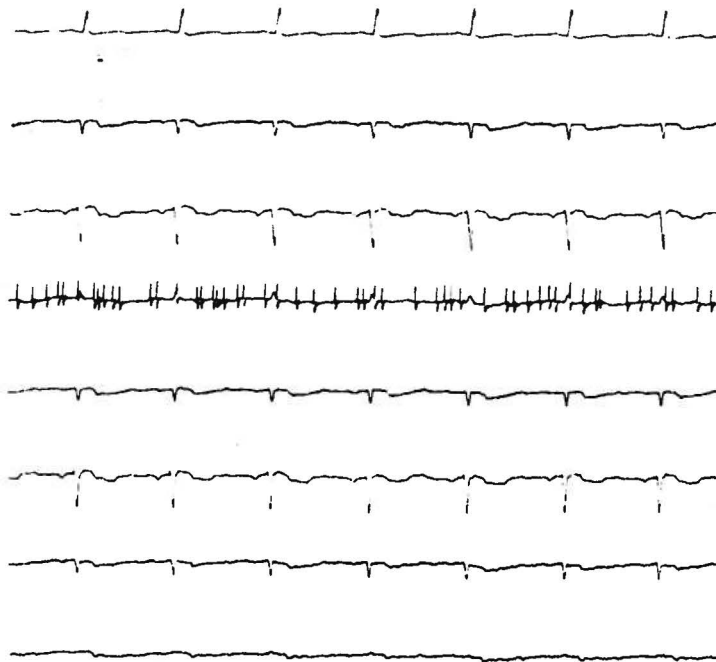
To avoid confusion, it is recommended that nonphysiological terms such as "isoelectric" or "linear" should not be used to describe the recordings obtained during brain death. The appropriate term is "electrocerebral silence." Electroencephalographic silence, or electrocerebral inactivity, is defined as

... no electrocerebral activity over 2 μ v when recording from scalp or referential electrode pairs 10 or more centimeters apart with interelectrode resistances under 10,000 ohms or (impedances under 6000 ohms) over 100 ohms.²

The reason for using the term "electrocerebral silence" is that the cardiac action and artifacts from various causes produce electroencephalographic changes (Fig. 21-2). As a result, the recordings are not truly flat or isoelectric.

Once electrocerebral silence has been noted, there is a high degree of correlation with ultimate death; these findings have, however, been present for more than 24 hours and yet some patients recover.^{12,32,37,41} Also, a few patients may be deeply comatose, have electrocortical silence, and yet have functioning brain stems.^{6,16} In fact, an elderly woman has been reported to have electrocerebral silence and yet to breathe spontaneously.⁷¹

These reports suggest that although the electroencephalogram is a valuable aid in diagnosing cerebral death, it has to be used in the context of the entire clinical problem or situation and cannot be used as a single



The montage is as follows:

Channel	Electrodes
1	F ₁₁ - A ₂
2	C ₁ - A ₂
3	O ₁ - A ₂
4	F ₁₂ - A ₁
5	C ₁ - A ₁
6	O ₂ - A ₁
7	T ₁ - A ₂
8	T ₄ - A ₁

Calibration: Major time line, 1.0 seconds; sensitivity, 1 μ v per millimeter.

Figure 21-2 Electroencephalogram of a 34-year-old man with cerebral death. All waveform changes are related to cardiac or muscle activity. Channel 4 shows muscle artifacts. There is no electrical activity of cerebral origin that is greater than 2 μ v. These electroencephalographic findings would confirm the clinical evidence of cerebral death. (Courtesy of Dr. A. Gabor.)

test for it. As Bennett has stated, "in the state of brain death, the EEG is always silent; however ECS does not always mean death."⁷

In order to standardize recordings and to minimize errors in determining electrocerebral silence, the American Electroencephalographic Society has set forth the following recommendations for use in making the recordings.

1. Use of a minimum of eight scalp electrodes and ear lobe reference electrodes.
2. An interelectrode impedance under 10,000 ohms but over 100 ohms.
3. Test of integrity of recording system by artifact potential.
4. Use of interelectrode distances of at least 10 centimeters.
5. Sensitivity increase from 7 μ v per millimeter to 2 μ v per millimeter during most of the recording with inclusion of appropriate calibrations.
6. Use of time constants of 0.3 to 0.4 second during part of the recording.
7. Use of monitoring devices such as the electrocardiogram and others as needed to detect artifacts emanating from the patient or induced by the surroundings.
8. Use of tests for electroencephalographic reactivity to intense stimuli such as

pain (e.g., pinch), loud sound, and (optionally) strong light (stroboscopic if available).

9. Recording time of at least 30 minutes.

10. Recordings to be made only by qualified technologists.

11. A repeat electroencephalogram if doubt exists about electrocerebral silence.

12. Telephone transmission of the electroencephalogram not to be used for determination of electrocerebral silence.²

Before the electroencephalogram is performed, the patient should be in a stable state, since shock or hypothermia may depress the amplitude of the recording. Also, it is essential to insure that drugs are not present in sufficient quantities to depress the recording. Drugs that are often associated with electrocerebral silence include barbiturates, methaqualone, diazepam, mecloqualone, meprobamate, and trichloroethylene. Drugs that can be ingested in toxic quantities and not produce electrocerebral silence as a primary effect include phenothiazides, atropine sulfate, tricyclic antidepressants, nitrazepam, salicylates,

* See references 11, 12, 30, 31, 35, 39, 44, 45, 51, 60, 63, 69, 73.

heroin, insecticides, glutethimide, and amanita phalloides (mushroom poisoning). If sedative or intoxicating drugs are present the diagnosis of cerebral death must be delayed until their concentration is below toxic levels.

Evoked Potentials

Another electrophysiological means of evaluating brain function involves the measurement of auditory brain stem responses. The test is an objective method of measuring sensory pathways transversing the brain stem. Starr found that these responses were either absent or markedly attenuated in 27 patients who met the clinical criteria of brain death. In addition, in patients who progressed from mere coma to brain death, a decrease in amplitude and a prolongation of the latency of the later components of the characteristic evoked waveform were noted.⁶⁴ The technique can be used as a corroborative test along with the electroencephalogram, especially in evaluation of the brain stem. The American Electroencephalographic Society Ad Hoc Committee on Cerebral Death recommended that an effort be made to evoke potentials by auditory, visual, and tactile

stimulation when a patient suspected of having cerebral death is being evaluated.⁶³

Atropine Tests

Normally the cardiac activities are under the antagonistic influences of the intracranial parasympathetic system (vagal dorsal nucleus) and the extracranial sympathetic system. In brain stem death the cardiac activities are influenced only by the sympathetic system without regulation from the intracranial centers. As a result the intravenous injection of 2 mg of atropine will not cause an acceleration in the cardiac rate. In a study of 42 successive patients who had cerebral death there were no exceptions to these findings.⁵⁷

Combined Testing

Quaknine reported on 13 types of studies that may be performed antemortem to confirm cerebral death. Forty-two patients were included in the series, and various numbers of patients were given each type of test (Table 21-2).⁵⁷ From a study of his findings, it is apparent that cerebral death can be confirmed by a consistent lack of cerebral and brain stem function, absence

TABLE 21-2 TESTS PERFORMED IN 42 PATIENTS IN BRAIN DEATH*

TEST	NO. OF CASES	RESULTS	REMARKS
Electroencephalography	32	Flat tracing even after amplification and stimulation	13 cases under scope only
Atropine test	42	No tachycardia after intravenous injection of atropine (2 mg)	32 cases under ECG
Caloric test	42	No eye movements	With ice water or ethyl chloride into the external auditory meatuses
Electronystagmography	22	Flat tracing	With ice water or ethyl chloride into the external auditory meatuses
Echoencephalography	26	No echopulsations in the scope	Demonstrated in 10 cases by photo with three different exposures
Carotid and vertebral angiographies	26	Circulatory arrest at the base of the skull	Injection under pressure in five cases
Intracranial pressure	7	Very high (>100 mm Hg)	Measured by intraventricular catheter
Brain temperature	6	Brain T° always less than rectal T°	Even in cases of hypothermia (ex: 29° < 32°C)
Cerebral blood flow	8	No significant flow: <10 ml min ⁻¹ 100 gm ⁻¹ of brain	Xenon, two cases
Cerebral oxygen consumption	4	<1.5 ml of O ₂ min ⁻¹ 100 ml ⁻¹ of blood	Hippuran: six cases
Brain scanning	12	"Cold brain area" and no appearance of the sup. long sinus in AP projection	Blood taken from carotid bifurcation and jugular bulb
Gamma camera	8	"Cold brain area" and no appearance of the sup. long sinus in AP projection	Intravenous technetium
Intrathecal injection of radioiodinated serum albumin	6	No cerebrospinal fluid flow	Even after 48 hours
Brain autopsy	28	From cerebral edema to complete lysis of brain	Corresponding to brain death duration (1-7 days)

* From Quaknine, G. E. Bedside procedures in the diagnosis of brain death. *Resuscitation*, 4: 159-177, 1975. Reprinted by permission.

of cerebral blood flow, brain temperature markedly lower than body temperature, or increased intracranial pressure of a degree that would preclude cerebral blood flow. The test of function of the brain can be accomplished by electroencephalography, the atropine test of heart rate, the caloric test, or electronystagmography. The status of the cerebral circulation may be determined by arteriography or isotope studies. Determination of the brain temperature or the intracranial pressure requires the placement of intracranial probes of an appropriate nature.

Autopsy

At autopsy after brain death, 90 per cent of the brains appear to be abnormal by gross examination.⁷³ If the patient has required a respirator for more than 24 hours, over 60 per cent will have cortical abnormalities including pericellular edema, necrosis, neuronal loss, hemorrhage, and infarction. About 40 per cent of the cases will have the characteristic findings of the "respirator brain." These findings are a soft brain that is difficult to remove from the calvarium, a gross appearance of generalized swelling, poor fixation, a congested cortex, and a macerated cerebellum of which fragments are found in the spinal canal. Microscopic findings included pyknosis of neuronal cytoplasm in some cells of all sections, little or no inflammation, scattered neuronal changes or loss, and glial, microglial, or vascular alterations at the site of the microscopic findings.

FORMAL CRITERIA OF BRAIN DEATH

Harvard Criteria

In 1968, the need for a better understanding of the concept of cerebral death and the need for obtaining organs for transplantation earlier than at death with cessation of heart beat led the faculty of the Harvard Medical School to appoint an ad hoc committee to study the matter.²² The goals of this committee were to help identify those patients who had brain death despite sustained heart function and to delete obsolete criteria for definition of death that could

lead to controversy and delay in obtaining organs for transplantation. Prior to the pioneering work of this committee, the concept of cerebral death was vague. A large portion of the medical community did not understand or accept the concept, and those who did use it were without legal sanction.

The ad hoc committee recommended that criteria be set up so that the issue of the time of death could be considered solely as a medical one. Further, they emphasized that the patient should be declared dead before the respirator was stopped rather than afterward, since in the latter situation, the physician would be withdrawing respiratory support from a patient who was, under the existing law, still alive. To make the diagnosis of cerebral death safely in a medical and legal milieu in 1968, the committee suggested four criteria to be met in patients in whom hyperthermia or central nervous system depressants such as barbiturates were absent. The criteria were: (1) Unreceptivity and unresponsivity with total unawareness to externally applied stimuli and inner need, with even the most intensely painful stimuli evoking no vocal response, withdrawal of the limb, or quickening of respirations. (2) No movement or breathing over a period of one hour. If the patient was receiving mechanical respiratory support, spontaneous breathing should be totally absent for three minutes after the respirator was removed. (3) The absence of all elicitable reflexes, the absence of postural activity (decerebrate or other), and the presence of fixed and dilated pupils that would not respond to a direct source of bright light. (4) A flat or isoelectric electroencephalogram with the machine run at standard gains of 10 μv per millimeter and 50 μv per 5 mm and at double the standard gain, which is 5 μv per millimeter or 25 μv per 5 mm. All these tests were to be repeated at least 24 hours later with no change. The committee regarded items 1, 2, and 3 as making the diagnosis, the confirmation being made with the fourth item, the electroencephalogram.²²

The so-called Harvard criteria were a notable advance, but probably were more strict and relied more heavily on the electroencephalogram than was necessary or justified in some cases. In particular, the requirement for re-evaluation in 24 hours often caused needless delays and damage to organs to be transplanted. Later criteria

were published by other groups that reduced the period of observation to 12 hours and noted that segmental spinal reflexes such as deep tendon reflexes and triple flexion responses might be present. Further it was noted that the electroencephalogram and cerebral angiography "may provide supportive data and diagnosis of brain death, but they are not essential."²¹

American Association of Neurological Surgeons Guidelines

In the last decade numerous organizations and institutions have set forth criteria for cerebral death based on known physiological principles and observations that were post hoc.^{5,13,19,24,39} Among them was the American Association of Neurological Surgeons, which issued the following guidelines for diagnosing cerebral death.

1. Cerebral unresponsivity.
2. Apnea.
3. Absence of cephalic reflexes including the pupillary, audio-ocular, and oculocephalic.
4. Dilated pupil (5.0 mm). In the event that the pupil is less than 5.0 mm, the possibility of a toxic factor is heightened, and determination of blood drug levels or studies of the cerebral circulation or both may be required to eliminate this possibility.
5. Electrocerebral silence. Findings meeting the American Electroencephalographic Society's criteria must be observed for a minimum recording period of 30 minutes at a time when the requisite clinical conditions have persisted for at least six hours. These findings should be re-examined and confirmed on a second occasion at least six hours later. (These criteria may be inapplicable to children under 5 years of age, since there are indications that the immature nervous system can survive significant periods of electrocerebral silence.)¹⁵

The arguments in favor of the American Association of Neurological Surgeons criteria are: (1) Since brain function is what is being evaluated, only cerebral reflexes are important. (2) The presence of a fixed but nondilated pupil increases the possibility of a toxic factor and therefore requires special consideration. (3) The time frame is shortened because it has been recognized that when the criteria have been met for even a few minutes brain survival is unlikely and

unreasonable measures may be required to maintain cardiovascular function for the 24 hours suggested by the Harvard ad hoc committee. (4) When any question arises about the validity of other findings the demonstration of complete cessation of intracranial circulation verifies brain death.

Evaluation of Criteria

To test the criteria of brain death in a prospective manner, the National Institute of Neurological and Communicative Disease and Stroke supported a collaborative study at nine medical centers distributed geographically throughout the United States.³ The study collected data on the clinical findings, the electroencephalograms, and the laboratory analyses for drugs of the patients as well as the neuropathological reports on the dead brains. The protocol required that every patient over 1 year of age admitted to the participating medical center hospital in a cerebrally unresponsive state and apneic for 15 minutes be admitted to the study regardless of the cause of these findings. To be considered in the group for a diagnosis of brain death, the prerequisites were absence of sedative drug intoxication, hypothermia, cardiovascular shock, or a remediable primary disorder, and the presence of cerebral unresponsiveness, apnea, and electrocerebral silence.

The combined study demonstrated the practical problems of applying such a protocol in the diagnosis of cerebral death. For instance, in assessing the presence of sedative drug intoxication, it was found that the history of drug ingestion was often unreliable, it was virtually impossible to obtain accurate analysis of toxic agents within a few hours, and it was difficult to evaluate the significance of minimal amounts of drugs in the blood. The determination of normothermia and the absence of cardiovascular shock was less of a problem. Insuring the absence of a remediable lesion often required detailed laboratory studies such as computed tomography or angiography. The average time for obtaining those studies was 7.4 hours. Determining the presence of cerebral unresponsivity was straightforward except in 9 per cent of the cases; in these confusion was caused by spinal reflex movements. Although apnea is easily recognized at the bedside, its deter-

mination in this study was imprecise because of the need to maintain artificial respirations. After the diagnosis of brain death had been established by other criteria, removal of the respirator "was rarely followed by any respiratory effort and never by sufficient chest movement to sustain life." Determination of electrocerebral silence was complicated by three factors: technical inadequacies, observer error (misinterpretation in the reading of the record), and the degree of validity of a single recording. There was a 3 per cent disagreement between the panel reviewing the studies and the original interpreter of the recording. Most of the disagreement concerned the confusion of artifact with biological activity. In only 1 per cent of the cases was there disagreement in which the original reader diagnosed electrical cortical silence and the review panel considered that biological activity was present. The report states:

Though on critical analysis some "flat records" may be considered by reviewers who know the complete history of the case as showing biological activity, such varied opinions regarding 1 to 3 per cent of the cases are inevitable at the present state of the art of electroencephalography.³

When all drug-induced comas were excluded from the study, no patient in this series recovered after having a 30-minute period of electrical cortical silence.

The cephalic reflexes—pupillary, corneal, oculoauditory (blink to a clap), oculocephalic (doll's eye), oculovestibular, cilio-spinal, snout, cough, pharyngeal (gag), and swallowing—were noted to have varying sensitivity as indicators of brain stem dysfunction. The addition of these reflexes to the basic factors to be considered did not improve the accuracy of the diagnosis of brain death.

Although dilated and fixed pupils have commonly been thought to be present in brain death, they occurred in less than half the patients in this series. Of the 187 patients meeting the three basic criteria for brain death, 128 had dilated, 44 had small, and 15 had unequal pupils. Two patients with drug intoxication had small pupils.

Almost 70 per cent of patients had absence of muscle tone in either arms or legs, and 60 per cent lacked it in both. Another 10 per cent lost their muscle tone sometime before cardiac arrest. In this same group,

abnormal posturing was noted in 14 per cent of cases at the time of the initial examination, but in only half the number at the time of final examination before cardiac arrest.

The spinal reflexes as manifested by tendon jerks with the arms and legs are poor indicators of the state of the brain. Of the 187 patients meeting the basic criteria for brain death, 101 had no reflexes and 71 had active reflexes; the remaining 15 were not examined for their reflexes.

The directors of the combined study concluded that the minimal criteria for diagnosis of cerebral death should be that (1) all appropriate diagnostic and therapeutic procedures have been performed; and (2) the patient is in coma with cerebral unresponsivity and apnea; has dilated pupils, absence of cephalic reflexes, and electrocerebral silence; and these findings have been present for a period of 30 minutes at least six hours after the onset of coma and apnea. If an early decision about cerebral death is desired and particularly if any of the critical findings are not definitive, it was suggested, a confirmatory test to insure the absence of cerebral blood flow should be made.

Ideal Criteria

The ideal criteria for determination of cerebral death would give unequivocal and reliable results that could be accepted without question by the medical and lay public. Further, they would be simple and clear so that any physician could apply them by merely referring to the list of requirements necessary for making the diagnosis. Unfortunately, criteria that cover all circumstances in the most ideal and expeditious manner do not exist. As a result, the diagnosis of cerebral death should be a medical decision based on the physician's judgment that is made after all factors have been considered. A strict protocol cannot encompass all circumstances that arise, and if one is imposed by institutional policy or legal requirements, needless delays will occur in obtaining organs to be transplanted and needless expenses will be incurred to render treatment that is useless. As a workable, practical, and safe approach to the problem, the authors of this chapter suggest the following factors be considered in making the diagnosis.

1. There should be *cerebral* unresponsivity and unreceptivity. There should be no evidence of a cerebral type of response to intensely painful stimulus, noise, or visual stimuli. Spinal cord or lower brain stem function may be present.

2. There should be no suspicion that the coma is due to depressant drugs. A careful drug history and chemical screening for drug levels is essential in all situations except those with a firm diagnosis of a major intracerebral lesion that is clearly capable of causing brain death.

3. Spontaneous respiration should have ceased. With the blood oxygen tension at normal or higher levels, trials of at first three and then five minutes without the respirator should not produce efforts of spontaneous breathing. To protect against hypoxia, 5 liters per minute of oxygen may be perfused through an intratracheal catheter. If facilities to measure oxygen tension are not present and no organs are to be donated, then the trial without the respirator should be 10 minutes. Since the carbon dioxide tension increases at the rate of approximately 3 mm of mercury per minute, the carbon dioxide build-up should be adequate to stimulate breathing.⁶⁰

4. The patient should have an untreatable brain lesion. This situation may be obvious within hours of a severe head injury, spontaneous intracerebral hemorrhage, or craniotomy. With cardiac arrest, hypoxia, or severe circulatory insufficiency with cerebral anoxia or cerebral embolism, longer periods of observation may be necessary.

5. Primary hypothermia and significant abnormalities of metabolic and endocrine factors should be excluded. It is acknowledged that marked abnormalities of these factors may develop during treatment of the patient over a prolonged time and should not delay the diagnosis of cerebral death if other appropriate factors are present. Whereas *primary* hypothermia should be ruled out, secondary hypothermia develops in a majority of patients with cerebral death. In these patients the temperature may be 96° F or lower.

6. Although a reliable diagnosis of brain death can be made on the basis of the clinical findings and course of events in most cases, additional confirmation may be desirable in other cases. In particular, if there is a question of homicide or other factors that may lead to legal questions the confir-

mation of brain death by laboratory tests may be particularly desirable. This confirmation can be obtained by several tests or combination of them. Absence of cerebral blood flow may be demonstrated by angiogram, isotope studies, or absence of midline echopulsation. Absence of cerebral blood flow and presumed cerebral infarction may be inferred from persistent intracranial pressure measurements sufficiently elevated over systemic blood pressure to preclude intracranial flow. Electroencephalogram silence on the electroencephalogram denotes lack of cerebral function. If suppressant drugs are absent, it is presumptive of cerebral death. Brain stem function and reflexes may or may not be present with electroencephalogram silence. If a known structural, untreatable brain lesion of the type that can produce cerebral death is not present, the electroencephalographic electrocortical silence should be confirmed by recordings 24 hours later.

DISCUSSION WITH SURVIVORS

Explaining the concept of brain death to the surviving family and friends requires patience and an understanding of their emotional distress. The question of organ transplantation may be raised by the family, but usually it has to come from the physician attending the patient. When appropriate, the physician should assume a positive role, informing the family of the opportunity to get healthy organs to benefit the victims of chronic disease. After effective communication is established with the family and the criteria for brain death have been met, the declaring of death and removal of the patient to the operating room for the transplantation procedure should cause no difficulty. By arranging this sequence of events, the physician may have aided the family to assuage their grief by helping them to know that the death of their loved one has, through organ transplantation, permitted another person to have an additional gift of life.

Regardless of whether or not organs are to be used for transplantation, the physician and ancillary members of the medical team such as the nurses and social workers must be knowledgeable about the course of events and be willing to explain them, as often as needed, to all members of the fam-

ily in a kind, calm, and sympathetic manner. Finally, the diagnosis of cerebral death and action based on it, such as discontinuing respiratory assistance, are medical matters. The survivors should not be burdened with the decision about when to stop the respirator. Of course, they should be informed of the plans in a clear, straightforward manner. In most instances they will agree with the suggested course of action. If they disagree, however, then further discussion is in order and the respiratory assistance should be continued until a full understanding is reached or cardiac arrest ensues to settle the matter.

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University of Pittsburgh

SCHOOL OF MEDICINE
Transplant Foundation

August 23, 1984

Senator Ollie Speraw, Chairman
Senate Select Committee on Anatomical Transplants
California Legislature
Room 4082, State Capitol
Sacramento, California 95814

Dear Senator Speraw:

I am sorry I must decline your generous offer to testify in person at your hearings on brain death to be held on September 18, 1984. I am, however, writing to you to try to answer some questions you identified in your recent letter to me that possibly could be helpful to you during these hearings.

As you stated, all states have adopted a Uniform Anatomical Gift Act and many states have also adopted a brain death law. I am enclosing for your information a copy of the law which was passed in Pennsylvania and signed into law late 1982. This law went into effect early 1983. The Pennsylvania law, like most laws passed, simply states that brain death is the legal death of the individual. No specific criteria is stated in the law, however, the law does state that accepted medical criteria must be utilized for the determination of brain death.

To specifically answer your questions, your first question was "What criteria should be accepted in determining brain death?" The criteria utilized for brain death normally not only differs from state-to-state, but from hospital-to-hospital. Although a majority of hospitals still follow the original Harvard criteria for the determination of brain death, many institutions have adopted new policies and procedures over the past 17 years. The basic concepts for the determination of brain death have remained the same, but time factors and confirmatory criteria have been changed. I am enclosing a copy of the Guidelines for the Determination of Death, which was a report to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Hopefully this will give you some starting point as to what criteria could possibly be utilized.

Your second question is, "Should brain death be accepted as legal death?" This question is very simply answered as in over 35 states today who have passed the brain death law, brain death is the legal death of the individual. I am enclosing a copy of the Pennsylvania Uniform Determination of Death Act, which states this in the body of the law.

Senator Ollie Speraw, Chairman
August 23, 1984
Page II

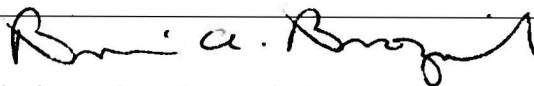
Question three: if we determine that brain death is, in fact, death even though we can maintain the body on support systems, should a local coroner have jurisdiction when such a body is transported into California under medical supervision for transplantation? This is a question I am sure that must be answered by your local coroners association. Our experience in Pennsylvania in transporting patients who have succumbed to brain death, but whose body functions are supported by mechanical means, have not fallen under the jurisdiction of the local coroner, since the body will be returned to the location where death was determined.

Question four: when brain death has been certified in another state, should we require legal reaffirmation by California doctors prior to harvesting any organs or tissues? Again, I can only speak from our experience at the University of Pittsburgh on this particular question. We do not require our physicians to reaffirm brain death, as long as the criteria utilized for the pronouncement of brain death is acceptable and close to the criteria we utilize ourselves.

Brain death, if documented with certainty, is the legal death of the individual in many states. I personally feel that if the death of an individual can be documented through brain death, it is wrong to maintain this person's vital organ functions artificially, unless the individual's family has agreed to organ donation. Many, many patients in this country are needlessly and hopelessly maintained for prolonged periods of time simply because laws do not exist stating that brain death is the legal death of that individual. This not only causes great anguish and prolonged suffering for that patient's family, but also wastes valuable hospital space and an enormous amount of funds that could be utilized for other lifesaving purposes.

I hope that this information is of some use to you and wish you well in your hearings.

Sincerely yours,



Brian A. Broznick
Organ Procurement Coordinator

BAB:PNK
Enclosures

No. 1982-323

AN ACT

SB 1092

Providing for determination of death.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the "Uniform Determination of Death Act."

Section 2. Uniformity of construction and application.

This act shall be applied and construed to effectuate its general purpose to make uniform the law with respect to the subject of this act among states enacting it.

Section 3. Determination of death.

Only an individual who has sustained either:

(1) irreversible cessation of circulatory and respiratory functions;

or

(2) irreversible cessation of all functions of the entire brain, including the brain stem;

is dead. A determination of death must be made in accordance with accepted medical standards.

Section 4. Effective date.

This act shall take effect in 60 days.

APPROVED—The 17th day of December, A. D. 1982.

DICK THORNBURGH

Guidelines for the Determination of Death

Report of the Medical Consultants on the Diagnosis of Death to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

The guidelines set forth in this report represent the views of the signatories as individuals; they do not necessarily reflect the policy of any institution or professional association with which any signatory is affiliated. Although the practice of individual signatories may vary slightly, signatories agree on the acceptability of these guidelines: Jesse Barber, MD; Don Becker, MD; Richard Behrman, MD, JD; Donald R. Bennett, MD; Richard Beresford, MD, JD; Reginald Bickford, MD; William A. Black, Jr, MD; Benjamin Boshes, MD, PhD; Philip Braunstein, MD; John Burroughs, MD, JD; Russell Butler, MD; John Caronna, MD; Shelley Chou, MD, PhD; Kemp Clark, MD; Ronald Cranford, MD; Michael Earnest, MD; Albert Ehle, MD; Jack M. Fein, MD; Sal Fiscina, MD, JD; Terrance G. Furlow, MD, JD; Eli Goldensohn, MD; Jack Grabow, MD; Phillip M. Green, MD; Ake Grenvik, MD; Charles E. Henry, PhD; John Hughes, MD, PhD, DM; Howard Kaufman, MD; Robert King, MD; Julius Korein, MD; Thomas W. Langfitt, MD; Cesare Lombroso, MD; Kevin M. McIntyre, MD, JD; Richard L. Masland, MD; Don Harper Mills, MD, JD; Gaetano Molinari, MD; Byron C. Pevehouse, MD; Lawrence H. Pitts, MD, A. Bernard Pleet, MD; Fred Plum, MD; Jerome Posner, MD; David Powner, MD; Richard Rovit, MD; Peter Safar, MD; Henry Schwartz, MD; Edward Schlesinger, MD; Roy Selby, MD; James Snyder, MD; Bruce F. Sorenson, MD; Cary Suter, MD; Barry Tharp, MD; Fernando Torres, MD; A. Earl Walker, MD; Arthur Ward, MD; Jack Whisnant, MD; Robert Wilkus, MD; and Harry Zimmerman, MD.

The preparation of this report was facilitated by the President's Commission but the guidelines have not been passed on by the Commission and are not intended as matters for governmental review or adoption.

tional Conference of Commissioners on Uniform State Laws, and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research have proposed the following model statute, intended for adoption in every jurisdiction:

UNIFORM DETERMINATION OF DEATH ACT

An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

This wording has also been endorsed by the American Academy of Neurology and the American Electroencephalographic Society.

The statute relies on the existence of "accepted medical standards" for determining that death has occurred. The medical profession, based on carefully conducted research and extensive clinical experience, has found that death can be determined reliably by either cardiopulmonary or neurological criteria. The tests used for determining cessation of brain functions have changed and will continue to do so with the advent of new research and technologies. The "Harvard criteria" (*JAMA* 1968;205:337-340) are widely accepted, but advances in recent years have led to the proposal of other criteria. As an aid to the implementation of the proposed uniform statute, we provide here one statement of currently accepted medical standards.

INTRODUCTION

The criteria that physicians use in

THE ADVENT of effective artificial cardiopulmonary support for severely brain-injured persons has created some confusion during the past several decades about the determination of death. Previously, loss of heart and lung functions was an easily observable and sufficient basis for diagnosing death, whether the initial failure occurred in the brain, the heart and lungs, or elsewhere in the body. Irre-

To recognize reliably that death has occurred, accurate criteria must be available for physicians' use. These now fall into two groups, to be applied depending on the clinical situation. When respiration and circulation have irreversibly ceased, there is no need to assess brain functions directly. When cardiopulmonary functions are artificially maintained, neurological criteria must be used to assess whether brain functions have ceased irreversibly.

More than half of the states now recognize, through statutes or judicial decisions, that death may be determined on the basis of irreversible cessation of all functions of the brain. Law in the remaining states has not yet departed from the older, common-law view that death has not occurred until "all vital functions" (whether or not artificially maintained) have ceased. The language of the statutes has not been uniform from state to state, and the diversity of proposed and enacted laws has created substantial confusion. Consequently, the American Bar Association, the American Medical Association, the Na-

For editorial comment see p 2194.

versible failure of either the heart and lungs or the brain precluded the continued functioning of the other. Now, however, circulation and respiration can be maintained by means of a mechanical respirator and other medical interventions, despite a loss of all brain functions. In these circumstances, we recognize as dead an individual whose loss of brain functions is complete and irreversible.

Reprint requests to Joanne Lynn, MD, Assistant Director for Medical Studies, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Suite 555, 2000 K St NW, Washington, DC 20006

determining that death has occurred should (1) eliminate errors in classifying a living individual as dead; (2) allow as few errors as possible in classifying a dead body as alive; (3) allow a determination to be made without unreasonable delay; (4) be adaptable to a variety of clinical situations; and (5) be explicit and accessible to verification.

Because it would be undesirable for any guidelines to be mandated by legislation or regulation or to be inflexibly established in case law, the proposed Uniform Determination of Death Act appropriately specifies only "accepted medical standards." Local, state, and national institutions and professional organizations are encouraged to examine and publish their practices.

The following guidelines represent a distillation of current practice in regard to the determination of death. Only the most commonly available and verified tests have been included. The time of death recorded on a death certificate is at present a matter of local practice and is not covered in this document.

These guidelines are advisory. Their successful use requires a competent and judicious physician, experienced in clinical examination and the relevant procedures. All periods of observation listed in these guidelines require the patient to be under the care of a physician. Considering the responsibility entailed in the determination of death, consultation is recommended when appropriate.

The outline of the criteria is set forth below in boldface letters. The lightface text that follows each heading explains its meaning. In addition, the two sets of criteria (cardiopulmonary and neurological) are followed by a presentation of the major complicating conditions: drug and metabolic intoxication, hypothermia, young age, and shock. It is of paramount importance that anyone referring to these guidelines be thoroughly familiar with the entire document, including explanatory notes and complicating conditions.

THE CRITERIA FOR DETERMINATION OF DEATH

An individual presenting the findings in *either* section A (cardiopulmonary) *or* section B (neurological) is

dead. In either section, a diagnosis of death requires that both cessation of functions, as set forth in subsection 1, and irreversibility, as set forth in subsection 2, be demonstrated.

A. An individual with irreversible cessation of circulatory and respiratory functions is dead.

1. Cessation is recognized by an appropriate clinical examination.

Clinical examination will disclose at least the absence of responsiveness, heartbeat, and respiratory effort. Medical circumstances may require the use of confirmatory tests, such as an ECG.

2. Irreversibility is recognized by persistent cessation of functions during an appropriate period of observation and/or trial of therapy.

In clinical situations where death is expected, where the course has been gradual, and where irregular agonal respiration or heartbeat finally ceases, the period of observation following the cessation may be only the few minutes required to complete the examination. Similarly, if resuscitation is not undertaken and ventricular fibrillation and standstill develop in a monitored patient, the required period of observation thereafter may be as short as a few minutes. When a possible death is unobserved, unexpected, or sudden, the examination may need to be more detailed and repeated over a longer period, while appropriate resuscitative effort is maintained as a test of cardiovascular responsiveness. Diagnosis in individuals who are first observed with rigor mortis or putrefaction may require only the observation period necessary to establish that fact.

B. An individual with irreversible cessation of all functions of the entire brain, including the brain stem, is dead. The "functions of the entire brain" that are relevant to the diagnosis are those that are clinically ascertainable. Where indicated, the clinical diagnosis is subject to confirmation by laboratory tests, as described in the following portions of the text. Consultation with a physician experienced in this diagnosis is advisable.

1. Cessation is recognized when evaluation discloses findings of a and b:

a. Cerebral functions are absent, and . . .

There must be deep coma, that is, cerebral unresponsiveness and unrespon-

siveness. Medical circumstances may require the use of confirmatory studies such as an EEG or blood-flow study.

b. brain stem functions are absent.

Reliable testing of brain stem reflexes requires a perceptive and experienced physician using adequate stimuli. Pupillary light, corneal, oculocephalic, oculovestibular, oropharyngeal, and respiratory (apnea) reflexes should be tested. When these reflexes cannot be adequately assessed, confirmatory tests are recommended.

Adequate testing for apnea is very important. An accepted method is ventilation with pure oxygen or a oxygen and carbon dioxide mixture for ten minutes before withdrawal of the ventilator, followed by passive flow of oxygen. (This procedure allows P_{aCO_2} to rise without hazardous hypoxia.) Hypercarbia adequately stimulates respiratory effort within 30 seconds when P_{aCO_2} is greater than 60 mm Hg. A ten-minute period of apnea is usually sufficient to attain this level of hypercarbia. Testing of arterial blood gases can be used to confirm this level. Spontaneous breathing efforts indicate that part of the brain stem is functioning.

Peripheral nervous system activity and spinal cord reflexes may persist after death. True decerebrate or decorticate posturing or seizures are inconsistent with the diagnosis of death.

2. Irreversibility is recognized when evaluation discloses findings of a and c:

a. The cause of coma is established and is sufficient to account for the loss of brain functions, and . . .

Most difficulties with the determination of death on the basis of neurological criteria have resulted from inadequate attention to this basic diagnostic prerequisite. In addition to a careful clinical examination and investigation of history, relevant knowledge of causation may be acquired by computed tomographic scan, measurement of core temperature, drug screening, EEG, angiography, or other procedures.

b. the possibility of recovery of brain functions is excluded, and . . .

The most important reversible conditions are sedation, hypothermia, neuromuscular blockade, and shock

In the unusual circumstance where a sufficient cause cannot be established, irreversibility can be reliably inferred only after extensive evaluation for drug intoxication, extended observation, and other testing. A determination that blood flow to the brain is absent can be used to demonstrate a sufficient and irreversible condition.

c. the cessation of all brain functions persists for an appropriate period of observation and/or trial of therapy.

Even when coma is known to have started at an earlier time, the absence of all brain functions must be established by an experienced physician at the initiation of the observation period. The duration of observation periods is a matter of clinical judgment, and some physicians recommend shorter or longer periods than those given here.

Except for patients with drug intoxication, hypothermia, young age, or shock, medical centers with substantial experience in diagnosing death neurologically report no cases of brain functions returning following a six-hour cessation, documented by clinical examination and confirmatory EEG. In the absence of confirmatory tests, a period of observation of at least 12 hours is recommended when an irreversible condition is well established. For anoxic brain damage where the extent of damage is more difficult to ascertain, observation for 24 hours is generally desirable. In anoxic injury, the observation period may be reduced if a test shows cessation of cerebral blood flow or if an EEG shows electrocerebral silence in an adult patient without drug intoxication, hypothermia, or shock.

Confirmation of clinical findings by EEG is desirable when objective documentation is needed to substantiate the clinical findings. Electrocerebral silence verifies irreversible loss of cortical functions, except in patients with drug intoxication or hypothermia. (Important technical details are provided in "Minimal Technical Standards for EEG Recording in Suspected Cerebral Death" [*Guidelines in EEG 1980*, Atlanta, American Electroencephalographic Society, 1980, section 4, pp 19-24].) When joined with the clinical findings of absent brain stem functions, electrocerebral silence confirms the diagnosis.

Complete cessation of circulation to the normothermic adult brain for more than ten minutes is incompatible with survival of brain tissue. Documentation of this circulatory failure is therefore evidence of death of the entire brain. Four-vessel intracranial angiography is definitive for diagnosing cessation of circulation to the entire brain (both cerebrum and posterior fossa) but entails substantial practical difficulties and risks. Tests are available that assess circulation only in the cerebral hemispheres, namely radioisotope bolus cerebral angiography and gamma camera imaging with radioisotope cerebral angiography. Without complicating conditions, absent cerebral blood flow as measured by these tests, in conjunction with the clinical determination of cessation of all brain functions for at least six hours, is diagnostic of death.

COMPLICATING CONDITIONS

A. Drug and Metabolic Intoxication.—Drug intoxication is the most serious problem in the determination of death, especially when multiple drugs are used. Cessation of brain functions caused by the sedative and anesthetic drugs, such as barbiturates, benzodiazepines, meprobamate, methaqualone, and trichloroethylene, may be completely reversible even though they produce clinical cessation of brain functions and electrocerebral silence. In cases where there is any likelihood of sedative presence, toxicology screening for all likely drugs is required. If exogenous intoxication is found, death may not be declared until the intoxicant is metabolized or intracranial circulation is tested and found to have ceased.

Total paralysis may cause unresponsiveness, areflexia, and apnea that closely simulates death. Exposure to drugs such as neuromuscular blocking agents or aminoglycoside antibiotics, and diseases like myasthenia gravis are usually apparent by careful review of the history. Prolonged paralysis after use of succinylcholine chloride and related drugs requires evaluation for pseudocholinesterase deficiency. If there is any question, low-dose atropine stimulation, electromyogram, peripheral nerve stimulation, EEG, tests of intracranial circulation, or extended

observation, as indicated, will make the diagnosis clear.

In drug-induced coma, EEG activity may return or persist while the patient remains unresponsive, and therefore the EEG may be an important evaluation along with extended observation. If the EEG shows electrocerebral silence, short latency auditory or somatosensory-evoked potentials may be used to test brain stem functions, since these potentials are unlikely to be affected by drugs.

Some severe illnesses (eg, hepatic encephalopathy, hyperosmolar coma, and preterminal uremia) can cause deep coma. Before irreversible cessation of brain functions can be determined, metabolic abnormalities should be considered and, if possible, corrected. Confirmatory tests of circulation or EEG may be necessary.

B. Hypothermia.—Criteria for reliable recognition of death are not available in the presence of hypothermia (below 32.2 °C core temperature). The variables of cerebral circulation in hypothermic patients are not sufficiently well studied to know whether tests of absent or diminished circulation are confirmatory. Hypothermia can mimic brain death by ordinary clinical criteria and can protect against neurological damage due to hypoxia. Further complications arise since hypothermia also usually precedes and follows death. If these complicating factors make it unclear whether an individual is alive, the only available measure to resolve the issue is to restore normothermia. Hypothermia is not a common cause of difficulty in the determination of death.

C. Children.—The brains of infants and young children have increased resistance to damage and may recover substantial functions even after exhibiting unresponsiveness on neurological examination for longer periods compared with adults. Physicians should be particularly cautious in applying neurological criteria to determine death in children younger than 5 years.

D. Shock.—Physicians should also be particularly cautious in applying neurological criteria to determine death in patients in shock because the reduction in cerebral circulation can render clinical examination and laboratory tests unreliable.

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SAN FRANCISCO, CALIFORNIA 94143

September 14, 1984

Ollie Speraw, Chairman
Senate Select Committee on Anatomical
Transplants
Room 4082, State Capitol
Sacramento, CA 95814

Dear Senator Speraw:

I received a copy of your letter and news release concerning Tuesday's hearing on brain death and organ donation from Joseph Spinelli, Director of the UCSF Animal Care Facility. Frankly, I am quite disturbed that you find the California Determination of Death Act "vague and ill-defined" and a potential source of "error and confusion."

The current statute of the California Health and Safety Code (7180) reads as follows:

"An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards...."

This phrasing is identical to the uniform statute proposed by the President's Commission for the Study of Ethical Problems in Medicine, the American Bar Association, the American Medical Association and the National Conference of Commissioners on Uniform State Laws.

The document of the President's Commission entitled Defining Death explains at length why this definition is adequate from an ethical and legal point of view. Therefore, no further amendment should be undertaken at this time. As a member of the President's Commission, I recommend this document to you. You may obtain it from the U.S. Government Printing Office, Library of Congress #81-600150.

Sincerely,

Albert R. Jonsen, Ph.D.
Professor of Ethics in Medicine
Chief, Division of Medical Ethics

cc: Oscar Salvatierra, M.D.
Lawrence Pitts, M.D.
Franklin Jacobson
Susan Hopper, RN, MSN
Joseph Spinelli, DVM
George Wilson, M.D.



STANFORD UNIVERSITY MEDICAL CENTER

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THOMAS A. RAFFIN, M.D.
Assistant Professor of Medicine (Respiratory)
Assistant Chief of Medicine
Medical Director, Respiratory Therapy
Room C356 • (415) 497-6381

September 13, 1984

Senator Ollie Speraw
Chairman, Senate Select Committee
on Anatomical Transplants
California Legislature
Room 4082
State Capitol
Sacramento, CA. 95814

Dear Honorable Senator Speraw:

Dr. Lewis Wexler referred you to me concerning the question when does brain death actually and legally occur? I have included for your information one of the most important references in the medical literature and it is entitled **GUIDELINES FOR THE DETERMINATION OF DEATH: REPORT OF THE MEDICAL CONSULTANTS ON THE DIAGNOSIS OF DEATH TO THE PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH.** This outstanding document reflects my opinions and is referenced frequently when discussing this issue during the practice of medicine.

To briefly summarize: 1) The criteria in this article should be used to determine brain death; 2) Brain death is legal death; 3) If a brain dead individual is transported into the State of California for any reason (for example, for consideration of use of one of his organs in a transplantation operation) no governmental or judicial official should have any jurisdiction over the body unless a crime has been committed. In other words, a local coroner should absolutely have no jurisdiction when such a body is transported into California. The physicians taking care of the patient should supervise the proceedings. 4) When brain death has been certified in another state and a patient is being transported into California, then clearly the California physician must evaluate the patient and make sure the diagnosis is correct. No legal reaffirmation involving any governmental or judicial body should be involved. ~~Again, this is a straight-forward and normal activity for a physician and bureaucratic meddling can only serve to complicate the process, delay it, and possibly place a potential transplant recipient's life into jeopardy.~~ If a governmental or judicial official believes a crime is being committed, then action should be taken.

Senator Ollie Speraw
September 13, 1984
Page 2

I hope I have been of assistance to you. If you have any further questions please don't hesitate to get in touch with me. With warm regards.

Sincerely,

A handwritten signature in cursive script that reads "Tom Raffin".

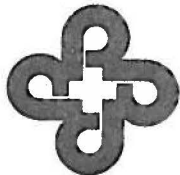
Thomas A. Raffin, M.D.
Assistant Chief of Medicine

TAR/kls

Enc.

cc: Lewis Wexler, M.D.

Pacific Medical Center



11 September 1984

Senator Ollie Speraw
Chairman
Senate Select Committee on
Anatomical Transplants
Room 4082
State Capitol
Sacramento, California 95814

Dear Senator Speraw:

Mr. Tom Harlan, our associate administrator at Pacific Medical Center in San Francisco, has forwarded to me a copy of your letter to him for comment.

I am a clinical neurologist and the chairman of the department at Pacific Medical Center. The concept of brain death is, of course, something I deal with on a constant basis and one with which I am concerned as far as legislation goes.

At present, I think most neurologists are quite happy with the California law on brain death. It does not set criteria and this is highly desirable. In fact, the law has been praised in medical journals for this very reason. The criteria for the pronouncement of brain death have evolved over a period of years. To some degree they will probably still evolve. It would therefore not be desirable to lock into law criteria from which we would then have to deviate as capabilities to accurately recognize brain death change.

As an example, the Harvard criteria of 1968 were too rigid and it was soon recognized that they could be liberalized. I think in essence the present law is quite satisfactory and need not be changed.

When brain death is pronounced, I think like any other pronouncement of death, it can be accepted as legal death.

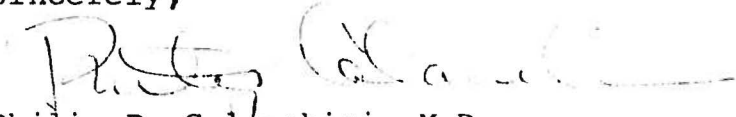
I can't really comment on when a local coroner should have jurisdiction in a body that is transported over the state line. However, if brain death has been certified in another state by competent physicians, I think that this should be acceptable to the physician who is harvesting the kidneys. What they do need,

Senator Ollie Speraw
9/11/84
Page 2

however, is a copy of the doctor's note which allowed him to conclude that brain death was present. If that is not satisfactory to the harvesting surgeon, then he should have a local opinion obtained.

I hope this is of help to you in your hearings.

Sincerely,



Philip R. Calanchini, M.D.

PRC:da
cc: Mr. Tom Harlan

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August 21, 1984

Please reply to:

David A. Ogden, M.D.
Renal Section
University of Arizona
College of Medicine
1501 North Campbell Avenue
Tucson, AZ 85724

Senator Ollie Sperow
Chairman, Senate Select Committee
on Anatomical Transplants
Room 4082, State Capitol
Sacramento, CA 95814

Dear Senator Sperow:

Thank you for the invitation to testify concerning California legislation concerning brain death in the September 18th hearing. Unfortunately, a prior commitment for this date precludes my appearing to testify at this hearing.

I am enclosing an article you may find available. As you can see, brain death is a legal basis of declaring death by statute in 25 states and based on court decisions in 7 additional states. Medical criteria for brain death are well defined and accepted now by all appropriate medical organizations. This would seem to respond to your first two questions. In response to your third and fourth questions, if death has already been pronounced and a cadaver is transported to California for transplant surgery, the cadaver is exactly that - a cadaver. I see no need for a local coroner to have jurisdiction or for a California doctor to recertify death unless the same is required for a cadaver shipped from another state to California for burial.

Finally, Oscar Salvatierra, M.D., Chief of Transplant Surgery at the University of California San Francisco, is expert in these matters and would be an excellent resource person for your committee.

Sincerely,

David A. Ogden, M.D.
President

DAO/fc

1984
Annual Meeting
Sheraton Washington Hotel
Washington, D.C.
December 5-9

CITATIONS

"Hitch" People v. Hitch (1974) 12 Cal 3d 641

"Nations" People v. Nations (1980) 26 Cal 3d 176

See also People v. Mejia (1976) 56 CalApp 3d 574
People v. Goss (1980) 109 CalApp 3d 457
(per Boyd Stevens)

"Bowman" In re Bowman (1980) 619 Pac Rptr 2d 731

"Dority" Dority v. Superior Court (1983) 145 Cal App 3d 273