



e-Network Forum

CALIFORNIA BLOOD BANK SOCIETY

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Use of NAT-untested platelets during severe shortages

As you recall, a transfusion service in Saint Louis asked the e-Network membership for feedback regarding experience with the use of NAT untested platelet products during times of severe platelet shortages. The Saint Louis transfusion service was recently faced with severe platelet shortages and their local blood supplier was unable to provide enough NAT negative platelets. In order to deal with the shortage situation, the **local blood provider requested the hospitals that it serves to agree to a protocol for release of NAT untested platelet products during severe blood shortages.** However, **in the event a hospital refused to agree to the protocol, a written 'exceptional release' document would be sent to the hospital along with each NAT untested product.** This document would need to be signed by the Blood Bank Medical Director. The e-Network membership was asked for its opinion/experience regarding this situation.

Here are the opinions that were submitted:

Opinion/experience #1: Ever since NAT testing started, Red Cross deliveries to our hospital have arrived later than usual, often causing us to substitute pools of Random Donor Platelets for Single Donor apheresis platelets. This substitution has been necessary in order to transfuse patients while the Outpatient Transfusion Service is open. As Medical Director of our Transfusion Service, **I have signed Emergency Release forms** for Red Cross to send us NAT untested platelets. I have not be "caught" with a NAT positive unit yet, but it's only a matter of time before this situation gets us in a predicament.

Opinion/experience #2: We have an internal protocol to release NAT untested components, either because of urgent inventory need, or because the sample was not sufficient and it will never be NAT tested. Of course, all the FDA required tests are done, and negative, otherwise the product would not be released. After NAT becomes mandated, we will not be able to do this, but for now, it is still an investigational test. A Medical Director has to sign and justify each time a NAT untested platelet product is released.

Opinion/experience #3: We have an exceptional release procedure with justification forms filled out at our facility and by the requesting physician. Under ordinary circumstances all test results are completed within 24 hours. Occasionally, run failures in either EIA or NAT will delay release, putting pressure on platelet inventories. We, however, **have not had to use exceptional release protocols since instituting NAT release requirements.**

Opinion/experience #4: We have signed a letter with one of our blood suppliers which allows them to send NAT untested products, if they must, for our use. This negates the need for a specific letter with each and every event. Until all the wrinkles are worked out with NAT (it is still under an IND) there will be times (albeit very infrequent) that NAT untested products must be used. All such cases should, obviously be documented. This scenario also infrequently occurs with the apheresis platelets we collect in our donor room when the lab doing the NAT has a failed run or problem with a run. **We must then potentially release and possibly transfuse platelets prior to NAT results being reported. This has occurred twice in the last 2-3 months.**

Opinion/experience #5: I think that the Red Cross regions have been required to handle NAT issues, as described by the Saint Louis transfusion service. The approach used should be similar for any hospital supplied by the ARC. **Our blood supplier, requires us to sign an exceptional/emergency release document, for each product.** There is also a space on the form for the name of the patient's physician, too. I also have the patient's physician acknowledge their responsibility. This is **a rare event here**, and our blood supplier has had a very good turnaround for NAT for quite a while.

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Addenda:

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