Resident's Page

Informed consent in dermatology: What's known and what's new?

Balakrishnan Nirmal, Sarvajnamurthy A. Sacchidanand

INTRODUCTION

Dermatologic surgery and esthetic dermatology have grown by leaps and bounds in the last decade. Dermatologists are expanding their skills in these fields and the horizon looks bright. Educating the patient about realities and obtaining informed consent before subjecting a patient to any procedure, surgery, or clinical trial is very essential. Informed consent is an instrument of mutual communication between doctor and patient.[1] Mutual trust forms the foundation for a good relationship between the doctor and the patient. The doctor should adhere to the protocols, so that standard care is being provided to the patient. The basic dictum of at least do no harm should always be practiced. Taking into consideration the increasing number of interventional procedures in dermatology, litigation rates are likely to rise when the results of the procedures do not match the expectations of the patient.

HISTORY OF CONSENT

Informed consent has come a long way from Hippocrates oath which refrains physicians from giving most information to patients in order to give the patients the best care, because the patient is not likely to have better ideas about their treatment than the doctor's. The earliest expression of this fundamental principle based on autonomy was found in the Nuremberg Code of 1947. It was adopted immediately after World War II in response to experimental medical atrocities committed by the German Nazi regime and the ethical violation in the Tuskegee syphilis experiment. The code makes it mandatory to obtain voluntary and informed consent of human subjects. Declaration of Helsinki was adopted by the World Medical Association in 1964 emphasizing the importance of obtaining informed consent for medical research. The legal right to autonomy and self-determination is dealt in article 21 of Indian constitution.[2] Supreme court of India ruled that it is not just the "consent" or "informed consent," but it has to be "prior informed consent."[3]

TYPES OF CONSENT

Consent can be of two types: Implied and Expressed. The patient in the doctor's cabin expressing their problems is implied consent, which is sufficient for general physical examination and routine interventions. Expressed consent in writing is imperative for interventions involving risk, cosmetic procedures, dermatologic surgeries, and clinical trials.

COMPONENTS OF CONSENT

A simple description of the procedure must be explained to the patient. Any procedures that are experimental must be disclosed. Benefit that can be reasonably expected must be described. If deception is involved for example in case of using placebos as control, patient should be informed that details of medications cannot be fully described at this time, but an explanation will be provided after completion of the entire treatment session. A description of any

Department of Dermatology, Venereology and Leprosy, Bangalore Medical College and Research Institute, Bangalore, Karnataka, India

Address for correspondence: Dr. Sacchidanand. S, Department of Dermatology, Venereology and Leprosy, Bangalore Medical College and Research Institute, Bangalore - 560 002, Karnataka, India. E-mail: sacchi1260@yahoo.com

Access this article online	
Quick Response Code:	Website: www.ijdvl.com
	DOI: 10.4103/0378-6323.125520

How to cite this article: Nirmal B, Sacchidanand SA. Informed consent in dermatology: What's known and what's new?. Indian J Dermatol Venereol Leprol 2014;80:58-61.

Received: March, 2013. **Accepted:** July, 2013. **Source of Support:** Nil. **Conflict of Interest:** None declared.

reasonably foreseeable risks including physical, psychological, social, or economic harms must be given before the intervention. The patient should also be free to withdraw his consent or to discontinue treatment at any point of time. Patient's safety must be of supreme concern.

In case of clinical trials, the following aspects must be included in the informed consent form: purpose of the study, who can take part, what will happen during the trial, role of the subject during the study, confidentiality of information, voluntary participation, and whom to contact in case of any queries.

The mnemonic "LASERS" encompasses the important aspects of informed consent which stands for: Liability waiver, type of Anesthesia, Surveillance, no Expectations/guarantee clause, Revocation of consent process, and Snapshots.[4]

A model consent form for hair transplantation comprising of all these elements is given at the end of the article.

FEATURES OF CONSENT

Age

Any patient who has attained 18 years of age, of sound mind, and not disqualified by any law are licensed to give consent.[5] Parent or guardian can give consent in cases of children and incapacitated persons.

Language

Adequate and relevant information must be provided accurately in simple terms and in the language that the patient can understand.

Information disclosure

The information provided to a patient should include all possible risks but should not be too exhaustive to the level of absurdity that the patient does not wish to undertake the procedure.

Choice of alternatives

Opportunity should be given to question and clarify doubts and the patient should also be informed about the existing alternatives.

Records

The form should be dated and signed by the patient or guardian, the doctor and an independent witness. A copy of informed consent should be handed over to the patient and the original copy should be preserved for at least 3 years. An aggrieved patient can approach the consumer forum with a complaint of medical negligence within a period of 2 years from the date of cause of action.[6]

Blanket consent

A blanket consent to authorize a doctor for the entire course treatment is not valid. It should be specific for every single procedure and a separate form should be used if another procedure is performed in the patient. The doctor performing or assisting each procedure must be mentioned in each of the consent forms.

The informed consent, hence, has to be a dynamic process,[7] where the doctor must continue to inform the developments which alter the risk-benefit ratio recorded in the original informed consent documentation. It is not just patient's signature on a dotted line at the end a printed paper.[8]

AUDIOVISUAL PRESENTATION OF INFORMATION FOR CONSENT

Audiovisual presentation is a pre-recorded audio-visual material of the clinical intervention presented to the patient through internet, digital video disk or video. A Cochrane study revealed that the use of audio-visual interventions for the informed consent process increased the knowledge and improved recall even after 4 weeks after the intervention. It is also seen to increase the willingness of the subject to participate in the clinical trial or intervention.[9]

AUDIO/VIDEO RECORDING OF CONSENT

The Union Health Ministry of India is set to make changes in the Schedule Y of Drugs and Cosmetics Rules making audio/video recording of the informed consent mandatory in clinical trials.[10] The subject's willingness to agree for the consent process to be taped must be recorded as a separate line on the consent form. Audio/video recording of consent should be made necessary for interventions involving risk, major dermatologic surgeries, and clinical trials. If the recording is to be used for any purpose other than that for which the original consent was obtained, then specific additional consent must be acquired. The other purposes of audio/video recording include the following:

1. Teaching: Illustration of interviewing techniques
2. Training: For demonstration purposes to others in the research team

3. Research: As a defined aspect of a clinical study.

Patient information sheet

The patient will be given both verbal and written information regarding audio/video recording of consent. This will include that taking part in the taping sessions is entirely voluntary patient's identity and location will remain strictly confidential, non-participation in taping the session will not prejudice the treatment offered, and the patient has a right to withdraw consent at any time, including before, during, or after the recording. The extent to which subject's identity would be masked like facial features made opaque, not including facial pictures or recording will include full face will also be informed.

Making the recording

Every competent individual has the right to refuse permission for audio/video recording. If there is unwillingness to agree, an exploration of the reasons for this reluctance may facilitate consent. However, the patient should not be forced to allow video/audio taping of any session. They must be cautioned before the recording to refrain from mentioning names or identifying information about third parties. If done inadvertently, the recording should be stopped and the identifying information erased before resuming taping. After or during the recording if the patient does not give consent for the recording to be kept, the recording must be stopped and deleted immediately.

Storage and erasure of recordings

Audio/video recordings made for clinical purposes are a part of the medical records. Hard copies of recordings will be stored in a locked area. Patients will also be informed how long the recording will be stored.

A professional tape wiper should be used to erase video tapes. DVD or CD hard copies that cannot be erased must be physically destroyed. The patient should receive a written notification that the recording has been erased.

Copyright of recordings

Audio/video recordings need to be treated in the same way as written medical records with regard to confidentiality. Similar to medical records, they can be subpoenaed by the courts. In ensuring the safe storage of recordings within institutes, it is desirable to create an audit loop to check for adherence to institutional guidelines.

CONCLUSION

Even after taking all these precautions to include all the information and risks involved in the procedure, the validity of consent is not known till the lawsuit is resolved in court. Hence, having a cordial relationship with the patient is of paramount importance. In addition, audiovisual presentation and recording of informed consent will make sure that the subject is adequately informed about the risks and benefits of enrolling in the study and also to ensure that their participation is voluntary. The audio/video recording will, thus, serve as a proof of a well-informed consent.

REFERENCES

1. Satyanarayana Rao KH. Informed consent: An ethical obligation or legal compulsion? J Cutan Aesthet Surg 2008;1:33-5.
2. Nandimath OV. Consent and medical treatment: The legalparadigm in India. Indian J Urol 2009;25:343-7.
3. Liesegang TJ. The meaning and need for informed consent in research. Indian J Ophthalmol 2007;55:1-3.
4. Cosmetics Challenge: Informed Consent as a Process. Available from:http://bmctoday.net/practicaldermatology/2010/03/article.asp?f=cosmetics-challenge-informed-consent-as-a-process [Last accessed on 12 Feb 2013].
5. Gupta UC, Kharawala S. Informed consent in psychiatry clinical research: A conceptual review of issues, challenges, and recommendations. Perspect Clin Res 2012;3:8-15.
6. Rao KH. IADVL Dermatosurgery Task Force. Safer practice of dermatosurgery. Indian J Dermatol Venereol Leprol 2008;74:S75-7.
7. American Society of Clinical Oncology. American Society of Clinical Oncology policy statement: Oversight of clinical research. J Clin Oncol 2003;21:2377-86.
8. Pranati. Informed consent: Are we doing enough? Perspect Clin Res 2010;1:124-7.
9. Audio-visual presentation of information for informed consent for participation in clinical trials (Ryan *et al*. 2007). Available from: http://www.latrobe.edu.au/chcp/assets/downloads/HKN_evidence bulletin_310308.pdf [Last accessed date on 12 Feb 2013].
10. D and C Rules to be amended to make audio/video recording of informed consent mandatory. Available from: http://pharmabiz.com/NewsDetails.aspx?aid=71024 and sid=1 [Last accessed date on 12 Feb 2013].

MODEL CONSENT FORM FOR HAIR TRANSPLANTATION

My signature below constitutes my acknowledgement that I _____, aged __ years, residing in _____have been advised to undergo hair transplantation.

1. Alternatives: I have been explained that the procedure of hair transplantation is cosmetic in nature and I have been involved in decision making about the choices of treatment which includes doing nothing at all, wigs, medical treatment, or having another form of hair restoration surgery. I have the right to revoke my consent before the procedure at any time without giving any reason for the same.

2. Photography: I understand that digital photographs will be taken before and after treatment sessions to assess the improvement. I give permission to use my photographs to explain other patients about points of clinical relevance and also as part of scientific publication in journals or presentations in conferences without revealing my name or identity.

3. Anesthesia: I have been explained that the transplant will be done under local anesthesia which includes bupivacaine and lignocaine with or without adrenaline. It may cause adverse effects on different organ systems like allergic reactions, irregular heartbeats, or heart attacks.

4. Procedure: I understand that hair transplantation is a minor surgical procedure by which a strip of hair from occipital region of the scalp is transferred to areas of hair loss or thinning. This donor area is then closed with sutures which are usually removed after 7-10 days.

5. Possible complications: These include but are not limited to permanent scarring, temporary bleeding, superficial crusting, infection, pimples, swelling, temporary shedding of some of the existing hair, and numbness over the area. A raised scar is also possible, more likely in patients with a history of hypertrophic scarring,though every effort will be made to make the scar inconspicuous.

6. Rare complications: Although hair transplantation is generally a safe procedure; however, I am aware that complications such as unanticipated reaction to medications, uncommon infections, and unusual healing responses are possible. Every unforeseen complication may not have been discussed with me in detail, but I understand that such risks do exist.

7. Results: As with all surgical procedures, results cannot be guaranteed; whereas every effort will be made to achieve the maximum yield. I understand, I will not have hair of the same thickness/density as I had prior to the onset of my hair loss. I am aware that I will be able to see the full effect of hair transplant only after 9-10 months.

8. Follow-up: I understand the success of the hair transplant procedure is dependent upon my closely following all instructions and I might have to take medical treatment post-transplant as hair loss may continue after surgery.

9. Audio/video recording: I agree to the audio/video recording of the consent process which includes recording of full facial pictures without revealing my name. It will be stored for records for a period of __ years and erased after that. A receipt confirming the erasure will then be sent to me.

I authorize Dr._____ or his qualified assistant Dr._____ to perform my hair transplant and any other medical treatment required during the procedure. I certify that I fully understand the provisions of this form and give consent to the above listed procedures and photography.

Patient signature: _____ Date:
Witness signature: _____ Date:
Doctor signature: _____ Date: