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Informed consent: How much should our patients really know?

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Informed consent: How much should our patients really know?

Abstract
Due to the increasing incidence of law suits involving malpractice claims in the United States, health professionals must be proactive in informing their patients about the risks and benefits, and the possible side effects of any procedure. A hand written entry in the patient's record or the patient's signature on a consent form should be completed for each of the following: pupillary dilation or a cycloplegic examination, the use of contact lenses and their care, particularly with extended wear soft contact lenses, and prolonged drug therapies as found in the treatment of glaucoma. In addition to discussing the issues necessary to understand informed consent, this paper includes forms that may be helpful for the practitioner.

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INFORMED CONSENT: 
HOW MUCH SHOULD OUR PATIENTS REALLY KNOW?

by

KAVITA BANSIL

A thesis submitted to the faculty of the 
College of Optometry 
Pacific University 
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Dr. Nada J. Lingel
Kavita Bansil is from Nairobi, Kenya. She completed her undergraduate work at Pacific University receiving a Bachelor of Science degree in Visual Science. While attending Pacific University she was on the Dean's List and was recognized in Who's Who Among International Students in Colleges and Universities. She is now completing her graduate work at Pacific University, College of Optometry. As a graduate she has received BSK recognition as an honor student. Even though Kavita's family is still in Kenya, she plans to settle down in the United States, hopefully in the Seattle, Washington area.
ABSTRACT:

Due to the increasing incidence of law suits involving malpractice claims in the United States, health professionals must be proactive in informing their patients about the risks and benefits, and the possible side effects of any procedure. A hand written entry in the patient's record or the patient's signature on a consent form should be completed for each of the following: pupillary dilation or a cycloplegic examination, the use of contact lenses and their care, particularly with extended wear soft contact lenses, and prolonged drug therapies as found in the treatment of glaucoma. In addition to discussing the issues necessary to understand informed consent, this paper includes forms that may be helpful for the practitioner.
INTRODUCTION

Informed consent goes beyond the legal aspects of ensuring that the patient is informed of the nature, purpose, risks and benefits of an optometric procedure. It builds the ethical foundation in which the doctor ensures that the patient's health care needs are fully met.\(^1\) Informed consent formalizes both the ethical and legal relationship between the patient and the doctor.

In previous years, patients seldom questioned the treatment options offered by the physician. This is still the case in several nations, but medicine in the United States has taken a different trend. For the past fifty years, the increasing threat of malpractice litigation has resulted in the need for informed consent.

Informed consent can be defined as a patient's authorization to a doctor to initiate a procedure or a treatment plan. This is valid only if the patient is fully informed of the nature of the procedure, its risks and benefits, and the alternative options available to the patient.\(^2\) Once the patient understands these elements, he/she can choose to undergo or forego the procedure or treatment. Regardless of the option that the patient chooses, the doctor needs to offer treatment that conforms to a certain standard of care to ensure that the patient is protected from harm.\(^3\) If a practitioner fails to adhere to this, he/she may be inviting a malpractice lawsuit.

The first reported case of optometric malpractice in 1939 established that optometrists would be held liable if they did not meet an expected standard of care.\(^4\) John Classe offers us an ideal definition of the standard of care stating that "a doctor is expected to exercise reasonable care in the treatment of his patients and to possess a standard minimum of special knowledge and ability."\(^5\) In most jurisdictions, the standard of care is based upon the patient's ability to understand, and the physician must disclose whatever information is pertinent to allow a reasonable patient to make a decision about their medical care.\(^6\)
Other than the failure to adhere to a standard of care, there are several other sources for litigation. In fact, the most common cause of malpractice suits against optometry is misdiagnosis. This includes the failure to detect a disease or to inaccurately diagnose disease in a patient who is healthy. If disease is detected, the optometrist must obtain proper referral in a timely manner as the failure to refer and the failure to follow a patient are also sources for malpractice suits. In 1980, the National Association of Insurance Commissioners (NAIC) performed a study which compared malpractice claims by profession between 1975 and 1978. Of five professions compared by Classe, optometry had only 40 malpractice claims filed during this three year period. This is the lowest number of any of the professions studied. Ophthalmology had the highest number of claims with 354 claims filed during this period. In addition ophthalmology paid twice the amount as optometry did per claim. Regardless of the number of claims or the expenses involved, the most common error for optometrists was misdiagnosis.

Even though there are several avenues leading to malpractice, John Classe offers fifteen pointers in his "Legal Aspects of Optometry" to help optometrists avoid malpractice but warns us that "no one is immune from suit." To further minimize malpractice lawsuits, informed consent forms should be completed for such things as pupillary dilation, the use of contact lenses, and prolonged drug therapies.

INFORMED CONSENT:

The decision made by the patient to either accept or reject the procedure to be performed or the treatment offered needs to be documented as informed consent. This can be done by making a handwritten entry in the patient's record or by using a standardized consent form. If a standardized consent form is used, double ply NCR paper is highly recommended because it allows the original form to be kept in the patient's file and a copy to be given to the patient for his or her personal records.
Any standardized informed consent must address the nature of the procedure or treatment, its risks and benefits, and any possible side effects. These items are known as the elements of disclosure. The nature of a procedure must be described to the patient clearly and in understanding terms. It may include the part of the body that is involved and whether the procedure is invasive or not. It must also indicate if a procedure is diagnostic or therapeutic. If the procedure is therapeutic, the informed consent must include the expected duration of treatment and indicate the need for local or general anesthetic. If a procedure is experimental or a part of research project, this must also be clear to the patient.

The most important element to be included in the informed consent is the risk associated with or secondary to the procedure or therapy. The nature, magnitude and the probability of the risk developing must be explained. For example, for pupillary dilation the nature of the risk includes angle closure which may result in loss of vision. The probability of the risk materializing in a Von Herrick grade 4+ angle is minimal but quite substantial for a 1 or 2+ angle. In some states, the remote or minor risks where the patient will not suffer substantial harm or discomfort, need not be disclosed to the reasonable patient. These are referred to as the negative elements of disclosure as they would not alter the decision made by a reasonable patient.

The inclusion of the benefits of a procedure or treatment plan is not crucial. However they do need to be mentioned if a procedure is diagnostic. For example, pupillary dilation is beneficial to the patient because it allows the doctor to view the interior of the eye and better detect any disease which may be present. Even though the benefits of a procedure are not essential, the failure to disclose them may cause a patient to question the need for the procedure to be performed.

Once the elements of disclosure have been explained to the patient, he/she is responsible for making a decision to undergo or refuse the procedure or treatment. Essentially the definition of informed consent is that the patient fully understands the
procedure or treatment and based on that understanding he/she chooses to undergo or forego the procedure. If a patient refuses treatment, alternatives or options to the recommended therapy must be offered. Again, the nature, risks and benefits of the alternative therapy should be disclosed. In most cases the alternative is less preferable to the initial therapy plan usually due to decreased effectiveness or increased side effects. The patient must understand this difference.

Regardless of the method informed consent is obtained, three signatures are essential for a consent form. These include the signature of the patient (or a parent/guardian if the patient is a minor), the signature of the doctor performing the procedure or administering the treatment, and the signature of a witness. Another important element in standardized consent forms is that the procedure or treatment must be explained in non-technical terms which allows the patient to understand the content of the form.

**Pupillary Dilation**

Now that each state allows the use of diagnostic pharmaceutical agents, pupillary dilation is considered the standard of care. Failure to routinely dilate all first-time patients, patients that are at an increased risk for ocular diseases such as high myopes, diabetics and patients with a high risk of glaucoma, or patients that present with symptoms that indicate the need for pupillary dilation may result in a malpractice lawsuit. However, merely dilating these patients without educating them about the nature, risks and benefits of pupillary dilation may also lead to litigation. The patient must be educated about the increased ability to detect disease through pupillary dilation which allows prompt treatment when necessary. In addition, they must be warned that their ability to drive or work may be impaired secondary to the blurred vision which they may experience. With all this information at hand, if a patient still refuses to undergo pupillary dilation, an informed consent form must be signed indicating refusal.
It is important to take a thorough case history to ensure that a patient has not had an adverse reaction to pupillary dilation in the past. Even though the probability of an angle narrow enough to result in angle closure is only 0.4-1.64%\textsuperscript{11}, anterior chamber angles must be checked with either the Von Herrick technique or gonioscopy. Regardless of whether the patient has narrow angles and is at risk for angle closure, all patients should sign an informed consent form prior to undergoing pupillary dilation. This greatly reduces the chance of litigation and educates the patient on the procedure, risks, benefits and side effects. If such a detailed consent form is not available, a note in the patient’s file must indicate that you have warned the patient of the risks, benefits and side effects of the procedure. In the case where the procedure is refused, a succinct chart note should be made indicating the patient’s decision.
INFORMED CONSENT FOR ROUTINE PUPILLARY DILATION

Pupillary dilation is a common procedure used by eye care practitioners which allows the examiner to view the structures inside the eye. This provides a more thorough examination and aids the doctor in detecting disease or ensuring that your eyes are healthy.

In order to dilate your pupils, the following drops must be administered:

__________________________
Time:

It may take up to half an hour before your pupils are as large as they can be. Once this happens, most people will be more sensitive to light. Sunglasses will reduce this sensitivity. If you do not have a pair of sunglasses with you today, the office will provide you with a pair of disposable ones. Your ability to see clearly, particularly up close, will be temporarily impaired and you may also have blurry vision in the distance. If you experience this blur it will take four to six hours before you are able to see clearly again. Please use extreme caution when walking, climbing up or down stairs and driving during this time. If you have any special transportation needs please let one of our staff members know and we will be happy to arrange it for you prior to this procedure.

In approximately 0.4-1.64% of the population, there is risk of developing increased pressure inside your eyes with pupillary dilation. If you are at risk the doctor will discuss it with you because it is important that you understand this complication before consenting to and undergoing this procedure. If the pressure in your eyes is elevated after pupillary dilation, it may be necessary to administer a second set of eyedrops or use oral medications to decrease the pressure. In addition, you may need to undergo surgical treatment to prevent this from occurring again.

We highly recommend that you have your pupils dilated because it allows the doctor to look for the presence of eye diseases. Some diseases such as glaucoma typically have no symptoms and you may not be aware of them until you have lost vision permanently. The earlier a disease is found the more likely it is to be treated successfully.

You have the right to refuse this procedure. If you have questions about any of the information that has been provided to you, please ask us so that we are able to address your concerns.

Please check the appropriate box and then sign the form in the presence of the doctor or one of our office staff.

[ ] I understand the risks, benefits and side effects of pupillary dilation and chose to undergo the procedure.

[ ] The risks, benefits and side effects of pupillary dilation have been explained to me, nevertheless, I refuse to undergo the procedure.

Signature of the Patient/Parent/Guardian ____________________________ Date ____________

Signature of the Doctor ____________________________ Date ____________

Signature of a Witness ____________________________ Date ____________
Extended Wear Contact Lenses

During the 1960's claims against optometrists increased by one third. One of the two reasons for this increase was contact lenses. 47% of the contact lens claims filed were due to injuries that the patients had incurred from wearing the lenses. Therefore contact lens patients need to be informed of the risks and benefits associated with contact lens wear. Since compliance is important for healthy and successful contact lens wear, a fitting, service and compliance agreement is useful to protect oneself against liability and to educate the patient on its critical importance. Even though some patients will present to your office for contact lenses only, a complete eye health evaluation including pupillary dilation must be performed prior to fitting the patient.

Extended wear contact lenses impose a greater responsibility on the eye care practitioner. Since many patients have poor compliance and because extended wear lenses are associated with an increased risk of infection, special attention in the selection of the contact lens material, the care regimen and timely follow up care on the part of the doctor is essential. Informed consent helps protect the doctor against a lawsuit by helping the patient understand the risks of extended wear contact lenses, the importance of periodic checks and the possibility that the extended wear schedule may need to be discontinued. These patients must also be educated on the signs and symptoms of corneal ulcers and advised that if they experience persistent redness or pain, cloudy or foggy vision or unusual symptoms at any time, an immediate office visit should be made.

The following consent form also includes that patient failure to adhere to the care regimen which has been selected by both the doctor and the patient, or to attend follow up appointments make the patient solely responsible for the health of his/her eyes. The type of lens and care regimen selected should be the outcome of a discussion between the patient and the doctor. This allows the doctor to fit the optimal lens and place the patient
on a care regimen that fits comfortably into the patient's schedule to improve both patient compliance and satisfaction.
INFORMED CONSENT AND CONTACT LENS COMPLIANCE

Contact lenses are medical devices that are used for the correction of nearsightedness, farsightedness, presbyopia, keratoconus and other anomalies. Even though contact lenses are manufactured specifically for the human eye, they can cause severe complications when the correct care regimen is not followed. It is important for you to understand this before you start wearing contact lenses.

You have the following type of contact lens:

[ ] Daily wear rigid gas permeable
   These contact lenses are worn on a daily basis ONLY and must be removed from the eye daily, cleaned thoroughly and stored in the appropriate solution. They must not be worn overnight. These lenses need to be replaced at least every 12-18 months.

[ ] Daily wear soft hydrophilic contact lenses
   These contact lenses are worn on a daily basis ONLY and must be removed from the eye daily, cleaned thoroughly, and stored in a disinfecting solution overnight. These contact lenses must be replaced at least every 9-12 months.

[ ] Daily wear soft hydrophilic contact lenses, planned replacement
   These contact lenses are worn on a daily basis ONLY and must be removed from the eye daily, cleaned thoroughly, and stored in a disinfecting solution overnight. These contact lenses must be replaced every ___ weeks.

[ ] Extended wear soft hydrophilic contact lenses, disposable
   These contact lenses need to be removed from the eye and thrown away at least every ___ days. They should be replaced with a new, sterile pair of contact lenses. These contact lenses require responsibilities unlike those for soft daily wear lenses.

Based on the type of contact lenses that you and your doctor have decided is best for your schedule, you have been placed on the following care regimen:

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<th>Name of solution</th>
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<th>Name of enzyme</th>
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Based on the contact lens that has been chosen by you and your doctor a follow up contact lens check is required every ___, ___, and ___ months to ensure your eyes stay healthy.

I fully understand that I must comply with the appropriate care regimen in order to ensure my eyes stay healthy. If I chose to adhere to another care regimen that does not follow the parameters of this agreement, then I am solely responsible for the health of my eyes.

In addition I understand the importance of periodic appointments and agree to keep them.

_________________________________________ Date
Signature of the Patient/Parent/Guardian

_________________________________________ Date
Signature of the doctor
Therapeutic Treatment

The passage of therapeutic drug laws has caused a new trend in optometry to occur which has also increased the potential source for liability. Most of the malpractice cases reported involve prolonged corticosteroid therapy which lead to fungal growth, cataract formation and steroid induced glaucoma.\textsuperscript{14} Other side effects of corticosteroid therapy include retardation of corneal epithelial healing, uveitis, mydriasis, ptosis and transient ocular discomfort.\textsuperscript{15} In the January 1993 issue of the Review of Optometry, the Optometric Study Center suggested some guidelines to follow for therapeutic management. These included a complete case history prior to initiating therapy, using the least number of drugs in the lowest concentrations and the least frequent doses for the condition, improving and monitoring patient compliance and carefully considering the risk of refilling prescriptions over the telephone.\textsuperscript{16} Even though only a small percentage of your patients will be on heavy corticosteroid therapy, it is important to ensure that they are aware of the side effects as they may be irreversible.

The included informed consent is not applicable to all patients on steroid therapy. For example, the chances of the side effects materializing is relatively low in the case of a post cataract patient who needs to be on steroid therapy for approximately one to two weeks. However, in the case of a chronic iritis patient who may need steroid therapy on and off for an unlimited period of time, it is appropriate to inform the patient and get his/her consent. Since the use of steroids is fairly limited, the use of such a consent form will also be limited and a short entry in the patient's record indicating that you have explained the possible side effects of steroid therapy may be adequate.
INFORMED CONSENT AND PROLONGED STEROID THERAPY

Ocular steroids may cause complications when used for a significant period of time. Some of these side effects are irreversible and others may need additional drug therapy in order to treat them.

Cataract formation can occur as a side effect of prolonged steroid therapy. The probability of cataract formation increases with the strength of the drug and length of treatment. Studies have shown that adults who are on steroids for a period of 1-4 years are more likely to develop cataracts.

Topical steroids can increase the pressure inside your eye. If this occurs the pressure usually returns to normal 1-3 weeks after steroid therapy is discontinued. This increase in pressure tends to run in families. Therefore, you may or may not respond to the steroid therapy. However, if the pressure in your eyes raises significantly inducing glaucoma, then additional medication may be needed to lower the pressure and prevent further complications.

Other side effects may include an increased risk of infections, slower healing of your eyes, discomfort to your eyes, lid drooping and slight pupil enlargement.

If you have any questions, please ask your doctor prior to signing the consent form.

I understand that there may be certain complications associated with the steroid therapy that I am undergoing.

Signature of the Patient/Parent/Guardian Date

Signature of the Doctor Date

Signature of a Witness Date
Another area that lacks compliance and needs to be addressed is the therapeutic treatment of glaucoma. A practitioner may fail to fully inform the patient of the seriousness of the disease or the patient may simply choose not to comply because of inconvenience. The impact of both these issues can be lessened with an informed consent form.

Studies have shown that the prevalence of primary open angle glaucoma in patients over the age of forty is 0.43 to 1.02%.[17] Even though this is a small percentage of patients, it is absolutely critical that they are educated on the occurrence, progression and treatment of glaucoma. Since there are several etiologies to the development of glaucoma, the eye care practitioner must sit down and spend some time explaining to the patient the most likely reason he/she has developed glaucoma. The basic mechanism of the progression of glaucoma is essentially the same in all patients. They must understand that the therapy they are undergoing is not a cure but instead significantly reduces the progression of the disease. They must also understand that poor compliance can lead to irreversible visual field loss and eventual blindness.

Like every informed consent form, this one must inform the patient of the side effects of the medication(s) they are taking. Except for the carbonic anhydrase inhibitors and the cholinergic agonists, most of the anti-glaucoma medications have relatively mild side effects. Therefore, only the most potent side effects need to be identified. Since your staff members/technicians may write the side effects on the informed consent form, it may be a good idea to have a standardized list of the most potent side effects for each anti-glaucoma medication. Your staff can then simply copy them onto the form once you have selected the anti-glaucoma medication that is the best for the patient.

Since each patient will be on a different medication or combination of medications the dosage must be entered on each form. For example, if you have decided to put your patient on Betoptic 0.5% BID then the informed consent form should be filled in the following manner:
You have been put on the following medication:

*Betoptic 0.5% twice daily in each eye approximately 12 hours apart*

If the therapy regimen indicates that the drop needs to be administered more than once a day, the time period between drops must be specified to ensure patient compliance.
INFORMED CONSENT AND GLAUCOMA THERAPY

Glaucoma is a disease in which the pressure inside the eye is elevated. This may be due to the production of too much fluid inside your eye or the inability of a normal amount of fluid to drain from your eye. Your doctor can usually identify the cause of the glaucoma that you have.

You have been put on the following medication(s):


It is absolutely essential that you use the medication as you have been directed. After instilling the drop(s) in your eye(s) close them for approximately 2 minutes and pinch the inside corners of your eyes. This allows the drop to stay in your eyes without draining into your nose and/or throat. This increases the effectiveness and decreases the side effects that the drops may have on your body.

If you are using a new medication or one that you have not used before, please make sure you know what side effects can be expected. If you cannot tolerate the medication due to the side effects discontinue the medication and call our office to make an appointment as soon as possible.

Since each medication causes several side effects only the most potent ones are identified below:


I fully understand that the medication(s) that I am currently taking for the management of my glaucoma has the above side effects. I also understand that I need to instill the drops as I have been advised. If I do not comply with the dosage that my doctor has put me on then I am solely responsible for any vision loss that occurs due to my lack of compliance.

Signature of the Patient/Guardian __________________________ Date ________________

Signature of the Doctor __________________________ Date ________________
CONCLUSION:

Since a physician can be held liable for failure to obtain informed consent, he/she needs to provide the patient with all the information a reasonable patient will find necessary to make an intelligent decision about his/her medical care.

The nature of a procedure, its risks and benefits, and the possible side effects must be disclosed and explained. If a particular diagnosis has been made, only the information pertinent to treatment needs to be disclosed not the diagnosis itself. A patient must also be informed if they are at high risk for developing a disease. For both diagnostic and therapeutic procedures, alternative tests and/or treatment options should also be given to the patient. In most cases the alternative options are less preferred by the doctor as they may be less effective or may have an unusually high incidence of side effects. This must also be disclosed to the patient and informed consent should be obtained.

As the health care system changes and as our patients become much more aware of the medical procedures and therapeutic treatment that they may undergo, we also need to be more concerned with the issue of informed consent.
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