Commentary

Hyperbaric Oxygen Therapy for a Neurologically Devastated Child: Whose Decision Is It?

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A recent case highlights one of the on-going and unresolved controversies in pediatric ethics: who makes treatment decisions for children. Children, by definition, do not have the maturity to make medical choices. Those decisions must be made for them. The issue remains by whom and on what standard those choices should be made.
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THE CASE

The case involves a near drowning of a 20-month-old Florida boy who wandered from his parents during a holiday barbeque and fell unnoticed into the family swimming pool. The father, an ophthalmologist, found his son at the deep end of the pool, pulled him from the water and initiated resuscitation. The child was transported by ambulance to a hospital where heartbeat was finally restored. The child was then admitted to a pediatric intensive care unit (PICU).

Some 8 days postevent the child remained unconscious. The father, desperate to try any measure that might increase his son's chances for neurological recovery, contacted a local for-profit hyperbaric oxygen therapy clinic. The clinic's medical director, who claims to run the largest hyperbaric neurological clinic in the world, treats children with cerebral palsy and brain injuries who, as he puts it, ''Are the end of the line.'' In his words, ''When everybody gives up, we get them.''[1] The goal of the clinic's therapy is ''to jump start'' and ''awaken'' dormant brain cells.

The pediatric intensivists caring for the child were unwilling to impose an unproven therapy on an acutely compromised child without some evidence as to its potential efficacy. Though the literature reveals that hyperbaric oxygen chambers have been approved by the FDA for multiple medical conditions, such therapy, as the Director of Pediatric Critical Care Medicine for the University of Miami notes, ''has not been shown to change the extremely poor outcome and grim prognosis of the oxygen starved brain.''[2]

Further, there are reports of complications of hyperbaric oxygen therapy including such high-risk events as severe respiratory distress from treatment-associated aspiration and embolus-induced acute nonhemorrhagic cerebral infarction.[3] An additional threat to the patient in this case would occur if he suffered a cardiac arrest while undergoing treatment in one of the $8' \times 3'$ cylindrical oxygen chambers utilized by the for-profit clinic. The 15 minutes it would take to decompress the chamber before cardiac resuscitation could be initiated would result in further anoxic damage that might eliminate whatever potential the toddler had to recover consciousness.

The father took his case to the media and then to court. The local press and television stations provided daily reports on the physician father's quest for a treatment to save his son.[4] Prominent coverage also was given to the unwillingness of the hospital and its doctors to give the boy his ''only chance for recovery.''[5] When the father was unable to persuade the hospital to allow the outside clinic physician to provide the desired treatment, he petitioned the circuit court for an order compelling the hospital to do so.

The circuit court judge, finding that the parents were willing to pay for the therapy and to waive any liability arising from the treatment, held there was no reason why the child should not be offered ''another [treatment] option.'' As he put it, ''If I don't do anything, nothing [good] is going to happen. But if I do something, something might happen.''[6] The judge issued an order directing the hospital to install a hyperbaric oxygen chamber in its facility so that the clinic physician could treat the child in close proximity to the PICU. By this stage, the boy's neurological devastation was such that he was described in the press as being in a persistent vegetative condition. If so, he was now beyond any further neurological damage short of brain death.

DISCUSSION

Prescinding from the well-known problems associated with physicians attempting to treat family members,[7] this case presents several ethical issues: Who ultimately decides treatment choices for

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an infant? What, if any, are the limits of parental authority in demanding medical treatment for their children? What standard should be used for such decisions? Are those standards different when investigational procedures are utilized?

In the nearly two decades since the now infamous "Baby Doe" Regulations[8] were issued by the US. Department of Health Education and Welfare in an attempt to provide federally mandated rules on treatment of neonates, the norms about who is to make treatment decisions for newborns and on what standard have been significantly altered and revised.[9] There is now a strong consensus in the medical, legal and ethical literature in the US that it is the best interests of the child — not the desires of the parents or the determination of the physician — which must prevail in the care of children.[10] That standard, unlike *substituted judgment*, does not rest on autonomy or self-determination, but solely on the protection of the patient's welfare. That protection is particularly important with regard to infants and children because with it they are now seen not merely as the property of parents, but as patients in their own right.[11] The implication is that although parents may continue to be involved in decision-making for their children, they do not have an absolute right to refuse — or to require — medical treatment for their child. It is the child's best interests, and those alone, that are to be the focus and goal of medical treatment decisions made on behalf of children.

Translated into practice, that standard means if the burden on the infant is overwhelming or the prospects are extremely bleak, as is true in the presence of a lethal abnormality, there is no obligation to subject the infant to further procedures.[12] In such cases, the parents' decision to omit further treatment is to be respected. Alternatively, if out of ignorance, fear, misguided pessimism, or simple refusal to accept a compromised infant, parents were to decline relatively low-level, high-benefit interventions that would save the life of a child, even if the child were to evidence some permanent handicap, there is no question today that the physicians should treat.[13]

The issue in this case, however, is not that of parents wanting to stop treatment — which in the circumstances of this case would have been an ethically acceptable choice — but of parents' desire to provide an untested, nonconventional therapy that has the potential for significant additional harm to the child. The harm aspect of the issue is the easier to resolve. The physician's primary commitment to the patient, captured in the Hippocratic dictum: ''First do no harm,'' precludes putting the child at undue risk. Although generally the risk–benefit assessment belongs to the patient or the patient's proxy, where children are involved the physician has the added duty of protecting the child's ''best interests'' against even the well meaning but perhaps ill-informed or misguided directives of the parents. In this case the guilt and anxiety of the parents could prove so overwhelming as to cloud what would otherwise be a carefully reasoned parental judgment.

The commitment not to put the child at undue risk is intensified when the proposed procedure involves an unproven or unconventional therapy.[14] It is well known that desperate parents of desperately ill children are truly desperate. They are willing to try anything. They will grasp at any hope, push for any possibility no matter how far fetched or improbable. That proved all too true in the tragic example of Baby Fae — the case in which the despairing mother of an infant with hypoplastic left heart syndrome gave ''informed consent'' for the doctors at Loma Linda Hospital to transplant a baboon heart into her newborn child.[15] It was also true in this case where the father pleaded, ''I just want my son to have a chance.'' As he put it, ''How much more can you hurt him if you want me to kill him?''

But as Francis Moore, the distinguished Chief of Surgery at Harvard Medical School, has warned before undertaking an untested procedure on a patient, ''There must be a rationale on which the desperately ill patient may be offered not merely pain, suffering, and cost, but also a true hope of prolonged survival [without devastating sequelae].''[16] The statement of the physician running the hyperbaric oxygen clinic that, ''I don't know if [oxygen therapy] will help, but there is a child in the hospital where the option is to pull the plug. The treatment is very safe. The book should not be closed until this is done,''[4] does not meet that criterion. Nor does the comment of a second physician at the clinic that the court order ''Is great news because it means there is very, very low likelihood of long-term neurological deficits,''[17] offer true hope.

There is no scientific basis for the optimism expressed in that statement. In fact, the evidence from a randomized multicenter trial on the effect of hyperbaric oxygen therapy for children with cerebral palsy shows that ''hyperbaric oxygen treatment in children with cerebral palsy does not produce any improvements greater than those seen in children treated with slightly pressurized [room] air.''[18] And as a recent editorial in *The New England Journal of Medicine* on the positive benefits of hyperbaric oxygen therapy in reducing the risk of cognitive sequelae in the aftermath of acute carbon monoxide poisoning concluded, ''Neither hyperbaric oxygen nor any other current therapy can be expected to prevent cognitive sequelae due to cellular injuries sustained at the time of exposure''.[19]

Since medicine is a science, as well as an art, the justification for utilizing any therapeutic intervention must be the expectation, based on data from the literature, that the proposed technique, drug or procedure offers some potential benefit to the patient. When the physician ventures beyond the proven to explore and test a new hypothesis or theory, the physician leaves the area of the known and enters, at best, into the experimental or investigational. The experimental is a legitimate area of medicine. But as Ezekial Emanuel notes, it is one that it is governed by different rules and standards from those employed with well-established therapeutic techniques.[20]

Informed consent alone is not a sufficient basis on which to embark on an investigational procedure.[21] As Moore has observed, there must be a well worked-out theoretical basis for the proposed

intervention, careful laboratory studies on animals and extensive ''field experience'' by the researcher before the physician submits a patient to such treatment. Even then the physician has a heightened obligation to be aware of potential harm to the patient.

The recent death of 18-year-old Jesse Gelsinger during a gene-therapy trial at the University of Pennsylvania[22] and of Ellen Roche, a young technician at the Johns Hopkins Medical Center who died after inhaling an asthma medication administered while volunteering as part of a clinical trial,[23] have brought the concern for the protection of human research subjects, first articulated in the Neuremberg Code, back into public focus. As those cases illustrate, even with IRB oversight, there continues to be serious and substantial concerns about the degree of protection afforded to participants in research involving human subjects.

A new report on ''Responsible Research'' issued by the Institute of Medicine[24] as a response to the Gelsinger death highlights some of the concerns in the protection of human research subjects. Among the more important considerations in protecting participants in research protocols is the problem of the ''therapeutic misconception'' that is, the belief by subjects that participation in an investigational trial is likely to benefit them directly.[25,26] The confusion on potential benefit of experimental treatments is exacerbated when the line between research and therapy is not sharply defined. What was once a clear demarcation between clinician and researcher has now become blurred. Today many clinicians are paid by pharmaceutical companies to solicit patients for Phase III drug studies as a way to complete those studies more quickly.[27] And some physicians have found it highly profitable to enlist their own patients into those studies. The physician as ''double agent'' takes an increased significance when doctors — as is true of those at the for-profit hyperbaric oxygen clinic — have a direct financial interest in the utilization of a new treatment.[28] As the Institute of Medicine report notes the concern over potential conflicts of interest ''is particularly acute regarding financial conflicts of interest.''

It is also important to distinguish medical research, in which there is a working hypothesis and an IRB-approved research protocol, from the indiscriminate use of an unproven device in the hope it might just work. In the case under discussion the use of hyperbaric oxygen therapy to overcome the anoxic damage occasioned by a near drowning was not a part of a research protocol; it was being proposed as a therapeutic remedy. The clinic physician told the judge, ''Each hour that passes could make a difference in the treatment's effectiveness.'' Further, while offering no promises in this case, he assured the court, ''Amazing recoveries have occurred, including that of a child who was in a similar situation, but who eventually made a full recovery.''[29]

There is no basis in the medical literature for that assurance. Hyperbaric oxygen therapy, which was first used to overcome decompression sickness in deep sea divers,[30] is now highly useful in a wide variety of medical settings such as carbon monoxide poisoning, gas gangrene, soft tissue anaerobic infections, burns, and sudden deafness.[31] It is also reported to be helpful in the treatment of Bell's palsey,[32] radiation morbidity,[33] and the treatment of diabetic ulcers.[34] There are, however, no reports of the therapy being useful in the treatment of cerebral palsy and none of its use on patients suffering severe anoxic insult from near-drowning accidents.

The medical aspects of hyperbaric oxygen therapy are well documented. Frey et al.[35] have noted that therapy is ''based on clearly defined physical laws and physiological regularities.'' It is known, for example, that oxygen therapy increases the bactericidal capacity of leukocytes, reduces tissue edema, protects intracellular ATP, and protects from lipid peroxidation.[36] There are also well recognized adverse side effects to the therapy such as barotrauma of the lungs and oxygen toxicity to the central nervous system. This therapy, like any complex medical intervention, requires special knowledge of its effects, risks, and adverse effects. As Frey warns, it is not to be administered unless there is ''a clear and distinct indication [for its usage].''

When, as was true in the case on which we report, the treating physicians could find no evidence in the literature of the proposed therapy's efficacy in ameliorating the patient's condition — and the treatment itself had the potential to destroy whatever hope there was for the patient's recovery — there is no ethical justification for its use. The father's desire to try ''anything'' to assist his son's recovery is not warrant enough to overcome the ethical barrier against imposing an unproved and potentially dangerous therapy on a patient even as a ''desperate last measure.'' In such a situation, the only ethical way to proceed is to follow medicine's first priority: ''Do no harm.''

Once, however, the child's condition deteriorates to the point that no further neurological devastation short of brain death could occur, it becomes a matter of indifference to the patient's ''best interest'' whether or not unconventional interventions are utilized. The primary goal then shifts to helping the parents cope with the tragedy. If and when that condition is met, if the proposed ''desperate measure'' does not violate the child's dignity or impose excessive costs on the community, its use might be considered a socially acceptable accommodation to the parents' need to assure themselves ''everything possible'' was done for their child.

Some 6 weeks after his initial hospitalization — and 40-hour-long sessions of hyperbaric oxygen therapy — the child was discharged home with no reported improvement in his neurological status.

CONCLUSION

This case demonstrates that while parents have the primary responsibility to determine treatment choices for their children, that authority is not absolute. The physician has an independent obligation to act in the best interests of the child. That obligation is not ended with the ''informed consent'' of a parent to utilize an unproven or unconventional therapy. Nor does a waiver of liability

or a court's authorization for a procedure absolve the treating physician — so long as there is a realistic opportunity of benefit or protection against harm — from the commitment to act as an advocate for the patient's well-being.

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