

Seeking patient's consent for examination and treatment: Introducing a consent form to be used in government hospitals in Sri Lanka.

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Background

Respect of the patient's right to self determination (autonomy), through informed consent is considered the foundation of *doctor – patient relationship*.

Despite the considerable development in health infrastructure and human resources, a regular practice of modern ethical standards has not yet been appropriately established. So far the country has failed even to reach a consensus regarding informed consent. Frequently the “consent for medical examination and treatment” was looked from a paternalistic view point, often only as a tool of defense against litigation. Obtaining consent was merely limited to getting any person, accompanying the patient to hospital, to sign on bed head ticket (BHT), next to a “stereotype” phrase: “*No property, consent for operation*”. Usually no doctors were involved in this process, a nurse, receiving patient to the ward, write the phrase. Patient information about the nature and consequences of procedures or available treatment options were often ignored.

The situation is being changed to the better. Many doctors are exploring ways of obtaining consent; formats are being designed by individual clinicians. Incompleteness in view of legal validity and unsuitability for use in different situations were among many shortfalls noted in those consent forms.

The purpose of this paper is to focus on practical medico legal issues concerning consent and clinical ethics and to propose a format which may be appropriate and applicable in many of the clinical scenarios for obtaining consent.

Main Objective

The main objective was to design a suitable format to obtain informed consent of patients for various surgical, investigative and therapeutic procedures in clinical practice.

Specific objectives

1. Identify the quantity and the quality of information, that patients should be given in order for the consent to be valid
2. Design a widely acceptable format to obtain informed consent of patients for various surgical, investigative and therapeutic procedures in clinical practice

Ethical principles concerning the informed consent

Patient consent is required on occasions where the doctor wishes to initiate an examination or treatment or any other intervention, except in emergencies or where the law prescribes otherwise (such as where compulsory treatment is authorized by mental health legislation). Consent may be explicit or implied. Explicit (or expressed) consent is when a person actively agrees, either orally or in writing. Implied consent is when signaled by the behavior of an informed patient. Implied consent is not considered a lesser form of consent but it only has validity if the patient genuinely knows and understands what is being proposed

Failure to follow the recommended protocols for obtaining meaningful, lawful consent is unethical and can harm patients both physically and psychologically.

Interventions without obtaining consent can end in either civil litigation or in rare cases, criminal prosecution. A quality health care demands more than mere technical proficiency, and wherever possible it needs to allow for active patient participation. This cannot be achieved in an atmosphere of mistrust, or if patients feel that what they think and say is of no real consequence.

Consent is a process, not a one-off event, and it is important that there is continuing discussion to reflect the evolving nature of treatment. A consent form simply documents that some discussion about the procedure or investigation has taken place. It is only an evidence of a process, not the process itself.

The provision of sufficient accurate information is an essential part of seeking consent. Competent adult patients are entitled to refuse consent to treatment, even when doing so may result in permanent physical injury or death. Compliance when a patient does not know what the intervention entails, or is unaware that he or she can refuse, is not 'consent'. Doctors must respect a refusal of treatment if the patient is an adult who is competent, properly informed and is not being coerced.

The doctor who recommends that the patient should undergo the intervention should have responsibility for providing an explanation to the patient and obtaining his or her consent. In a hospital setting this will normally be the senior clinician. In exceptional circumstances the task of reaffirming consent can be delegated to a doctor who is suitably trained and qualified, is sufficiently familiar with the procedure and possesses the appropriate communication skills.

Any discussion, however, should be recorded in the patient's medical notes.

Generally there is no legal requirement to obtain written consent but in some cases it may be advisable.

Extent of patient information required for a valid consent

The information that patients should be provided with, includes,

- Purpose of the investigation or treatment, details and uncertainties of the diagnosis,
- Options for treatment, including the option not to treat, explanation of the likely benefits and probabilities of success for each option the risks such as known possible side effects,
- Complications and adverse outcomes including where intervention and/or treatment may fail to improve the condition,
- The name of the doctor who will have overall responsibility,
- A reminder that the patient can change his or her mind at any time.

A careful balance needs to be struck between what patients want to know and ought to know (i.e. listening to what the patient wants and providing enough information) in order that the patient's decisions are informed

Introducing the proposed consent form

The proposed consent form is believed to be appropriate for obtaining written consent from patients for examination and treatment in government hospitals in Sri Lanka. The development of this format took more than 03 years of consultation and discussion with different medical/surgical specialists attached to Matale and Anuradhapura hospitals during the period between 2008 and 2010.

Efforts had been made to make the form to be complete and comprehensive while being concise to be user-friendly.

- Important information referring to identity of the patient and nature of the proposed intervention is included in the given format.

- Further it elaborates the areas of most valuable concern in the discussion leading to informed consent, though it does not contain the concrete constituent facts.
- The document guides both clinicians and patients into their rights and responsibilities.

(Sinhalese/English and Tamil/English versions of proposed consent form are given below.)

Since the amount of information which, doctors should provide to each patient will vary according to factors such as the nature and severity of the condition, the complexity of and the risks associated with the treatment or procedure and the patient's own wishes, it is simply impossible to design a universal consent form carrying all necessary information. As such this consent form needs to be supplemented with provision of information applicable to respective areas of medical practice or disciplines, clinical scenarios, individual interventions and procedures. Good quality information leaflets that patients can take away with them can be a useful way of improving information provision but these should not be seen as an alternative to discussion.

Separate Sinhalese/English and Tamil/English versions were thought to be justifiably appropriate to use for any patient.



රෝහල மாவட்ட பொது Hospital

ඉලය කර්මයක් හෝ විශේෂිත පරීක්ෂණයක් හෝ ප්‍රතිකාර ක්‍රමයක් සඳහා එකඟතාවය ප්‍රකාශ කිරීම.
Declaration of Consent for Surgical or Special Investigative or Therapeutic Procedure.

1. රෝගියාගේ නම (සම්පූර්ණයෙන්) }
 Name of Patient (in full) }

2. වයස }
 Age }

පුරුෂ Male	ස්ත්‍රී Female
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 4. ඇඳ ඉහපත් අංකය }
 BHT No. }
 5. වාට්ටුව }
 Ward }

6. අවශ්‍යවන ඉලයකර්මයේ / විශේෂිත පරීක්ෂණයේ / ප්‍රතිකාර ක්‍රමයේ ස්වභාවය.
 Investigative / Therapeutic intervention required වේ නම් විශේෂයෙන් සඳහන් කරන්න / is to be performed
 & Nature of the Surgical

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6.1 අවයවයක් හෝ කොටසක් ඉවත්

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6.2 අවශ්‍යවන නිර්වින්දනයේ ස්වභාවය /

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7. ඉහත නම සඳහන් කරන ලද ඉලයකර්මයේ / විශේෂිත පරීක්ෂණයේ / ප්‍රතිකාර ක්‍රමයේ අවශ්‍යතාවත්, මාගේ රෝගයට ප්‍රතිකාර කිරීම සඳහා එහි වැදගත්කම මෙන්ම, එවැන්නක හා නිර්වින්දනයේ දී සිදුවීමට ඉඩඇති අතුරු ආබාධ හා සංකුලනා පිළිබඳවත් වෛද්‍ය නිලධාරී Dr.පැහැදිලි කර දෙන ලදී.

Explained me about the necessity, and importance of the above mentioned procedure in treating my illness and possible risks and complications of such a procedure and anaesthesia.

8. යම් විශේෂිත වෛද්‍යවරයෙක් විසින් මෙම ඉලයකර්මය / විශේෂිත පරීක්ෂණය / ප්‍රතිකාර ක්‍රමය කරන බවට පොරොන්දුවක් දී නොමැත. කෙසේ වුවද එම කටයුත්ත සඳහා සුදුසුකම් ලද, ප්‍රවීණතාවක් ඇති වෛද්‍යවරයකු කාර්යය කරනු ලබන බව මම දනිමි. I have never been promised that a particular doctor would do this procedure. However, I understand that a doctor with necessary qualification, skill and proficiency would be attending to the procedure.

9. ආසාත්මිකතා හා විෂවීම් / Allergies and toxicity (අදාල නොවන ඡේදය කපා දමන්න. Delete inappropriate section)

9.1 මාගේ දැනුමේ හැටියට මීට පෙර කිසිදු අවස්ථාවක යම් බෙහෙතක් හෝ ආහාරයක් නිසා ආසාත්මිකතාවක් හෝ විෂවීමක් මාහට ඇතිවී නැත. To the best of my knowledge I have never had any allergy or toxicity after taking any drug or food

9.2 ඖෂධය / ආහාර වර්ගය නිසා ආසාත්මිකතාවක් / විෂවීමක් මාහට ඇති විය. I have experienced an allergic / a toxic reaction to following drug / food item

10 මෙම ඉලයකර්මය / විශේෂිත පරීක්ෂණය / ප්‍රතිකාර ක්‍රමය සඳහා පෙර සූදානම් වීමේදී වෛද්‍යවරයා / හෙද නිලධාරී විසින් ලබාදෙන උපදෙස් අනුගමනය කලයුතු බවත්, එසේ නොවීමෙන් සංකුලනාවන් ඇතිවිය හැකි බවත් මම දනිමි. යම් උපදෙසක් කඩවූ අවස්ථාවක් වේ නම් ඒ බව ඉලයකර්මය / විශේෂිත පරීක්ෂණය / ප්‍රතිකාර ක්‍රමය ආරම්භ කිරීමට පෙර දැනුම් දීමට එකඟ වෙමි. I understand that I must strictly follow the instructions given by the Doctor / Nurse while preparing for the procedure and I understand that any breach would result in complications. I undertake the responsibility of informing of such breach if any before commencement of the procedure.

11 ඉහත කරුණු සියල්ල මා හට ඉතා හොඳින් පැහැදිලි කර දුන් බවත්, මට ඇති ගැටලු සහගත තැන් පිළිබඳව ප්‍රශ්න කිරීමට අවස්ථාවක් ලැබුණු බවත්, මාගේ ගැටළු වලට සෘතිමකට පත්විය හැකි පිළිතුරු ලද බවත් සහතික කරමි. ඒ අනුව ඉහත සඳහන් ශල්‍යකර්මය / විශේෂිත පරීක්ෂණය / ප්‍රතිකාර ක්‍රමය සඳහා මම අවබෝධයෙන් යුතුව නිදහසේ හා ස්වාධීනව එකඟතාව පළකරමි

I certify that everything mentioned above was explained to me carefully and I was given the opportunity to question and clarify all my queries to my satisfaction. Accordingly, I express my free and voluntary informed consent for the above mentioned procedure.

රෝගියාගේ අත්සන }
Signature of Patient }

සාක්ෂි/Attestation }
අත්සන/Signature
නම/Name
ලිපිනය/Address }

රෝගියාට ඇති සම්බන්ධය }
Relationship to the Patient }

වෛද්‍ය නිලධාරී }
Medical Officer }

දිනය }
Date }



රෝහල
மாவட்ட பொது
Hospital

சத்திரசிகிச்சை அல்லது விசெட பரிசொதனை அல்லது சிகிச்சைக்காக இணக்கம் டிதரிவித்தல்
Declaration of Consent for Surgical or Special Investigative or Therapeutic Procedure.

1. நொயாளியின் டிபயர் (முடிமையாக) }
Name of Patient (in full) }

2. வயது }
Age }
டிபண் }
Female }
ஆண் }
Male }
4. கட்டழல் இலக்கம் }
BHT No. }
5. வாட்டு }
Ward }

6. அவசியப்படும் சத்திரசிகிச்சையின் / விசெட பரிசொதனையின் / சிகிச்சையின் தன்மை Nature of the Surgical /
Investigative / Therapeutic intervention required. (ஏதாவது அவையவர்கள் அல்லது பகுதியை அகற்றல்
அல்லது டிபாருத்துதல் பற்றி விசெடமாகக் குறிப்பிடவஜம்) / please specifically state if removal of any organ
or part or any grafts is to be performed)

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.....
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6.1 அவயவ்கள் அல்லது பகுதியை அகற்றல் அல்லது இணைத்தல் /Removals or grafts

.....
.....

6.2 தெவையான மயக்கவியலின் தன்மை / Nature of anaesthesia required.

.....
.....
.....

7. மெலெ டிபயர் குறிப்பிடப்பட்ட சத்திரசிகிச்சையின் / விசெட பரிசொதனையின் / சிகிச்சை முறையின் அவசியமும்
முக்கியத்துவமும் மற்றும் மயக்கவியலினால் ஏற்படக்வுடிய இடர்பாடுகள் பற்றியஜம் தீமைகள் பற்றியஜம் வைத்திய
அதிகாரி Dr. அவர்களால் எனக்கு விளக்கமளிக்கப்பட்டுள்ளது.
explained me about the necessity, and importance of the above mentioned procedure in treating my
illness and possible risks and complications of such a procedure and anaesthesia.

8. யாராவது டிபயர் குறிப்பிட்ட விசெட வைத்தியரால் இந்த சத்திரசிகிச்சை / விசெட பரிசொதனை/ சிகிச்சை முறை
டிசய்யப்படுவதாக உத்தரவாதம் அளிக்கப்படவில்லை. எவ்வாறாயினும் அந்த விடயத்தினை தகைமை டிபற்ற
நிபஜணத்துவம் ஜடிபற்ற வைத்தியரால் அவ்விடயம் நிறைவேற்றப்படும் என்பதை நான் அறிவென;
I have never been promised that a particular doctor would do this procedure. However, I understand
that a doctor with necessary qualification, skill and proficiency would be attending to the procedure.

9. ஒவ்வாமை அல்லது விசமாதல் கூ யுட்டநசபநைள யனெ வழஓஓஓவைல (தெவையற்ற விடயத்தை டிவட்டிவிடவஜம்.).
Delete inappropriate section)

9.1 எனது அறிவஜக்கு எட்டிய விதத்தில் இதற்கு முன் எந்தடிவாரு சந்தர்ப்பத்திலும் ஏதாவது மருந்து அல்லது
உணவஜ வகையால் ஒவ்வாமை அல்லது விசத்தன்மை ஏற்படவில்லை. To the best of my knowledge
I have never had any allergy or toxicity after taking any drug or food.

9.2 சாப்பிட்டால் ஒவ்வாமைத் தன்மை .: விசமாகுதல்
எனக்கு ஏற்படுவது உண்டு. I have experienced an allergic / a toxic reaction to following drug / food item

.....

10. இந்த சத்திரசிகிச்சை / விசெட பரிசொதனை / சிகிச்சை முறைக்கு முன்னாயத்தமாகும் பொது வைத்தியர்/தாதியர்களால் வரீகப்பட்ட ஆலொசனைகள் கட்டாயமாக பின்பற்றப்பட வெண்முயதன் அவசியத் தையஜம் அவ்வாறு இல்லாத சந்தர்ப்பத்தில் பாதிப்பஜக்கள் ஏற்படும்` என்றும் நான் அறிவேன்.ஏதாவது ஆலொசனைகள் மீறப்படுமானால் அதனை சத்திரசிகிச்சை / விசெட பரிசொதனை முறை ஆரம்பிப்பதற்கு முன் அவற்றைச் டிசால்வதற்கு நான் உடன்படுகின்றேன்.

I understand that I must strictly follow the instructions given by the Doctor / Nurse while preparing for the procedure and I understand that any breach would result in complications. I undertake the responsibility of informing of such breach if any before commencement of the procedure.

- 11 மெற்குறிப்பிடப்பட்ட எல்லா விடய்களையஜம் மிக நன்றாக எனக்கு விளக்கியஜள்ளதொடு எனக்கு உள்ள ஜய்கள் சம்பந்தமாக நான் கெள்வி கெட்பதற்கு சந்தர்ப்பம் வரீகப்படுள்ளதொடு எனது கெள்விகளுக்கு திருப்தி அடையக்வுமுயவாறு விடைகள் டிபறப்பட்டுள்ளதாகவஜம் உறுதி வறுகின்றேன். அதனழப்படையில் மெற்குறிப்பிட்ட சத்திரசிகிச்சை / விசெட பரிசொதனை / பரிசொதனை முறைக்காக எனது அறிவஜக்கு எட்டமுய வகையில் சுதந்திரமாகவஜம் மற்றும் சுயாதீனமாகவஜம் உடன்படுகின்றேன். I certify that everything mentioned above was explained to me carefully and I was given the opportunity to question and clarify all my queries to my satisfaction. Accordingly, I express my free and voluntary informed consent for the above mentioned procedure.

நொயாளியின் பெயர் }
Signature of Patient }

சாட்சி/Attestation } கைடியாப்பம் /Signature
} டிபயர் / Name
} விலாசம் / Address }

நொயாளியஜடனான உறவஜமுறை }
Relationship to the Patient }

வைத்திய அதிகாரி }
Medical Officer }

திகதி /Date }

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