A Medico-legal Review of Some Current UK Guidelines in Orthodontics: A Personal View

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Abstract. *This article is a critical analysis from a medico-legal perspective of some current authoritative UK clinical guidelines in orthodontics. Two clinical guidelines have been produced by the Royal College of Surgeons of England and four by the British Orthodontic Society. Each guideline is published with the analysis immediately following it. Following recent UK case law (Bolitho v City & Hackney Health Authority, 1997) which allows the courts to choose between two bodies of responsible expert medical opinion where they feel one opinion is not 'logical', it is likely that the UK courts will increasingly turn to authoritative clinical guidelines to assist them in judging whether or not an appropriate standard of care has been achieved in medical negligence cases. It is thus important for clinicians to be aware of the recommendations of such guidelines, and if these are not followed the reasons should be discussed with the patient and recorded in the clinical case notes. This article attempts to highlight aspects of the guidelines that have medico-legal implications.*

Index words: Consent, Ectopic Maxillary Canine, Orthodontic Materials, Orthodontic Radiography, Unerupted Maxillary Canines.

Introduction

In this article some specific U.K. guidelines which have been produced by the Royal College of Surgeons of England and the British Orthodontic Society are discussed from a medicolegal perspective.

There are two clinical guidelines produced by the Faculty of Dental Surgery of the Royal College of Surgeons of England:

1. Management of the palatally ectopic maxillary canine.
2. Management of unerupted maxillary incisors.

There are four clinical guidelines produced by the British Orthodontic Society (BOS):

1. Reuse of orthodontic materials.
2. Advice on the use of facebows.
3. Consent in orthodontic treatment.
4. Orthodontic radiography.

Royal College of Surgeons of England Clinical Guidelines

I. Management of the Palatally Ectopic Maxillary Canine

The maxillary canine is second only to the mandibular third molar in its frequency of impaction. The prevalence is about 1·7 per cent. The canine becomes ectopic more often palatally than buccally in a ratio of 6:1. Management of this condition often faces general dental practitioners and orthodontic specialists. Mismanagement and failures in diagnosis may be costly in terms of clinical time (both for the practitioner and patient) and in litigation (if damage occurs to adjacent teeth and proceeds unchecked).

The aetiology of the canine ectopia remains unclear. However, it has been reported that palatal canine ectopia is more common in spaced arches, or where the adjacent lateral incisor is missing or anomalous/abnormal in shape or size. Also there is some evidence that palatally ectopic canines occur more often among family members. The erupting maxillary canines should be palpable in the buccal sulcus from 10 to 11 years of age. Those maxillary canines erupting after 12.3 years in girls and 13.1 in boys may be considered late.

Sequelae of Canine Ectopia

It has been estimated that 0·7 per cent of children in the 10–13-year-old age group have permanent incisors resorbed, as a result of canine ectopia. Root resorption can be expected in about 12·5 per cent of the incisors adjacent to ectopic maxillary canines.

Diagnosis and Management

1. History and Examination. The success rate associated with early diagnosis and treatment of the palatally ectopic canine has been highlighted in recent years. Practitioners should become suspicious of the possibility of canine ectopia if the canine is not palpable in the buccal sulcus by the age of 10–11 years of age or if palpation indicates an asymmetrical eruption pattern. The patient with an ectopic maxillary canine must undergo a comprehensive assessment of the malocclusion including accurate localization of the ectopic canine.

1.1. Radiographic examination. This usually involves taking two radiographs (orthopantomogram or equivalent and Standard Upper Anterior Occlusal), and the use of the principle of vertical or horizontal parallax

Horizontal Parallax:

(1) anterior occlusal and periapical;
(2) two peri-apicals.

Vertical Parallax:

(1) anterior occlusal/OPT;
(2) peri-apical/OPT.

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It has been suggested that radiographic procedures prior to the age of 10 years are of little benefit in terms of the knowledge gained.

2. Treatment. Radiographic examination should be carried out initially to confirm the position of the unerupted canine. Patient and parent counselling on the various treatment options is essential.

2.1. Interceptive treatment by extraction of the deciduous canine.

- The patient should be aged between 10 and 13 years.
- The need to space maintain requires consideration.
- Better results are achieved in the absence of crowding.
- If radiographic examination reveals no improvement in the ectopic canine's position 12 months after extraction of the deciduous canine, alternative treatment should be considered.

2.2. Surgical exposure and orthodontic alignment.

- The patient should be willing to wear fixed orthodontic appliances.
- The patient should be well motivated and have good dental health.
- The patient is considered to be unsuitable for interceptive extraction of the deciduous canine.
- The degree of malposition of the ectopic canine should not be too great to preclude orthodontic alignment.

2.3. Surgical removal of the palatally ectopic permanent canine.

- This treatment option should be considered if the patient declines active treatment and/or is happy with their dental appearance.
- Surgical removal of the ectopic canine should be considered if there is radiographic evidence of *early* root resorption of the adjacent incisor teeth. Exposure and alignment of the ectopic canine is usually indicated in cases where *severe* root resorption of the incisor teeth has occurred necessitating the extraction of the incisor.
- The best results are achieved if there is good contact between the lateral incisor and first premolar or the patient is willing to undergo orthodontic treatment to substitute the first premolar for the canine.

2.4. Transplantation.

- This treatment option should be considered if the patient is unwilling to wear orthodontic appliances or the degree of malposition is too great for orthodontic alignment to be practical.
- Transplantation would not normally be considered unless interceptive extraction of the deciduous canine has failed or is considered to be inappropriate.
- There should be adequate space available for the canine and sufficient alveolar bone to accept the transplanted tooth.
- The prognosis should be good for the canine tooth to be transplanted with no evidence of ankylosis. The best results are achieved if the ectopic canine can be removed atraumatically.

2.5. No active treatment/leave and observe.

- The patient does not want treatment or is happy with their dental appearance.
- There should be no evidence of root resorption of adjacent teeth or other pathology.
- Ideally, there should be good contact between the lateral incisor and first premolar or the deciduous canine should have a good prognosis.
- Severely displaced palatally ectopic canines with no evidence of pathology may be left *in situ*, particularly if the canine is remote from the dentition. If the ectopic canine is left *in situ* radiographic monitoring is recommended to check for cystic change or root resorption.

Explanatory Notes

Treatment planning for patients with palatally ectopic maxillary canines is not straightforward due to the large number of patient factors and orthodontic factors which must be considered. It is strongly recommended that practitioners seek the opinion of an orthodontic specialist prior to initiating any of the above treatment options.

2.1. Inspection and palpation in the canine region is recommended annually from the age of 8 years. It is probable that early diagnosis and treatment of ectopic canine eruption will reduce the potential for root resorption of the adjacent incisors. An initial study found that 78 per cent of palatally ectopic canines reverted to a normal path of eruption following the extraction of the primary canine. A more recent study found the success rate to be slightly lower (62 per cent). Nonetheless, in many cases interceptive extraction of the adjacent deciduous canine can be a highly successful and cost-effective method of correcting canine ectopia.

2.2. Much of the evidence supporting surgical exposure and orthodontic alignment as a treatment approach is derived from case studies. However, clinical experience has shown that surgical exposure and orthodontic alignment of a palatally ectopic canine is a highly successful treatment approach. As with all orthodontic treatment the co-operation and motivation of the patient is paramount. The general dental health should be good since the treatment time is often prolonged. It is generally agreed that the optimal time for surgical exposure and orthodontic alignment is during adolescence.

2.3. Surgical removal of the ectopic canine is most often considered when dental aesthetics are acceptable with good contact between the lateral incisor and the first premolar. If necessary fixed orthodontic appliances can be used to bring the first premolar forward to simulate a canine tooth. Mesiopalatal rotation of the premolar, and grinding of the premolar palatal cusp can also help to improve aesthetics. The prognosis for primary canines which are left in the arch remains unknown due to a lack of longitudinal research. Clinical experience would indicate that there is a large variation in the life-expectancy of retained deciduous canines.

2.4. Transplantation is sometimes considered for grossly displaced ectopic maxillary canines or when prolonged orthodontic treatment is unacceptable to the patient. Early studies revealed disappointing long-term results when this approach was adopted with a high frequency of root resorption occurring. More recent studies using a meticulous atraumatic surgical technique and stabilisation of the transplanted tooth with a sectional archwire for 6 weeks have reported better results. However, the long-term (>5 years) prognosis of transplanted palatally ectopic canines has yet to be evaluated.

2.5. It has been reported that root resorption of incisors by palatally ectopic canines rarely starts after 14 years of age and that root resorption occurs most frequently between 11 and 12 years. The frequency of cystic degeneration associated with palatally ectopic canines is unknown, but is thought to be low.

Critical Analysis of the Guideline Management of the Palatally Ectopic Maxillary Canine

The first paragraph stresses the importance of diagnosing this condition and points out that failure to do so or subsequent mismanagement '*may be costly in terms of clinical time (both for the practitioner and patient) and in litigation (if damage occurs to adjacent teeth and proceeds unchecked)*'.

Comment

The introductory paragraph in these guidelines states unambiguously the importance of diagnosing and managing this clinical condition correctly, and specifically mentions medico-legal implications.

Diagnosis and Management

This section highlights the fact that early diagnosis and treatment of the condition is important to achieve a successful outcome. Practitioners are advised to look for identifiable clinical signs by 10–11 years of age. Specific radiographic examination techniques are recommended to provide the clinician with the appropriate clinical information to enable an accurate diagnosis to be made.

Comment. These guidelines mean that if a general dental practitioner fails to diagnose a palatally ectopic maxillary canine by say 15 or 16 years of age, and the patient had been under his continuous care during the preceding years it would be difficult to defend an action for negligence, particularly if damage to the adjacent teeth had occurred.

Treatment

The guidelines state that after the unerupted canine has been located radiographically '*patient and parent counselling on the various treatment options is essential*'. Five different management strategies are then described for the condition depending upon clinical findings and patient motivation.

Comment. By recommending that the various options are discussed with the patient it would be difficult to fully defend a subsequent action if the clinician only recommended one line of treatment without mentioning other relevant possibilities especially when some of the options involve a general anaesthetic.

Explanatory Notes

This section of the guidelines highlights the difficulty of diagnosing the condition of palatally ectopic maxillary canines. It states: '*It is strongly recommended that practitioners seek the opinion of an orthodontic specialist prior to initiating any of the above treatment options*'.

Comment. A clinician, who is not a specialist and did not seek specialist help in the management of this condition, would find it difficult to defend his actions in any subsequent litigation if his case management was ill-judged or inappropriate.

Recognition of the Condition by a GDP

There have been numerous articles published in the literature over the years about the importance of early recognition of unerupted impacted maxillary canines. Crawford v Charing Cross Hospital (1953) indicates that where there is only one article on a topic then a clinician might not have had the opportunity to read it. This would not be the case here. These guidelines are likely to be regarded as authortative by the courts as they are produced by the Royal College of Surgeons of England. As Harpwood (1998) has argued, the increasing use of computers and advances in information technology will allow such guidelines to be disseminated and available to clinicians. As part of continuing medical education it would be reasonable to expect a practitioner to be aware of these guidelines. It would not be reasonable to expect the average GDP to be able to treat the condition, but it would be reasonable for him/her to recognize the condition and make a referral at the correct developmental stage.

Assessment

Patients may be referred as early as 9–10 years of age for assessment, yet there is no mention of consent in the guidelines. Normally, patients of this age would be accompanied by a parent or legal guardian, but what if a patient attended unaccompanied and requested assessment/investigation? It is better to have a parent/legal guardian present in these circumstances. In a child under the age of 16 it would be for the GDP to assess whether or not the child was 'Gillick competent' (Gillick v West Norfolk and Wisbech Health Authority, 1985). (More detail on Gillick competency is provided later in this article when discussing the guideline on Consent to Treatment.)

General Comment

The clinical management of the palatally impacted maxillary canine requires co-operation between practitioners in primary and secondary care. It is important that the condition is recognised as early as possible and referral made if necessary to a specialist for assessment. These clinical guidelines give clear guidance to general dental practitioners (GDPs) as to the age at which the condition is likely to occur and the clinical signs that indicate an impaction.

Royal College of Surgeons of England Clinical Guidelines

II. Management of Unerupted Maxillary Incisors

Missing and unerupted maxillary incisors can have a major impact on dental and facial aesthetics. Visibly missing anterior teeth was considered to be the most unattractive deviant occlusal trait in one American study. There are very few studies reporting any functional problems from missing anterior teeth, although some speech difficulties have been reported. Most of these studies were undertaken during the transition of the dentition from deciduous to permanent dentitions. Difficulties were reported with the 's' sound. There have been no studies reporting functional disturbances on older children or adults. As missing upper incisors are regarded as unattractive this may have an effect on self-esteem and general social interaction, and it is important to detect and manage the problem as early as possible.

This guideline has been written based on current evidence. As with any guideline it will be continually developed as further clinical evidence is made available.

1. Diagnosis and Management

1.1. Definition. Delayed eruption of maxillary incisors requires monitoring or intervention when:

- eruption of adjacent teeth occurred 6 months previously (with both incisors unerupted—lower incisors erupted one year previously).
- deviation from normal sequence of eruption, e.g. lateral incisors erupt prior to the central incisor.

1.2. Causes of delayed eruption. The delayed eruption can be classified into two groups.

1.2.1. Hereditary factors. Supernumerary teeth, cleft lip and palate, cleidocranial dysostosis, odontomes, abnormal tooth/tissue ratio, generalised retarded eruption, gingival fibromatosis.

1.2.2. Environmental factors. Trauma, early extraction or loss of deciduous teeth, retained deciduous teeth, cystic formation, endocrine abnormalities, bone disease.

2. Incidence/prevalence

The true incidence of unerupted maxillary incisors is not known. However, the prevalence in the 5–12 year-old age group has been reported as 0·13 per cent.

In a referred population to regional hospitals the prevalence has been estimated as 2·6 per cent.

3. Detection of Causes of Failure of Eruption

Dental and medical history. A detailed dental and medical history should be obtained to determine possible hereditary or environmental factors which may be contributory to the delay in eruption.

4. Examination

An intra-oral examination should be undertaken to identify retained deciduous teeth, buccal or palatal swelling and availability of suitable space for the incisor (9 mm for a central and 7 mm for lateral incisors).

If an obvious cause cannot be identified radiographs should be taken. An anterior occlusal radiograph can be taken for general assessment purposes. For detailed assessment of position, root and crown morphology two periapical radiographs should be taken using the parallax technique.

5. Management principles

5.1. Remove retained deciduous tooth. The retained deciduous tooth should be extracted,

5.2. Create and Maintain Sufficient Mesial and Distal Space. Seventy-five per cent of incisors erupt spontaneously, of these, 55 per cent align spontaneously. Thirty-four per cent will require orthodontic alignment.

5.3. Physical obstruction. The presence of supernumerary teeth and odontomes does not necessarily cause delayed eruption of incisors. Tuberculate supernumerary teeth are more likely to cause an obstruction than conical supernumerary teeth (1 in 5 compared to 1 in 1). In addition, one-third of compound odontomes and one half of complex odontomes prevent eruption of teeth (compound odontomes are four times more common than complex odontomes). If there is an obstruction it should be removed. In 54–78 per cent of supernumerary teeth removal the incisors should erupt spontaneously within an average time of 16 months. The incisor may also be exposed at the same time as the supernumerary tooth is removed.

If the incisor fails to erupt with no obvious obstruction there are two possible options:

5.3.1. Exposure. The minimalistic approach can be employed in which a small window could be created if the incisor is close to the surface and if attached gingiva is wide and enough can be preserved at the gingival margin. Otherwise, palatal or buccal mucosa flaps should be raised to reveal the tooth. In the case of a buccal flap, as much attached gingiva as possible should be preserved using an apically positioned flap. The exposure may need to be maintained using a non-eugenol based periodontal dressing. A whiteheads varnish pack may cause discoloration of the underlying tooth. A chlorhexidine mouthwash could be prescribed to reduce gingival inflammation.

5.3.2. Closed eruption technique. A flap is raised and a bracket attached to a gold chin, steel ligature, magnet, or elastomeric material bonded to the tooth followed by the palatal flap being replaced. Orthodontic traction should then be applied. the bracket should be bonded as palatally as possible so that early buccal fenestration does not occur to avoid unfavourable gingiva contour.

5.4. Unfavourable root formation. A study of 41 dilacerated unerupted maxillary central incisors revealed that 7 per cent were associated with cysts or supernumerary teeth, 22 per cent resulted from trauma to the deciduous predecessor and the remaining 71 per cent were developmental in nature. The dilacerated incisor may be brought into the line of the arch by exposure and closed technique. Elective root filling and apicectomy may be undertaken on unfavourable labial root dilaceration. If the dilaceration is severe the incisor could be removed.

5.5. Incisor removal. If a permanent incisor has to be removed (e.g. if it is ankylosed) space must be maintained initially with a fixed or removable prosthesis. An implant should be considered as a long term solution. Auto-transplantation of lower premolars should also be considered if there is crowding in the lower arch.

6. Discussion

The strength of a guideline is only as good as the evidence made available. In the search through the literature there were no controlled trials. There were 21 retrospective case studies reporting on 12 to 213 cases, four epidemiological studies reporting on 41 to 48,550 individuals, 40 case reports, and 12 articles portraying clinical techniques, overviews, and personal impressions.

The occurrence of unerupted maxillary incisors are associated with hereditary and environmental factors, however, the relevant importance of possible factors is not known. For example, the presence of supernumerary teeth does not necessarily mean that the incisor will be prevented from eruption. The prevalence of supernumerary teeth in cleft lip and palate children has been reported as 42 per cent. In addition, 5.5 per cent of supernumerary teeth become cystic. The accumulation of certain factors or variables will heighten the problem and impact.

The management of unerupted incisors is based on referred population samples recorded in either or both theatre operation records and orthodontic records. Often there are patients with incomplete or missing records, and these cases are often excluded from the study which tends to focus on treatment and is, therefore, creating an obvious bias.

For instance, one study in the Netherlands reported 54 per cent of incisors erupted when supernumerary teeth were removed. However, this finding was determined from a group of 56 children from a larger sample of 110 children. Therefore, the success of eruption of incisors could possibly be worse or much better than the reported 54 per cent. Another study in the U.K. looked at 96 patients and reported 78 per cent of delayed teeth spontaneously erupted after supernumerary removal. However, the number of patients without complete records were not included in the sample and therefore may also affect the result. The success rate has a direct bearing on the cost of treatment and will undoubtedly vary between patients, clinicians and centres. A success rate of greater than 70 per cent would arguably indicate supernumerary tooth removal first. If the tooth does not erupt exposure and closed technique may be appropriate at a later date.

Often, the position of impacted incisors determines the surgical procedures (distance from alveolar crest, rotation, angulation, and inclination). However, one study of 30 patients suggested that the closed technique resulted in more aesthetically pleasing gingiva than the apically repositioned flap. However, there was no significant difference between the techniques regarding periodontal attachment.

The method of closed eruption has never been subject to a randomized controlled trial and the cost-effectiveness of techniques such as gold chain, wire, and elastic has obvious implications. The use of magnets would not necessarily be recommended at this time.

The timing of intervention has been suggested as being important several studies suggesting that the younger the age the quicker the tooth erupts, and other studies suggesting that age of intervention has no effect. To some extent the differences can be explained by the small mean time difference of about 3 months in eruption, inadequate sample sizes, and unmatched age groups.

7. Summary

Because of the nature of the problem, low prevalence across the age group 3 years to 14 years, the findings of the studies reviewed did not tend to model the data sufficiently to be confident of which factors singularly or in combination were important in affecting the eruption and management of maxillary incisor teeth. Further studies should be undertaken to assess the cost-effectiveness of various clinical management procedures for the unerupted maxillary central incisor.

Critical Analysis of the Guideline: Management of Unerupted Maxillary Incisors

These are guidelines from the Royal College of Surgeons on the management of a clinical condition that '*can have a major impact on dental and facial aesthetics*.' It states in the guidelines that there are very few studies that report functional problems from missing incisors although in some, speech difficulties have been recorded. The observation is made that missing upper incisors may have an effect on '*self esteem and general social interaction*' and, accordingly, early diagnosis and intervention is recommended. Emphasis is placed on the necessity to update the guidelines as further clinical evidence becomes available.

Comment

It has been established that a healthcare professional's duty of care to his patient involves not only physical health but also mental health. There could, therefore, be a claim for psychological damage, as well as any functional or speech

difficulties associated with inappropriate assessment and/or treatment of this condition. There is mention of '*further clinical evidence*' to update the guidelines as necessary, but it would be more appropriate to make reference to evidence-based medicine and audit to provide this information.

Detection of Causes of Failure of Eruption

Medical and dental history. The guidelines recommend a detailed medical and dental history to determine possible hereditary or environmental factors, which may be contributory to the delay in eruption.

Comment. It would thus be prudent for a clinician to follow this advice and record the fact this had been done in the clinical case notes.

Examination

Comment. This is a condition which should be detected in young children. Consent to examination should accordingly be obtained as this condition may be detected in children as young as 7 or 8 years of age who are unlikely to be 'Gillick competent' (Gillick v West Norfolk and Wisbech Health Authority, 1985). (More detail is provided about Gillick competency when discussing the guideline on Consent to Treatment.)

Radiographic examination is recommended by the guidelines if there is no obvious cause for delayed eruption. Specific radiographs are advised to provide the appropriate clinical information. Clinicians would therefore be advised to take these radiographs and record this fact in the clinical case notes. Clinicians who had not carried out these investigations without recording a valid reason for this could have difficulty in defending a subsequent medical negligence suit.

Management Principles

Comment. The different clinical management options are then discussed. It does not stress the importance of not only fully involving the patient (as much as competence will allow), but also the parents/legal guardians in any decision-making process; the relevant facts should be recorded in the case notes. This is important as one clinical technique involves only removing any physical instruction to prevent an incisor from erupting without bonding a gold chain at time of surgery under general anaesthetic. The significance is that if the permanent incisor subsequently fails to erupt, then a further general anaesthetic is required. This latter approach has to be balanced against increasing the length of time of the first operation if a gold chain were to be bonded at time of surgery. Further evidence is required by audit to update the guidelines and make specific recommendations to provide firmer guidance between these two techniques; in the mean time it should be stressed in the guidelines that there should be full discussion of the options with the patient and parent/legal guardian to enable 'informed consent' to be obtained.

Discussion

The guidelines state: '*The strength of a guideline is only as good as the evidence made available*'. The literature search revealed there were no controlled trials and, therefore, it is advised that further studies be undertaken to asses the cost-effectiveness of various clinical management procedures for the unerupted maxillary central incisor.

Comment. In other words, we require more evidence-based medicine and clinical audit.

British Orthodontic Society Clinical Guidelines

I. Re-use of Orthodontic Materials

Some concern had been raised by the British Dental Trade Association on the question of re-using orthodontic brackets, bands, wire, etc., which have been previously used in the mouth of another patient. They highlighted two main areas of concern:

1. Patients/parents may be unhappy if they found that orthodontic materials used in their mouths had previously been in the mouth of another patient (despite the knowledge that these materials had been totally sterilised and reprocessed). Public perception of the dental profession may be harmed especially if the press obtained any information on this matter.
2. Many manufacturers of orthodontic materials make it clear that materials are for single use only. So who takes responsibility if a problem arises with a reprocessed materials? The Medical Devices Agency have produced advice regarding the re-use of medical devices.

Medical Devices Agency (MDA): Who are They?

The MDA are a regulatory authority that implements directives with regard to medical devices. The agency publish regular safety notices and provide information/advice on issues affecting the safe use of medical devices.

Currently, medical devices are categorized into various classes depending upon the level of risk associated to the patient, e.g. how long a device is left in place. At present there are a series of three directives regulating the safety and marketing of medical devices throughout the European Community, which came into effect from January 1993.

Dental materials, appliances, instruments, and equipment are regarded as medical devices and are covered by the Regulations, which implement Directive 93/42/EEC (Medical Devices Directive). The directives are not designed to interfere with professional/clinical freedom.

How Will a Clinician Know a Medical Device is Safe to Use?

By June 1998, all medical devices (except custom-made devices or those used in clinical trials) will have a mark of conformity (CE) stamped on its product or labelled on its packaging by the manufacturers. This CE mark of conformity means the medical device satisfies the essential

requirements for it to be fit for its intended purpose, i.e. it is safe to use. Essentially if something goes wrong with the device, the manufacturer can be made liable. Dental appliances, specifically made for a patient are classified as custom made devices.

When Did This Directive Come into Force?

It came into force from January 1995 and there will be a transitional period until June 1998 for manufacturers to allow changes to take place.

Effects of the New Regulations for Dentists (Information Sheet from MDA)

1. Dentists have to be aware that all materials, instruments and equipment they purchase should carry the CE marking by June 1998.
2. Dental laboratories and dentists who make appliances (custom-made) must conform with the regulations and register with the MDA by June 1998.
3. Dentists should continue to report adverse incidents involving medical devices to the MDA Adverse Incident Centre and also inform the manufacturer.

Re-use of Orthodontic Materials Intended for Single Use: Who is Legally Responsible if an Injury Arises?

Summary of the legal opinion obtained from The Medical and Dental Defence Union of Scotland.

1. Any member who reprocesses an orthodontic device intended by the manufacturer for single use only, will be held to be in the same position as the original manufacturer. They will have to ensure that the device complies with all relevant safety standards. If an injury occurs with such a reprocessed device any liability will be on the member.

2. If the reprocessing is simply a case of cleaning or sterilising a medical device, this would not normally transfer liability. **However**, if a manufacturer has issued a specific warning against re-use of such a medical device, a clinician would not be breaking the law in simply re-using the material, but would be responsible should any injury arise. It may be that most re-use of this type is entirely safe and this is a negligible risk. At the present time there is no real authority on which to rely, as no case has gone to court. It is best to err on the side of caution.

Conclusions (MDA DB 9501-bulletin)

Medical devices which are labelled 'single use' should not be reprocessed and reused unless the reprocessor:

(1) can observe all stringent technical requirements needed to ensure safety of each reprocessed item;
(2) can produce evidence of successful validation studies of the reprocessing method to confirm that the method produces a safe and effective product, fit for the intended purpose;
(3) has a system for retaining full reprocessing records, should problems arise later.

Critical Analysis of the Guideline: Re-use of Orthodontic Materials

These guidelines provide guidance to clinicians concerning the re-use of clinical materials used in orthodontics; they were formulated in response to orthodontic materials/products being re-used/recycled. Two issues of concern were raised:

1. Patients'/parents' concern that orthodontic materials had been in another patient's mouth despite being fully sterilized.
2. Where manufacturers make it clear that the product is for single use, who takes 'legal responsibility' if such a product is reused by a clinician?

Comment

1. Provided the components have been fully sterilized, as opposed to being disinfected, *and this does not affect the performance of the product* (my emphasis), then there would be no difference in principle between the reuse of these materials between patients from the re-use of instruments which have been sterilized and subsequently re-used in operations on different patients. Manufacturers have an incentive for products not to be recycled as this increases sales, whereas clinicians would prefer to re-use products as this keeps down costs.
2. The guidelines provide a summary of legal opinion obtained from the Medical and Dental Defence Union of Scotland as to who is legally responsible if any injury arises from the re-use of orthodontic materials intended for single use.

It states that a clinician who reprocesses and uses an orthodontic device which was intended by the manufacturer for single use only will be held to be in the same position as the original manufacturer, i.e. would need to show that the device/product complies with all relevant safety standards and if an injury occurs with such a reprocessed device/product any liability will be on the clinician.

Comment

Action could be taken against the clinician on the basis that there is a duty of care and if the clinician uses a product which is designed for single use only there is a breach of that duty; it would then be necessary to show damage flowing from the breach, i.e. causation. In addition, the patient could have action under Part 1 of the Consumer Protection Act (1987); this would apply to products put into circulation after the 1st March 1988. Section 2(1) of the 1987 Act provides that: '*where any damage is caused wholly or partly by a defect in a product, every person to whom subsection 2 below applies shall be liable for the damage*'. A right of action is therefore given to any person who suffers

damage as a result of a defective product. Unlike the tort of negligence, it is not necessary to establish that the plaintiff was foreseeable as likely to be affected by the defect nor that the defendant clinician was negligent, i.e. there is strict liability; there are defences to the 1987 Act, e.g. the development risks defence which excludes liability for unforeseeable design defects. Section 3(2)(c) of the 1987 Act takes into account whether or not the product as supplied by the producer was or was not defective when it left his hands. If a product had deteriorated since it left the producers hands because its 'shelf life' had expired or due to *repeated use or mishandling* (my emphasis) then there would be contributory negligence on the part of the user of the product, e.g. the clinician who had recycled a product designed for single use which was subsequently re-used and caused harm to a patient.

The guidelines state that a clinician would not be breaking the law by re-using a material where a manufacturer has issued a specific warning against such re-use, but would be responsible should any injury arise. As already discussed there would be liability both under the tort of negligence and under Part 1 of the Consumer Protection Act. It then states in the guidelines that: '*It may be that most re-use of this type is entirely safe and this is a negligible risk*'.

Comment

It is not sensible to have this statement in such guidelines until the extent of the risk has been evaluated; trials would have to be undertaken in laboratory circumstances trying to simulate as closely as possible a clinical environment to see whether or not the properties of a product would be affected by sterilization and re-use. It could be argued that this recommendation in the guidelines is not a good one, and the courts would find it to be not logical. It is important that clinical guidelines are seen to be logical in view of the comments by Lord Browne-Wilkinson in Bolitho v City & Hackney Health Authority (1997) concerning expert medical testimony. Despite this reasoning the guidelines then go on to say that there is no authority upon which to base this advice and therefore it is '*best to err on the side of caution*'. There seems to be some inconsistency here.

The Conclusions (MDA DB 9501-bulletin)

Within these conclusions there should be a warning that clinicians who re-use medical devices which are labelled single use who cannot demonstrate the requirements identified in (a), (b), and (c), which would be difficult to do, may well be found not to have exercised an appropriate standard of care in re-using a product designed for single use. There may also be contributory negligence under Part 1 of the Consumer Protection Act 1987, where there is strict liability for manufacturers who produce defective products.

Reference in the guidelines is made to the Medical Devices Agency, which is a regulatory body, that implements directives concerning medical devices. The guidelines explain that medical devices are categorised into various classes depending upon the level of risk for the patient, for example the length of time a device is left in place. Dental materials, appliances, instruments, and equipment are regarded as medical devices and are covered by the Medical Devices Directive (Directive 93/43/EEC).

When did this Medical Devices Directive come into force and how will a clinician know a medical device is safe to use? The guidelines explain that the directive came into force in January 1995, but there was a transitional period until June 1998. By this latter date all medical devices, except custom-made devices or those used in clinical trials had to carry a mark of conformity (CE) stamped on it or its packaging; this is a type of 'kite mark' and means that the medical device satisfies the essential requirements for it to be fit for its intended purpose, i.e. it is safe to use.

Effects of the new regulations for dentists. From June 1998, all materials, instruments, and equipment purchased by dentists carried the CE kite mark. Dental laboratories who construct custom-made appliances for dentists had to conform with the regulations in the directive and register with the Medical Devices Agency by June 1998. It is the responsibility of dentists to make certain that the laboratories they deal with have conformed with the regulations and registered with the Medical Devices Agency. The guidelines also point out that there is a responsibility for dentists to continue to report adverse incidents involving medical devices to the Medical Devices Agency Incidents Centre and also inform the manufacturer.

British Orthodontic Society Clinical Guidelines

II. Advice on the Use of Facebows

There have been reports in the dental literature indicating that soft tissue and eye injury can occur from headgear components. The incidence is very low, but when an eye injury does occur it can have serious consequences. Because wounds are contaminated by oral bacteria and are difficult to treat, eye injuries may result in impaired vision or even loss of the eye. Another serious consequence can be sympathetic opthalmitis.

Injuries from headgear can occur due either to recoil, where the appliance is actively pulled, or as a result of accidental disengagement, particularly during sleep. the dangers arising from accidents during play or incorrect use are known and have been recognised for some time. Manufacturers now produce safety neck straps and anti-recoil headgear, but even so, anti-recoil devices alone do not make headgear totally safe. It has been reported that the greatest incidence of disengagement occurs at night and it is therefore essential when using headgear at night that the headgear is securely attached to the appliance.

The following gives some advice for the safe use of headgear. It is the responsibility of the orthodontic practitioner to ensure that proper instruction in its safe use is given to the patient and parents. It is good clinical practice to check the use and fitment of headgear at each appointment, and make appropriate notes in the patients records, even when all is satisfactory.

Operators who are inexperienced in the use of headgear should exercise extreme caution on its use and preferably do so under supervision. It is the operator's responsibility

to keep abreast of developments in anchorage maintenance, buccal occlusion correction, non-compliance techniques, and new developments in headgear safety.

Safety Mechanisms

It is important that, where possible, all headgear has **two safety mechanisms**. One to prevent accidental disengagement and the second to prevent recoil injuries. It is the orthodontists responsibility to select the most appropriate combination of headgear safety features for each case in question.

Fixed Appliances.

There are a number of examples of safety mechanisms:

Prevention of accidental disengagement.
Rigid neck strap: prevents the forward movement of the face bow, but must be correctly fitted to prevent the bow disengaging from the buccal tubes and the safety strap from the bow. This may be too tight for some patients to tolerate.
Locking mechanisms: these ensure that the face bow cannot be removed from the buccal tubes, but they may be difficult for the patient to fit and remove.
Locating elastics: short strong elastics may be used between hooks on the inner bow and the buccal tubes to reduce the likelihood of disengagement. They may be variable in effect, and may present difficulties for the patent to fit and remove.

Prevention of recoil injuries.
Anti-recoil devices: these are designed to 'break-away' when excessive force is applied to the headgear. However, there is considerable variation in the amount of force required to activate the break-away mechanism and they do not prevent disengagement of the face bow from buccal tubes.
Rigid neck strap: prevents the forward movement of the face bow, but must be correctly fitted to prevent disengagement from buccal tubes—this may be too tight for some patients to tolerate.

Other safety mechanisms.
'*Safe ends*': These **do not** prevent the accidental removal of the face bow from the buccal tubes, but provide a blunt end which may reduce the incidence of penetrating injuries.

Removable Appliances

Clip-over appliances:consideration should be given to the use of cemented bands to which a face bow is securely locked whilst in use, over which the removable appliance can be clipped. When headgear is used directly to a removable appliance it is important to ensure that the appliance is securely retained in the mouth.
Integral face bow: when practical, consideration should be made to having the face bow constructed as an integral part of the removable appliance.
Locking mechanisms: mechanisms similar to those used for fixed appliances may be used to positively locate the face bow to the appliance. When face bows are used in conjunction with removable appliances, the patient should be instructed to fit the face bow with the appliance out of the mouth.

Written and verbal advice should be given to patient and parent

For example:

1. Remove the headgear *before* the inner bow. Never remove or fit the headgear in one piece by pulling the headgear over the face/head.
2. Do not wear headgear while playing sports or rough games.
3. At night *always* ensure that the safety mechanism(s) are in place to prevent accidental removal of the headgear and face bow.
4. If the headgear comes detached during sleep, stop wearing the headgear and contact your orthodontist.
5. If *any* eye injury associated with the headgear occurs, it must be treated as a medical emergency. Attend your local Accident and Emergency Department for an ophthalmic opinion as son as possible.
6. Bring your headgear to each appointment and report any problems to your orthodontist.

Critical Analysis of the Guideline: Advice on the Use of Facebows

Facebows are a part of extra-oral traction, which is sometimes used as part of orthodontic treatment. They can cause serious soft tissue injury with occasionally tragic consequences if an eye is involved with subsequent loss of vision. It is thus vital that if facebows are used adequate safety precautions are carried out as the courts expect more precautions where potential risks are higher (Paris v Stepney Borough Council, 1951). These guidelines give advice to clinicians as to the clinical management of the product. They also stress the importance of written and verbal advice to patients. This would be important in any case of accidental injury to show there had been full instruction and this should be recorded in the clinical case notes.

There is advice in the guidelines that headgear (of which the facebow is part) should be checked each visit and the fact recorded in the clinical case notes. This documentation would be important to show that the clinician has met an appropriate standard of care. The guidelines state that inexperienced operators should '*exercise extreme caution in its use and preferably do so under supervision*'. This clear statement means that a clinician who has not been trained in the use of headgear would find it more difficult to defend a medical negligence action where a complication had arisen from a facebow injury [Nettleship v Western (1971) demonstrated that people who are learning a skill must exercise the same standard of care as those who are already proficient in that skill.] The guidelines also state: '*It is the operator's responsibility to keep abreast of developments in anchorage maintenance, buccal occlusion correction, non compliance techniques and new developments in headgear safety*.' This is emphasizing the importance of clinicians keeping up-to-date with the new developments published

in the literature so that their patients can benefit. Crawford v Charing Cross Hospital (1953) demonstrated that the courts may not find a clinician guilty of negligence where he has not read one article on a topic warning of dangers, but with the advent of increased development in information technology the courts might not take so generous a view, particularly where there is a specific warning in authoritative clinical guidelines. Clinicians would need to ensure they were aware of new developments, particularly where clinical audit and highlighted benefits/risks.

The guidelines do not mention any counselling of patients in respect of risk/benefit when using headgear as part of orthodontic treatment. It may be that this should be specifically mentioned in any consent to treatment with the option of not using headgear discussed with the patient and parents/legal guardian being involved in the final decision as to whether or not this adjunctive procedure is used as part of clinical treatment.

British Orthodontic Society Clinical Guidelines

III. Consent in Orthodontic Treatment

Introduction

Orthodontic examination and treatment involves contact with patients. the defence societies in the United Kingdom and the NHS Management Executive advocate that consent is obtained prior to these procedures in order to avoid potential legal proceedings. The following is a brief explanation of the relevant aspects of consent in respect of orthodontics. The points have been adapted from the NHS Management Executive document 'A Guide to Consent for Examination or Treatment'.

Also included is a consent form designed for orthodontic treatment and a list of information items to be explained to the patient when considering orthodontic treatment. The Medical Defence Union, the Medical Protection Society and the Medical and Dental Defence Union of Scotland have approved these forms and recommend their use.

A Patient's Rights in Accepting Treatment

1. A patient has the right under common law to give or withhold consent prior to examination or treatment. This is one of the basic principles of health care. The Orthodontist and/or Health Authority may face an action for damages if a patient is examined or treated without consent.
2. Patients are entitled to receive sufficient information in a way that they can understand about the proposed treatments, possible alternatives and any substantial risks, so that they can make a balanced judgement. Patients must be allowed to decide whether they will agree to the treatment, and they may refuse treatment or withdraw consent to treatment at any time.
3. Care should be taken to respect the patient's wishes. This is particularly important when patients may be involved in the training of professionals and students. An explanation should be given of the need for practical experience and agreement obtained before proceeding.

The Orthodontist's Role in Advising the Patient or Obtaining Consent to Treatment

Advising the patient.

1. Where a choice of orthodontic treatment might reasonably be offered, the orthodontist should always advise the patient of his/her recommendations together with reasons for selecting a particular course of action. Enough information must be given to ensure that the patient and/or parent/guardian understand the nature, consequences, and any substantial risks of the treatment proposed, so that they are able to make a decision based on that information.
2. The patients ability to appreciate the significance of the information should be assessed. For example, with patients who:
   - have difficulty in understanding because of language differences;
   - have impaired sight, hearing, or speech;
   - are suffering from mental disability, but who nevertheless have the capacity to give consent to the proposed procedure.
3. Since most orthodontic treatment is carried out on children it is advisable for a parent or guardian to be present at the discussion when consent is sought. Where there are language problems, it is important that an interpreter be sought whenever possible.
4. An orthodontist will have to exercise his or her professional skill and judgment in deciding of what risks the patient should be warned and the terms in which the warning should be given. The orthodontist has a duty to warn patients of substantial or unusual risks inherent in any proposed treatment, especially so in treatment involving surgery.

Obtaining consent

5. Consent to treatment may be implied or expressed. In many cases, patients do not explicitly give express consent but their agreement may be implied by compliant actions, e.g. by opening their mouth for a dental examination. Express consent is given when patients confirm their agreement to a procedure or treatment in clear and explicit terms, whether orally or in writing.
6. Implied consent may be sufficient for the vast majority of orthodontic examinations. Written consent should be obtained for any orthodontic treatment carrying any substantial risk or substantial side effect. Written consent should always be obtained for orthodontic treatment involving surgery. Oral or written consent should be recorded in the patient's notes with relevant details of the orthodontist's explanation. Where written consent is obtained it should be incorporated in the notes.

Orthodontic consent form

7. The main purpose of written consent is to provide documentary evidence that an explanation of the proposed orthodontic treatment was given and that consent was sought and obtained.
8. It should be noted that the purpose of obtaining a signature on the consent form is not an end in itself. The most important element of a consent procedure is the

duty to ensure that patients/parents understand the nature and purpose of the proposed treatment. Where a patient has not been given appropriate information then consent may not always have been obtained despite the signature on the form.

9. Consent given for one procedure or episode of treatment does not give any automatic right to undertake any other procedure.

Special Circumstances

Treatment of children and young people.

10. *Children under the age of 16 years*: where a child under the age of 16 achieves a sufficient understanding of what is proposed, that child may consent or not, to an orthodontist who is proposing to make an examination or provide treatment. The orthodontist must be satisfied that any such child has sufficient understanding of what is involved in the treatment which is proposed. A full note should be made of the factors taken into account by the orthodontist in making his or her assessment of the child's capacity to give a valid consent. In the majority of cases children will be accompanied by their parents during consultations. Where, exceptionally, a child is seen alone, efforts should be made to persuade the child that his or her parents should be informed. Parental consent should be obtained where a child does not have sufficient understanding and is under the age of 16.
11. *Young People over the age of 16 years*: the effect of Section 8 of the Family Law Reform Act 1969 is that the consent of a young person who has attained 16 years to any surgical, medical, or dental treatment is sufficient in itself, and it is not necessary to obtain a separate consent from the parent or guardian. In cases where a child is over the age of 16, but is not competent to give a valid consent, then the consent of a parent or guardian must be sought. However, such power only extends until that child is 18.

Information to be Explained to the Patient by the Orthodontist or Dentist

1. Benefits. Explanation of the proposed benefits of orthodontic treatment should be directed toward the patient's/parent's concerns. Benefits should be explained in terms of minor, moderate or major improvements to dental alignment, health and function, and/or to facial appearance. Where patients/parents are not concerned by the orthodontic condition, then explanations of benefits should be understandable and unbiased so that patients/parents can decide if the proposed benefits are relevant to their needs.

2. Drawbacks. Every opportunity should be taken to emphasise the need for sustained patient co-operation and compliance throughout a possibly prolonged period of appliance therapy.

3. Limitations and Expectations. The patients and parents should be realistic about expectations, especially if the treatment objectives are limited and where extensive treatment is required to produce relatively small changes. The operator should make it clear to patient and parent, the amount of benefit they can expect from treatment in return for the amount of commitment.

4. Risks. Specific risks in the orthodontic treatment should be covered. First, potential damage to tooth tissue during treatment, for example, demineralization and root resorption. Secondly, the risk of damage to the patient by appliances such as headgear. Finally, the risk of treatment being ineffective or of relapsing post-treatment. It is important to stress that patients must continue to see their own dental surgeon regularly for check ups, throughout orthodontic treatment.

5. Options. The benefits and risks of realistic options must also be given to the patient.

6. Commitment. Patients and parents must fully understand the commitment and co-operation required for treatment to be successfully completed. Patients must fully understand the strict guidelines laid down to ensure that treatment risks are minimal, especially in respect of hygiene, diet restriction, and preventive techniques. Functional appliance and headgear therapy require a special emphasis on the co-operation required for treatment to be safe and effective.

7. Time scale. It is important to give the patient and parent a realistic time estimate for the treatment and retention phases of orthodontic therapy. It is also advisable to identify how often the patient will need to be seen during active treatment and retention. If at some point, you feel more time is required to complete therapy, it should be made clear to the patient and parent so that they can plan accordingly.

8. Cost. If cost is involved, it is important that the patient and parent understand fully the cost of treatment, failed appointments, and of replacement of broken or lost appliances. The method of payment and whether it is an NHS or private contact should be made clear and agreed.

9. Necessity. Orthodontic treatment is optional and parents and patients must decide at this point whether they agree the therapy is necessary.

Notes to consent form

Orthodontist/dentist. A patient has the legal right to grant or withhold consent prior to examination, or treatment. Patients should be given sufficient information in a way they can understand, about the proposed treatment and the possible alternatives. Patients must be allowed to decide whether they will agree to the treatment, and they may refuse or withdraw consent to treatment at any time. The patient's consent to treatment should be recorded on this form (further guidance is given in HC(90)22 *A Guide to Consent for Examination and Treatment*).

Patients. The orthodontist or dentist is here to help you. They will explain the proposed treatment and what the alternatives are. You can ask any questions and seek further information. You can refuse the treatment.

CONSENT FORM FOR ORTHODONTIC TREATMENT

Patient's

Surname_____

Other Names_____

Date of Birth_____

Sex (please tick)------ Male [ ] Female [ ]

TO BE COMPLETED BY ORTHODONTIST OR DENTIST *(See notes overleaf)*

TYPE OF ORTHODONTIC TREATMENT

I confirm that I have explained the nature of the orthodontic treatment proposed and such appropriate options as are available, to the patient in terms which in my judgement, are suited to the understanding of the patient and/or to one of the parents or guardians of the patient.

*Signature*_____ *Date*___/__/___

*Name of Orthodontist or Dentist*_____

TO BE COMPLETED BY THE PATIENT/PARENT/GUARDIAN

1. Please read this form and the notes overleaf carefully.
2. If there is anything that you don't understand about the explanation or if you want more information, you should ask the orthodontist or dentist.
3. Please check that all the information on the form is correct. If it is, and you understand the explanation and wish to proceed with orthodontic treatment, then sign the form.

I am the patient/parent/guardian (*delete where necessary)*

I agree

- that the orthodontic treatment proposed has been explained to be by the orthodontist/dentist named on this form and is necessary and desirable.

I understand

- the length of time and commitment required for the orthodontic treatment to be effective.
- the anticipated limitations, risks and drawbacks which have been explained to me.

I have told

- the orthodontist/dentist about any additional procedures I would not wish to be carried out without my having the opportunity to consider them first.

I,_____ of _____

Name Address

* hereby consent to the above patient undergoing orthodontic treatment.

* I understand the costs involved, (details of which will be provided separately)

*Signature*_____ *Date*___/___/____

* Delete whichever is inapplicable

You may ask for a relative, or friend, or nurse to be present.

The training of health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for student training, where necessary under the careful supervision of a senior orthodontist or dentist.

You may refuse any involvement in a training programme.

Critical Analysis of the Guideline: Consent in Orthodontic Treatment

These guidelines explain the importance of obtaining consent before examining or providing orthodontic treatment for a patient. Many of the points in the guidelines have been adapted from the Health Circular (HC(90)22), *A Guide to Consent for Examination and Treatment.*

A patient's Rights in Accepting Treatment

1. This states, correctly, that the patient has a right to give or withhold consent prior to examination or treatment. It rightly warns that the clinician and/or health authority may face an action for damages if a patient is examined or treated without consent. What is not said, but which should be, is that the legal purpose of consent is to provide a clinician involved in patient care with a defence to a criminal charge of assault or battery, or a civil claim for damages for trespass to the person. Consent does not necessarily provide a defence to a claim of negligent treatment.

Battery or negligence? In Chatterton v Gerson, (1981) counsel for the plaintiff argued that, because the plaintiff had not been informed about all the risks associated with treatment, her consent was vitiated and, accordingly, the

defendant doctor was liable in battery. The court did not accept this argument and the trial judge Bristow J ruled that once a patient was informed in **broad terms** (my emphasis) of the procedure or operation to be carried out, then a claim for failure to discuss the risks and implications of a procedure was negligence not trespass to the person or battery. This approach was confirmed in Hills v Potter (1983) and by the Court of Appeal in Sidaway v Bethlem Royal Hospital Governors (1985). The courts have thus differentiated between information being withheld or not provided about the nature of a procedure, which would give rise to an action in battery, and insufficient information about the risks of a procedure, where the action would be in negligence.

2. The guidelines also stress the importance of providing patients with sufficient information so they can make an 'informed consent' with the knowledge of the risks and benefits associated with treatment.

3. This section states the importance of respecting a patient's wishes particularly when they are involved in the training of professionals and students. It states: 'An explanation should be given of the need for practical experience and agreement obtained before proceeding'.

Comment. It is important to distinguish between undergraduate and postgraduate teaching and training. It is the responsibility of a named consultant to decide who carries out procedures on patients under his care, and to ensure that such postgraduate trainees are either experienced enough to do specific procedures on their own, or are supervised, or directly assisted according to the individual's degree of experience or training. Within the National Health Service, a patient cannot insist that an operation or procedure is carried out by a specific member of staff, for example, a consultant, although a named consultant will take overall responsibility. There is, however, a responsibility for a health authority or Trust to provide doctors of sufficient training/experience. In the case of Wilsher v Essex Area health Authority (1988), Lord Browne-Wilkinson ruled that where a health authority failed to provide doctors of sufficient skill and experience it could be held directly liable. This would mean that a patient could sue a health authority or Trust directly as opposed to waiting until a doctor made a mistake and then suing because of the vicarious liability a health authority or Trust would have for its employee doctors. Where, however, unqualified medical or dental students participate in patient care, patients should be aware of the fact that they are unqualified and their specific consent obtained if they agree to such undergraduate students carrying out procedures for them.

The Orthodontist's Role in Advising the Patient or Obtaining Consent to Treatment Advising the Patient

1. This states the importance of explaining treatment options to the patient/legal guardian and the reasons for a recommendation of a particular procedure. It stresses the importance for sufficient information to be provided so that the patient can '*understand the nature, consequences and any substantial risks of the treatment proposed so they are able to make a decision based on that information*'. It states that the patient and/or parent/guardian must have sufficient information to be able to make a decision based on that information. This is effectively moving away from the principle expressed in Sidaway v Bethlem Royal Hospital Governors (1985) where the House of Lords said that if what a defendant doctor had told a patient about clinical risk would be that which a '*responsible body of medical opinion*' would have told the patient, then the doctor had not been negligent. These guidelines are recommending more than that and are advising 'informed consent'.

The guidance, however, on this issue is not as explicit as that produced by the Senate of Surgery of Great Britain and Ireland in their booklet '*The Surgeon's Duty of Care—guidance for surgeons on ethical and legal issues*. In this booklet it says, '*Inform competent adult patients aged 16 and above of the nature of their condition, along with the type, purpose, prognosis, common side-effects and significant risks of any proposed surgical treatments. Where appropriate, alternative treatment options (including non-surgical) should also be explained together with the consequences of no treatment. This information should be provided in the detail required by a reasonable person in the circumstances of the patient to make a relevant and informed judgement*'. Foster (1998) argues that this guidance which is very specific has perhaps unknowingly removed from surgeons the protection which Sidaway (1985) gave them by stressing that consent must be informed. The guidelines in this document would certainly be regarded as authoritative and the courts may well decide that all responsible doctors should adopt them. Foster speculates further as to whether it was knowledge of this booklet which led Lord Browne-Wilkinson in Bolitho (1997) to re-emphasize the relevance of the *Bolam* test in respect of diagnosis and treatment, but no reference was made to Sidaway and disclosure of risk. While the move to 'informed consent' by healthcare professionals is generally to be welcomed, this may not have the effect on medical negligence actions that would at first seem to be the case. Patients would still have to convince the courts that had they been in possession of additional information concerning risks, they would have declined the procedure/operation, i.e. show causation.

2. Emphasis here is placed on the importance of making allowance for any disability such as impaired sight, hearing, or speech or language difference when providing information. This is important because a clinician would need to be able to refute any allegation of 'discrimination' under either the Disability Discrimination Act (1995) or the Race Relations Act (1976) if a patient belongs to an ethnic minority where English is not the first language. It also states the importance of assessing if patients who '*are suffering from mental disability, but who nevertheless have the capacity to give consent to the proposed procedure*'. The statement does not give any guidance in assessing whether or not patients in this category have the necessary 'capacity' to give consent. The Executive Letter (EL (97) 32, 1997) advises that: '*a person lacks capacity if some impairment or disturbance of mental functioning renders the person unable to make a decision whether to consent to or to refuse treatment.*'

3. The advice here is reasonable in stating that it is advisable where possible that a parent or legal guardian be present at any discussion when consent is sought for the treatment of children. The position of 'Gillick competency' (Gillick, 1985) will be discussed later.

4. This recommends that a clinician '*exercise his or her professional skill and judgement in deciding of what risks the patient should be warned and the terms in which the warning should be given*.' This leaves very much in the hands of individual clinicians as to how much information should be provided to a patient rather than recommending that sufficient information be provided as would be expected by a 'reasonable patient'. (This to a degree contradicts the guidance given earlier in '1'). The guidelines then stress the importance of discussing risks with patients under these circumstances. Although in Sidaway (1985) the English court decided that rare risks do **not** have to be discussed if it is in line with a '*responsible body of medical opinion*', in the Australian case of Rogers v Whitaker (1993) it was decided 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.

Obtaining consent.

5. This explains that consent can be implied or expressed, oral or written. It is correctly pointed out that patients provide implied consent by presenting themselves for examination and/or treatment, e.g. sitting in a dental chair and opening their mouth. (This is analogous to the situation where if a doctor tells a patient he wants to give him an injection and the patient holds out his arm this will be taken to be implied consent.) It then correctly states that express consent is given when patients give their consent either orally or in writing to an examination or specific procedure.

6. The guidelines correctly state that implied consent '*may be sufficient for the vast majority of orthodontic examinations*'. The issue of patients who are under 16 years of age is discussed later in the guidelines. There is sensible advice to obtain written consent for any '*orthodontic treatment carrying any substantial risk or substantial side effect*' and '*always be obtained for orthodontic treatment involving surgery*'. There is then advice to record in the notes details of consent either written or oral and that written consent should become part of the clinical case notes. This is important because as orthodontic treatment can take up to two years, memories can fade. Clinicians would be better placed to defend certain aspects of litigation if written consent was obtained for all procedures accompanied by appropriate explanation.

Orthodontic consent form.

7. This states that: '*The main purpose of written consent is to provide documentary evidence that an explanation of the proposed orthodontic treatment was given and that consent was sought and obtained*'.

Comment. What should also be stated is that: *'The patient's consent to medical treatment, or indeed any procedure which involves a touching of the patient's body, is essential because it renders lawful what would otherwise constitute the tort of battery, and indeed, a serious invasion of the person's bodily integrity'* (Jones, 1996).

8. This stresses the importance of patients understanding the implications of the consent form. It rightly points out that without appropriate information presented in a way that a patient understands consent may not have been obtained despite the 'signature on the form'.

Comment. This is correct and was held to be the case in Coughlin v Kuntz (1987).

9. This explains that: 'consent given for one procedure or episode of treatment does not give any automatic right to undertake any other procedure'.

This is true as demonstrated in Potts v North West Regional Health Authority (1983), where the plaintiff agreed to be vaccinated against rubella, but unknown to her the syringe also contained the long acting contraceptive drug Depo-Provera; the defendants were held liable in **battery** (my emphasis) and the plaintiff was awarded £3000 in damages. The trial judge said, '*To deprive her of the right to choose is to deprive her of the basic human right to do with her body as she wishes*'. Similarly, a number of women have been sterilized without their consent when having other procedures, and the responsible clinicians subsequently held to be liable in negligence or guilty of battery (Devi v West Midlands Health Authority, 1981).

Special Circumstances

Treatment of Children and Young People

10. Children under the age of 16 years. A child who is under the age of 16 who achieves a sufficient understanding may consent to treatment without the consent of a parent or legal guardian. A child under 16 in these circumstances would be deemed 'Gillick competent' (Gillick, 1985). The guidelines rightly point out that these circumstances are likely to be exceptional, and every effort should be made to persuade the child to discuss the position with his or her parents and obtain their agreement.

Comment. The Family Law Reform Act (1969) reduced the age of majority from 21 to 18 years of age. Section 8(1) of the 1969 Act stated:

> *The consent of a minor who has attained the age of 16 years to any surgical, medical or dental, treatment . . . shall be effective as if he were of full age: and . . . it shall not be necessary to obtain any consent from his parent or guardian.*

Section 8(3) went on to state:

> *Nothing in this section shall be construed as making ineffective any consent which would have been effective if this section had not been enacted.*

Section 8(3) therefore emphasized that the Act does not over-rule common law consent. The case of Gillick v West Norfolk and Wisbech AHA (1985) concerned a directive from the Department of Health to general medical practitioners that they were able to prescribe oral contraceptives to girls beneath the age of 16 years without parental knowledge and consent. Mrs Gillick objected strongly to this and the case was finally decided by the House of Lords. Lord Scarman ruled that:

> *. . . parental right to determine whether or not their minor child below the age of 16 will have medical treatment terminates if and when the child achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed.*

Thus, a child could be competent at as young an age as 12 or 13 years, but the complexity/seriousness of the procedure/operation proposed will obviously have an influence in assessing competence in such a minor.

Refusing to consent to treatment. The guidelines do not give guidance on refusal to consent to treatment. In the case of Re R (A Minor) (1991), a 15-year-old girl who was in the care of a local authority refused to submit to a course of drug therapy to treat her mental health condition. The local authority were not willing to consent on her behalf on the basis that she was 'Gillick competent' and thus able to refuse treatment in her own right. The Court of Appeal ruled that where consent is concerned, both parents and a 'Gillick competent' child are 'key holders' who may jointly or independently unlock the door to medical treatment by appropriate consent. A parent cannot lock the door to medical treatment provided the child is 'Gillick competent'. Where refusal is the issue for a child under 16, if the child refuses to consent then a parent may consent on her behalf, and this consent overrides her refusal and allows medical treatment to be undertaken lawfully, where it is considered to be 'in the child's best interests'.

What is the position in law for persons under the age of sixteen years where healthcare professionals advise treatment, but consent is not given by the patient, either because he or she is not deemed to be 'Gillick competent' or else refuses treatment and, in addition, the parents/legal guardians refuse to consent? The court's view has been where emergency treatment is required to save life, for example a blood transfusion for a Jehovah's Witness, then the courts will give consent (Re E, 1993; Re S, 1994). Under the Children's Act (1989) the courts have the power to decide what is in the best interests of the individual child.

11. Young people over the age of 16. The guidelines correctly state that under Section 8 of the Family Law Reform Act 1969 that a young person who has obtained 16 years of age can consent to any surgical, medical, or dental procedure, and it is not necessary to obtain a separate consent from the parent or guardian. The guidelines also correctly say that where a child is 16 or 17 years of age, '*but is not competent to give a valid consent, then the consent of a parent or guardian must be sought*'.

Information to be explained to the patient by the orthodontist or dentist. This is essentially a risk/benefit management strategy which attempts to outline the principle benefits from treatment and the commitment from the patient together with possible risks associated with treatment procedures. It is important that the patient is fully aware of whether or not any treatment is to be provided under private contract or the NHS.

Consent form for orthodontic treatment. This states: '*I understand the anticipated limitations, risks and drawbacks which have been explained to me*'. There should be reference here to the fact that such limitations, risks, and drawbacks which have been identified are recorded, preferably in the case notes, otherwise it will be difficult to remember in 3 or 4 years time or longer which risks and drawbacks were identified and which were not. It also states: '*I have told the orthodontist/dentist about any additional procedures I would not wish to be carried out without my having the opportunity to consider them first'.*

Comment. It would be difficult for the average patient to identify a list of procedures which he or she did not wish to have carried out. Anything substantial ought to be rediscussed with the patient, otherwise consent is not valid unless such additional procedures are carried out in emergency situations.

It then states, '*I hereby consent to the above patient undergoing orthodontic treatment*'. This assumes that in the majority of cases a parent or legal guardian will be consenting for a child. It might be more appropriate to have, in addition to this, a line which enables an individual to consent for him or herself, and whichever line is inappropriate can then be deleted with the appropriate consent signed.

'*I understand the costs involved, (details of which will be provided separately)*': if the treatment is to be provided under private contract it might be better to have the terms of such contract recorded separately from consent to treatment. If it is not recorded separately then a patient could be consenting to a private contract without knowing the exact details of costs, which would be unacceptable.

Under the notes to patients it states, '*You may refuse any involvement in a training programme*'. Patients do not have to take part in undergraduate medical or dental training. However, where the care of a patient is under the responsibility of a named consultant, a patient may have some of his or her treatment provided by a postgraduate in training (e.g. Senior House Officer/Registrar). The National Health Service does not guarantee that treatment will be provided by a specific named individual. Therefore, all patients who are treated by junior medical staff, are being treated by individuals who are in training programmes. It is thus important to the guidelines to differentiate between undergraduate and postgraduate training programmes, as the latter individuals are qualified professionals on the appropriate register.

British Orthodontic Society Clinical Guidelines

IV. Orthodontic Radiography

Medico-legal Aspects of Radiography for Orthodontic Purposes

Need for radiography. The international principles of ethics for the dental profession formulated by the Federation Dentaire Internationale state, 'The primary duty of the dentist is to safeguard the health of patients . . .'

Radiographs may be required as part of the proper treatment of a patient, but their use should always be established initially through the taking of a history and following an appropriate clinical examination.

The clinical decision on the need for radiography is influenced by many factors, but it is unethical to take radiographs for medico-legal or administrative reasons alone. In particular, taking post-treatment radiographs solely for medico-legal purposes is not justified unless there is a clinically observed reason. It has been stated that, 'if as a

result of careful clinical examination you decide that an x-ray is not necessary for the future management of the patient, your decision is unlikely to be challenged on medico-legal grounds' (Royal College of Radiologists, 1991).

It is the legal responsibility of all clinicians to be aware of all relevant current legislation relating to radiography.

Storage and retention of radiographs. Radiographs are a diagnostic aid, which form part of a patient's treatment records and remain the property of the practitioner or hospital.

The situation as regards the legally required time to retain records is complex. The Limitation Act (1980) would suggest that the minimum time for retention of radiographic records should be 6 years, whilst the relevant health service circulars HC(80)7 and HC(89)20 would suggest that children's records should be retained until their 24th birthday or 8 years after the last entry, whichever is the longer. However, the Consumer Protection Act (1987) is also of some relevance to this issue. An action arising from this act (Injury from Defective Product) may occur 10 years after the knowledge of such an episode. It would therefore seem wise to arrange to retain radiographic records in some useful form until 27 years of age or 11 years after the last recorded entry (making a 1 year allowance for the due process of law), whichever is the longer.

When an original radiograph has been sent with a patient and providing it is of sufficient quality, it should either be retained for the period of the treatment or it should be copied, the original being returned to the referring practitioner. 'Whole film' computer storage may make this process simpler for both hospitals and practices in the future. Where films are retained for the course of a treatment, a suitable mechanism must be established with the original referring clinician for the safe storage of that record for the required time.

Goods records are often critical in refuting allegations of negligence. Defence may prove impossible if:

(1) radiographs were not taken when there were reasonable clinical grounds for obtaining additional information in this manner;
(2) radiographs which were taken have been lost;
(3) radiographs which have been taken are of such poor quality as to be of little clinical use.

Critical Analysis of the Guideline: Orthodontic Radiography

The Federation Dentaire Internationale states in its code of ethics that '*The primary duty of the dentist is to safeguard the health of patients*'. This is an ethical duty which would apply to most healthcare professionals.

The guidelines then state that radiographs should only be taken after a clinical examination and for clinical reasons and not for medico-legal or administrative purposes. It then quotes a statement by the Royal College of Radiologists in 1991: '*if as a result of careful clinical examination you decide that an x-ray is not necessary for the future management of the patient, your decision is unlikely to be challenged on medico-legal grounds*'. It does not say on what basis your decision is unlikely to be challenged, but presumably this would be on the basis of the *Bolam* test, whereby a responsible body of medical opinion would agree with your decision not to take a radiograph in those particular circumstances.

Comment

It would seem more reasonable to say that if you decided not to take a radiograph in a given clinical situation after careful consideration, and this was also in accordance with clinical guidelines drawn up by an authoritative body, then it would be easier to defend your decision if challenged medico-legally.

There is then a statement that: '*It is the legal responsibility of all clinicians to be aware of all relevant current legislation relating to radiography*'.

Comment

The relevant regulations concerning radiography are covered by the Ionising Radiation Regulations 1985—Approved Code of Practice and Notes of Guidance and the Ionising Radiation (Protection of Persons undergoing Medical Examination or Treatment) Regulations, 1988. These regulations have statutory status and are enforced by the Health & Safety Executive.

Storage and Retention of Radiographs

The guidelines state that '*Radiographs form part of the patient's treatment records and are the property of the practitioner or hospital*'.

Comment

Kennedy and Grubb (1995) argue that the person who owns a patient's medical records *prima facie* depends on who owns the paper being used in the construction of such records. In paragraph 4.1 of the BMA document Rights and Responsibilities (1992) the BMA view is that '*Medical records written by hospital doctors are made on NHS property*' and, thus, belong to the relevant health authority. It could be argued that even if a healthcare professional used his own paper when working as an NHS employee then any such record would still be the property of a health authority who employed the healthcare professional and ultimately the property of the Secretary of State for Health. The same argument could apply to a healthcare professional working in a private hospital depending upon whether the healthcare professional was employed by the private hospital or was an independent contractor paying for services provided. This line of reasoning could be applied to radiographs as part of a patient's medical records. The guidelines are therefore correct that such radiographs are not the property of the patient but of the relevant NHS Trust or health authority, and ultimately the Secretary of State for Health, and within the private sector either the private hospital or the healthcare professional (when the latter is practising from his or her own consulting rooms). There are circumstances where the courts would be

likely to rule that a patient should be entitled to possession of medical records where this is necessary for his continued healthcare provision, for example, a change of family doctor or when seeing a second medical opinion (McInerney v McDonald, 1991). The guidelines do not mention that under the Data Protection Act (1984) and The Health Records Act (1990) a patient has access to his or her health records.

The guidelines indicate that the legally required time to retain patients' records is complex. It is stated that under the Limitation Act (1980) that the 'minimum time for retention of radiographic records should be six years, whilst the relevant Health Authority Circulars HC (80)7 and HC (89) 20 would suggest that "*children's records should be retained until their 24th birthday or eight years after the last entry, whichever is the longer*".'

Comment

There is some confusion in this guideline. It is true that claims brought under an action in tort must be within 6 years from the date on which the cause of action accrued (Limitation Act, 1980). Where personal injuries are concerned (to include those caused by alleged medical negligence) this is covered by Sections 11–14 and 33 of the 1980 Act; there is a 3-year limitation period, which is held to start either from the date on which the cause of action accrued or, if later, the date of knowledge on the part of the person suffering a personal injury. Section 33 of the 1980 Act provides the courts with discretion to wave the three year period in exceptional circumstances. Most of the case law has thus involved the date of knowledge and whether or not this should be a subjective or objective test concerning the plaintiff.

Early Disposal of Radiographic Records

In Hammond v West Lancashire Health Authority (1998) the judge at first instance was extremely critical of an NHS Trust's policy not to keep patients' radiographic records for more than three years. He described this as showing '*a cavalier disregard*' for patients' rights in accessing their medical records.

Persons Under a Disability and Minors

Under the Limitation Act 1980, a person who is under a disability at the date on which the action was accrued, time is not deemed to run until the disability ceases or death occurs, whichever happens first. A person of unsound mind would also be classed as under a disability and provided the disability still was in existence there would be no limitation from which an action could be brought. A minor is classed as a person under the age of 18 (Family Law Reform Act, 1969) and there is a right to bring an action for personal injury for a further 3 years after the person attains the age of 18, i.e. until 21 years of age (or later if the person concerned can show the courts that he or she did not have knowledge).

Recent Guidance on Storage of Clinical Records

A draft protocol document produced by the Lord Chancellor's Department on 24th March 1998 on clinical dispute resolution provides a Code of Practice to healthcare professionals when there is a possibility of litigation. This document advises that clinical records should be stored in accordance with the Department of Health guidance for at least 8 years, and for the specialities of obstetrics and paediatrics for 25 years.

The guidelines mention the Consumer Protection Act 1987; under this Act, a plaintiff has 3 years within which to bring an action either from the date on which the action accrued or if later, the date on which the plaintiff had knowledge. Again under section 33 of the 1980 Act the court has discretion to override the 3-year limit in cases of personal injury, but under the 1987 Act there is an overall 'long stop' after 10 years when the product was put into circulation beyond which no action can be brought under any circumstances.

Comment

The clinical guidelines recommendation that the radiographic records should be stored '*in some useful form until 27 years of age or 11 years after the last recorded entry*' would thus more than cover legal requirements for the storage of such records.

The final part of the guidelines concerns the desirability of not duplicating radiographs, and where patients are referred for specialist advice, relevant radiographs should be sent and copied, thus eliminating any unnecessary ionizing radiation for patients. This is good clinical practice. Finally, the guidelines discuss the importance of good radiographic records in defence of allegations of medical negligence stressing the importance for taking radiographs where appropriate and ensuring such radiographs are appropriate, kept safe, and of good quality.

Comment

These recommendations are logical and it is likely that the courts would not be sympathetic with healthcare professionals who had not complied with their recommendations.

Conclusion

This article has looked at specific guidelines in orthodontics produced by the Royal College of Surgeons of England and the British Orthodontic Society. Their content and recommendations are analysed and discussed from a medico-legal perspective. It is important that such guidelines are updated in the light of research findings and clinical audit. Clinicians should be aware of such guidelines and the legal implications of failing to at least consider them (if applicable) when providing advice and/or treatment for patients.

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