



e-Network Forum

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Can We Use Lidocaine for Numbing a Donor Phlebotomy Site Without a Physician's Prescription?

As you may recall, a member wrote that lidocaine was being used to numb the phlebotomy site of whole blood and apheresis platelet donors, in order to alleviate the pain and anxiety of the big bore donor needle. However, the lidocaine was being injected without a physician order. Recently, the administration of this member's institution **questioned the wisdom of not having a physician order for the lidocaine (since it is a prescription drug) prior to injecting a blood donor with lidocaine**, even though the use of the lidocaine was detailed in the donor program's SOP. The inquiring member indicated that several neighboring facilities collect blood donations with the aid of lidocaine injections, but without a specific physician order. In spite of the local practice of other hospitals, the Administration at the member's institution insists that a physician's order must be obtained prior to injecting lidocaine, and that the donor program SOP must be updated to reflect this requirement. The inquiring member asked other institutions who use lidocaine to numb the donor phlebotomy site without a doctor's order, if they were doing this practice with the knowledge and approval of their administration.

To which the following replies were received:

1. One member indicated he was **not aware of literature that validated the use of lidocaine or EMLA cream on blood donors with respect to the effects that numbing lidocaine might have on the purity, potency or safety of the blood products that derive from a lidocaine assisted donation**. In other words, he is not certain that a blood product would meet the **FDA's requirements** for safety, potency and purity, if a product is obtained using a phlebotomy site that was 'prepped' with lidocaine. This member would like to use lidocaine or Emla cream on donors, but he has had to back off implementing the use of the drug, based on the above concern/consideration. Furthermore, putting aside the issue of safety, potency, and purity of a lidocaine assisted donation, the member comments that the need for a physician order for lidocaine could probably be met in much the same way as his institution approaches the collection of "double" red cells and plasma. The member's institution administers IV fluids (saline) to donors of double red cells and plasma, under a **blanket order from a physician**.
2. A **second** member commented that his institution (which collects many hundred thousand donations annually) does not use lidocaine to assist donations. This member comments that a **prescription medication such as lidocaine could only be given under the order of a physician**. The labeling of prescription drugs lists that as a requirement. The member cautions that others should be careful in administering a prescription drug without a physician's prescription/order.
3. A **third** member (who works in a **hospital** setting) commented that at her hospital, the nurses are permitted to use intradermal lidocaine on 'patients' **prior to the insertion of IV catheters** (for administration of IV fluids). It is not an uncommon practice for the nurses at this institution to use lidocaine **prior to obtaining a physician order** (since the lidocaine is a standard ward stock item) and to obtain a physician order 'after the fact'. In fact, most of the nurses actually prefer to use topical lidocaine (Emla cream) or topical ethyl chloride to prevent 'sticking' the patient an extra time. Ethyl chloride is also a ward stock item, so the nurses will often obtain a physician order for this item after the fact. Emla cream, on the other hand, is only dispensed by the pharmacy and is a patient chargeable item; the pharmacy will not dispense Emla cream without an MD order.
4. A **fourth** member commented that it appears that the Administration at the inquiring member's institution is viewing lidocaine as a prescription drug and, as with any prescription drug, prescription "logistics" would apply to each donor who receives the drug, i.e., a physician must approve the prescription. In today's litigious environment, it may not be such a bad idea to proactively minimize chances of litigation. For example, the member who submitted this reply suggests that each institution using lidocaine to numb donor phlebotomy sites should **ask their donors** if they want to be injected with the lidocaine rather than telling the donors (something to the order of) "we are going to inject you with lidocaine which would reduce the pain from the insertion of the needle" This

member is **unaware of any specific Biologics rule or regulation** that specifies the need for a physician's order for the use of lidocaine to minimize pain for donor blood / blood product collection. However, the **California Business and Professions Code, Sections 4015 through 4043**, implies that **prescription drugs must have a specific order for use by a specific patient** who, in turn, has the "right" (upon request) to receive a legible, clear notice of the condition for which the drug is being prescribed. Also, it is noted that the context of these regulations are in the **"healthcare" setting** and one may disagree with their applications in a **Biologics environment** where the "donor" is not ill nor is the donor considered a "patient". One may approach the signing of the facility's SOP as "documented" evidence that the physician has "approved" the routine use of the lidocaine. Consider the **cost** of litigation and consider the cost of implementation of extra documentation. As "routine" as the use of lidocaine may be, the **bottom line is that it still remains a prescription drug and the medical logistics that follow all prescription drugs may still apply.**

ADDENDUM April 19, 2001

5. An e-Network Forum member (who is a medical director of a community blood donor center) commented that during an **FDA inspection** of her center several years ago, the practice of using lidocaine during arm preparation was questioned. The inspector made no observation pending an opinion from CBER. The medical director states that eventually the FDA issued the following letter to the facility:

"Your submission of May 14, 1996 to supplement your product license application for Whole Blood to include a revised Standard Operating Procedure for the use of lidocaine during arm preparation in your facility, has been **reviewed, accepted and placed in your file.** **Please note that the FDA discourages the routine use of topical or intradermal anesthetics because of the possibility of allergic reactions in donors. In addition, the FDA recommends that the lidocaine injection occur before arm preparation to ensure that cleanliness around the intended venipuncture site is maintained.**" Signed by Mary Gustafson for Dr. Jay Epstein.

The facility medical director goes on to say that they have had a much greater issue with the fact that in California some consider the injection of lidocaine to be within the scope of the **Nurse Practice Act**. According to this medical director, if a donor wants to have lidocaine to numb the pain of the big needle insertion, but is being drawn by an unlicensed member of the collection staff, a licensed staff member needs to be called over to inject the lidocaine and then let the phlebotomist finish the procedure. While this medical director does not necessarily agree with the interpretation that the injection of lidocaine falls within the scope of the Nurse Practice Act, she has chosen not to take on that battle.

The issue of whether or not a physician's order is required for each injection of lidocaine was also handled when questioned in the course of inspections by both the AABB and the FDA. As the Medical Director of the facility, this member reports that she has a **"standing order" for lidocaine with the criteria for which it is used** (requested by the donor without prompting by donor room staff, no allergy to lidocaine, intradermal injection, skin inspected and appropriate for phlebotomy). The standing order is renewed annually. The facility's stock supply of lidocaine is obtained from a local pharmacy with a written prescription from the facility medical director. This is similar to the practice in many hospitals where patients undergo chronic therapy.

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

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