



e-Network Forum

CALIFORNIA BLOOD BANK SOCIETY

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Collecting allogeneic units from donors with hemochromatosis?

On October 8, 2000, a member of the e-network requested that blood centers and hospital-based collection facilities respond to the following inquiry.

How many collection facilities considered, plan to, or are already collecting allogeneic units from donors with hemochromatosis (within the FDA framework - i.e., not charging anyone with hemochromatosis, getting an FDA variance, etc)? ***By what percentage do you think your allogeneic collections would increase*** if you were to draw from this group of donors? ***What have your financial analyses/projections shown*** regarding the impact of collecting from all comers without charging (loss, break-even, or gain). If you are a collection facility drawing from donors with hemochromatosis under the new FDA guidelines, what has your experience been so far, in terms of financial impact, impact on collections, etc. If you had it to do over again, would you?

To which the following replies have been received:

1. We are a large HMO, and we have 4 hospital-based donor centers in our Southern California region. One of these centers recently started drawing hemochromatosis donors, after receiving the approval from the FDA, and waiting for the 20th edition of Standards to be accepted. Because we have been collecting these donors free of charge for several years and discarded the units, we cannot accurately assess the increase of cost to us by changing the process. I think it is **a little early to determine what the benefit or operating costs will be**, as we do not know how many of these donor/patients will pass the screening process. Given time to collect data, numbers can be more accurately provided.
2. We have evaluated our **current** therapeutic donors for eligibility and found that **the majority would not qualify as a volunteer donor under a variance**. We may still consider it to attract hemochromatosis patients/donors who are **not** in our system but would qualify. While drawing these donors may or may not be cost effective, with the blood shortages we are having, even 10 extra donations a month would be great. In our initial study with current therapeutic donors, we would lose by not charging.
3. **Until the 20th edition of Standards becomes California State law (January 1, 2001), blood from therapeutic phlebotomy in California may not be used for transfusion**. If the State does not delete this proposed change to Standard, the use of therapeutic blood could be considered in California after January 1, 2001. This topic has been placed on the scientific program for this year's **CBBS annual meeting** to be held May 3-5 in Long Beach, CA. We hope to have a speaker who has implemented such a program, as well as discussions of the pros and cons. The Blood Centers of California Medical Technical Advisory Committee will also be discussing this subject at its meeting later this month.
4. The **American Red Cross**, Southern California Blood Services is **not collecting allogeneic units from donors with hemochromatosis at this point**. Evaluation of ways to meet the FDA framework and the feasibility of doing so in a real-time practical way are ongoing. Change is not likely soon. Various individuals have looked at this question, and it depends on some underlying assumptions that have varied widely between individuals/groups studying this. It is likely that major increases in donor numbers would **not** be seen. There would be some increase in donations, however, and there are varying estimates as to whether these increased donations would offset the costs of the program necessary to meet the FDA framework. In the long run, my hunch is that the extra collections would be at least break even to the costs of instituting the program, but this is still being evaluated.
5. In **Pennsylvania**, we are **not** planning on collecting allogeneic blood from hemochromatosis patients. The question came up at our Medical Advisory Committee meeting as there have been one or two inquiries from hemochromatosis patients. I personally do not feel that this issue has been adequately studied or discussed from safety and logistical standpoints. I remain concerned that access to free phlebotomies may compromise the truthfulness of the medical histories obtained

from these donors.

6. In answer to your questions on taking units of blood from hemochromatosis patients, I can provide the following information: **We do not collect** units of blood from hemochromatosis patients for transfusion even with the new FDA "guidance", and do not plan on doing so in the foreseeable future. **We do not think it would augment our blood supply very much because** about 17% of our autologous patient/donors have **abnormal test results**, about 25% of our hemochromatosis patients **do not qualify** as allogeneic donors, and **many are bled more frequently than every 8 weeks** and at hematocrit levels below 38%. Besides, in our area of California, we have an excess of donations of blood and platelets from our regular, qualified, allogeneic, many time repeat volunteer donors and do not need blood for transfusions from patients. **We believe we would lose money** on units drawn from hemochromatosis patients, primarily because of the losses of units noted above, as well as not being able to charge any patients for phlebotomy whose units would not meet the qualifications of an allogeneic unit. Finally, if the federal government wants to pay for the phlebotomy of hemochromatosis patients, we might consider a program to draw them to see how many would actually be usable for transfusion. I am also **concerned about the "study" we are supposed to do** to show that donations from such patients are not more risky than our allogeneic donations. The marker rate in the former has to be higher than our mainly repeat donors. Unfortunately, the FDA announcement raised the hopes of many patients and we are getting calls from some patients who would like not to have to pay for their phlebotomies. I am **not convinced they would be truthful** if there was an economic incentive to donate.
7. We **do not plan to collect** allogeneic units from donors with hemochromatosis.
8. We **are planning to start collecting** allogeneic units from hemochromatosis patients early next year. We are expecting about a 5-10% increase in allogeneic collections from doing this. We are a prepaid HMO which already does therapeutic phlebotomy without charge so that there will be no financial loss from converting these units to allogeneic units other than the usual costs of allogeneic processing.
9. On the issue of hemochromatosis, we are curious about this ourselves. We currently do not accept them as blood donors, nor have we applied for an FDA variance. Any cost/benefit analysis depends on how many people would come forth and of those, how many we would have to throw away ... information that we do not have. Right now, I guess you could say **we're just taking a wait-and-see approach**. I got my first call from someone in Albuquerque about this issue about a week ago.

Please submit comments to the [e-Network Forum](#).

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Posted: October 19, 2000

Addenda: Oct. 29, Nov. 2, 9 and 10, 2000; Aug. 29 & Sept. 1, 2006



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ADDENDA October 29, 2000

10. I am a retired pediatrician with 30 years of experience at Kaiser Permanente in Harbor City, as well as having been a clinical professor at Harbor-UCLA Medical Center and past chair of the research committee, and chair of the board of directors of the REI. I can see no logical reason why blood banks should not take donations from patients with hemochromatosis, if those individuals have no other contraindications to donation. **I was diagnosed two years ago with hemochromatosis**, after having symptoms of the disease that were missed for over 15 years. I had typical symptoms and had been seen by many doctors at both Kaiser and UCLA. I missed the diagnosis too. Early diagnosis would have saved over half a million dollars in hip replacement surgery, cardioversions, consultations and arthritis treatment, not to mention the pain and suffering I have had. Interestingly, prior to my diagnosis I had given over 80 units of blood to the Red Cross, Kaiser and UCLA. Since my diagnosis I have had nearly as many units of blood phlebotomized and thrown away. Hemochromatosis is not a problem with a donor's blood but one of iron absorption. **There is no logical reason to throw away these valuable units**. One in 200 people in this country have the problem and while most of them are not being diagnosed, this is rapidly changing. I hope that blood banks change their policies to allow individuals who are healthy, except for a genetic predisposition for hemochromatosis, to be regular blood donors. We need such a policy to save this precious product. I do not feel that money is a reason to not take the donation. In most cases insurance pays and in my case Medicare pays between \$300 and \$600 a donation to the hospital lab (our tax dollars at work). Thanks for your interest and I will be willing to help in any way I can.

ADDENDA Nov. 2, 2000

11. **The Rhode Island Blood Center has received a variance approval from the FDA to accept hemochromatosis donors.** We are currently working to implement this sometime early next year.

ADDENDA Nov. 9, 2000

The following comment has been submitted by blood center physician, who attended the recent AABB Annual meeting in Washington DC.

12. As we are pondering how to address this issue, there are **many other issues to consider** besides the ones laid out by the physician who is advocating that we accept people with hemochromatosis. Briefly, they are:

1. Jay Epstein informed membership at the AABB "Ask the FDA" session, that physician evaluation (similar to that required for directed donors who donate whole blood more than once every eight weeks) would apply **to donors with hemochromatosis who donate more frequently than every eight weeks**. This means that a blood center doctor would have **to evaluate** by "touch and feel" such donors on the day of donation. This would present logistic difficulties for both physicians and donors.
2. Jay Epstein also said that the FDA would like **voluntary collection of "safety data"** (not yet defined) on such donors. This adds an administrative burden, should a center choose to collect such data.
3. Plasma **fractionators will not accept plasma** from therapeutic phlebotomies, including those with hemochromatosis. This represents a potential financial loss for blood centers (I don't think anyone would disagree with the importance of blood centers behaving in a financially responsible way).
4. At an AABB workshop (sorry - can't cite which one), legitimate concerns were raised about **whether it was fair/ethical to provide therapeutic phlebotomy services at no charge only to donors with hemochromatosis**, while excluding patients who also could benefit from therapeutic phlebotomy. Blood centers could face problematic **PR issues** as a result.
5. The **increase in blood availability** that would be realized by our center is **quite small** (overall, we collect about 75,000 units of whole blood annually). Based on a review of one hundred donors with hemochromatosis from our center (representing most of our pre-

SafeTrace donors with hemochromatosis), we would have only 120 usable units per year, and we would have to toss almost twice that from donors whose blood would be medically or infectious disease test ineligible for allogeneic transfusion. I have not costed this out yet, but if we broke even, it would only be by a small amount. We may not be representative of other blood centers, but as far as I know we are the only ones who have done this kind of detailed evaluation.

6. It is not known **how many patients, who now are phlebotomized in hospitals or their doctors' offices would begin coming to blood centers for the free service.** It is certainly possible that many of these potential donors would not qualify to serve as allogeneic donors. So this is a bit of a wild card and **could add to the financial risk** that blood centers would incur by offering "free for all" services."

13. **AND YET ANOTHER PHYSICIAN RESPONDS TO THE ABOVE REMARKS** Nov. 10, 2000

1. Each blood center submitting a variance may decide what to apply for. Our variance requested that donations more frequently than every 8 weeks prescribed by a **referring** physician **not require a physician examination.** However, **self-referred** donors presenting more frequently than every 8 weeks **would** require a physician examination.
2. Our data will consist of **infectious disease testing** information.
3. **Each center** would do well to **check with the specifications of the plasma fractionator.** The ZLB states that donor selection shall be performed according to FDA-approved procedures and for centers that receive variances, the hemochromatosis donor has been FDA-approved. These donors are **no longer therapeutic donors.**
4. I **agree** with this concern so our variance provides free phlebotomy regardless of diagnosis.
5. **This number may differ from center to center.** We collect about 70,000 annually. At our center based on phlebotomies over the last 2 years I estimate about 280 additional donations from 68 individuals. Based on pre-safetrace information and deferral information, we can add 270 new eligible donors. In addition, there may be hospitals in your areas performing phlebotomy and if you apply and receive a variance, there may be unexpected numbers of individuals who will be eligible to donate. My view is that **even if we only break even, but we improve the blood supply, it's worth the effort.**
6. Yes, this is true. We will see what happens. At this time, we are gearing up for implementation of the variance.

Maybe next year we will be able to present our experience.

AND ANOTHER ... Nov. 10, 2000

14. "Based on lack of true gain of a significant amount of donations and logistical problems, **I don't think it's viable** to begin accepting patients with hemochromatosis for donation."

ADDENDA Aug. 29, 2006

15. **An otherwise healthy adult male in California asks if he can be a blood donor,** even though he is currently undergoing periodic **therapeutic phlebotomy** to prevent the organ damaging effects of **hemochromatosis.**
The following link, <http://www.fda.gov/cber/blood/hemochromvar.htm> lists blood establishments that have been granted approval for a variance to 21CFR640.3(d) and 21CFR640.3(f) in order to collect blood and blood products from patients with hemochromatosis. The federal codes mentioned in the variance are:

21 CFR 640.3(d) - blood withdrawn in order to promote the health of a donor otherwise qualified under the provisions of 640.3, shall not be used as a source of Whole Blood unless the container label conspicuously indicates the donor's disease that necessitated withdrawal of blood

21 CFR 640.3(f) - a person may serve as a source of Whole Blood more than once in 8 weeks only if at the time of donation the person is examined and certified by a physician to be in good health, as indicated in 640.3(b).

ADDENDA Sept. 1, 2006

16. **A colleague at the Pacific Northwest Region of the American Red Cross** reports that they have received a variance from the FDA to collect these units, and that they have **implemented the process successfully.**

17. **The editors** note that the following publications may be germane to this discussion:

- Leitman SF, Browning JN, Yau YY, Mason G, Klein HG, Conry-Cantilena C, Bolan CD. **Hemochromatosis subjects as allogeneic blood donors: a prospective study.** Transfusion. 2003 Nov;43(11):1538-44.
- **Comment on the above publication:** Newman B. Hemochromatosis blood donor programs: marginal for the red blood cell supply but potentially good for patient care. Transfusion. 2004

Oct;44(10):1535-7; author reply 1537-8.

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