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Clinical Standards

Standard 2
Patient Consent

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Standard 2 - Patient Consent

Consent is at the heart of the relationship of trust between patient and practitioner. Before embarking on any examination or treatment, you must be satisfied that your patient, or somebody with authority to do so on their behalf, has given their valid consent to the procedure you are about to undertake.

In this guidance, aimed at podiatrists, chiropodists and assistant practitioners practicing in the UK, we summarise the key principles of consent in order that they can be incorporated into your day to day practice.

The law governing consent varies across the nations of the United Kingdom, particularly where issues of capacity are concerned. It is therefore important you understand how the law applies in the area where you work.

Key Points

- Podiatrists are legally, professionally and ethically obliged to obtain informed consent prior to examining patients or undertaking investigations or treatment.
- Signed consent should be obtained prior to initial treatment.
- Adults (aged 18 and over) are assumed to have capacity to consent.
- Young adults of 16 or 17 years of age can consent to treatment. Their entitlement to refuse treatment which is in their best interests is more complex.
- Persons aged 15 and younger can give consent to treatment in their best interests if they are 'Gillick competent' (see page 7).
- When the patient lacks capacity, or is not competent to consent, treatment can be provided in the patient's best interests subject to requirements detailed below.
- Consent will only be valid if it is informed and freely given by an individual who has capacity to consent.

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- Patients should receive the information they require to support their decision making in a format which is clear and easily understood.
- Patients must be given sufficient time to consider their decision before treatment is provided. The amount of time required will be proportionate to the significance of the decision to be made.
- Patients are free to withdraw their consent at any time.
- The consent process must be supported by clear, contemporaneous and accurate records which should include details of the information provided with respect to diagnosis, prognosis, treatment options (including no treatment), risks and benefits of the proposed treatment and the reasonable alternatives, concerns or questions raised by the patient and their reasons for choosing their preferred option.
- Even when informed consent was obtained a failure to maintain adequate details of the decision-making process will leave registrant's vulnerable if the validity of consent is challenged.
- A signed consent form is not proof of informed consent. It is one aspect of the recording of a patient's consent.
- A failure to obtain informed consent exposes practitioners to a real risk of criminal or civil liability and to a risk of action against their registration by the Health and Care Professions Council (HCPC) your regulatory body.

Introduction

The process of shared decision-making is about enabling patients to make choices which are right for them. People's attitudes vary on issues such as the amount of risk or pain they are prepared to accept so it is important that you provide information in a balanced and unbiased manner and without trying to influence the patient unduly. As clinicians we must recognise that different patients will make different choices in apparently similar situations. What is important is that patients are enabled to make the choice which best reflects their own goals and values.

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Clinicians should obtain informed consent before carrying out any examination, investigations or treatment. A failure to obtain a patient's consent before conducting an examination, undertaking investigations or carrying out treatment could lead to civil or criminal liability or to action being taken against you by the HCPC or the College's Conduct Committee.

The Professional Obligation

The HCPC Standards of Conduct, Performance and Ethics contains professional obligations to protect and promote the interests of service users; communicate appropriately and effectively and keep records of their work. Each of those professional obligations is engaged in the consideration of patient consent. Please see the HCPC website for further information:

http://www.hcpc-uk.co.uk/standards/standards-of-conduct-performance-and-ethics/

The Legal Obligation

Treating a patient without obtaining informed consent may lead to a civil claim for damages or criminal proceedings for assault or more serious criminal offences. At present the most authoritative statement of what the law of informed consent requires is contained in the Supreme Court judgment in the case of *Montgomery v Lanarkshire Health Board*.

The practitioner is under a duty to take reasonable care to ensure that the patient is aware of:

1. Any risks involved in any recommended treatment.
2. Any reasonable alternative or variant treatments.

A risk is when:

3. a reasonable person in the patient's position would be likely to attach significance to the risk; or
4. the practitioner is or should reasonably be aware that the particular patient would be likely to attach significance to it.

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Consent is also relevant to the use of personal data and/or confidential information, but those issues fall outside the scope of this document. Please see the College's Standards on Standard 1 - Confidentiality and Standard 5 - Record Keeping.

Consent at the initial consultation

Due to the litigious nature of health care today, it is strongly advised to obtain signed consent at the patient's first treatment when undertaking general Podiatry care. This could be alongside a medical questionnaire that is filled out by the patient (and checked by the Podiatrist), or this could be a separate consent form. This is so that the patient can confirm they understand they are to be treated by a Podiatrist who may use sharp instruments. This is on top of the express consent from the patient for each treatment described below.

The College has template consent forms available at:

https://membersarea.cop.org.uk/podiatric-practice/private-practice-resources-area/patient-resources

Types of Consent

Practitioners must obtain the patient's consent for any examination, investigations or treatment. Patients can give consent either verbally or in writing. Silence does not constitute consent. In the past many practitioners relied on the patient's actions as indicating their "implied consent" to treatment e.g. where a patient removed footwear to facilitate an examination. This approach risks misunderstandings going unnoticed. Having explained your intentions to the patient it is a simple matter to ask whether they have understood and to confirm their agreement. This must be recorded in the patient notes. Reliance on implied consent must be avoided.

Whether consent is obtained verbally or in writing, you must maintain a written record of when and how consent was obtained in the patient notes.

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Recording Consent

A record of relevant discussions in respect of diagnosis, options, risks and benefits, must be included in the clinical record in respect of all examinations, investigations, treatments. Any questions or concerns which the patient has expressed should be recorded in the patient record. When patients choose between alternatives you should explore the reasons for their choice and record them.

A signed consent form is only one part of the overall evidence that informed consent has been obtained. It is not a substitute for an appropriate entry in the clinical record. Courts are alert to the possibility that patients may sign forms without reading or understanding them.

Where procedures are invasive and/or carry significant risks patients must be asked to sign a consent form. This includes the following:

- All invasive procedures
- Any treatment requiring local anaesthesia
- Any treatments involving caustics, cryotherapy, dry needling and alternative therapies or treatments which use substances that a patient may have a reaction to.
- All verrucae treatments
- All injections of medicines
- Acupuncture
- Where a student, or someone in training situation is to undertake the procedure
- A procedure which may cause particular pain, discomfort or bleeding e.g. the enucleation of a large and very deep corn.

Special considerations arise in relation to clinical photography and video recordings and the question of consent in respect of those matters is addressed in Standard 5 on Record Keeping.

When completed, consent forms should be kept with the patient's notes. In the case of computerised records, you can scan the signed consent form and save it on the electronic patient record. The original will then need to be treated as confidential waste (See Standards on Disposal of Waste and Record keeping). Generally, as with all records, they should not be altered. Any changes

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to the form, made after the form has been signed, should be initialled and dated by both the patient and the podiatrist. The reasons for the amendment should be recorded in the clinical notes.

Some electronic patient record systems also have the facility to obtain a digital signature from the patient which is then embedded into an electronic consent form. This is perfectly acceptable as long as the patient can see what they are signing for and the form can be printed should you notes get requested at any time.

Consent is a process. Patients may withdraw consent after they have signed a consent form and therefore you should check before commencing treatment to confirm that the patient has not had a change of mind and note this in the record.

What form should I use for written consent?

Where written consent is sought the College has produced template consent forms for members to use. There are six consent forms, two for each of the following situations;

- consent for investigation and treatment.
- consent for photography or video recording.
- consent for examination and treatment by a student or someone in training situation.

There are forms for use where a patient is able to give consent himself or herself and forms for young persons under the age of 18. In the case of the latter, both the parent/guardian and the young person should sign the form, where you judge that the young person is able to understand what is being said. These forms can be found in on the College's website:

https://membersarea.cop.org.uk/podiatric-practice/private-practice-resources-area/patient-resources

Who can give consent?

Before relying on consent, you must be satisfied that the person providing consent is entitled to do so. This is usually a straightforward issue. All persons aged 18 or above (16 in Scotland) are assumed

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to be competent to either give or refuse consent. That presumption may be rebutted if there is evidence that the individual lacks capacity (see below).

At the ages of 16 and 17 competent individuals may give valid consent to medical treatment which is in their best interests without parental approval. Parental involvement should be encouraged particularly for important medical decisions such as potential painful procedures. If a person aged 16 or 17 years lacks capacity to give consent or has chosen to leave it to their parents to give consent, then parental consent will be required before the treatment is given.

A young person aged 15 or under, may give valid consent to medical treatment without their parents' consent provided they understand the treatment and what it involves. The practitioner must satisfy themselves that the young person is able to understand the risks and benefits as well as the options available to them. This is known as being "Gillick competent" after the legal case which determined the principles.[1] Where a person under 16 does not meet this test i.e. because they are not able to understand the treatment, what it involves and the options available to them, they will not be able to give consent and parental consent will be required before the treatment is given.

When treating a child or young person who has capacity to consent it is prudent to explore the possibility of involving their parent or guardian in the process. Where a young person has capacity, you will need their consent to disclose confidential clinical information to their parent/guardian.

In the context of private treatment, a separate issue arises in relation to agreeing to the costs of treatment.

Refusals of consent

A competent adult is entitled to withhold their consent to treatment for any reason or none. Their decision must be respected. You must take care to make an appropriate note of the discussions

[1] Gillick v West Norfolk and Wisbech AHA [1986] AC 112. In Scotland the relevant provisions are set out in the Age of Legal Capacity Act 1991.

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which you have had with the patient, any advice or recommendations which you have made and their decision including any reasons which they have given for their decision.

Young Person's 17 and younger

If a young person aged 17 or younger refuses consent to treatment this might be capable of being overridden by an adult with parental responsibility if the treatment is considered in the patient's best interests. In Scotland it is likely that neither parents nor the courts are entitled to override a competent young person's decision.

Treating a patient who has refused consent presents a variety of clinical, ethical and legal challenges. It is a decision which requires careful consideration and should not be undertaken without obtaining legal advice appropriate to the region in which you are practicing. It is difficult to envisage scenarios where treatment could not reasonably be deferred. The urgency with which advice should be sought will depend on the clinical presentation. You should consider whether the involvement of other healthcare professionals would assist in resolving the matter.

Where a patient refuses a particular intervention, you may continue to provide alternative treatment to which they have consented, if that is appropriate.

Who can give parental consent?

Only people with 'Parental Responsibility' may give consent on behalf of persons under the age of 16. 'Parental Responsibility' is a legal term with a strict meaning.[2] Not all parents have parental responsibility for their children, for example, unmarried fathers do not automatically have such responsibility if they are not named on the birth certificate, although they may acquire it.

It is always advisable to enquire of the adult accompanying a child whether they have Parental Responsibility and to record details of the individual providing consent, and their relationship to the young patient, in the clinical records. You should seek advice if it is unclear whether the individual

2 The definition of Parental Responsibility is set out in legislation and differs between England and Wales and Scotland.

providing consent has Parental Responsibility. A relative, nanny or childminder would not normally have parental responsibility and thus would not normally be able to provide consent. Where necessary you should defer treatment in order to ensure that valid consent is obtained.

Where written consent is obtained the form must be signed by the person whose consent is being relied upon. This needs to be fully informed consent and therefore should be done face to face. On the rare occasion the consenting adult is not able to be present i.e. they work abroad, you must have had an appropriate discussion with them providing the relevant information and affording them the opportunity to ask questions and this must be detailed in the notes. You should also have done due diligence to confirm who it is that you are corresponding with and that they have the right to give consent for the patient involved.

What is the test for Capacity?

The test for capacity is decision specific and involves a requirement that the individual can understand the information, which is relevant to the decision to be made, can retain the information for long enough to use or weigh it and can communicate their decision. At any given time, an individual may have capacity to make some decisions but not others.

If you are concerned that a patient aged 16 or over does not have capacity, you should not rely on their consent to provide treatment. You should defer treatment and seek further information to assist in determining whether they have capacity. You should consider taking legal advice and liaising with other healthcare professionals who may be better placed in determining whether the patient has capacity.

Lack of Capacity and Best Interests

If a patient lacks capacity because they do not have the ability to understand and weigh up the information needed to make an informed decision, for example due to dementia, you should first consider whether the patient has made a an arrangement which permits a third party to consent on the patient's behalf. Such an arrangement may be in the form of a Lasting Power of Attorney for Health and Welfare (or similar) or arise from the decision of a court to appoint an individual for that

purpose. Members should be aware that the terminology for different types of Power of Attorney in Scotland differs to that in England. For more information about mental capacity in Scotland see our related guideline:
https://membersarea.cop.org.uk/api/documentlibrary/download?documentId=56

If a patient lacks capacity, you may still treat the patient if the treatment would be in their best interests. To decide if the treatment is in the patient's best interests, you should determine the patient's likely preferences by discussing the procedure with the patient's relatives, carers and friends. However, it is important to appreciate that the patient's relatives, carers and friends cannot give consent on the behalf of the patient; they can only assist in determining the patient's best interests by indicating the patient's likely preferences based on previous experience. Where the proposed treatment is invasive particular care should be taken. Where possible you should liaise with the patient's GP and seek their views on whether the proposed treatment is in the patient's best interests.

If the information from relatives, carers and friends indicate that had the patient been competent to give consent, they would have refused treatment, then you should not treat the patient. If this places the patient at risk, then with the consent of the relative, carer or friend, you should refer the matter to the patient's General Practitioner or hospital Consultant, whichever is appropriate.

Where a decision to provide treatment is taken on the basis that this is in the patient's best interests then you should record in the patient's notes the reason for this decision and the information upon which it was based. A note should also be made of whom you consulted when making this decision. It would not be appropriate to complete a written consent form, if this had otherwise been indicated.

When treating patients in a care or nursing home it is your responsibility not the homes to confirm the patient's capacity or lack there of and any power of attorneys they may have. The home may be able to provide a signed document that the power of attorneys has given them permission to consent to routine medical treatment but you need to check that this document applies to podiatry care and document it in your patient records. If the patient does have a power of attorney and they

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have not given the home permission to make medical decisions, they must be contacted so that they can give consent to treatment and sign any appropriate consent forms. If the home will not allow you to contact the power of attorney initially ask them to contact them with your details so you can speak to them directly. Ideally you should meet the power of attorney(s) at least once face to face, however, if this can not be done i.e. they do not live in the area, then you should still have a verbal conversation with them and then post information/consent forms to them by record delivery both ways. All of this should be documented in the patient's record.

For further information see the Mental Capacity Act 2005 or the Adults with Incapacity (Scotland) Act 2000 or Mental Capacity Act (Northern Ireland) 2016.

What if there is a communication problem?

If the reason that someone cannot understand is because they cannot speak English then you should allow them to be accompanied by an interpreter. Ideally the interpreter should be independent, and you must have regard to the risk that where a family member acts as an interpreter they may be exercising undue influence over the patient. If the reason that someone cannot understand is because they cannot hear, you should explore alternative means of communication.

What if I work in the NHS – do I have to follow these guidelines?

If you work within the NHS your Trust will have their own policy and probably use the Department of Health consent forms. If this is the case, you should follow your Trust's guidance.

Who can seek consent?

It is always best for the person actually treating the patient to seek the patient's consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question. You must make an appropriate note of your discussions with the patient so that others involved in the patient's care can see the basis on which the patient's consent has been obtained.

Where another practitioner has taken the patient's consent it remains the operating practitioner's responsibility to ensure that valid informed consent has been obtained before commencing treatment. You must review the records of the previous discussions, check the patient's understanding and confirm their consent prior to undertaking the investigation or treatment.

The timing of consent

Consent must be given voluntarily and not under any form of duress or undue influence from health professionals, family or friends. Patients should never be rushed into making a decision. However, for most podiatric practice (non-invasive and low risk procedures) it would be acceptable to provide treatment immediately after discussing it and obtaining consent. The exception being where it is advisable that signed written consent is sought (see above), in such situations it is recommended that consent should be sought in advance of the day of treatment, wherever practicable (particularly for nail surgery) and that information is given to the patient in written format and recorded in the patient's notes.

However, you can use your own clinical judgement as to whether it is beneficial to the patient to proceed on the same day. For example, a bleb of local anaesthetic being used to remove a very painful nail spicule, or verrucae treatment which may be in the best interest of the patient that this was consented for at the time of treatment rather than waiting until the next day.

If a course of treatment is recommended i.e. a course of salicylic acid verruca treatment, you do not need to complete a new consent form at each visit. The consent form signed at the beginning of the treatment which states the planned course will suffice, however, practitioners need to be aware of how many treatments the patient has consented to i.e. if they consent to 4 treatment specifically you must get them to sign a new form on the 5th treatment. You must also confirm the patient's consent verbally at each attendance and make an appropriate entry in the clinical records. If you change the treatment to a different method e.g. cryotherapy a new consent form needs to be signed and the reasons for the change in approach should be documented in the clinical notes.

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Practitioners should consider ways in which relevant information can be provided to patients in advance of their appointment. It may be possible to provide the patient with relevant information i.e. leaflets, in writing at the same time as confirming their appointment arrangements.

What information should be given to the patient?

If the patient's consent is to be valid, it is important that they first have sufficient information so that they may make a genuinely informed decision.

When seeking consent, you should inform the patient of the working diagnosis and explain why treatment is being proposed, what it is intended to achieve and what would happen if nothing were done. You should also explain the available treatment options, the likely success rates and the risks, if any, of each option and provide information about the costs involved. You should explain the likely recovery period and any restrictions which will apply during the recovery phase. The information should take account of the patient's own circumstances, e.g. risks may be higher for diabetic patients. You must also take account of the patient's desired outcome. Where local anaesthesia will be used you should also explain what they could expect to feel after the procedure, when they will be able to drive and go back to work/school.

For surgical procedures you should inform the patient how the success rates compare to national statistics, where they exist. Patients will also need to be informed about the effects on foot function generally, and whether having surgery may affect the patient's occupation, lifestyle or choice of footwear.

The following is not an exhaustive list, but many patients will be interested in the following types of information:[3]

[3]An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

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- The diagnosis including any uncertainty about the diagnosis.
- The nature and purpose of proposed investigation or treatment and the material risks.
- The consequences of no investigation/treatment.
- The reasonable alternatives or variant options, their comparative risks and benefits and likely success rates including the likelihood and seriousness of potential risks.
- The potential side-effects and complications including pain, infection or loss of function
- Recovery periods and post treatment restrictions.
- The costs of treatment.

While infection may be a rare complication of podiatric treatment its consequences may be devastating. Whenever undertaking procedures in which the skin may be breached the risk of infection must be included in the discussion with the patient. This would also apply if you accidently cut the patient during the course of your normal treatment.

The information provided must be tailored to the needs of the particular patient. The podiatrist will need to have relevant information about the patient's home circumstances, mobility, hobbies, transport, and employment. Recording those discussions will assist in demonstrating that you have facilitated the patient in making an informed choice which reflects their individual circumstances.

You should bear in mind that the timing of procedures may be of significance to the patient. A promising young athlete will want to think carefully about the timing of an elective procedure such that the recovery period does not interfere with crucial training or competition. Equally patients may need to plan around work commitments, childcare arrangements or a range of other personal considerations.

The patient must understand the professional status and qualifications of the individual who will be performing the procedure. It is essential that the patient understands that the practitioner is a podiatrist or podiatric surgeon and is HCPC registered or is being seen by an appropriately trained assistant practitioner (podiatry assistant). Where a procedure may be performed by a student or by

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a clinician under supervision, then the patient should be informed at the time the appointment is made and appropriate consent forms signed.

Uncertainty

It is important that patients have an understanding of elements of uncertainty in the available information, whether it relates to the diagnosis or the effectiveness of available treatment options.

How should the information be provided?

The process of consent requires a dialogue with the patient. It may be sufficient for information to be given verbally but it is best to provide written information (for example a leaflet) to supplement those discussions, in particular for treatment types requiring written consent (see above). Information should always be presented as simply and clearly as possible. The clinical notes must record the nature of the information provided including what information leaflets were provided and details of any additional sources to which the patient has been directed such as reputable websites.[4] Where a specific leaflet is given, then the title and version of the leaflet should be documented in the patient record. A copy of all versions of the leaflets should be kept by the podiatrist in case the patient records are ever requested, and that version is needed.

What should I do if the patient does not want to know what is involved?

There may be occasions when a patient would rather not know about certain aspects of the treatment and ask you not to tell them. In such circumstances it is important to ask if they have any particular worries or concerns about the treatment.

[4] "… the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form." *Montgomery v Lanarkshire.*

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Encourage the patient to ask anything they wish about the diagnosis or proposed treatment. If you feel it appropriate you may always suggest that they have a chat with their General Practitioner or bring a family member or friend to the next appointment. If they refuse information about the risks and benefits or certain aspects of their treatment, their decision should be respected and documented in the notes.

What should I do if the patient wants more time to consider things?

If the patient expresses a wish for more time to consider their decision, or you suspect that they would like, or would benefit from more time, then arrange another appointment. An exception may arise in the management of the at-risk foot. In such circumstances you should explain to the patient the possible consequences of delaying treatment. If they still refuse, offer to make an appointment with an appropriate medical practitioner for the following day or direct them to emergency services if appropriate. Consider arranging immediate antibiotic cover if clinically indicated. You should ensure that you maintain a detailed record of the discussions and advice in the patient's record.

What if the patient has a living will or advanced directive?

The detailed arrangements for "living wills", advanced decision making, and the appointment of surrogate decision makers vary between the regions. Before relying on an advanced decision or the consent of a surrogate decision maker you should satisfy yourself that they are valid in the area where you are practicing. If in doubt you should seek advice. More information can be found at **https://www.nhs.uk/conditions/end-of-life-care/advance-decision-to-refuse-treatment/**.