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Informed Consent and Orthodontic Treatment

Abstract: Informed consent is a fundamental component of good clinical practice and clinical governance. Dental practitioners must be aware of the principal factors that need to be addressed to ensure that consent is valid. This paper provides a comprehensive review of current English law on consent issues and relates these to proposed orthodontic treatment.

Clinical Relevance: Orthodontic treatment is not without risk to the patient. The clinician undertaking treatment must aim to provide the competent patient with enough information to perform a risk-benefit analysis, supported by best current scientific evidence, so that an informed decision can be made prior to commencing orthodontic treatment.

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The Nuremberg Code (1947)¹ is generally regarded as the first document to establish ethical regulations in human experimentation based on informed consent. Later, the Declaration of Helsinki (1964),² developed by the World Medical Association, made informed consent a central requirement for ethical research.

In English law, there is no overall statute which sets out the general principles of consent. However, case law ('common law') has established that touching a patient without valid consent may constitute the civil or criminal offence of battery. Therefore, consent prior to active treatment is a general legal and ethical principle that is fundamentally central to all forms of healthcare. With the advent of Modernising NHS Dentistry (2000)3 and issues of clinical governance, valid consent prior to treatment is absolutely central to ensure the provision of a high standard of clinical dental care4 and is advocated by the defence societies of the United Kingdom and the NHS Management Executive.

A comprehensive summary of current English legal requirements for obtaining valid consent and on the situations where the law recognizes exceptions to common law has been published by the Department of Health in England (DH).⁵

This document also includes references to legal cases and good practice guidance from regulatory bodies such as the General Medical Council. Along with this article, a recent circular (HSC 2001/023),6 aimed at clinicians, focused on the action necessary and required time-scales for implementing the model consent documentation in day-today NHS practice. A number of DH guidance documents and leaflets on consent for patients^{7,8} are also available from the DH website (www.dh.gov.uk). As highlighted in The NHS Plan (2000),9 a DH advisory group produced national consent guidance to ensure that best practice, when patients consent to examination or treatment, was adopted throughout the NHS. The guidance included a model consent policy and four model consent forms to be used locally as part of their 'good practice in consent' initiative.10

By following consent principles, the clinician may be protected, under the law of tort, from liability from patient complaints (through the NHS complaints procedure or to professional bodies), civil claims and claims of negligence but NOT criminal charges. However, the NHS Litigation Authority has recently issued an alert regarding changes to the law on informed consent. As highlighted by the recent case of Chester v Ashfar

(2004),¹¹ the House of Lords decision had the effect of significantly extending clinicians' liability in cases where less than full consent is obtained. Despite the acknowledgment that there had been *no* clinical negligence, the adverse outcome, combined with the invalid consent (as the patient claimed lack of information), led to the successful judgement of negligence.

It must be appreciated that case law on consent is a constantly evolving area and health professionals have a duty to remain up-to-date with regard to legal developments which may affect their practice.

What is consent?

Consent is defined as:

The voluntary and continuing permission of the patient to receive particular treatments. It must be based upon adequate knowledge of the purpose, nature, likely effects and risks of that treatment, including the likelihood of its success, and a discussion of any alternative to it.¹²

Normally, it is the patient undergoing orthodontic treatment that gives consent, although there are occasions whereby the consent of a parent/guardian is required (discussed later). There are two main

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	TISSUE	RISK	COMMENTS
EXTRA-ORAL	Soft	Trauma Skin allergy Burns	UK - 3.6% extra- and intra-oral injuries with Klöen type facebow; ³⁷ eye injury - rare HG strap or whisker/bonding agents (rare)/latex Uncommon. Chemical acid burn from etchant/thermal
	TMJ	Temporomandibular dysfunction (TMD)	Common in population. Multifactorial aetiology. <i>Good</i> evidence – orthodontics does not cause or cure TMD ³⁸
	Profile	Profile damage	Evidence – very little. Extractions may have a small effect on profile (not necessarily detrimental). No significant difference in facial profile of extraction v non-extraction cases. Facial growth - overriding factor ³⁹
INTRA-ORAL	cari	Decalcification/	Common. 2–96% incidence ⁴⁰
		caries (Figure 1) Fracture/wear	Risk of abrasion – Ceramic brackets > metal brackets
	Periodontal	Gingival inflammation (Figure 2) Alveolar bone loss	Transient. Nearly all FA wearers. Attachment loss – rare
			Uncommon. Minimal crestal loss (0.5–1 mm) and no long- term effect ⁴¹ (if no pre-existing periodontal disease)
	Pulp	Pulpal reactions	Transient pulpitis (90%). Loss of vitality – increased risk in previously traumatized teeth ⁴²
	Root	Root resorption ^{43,44} (Figure 3)	Some degree of external root resorption inevitable Risk factors: Blunt and pipette-shaped roots/short roots (16.5% of teeth – loss of root length exceeding 2.5 mm). ⁴⁵ Previous tooth trauma (periapical radiograph monitoring preand during treatment is essential). Treatment mechanics – heavy forces/FA/rectangular AW/Class 2 traction/↑ treatment time/distance of tooth movement/tooth intrusion and torque. Long term effects – rare
	Other	Soft tissue trauma (Figure 4)	Common. Ulceration from AW/brackets/HG whisker
	Allergy		Rare. Nickel ⁴⁶ (most common allergen) – AW/bands/ brackets/HG. Latex – elastics/gloves. Bis-GMA – bonding agents
	Pain		Highly subjective. After FA adjustment: intensity dependent on age and diurnal variation. Duration: 5–6 days; ⁴⁷ initial pair perceived at 2 hours, peak at 24 hours and reduction by day 3 ⁴⁸
	Restorations (Figure 5)		Risk of damage to the restoration (eg veneer/crown)/Heavily restored teeth at debond
	Ectopic canines ^{49,50} (Figure 6)		Particularly upper canines undergoing orthodontic alignment. <i>Risks</i> : discoloration, ankylosis, root resorption, relapse
SYSTEMIC	Allergy		Rare. Sources as above
	Infective endocarditis ⁵¹		Risk procedures: Extractions/banding/separation/cleaning and polishing/?traction to unerupted teeth
	Cross infection		Consider: Bacterial/viral/fungal/prion and new variant CJD
	Radiation		↑ radiation exposure – DPT/lateral cephalogram/intra-oral films

Table 1. Summary of the potential extra-/intra-oral and systemic iatrogenic risks associated with orthodontic treatment. (Abbreviations – HG: headgear; FA: fixed appliance; AW: archwire).



Figure 1. Extensive decalcification of the dentition following orthodontic treatment.



Figure 2. Severe inflammation of the gingival tissues immediately following orthodontic treatment.



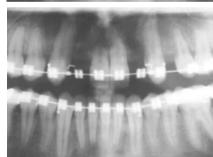


Figure 3. Marked root resorption of the upper central incisor teeth during fixed appliance orthodontic treatment: **(a)** pre-treatment; **(b)** during treatment.

types of consent:

b

- Implied (eg voluntarily opening the mouth to allow examination); or
- Expressed (oral or written to an examination or specific procedure).

At present, there is no requirement in common law for written



Figure 4. Trauma to the buccal mucosa during fixed appliance orthodontic treatment.



Figure 5. Decoronation of the first permanent molar on removal of the rapid maxillary expansion (RME) device.



Figure 6. Ankylosis of the upper right canine during orthodontic alignment with fixed appliances and consequent severe disruption of the occlusal plane.

consent and it makes no difference whether a form is signed by a patient to indicate his/her consent or whether it is given orally or nonverbally. Also, English law does not directly prescribe a threshold above which a formal conversation between the treatment provider and patient concerning consent should occur. However, as a general rule, the more complex the treatment becomes, the greater the need to ensure that the patient has given his/ her consent. The value of a signed consent form is that it provides some evidence of an agreement between the patient and the clinician and, for the sole purpose of defending against negligence claims, signed consent should be mandatory. An important

caveat that must be remembered is that a consent form is only a record and not proof that genuine consent has been obtained. Hence, the conclusion that a signed consent form is synonymous with valid consent is misleading.

For consent to be *valid*, the person (child or adult) must:

- Be capable of making that particular decision ('competent');
- Act voluntarily and freely (without duress or pressure) from emotional situations and not taking drugs or medicines that could influence understanding;¹³
- Be provided with enough information to enable them to make a decision.

It is paramount that the patient undergoing the proposed treatment fully understands the factors involved. The orthodontic provider has the responsibility of providing the information (properly recording this in the notes) and explaining it carefully and comprehensively in terminology that the patient understands. This particularly applies to children and, in addition, should take into account that English may not be the patient's first language, whereby an interpreter should be involved. Time should also be given to allow the patient to digest the disclosed information.

What information should be disclosed?

There are key principal factors that need to be discussed jointly between patient and orthodontic provider when seeking valid consent prior to treatment. The information to be provided presents a relatively exhaustive list of potential topics for discussion and essentially represents a risk-benefit management strategy. 14 For orthodontics, these factors include:

- The nature and purpose of all viable treatment options (including the implications of non-treatment);
- What each proposed treatment will and will not achieve (particularly if treatment objectives are limited) and the likelihood of success;
- The proposed benefits, limitations and risks of treatment;
- The degree of patient commitment required. Important practical information that patients/parents need include an estimation of treatment time, the frequency of appointments, the need for additional appointments if breakages occur and the need for retention;
- The cost of the treatment (if applicable).

 As a result of the ruling in the Chester v Afshar case (2004), the NHS Litigation Authority (2004) announced the following recommendations:

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- Extreme care in the taking of consent is even more crucial than ever;
- Careful and comprehensive warnings about all significant possible adverse outcomes must be given;
- These warnings must be *properly recorded* in the notes;
- Patients should be invited to sign the relevant entry to confirm that he/she has been given the warning, has understood it, and accepts the risk;
- It is equally important to make a full entry in the notes, preferably signed by the patient, if treatment is *refused*, including the reason when given;
- Whenever possible, the clinician who discussed and is able to perform the treatment should be the one who obtains the consent.

Does the patient have the capacity to consent?

The current DH booklet Seeking Consent: Working with Children (2001)¹⁵ provides comprehensive guidance to healthcare practitioners on how to seek consent from children in their care. Generally, if children are competent to give consent for themselves, it should be taken directly from them before examination and treatment. However, the legal position regarding 'competence' is more complex in English law for children aged above and below 16 years of age. As the current law stands, the basic principles are as follows.

Children aged 16 and 17 years

According to Section 8(1) of the Family Law Reform Act (1969), ¹⁶ young people (aged 16 years and over) are presumed in law to be competent to consent for themselves for medical, surgical or dental treatment. Therefore, this means that in many respects they should be treated as adults and it is not necessary to obtain a separate consent from the parent or guardian. If a competent child consents to orthodontic treatment and the requirements of valid consent are met, a parent cannot over-ride that consent except in exceptional circumstances (although this is unlikely to occur in orthodontics).

Younger children (under 16 years)

For the management of minors, clinicians should seek the agreement of the parent or carer. However, patients below 16 years of age who have sufficient competency and maturity to understand the consequences of their orthodontic treatment may also, in principle, give consent independent of parental or legal guardian responsibility. This is now referred to as 'Fraser ruling competent' as opposed to

Gillick competent (coined by Lord Scarman in 1985).¹⁷ However, it must be remembered that a child's capacity can only be determined in the context of the proposed treatment. Consequently, the understanding of minors may vary, depending on different treatment procedures and, therefore, the issue of the consent being valid may arise.

In England and Wales, the Fraser ruling does not apply to unreasonable refusal by a child to receive treatment which is in the child's best interest. Legally, a person with 'parental responsibility' or a court can, in certain circumstances, over-ride the decision of a competent child (under 16) if he or she refuses treatment. Under the *Children Act* (1989), ¹⁸ this action is considered if it is 'in the child's best interests' but is an unlikely event in orthodontic treatment. In Scotland, however, children may refuse treatment provided they are competent.

Ultimately, for an ideal orthodontic outcome, parental support and involvement in the decision-making process are key factors for the success of treatment and valid consent should be sought from the patient and assent from the parent.

Treating non-competent patients

One issue that poses a problem for clinicians assessing competence are those patients in which competence is doubtful, hence their ability to provide valid consent is questionable. In England and Wales (not Scotland), no adult, including next-of-kin, can give consent for treatment on behalf of another adult (aged 18 or over). As it stands, current English law allows a patient who lacks the capacity to consent to be treated without consent if the proposed treatment is necessary and in the patient's best interest. The Mental Capacity Act (2005),19 which came into force in April 2007 in England and Wales, provides a statutory framework to empower and protect vulnerable people who are unable to make their own decisions. It sets out clear legal requirements for both assessing patient competence (referred to 'capacity' in the act) and the treatment of non-competent patients. Generally, the act applies to people aged 18 and over but may also apply to 16 and 17 year-olds whose incompetence is likely to persist into adulthood.

The Act is governed by the following five key principles:

- A presumption of capacity every adult has the right to make his or her own decisions and must be assumed to have the capacity to do so unless it is proved otherwise;
- The right for individuals to be supported to make their own decisions people must be given all appropriate help before anyone concludes that they cannot make their own decisions;

- That individuals must retain the right to make what might be seen as eccentric or unwise decisions;
- Best interests anything done for, or on behalf of, people without the capacity must be in their best interests;
- Least restrictive intervention anything done for, or on behalf of, people without the capacity should be the least restrictive of their basic rights and freedoms.

If a child is not competent to give consent directly, it should be sought from a person (legally, only one is required) with 'parental responsibility' and normally this means the child's parent(s). However, the Children Act (1989) has identified a number of people who may have legally acquired parental responsibility.18 Principally, it discusses the issues related to whether the parents are legally married or not, the role of a legally appointed guardian and the role of a local authority if designated. For example, a natural father not married to the child's mother at the time of the child's birth has no parental responsibility unless it has been acquired under the terms of the Children Act (1989).18 Under the Act, generally in an emergency situation, the clinician should proceed with treatment if it is in the patient's best interest. More complex issues regarding children and consent are provided by the DH publication on Seeking Consent: Working with Children (2001).15

Orthodontic management

As highlighted, effective communication is a key process in healthcare provision. So that valid consent may be obtained, it is paramount that patients are fully versed of the various aspects of orthodontic management that raise consent issues (eg the benefit versus the risk of treatment). In most orthodontic cases where written consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being performed. The consent process will therefore have at least two stages.

After the initial consultation, patient leaflets are an invaluable source of information to reference for patients considering treatment. However, a recent study has highlighted the inadequacies of a number of current orthodontic patient information leaflets (PILs) from professional organizations and commercial companies. Specifically, the mean readability of all the PILs was deemed 'fairly difficult' to understand for 60% of the UK population.²⁰ Also, information recall (15 to 30 minutes later) from both patient and parent after explanation from the orthodontic provider regarding the proposed orthodontic treatment (eg the reasons for

treatment, the risks, etc) is low²¹ (particularly in less educated, low-income patients). Therefore, some patients may not fully comprehend the information given during informed consent discussions. Consequently, this may have important implications when assessing whether the informed consent is actually valid.

The Developments and Standards Committee of the British Orthodontics Society (BOS) has produced a number of clinical guidelines, which have been critically reviewed from a medico-legal perspective,²² and three consent documents.²³ For orthodontic management, the relevant BOS advice sheets include:

- Consent in Orthodontics (including multidisciplinary management);²⁴
- The use and storage of digital photographs;²⁵
- The use of headgear and facebows.²⁶
 However, despite the importance of obtaining valid consent, a recent survey of all consultant orthodontists on the BOS database showed that written information on orthodontic treatment was provided by only 56% of respondents and that written consent was only obtained by 41%.²⁷

Orthodontic treatment

Orthodontics encompasses a spectrum of treatment modalities to correct malocclusions which may be a result of tooth irregularity, disproportionate

jaw relationships, or both. It is considered good clinical practice for the orthodontic provider to obtain written consent before any proposed orthodontic treatment. This includes:

- The extraction of teeth (primary and secondary) as part of the treatment plan;
- The provision of removable (including retention appliances), functional and fixed appliances;
- The provision of headgear;
- Multidisciplinary treatment.

Appliance therapy may or may not be indicated, depending on a number of patient (eg compliance) and clinical factors, as assessed by the dental health and aesthetic components of the Index of Orthodontic Treatment Need (IOTN).28 Ultimately, treatment should be based on a comprehensive risk-benefit analysis and the clinician should seek to minimize risk and employ risk management strategies.²⁹ As some patients are more at risk than others, when orthodontic treatment is to be undertaken, it is paramount that the competent patient is fully versed in the reasons for treatment and the risks so that a fully informed decision can be made and valid consent obtained.

Importantly, it must be remembered that consent is dynamic and can be withdrawn at any time, even in the middle of orthodontic treatment. If a patient wishes to terminate treatment early, advice

should be given to the patient on the likely adverse consequences. Subsequently, the fixed appliances must be removed if the patient still wishes to terminate treatment prematurely and the incident recorded in the patient's notes.

Multidisciplinary treatment

Patients who require both orthodontic treatment and a procedure from another dental specialty (eg major surgery and/or complex restorative procedures) need particular care. Good inter-specialty communication and the appropriate liaison between clinicians (eq joint specialist clinics) is essential. Sufficient clarity and detail must be provided from each of the specialties on who is to provide what treatment. This ensures that the patient can decide and provide valid consent for both procedures before either treatment is started. For restorative procedures, particular emphasis should be placed on the long-term implications. In all multidisciplinary cases, it is good clinical practice to obtain written consent.

Digital photography

The use and storage of digital images is an essential component of orthodontic patient records. However, at present, there is an absence of clear DH guidelines owing to the local nature of the advice between various employing

	BENEFIT	COMMENTS
Appearance	Dento-facial aesthetics	Evidence – improved psychological health ⁵⁹
Function	Mastication	Evidence – equivocal
	Speech	Evidence – none that orthodontic treatment will correct disorders
Dental health	TMD ³⁸	Evidence – weak linking ↑ predisposition to TMD
	Tooth impaction	? $↓$ risk of dentigerous cyst formation associated with unerupted canines
	Caries	Multifactorial aetiology. <i>Evidence</i> – none that orthodontic treatment reduces caries risk
	Periodontal disease ⁵⁸	Evidence – none that orthodontic treatment reduces risk of long-term periodontal disease Evidence – some ↓ migration of incisors where OJ has been ↓
	Trauma	Reducing an OJ:? ↓ reduces risk of future tooth trauma ⁶⁰ OB: labial and palatal trauma 2° to deep OB but no long-term problems if oral hygiene is good
Psychological	Well-being/self-esteem14	Teasing about teeth caused greatest distress Evidence – none that malocclusion causes poor self esteem in long-term

Table 2. Summary of the proposed benefits of orthodontic treatment. (Abbreviations – OJ: overjet; OB: overbite).

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organizations, ie particularly NHS Trusts. Nevertheless, it is important to consider obtaining consent and to comply with the rules of the *Data Protection Act (1998)*, which came into force in March 2000. The following points are adapted from BOS Advice Sheet 5²⁵ and summarize the general advice:

Do I need consent for photography?

DH model consent policy: states that 'if there is no prospect of a patient being recognised from a clinical photograph, then it may be used within the clinical setting for education or research purposes without the express consent of the patient. However, where it is possible to identify the patient, specific written consent must be obtained.'

The Institute of Medical Illustrators (IMI) model consent policy (http://www.imi.org.uk): states that 'subjective interpretation of whether a patient is likely to be identified from a clinical photograph is not sufficient and written consent must be obtained'.

If there is any doubt, obtaining written consent is advisable.

What about dental practice and the Data Protection Act?

A dental practice should be registered with the Information Commissioner's Office (ICO), even if not computerized, because it holds personal information that can be directly traced to the patient. With the advent of digital image use and storage, a dental practice may need to seek advice from and notify the ICO. The ICO (www.dataprotection.gov.uk/) is an independent public body set up to promote access to official information and to protect personal information. It aims to regulate and enforce the Data Protection Act and provides quidance to organizations and individuals.

What about hospital and community departments?

Local rules apply and it is important to seek advice from the Trust's data protection officer who ensures the Data Protection Act is complied with. In some Trusts, employees (including trainees) are considered independent data controllers and must register with the Data Protection Act. In others, individuals may already be covered by the Trust/University data registration provided they comply with the local rules of the Trust. If in doubt, seek advice from the local Trust's data protection officer.

Compliance with the Data Protection Act is fundamental as part of the consent process. It is prudent to ensure that patients are aware of the use of their images, particularly if they are to be used in patient information leaflets, for publication or on the World Wide Web. It is important that valid consent should be obtained and that this be recorded in the patient records under the relevant heading in the locally issued consent form.

RISKS of orthodontic treatment

Regarding the possible risks of orthodontic treatment and what information should be disclosed to the patient so that the clinician may avoid a claim of negligence, English law is continually evolving, as highlighted by the number of 'milestone' cases.

Currently, English law utilizes the Bolam (1957)31 test in cases of alleged dental negligence. Essentially, the judgement ruled that a clinician is not negligent if he/ she informs the patient of the same risks as a 'responsible body of medical opinion', this representing the 'professional standard'. Furthermore, as illustrated by the Sidaway case (1985)32, the House of Lords extended the Bolam test and described which risks should be explained to inform the patient. The House was increasingly determined to make clinicians more accountable for their actions and, if the clinician was too lax in informing the patient, then the courts may intervene. The prevailing view was that the standard of information provision should be judged according to the Bolam criteria.

Since Sidaway, it is evident that English law is moving towards making consent more patient-centred where the main issue is what a 'reasonable' patient (an objective standard) would expect to be informed about as the standard. This was highlighted by the case of Pearce v United Bristol Healthcare NHS Trust (1998)³³ whereby Lord Woolf concluded that:

if there is a significant risk which would affect the judgement of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk; if the information is needed so that the patient can determine....what course he or she should adopt.

The Australian adoption of the objective 'reasonable' patient was undertaken following the case of Rogers v Whittaker (1993),³⁴ which judged that, even a *remote* risk should be disclosed if it had *potentially serious consequences*, regardless of the view of a responsible body of medical opinion.

Therefore, for valid consent, ideally all risks, however low, should be highlighted to the patient and parent *prior* to the start of orthodontic treatment so that a mutual decision can be made as to whether treatment should commence.

The potential hazards of orthodontic treatment and prevention

strategies have been broadly reviewed^{35,36} and include:

- Tissue damage;
- Treatment failure and relapse;
- Greater predisposition to dental disorders.

Tissue damage

(Table 1)

Treatment failure and relapse

It has been estimated that failure to complete orthodontic treatment is high (4–23%)⁵² and may be attributed to patient non-compliance, incorrect diagnosis or incorrect management (eg incorrect choice of appliance).³⁵

Post-orthodontic treatment relapse⁵³ may result secondarily to:

- Soft tissue factors (eg teeth initially severely rotated);
- Late facial growth and occlusal development (eg leading to lower labial segment crowding);
- Supporting tissue factors (eg compromised periodontal support);
- Occlusal factors (eg insufficient overbite to maintain a corrected Class III incisor relationship);
- Non-compliance with recommended retention regime;
- Persistence of habits.

There are currently no predictive factors⁵⁴ that enable clinicians to identify patients that are likely to relapse or suffer late lower incisor crowding. Therefore, to guarantee long-term tooth alignment after orthodontic treatment, it is important to explain to patients about the requirement to wear retaining appliances on a long-term basis *before* commencing treatment.

Greater predisposition to dental disorders

Supposedly, orthodontic treatment may increase the predisposition to a number of certain problems, including temporomandibular joint dysfunction syndrome (TMJDS) and periodontal disease. At present, a large contingent of studies^{55,56,57} have concluded that the evidence directly linking orthodontic treatment to TMJDS is equivocal at best. There is also no evidence to suggest that patients undergoing orthodontic treatment are at a greater risk of long-term periodontal disease.⁵⁸

Benefits of orthodontic treatment

As well as being fully informed of the potential iatrogenic risks of orthodontic therapy, the patient should be advised of the proposed benefits to dento-facial aesthetics and dental health from orthodontic treatment (Table 2).

Conclusion

Ultimately, orthodontic treatment

aims to provide the patient with optimum dento-facial aesthetics and a functional, stable occlusion. If these principal factors are to be achieved, shared responsibility between the orthodontic provider and the patient must be sought and valid consent obtained *prior* to active treatment. Consent issues can be complex (particularly with respect to the treatment of children) and are constantly changing. It is imperative that clinicians maintain an up-to-date knowledge of the legal aspects of consent so that optimum clinical care can be delivered.

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