Donor deferral registries: an ineffective system whose time is passed

Donor deferral registries (DDRs) were initially set in place at blood collection agencies, and at the state level in some areas, in the 1970s. The intent of having DDRs was to detect individuals who should not donate blood, blood components, or plasma whether due to risk factors, known transfusion-transmissible infections, or reactive blood screening results. There were never any data to support or prove the efficacy of DDRs in deferring donors whose blood or components might pose risk for patients. There was simply a belief that DDRs would make blood transfusions and plasma derivatives safer, at a time when we had only one, not very sensitive, test to detect carriers of the hepatitis B virus (HBV), the hepatitis B surface antigen (HBsAg) test. Unfortunately, to eliminate DDRs, we seem to need to provide data to show their lack of efficacy.

In this issue of **TRANSFUSION,** Cable and colleagues[1] present the results of use of the American Red Cross (ARC) DDR to interdict first time donors, found to have a repeatedly reactive (RR) screening test for human immunodeficiency virus (HIV), hepatitis C virus (HCV), or HBV, from a subsequent donation. Although they titled their article, "Limited effectiveness . . . ," I believe that they showed no efficacy of the ARC DDR itself to prevent the transfusion transmission of HIV, HCV, and HBV. Potentially infectious donations from the next visit of the first-time donors with RR tests for the three viruses were not exclusively prevented by their DDR. With the manifold means currently in place to make the blood supply very safe, it is time to abandon DDRs. DDRs only had perceived efficacy, not proven efficacy; we now have some proof of their lack of effectiveness.

The potential value of a DDR to prevent collection or release of a unit from a deferred donor is dependent on two major factors. First, there must be specific identifiers for donors and, second, the deferred donor must return to the collection agency, or attempt to donate in the same state with a statewide DDR, where he or she was deferred. The social security number (SSN) has been used as a unique identifier by blood centers for years but it is not required to sell plasma or be a blood donor. Further, with concerns about identity theft and privacy, many are reluctant to provide their SSN. Without this unique number, a deferred donor whose name changes, for example, due to marriage or citizenship, living at a different address, especially if in another state, could return to a blood collection agency that had him or her on a DDR and successfully donate. A deferred donor at one center or agency could donate at another unrelated one in the same area, or in another state where there is not a state DDR, as California used to have. In either case, persistence of a true-positive infectious disease marker picked up by the center's testing laboratory would be the only way to prevent transfusion of a potentially infectious unit.

Cable and colleagues stated that "a relatively large number (1.2%) of . . . test-deferred donors returned . . ." Actually, 98.8 percent did not! Therefore, the vast majority of donors with a RR test for HCV, HIV, and/or HBV did not attempt to donate again to the ARC. If we presume that the 1.2 percent who did return to donate a second time had received notice of their deferral, and understood it (regarding their deferred status and its reason), we still do not know if they returned because they did not believe their RR results and/or wanted a repeat test. This scenario may have been especially true for those with an unconfirmed, indeterminate, or falsely reactive test result. Some may have even been accidentally recruited again.

False-positive tests represent a real challenge for blood centers. The concept of a false "positive" test result is not always appreciated by patients' physicians, let alone lay individuals who perceive themselves as healthy when they present to a blood collection agency. When notifying a donor of an RR (i.e., reproducibly) positive test, which does not confirm, one must convey the mixed message that the result is likely inconsequential, but nonetheless is grounds for indefinite, usually permanent, deferral as a blood donor. This message is confusing and seems contradictory. The donor is often even more confused when similar testing by his or her own physician is negative or other testing reveals no apparent pathology. Some donors and their physicians often conclude that testing at the blood center is inaccurate. Such an impression may prompt a deferred donor to try to donate again at another center, or even the same center, to see if the false test persists. This pathway assumes that the deferred donor is not so turned off that he or she will not even attempt to donate again and will not tell others about the

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TRANSFUSION 2008;48:6-7.

unsatisfying experience, discouraging potential donors from attempting to donate blood or blood components.

DDRs require time and effort to maintain and use. Blood centers are hard pressed to do all that is required of them today, besides using the DDR. Resources are consumed by DDRs, which could be better allocated to tasks which do positively impact the safety of transfusions. Between the California State Donor Deferral Register and the blood center's in-house DDR, almost a full-time equivalent was occupied at the blood center that I directed for years. This time allocation did not count time talking to upset donors and their physicians and trying to clear possible matches, to remove deceased individuals, and to correct errors on the state DDR. Insufficient identifying information and common names, coupled with only 365 birthdates, would make some apparent "matches" especially troublesome, delaying, and even preventing, release of units that were otherwise satisfactory in every other aspect. In California, physicians were to report patients with hepatitis or AIDS to the DDR (without identifying the disease), but not always with sufficient identifying information nor with an SSN; blood centers were to report donors implicated in a case of transfusion associated hepatitis whether deferred indefinitely (single donor involved) or not (one of more than a single unit to a recipient diagnosed with viral hepatitis after a transfusion).

Some readers of the report by Cable and coworkers could take a different view of these data and suggest that we need to implement a comprehensive nationwide DDR involving all plasma and blood collections to achieve efficacy. Although this process might enhance the limited efficacy of the disconnected system of DDRs currently in place, the costs of such a system would be large and not worthy of the effort in my opinion. We have multiple layers in place to help ensure the safety of the blood supply today. DDRs are not one of them and never had proven effectiveness. Thanks to Cable and coworkers we now have some excellent proof of lack of efficacy of DDRs; therefore, they should be eliminated. If we want to make transfusions even safer, from the known blood-transmissible agents,[2] as well as emerging ones, then the next logical step is to implement pathogen inactivation as soon as methods are licensed and available for individual components.[3,4]

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REFERENCES

1. Cable R, Musavi F, Notari E, Zou S; ARCNET Research Group. Limited effectiveness of donor deferral registries for transfusion-transmitted disease markers. Transfusion 2008; 48:34-42.
2. Satake M, Taira R, Yugi H, Hino S, Kanemitsu K, Ikeda H, Tadokoro K. Infectivity of blood components with low hepatitis B virus DNA levels identified in a lookback program. Transfusion 2007;47:1197-205.
3. Klein HG, Anderson D, Bernardi M-J, Cable R, Carey W, Hoch JS, Robitaille N, Sivilotti ML, Smaill F. Pathogen inactivation: making decisions about new technologies—preliminary report of a consensus conference. Vox Sang 2007;93:179-82.
4. Nussbaumer W, Allersdorfer D, Grabmer C, Rheinschmidt M, Lin L, Schönitzer D, Lass-Flörl C. Prevention of transfusion of platelet components contaminated with low levels of bacteria: a comparison of bacterial culture and pathogen inactivation methods. Transfusion 2007;47: 1125-33.