Valid consent and orthodontic treatment

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Valid patient consent is a legal and ethical principle that is fundamental to healthcare provision. Oral health practitioners (OHPs) must understand the principles that need to be addressed to ensure that the consent given by a patient is valid. Failure to obtain consent may result in a negligence claim or a complaint of professional misconduct against the OHP. Orthodontic treatment is mostly elective but is not without risk to the patient. Obtaining and maintaining valid consent for orthodontic treatment presents additional challenges in comparison with other dental procedures as the treatment lasts over a longer time and is most commonly performed in adolescents. In addition, prospective patients need to be informed regarding ‘lifelong’ management in the retention phase to minimise the risk of relapse. The present paper outlines the principles of valid consent with particular regard to orthodontic treatment in the adolescent patient. OHPs must ensure that they are satisfied that the competent patient has the capacity to voluntarily consent. Clinicians must also recognise that valid consent is not a one-off ‘tick the box’ procedural exercise but an ongoing process of effective information sharing in light of changing laws and an ever-changing scientific evidence base within a patient-centred model of healthcare.

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Introduction

In recent times, Australian healthcare has moved from a paternalistic ‘doctor knows best’ approach to a more patient-centred model which promotes self-determination and autonomy. Autonomy defines patients as individuals who are capable, in the most part, of making decisions regarding their healthcare, as long as they are well advised and informed. The universal acceptance that an adult individual, of sound mind, has a right to determine what happens to their own body underpins good practice in medicine and dentistry. Valid consent is an individual’s ‘voluntary decision’ regarding his/her health care and is made with knowledge and understanding of the benefits and risks involved.

Valid consent is a general legal and ethical principle that is fundamental to all healthcare and necessary for the protection and wellbeing of patients and the OHP. The terms ‘Informed consent’ and ‘Valid consent’ appear to be used interchangeably. The more commonly-used term ‘Informed’ consent has been erroneously perceived as being the same as ‘Valid’ consent. The requirement that consent be informed, however, is only one (although essential) component of valid consent. Without valid consent to treatment, an OHP is vulnerable to claims of assault and/or negligence, which may lead to criminal charges and/or civil claims against the OHP. In addition, doubts regarding the genuine validity of consent increasingly underpin many complaints made by patients to the Australian Health Practitioners Regulation Agency (AHPRA).

Recent court cases, however, suggest that consent may not be a fully understood concept within dentistry. There is evidence that health professionals often view obtaining consent as a ‘procedural formality’ only. Consequently, their process may fail to meet ethical and professional requirements. Guidance for OHPs on the consent process is available through the National Health and Medical Research Council (NHMRC) publication General Guidelines for...
Medical Practitioners in Providing Information to Patients (www.nhmrc.gov.au), the Dental Board of Australia, Australian Dental Association and dental defence societies.

In Australia, there is no statute that sets out the general parameters of consent. Laws regarding consent are continually changing and developing as the courts interpret legislation and the common law. The findings in international courts may also be an influence on how valid consent is determined at a national level. A recent landmark case in the UK, for example, crystallised the standards of communication required to fully inform patients. In addition, the scientific evidence base is ever changing, which may influence the interpretation of what constitutes valid consent.

Obtaining and maintaining consent for orthodontic treatment presents additional challenges compared with other dental procedures as treatment lasts over a longer time and is most commonly carried out in adolescents.

The aims of this article are, therefore, to:

- Define consent
- Outline the principles of valid consent in the adolescent patient, and
- Briefly outline consent with regard to orthodontic management.

Consent

Consent has been defined as ‘the voluntary and continuing permission of a 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 option. Consent is the final outcome of a two-way communication process between the OHP and the patient. Additionally, there may be third party involvement with a parent or guardian (a tripartite relationship), which is commonly the case in orthodontics.

Two main forms of consent have been described:

- Implied (for example, voluntarily opening the mouth to allow dental examination), or
- Expressed (oral or written for a specific procedure).

Consent is valid when it satisfies the three distinct and legal components (the ‘Consent Triangle’) that underpin it.

Principles of valid consent (‘The Consent Triangle’)

Volition/voluntary decision-making’

Consent must be voluntarily given by a patient without coercion, persuasion or manipulation by the patient’s family, the OHP or staff. Patients should not be taking drugs (legal or illegal) that could influence understanding or be in any condition (for example, suffering from sleep deprivation) in which cognitive processes may be impaired. The OHP and wider team must avoid influencing the patient by the use of certain words, tone of voice and body language, remembering that coercion may be a subtle and unintended outcome of the feelings of the OHP about that procedure or the patient on that day. The OHP may state their preferred option but care should be taken that all information is discussed in a fair and controlled manner without any undue influence so that consent is provided by the patient on a voluntary basis.

Capacity

An adult has the right to make his or her own decisions and is assumed to have the capacity or competence to do so unless proven otherwise. Legislation determining the age at which children and adolescents can be considered competent is complex and varies across Australia. Each State and Territory has a government/statutory authority that is responsible for co-ordinating the policies affecting children and adolescents. As a result, the age of consent for medical and dental treatment varies across Australia but it is broadly accepted as 18 years of age, with the exceptions of New South Wales in which it is 14 years of age, and South Australia and Queensland in which it is 16 years of age.

A landmark court case in the UK found that children and adolescents who fully understand the proposed treatment can give consent to that treatment. This is termed ‘Gillick competence’ and this decision has been upheld in Australia. For an individual to be deemed Gillick competent, the OHP must determine that the nature of the advice and information is understood as
well as being satisfied that the adolescent has sufficient ‘maturity’ to comprehend their involvement and consequences of potential treatment.

Two categories of rights for children have been described:

- Protective rights, which are interpreted as the right of the child to receive protection and assistance while developing, and
- Self-assertion rights, including the right to make decisions.

At some point during the developmental period, a transfer of autonomy from the parent to the adolescent occurs. This may take place during the course of orthodontic treatment and may lead to a conflict between the two rights and parties, one of which may need to be prioritised.26 There may be overlap between the two rights as ‘growing-up’ is a transitional process.19 As adolescents mature they may seek to make decisions for themselves regarding their orthodontic treatment whilst continuing to look to the OHP and their parents for support.22 If the OHP believes the adolescent to be Gillick competent, the right of self-assertion would take priority over protection. Any assessment of the adolescent’s maturity, however, should be made independently of an evaluation of the adolescent’s opinion.27

It is important that self-assertion rights are respected. Children have also been shown to want increased involvement in consenting to dental treatment and may be more compliant during treatment when they are active participants in the consent process.28 It would, therefore, seem prudent for the OHP to encourage this.22

One suggested approach is a ‘staged’ process to decision-making for children and adolescents:

- Stage 1 – information sharing with the adolescent
- Stage 2 – shared decision-making between parent and adolescent
- Stage 3 – adolescent capable of autonomous decision-making ability.15,29

Difficulty may arise if a ‘coalition’ develops between the parent and the OHP with the parent requesting treatment be carried out (or stopped) against the adolescent’s wishes. This coalition may be interpreted as acting against the patient’s autonomy and their preferences.19 An alternative ‘coalition’ may form between the patient and the OHP, in which the OHP respects the patient’s autonomy and accepts their consent for treatment. This may present concern particularly if financial consent is required from the parent/guardian for payment of the treatment.12 If consent has only been provided by the ‘Gillick competent’ patient, and they are not the responsible person covering the treatment costs, it may be prudent to delay the commencement of treatment until financial consent has been received from the parent/guardian. Interestingly, however, patient records cannot be provided to third parties without the express consent of the ‘Gillick competent’ patient, rather than the parent/guardian who has provided financial consent. It is important then to consider that consent to treatment and financial consent, although intertwined, are two separate aspects of provided care.

An adolescent may choose a decision that is not in agreement with their parents or their OHP, and in this case the clinician must not discount the adolescent’s opinion as evidence of a lack of competence. Rather, it may be a reflection of a difference in values between the OHP, patients or their parents.13,14 Patients, therefore, have the right to make what might be perceived as an eccentric or unwise decisions. A reasonable choice to one individual may not be reasonable to another.30

The ‘coalition’ of the parent and the patient may request treatment that the OHP may not feel is clinically appropriate, and the refusal of treatment may be on the part of the OHP. All parties have the right to hold their view, however, and sometimes the solution is for the OHP to withdraw from treating the patient.8

In situations in which the adolescent is believed to be capable of giving / refusing / withdrawing consent (as per Gillick competence), it is strongly advisable to fully involve the adolescent’s guardian / family in the consent process and encourage consensus.5,8 Great care must be taken in correctly establishing and recording which ‘parent/guardian’ can legally provide consent. A step-parent, for example, may not be automatically presumed to be legally entitled to consent to treatment.

How to determine capacity?

An OHP will have to determine whether an individual patient has the capacity to consent for treatment.24 Capacity may be lost due to poor health, age or illness. A mental illness, however, does
not necessarily preclude the ability to consent to or refuse treatment. An OHP needs to establish a link between the impairment and the decision to accept or decline treatment to determine incapacity. Australia has adopted the English approach for determining capacity; namely, whether the patient is able to:

- Understand and absorb the information relevant to the decision being considered
- Retain the information
- Accept and comprehend the information
- Evaluate the risks and make a fully informed decision, and
- Communicate that decision (either verbally or non-verbally; for example, through sign language).

Capacity is usually determined at the time of accepting or refusing treatment and has been incorporated into legislation. A useful way for the OHP to assess capacity may be to ask the patient to paraphrase what was explained to them regarding the proposed treatment. Based on the patient’s replies, the OHP will be able to determine the patient’s capacity to consent. It may be helpful to look at the facial expression and body language of the patient (and parent/guardian, if applicable) for any signs of confusion during the process. This provides the OHP with the opportunity to clarify and correct any misunderstanding and helps to build up an equal and trusting relationship.

**Incapacity**

If a patient lacks the capacity to consent for dental treatment, the Guardianship Board has the power to appoint a suitable person to make decisions on their behalf. The Board is also able to grant acceptance to, or refusal of, dental treatment for a person without someone appointed to consent on their behalf. The following principles should be considered when treating the incompetent adult (which may be a consideration when a competent adult undergoing orthodontic treatment subsequently becomes apparently incompetent):

- A presumption of capacity: Every adult has the right to make his/her own decisions and is assumed to have capacity to do so unless proved otherwise
- Individuals should receive support to help them make their own decisions
- People have the right to make decisions that others might think unwise
- Any act done, or decision made, on behalf of an individual who lacks capacity must be in his/her best interests
- Anything done for or on behalf of a person who lacks capacity should be the least restrictive of their basic rights and freedoms

Whilst the understanding/capability of a patient must be taken into account, the legal age of consent still applies. The age of consent and the capacity to consent must run in tandem and this can be potentially problematic for the treating OHP. In such situations, advice from an indemnity organisation may be prudent.

**Specificity**

The third component underpinning valid consent is the provision for the delivery of sufficient information to make an informed decision. What constitutes sufficient information, however, has been a cause for debate and has developed and changed as the courts interpret the common law and related legislation. Three broad levels, however, have been identified through this process:

- The professional standard
- The objective (or reasonable patient) standard, and
- The subjective (or particular patient) standard

**Consent and orthodontic management**

Orthodontic treatment aims to provide the patient with optimum dento-facial aesthetics and a functional, stable occlusion. It differs from other dental procedures as treatment lasts over a longer time period and is most commonly carried out in adolescents. Effective communication is a crucial element of healthcare provision. It is essential that the competent prospective orthodontic patient is fully informed and understands:

- The nature and purpose of all viable treatment options (including the option of, and implications of, no treatment)
- What each proposed treatment will and will not achieve (including if treatment objectives are limited) and the likelihood of success
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- The proposed evidence-based benefits, limitations and risks of treatment
- The level of patient commitment required
- Who will be carrying out the treatment
- The cost of the orthodontic treatment
- The estimated treatment duration
- Management of the post-orthodontic retention phase
- Advice about whether a proposed treatment is experimental
- A reminder that they can change their minds about a decision at any time
- A reminder that they have a right to seek a second opinion.1,2,13,46,47

Orthodontic treatment should be based on a risk-benefit analysis.17,48 Table I summarises the commonly accepted benefits of orthodontic treatment. Table II summarises the commonly accepted general risks of orthodontic treatment. OHPs should be aware that some medical disorders influence orthodontic treatment decisions and management.49 Table III summarises the commonly accepted intraoral risks of orthodontic treatment.

In addition, patients need to understand that current evidence indicates that ‘life-long’ management with an orthodontic retainer is required after active appliance removal to minimise the risk of relapse.50

Some orthodontic patients may require joint management involving a different dental/medical discipline; for example, a combined orthodontic / restorative / orthognathic surgery treatment plan will require the involvement of more than one healthcare discipline.51-53 Sufficient detail must be given on

### Table I. Summary of the main proposed benefits of orthodontic treatment.

| Benefit                                      | Comment                                                                 |
|----------------------------------------------|-------------------------------------------------------------------------|
| **Dental Health**                            |                                                                         |
| Prevention of dental disease                 | - No apparent relationship between the presence of crowding and caries/periodontal disease susceptibility in the presence of good oral hygiene72 |
|                                              | - Weak evidence that ‘straight’ teeth may be easier to keep clean73      |
|                                              | - Reestablishment of periodontal health on correction of traumatic overbite or an anterior crossbite with mandibular deviation74 |
| Improvement in function                      |                                                                         |
| Prevention and treatment of temporal mandibular joint disorder | Correction of a crossbite with mandibular deviation may correct a reduced bite force73 |
| Prevention of dentoalveolar trauma           |                                                                         |
| Treatment of impacted teeth                  | - Early orthodontic treatment for children with increased overjet may be more effective in reducing the incidence of incisal trauma than providing one course of treatment when the child is in early adolescence77 |
| Improvement of speech problems               | - Orthodontic intervention for ectopic permanent canines may halt further progression of root resorption of adjacent incisors78 |
|                                              | - Removal of a supernumerary tooth impeding eruption of a central incisor and orthodontic treatment may facilitate eruption of a maxillary central incisors79 |
|                                              | - Orthodontic correction, +/- orthognathic surgery, in conjunction with speech therapy may be helpful80 |
| **Psychological well-being**                 |                                                                         |
|                                              | - ‘Psychological well-being reflects how content we are with ourselves’48 |
|                                              | - Short-term improvement in self-concept in orthodontically corrected increased overjets in patients (aged 8-10 years) compared with an untreated control77 |
|                                              | - May benefit those with low self-esteem who have particular concerns with their malocclusion48 |
| **Social and emotional well-being**          |                                                                         |
|                                              | - ‘Social well-being reveals how we interact with other people and with our community’48 |
|                                              | - Treatment allows individuals to cope more effectively in social situations without concern for their dental appearance |
|                                              | - Can help alleviate concerns associated with teasing and bullying81,82 |
|                                              | - May improve oral health quality of life particularly the emotional and social well-being domains83,84 |
who will provide the various aspects of treatment and the additional information must be explained with clarity. This ensures that the patient can decide and provide valid consent for all procedures before any treatment is started. For ‘restorative’ procedures, particular emphasis should be placed on the long-term implications. Patient/guardian knowledge of the training, expertise and registration status of the OHP may also be an important factor in decision-making. It may, therefore, be prudent for a non-specialist OHP to advise his/her patient that referral to a specialist orthodontist for assessment and treatment is an alternative option.

Many OHPs obtain a signed consent form from patients. Obtaining valid consent is not a one-off ‘tick the box’ exercise. It is a record and not proof that valid consent has been obtained. Confirmation in the patient’s treatment notes of the consent process and patient agreement, however, is strongly advisable. It may be appropriate to have more than one consultation with the patient (and parents) prior to commencing treatment to ensure consent is valid. It may also be prudent to revisit the consent process at particular time-points during the course of treatment to maintain the ‘validity’ of the consent. This is particularly important as patients may progress from a ‘pre-Gillick’ state of competence to become Gillick competent in the ‘eyes of the law’, during the course of treatment.

Orthodontic treatment risks and benefits should be individually tailored to each patient and be based on the best available evidence. The communication

| Risk                      | Comment                                                                                      |
|---------------------------|--------------------------------------------------------------------------------------------|
| Trauma                    | Risk of soft tissue and/or ocular trauma with extra-oral headgear\(^{85}\)                  |
|                           | Fixed orthodontic appliances are a potential risk factor for traumatic dental injuries during sports participation\(^{86}\) |
| Radiation                 | Increased radiation exposure\(^{87}\)                                                       |
| Allergy                   | Natural rubber latex                                                                      |
| Nickel                    | Those at risk may require a “latex-safe” treatment environment\(^{88}\)                     |
| Bonding agents            | Most common allergen although intraoral signs and symptoms relatively uncommon\(^{89}\)  |
| Bonding agents            | Methyl methacrylate and Bisphenol-A are cytotoxic and may cause tissue irritation\(^{90}\) |
| Medication effects        | May influence tooth movement – especially bisphosphonates\(^{90}\)                         |
| Discomfort/pain Dental    | Pain experience with fixed appliances is subjective and variable\(^{91}\)                   |
|                           | Pain starts at 4 hours, peaks at 24 hours and declines over next 3 days after placement of fixed appliances\(^{92}\) |
|                           | Each adjustment visit, pain tapers off over 2-3 days\(^{93}\)                               |
|                           | Variable pain experience at “orthodontic deband”\(^{94}\)                                  |
| Soft tissue/mucosal       | Burns from acid-etchant, ulceration from appliance components and trauma from clumsy instrumentation\(^{95}\) |
| Adverse changes to facial profile | The evidence is weak that extractions as part of an orthodontic treatment plan do not have adverse effects\(^{96,97}\) |
|                           | Facial growth may be the principal factor\(^{98}\)                                           |
| Temporal mandibular joint disorder (TMJD) | No evidence that orthodontic treatment causes or cures TMJD\(^{99}\) |
|                           | Appropriate management of patients with TMJds required before and during orthodontic treatment\(^{99}\) |
| Speech                    | Lingual fixed appliances, palatal expanders and Hawley retainers may impact on speech production\(^{100}\) |
| Eating                    | Restriction of food choice and problems associated with the eating process\(^{101}\)       |
| Relapse                   | Some relapse is inevitable\(^{102}\)                                                        |
|                           | Lifelong retention required to minimise the risk of relapse and age related occlusal changes\(^{47}\) |
| Treatment failure         | Patient non-compliance, incorrect diagnosis and incorrect management may lead to earlier ‘deband or unsatisfactory outcomes’\(^{103}\) |
|                           | Failure may occur in up to 24% of cases\(^{104}\)                                          |
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The process should reflect this, with individual patients allowed to attach their own significance to that risk. How much a patient needs to know and how much the OHP should disclose regarding the risks of treatment has changed considerably over the decades. For many years, OHPs utilised the Bolam principle when deciding what to discuss with their patients. OHPs could use their own discretion to disclose information that the ‘OHP in that situation would normally be expected to explain’.

The High Court of Australia in Rogers v Whitaker (1992) 175 CLR 479 and Rosenberg v Percival (574, #668) 205 CLR 434 chose to ignore the Bolam principle and held that in providing information to patients there is a duty to warn of a material risk inherent in a proposed treatment. Material risks are those that, in the particular circumstances, would significantly influence the likelihood of a ‘reasonable person in the patient’s position’ consenting to the proposed treatment. In considering whether a risk is material, the OHP must give consideration to the circumstances of the particular patient.

The outcome of the Montgomery (Appellant) v Lanarkshire Health Board (Respondent) case in the UK has also moved away from the Bolam principle and determined that the OHP should base the discussion of consent upon the risks that the patient believes hold particular significance for themselves; that is, what the ‘reasonable patient’ would want to know.

A further UK landmark case (Chester v Afshar) has also found that a patient cannot be said to have given consent to treatment in the ‘full legal sense’ if the patient had not been fully informed of all treatment ‘significant’ risks, no matter how small the percentage risk.
In a consideration of the above, it is no longer acceptable to simply quote, for example, the percentage risk of enamel demineralisation as part of the consent process for orthodontic treatment. The true significance of a given risk may be more effectively explained by placing the risk in context and describing the possible consequences it could have upon that patient’s quality of life and wellbeing.\(^\text{1}\) Optimal patient-centred methods of assessing and describing risks are being explored.\(^\text{28,44}\) Focus groups encourage communication between participants in order to explore people’s knowledge, experiences and concerns.\(^\text{13}\) The use of such groups has been shown to be an effective way of determining what information patients want regarding their health and available treatment options.\(^\text{28}\) Their use in orthodontics may improve the information provided to patients and produce a more patient-led consent process.

**Shared decision-making**

Shared decision-making is the ‘collaborative deliberation’ regarding treatment options between the OHP and patient.\(^\text{11,45}\) It is a crucial element of patient-centred care and is becoming the preferred model for communication in the healthcare environment.\(^\text{44,59}\) ‘Preference sensitive care’ describes those situations in which the benefits and risks of any given treatment option, such as those found in orthodontics, are not ‘clear-cut’.\(^\text{11,60}\) Decision aids may, for example, help OHPs and patients decide about treatment in some situations.\(^\text{61,62}\) The decision aids may be time consuming and labour intensive to produce, but aim to provide an evidence-based framework on which the consultation and decision-making process can be based.\(^\text{44}\) Impartial, balanced and accurate patient information leaflets (PILs), ‘Apps’ and DVDs, for example, are potentially invaluable sources of information to reference for patients considering treatment.\(^\text{11,44,63}\) A UK study, however, has shown the inadequacies of a number of available orthodontic PILs from professional organisations in that country. The mean readability of all the PILs was deemed ‘fairly difficult’ to understand for 60% of the population assessed.\(^\text{64}\) A more recent investigation showed that available paediatric oral health education materials in Australia varied widely in quality and readability.\(^\text{65}\) Current evidence suggests that verbal information supplemented with additional written and/or visual information may be superior in facilitating patient recall of information regarding fixed appliances during the consent process for orthodontic treatment, compared with verbal information only.\(^\text{16,66-68}\)

‘Orthodontic-related information’ derived from the Internet is often inaccurate.\(^\text{69,70}\) General and dental specialist practice as well as national and international orthodontic societies can take a lead in producing high quality evidence-based patient information via their websites, such as the patient information provided by the Australian Society of Orthodontists (https://orthodonticsaustralia.org.au/about/). Professional organisations should also consider ensuring that their sites appear on the first results page when patients undertake Internet searches. Knowledge of the terms that patients/members of the general public use is required.\(^\text{71}\) This may increase the likelihood that prospective and current patients will access high quality, evidence-based information regarding their treatment.

Further research, however, is required to determine:
- What risks patients feel are important
- How much information patients want regarding orthodontic treatment and
- How that information is effectively delivered.

**Conclusions**

To ensure consent is valid, the OHP should:
- Be satisfied that the competent patient (or anyone else acting on the patient’s behalf) has the capacity to voluntarily consent
- Be aware that the provision of orthodontic treatment to adolescent patients presents additional challenges compared with other dental procedures
- Recognise that valid consent is not a one-off ‘tick the box’ procedural exercise but an ongoing process of information sharing (relating to the patient and his/her needs and circumstances), which facilitates a fully-informed decision to accept, decline and/or continue with treatment
- Effectively communicate with patients in light of changing laws and an ever-changing scientific evidence base within a patient-centred model of healthcare.
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