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Traumatic Brain Injury/Brain Death

The implementation of a protocol promoting the safe practice of brain death determination ☆

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ABSTRACT

Purpose: The purpose of the study is to describe the implementation of measures introduced in Israel in 2009 to promote the safe practice of brain death determination (BDD).
Materials and methods: The measures require (1) physicians to undergo a mandatory training course, (2) the mandatory performance of an ancillary test, and (3) retrospective examination of all BDD forms by an independent committee. Any deviations from practice parameters were noted. Surveys were also undertaken to assess (i) the attitude of local physicians to the measures and (ii) whether similar measures are in place in Europe and whether they were considered necessary.
Results: After implementation, the measures resulted in the absence of deviations from practice parameters over time. A majority of local physician (n = 64) felt the measures added a sense of security to BDD (73%) and ensured its proper performance (85%). The European survey (n = 20 countries) revealed (1) specialized BDD training is required in 60%, provided in 50%, while felt necessary by 80%; (2) independent supervision of BDD is performed in only one other country; and (3) BDD is performed country-wide using the same criteria in 80% while felt necessary by 95%.
Conclusion: The measures were successfully implemented, reduced diversity in patient testing, and positively accepted by local physicians. Wider application of the measures may be appropriate as suggested by the results of a European survey and the variability of BDD reported in the literature.

1. Introduction

The concept that patients with irreversible loss of brain function are, in fact, dead has become nearly universally accepted. In this regard, practice parameters for brain death determination (BDD) exist in most Western countries [1] and are typically adopted from the American Academy of Neurology (AAN) practice parameters [2], which have recently been updated [3].

The importance of the determination is clear, both for declaring a patient dead and, where appropriate, proceeding with organ and/or tissue retrieval and transplantation. However, studies have shown that there is great variability in the practice of BDD. A very recent study examining the actual practice of BDD relative to contemporary AAN guidelines from 68 heterogeneous hospitals in the Midwest United States found that only 44.7% of 226 determinations met level I (strict) criteria for adherence to AAN guidelines, 37.2% met level II (loose) criteria, and 18.1% met level III (incomplete) criteria [4]. Deviations from practice guidelines included core body temperature less than 36.6 in 15.5%, absence of complete documentation of brainstem areflexia, and absent motor responses in 54.9% and failure to perform an apnea test in 7%. In a study of the top 50 institutions for neurology and neurosurgery in the United States, variability existed in the guidelines' requirements for performance of the evaluation, prerequisites prior to testing, specifics of the brainstem examination and apnea testing, and what types of ancillary testing could be performed [5]. Finally, a study of 600 hospitals randomly selected from the American Hospital Association registry revealed significant variability in policy criteria compared with the AAN practice parameters and other authoritative standards [6]. These differences were greatest in specifying methods of cranial nerve examination and in identifying conditions/agents that may confound the accuracy of testing. In addition to this variability, conditions have been described, which may mimic brain death, including cases of Guillain-Barre syndrome [7,8] and others related to the effect of medications [9,10], further emphasizing the need for strict adherence to AAN guidelines.

The variability in practice may also contribute to doubts and misconceptions about the concept of brain death in the general public, fueled by reports in the lay press purporting to describe instances

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where brain death was diagnosed but the patient subsequently recovered [11].

In many countries, the diagnostic procedures for BDD are not defined by the legislature but rather are the responsibility of national medical societies [1,12]. In very few countries, Finland, being one example [13], have detailed instructions for BDD been written into law. In Israel, an act formally validating the concept of brain death was passed into law in March 2008 and came into effect in June 2009 [14].

In this article, we describe the implementation of measures, central to the new act, which were intended to promote the safe practice of BDD. The changes in BDD were largely driven by societal demands resulting in an interaction between religious and medical authorities, which we have previously described [15]. In addition, we performed a survey of (i) local physicians to assess their attitudes to the measures and (ii) practices in Europe to assess whether similar measures are in place and considered necessary.

2. Materials and methods

Permission to conduct the study, which covered the period from November 2011 to December 2013, was obtained from the Israel Ministry of Health who waived the need for Helsinki approval as this was a retrospective, observational study using data entered into a central databank.

2.1. Description of measures to promote the safe practice of BDD

Physicians taking part in BDD are required to undergo a training course whose content includes medical, ethical, legal and religious aspects related to the procedure (Fig. 1). An accreditation committee was established to define the content of the physician training course. The committee comprises physicians; rabbis; representatives from the disciplines of ethics, philosophy, and law; and a member of a religious group other than a Jew. Importantly, none of the members play an active role in the organ donation processes. Physicians undergoing the course are designated by the directors of their hospitals according to profession (from the disciplines of neurology, neurosurgery, intensive care, anesthesia, cardiology, and internal medicine) and seniority (certified specialists). After the training course and the successful completion of a multiple-choice examination, physicians receive accreditation and a unique identification number. The training course is available via an interactive Internet presentation, whereas the examination is conducted on a formal basis. Brain death is determined according to AAN practice parameters [3] with the exception that the performance of an apnea test and ancillary test is mandatory [15]. After the determination, a BDD form is completed (the same form is used throughout Israel) and signed by the examining physicians and by the expert physician performing the accessory test. Finally, 4 physicians from the accreditation committee, whose specialty qualifies them to perform a BDD, are responsible for the retrospective supervision of all BDD forms. All completed BDD forms are forwarded to the supervising physicians and thereafter to the full accreditation committee, either (i) immediately, in the absence of any queries regarding the BDD, or (ii) after receiving clarification/s from the relevant physician/s where queries are raised. The full accreditation committee then finally approves each BDD.

2.2. Survey of local physician attitudes

A survey relating to the measures described above was conducted in August 2013. The survey was distributed personally to all physicians who had participated in the accreditation process and who were actively involved in BDDs. The survey comprised 5 questions, and answers were based on a 5-point Likert scale (from not at all to a large extent). In addition, respondents were asked to provide information regarding their medical specialty (intensive care, internal medicine, neurology, pediatrics, anesthesia, or cardiology) as well as whether they had performed BDDs before the new measures.

2.3. Survey of European national transplant agencies

This survey, conducted in June 2013, was designed to assess to what extent the measures were unique to Israel and considered necessary and/or desirable. The questionnaire, which was available only in English, was sent by email to senior representatives of national transplant agencies in Europe ($n = 25$).

2.4. Data collection

The following data were also collected: the number of physicians undergoing the training course, the number passing the multiple-choice examination and receiving accreditation, the number of BDDs performed since the implementation of the present system, and the findings of the supervising committee.

3. Results

3.1. Training course

Since implementation of the requirement, 149 physicians have completed the training course, of whom 148 subsequently passed the examination and received accreditation.

3.2. Supervisory committee findings

Over the study period, 160 BDD forms were forwarded to the supervisory committee for evaluation. Of these, 128 were approved immediately and 32 after further clarification. Reasons for clarification

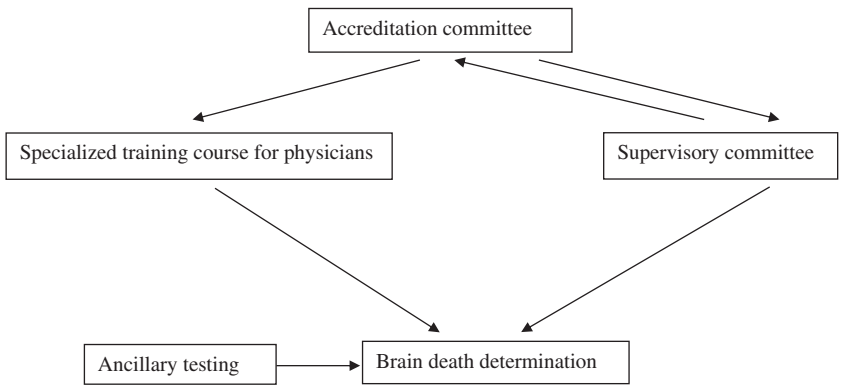

Fig. 1. Flow chart of measures implemented to promote the safe practice of BDD.

Table 1
Findings of supervisory committee (from November 2011 to December 2013)

	Number (total, 160 BDD forms)
Forms approved without queries	128
Clarification required	32
Reasons for clarification	
Failure of examining physician to sign BDD form	8
Failure of examining physician to note accreditation number	3
Date of BDD not noted	7
Failure of specialist performing accessory test to sign report	8
Failure to describe details of the accessory test performed	3
Apnea test not performed according to practice parameters	1
Body temperature not noted prior to examination	1
Oculovestibular reflex response not noted	1

are shown in Table 1. These included failure of an examining physician to sign the completed form (8 cases); failure of an examining physician to note his/her unique accreditation number (3 cases); related to performance of the ancillary test, namely, failure of the specialist to sign the report (n = 8), failure to describe details of the test performed (n = 3); failure to note the date of the BDD (n = 7); apnea test declared compatible with brain death (BD), although the recorded pCO_2 did not reach the required level (n = 1); body temperature not noted before the clinical examination (n = 1); and failure to perform the oculovestibular reflex (n = 1). No deviations from the BDD requirements were noted in the last 6 months of the study.

3.3. Results of the local survey

Responses were received from 64 physicians (response rate, 43%). Of these, 29% were critical care specialists; 26%, specialist physicians; 21%, anesthesiologists; 12%, neurologists; 7%, pediatricians; and 5%, cardiologists; 71% had experience with BDD before the new regulations. The findings of the survey are shown in Table 2. Most responded that (i) the requirements of the new act added a sense of security to performing the BDD (42% to a very large and 34% to a large extent), (ii) accreditation was a valuable source for refreshing knowledge (37% to a very large and 33% to a large extent) and a necessary and relevant process (51.5% to a very large extent), and (iii) the supervisory committee ensured proper performance of the BDD (51% to a very large and 34% to a large extent). Half of the respondents felt that this resulted in an increased workload (25% to a small and 25% to some extent).

Table 2
Results of local physician attitude survey (n = 64; response rate, 43%)

	To a very large extent	To a large extent	To some extent	To a small extent	Not at all
To what extent does the new act					
Give physicians a sense of security in performing BDD (n = 62)	26	21	10	3	2
Create excessive work for physicians (n = 64)	7	13	20	16	8
To what extent is the accreditation process (n = 64)					
A source of knowledge	24	21	10	5	3
Relevant or necessary	33	5	9	4	2
To what extent does the supervision process ensure BDD is properly performed (n = 61)	31	21	2	9	2

Table 3
Results of European survey (n = 20; response rate, 80%)

	Yes, n (%)	No, n (%)
Do physicians determining BD require special training?	12 (60)	8 (40)
Do physicians determining brain death receive any special training?	10 (50)	10 (50)
During their general specialist training	8	
Specific training for BDD	2	
Do you think physicians should have special training for the BDD?	16 (80)	4 (20)
Is there any supervision of the brain death determination?	11 (55)	9 (45)
Supervision by independent agency	1	
Each physician of BD committee supervises the other	10	
Do you think there should be supervision in any way of the BDD?	12 (60)	8 (40)
Is the BDD performed using the same criteria throughout your country?	16 (80)	4 (20)
Do you think the BDD should be performed using the same criteria throughout your country?	19 (95)	1 (5)

3.4. Results of the international survey

Of the 25 questionnaires sent out, 20 responses were received (response rate, 80%). The survey revealed that specialized training for BDD is required in 60% of countries, received in 50%, whereas felt necessary by 80%. Independent supervision of the BDD was performed in only 1 country, namely, France, whereas in 9 others, supervision was considered internal, that is, physicians performing the BDD supervise each other. Some supervision of the BDD was considered necessary by 60%. The BDD is performed using the same criteria in 80% of countries, whereas considered necessary in 95% (Table 3).

4. Discussion

We have described the implementation of a bundle of measures introduced in the new BD act with the aim of promoting the safe practice of BDD. Initial experience revealed that the process was successfully implemented and feedback provided by the supervisory committee has resulted in the absence of deviations from practice parameters. A survey of local physicians revealed an overall high level of satisfaction with the measures, whereas certain elements of the bundle were found to be unique and considered necessary in a survey of European countries.

In light of the importance of promoting safe practices of BDD for both patients and health care professionals, many authors have concluded that standardization be considered so as to ensure the highest possible accuracy and reliability of the diagnosis [1,5,6]. In addition, it has been suggested that physicians performing BDDs be intimately familiar with BD criteria and to have demonstrated competence in the examination [3]. In this regard, several measures were recently undertaken in Israel. First, determinations are restricted to physicians who have received accreditation after a training course. This is in line with the conclusions of Shappell et al [4], based on their study demonstrating wide variability in the documentation of BDD likely reflecting similar variability in practice, calling for comprehensive and targeted educational initiatives to ensure consistently contemporary approaches to the BDD in every patient. An interactive e-learning tool has also been developed allowing easy access to a practical resource, which provides real-time assistance with the BDD when needed. This may be especially relevant in peripheral hospitals where the number of BDDs is lower. It should be stated that the requirement for training and accreditation was not initially universally accepted. Some physicians refused to participate in these courses due to rejection of elements of the new act (eg, the compulsory performance of ancillary testing) and resentment of the fact that a senior physician with many years of experience was required to undergo “retraining.” For this reason, a survey of physicians was conducted 2 years after introduction

of the act to assess their attitudes to the measures. The results revealed that most considered the accreditation process to be necessary and relevant, to provide knowledge and to impart a high level of certainty in the BDD. Most, however, felt that this was at the price of an increased workload. Second, physicians are required to complete and sign a BDD form, in effect a checklist, which includes all elements of the determination, regarding both the clinical examination and the accessory test performed. This form then comprises the third element of the measures introduced, namely, the retrospective supervision of the BDD. In this regard, ensuring compliance with and accountability for upholding BD criteria has been advocated by a number of authors [5,6]. In our experience, deviations from practice parameters were largely related to administrative errors (eg, failure to sign or date the BDD form, etc); however, 3 instances directly related to the performance of the BDD were also noted (body temperature not noted, oculovestibular reflex not performed, and target pCO_2 not reached during apnea testing). All deviations are brought to the attention of the relevant physician/s both for clarification and as a learning opportunity. Indeed, in the last 6 months of the study, no deviations have been noted.

Another component of the practice parameters defined in the new act, namely, the mandatory performance of an ancillary test, may also promote uniformity of the BDD. Their routine use remains controversial, and they are not considered mandatory in many BDD guidelines [1] but typically recommended only in the presence of confounding factors [3]. In addition, numerous articles have stressed the potential pitfalls associated with their use [16-18]. However, a survey of brain death criteria throughout the world revealed that the requirement for mandatory confirmatory laboratory testing is common, being present in 28 of 70 practice guidelines, that is, 40% [1]. Indeed, some authors have recommended their more routine use, considering the complexities of the clinical examination and possible knowledge deficits concerning confounding factors, even when the determination is performed by experienced physicians [19,20]. In this regard, Bernat [21] has reported his personal experience of witnessing errors in the examination of patients purported to be brain dead who were not and has suggested that an accessory test showing the absence of intracranial blood flow be routinely practiced to confirm the clinical diagnosis and reduce variability.

The results of the limited international survey yielded 2 interesting findings. First, elements of the measures instituted in Israel appear to be unique. Thus, a requirement for special physician training for BDD is required in 60% of these countries surveyed and for the most part when provided (50% of countries), it is as part of a general medical education. An active process of supervision by an outside agency was reported in only one other country, namely France; in all other countries supervision of the process is implied by the fact that each physician of the BD committee supervises the other. In the majority, but not all (80%), the BDD is performed using the same criteria throughout the country. Secondly, most respondents felt that at least some of the measures were necessary. Thus, 80% felt that physicians should have special training for BDD, 95% felt that the BDD should be performed in the same way throughout their country, whereas a much smaller number (60%) felt that supervision of the BDD is necessary.

This study has several limitations. First, national practice parameters for BDD were in place before the new act. Because there was no external supervision of BDD at that time, no effective comparison for the 2 periods (before and after changes to the Act) can be made regarding deviations from practice parameters. However, the fact that deviations were found by the supervisory committee suggests that they may have also have occurred in the past. Second, the response rate from the local physician survey was relatively low, namely, 43%. The reason(s) for this are not clear. However, the fact that respondents included all medical disciplines performing BDD and physicians who both had and had not been involved in BDD before the implementation of the new measures and that the views expressed were largely uniform suggests that the sample may be representative of the larger group. Third, the international survey was limited to European countries because Israel Transplant is most closely linked with these countries in educational and quality control programs. In addition, the response rate, although high (80%), was expected to be 100%.

5. Conclusion

In conclusion, measures introduced to promote the safe practice of the BDD for both patients and health care professionals have resulted in reduced diversity of the determination. Wider application of the measures, which were readily implemented and positively accepted by local physicians, may be appropriate as suggested by the results of a European survey and the variability in BDD reported in the literature.

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References

[1] Wijdicks EFM. Brain death worldwide: accepted fact but no global consensus in diagnostic criteria. Neurology 2002;58(1):20–5.
[2] Practice parameters for determining brain death in adults (summary statement). The Quality Standards Subcommittee of the American Academy of Neurology. Neurology 1995;45(5):1012–4.
[3] Wijdicks EFM, Varelas PN, Gronseth GS, Greer DM. Evidence-based guideline update: determining brain death in adults. Neurology 2010;74(23):1911–8.
[4] Shappell CN, Frank JI, Husari K, Sanchez M, Goldenberg F, Ardelt A. Practice variability in brain death determination. A call to action. Neurology 2013;81(23):2009–14.
[5] Greer DM, Varelas PN, Haque S, Wijdicks EFM. Variability of brain death determination guidelines in leading US neurological institutions. Neurology 2008; 70(4):284–9.
[6] Powner DJ, Hernandez M, Rives TE. Variability among hospital policies for determining brain death in adults. Crit Care Med 2004;32(6):1284–8.
[7] Joshi MC, Azim A, Gupta GL, Poddar BP, Baronia AK, Singh RK. Guillain-Barré syndrome with absent brainstem reflexes: a report of two cases. Anaesth Intensive Care 2008;36(6):867–9.
[8] Rivas S, Douds GL, Ostdahl RH, Harbaugh KS. Fulminant Guillain-Barré syndrome after closed head injury: a potentially reversible cause of an ominous examination. J Neurosurg 2008;108(3):595–600.
[9] Richard IH, LaPointe M, Wax P, Risher W. Non-barbiturate, drug-induced reversible loss of brainstem reflexes. Neurology 1998;51(2):639–40.
[10] Ostermann ME, Young B, Sibbald WJ, Nicolle MW. Coma mimicking brain death following baclofen overdose. Intensive Care Med 2000;26(8):1144–6.
[11] http://www.nbcnews.com/id/23768436/ns/dateline_nbc-newsmakers/t/dead-man-recovering-after-atv-accident/. Accessed 20 June 2014.
[12] Haupt WF, Rudolf J. European brain death codes: a comparison of national guidelines. J Neurol 1999;246(6):432–7.
[13] Randell T. Medical and legal considerations of brain death. Acta Anaesthesiol Scand 2004;48(2):139–44.
[14] Brain-Respiratory Death Act 2008 (Israel). Book of Statutes 327 (in Hebrew).
[15] Cohen J, Ashkenazi T, Katvan E, Singer P. Brain death determination in Israel: the first 2 years' experience following changes to the Brain Death Law—opportunities and challenges. Am J Transplant 2012;12(9):2514–8.
[16] Wijdicks EFM. The case against confirmatory tests for determining brain death in adults. Neurology 2010;75(1):77–83.
[17] Busl KM, Greer DM. Pitfalls in the diagnosis of brain death. Neurocrit Care 2009;11 (2):276–87.
[18] Heran MKS, Heran NS, Shemie SD. A review of ancillary tests in evaluating brain death. Can J Neurol Sci 2008;35(4):409–19.
[19] Webb A, Samuels O. Brain death dilemmas and the use of ancillary testing. Continuum (Minneap Minn) 2012;18(3):659–81.
[20] Roberts DJ, MacCulloch KA, Versnick EJ, Hall RI. Should ancillary brain blood flow analyses play a larger role in the neurological determination of death? Can J Anesth 2010;57(10):927–35.
[21] Bernat JL. Brain death. In: Laureys S, Tononi G, editors. The neurology of consciousness. Elsevier Ltd; 2009. p. 151–62.