



e-Network Forum

CALIFORNIA BLOOD BANK SOCIETY

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Experience with the Electronic Crossmatch?

Consultants advised an e-Network member that his laboratory might realize potential saving from implementing an electronic crossmatch (E-XM). The e-Network member wanted to know if anyone had experience with an E-XM, and if so, what were the benefits and the problems associated with using this test?

The following information has been provided:

1. A **blood banker from Florida** reports that his institution has been using the electronic x-match in their regionalized compatibility testing since 1993. They perform over 100,000 crossmatches annually, 98% of them electronically (2% require serologic crossmatch due to history of, or presence of, clinically significant alloantibodies). Their system wide C:T ratio is 1.2 to 1.3 They have not had an acute intravascular hemolytic transfusion reaction since its use. According to the responding member, **the system allows people to focus on the real important things**: careful assessment of blood samples received, ABO/Rh typing, antibody screening, prior transfusion history, etc. instead of "shaking more tubes". **Cost reductions** were achieved by the reduced number of staff required, the reduced technical qualifications required to crossmatch electronically, drastic reductions in blood units tied up in the crossmatched blood inventory, reduced blood ordering practices (since the turnaround time is shortened), and less paperwork involved. Since this member's institution was among the "pioneers" to implement an E-XM, they had to develop their own software. The process of getting **FDA clearance** took a nightmarish two years, required sending "half a truckload" of validation materials, and a myriad of back and forth communications. The responding member understands that the process has been streamlined now, and has become a lot easier to implement. Since this member's SOPs are copyrighted, it would violate their copyright policy to distribute them in a public forum such as this. They are provided to institutions that engage this blood center for consulting purposes. There are **very few** disadvantages to using an E-XM, so long as the system is built with a strong logic, but at the same time allows for flexibility dealing with customized ("boutique") services, such as autologous and directed donations, HLA-matched, CMV-negative, irradiated, etc. **A great advantage** of such a system can be the prevention of the inappropriate release of components (e.g. allogeneic units, when there are autologous units available). It is important to have good backup systems, in the event of unplanned periods of computer downtime. Overall, this member believes it is worth the effort and investment.
2. A **blood banker in Las Vegas** commented that his facility has used an electronic crossmatch, and before that a "records-check only crossmatch" at multiple hospitals for many years. The responding blood banker has volunteered his blood bank supervisor, Dhyana Krampetz, who works at their central laboratory, to discuss their protocol with anyone interested (800-433-2750, extension 3239) and would also share their methods and procedures. An on-site visit in Las Vegas to see their electronic crossmatch in action is also a possibility.
3. A blood banker in Michigan suggests that the e-Network Forum might find the following articles helpful.
 - Butch SH et al. Electronic verification of donor-recipient compatibility: the computer crossmatch. *Transfusion* 1994.
 - Judd WJ. Requirements for the electronic crossmatch. *Vox Sang* 1998.
 - Judd WJ. The electronic crossmatch: an alternative to the immediate-spin crossmatch to detect ABO incompatibility. *Advance* 1998;10(15):16-23.
 - Butch SH, Judd WJ. Experience with the electronic crossmatch: errors and suggested improvements. *Transfusion* 1995;35(S):25.

The **Advance** article gives details of **filing for variance** to the CFR, and the extent of the **validation data** required. A **monograph** written by John Judd on "Issues in Implementing an Electronic Crossmatch" is currently available from Ortho Clinical Diagnostics. As far as the filing of variance requests, **the FDA indicated** some two years ago that it was going to change wording in the CFR that would essentially **eliminate the filing requirement**. To the responding member's

knowledge, he is still waiting for this to happen. Even if it were to happen, facilities would still need to have detailed validation data available for review at their next FDA inspection.

4. An e-Network Forum member who works in the **Pacific Northwest** reports that she recently had the opportunity to speak with Mary Ann Denham of the **FDA** about the filing requirement for the E-XM. According to this conversation, the document eliminating the need to apply for a variance to perform electronic crossmatch would be signed "any day". The e-Network is encouraged to watch the FDA web site for the update, should it occur.
5. A **university hospital in Northern California** has utilized an electronic crossmatch for many years. They originally used Western Star, and are now using Cerner as their Lab Information System. They report that the system is **extremely reliable**. The major advantage is the ability to issue an unlimited number of units quickly once the initial antibody screen is done (and found to be negative). Other advantages are that there is essentially a 1:1 crossmatch to transfusion ratio since you do not need to "crossmatch" units until they are needed. This keeps blood available in inventory for all patients until actually needed by a specific patient. The **major limitation** of the system is that they had to design their own computerized check that reviews the patient's serologic history to determine whether the patient is eligible for electronic crossmatch, since this was not specifically built into the Cerner system. The responding member refers e-network members to published articles that review the use of electronic crossmatch:
 - [Butch Sh and Oberman HA](#). The computer or electronic crossmatch. *Transfus Med Rev* 1997
 - [Butch SH et al](#). Electronic verification of donor-recipient compatibility: the computer crossmatch. *Transfusion* 1994 (same as #3, above)

In addition to the technological considerations, the reporting member urges the e-network forum to also **consider how to recover costs**, as a facility may lose revenue as a consequence of implementing an E-XM.

6. A **technologist** wrote that in her experience, electronic crossmatching **can permit a laboratory to reduce the number of FTE's (and the budget for salaries), but that such a reduction is not automatic**, and should not be done without careful thought. She points out that **if the lab staff cross cover** multiple areas of the lab, as well as the blood bank, the lab might **not** be able to reduce their blood bank staffing without affecting 'overall' lab performance. The responding member manages two medium-sized transfusion services, and she formerly managed a large transfusion service; all sites use electronic crossmatches. At the large institution, they were getting some pressure to go to a computer system, which (at the time) did not have an electronic crossmatch module. It was calculated that 4 FTEs would have to be added if the electronic crossmatch was dropped, to perform the additional serologic testing (immediate spin XM) and handling units. (As a result, the lab stayed with the system that allowed E-XM). When electronic crossmatching was implemented at her 2 current institutions, the institutions were able to decrease their FTE total by 2 each. At all sites, they have had no electronic crossmatch induced errors (human errors are another story).
7. An **e-Network member in Uppsala, Sweden** wrote that at his University Hospital they have used an "electronic crossmatch" **since 1983**. The procedure was published in [Vox Sang 1997;72:162-168](#) . According to one of the authors of the report, the paper offers a summary of the **experience of 12 years of continuous use** of the procedure, which (according to the author) has been very favorable. The author's institution calls the procedure ABCD-test (antibody screening, computerized delivery). In their minds it is **considerably safer than regular antiglobulin crossmatch**, because they find more antibodies and use a computer to check the delivery. In addition, the responding member states that it is **much less expensive**, and supports a 24 hour-a-day service. The procedure was developed in their laboratory and it is now the regular procedure all over Sweden. According to the responding member, the reason for waiting 12 years with publication was that the authors wanted to have real solid experience. During the period they used three different procedures for antibody screening and have stayed with the last procedure in the paper: the Dia Med ID Micro Typing System, which they have been found very reliable. The computer system has also undergone refinement. They are convinced that this is **a system that is superior to the traditional serologic crossmatch and saves money**.

ADDENDA Aug 7, 2001 **FDA Final Rule just announced!**

8. A **blood banker in Northern California** writes that if she understand the FDA final rule correctly, the amended CFR will now permit the use of electronic means to determine compatibility without the need to apply for a variance. The CFR wording on Compatibility Testing (item II-A in the Final Rule) has been changed from a requirement of "testing" to determine compatibility to "procedures" to determine compatibility. Members of the e-network who are considering implementing an electronic crossmatch might want to verify with the FDA that this member has interpreted the final rule correctly.
9. A similar interpretation was made by a **semi-retired ARC Medical Director in Northern California**:

Section 606.3(j) will define compatibility **testing** to mean "**procedures performed** to establish the matching of a donor's blood or blood components with that of a potential recipient" **and Sec. 606.151(c)** will require standard operating procedures for compatibility testing to include "procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type." To me, this sounds like what was being referred to as "eliminating the need to apply for a variance" by respondent #4 above. **Incredible timing!**

ADDENDA Aug. 9, 2001

10. A **member in Michigan** affirms that **effective September 5th, 2001 (per the FDA Final Rule above) the use of an electronic crossmatch is permitted.** § 606.3(j) defines compatibility testing to mean "procedures performed to establish the matching of a donor's blood or blood components with that of a potential recipient" and § 606.151(c) will require standard operating procedures to include "procedures to demonstrate incompatibility between the donor's cells and the recipient's serum or plasma type." (**Note:** this means that facilities are no longer required to apply for a variance from the FDA, but still will be required to keep the necessary **validation data on file** at the facility).

11. And this just in, from the **Director of Regulatory Affairs, AABB:**

"What a coincidence. The FDA published a final rule on on Aug. 6 that will permit electronic crossmatching without submitting a variance. However, it is important that they still do the necessary **validation** because they will need to have it on file. They just don't need to submit anything to FDA in advance. See AABB Pulse Points 474 issued August 6."

ADDENDA Aug. 15, 2001

12. **More** from the [Director of Regulatory Affairs, AABB:](#)

"While this FDA rule applies only to licensed facilities, it permits reporting of electronic crossmatches under Annual Report, which is considered a minor change. Thus **it must be reported to FDA in your next annual report after you begin doing it.** It is no longer included in the most restrictive category, Prior Approval Supplement (PAS) that would require FDA approval **before** you could begin doing it."

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Posted: August 6, 2001

Addenda: Aug. 7, 9 & 15, 2001