

# Informed Consent for Acupuncture - An Information Leaflet Developed by Consensus

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## **Summary**

Patients have the right to be fully informed about the likely benefits and risks of any proposed examination or treatment, and practitioners are obliged to obtain informed consent beforehand. Accurate information about the risks of acupuncture is available following publication of the results of two prospective surveys. At a joint meeting on the safety of acupuncture, members of the three largest UK professional bodies expressed a need to establish what information on risks patients should be given. A standard Information Leaflet was developed by consensus between these organisations, and is intended to be used as a stimulus for discussion of standard risks as well as any particular risks that might apply to individual patients. Additionally, it may be used as a form for written consent when this is required. To provide the context for using the Leaflet, the legal and ethical bases of informed consent for medical procedures are discussed.

## **Keywords**

*Acupuncture, informed consent, consensus, information leaflet.*

## **Introduction**

Acupuncture is increasingly used by health professionals in the UK, both within and outside the health service. As with all treatments, patients have the right to be fully informed about the likely benefits and risks, and practitioners are obliged to obtain informed consent beforehand. This paper will address the question of risks not benefit, since the benefits cannot be discussed in a standardised way. Currently, informed consent for acupuncture treatment is usually an informal matter. In other

words, most acupuncture practitioners probably provide information on the risks of acupuncture only when they are asked, and consent is assumed by the fact that the patient has turned up at the clinic and undresses in preparation for treatment. While this approach might reflect much of current practice, it is timely to reassess procedures in the light of recent research on safety, current legal opinion and developments in ethical practice. In meeting patients' rights, a balance should be struck between the informality that can engender a positive therapeutic environment and the formality in meeting ethical and legal requirements.

Patients have the fundamental right to be allowed to give consent to treatment; 'Respect for bodily integrity and privacy are values that are central to any theory of consent'.<sup>1</sup> One of the prime principles of ethical behaviour between practitioners and their patients is patient autonomy. This is also becoming increasingly a legal principle, and Human Rights legislation has been introduced as the basis of case law in the UK (Human Rights Act 1998, put into force in October 2000). Much case law governing medical practice predates this human rights legislation, so practitioners will remain somewhat in the dark until new cases are decided. Nevertheless, patients are entitled to best practice and practitioners need guidance now. It is therefore timely that the Department of Health recently issued a guide to informed consent based on the current legal opinion.<sup>2</sup> This is necessarily a 'catch-all' document that has been designed to be applicable to extreme situations that often bear little relationship to practitioners providing routine acupuncture to patients who have asked for treatment. Nevertheless, practitioners should be aware of the underlying principles as a firm basis for their actions. The

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authors of the Department of Health document are able to give detailed advice on every area of informed consent except, unfortunately, the crucial matter of 'disclosure of risk'. In other words, it is clear that patients have a right to be given relevant information before they decide to receive treatment, but it is not yet clear how to decide precisely what information is relevant.

While the question of which risks patients should be told about is still undecided, at least we can now be much clearer about what risks acupuncture actually poses, since the publication of two prospective surveys.<sup>3,4</sup> For the first time, discussion of the risk of acupuncture can be based on evidence rather than on clinical impression. All three major professional acupuncture organisations in the United Kingdom were involved in collecting the data for these surveys, and in celebration of this unanimity of purpose, a special joint conference on safety was held in June 2001. The conference delegates made a clear call for a standard information sheet on the risks associated with acupuncture treatment. It was agreed that the three registration bodies (the Acupuncture Association of Chartered Physiotherapists, the British Acupuncture Council and the British Medical Acupuncture Society) would be responsible for developing and agreeing this information sheet. This was achieved by meetings and email discussions among the authors representing their respective bodies, together with peer review by senior members from each organisation.

This article presents the standardised Information Leaflet agreed by this consensus procedure. Additionally, it summarises the formal legal background to situations that are most likely to be met in acupuncture practice, while accepting that patients should not be subjected to unnecessary formalities and that it is vital to maintain a common sense approach.<sup>1</sup> Readers who require more detail or information on other specific situations are advised to refer to the original sources.<sup>2,5</sup> In particular, the special conditions which apply to obtaining consent for video or sound recordings and to clinical trials are not dealt with here.

### ***The legal and ethical background***

The recent literature sources on informed consent on which this article is based are an editorial article,<sup>1</sup> the Department of Health website,<sup>2</sup> the guide on informed consent published by the General Medical Council (GMC),<sup>5</sup> and an information sheet currently in use in a German academic acupuncture clinic.<sup>6</sup> The Department of Health guide is based on current case law and legal opinion, whereas the GMC guide, produced by a professional body, also considers the ethical issues and as a result is in some respects more demanding.

Before examining, treating, or caring for competent adult patients, their informed consent must be obtained. In the normal practice of acupuncture, this will involve the practitioner giving appropriate information on benefits and on risks (for example, in the Information Leaflet, see Appendix A) and the patients implying consent by preparing themselves for treatment (e.g. by undressing and climbing on the couch). These procedures are clearly relatively informal, but they must be routinely applied.

Although normal practice relies largely on common sense, patients are ultimately protected by the law. This only comes into play in unusual circumstances or when things go wrong. Theoretically, any health professional who does not respect the principle of informed consent may be liable both to legal action by the patient and to action by their professional body. Touching a patient without valid consent, for example, may constitute the civil or criminal offence of battery. Further, if health professionals fail to obtain informed consent and the patient subsequently suffers harm as a result of treatment, this may be a factor in a claim of negligence against the professional.

Students are subject to additional requirements. If a student is using examination or treatment as part of the learning process, additional consent must be obtained. This additional consent is no longer a legal requirement once the student has been trained to carry out a procedure which forms part of the patient's normal care, though it is still good practice to tell the patient.

The key principles of informed consent are that

consent must be given by a patient

- a) voluntarily,
- b) who has the capacity to understand and
- c) who has been given appropriate information.

In respect of a) voluntariness, this means without any pressure or undue influence from family, friend or health professional. The use of acupuncture against the patient's wishes, for example in patients who are detained against their will, is an exceptional circumstance and is not considered here. In respect of b), the capacity to understand, patients must be able to understand and retain the information given and use it in forming a judgement. Adult patients are assumed to be competent unless proven otherwise; the procedure of acupuncture is relatively straightforward and few people will find it hard to understand. Apart from the special case of minors (see below) the question of the patient's competence is unlikely to arise in normal clinical circumstances relating to acupuncture. Special considerations apply to obtaining consent from adults and children who do not have the capacity to give informed consent (see DoH website<sup>2</sup>).

The matter of what is c) 'appropriate information' is not clearly defined and may be open to judgement. There are some principles to guide the practitioner. Patients must understand in broad terms the nature and purpose of the procedure. The duty of care also demands that patients should also be informed about any alternative treatments that may be available, and their benefits and risks. Deciding what information to provide was previously subject to the 'Bolam' test; in other words, the practitioner must do what conforms to a responsible body of medical opinion. However, this principle has subsequently been changed by case law (the Sidaway case<sup>7</sup>). The House of Lords ruled that the courts can decide that information about a particular risk is so obviously necessary that it would be negligent not to provide it, even if a 'responsible body' of professional opinion would not have done so. The courts will probably consider that it is necessary to inform the patient of any 'material' or 'significant' risks in the proposed treatment, any alternatives to it, and the

risks incurred by doing nothing.<sup>2</sup> It is also the responsibility of the clinician to inform a patient of 'a significant risk which would affect the judgement of a reasonable patient', even if this would lead to the patient declining treatment. The GMC guide adds the ethical demand that doctors should do their best to find out about patients' individual needs and priorities when providing information. In the very rare event that such information is withheld by the clinician on the grounds that it would be deleterious to the patient's health, this should be recorded in the notes. This decision by the practitioner needs real clinical justification - not just that the patient would be upset or might refuse treatment. Occasionally patients do not wish to know much about their treatment and will decline the offer of information, in which case this should be recorded in the notes. Any misrepresentation of information will invalidate the consent.

Who should provide information and obtain consent? Usually this will be the clinician, but acupuncture is practised in a variety of circumstances. For example, an anaesthetic consultant in a Pain Clinic may refer a patient to an acupuncturist in the clinic, who is assisted by nurses. It is the responsibility of the acupuncturist providing treatment to ensure that the patient has given valid consent before the treatment begins. However, the actual process of obtaining consent may be delegated to the nurses provided that they have sufficient knowledge of the procedure.

Consent may be given in writing, verbally, or by implication. The question arises whether the patient's signature should be obtained routinely before acupuncture. The answer in most cases is 'No' since informed consent is not made valid simply because the patient signs a form. The clinician must be certain that the information has been understood, retained and applied in reaching the decision. Consent can be implied from an appropriate action, e.g. climbing on to a treatment couch. Acupuncturists should be particularly sensitive to any hesitation by patients who may be overwhelmed by the strangeness of the procedure and unable to express their concerns. In such cases, it is recommended that explicit verbal

consent be obtained. The GMC and the Chartered Society of Physiotherapy suggest that, if doctors or physiotherapists do not use a consent form before conducting a procedure, they should record in the patient's notes the fact that consent was given, and the main details of the discussion.

Consent only covers the procedures that have been explained, so fresh consent should be obtained to cover any additional procedures that become necessary during the treatment. In the context of acupuncture, it seems likely that this would apply to interventions such as electroacupuncture and moxibustion.

Refusal to give consent must be respected, although it would be unusual for someone who requests acupuncture treatment to refuse consent. However, limited refusal may occur, such as patients who decline to have treatment to certain areas of the body. When consent is given it generally remains valid for an indefinite duration unless withdrawn. If new information (e.g. about the effectiveness of alternative treatment options) becomes available during a course of treatment, the GMC suggests that the clinician should tell the patient. Patients have the right to withdraw consent at any time, even during the procedure.

People aged 16 or 17 are entitled to give or refuse consent for their own medical treatment under the same terms as for adults. Although refusal may be overridden (by either a person with parental responsibility or by a court) it seems unlikely that any acupuncturist would proceed with treatment under these circumstances. While it is not strictly necessary to obtain consent from the parents as well as from the young person, it is good practice to do so unless the latter specifically does not wish this.

In the case of children below the age of 16 years, the concept of 'Gillick competence' applies. This means that children who have sufficient intelligence and capacity to understand what is involved in the proposed treatment will also have the capacity to give consent. The capacity to understand may vary with different medical or surgical procedures. Since it is relatively easy to understand what acupuncture treatment involves, it seems probable that even quite young children

should be involved in giving consent. It is important that this consent is given voluntarily and not under any influence of parents or other carers. If a Gillick competent child refuses consent, the parent may overrule them, for example if the child is at risk of 'grave and irreversible mental or physical harm', though this seems unlikely in clinical situations involving acupuncture.

### **Recommendations**

After discussion, the authors agreed that patients who wish to undergo acupuncture treatment should be informed of the risks in four categories, and these are included in the Information Leaflet. Leaflets with (Appendix A) and without (Appendix B) integral consent statement are presented.

Risks for which the evidence indicates an incidence of 1% or greater, even though none of these risks could truly be considered 'material' or 'significant'. This recommendation errs on the side of caution, since the authors of a recent survey argued that 'minimal' risks need not be discussed unless the patient specifically asked.<sup>4</sup> However, patients have varying expectations of acupuncture, and, for example, some even express surprise that acupuncture points bleed.

Certain other risks that were judged to be 'material' or 'significant', even though very rare. These include the risk of drowsiness, which affects road users.

Risks associated with particular clinical situations that apply in an individual patient. In order to reduce these risks, patients should give relevant information such as bleeding abnormality or pregnancy. This category also includes specific risks such as bacterial endocarditis with indwelling needles in patients with damaged heart valves. Sometimes the risk may be revealed only at the time of clinical examination, such as risk of pneumothorax in patients with thin chest walls and diseased lungs, for example in chronic bronchitis, emphysema or bronchiectasis. Discussion of these risks can be accompanied by specific advice to the patients on recognising adverse events when they arise.

Serious adverse events. Evidence from recent surveys indicate that these are very rare in

acupuncture. Patients should be informed that serious side effects do occur but the risk is minimal i.e. the incidence less than one per 10,000 treatments.

The order and wording of the Leaflet were carefully framed to give all required information truthfully and without misrepresentation, yet attempting to avoid inducing anxiety in the reader. The form is designed to be used either as an 'aide memoir' to the practitioner who is giving information when obtaining consent, or to be read directly by the patient before discussion with the practitioner (or, occasionally, another person who is knowledgeable on the subject). One version of the Leaflet includes space for the patient's signature. The general recommendation regarding obtaining the patient's signature is that it is not normally necessary, although health service trusts and other employers might require it. Merely reading the form, even if accompanied by a signature, may not be taken as evidence that the patient has fully understood the risks. It is the practitioner's responsibility to ensure the latter, although no advice on how was offered in our information sources.<sup>2,5</sup> We believe that it would be insufficient, for example, simply to ask the receptionist to hand the consent form to patients in the waiting room for signature without any opportunity to discuss it with the practitioner.

Since treatment of children under 16 with acupuncture is relatively uncommon, no specific facility was added for signed parental consent for this group.

### Comments

We recommend that the process of obtaining informed consent for acupuncture treatment under normal circumstances should be carefully reconsidered by all practitioners. As well as learning the potential benefits of treatment, we recommend that practitioners should explicitly discuss some of the risks of treatment. We do not recommend obtaining signed consent, but regard patient consent as sufficient if it is implied, e.g. by their climbing on the couch.

While these recommendations are based on good ethical practice, they are as yet limited in the sense that they are based on legal opinion rather

than actual case law. On the basis of recent research, Vincent concluded that 'acupuncture is a very safe intervention in the hands of a competent practitioner'.<sup>8</sup> We therefore take the position that the 'material' and 'significant' risks of acupuncture treatment given by trained and competent practitioners are minimal. Another issue which we have highlighted here is how the clinician needs to ensure that the patient has fully understood all of the risks and taken them into consideration in giving consent. We accept that some acupuncture practitioners will feel constrained by these recommendations, but this article arose in response to a need expressed by the majority of practitioners who attended the safety conference.

Whilst the Information Leaflet has already received wide review, it must be considered provisional rather than final. Future case law may affect the recommendations. Modifications to the Leaflet may be suggested after its wider use, and comments or suggestions are welcome from readers.

### Acknowledgements

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## Patient Information and Consent Form

*Please read this information carefully, and ask your practitioner if there is anything that you do not understand.*

### **What is acupuncture?**

Acupuncture is a form of therapy in which fine needles are inserted into specific points on the body.

### **Is acupuncture safe?**

Acupuncture is generally very safe. Serious side effects are very rare – less than one per 10,000 treatments.

### **Does acupuncture have side effects?**

You need to be aware that:

*drowsiness occurs after treatment in a small number of patients, and, if affected, you are advised not to drive;*

*minor bleeding or bruising occurs after acupuncture in about 3% of treatments;*

*pain during treatment occurs in about 1% of treatments;*

*symptoms can get worse after treatment (less than 3% of patients). You should tell your acupuncturist about this, but it is usually a good sign;*

*fainting can occur in certain patients, particularly at the first treatment.*

In addition, if there are particular risks that apply in your case, your practitioner will discuss these with you.

### **Is there anything your practitioner needs to know?**

Apart from the usual medical details, it is important that you let your practitioner know:

*if you have ever experienced a fit, faint or funny turn;*

*if you have a pacemaker or any other electrical implants;*

*if you have a bleeding disorder;*

*if you are taking anti-coagulants or any other medication;*

*if you have damaged heart valves or have any other particular risk of infection.*

**Single-use, sterile, disposable needles are used in the clinic.**

### **Statement of Consent**

I confirm that I have read and understood the above information, and I consent to having acupuncture treatment. I understand that I can refuse treatment at any time.

Signature

Print name in full

Date

## Patient Information Leaflet

*Please read this information carefully, and ask your practitioner if there is anything that you do not understand.*

### **What is acupuncture?**

Acupuncture is a form of therapy in which fine needles are inserted into specific points on the body. Some practitioners also use a smouldering herb called 'moxa' to warm these points.

### **Is acupuncture safe?**

Acupuncture is generally very safe. Serious side effects are very rare – less than one per 10,000 treatments.

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You need to be aware that:

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