



e-Network Forum

CALIFORNIA BLOOD BANK SOCIETY

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If a CBC before plateletpheresis reveals an abnormal WBC count, should the donor be deferred?

A blood bank physician works at an institution in Southern California that analyzes a **CBC before each plateletpheresis donation** in order to check the hemoglobin (which must be at least 12.5 gm/dl) and a platelet count (which must be at least 150,000/ μ l if < 4 weeks from the last collection). However, the CBC ALWAYS **includes a WBC count**, and if the WBC count is outside of a predetermined range, (the acceptable WBC count for prospective platelet donors at this institution is 4,000-10,000 WBC/ μ L), the donation is deferred. The institution has based the above acceptable WBC range on an analysis of 50 normal volunteers, when they installed a new hematology analyzer and set +/- two standard deviations from the mean WBC as the normal range. They lament that they are stuck with a WBC value for all specimens on which they run a CBC, and that they are deferring plateletpheresis donors as a result of this policy. The member's institution has found this policy to be restrictive, and the inquiring blood banker wanted to know from the e-network what the "standard limits of the community" are for acceptable pre-donation WBC counts. The institution also checks the platelet count prior to each collection to see if they can collect a double or triple product on their Trima.

In response to the above question, **two other institutions reported that they also use a WBC count to guide acceptability (and deferral) of plateletpheresis donation**. Here is what these institutions report as their practices:

One institution (located in **Northern California**) uses instrumentation that also automatically gives a WBC count with each CBC. That institution has a range of "normal" decided by a similar mechanism as the inquiring institution. If a donor falls outside the acceptable WBC range, **the Medical Director (or designee following prearranged criteria) evaluates the donor to see if there might be an exception to deferral of the donor**. Since almost all of the plateletpheresis donors at this institution are multi-time donors, the collection center personnel look at the **pattern** of the prospective platelet donor's WBC counts. Since using a +/- two SD normal range results in a predictable number of normal donors being a little above or below "normal", repeat donors are accepted if their prior results show consistent values over time. In addition, this institution collected data on WBC counts done (at a time when they were doing only post counts) and had differentials done on the high counts in allergy season. They found 100% correlation between high counts, and a donor reporting a **history of allergic symptoms** and significant eosinophilia. Subsequently, they added to their criteria that a count up to 15,000 WBC/ μ L was acceptable when the donor history indicated that the donor was currently experiencing allergic symptoms (hay fever, etc.). On the other hand in the course of 10 years of paying attention to the incidentally reported WBC values, they identified one donor who had an undiagnosed leukemia and another donor who had an early bacterial infection. Both of these unhealthy donors had counts that were above 20,000 WBC/ μ L.

A second institution (located in **Texas**) indicated that they have been using Baker instrumentation for several years. They also use a WBC count to qualify plateletpheresis donors. When they implemented the Baker, they performed a reference range study on over 500 donors, and they were able to get a wider range than the one provided by Baker (the person reporting for this institution thinks that the Baker range is 4,000-10,000). Also, for very regular platelet donors, they follow the WBC over time, and **if they note that a specific donor runs a WBC above the Baker mean** (say in the 9,000-10,000 range), then they will use the donor's cumulative record of WBC counts to calculate a donor-specific WBC count range. (They will not calculate a donor-specific mean and range based on only a few WBC data points; they require at least 5 WBC count readings extending over a two-year period, but usually have several data points. During the period when they are collecting data to perform a donor-specific WBC mean and range, they discard any donations for which the WBC count is greater than the Baker reference range). They have a few donors who routinely run a WBC count mean in the 9,000-10,000 range; if these donors have even a minimal elevation, then their WBC count may rise above the upper cutoff of the Baker. By having a donor-specific mean and range, this institution is able to use donations slightly above the Baker WBC cutoff. They have followed some of these donors for years and they comment that it is remarkable how stable the WBC counts remain are over time. For donors whose individual WBC

mean runs above the upper cutoff for the Baker, they usually **require physician intervention** to demonstrate that there is not a pathologic cause for the elevated WBC. Using this approach they only defer an occasional donation because of an elevated WBC count.

The above practices were **referred to experts** in the blood banking community. The responding experts are both involved with the AABB Standards Committee and at least one of these experts is involved with the publication of the Technical Manual. Here is what they had to say:

Expert #1: This expert **knew of no standard that requires WBC testing** as a eligibility criterion for plateletpheresis donation. The only Standard that this expert could think of that might come close to applying was 5.5.3.1 ..." The donor shall be tested appropriately to detect a developing cytopenia...." The expert went on to comment that she did not know how much of the above testing is being performed because of regulations or perceived regulations, and how much is being driven by instruments that give CBC results whether you want them or not.

Expert #2: This expert was **unaware of any AABB Standard** that would require donor deferral, notification or withholding a product if a WBC count was "out of range." However, the expert was quick to add that in his opinion, **there is an ethical imperative to contact a donor in the event that a result (whether you wanted to see it or not) is "medically significant."** For example, since the normal range for absolute PMN concentration is down to 1.5K in African Americans, it would be ill-advised to contact every donor with a WBC between 3-4K, as that might well be "normal" for a certain population group. This expert wrote a chapter on the ethics of donor testing (UNAVAILABLE 9-22-03), which he felt would be of value to the e-network to look at, in regards to the current discussion. That chapter discusses the ethical imperative of contacting a donor with a medically relevant result.

In addition to the above solicited opinions, several other blood bankers and pathologists submitted responses:

1. **A pathologist from Texas** wanted to know what was the medical reason to defer someone as a blood donor, merely due to a WBC count of 2500/ μ L (which is not an infrequent count in subjectively healthy people, especially African-Americans)? He went on to ask "Is this a rational criterion, or just blood banker paranoia"? Further, he suggested that a TOTAL white count has limited medical value without knowing the categories of white cells that are abnormal in amount.
2. **A blood banker in Seattle** commented that there are no requirements for doing a WBC count for platelet donation, either by AABB standards or the CFR. His donor center does not do WBC counts to determine eligibility of plateletpheresis donors. He points out that by setting stricter requirements, one is forced to live with them. The lesson to be learned is to give yourself as wide a tolerance limit as is safe and possible.
3. The **medical director of a large community blood collection center in Southern California** commented that his center only runs platelet counts on plateletpheresis donors (plus all the other FDA mandated testing).

ADDENDUM June 25, 2001

4. **A blood banker in Alabama** comments that he hadn't heard of using a WBC count as a criteria for platelet donation. He thinks that the WBC count should be considered as any other subjective or objective bit of evidence attesting to the donor's state of health. He commented that WBC counts are representative only of mid-stream venous flow and that many (50%?) of the circulating WBCs are marginalized to the periphery of the venous flow. Also, the ranges vary seasonally as well as with smoking, steroids, etc. He believes this is a case where the normal range definition of mean +/- 2SD is irrelevant, and the reference range (not "normal range") if it is to be used to defer patients, should be based on the value of the WBC count in determining the overall health of the patient.

ADDENDUM June 29, 2001

5. **A blood center in Southern California** reports that they used to use a WBC count between 4-10,000 for a number of years, but also found it somewhat restrictive, so they **increased the acceptable WBC count to 12,000**. According to the medical director, this has resulted in substantially fewer "false positive" deferrals, without, in their estimation, sacrificing recipient or donor safety.

ADDENDUM July 6, 2001

6. A European participant of the e-network commented that at the transfusion service at the Medical School of the **University of Vienna**, Austria they specialize in the collection of platelets by apheresis (8000 units/year). At their institution they use the ABBOTT counter that automatically gives a WBC count and differential count with each CBC. The CBC is measured before and after the apheresis procedure. According to the Austrian Health Authorities, plateletpheresis is **acceptable if**

the WBC is in the range between 4-12x10³/μl blood. Further acceptability criteria include Hb (> 12g/L) and a platelet count >150x10⁹/L. If a donor does not meet these criteria at a single donation, the donor is excluded from donation, and the CBC is **re-evaluated one week later** (which is possible in most of their donors, as the majority of our donor population are multi-time donors with a donation frequency of >12 per year). According to these guidelines, the short-time deferral rate of donors at a single donation is in the range of 1-2%. The range can be explained by seasonal variation WBC and/or seasonal variations in the incidence of common viral diseases. In addition, particularly in younger donors they identified **sporting activities** performed within two hours before donation as a sometimes under evaluated reason for leukocytosis. They therefore give their donors the advice, not to perform any sport activities at least 4 hours before plateletpheresis. If a donor is deferred from plateletpheresis, in nearly all of the donors re-examination of the WBC counts one week later show a return to normal values, and the donor is accepted for further donations. However, if a leukopenia < 4x10⁹/L or leukocytosis > 12x10⁹/L persists even after two control examinations, the donor is transferred to an hematologist for further evaluation. One point to the differential blood counts: Particularly in spring they see an increase in the number of donors expiring a significant **eosinophilia** (> 10% eosinophils even with WBC counts < 12x10⁹/L), most likely due to an allergic response (hay fever, etc.). Although the donors are not deferred from donation, the platelet product is plasma-depleted before transfusion in order to reduce the possibility of a passive IgE transfer to the recipient.



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Addenda: June 25, 29 & July 6, 2001