



Fluorescein Angiography: Preventing and Responding to Complications

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PURPOSE OF RISK MANAGEMENT RECOMMENDATIONS

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement these risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology's *Preferred Practice Patterns*, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. If legal advice is desired or needed, an attorney should be consulted. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

Version 3/29/07

Fluorescein angiography (FA) is a diagnostic procedure in which a rapid sequence of photographs is taken to document the blood circulation of the retina/choroid. The dye is usually injected into a vein in the arm, forearm, or hand. While generally well tolerated, angiography is an invasive procedure with associated risks, very rarely but notably of a life-threatening allergic reaction. The following risk management recommendations have been compiled to assist you and your staff so that you may both prevent and better respond to the risks of the procedure. Issues addressed here include delegation of tasks, informed consent, emergency response equipment, and management of complications.

DELEGATING TASKS TO UNLICENSED STAFF

Probably the most frequent question about FA is who can perform venipuncture and administer the intravenous (IV) fluorescein dye. The laws as to who can perform venipuncture and administer IV fluorescein vary by state. While all states allow unlicensed personnel to perform venipuncture, some have training and certification requirements that must first be met. Medications or dyes administered intravenously are rapidly absorbed, and thus place the patient at risk. Accordingly, many states allow only licensed personnel, such as registered nurses, to administer fluorescein. Other states give physicians broader delegating authority.

Proper licensing and the limits placed on delegation to unlicensed staff become important issues in medical malpractice lawsuits. If unlicensed ophthalmic personnel violate state law by administering IV

fluorescein, this paves the way for a plaintiff (the former patient) to assert negligence *per se*.¹ The doctrine of negligence *per se* declares the conduct of the ophthalmic personnel negligent if a plaintiff demonstrates that the injury resulted from an act which violated a statute intended to prevent the injury. The only issue remaining for a determination of negligence is the commission of the prohibited act. Under the legal doctrine of *respondeat superior*, a physician who delegates tasks to unlicensed personnel can also be held legally liable. To complicate matters further, if a lawsuit is brought by a patient injured during the course of treatment rendered by an employee outside the scope of the employee's license, a coverage dispute could arise with your insurance carrier.

Determine the laws governing venipuncture and the administration of IV fluorescein by contacting your state's legal website, medical society, or medical board. If the law does not specify who can perform these tasks, make patient safety a priority and ensure that staff members are properly trained and certified, and that their job duties include these tasks.

INFORMED CONSENT

Many ophthalmic practices can provide FA in their own office. In that case, the ophthalmologist requesting the procedure should discuss its risks, benefits, and alternatives with the patient. As with all informed consent discussions, time should be arranged for the patient's questions and concerns. The ophthalmologist should either document the informed consent discussion in the patient's record (making sure to note any of the patient's particular questions or concerns) or obtain the patient's signature on an informed consent document. When you choose to have the patient sign a consent form, the patient should be given time to read the consent document and ask questions. The form should be signed after the consent discussion, but prior to the FA; any delegated staff member may obtain the patient's signature on the consent. For patients who need repeat FAs, the consent is valid until it is either revoked by the patient or the patient's condition changes to the point that the risks and benefits are significantly different.

SCREENING, RESPONSE, EQUIPMENT, AND STAFF TRAINING

Each facility should have a protocol in place on how to prevent complications and handle an emergency. Facilities located within a hospital have the benefit of a code blue team. However, all facilities need to have an emergency response plan. Below are some elements for you to consider including in your written protocol.

To promote patient safety, staff members who perform the procedure should screen patients for possible contraindications by asking about pregnancy, food and drug allergies, and prior reactions to the dye. Patients who are pregnant or at risk for reactions should be cleared by the physician before the dye is injected. If the patient has allergies, the ophthalmologist should determine whether the patient needs to be pre-treated to reduce the likelihood of a reaction, or should have the procedure done in the hospital. Discussions with the patient should be documented in the medical record. Put your protocol in writing so that all staff can easily be made aware of the facility's procedure.

Staff should anticipate and be prepared to respond to the "worst case scenario," which in this procedure is a severe allergic reaction. Regardless of who administers the dye, your facility should establish a policy of having a physician on site when the injection is performed. The physician should

¹ Jean Hausheer Ellis, MD, and Paul Weber, JD, [Legal Issues Arise When Unlicensed Ophthalmic Personnel Administer IV Fluorescein](http://www.omic.com/resources/risk_man/deskref/medicaloffice/general/12.cfm), http://www.omic.com/resources/risk_man/deskref/medicaloffice/general/12.cfm

be told that an injection is about to take place and he/she should be immediately available to be able to properly respond to any complications that arise. Two staff members should be present (either in the room with the patient or within shouting distance) during the FA procedure. This way, in case of an emergency, one staff member can stay with the patient while the other can call for help, such as calling 911 if so ordered by the physician. Staff members who assist with FA procedures should be certified in Basic Life Support (BLS) for Healthcare Providers.

OMIC recognizes that the standard of care for emergency equipment is evolving and has no position on the need for an AED in physician offices. The decision is left to the practice. An AED affords an added margin of safety for all patients undergoing invasive procedures, and for those patients whose age predisposes them to cardiovascular problems. If the practice has one, ensure that the ophthalmologists and staff are trained to use it. There is arguably more liability if you have an AED and don't know how to use it than if your facility has no AED at all. Training on the use of AEDs is provided during BLS for Healthcare Provider courses offered by the American Heart Association.²

An emergency kit with basic emergency medical equipment and medication should be available, and checked regularly. Refer to the FA product insert as a starting point for what medications are needed. Also, schedule a few meetings with a "committee" of technicians, administrators, and physicians to discuss an emergency course of action. The American Society of Ophthalmic Registered Nurses (ASORN) has an excellent office procedure manual which includes a written protocol and equipment list for FA; this can be helpful in preparing the emergency kit. *Ophthalmic Procedures: A Nursing Perspective* can be viewed and ordered through the ASORN website at <http://webeye.ophth.uiowa.edu/asom/pubs.htm>. Document the decisions and formulate a written policy as to: (1) the proper procedure to be followed in the event of an emergency and (2) what, specifically, should be included in the emergency kit.

REACTIONS TO FLUORESCEIN

Patients have experienced a number of reactions to the fluorescein dye and injection process. These include nausea, vomiting, discomfort from local extravasation or leaking of the dye, fatigue, fainting, and skin eruptions such as urticaria and pruritis (itching). In the event of a reaction, the patient's signs and symptoms, actions taken in response, and discharge condition and instructions should be carefully documented. The FA procedure in the ASORN manual contains useful recommendations on preventing and treating these adverse events.

OMIC policyholders who have additional questions or concerns about fluorescein angiography may call our Risk Management Hotline at (800) 562-6642, extension 651 or 662.

² Office-Based Surgery for Adults, Anne M. Menke, RN, PhD;
http://www.omic.com/resources/risk_man/forms/medical_office/OfficeBasedSurgery.rtf