Policies on Donation After Cardiac Death at Children’s Hospitals
A Mixed-Methods Analysis of Variation

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DONATION AFTER CARDIAC death (DCD) potentially permits patients who do not meet the neurological criteria for death to donate solid organs. Controlled DCD occurs following planned withdrawal of life-sustaining treatment, and uncontrolled DCD occurs after unanticipated cardiac arrest. Potential controlled DCD donors include patients with irreversible catastrophic brain injury or end-stage neuromuscular diseases. Although DCD donors were the original source of organs for transplant, the focus shifted in the 1970s to organ recovery from “brain-dead” donors because of better outcomes. The persistent shortage of transplantable organs and requests from families generated renewed interest in DCD in the early 1990s.

The initial DCD proposals engendered controversy.1 Disputes concerned whether donors were really dead, premortem interventions hastened their deaths, and efforts to limit warm ischemia compromised palliative care. Subsequent consensus statements have articulated the ethical propriety of and standards for DCD, including an observation period of at least 2 minutes and no more than 5 minutes before declaring death.2-5 As of January 1, 2007, the Joint Commission requires all hospitals to address DCD, little is known about actual hospital policies.

Objective To characterize DCD policies in children’s hospitals and evaluate variation among policies.


Main Outcome Measures Status of DCD policy development and content of the policies based on coding categories developed in part from authoritative statements.

Results One hundred five of 124 eligible hospitals responded, a response rate of 85%. Seventy-six institutions (72%; 95% confidence interval [CI], 64%-82%) had DCD policies, 20 (19%; 95% CI, 12%-28%) were developing policies; and 7 (7%; 95% CI, 3%-14%) neither had nor were developing policies. We received and analyzed 73 unique, approved policies. Sixty-one policies (84%; 95% CI, 73%-91%) specify criteria or tests for declaring death. Four policies require total waiting periods prior to organ recovery at variance with professional guidelines: 1 less than 2 minutes and 3 longer than 5 minutes. Sixty-four policies (88%; 95% CI, 78%-94%) preclude transplant personnel from declaring death and 37 (51%; 95% CI, 39%-63%) prohibit them from involvement in premortem management. While 65 policies (89%; 95% CI, 80%-95%) indicate the importance of palliative care, only 5 (7%; 95% CI, 2%-15%) recommend or require palliative care consultation. Of 68 policies that indicate where withdrawal of life-sustaining treatment can or should take place, 37 policies (54%; 95% CI, 42%-67%) require it to occur in the operating room and 3 policies (4%; 95% CI, 1%-12%) require it to occur in the intensive care unit.

Conclusions Most children’s hospitals have developed or are developing DCD policies. There is, however, considerable variation among policies.

Context Although authoritative bodies have promulgated guidelines for donation after cardiac death (DCD) and the Joint Commission requires hospitals to address DCD, little is known about actual hospital policies.

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Little, however, is known about individual hospitals’ DCD policies. A “Report of a National Conference on Donation After Cardiac Death”5 included results of a survey of organ procurement organizations (OPOs) but did not describe the survey’s methods. A few institutions have described their policies or reported case series.8,9 Studies of analogous policies have found significant variation. For example, a study of neurological criteria found major discrepancies among institutions’ policies and variable adherence to the American Academy of Neurology’s guidelines.10

We conducted the current study to characterize DCD policies at children’s hospitals and evaluate variation among policies.

METHODS

We solicited policies from members of the National Association of Children’s Hospitals and Related Institutions (NACHRI), a voluntary membership association of not-for-profit hospitals and medical institutions, using their categories “freestanding children’s hospitals” and “primary teaching hospitals.”11 We also identified whether facilities were UNOS transplant centers. Canadian members of NACHRI are ineligible for UNOS membership.12

We requested that the chair of the hospital’s ethics committee indicate whether the hospital has a DCD policy; does not have a DCD policy but is developing one; or does not have nor is developing a DCD policy. If the hospital has a policy, he or she was asked to provide a copy. We mailed solicitation letters, response cards, and self-addressed stamped envelopes, followed by a reminder letter to nonrespondents. A final contact was made by telephone or electronic mail.13 Participation was voluntary and we provided no incentives. Contacts were made between November 2007 and January 2008.

We coded the policies using qualitative methods.14 After developing an initial set of coding categories based on authoritative statements,2,4,5 we added new categories and modified existing ones following a review of the preliminary coding. Categories include indications and restrictions, relationship between the decision to withdraw life-sustaining treatment and to donate, informed consent, palliative care, premortem interventions to increase organ viability, declaration of death, termination of organ recovery efforts, waiting periods, conflicts of interest, and role of the ethics committee. Each policy was assigned to 2 authors, without reference to its contents, who independently coded it and reconciled differences through mutual agreement. Policies were not deidentified because doing so would have interfered with data collection. For example, inclusion of upper age limits generally identified institutions as primary teaching hospitals.

All statistical analyses were performed using SAS software, version 9.1 (SAS Institute Inc, Cary, North Carolina). We calculated simple χ statistics, a measure of interrater reliability,15 and exact binomial confidence intervals (CIs) for proportions. We used the 2-sided Fisher exact test to compare the response rates between freestanding and primary teaching children’s hospitals and between institutions that are and are not UNOS transplant centers. We used the 2-sided Cochran-Armitage trend test to compare the status of policy development (coded as 3 ordered categories as described above) between the same 2 categories of institutions. Separate exact multiple logistic regression analyses were performed to jointly relate the presence of each of the individual policy elements to indicator variables designating whether or not facilities were freestanding children’s hospitals or UNOS transplant centers. Two-sided \( P < .05 \) is considered statistically significant for all analyses, without adjustment for multiple comparisons.

The institutional review boards at the authors’ institutions either exempted the study from review or approved it. Because this research does not involve human subjects, we did not request informed consent. We assured the institutions that we would not redistribute their policies and would present only deidentified results.

RESULTS

NACHRI identifies 124 freestanding primary teaching children’s hospitals. One hundred five institutions responded, a response rate of 85%. The response rate by institution type was 47 of 51 freestanding children’s hospitals (92%), 58 of 73 primary teaching children’s hospitals (79%), 72 of 87 UNOS transplant centers (83%), and 30 of 33 institutions that are not UNOS transplant centers (91%). Response rates were not significantly different comparing freestanding vs primary teaching hospitals (\( P = .08 \)) and UNOS transplant centers vs not (\( P = .39 \)). Of the 105 respondents, 76 (72%; 95% CI, 64%-82%) had DCD policies, 20 (19%; 95% CI, 12%-28%) were developing policies, and 7 (7%; 95% CI, 3%-14%) neither had nor were developing policies. The 2 remaining institutions had closed. Responses by institution type are shown in Table 1. Analysis of stage of policy development by institution type revealed a statistically significant association between being a UNOS transplant center and having or developing a DCD policy.

We received and coded 73 unique, approved policies and have used 73 as the denominator for all proportions unless otherwise indicated. One chair declined to share the policy because of legal counsel’s concerns, 1 responded but never sent the policy, and 2 institutions are campuses within the same system and use the same policy. With the exception of 1 institution, all policies are for controlled DCD. A single policy permits organ donation from “brain-dead” donors who experience cardiac death if the donor is already in the operating room.

Indications and Restrictions

Sixty-six policies (90%; 95% CI, 81%-96%; \( \kappa = 0.36 \)) list clinical indications and 16 (22%; 95% CI, 13%-33%)
articulate age restrictions (Table 2). Thirteen (18%; 95% CI, 10%-29%) have a minimum age restriction. Two policies require that donors be at least 36 weeks’ estimated gestational age and 3 specify the lower age limit as newborn. The 8 remaining minimum ages range from 1 to 60 months. Twelve policies (16%; 95% CI, 9%-27%) specify a maximum age restriction that ranges from 55 to 85 years; the most common are 60 (n=3), 65 (n=2), and 70 (n=2) years of age.

The 8 remaining minimum ages range from 1 to 60 months. Twelve policies (16%; 95% CI, 9%-27%) specify a maximum age restriction that ranges from 55 to 85 years; the most common are 60 (n=3), 65 (n=2), and 70 (n=2) years of age. Two policies (3%; 95% CI, 0%-10%) include minimum weight restrictions, both 10 kg.

**Relationship Between the Decisions to Withdraw Life-Sustaining Treatment and to Donate**

Sixty-five policies (89%; 95% CI, 80%-95%) require that the decision to withdraw life-sustaining medical treatment be separate from the decision to donate. Forty-three (66%; 95% CI, 53%-77%) describe the separation in conceptual terms such as “independent of” or “separate and distinct from.” Sixty-four of these policies (98%; 95% CI, 92%-100%) describe this separation in temporal terms such as “precede,” “prior to,” “only after,” or “following.” Fifteen of these 64 policies (23%, 95% CI 13%-34%) nonetheless explicitly permit discussion of organ donation prior to the decision to withdraw if the patient or the patient’s family raises the topic. For example, “If the family raises the question of organ donation, notify [OPO]. A brief discussion of DCD may occur, but it should be stressed that the decision regarding withdrawal of life-sustaining treatment must precede and be independent of a decision about organ donation.” Six policies (8%; 95% CI, 3%-17%) require families to initiate the request for organ donation.

**Informed Consent**

Fifty-one policies (70%; 95% CI, 58%-80%) specify minimum content for the informed consent process. The numbers of policies requiring disclosure of specific types of information, such as ability to withdraw consent at any time, are reported in Table 2.

**Palliative Care**

While 65 policies (89%; 95% CI, 80%-95%) indicate the importance of palliative care, only 5 (7%; 95% CI, 2%-15%) recommend or require palliative care consultation. Thirty-two policies (44%; 95% CI, 32%-56%) preclude the use of medications with the intention to hasten death. Fifty-two (71%; 95% CI, 59%-81%) indicate the importance of support for the donor’s family.

Policies differ in the location of withdrawal of life-sustaining treatment. Sixty-eight policies (93%; 95% CI, 85%-98%) specify the location. Table 2 reports the number of policies that require or permit withdrawal of life-sustaining treatment to occur in the operating room or the intensive care unit. The majority, 37 of 68 (54%; 95% CI, 42%-67%), require withdrawal to occur in the operating room. Other potential locations include areas adjacent to the operating room (13/68; 19%; 95% CI, 11%-30%) and the emergency department (3/68; 4%; 95% CI, 1%-12%). Of the 62 policies in which withdrawal must or may occur in the operating room, 31 (82%; 95% CI, 70%-91%) permit the family to be present and 30 (48%; 95% CI, 36%-61%; k=0.38) permit the family to remain until death is declared. Twenty policies (27%; 95% CI, 18%-39%) permit the family to view the body following organ recovery.

**Premortem Interventions to Increase Organ Viability**

Twenty-six policies (36%; 95% CI, 25%-48%) prohibit premortem interventions to increase organ viability if they might cause harm or pain. Two policies (3%; 95% CI, 0%-10%) prohibit all premortem interventions to improve organ viability. Table 2 lists the number of policies permitting medications or procedures in general and specific medications or procedures such as phentolamine and cannulation. Six policies (8%; 95% CI, 3%-17%) do not address premortem interventions.

**Declaration of Death**

Sixty-one policies (84%; 95% CI, 73%-91%) specify criteria or tests for declaration of death, including electrocardiogram (ECG) findings, pulselessness, apnea, and unresponsiveness (Table 2). While 44 policies require ECG monitoring (72%; 95% CI, 59%-83%), other policies replace ECG monitoring with different tests. One policy, for example, states that “[t]he loss of myocardial contraction and systemic perfusion, or acirculation, generally will occur before the loss of electrical (ECG) activity” and requires instead either arterial line monitoring or echocardiography. Eight of the 42
policies specifying pulselessness (19%; 95% CI, 9%-34%) do not indicate the method for determining pulselessness, and 10 (24%; 95% CI, 12%-39%) consider palpation sufficient.

**Waiting Periods**
Sixty-six policies (90%; 95% CI, 81%-96%) require waiting periods either between the time the criteria of death are first fulfilled and the declaration of death or between the declaration of death and the initiation of organ recovery (Table 3). One policy describes the latter type of waiting period as follows: “No incision will be made until 5 minutes following the determination of death.” Two institutions specify 5 minutes following the determination of death.” Seven policies require total or combined waiting periods. Four policies state that “No incision will be made until the criteria for heart or organ death are met.”

**Termination of Organ Recovery Efforts**
Sixty-one policies (84%; 95% CI, 73%-91%) also articulate a maximum time following the withdrawal of life-sustaining treatment for organ recovery. Duration of the waiting period ranges between 60 and 120 minutes (Table 2). In some policies, the time varies by organ type.

**Conflicts of Interest**
Policies vary in the role ascribed to OPO personnel. Many policies characterize their role(s) as obtaining informed consent, evaluating the potential donor, and/or assisting in scheduling organ recovery. Twenty-four (33%; 95% CI, 22%-45%; k = 0.33) explicitly exclude OPO personnel from participation in premortem management. Several policies incorporate the language contained in UNOS’ “model elements” protocol: “No member of the organ recovery team or OPO staff may participate in the guidance or administration of palliative care, or the declaration of death.”

Sixty-four policies (88%; 95% CI, 78%-94%; k = 0.30) preclude transplant personnel from declaring death and 37 (51%; 95% CI, 39%-63%) from involvement in premortem management. Nonetheless, transplant person-
Role of ethics committees
Termination of organ recovery efforts
Declaration of death
Specify criteria or tests
Electrocardiogram
Pupils unresponsive
Palpation sufficient
Do not specify method
Agree
Unresponsive

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<th>Policy Description</th>
<th>No. of Policies/Total (%)</th>
<th>K Value</th>
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<tr>
<td>Declaration of death</td>
<td>Specify criteria or tests</td>
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<td></td>
<td>Electrocardiogram</td>
<td>44/61 (72) [59-83]</td>
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<td></td>
<td>Pupils unresponsive</td>
<td>42/61 (69) [66-80]</td>
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<td></td>
<td>Palpation sufficient</td>
<td>10/42 (24) [12-39]</td>
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<td></td>
<td>Do not specify method</td>
<td>8/42 (19) [9-34]</td>
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<tr>
<td></td>
<td>Agree</td>
<td>35/61 (57) [44-70]</td>
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<td></td>
<td>Unresponsive</td>
<td>23/61 (38) [26-51]</td>
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<tr>
<td>Termination of organ recovery efforts</td>
<td>Maximum period for organ recovery efforts following withdrawal, min</td>
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<td>39/61 (64) [51-76]</td>
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<td></td>
<td>60-120</td>
<td>3/61 (5) [1-14]</td>
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<td>120</td>
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<td></td>
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<td></td>
<td>Transplant personnel prohibited from declaring death</td>
<td>64/73 (88) [78-94]</td>
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<td></td>
<td>Physicians caring for potential organ recipients excluded from premortem care and/or prohibited from declaring death</td>
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<td></td>
<td>Optional consultation</td>
<td>17/73 (23) [14-35]</td>
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<td></td>
<td>Mandatory prospective consultation of all cases</td>
<td>77/73 (10) [6-19]</td>
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<td></td>
<td>Mandatory prospective consultation in selected cases</td>
<td>2/73 (3) [0-10]</td>
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A k value of 0.21-0.4 represents fair agreement; 0.41-0.6, moderate agreement; 0.61-0.8, substantial agreement; and 0.81-1, almost perfect agreement.15

Note: Numbers of policies requiring the organ procurement organization to bear the costs associated with organ donation.2

Role of Ethics Committee
Thirty-one policies (42%; 95% CI, 31%-55%) specify a role for the hospital ethics committee, the chair of the committee, or an ethics consultant. Participation could be optional or mandatory, prospective or retrospective, and comprehensive or selective (Table 2). Twenty-five policies (34%; 95% CI, 24%-46%; k = 0.24) articulate a clinician’s right to refuse to participate in DCD.

Multiple Logistic Regression Analyses
A series of multiple logistic regression models were tested using the presence of each of the major policy elements listed in Table 2 as the dependent variable and the 2 institution types (freestanding vs primary teaching and UNOS transplant center vs not a UNOS transplant center) as independent variables. These analyses revealed only 1 nominally significant association: being a UNOS transplant center was associated with prohibiting physicians involved in the care of potential recipients from participating in premortem clinical management and/or declaration of death (odds ratio, 9.71; 95% CI, 1.32-43; P = .02; a P < .0018 would be required for significance with a Bonferroni adjustment for multiple comparisons). There was no statistically significant association between being a freestanding children’s hospital and prohibiting involvement of physicians caring for potential recipients (odds ratio, 1.07; 95% CI, 0.33-3.56; P > .99) and no evidence of an interaction between the 2 independent variables (P > .99).

COMMENT
This study demonstrates that, consistent with a national emphasis on increasing the supply of transplantable organs, a large number of children’s hospitals have developed or are developing DCD policies. There is, however, considerable variation among policies and, as we discuss, between policies and authoritative reports and/or consensus statements. We focus our discussion on 3 broad concepts: that the declaration of death is a major point of contention, that the articulation of established ethical norms encompasses many other issues, and that palliative care is an important area for additional research.

Declaration of Death
Transplantation currently operates under the dead donor rule—organ procurement must follow and cannot cause the donor’s death. In DCD, donors are declared dead according to cardiorespiratory criteria. Although controversial, the decision not to attempt resuscitation is generally considered sufficient to fulfill the requirement that the patient’s state is irreversible or permanent after an adequate period has elapsed to preclude spontaneous recovery of cardiorespiratory function. Most supporters of DCD do not require additional time for the donor to also fulfill neurological criteria for death.16

990 12/61 (20) [11-32] 0.80c
90 12/61 (20) [11-32] 0.80c
60-120 3/61 (5) [1-14] 0.89c
120 1/61 (2) [0-9] 0.89c

Conflict of interests
Organ procurement organization personnel excluded from premortem care
Transplant personnel excluded from premortem care
Transplant personnel prohibited from declaring death
Physicians caring for potential organ recipients excluded from premortem care and/or prohibited from declaring death

Role of ethics committees
Specify a role for ethics committee, its chair, or ethics consultant
Optional consultation
Mandatory prospective consultation of all cases
Mandatory prospective consultation in selected cases
Mandatory retrospective review of all cases
Conscience clause

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In the absence of definitive data, consensus statements have recommended waiting at least 2 and no more than 5 minutes to declare death. Our results show that the majority of policies are consistent with this recommendation. Sixteen of the 66 policies, however, characterize the waiting period as between the declaration of death and the recovery of organs. The justification for this framing is unclear. If the patient is dead, why wait to recover organs? A declaration-to-incision waiting period may create confusion or misunderstanding.

The American College of Critical Care Medicine and the Society of Critical Care Medicine argued that, because of objections that patients were not dead or that the criteria for death were manipulated to acquire better organs, institutions should use specific standards and objective evidence to declare death. Eighteen percent of policies do not provide specific criteria and, even among those that do, some permit the use of subjective evidence. For example, 10 policies permit determining pulselessness by palpation. The lack of clear, objective criteria for declaring death may affect public acceptance of DCD.

A national conference argued for the use of confirmatory tests because of the urgent time constraints. While this consensus statement contended that ECG monitoring is sufficient but not necessary, 44 policies require ECG monitoring. This contrasts with policies that confirm acirculation by arterial lines or echocardiograms. Further clinical investigation is required to determine whether reliance on ECGs adds substantial warm ischemic time and therefore affects the viability of recovered organs.

Articulation of Established Ethical Norms

The policies reviewed did not consistently articulate accepted ethical norms. Fear that physicians will prematurely declare death to obtain organs and mistrust of the medical profession are important reasons why individuals may decline to donate organs. Articulating ethical norms and acting consistently with them is essential to the organ transplantation system.

The use of premortem interventions to improve organ viability is potentially ethically problematic because they further the patient’s interest only to the extent the patient has expressed the desire to become an organ donor. Some critics of DCD have questioned whether anticoagulants and vasodilators may hasten or cause death. The Institute of Medicine asserted that informed consent is necessary for such interventions. The Society of Critical Care Medicine argues that medications required to improve the chances of successful donation are acceptable if they do not harm the patient. The policies we reviewed do not consistently articulate these norms: a minority of policies do not require informed consent for premortem interventions and the majority fail to state that they are unacceptable if they harm patients. While the majority of policies accept the use of heparin, a minority accept the use of vasodilators. These differences reflect continuing disagreement regarding whether such interventions actually harm patients and whether or how much harm is acceptable.

Policies should address the potential conflicts of interest inherent in the premortem management of potential donors. Organ procurement organization staff members may have extensive knowledge of the donation process and often have helped manage “brain-dead” donors prior to organ recovery. This does not create a conflict of interest because the donor has already died. In DCD, the donor does not die until immediately prior to organ recovery and, therefore, there may be conflicts between palliative care and organ recovery. A minority of policies address this issue.

Transplant team members also have potential conflicts, especially if involved in premortem interventions such as prepping and draping. Some policies attempt to manage these potential conflicts by requiring transplant personnel to leave the operating room prior to the withdrawal of life-sustaining treatment and not return until after the declaration of death.

Approximately one-third of policies preclude clinicians who are caring for potential recipients from involvement in premortem management and/or declaration of death. Preventing the appearance of a conflict may be important to maintain public trust but may also create staffing issues in smaller units where a single team cares for all critically ill patients. It may be difficult to predict prospectively who will become a potential donor or recipient. The frequency and magnitude of such conflicts will need to be identified and the threshold for action clarified.

Palliative Care

Donation after cardiac death occurs in the context of end-of-life care. While the policies we reviewed consistently state the importance of palliative care and support for the donor’s family, there is considerable variation in the described behavior. In most institutions, the withdrawal of life-sustaining treatment occurs in the operating room. While most hospitals permit family members’ presence, many also require the prepping and draping of patients prior to withdrawal to expedite organ recovery. We lack sufficient evidence to understand the effects different policies may have on bereavement.
This study has a number of limitations. Although policies of primary teaching children’s hospitals reflect those of the larger institutions of which they are a part, they may not accurately represent those of other, “adult” hospitals. Policies do not always contain relevant information or record information consistently. For example, many policies do not explicitly state which organs may be recovered. They also inconsistently record dates of approval or review, making it impossible to describe the temporal development of policies. The k value for the initial coding of several categories was below 0.41. This was compensated for by having 2 investigators code all policies and reconcile any differences in their initial coding. Although policies prescribe behavior, they frequently do not provide a rationale. Finally, the policies may not reflect actual behavior. Individuals may act contrary to the policy or act consistently in a way not addressed by the policy.

Most children’s hospitals have or are developing DCD policies. The policies exhibit notable variation both within those we studied and compared with authoritative reports and statements. Further research will be required to determine the importance of variation in the tests for declaring death or the processes for withdrawing life-sustaining treatment. In the long run, public policy may need to address strategies to promote adherence to recommendations for DCD processes based on sufficient clinical evidence and/or ethical justification.

Author Contributions: Dr Antommaria had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Antommaria, Trotchoad, Kinlaw, Frader.

REFERENCES