CLINICAL GUIDELINE

Informed Consent

Note: These guidelines are not a substitute for legal responsibilities and optometrists must ensure that they comply with State and Federal Law and Common Law responsibilities.

Informed consent is an agreement obtained without coercion from a person, following provision of information to them on the matter to which they are agreeing using language that they understand. In optometry, informed consent is a freely obtained agreement from a patient for a procedure, product, referral etc, after explanation of what this entails and the purpose, risks, benefits, costs and expected outcome. In most cases in optometric practice verbal consent is adequate but there are also occasions where written consent is necessary (eg. research procedures).

The underlying principle of informed consent is that people have the right to control what is done to them and that they give their consent without being deceived or coerced. There must be no undue pressure to consent. This does not mean optometrists cannot ‘advise forcefully’, where the health or well being of the patient is an issue, but research subjects, in particular, should not be offered inducements to consent to procedures.

To be able to make informed decisions about their health care, patients must receive sufficient information to make an intelligent choice. This requires:

- explanation of all clinical diagnoses (including disclosure of abnormalities or complications);
- explanation of all procedures and treatment or therapy, and alternative methods of treatment or management;
- description of benefits and adverse consequences (including complications/risks) of any diagnostic or treatment procedure;
- description of expected outcomes and limitations of recommended treatment and alternative methods of treatment;
- disclosure of the anticipated costs and time involved in any treatment;
- answers to queries and clarification of ambiguities and misinterpretations;
- advice on what can be expected if nothing is done.

The optometrist must not withhold necessary information nor misrepresent facts, and must provide all the information that they expect the patient would consider relevant in making a decision within a time-frame that is sufficient for the particular patient (this may vary depending on the seriousness of the matter).

The patient also has the right to receive information about any practitioner to whom the optometrist wishes to refer them and to know if the optometrist has a financial or other interest in any clinic to which they wish to refer the patient.
Information should be in a form and manner appropriate to the patient’s circumstances, personality, attitudes, temperament, level of understanding, expectations, fears, beliefs, values and cultural background.

The optometrist must also consider the nature of the treatment and the magnitude and likelihood of possible harm (information about serious harm should be given even if the possibility of such harm is slight; information about slight harm should be given if the risk of this occurring is great). Patients should be encouraged to ask as many relevant questions as are necessary about the examination, treatment and referral, to be able to make informed decisions about their care and they should be given sufficient time to make their decision.

Where necessary an interpreter should be used to assist the patient to understand the information given by the optometrist.

Failure by a practitioner to disclose the risks associated with a proposed treatment and possible alternative treatments may expose the practitioner to liability for damages if something goes wrong. For such an action to proceed it must be established that the practitioner’s failure to disclose the information was unreasonable and that this failure caused harm to the patient through the patient agreeing to something that they would otherwise have refused.

Patients have the right to withhold consent and to refuse treatment, advice or the performance of any procedure. They also have the right to withdraw their consent at any stage; thus they can terminate an examination or treatment at any stage and can comply or not comply with any advice or treatment given (including referral).

Although there are ethical and legal imperatives to obtain the patient’s informed consent, truly informed consent may be an impossible goal. Patients can only give consent when they are competent to do so. However, even when the patient is capable of understanding the information to give their informed consent, they still may not actually understand. Those who are very young, or very ill, those who are mentally impaired or have dementia and even those who are frail or confused may not be in a position to give informed consent. Where the patient is a minor or under the care of a guardian, the consent of the parent or guardian must be obtained for procedures and treatment. There could be situations when parental consent is required and parents have differing views regarding a course of treatment. Such issues could be difficult to resolve when parents are separated/divorced. The optometrist must establish who is responsible for decisions regarding the management of the patient and may need to seek legal advice. Where a patient is mentally unable to give consent eg. those suffering from dementia, it is necessary to gain permission from their guardian or the person who has their power of attorney.

There are some circumstances in which informed consent can be waived eg. where to do so may be harmful to the patient. Optometrists do not have to ask patients to sign a consent form for every procedure. The action of a patient employing the optometrist to perform an eye examination implies consent to the components of the examination. However, optometrists should gain informed consent for any ‘invasive’ procedure or procedures that pose some risk to the patient. Performance of an invasive procedure without consent may constitute a trespass to the person for which damages may be claimed, unless the failure to obtain consent is justified by necessity (eg. in an emergency).

In some cases it may be advisable for the optometrist to have a patient sign that their consent was given for a particular procedure; this would be mandatory in the case of any procedures of a research nature. In other cases it may be advisable for the optometrist to request the patient to sign that their consent was withheld eg. if they had refused to have procedures performed that the optometrist considered necessary such as tonometry, pupil dilation or referral.
Where an optometrist has expressly sought and received informed consent, it should be noted on the record card, indicating the particular aspect of treatment for which consent was sought and that the patient indicated their consent. It should be accompanied by the signature of the patient (or guardian) and be dated. (In the paperless office, typed or written information about the matter for which consent is sought and the patient signature could be scanned and stored on computer).

Informed consent must cover prescription of spectacles, contact lenses and other visual aids or training material prescribed by the optometrist. The patient should receive accurate advice in advance of likely costs of recommended treatment and receive an itemised account detailing fair and reasonable fees and charges.

Optometrists should take the time to gain informed consent so patients are better educated and less likely to be displeased with the course of treatment because of unrealistic expectations. Information can be provided using preprinted material, videotapes, or by an office assistant but these methods should not replace verbal discussions with the optometrist, as there may be no feedback to indicate the patient’s comprehension of the information.

Clinical Records
Informed consent is required for the release of personal information about a person e.g., clinical records. Patients must be informed of the purposes for which their records are to be released and the parties to whom the records are to be released. If they do not give their permission the records must not be released unless there are compelling or legal reasons to do so e.g., subpoena of records. Consent should also be obtained before providing a patient’s prescription details to a third party.

Reports and referrals
Patient consent should be obtained when a report is prepared for a second practitioner to whom the optometrist wishes to refer the patient. Verbal consent is adequate as the patient will be involved in the selection of the practitioner and the scheduling of the referral appointment. The referral letter can be sent to the patient to take with them when they attend. It is advisable to have a patient sign a form if they refuse referral to a second practitioner or if they refuse to have a referral letter prepared.

Instances of release of information without patient consent
There are situations where an optometrist may be obliged by law to release information about the patient without their informed consent e.g., legislation in South Australia requires optometrists to report patients who do not meet the vision standards for driving. Optometrists may release information in cases where they believe that this is necessary to prevent a serious and imminent threat to a person’s life, health or safety, or to public health and safety. The Privacy Act and state and territory legislation include legal requirements for releasing information without patient consent.

HIC information
The Health Insurance Commission (HIC) requires that the optometrist obtain the patient’s informed consent before they request the HIC to release patient information to determine appropriate itemisation of accounts, receipts or direct-billed claims.

Research and journal articles
Optometrists who wish to participate in research must obtain informed consent for the involvement of patients in research projects. If the optometrist wishes to use identifying information e.g., in the form of
details or photographs to be used in a journal article, they must obtain written informed consent from the patient in advance. (Optometrists may wish to seek advice from a university regarding the content of a consent form).

References