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by Robert S. Mendelsohn, MD

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IN THIS ISSUE:

IS RhoGAM SAFE? . . .
Beware of New Death Criteria

Q I have a seven-year-old Rh-positive son, and I had to have RhoGAM at his birth. About two years later, I had a miscarriage in my first couple of months of pregnancy--I did not receive the shot at that time. I now am expecting another baby, and blood work shows everything to be fine. We are hopefully anticipating a home birth.

I have read that the RhoGAM solution coagulates all the Rh-positive antigens so that the woman's system does not produce antibodies. These coagulated antigens disappear in about six weeks. How does this affect the woman? RhoGAM is always touted as a wonderful way of ensuring the baby's safety, and of course, I'm concerned about my baby. But at the same time, I wonder where these coagulated antigens go. Do they provide an added stress to the mother when she needs to regain strength?

I also believe there is a great possibility that the two blood types never mixed at all at birth. If that's the case, how necessary is the shot? Many doctors now advocate that the shot be given during pregnancy. I want to be able to make an educated choice about what is injected into my body, and I need to know all the pros and cons.--J.W.

A *Is RhoGAM safe?*

Since my own grandchildren were born at home as were the children and grandchildren of many of my patients and my friends, I seldom face the RhoGAM question.

The RhoGAM injection, given to Rh-negative mothers to prevent serious jaundice and brain damage in their offspring may be important because, in hospital births, where early clamping of the cord is routine, mixing of the maternal and fetal blood supplies is common. This intermingling of the two incompatible bloods, caused by the pulsations of blood in the umbilical cord cut before its time, results in sensitization of the mother --and hence trouble in subsequent pregnancies. Midwives and home-birth doctors, who delay clamping the cord until the blood has stopped pulsating, report an almost zero incidence of Rh problems.

While I have been wondering about the possible ill effect of RhoGAM all during the past few decades, the entire question now has risen to prominence because of public realization that RhoGAM is a human-blood product and therefore, despite all government reassurances, may contain the AIDS virus.

You--together with every other mother whose doctor recommends this injection either during or after pregnancy--should ask the doctor the intelligent, probing questions you raise in your letter. Doctors assume,

on the basis of no hard evidence, that RhoGAM is safe. But your concerns demand a response based not on assumptions, but on evidence. Ask your doctor to request the manufacturer to provide you with documented, printed evidence proving that RhoGAM is safe, both immediately and long term, for the baby and his mother.

I predict you will be shocked at the almost total lack of studies designed to answer your excellent questions.

Q

I have Rh-negative blood and am five months pregnant. My doctor wants to give me two shots of RhoGAM--one shot during my seventh month, the other after I deliver--if the baby is Rh positive.

Everything I have read on this subject says the drug should be given after delivery. I have never seen or heard anything about it being given during pregnancy. I am very cautious about taking any medication while pregnant and am worried about what this drug might do to the baby.

Is RhoGAM safe?--S.R.

A

Avoiding RhoGAM

You are quite correct that, until the last several years, RhoGAM (the injection given to mothers to prevent Rh disease in subsequent pregnancies) was given after delivery.

Since the administration of this human blood product before a delivery is still relatively new, you must ask your up-to-date doctor to give you references from a number of investigators who support his recommendation, so that you can determine whether RhoGAM given during pregnancy is a proven treatment or simply experimental.

Q

I know you have criticized RhoGAM injections (which block the sensitization of Rh-negative mothers to Rh-positive blood) because, being a human blood product, it might contain the AIDS virus. But I am an Rh-negative mother, and I don't know what to do to prevent any more children I have from developing the kind of jaundice in the newborn that can lead to brain damage.--N.M.

A

Perhaps you are seeing a doctor who is too young to be familiar with 20-year-old evidence which tells how to protect babies from that dangerous form of jaundice known medically as Erythroblastosis fetalis. So if your doctor says your baby will be brain-damaged unless you receive RhoGAM, tell him to ask his medical librarian to locate a scientific paper by obstetrician/gynecologist J.E. Doolittle, M.D., which appeared in Obstetrics and Gynecology in April, 1966.

This paper shows that the mixing of maternal and fetal blood that leads to Erythroblastosis fetalis is more likely to occur if the obstetrician pulls on the umbilical cord while delivering the placenta. Dr. Doolittle also warns obstetricians to avoid early clamping of the umbilical cord. Clamping the cord before pulsations have ceased leads to a backup of fetal blood, under pressure, into the maternal circulation. Again, this dangerous intermingling of the two blood supplies (fetal and maternal) can lead to maternal sensitization and subsequent infant jaundice in the next pregnancy.

Every Rh-negative mother who faces this problem should ask her obstetrician to obtain this fully documented study so that her babies can avoid being brain damaged, and she can avoid RhoGAM shots.

Q

My close friend is Rh-negative and is facing a decision about a shot of RhoGAM to prevent complications. She is asking a lot of questions. She is being pressured to have the shot at 28 weeks. I gave her some informa-

tion against the idea of RhoGAM shots, but the magazine article didn't carry any weight with her doctor, not the way a medical journal would.

Is it possible for her to have a RhoGAM shot prepared from the blood of a member of her family so that shot will not be contaminated with AIDS? I would appreciate any information you can give me to share with her.--P.L.

Q

I am writing you about a friend who is expecting twins. She is Rh-negative, her husband is Rh-positive. Her doctor has advised her to take RhoGAM at 30 weeks into the pregnancy. He told her the practice of preventive treatment for the possible dangers of maternal/fetal blood mixing is common.

I told her of the risks of AIDS from blood products, and I let her borrow one of your newsletters on the subject. She still thinks that RhoGAM is necessary, even though this is her first pregnancy. Is there anything else I can share with her about this doctor-recommended "preventive" measure?--T.D.

A

Both your friends are very fortunate to have you advising them. You both are raising the right questions.

My advice to every pregnant woman faced with a doctor's recommendation for a RhoGAM injection (used for the prevention of Rh-incompatibility complications) either during or after pregnancy, is to ask first for the prescribing information on RhoGAM.

She then will learn, for example, that RhoGAM is a human blood product which reduces, but does not eliminate the possibility of Rh sensitization. She also will learn that the manufacturer warns that no one knows whether when administered to a pregnant woman, RhoGAM causes damage to the fetus.

After carefully reading the prescribing information, your friends should ask their doctors for scientific articles that support the recommendations to use RhoGAM in their particular cases. They then can see whether the cases reported in those articles match their own situations.

For example, Ms. T.D., your friend would want to look for cases in which RhoGAM was administered during a first pregnancy. She then could ask the doctor if he remembers when sick newborns, not too many decades ago, were treated with blood administered intramuscularly. That led to Rh sensitization in female babies long before they became old enough to be pregnant. What does her doctor think of that medical mistake, and does he know the dangers today's RhoGAM shot may pose years later?

If this is not a first pregnancy, your friend should ask the doctor for information about her previous deliveries. Was the cord cut in a hurry? Or was the doctor patient, and did he wait until the cord stopped pulsating all by itself before he cut? In the latter case, he should be asked whether the risk of RhoGAM doesn't outweigh the risk of Rh sensitization.

Next, your friend must make sure the doctor shares information with her from the manufacturer that tells the AIDS status of the RhoGAM--a human blood product. Does the particular batch he wants to use carry the AIDS antibody? Does it carry the virus itself? What tests have been done to exclude the possibility? Are the tests accurate?

Ms. P.L., have your friend's doctor put her in touch with RhoGAM experts to determine whether it is possible to have her shot prepared from a selected donor(s) to avoid the potluck RhoGAM smorgasbord that results from combining the blood of many donors.

RhoGAM is now under attack by Mothering Magazine (Fall, 1987). In an article entitled "Is Prenatal RhoGAM Dangerous?" midwife Ina

May Gaskin of Summertown, Tennessee points out that until recently the use of this injection has not been controversial. Since the early 1980s, doctors and parents have become suspicious of RhoGAM's safety for two reasons.

Obstetricians used to give RhoGAM only after delivery, but now, they give it during pregnancy. Paul Hensleigh, M.D., of the Department of Obstetrics and Gynecology at Stanford University, criticizes the injection during pregnancy because there is no information on potentially damaging effects to the babies in utero. For example, there is some evidence that 4- to 12-year-old children who were given gamma globulin (RhoGAM is a form of human immune globulin) showed some compromise to their immune systems for at least five months. There is reason to suspect a similar effect on the much less mature immune system of a fetus.

Another development that has made people wary of RhoGAM is the AIDS epidemic. Even though no reported cases of AIDS have been traced to a RhoGAM shot, one should keep in mind that it is a human blood product, and it theoretically is possible for an infected donor to test negative for AIDS antibodies and yet still carry the virus. Thus, assurances of safety are somewhat less than perfect.

In case you are wondering how RhoGAM is made, human volunteers who are Rh-negative are injected with positive Rh factor, causing antibodies to be formed in their blood. The blood is then drawn and concentrated into a serum for injection. The antibodies in this pooled serum then coat the blood cells of the Rh-negative mother who is injected, subsequently preventing sensitization to her baby's blood. This protects the baby against heart failure, jaundice, anemia, brain damage and death due to mixing of the potentially incompatible blood of mother and baby.

An Rh-negative woman who wishes to avoid the use of RhoGAM altogether should avoid procedures that might cause mixing of her blood with that of her baby's (i.e., amniocentesis, early cutting of the umbilical cord, etc.). Normally, the blood of the mother and baby do not mix during pregnancy unless there are conditions or complications such as ectopic (tubal) pregnancy, miscarriage, bleeding from placenta previa, abdominal injury to the mother, multiple pregnancy or fetal death.

As important as our reservations may be about RhoGAM, the implications extend to all of medicine. RhoGAM joins a long list of medical interventions that once were considered to be beyond question but now are suspect. RhoGAM, like immunizations and silver nitrate in the eyes of newborns, has been a form of Holy Water in the Religion of Modern Medicine. Now all three of these Holy Waters have been defiled. Keep Modern Medicine's record in mind when its Priests try to sell you other new "miracles."

FDA "believes" RhoGAM carries no AIDS risks

I repeatedly have brought to your attention the risk of getting AIDS from blood products, RhoGAM included. Now, according to the Chicago Tribune, September 28, 1987, the FDA "believes there is no significant risk that a person can contract the AIDS virus from RhoGAM or other medicines derived from blood plasma."

That quote demands dissection. First, note that the FDA "believes." That means it doesn't know; it doesn't have evidence. A belief is akin to a guess, a conjecture, a hope, a wish--anything but scientific evidence.

Second, look at the words "no significant risk." Does that mean the risk is insignificant? How insignificant? To whom? Please notice that the FDA is smart enough not to tell you there is no risk.

This little item should give all you Rh-negative women out there another reason for asking your doctor plenty of questions.

As reported in AMA News, October 9, 1987, federal health officials

find it "highly unlikely" that a link will be found between an AIDS case and RhoGAM. This statement accompanied an investigation of an Army soldier and her child, both of whom had tested positive for AIDS antibodies. The woman, who later was diagnosed as having AIDS, had received RhoGAM.

Since that time, military hospitals have suspended the use of the lot or RhoGAM (distributed by the Ortho Diagnostic Systems in July, 1986) with which the woman with AIDS had been treated. The suspected lot contained 12,500 doses, and a spokesman for Ortho says it is "most likely" that all the doses from that lot already were administered.

The FDA says that tests show RhoGAM presents "little risk" of AIDS-related HIV infection. An FDA official has announced there was no evidence of an association between the use of RhoGAM and the acquisition of AIDS (neither is there any evidence indicating that there is no association between RhoGAM and AIDS).

Meanwhile, the Associated Press reports that a number of physicians are continuing to prescribe lots of RhoGAM other than the suspected lot RHG-636. The physicians have agreed that it is "unlikely" that HIV could be transmitted through the product.

Considering that 15 percent of pregnant women with Rh-negative blood are given RhoGAM, one would think that this important issue (now being investigated not only by the FDA but also by the federal Centers for Disease Control and by RhoGAM's manufacturer) would appear on the front pages of your daily newspaper. But since that is not the case, let me advise every woman faced with a syringe that contains RhoGAM to ask her doctor if, at the very least, he has checked the lot number of the dose he plans to inject.

If your doctor tries to frighten you about the consequences to your future children if you do not accept RhoGAM, you might point out to him that this substance is far from 100 percent effective. Some women become sensitized in spite of having been given RhoGAM after delivery. According to The British Medical Journal (April, 1987), of 33 deaths from Rh disease in England and Wales in 1985, eight resulted from sensitization, despite the mother having received RhoGAM after previous pregnancies (failure of prophylaxis). In 1984, the failure rate was nine out of 25.

Medical ethicists threaten Orthodox Jews

Orthodox Jews, beware! The Hastings Center is after you. For those of you readers who have not been aware of the recent strange turns and twists in medical ethics, the Hastings Center was established almost 20 years ago to consider ethical problems in medicine and biology. This eminent think tank (225 Elm Road, Briarcliff Manor, New York 10510) carries out research in such areas as genetic screening, artificial reproduction, professional ethics and death and dying. Its latest report concerns itself with "termination of life-sustaining treatment and the care of the dying."

The Hastings Center savants point out that persons used to be declared dead on the basis of cardiopulmonary criteria (i.e., the heart had stopped beating, and the lungs had stopped conducting respiration). But now, in most states, "neurologic criteria" (brain death, flat EEG, etc.) has replaced the "older" common-law view.

So far, so good. But then, a sentence on page 87 of the report caught my eye: "Although there is widespread agreement on the use of neurological criteria, the agreement is not universal. In particular, some religious groups, including Orthodox Jews, object."

I knew that. Four thousand years of Jewish legal tradition has quite firmly established cardiopulmonary criteria in determining death. Up until now, I have heard no objection from Orthodox Jews (or more properly, observant Jews) to neurologic criteria--as long as the concept of brain death is not used for them. After all, it's a free country, isn't it?

The very next sentence of the report underscores First Amendment

rights: "Religious freedom and pluralism are important values in our society." For that, I am reassured. The Hastings Center (like myself) still believes in the Bill of Rights. However, my reassurance is short-lived since, in the very next sentence, the Hastings Center scholars proclaim: "However, in many ways society is forced to have consistent standards. We believe that the societal needs for consistency and clarity in determining death mandates as much uniformity as possible in the criteria for declaring death. Accordingly, when a patient meets the neurological criteria, the [Hastings] Guidelines do not leave a declaration of death to the discretion of the health care professional, surrogate, family or others."

In other words, the Good Guys at Hastings no longer trust the doctor to determine when a patient is dead, even if both the doctor and patient are observant Jews. Perhaps it's a typographical or grammatical error, I thought. But then I read pages 137 and 138.

In this section entitled, "Accommodating Religious Values and Beliefs," the Hastings Center admits "that these decisions have controversial theological implications....Some, on religious grounds, reject using neurological criteria for declaring death. This is one area where society's needs should take precedence over individual autonomy and religious liberty. Allowing religious minorities to exempt themselves from society's criteria for recognizing and declaring death would create confusion; some patients would be considered alive instead of dead simply because of religious convictions. Uniform criteria, including neurological criteria, are necessary.

"In addition, the practice of allowing some dead bodies to be treated as if they were still alive, depending on the person's religion, could undermine confidence in the criteria for determining death."

This cavalier attitude toward religious freedom so surprised me that I turned back to the beginning of the report to discover who wrote it. I thought those involved in the report might be Christians who were unfamiliar with the practices and deeply-held convictions of observant Jews. But that is not the case; Jewish-sounding surnames abound. One certainly cannot accuse Jews, regardless of their religious affiliation, of unawareness of the practices of their observant Jewish brothers and sisters.

A better question is whether the Hastings scholars are angry about unnecessarily keeping braindead Orthodox Jews on mechanical life support systems. Are they angry about losing an important source of transplant organs which will not be suitable for harvesting if Orthodox Jews continue to wait for their traditional cardiopulmonary criteria for death?

Although I am not used to Orthodox Jews being a target of modern medicine and its disciples in the Hastings Center, the Kennedy Institute and other bastions of medical ethics, I <u>am</u> used to attacks on Jehovah's Witnesses. Having testified as an expert witness in several Witness cases in order to show the controversial aspects of blood transfusions, I have had first-hand exposure to modern medicine's almost universal hatred for the Witnesses.

The Hastings Center does not contradict this perception; it does not disappoint me. In its section on "Treatment For Life-threatening Bleeding," Hastings warns us that when the patient is a Jehovah's Witness, it may be necessary for the health-care professional to speak to the patient alone in order to determine if the patient is refusing voluntarily. Or, if the "patient is under pressure from family or others, he or she should be offered an opportunity to discuss the refusal of transfusion with a health-care professional...in order to ensure a voluntary decision."

The report goes on: "...sometimes a Jehovah's Witness may actually wish to have a court override his or her religious refusal. The health-care professional should attempt to find out whether this is the case."

I can just see the scenario. The doctor orders the family and friends out of the room so that he can be alone with the isolated Witness. He says to him, "Is this really a voluntary decision on your part to reject my

blood transfusion? Or are you just being pressured by family and friends around you?" It takes a pretty strong patient to stand up to this kind of grilling.

As a result of my involvement in the Witness cases, I have tried my best to warn Jews that, if they fail to come to the defense of the Witnesses now, they most likely will be the next target of modern medicine. The usual response I receive is, "You can't compare Jews with Jehovah's Witnesses."

Well, maybe that was true at one time. But the Hastings Center seems to have no problems lumping the two minority groups together. And which religious groups will be next?

As I write this on the day after Thanksgiving, I wonder whether it will be necessary for a new group of pilgrims to leave our country in order to find religious freedom elsewhere. Or will observant Jews, faced with the awesome choice between Hastings Center Guidelines and their religious law, now have to die in secret?

Whether you are Jewish or not, I recommend you obtain this 159-page report so that you can decide whether I am right in claiming that medical ethics today has become an oxymoron (a contradiction in terms). Its purpose is that of covering for the Religion of Modern Medicine so that it can make the unethical ethical.

Potpourri

Q

My 32-year-old daughter gets the 24-hour flu anytime she's around someone who has gotten a flu shot. Her doctors says it's just a coincidence that she gets chills, fevers, aches, etc., in this fashion--it has happened six times that we know of.

The only flu shot my daughter has had was that swine flu shot years ago, and she got terribly sick from that. If she were to get a flu shot in two small doses, would this keep her from getting the flu? Could it be possible that she could get the flu just from standing next to someone who has had a flu shot?--A.D.

A

Flu shots and flu symptoms

Your daughter's discovery of a relationship between her getting the flu when she is around people who have received the flu vaccine does not constitute scientific evidence. However, that does not mean that her observation lacks value.

Medicine is based on two major lines of evidence. One of these, the controlled study, satisfies scientific and statistical criteria. The other--case reports, anecdotes and testimonials--directs the attention of doctors and patients to possible relationships which they otherwise might have overlooked.

Your daughter's thinking stimulated me to draw an analogy to the cases of paralytic polio that some people acquire from standing close to someone recently inoculated with the polio vaccine, although there are differences between the polio vaccine and the flu vaccine. Still, in the absence of scientific studies that either confirm or deny the possibility that recipients of the flu vaccine may transmit the disease, your daughter's hypothesis should not be dismissed lightly.

It may not be practical for your daughter to ask everyone she meets if they have recently had a flu shot. In regard to dividing her own flu shot dosage, my readers already know my thumbs-down position on the flu vaccine. Encourage your daughter to pursue her research and to see whether she can find other people who might be able to make the same association. If she collects enough evidence, maybe we doctors will have to conduct an orderly scientific study to determine whether <u>all</u> those cases of flu are caused by dirty little viruses or whether some may be caused by the flu vaccine.

Another View

by Marian Tompson

Two recent articles, both of them written by midwives, have helped me to better understand the issues involved in the routine prenatal administration of RhoGAM to Rh-negative women.

Ina Mae Gaskin, writing in the Fall, 1987 issue of Mothering. and Penni Harmon, CNM, writing in the Winter issue of Midwifery Today, both point out that the 20-year-old practice of administering RhoGAM to Rh-negative women immediately after the birth of Rh-positive babies has dramatically reduced the incidence of newborn damage and fatalities due to blood incompatability. Until recently, there has been little controversy about the use of this drug.

Prior to 1987, somewhere between 10 to 16 percent of Rh-negative women became sensitized to their baby's blood when it became mixed with their own, usually at the time of delivery. When that occurred, the mother's body, reading the positive Rh-factor in the baby's blood as an invader, developed antibodies to search out and destroy those blood cells. If the mother became pregnant in the future, her body's defenses would identify the baby's positive blood factor as the enemy, attacking the baby's red blood cells. Sensitization also can occur as a result of miscarriage, amniocentesis, bleeding from placenta previa, abdominal pregnancy, ectopic pregnancy and transfusion with blood of the wrong Rh factor.

Traditionally, RhoGAM was given within 72 hours of birth. Harmon says the 72-hour recommendation "arose from the fact that the researchers developing protocols for giving RhoGAM postpartum used the 72 hour period because of the logistics of drawing blood from volunteers who were newly delivered and usually discharged by 72 hours. Since they had such a high success rate with this particular protocol, this 72 hour limit became sacred. However, immunologists know that the immune response is not initiated until the fetal cells are identified by the mother's spleen. This process can take weeks. Therefore, it is certainly advisable to administer the RhoGAM to a woman, even if she is more than 72 hours postpartum rather than to withhold it."

Since two percent of Rh-negative women still become sensitized even with treatment, researchers, seeking to better the percentage, began to give RhoGAM at 28 weeks of pregnancy. Antenatal RhoGAM was approved by the FDA, and in 1983 it was recommended by the American College of Obstetrics and Gynecology.

But not everyone is convinced of the wisdom of this procedure. Concern has been expressed about the lack of information on the potentially damaging effects to babies whose mothers are injected prenatally and about the ethics of research with experimental drugs in pregnancy. With prenatal RhoGAM, the future siblings are the ones who may benefit from the treatment, rather than the fetus who is subjected to the risk. Tests on babies whose mothers were given RhoGAM prenatally imply that the immunoglobulin reaches the baby in measurable amounts. No-one knows what the effect might be on an Rh-negative female fetus who later gives birth to Rh-positive babies.

There is little information on the health risks to volunteer blood donors who must be immunized in order to produce RhoGAM, and there is growing speculation about continuing a routine treatment which actually benefits only a small number of the treated mothers.

Gaskin suggests that the Rh-negative mother who wishes to avoid the use of RhoGAM altogether should avoid any procedures such as external version or amniocentesis that might cause mixing of her blood with that of her baby. Late cutting of the umbilical cord also may prevent some of these sensitizations. While blood incompatibilities have never been a problem in our family, I thank Gaskin and Harmon for sensitizing all of us to the problems inherent in the use of this blood product, which has become the standard of care, despite inadequate testing and lack of information on its long-term risks.

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