

The law is an ass: legal and ethical issues surrounding the bleaching of young patients' discoloured teeth

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Dentists in general, but paediatric dentists in particular, have important ethical and legal duties of care to young patients. When it comes to considering dental bleaching for young people in the UK there are some serious dilemmas that arise from various European Community (EC) directives and from the (somewhat flawed) thinking behind them. This article seeks to interrogate this troubling position and expose some of the more curious scenarios created by this complex regulatory environment. One of the big questions that needs to be addressed honestly and more openly is 'are dentists who follow these regulations without question and to the letter at real risk of compromising their greater and over-riding ethical duty of proper care for their younger patients?'

The problem in a nutshell

It is pertinent to these discussions that 'dental bleaching', which involves chemical oxidation and is not readily reversible, is used as the correct scientific term. The term 'tooth whitening' is both colloquial and confusing, has little scientific value, and should not be used as a synonym for dental bleaching.

There are some other common misconceptions. For instance, the process of dental bleaching has never been banned or restricted under law. The problems arise from the regulation of the supply of the products used to carry out bleaching treatments.

Under EC Directive 2011/84/EU (hereafter the Cosmetic Directive), products with concentrations above 0.1% hydrogen peroxide (H₂O₂) cannot be used on anyone under 18 years of age. This directive was introduced in September 2011 and amended the 1976 Council Directive 76/768/EEC. The EC Directive 2011/84/EU (which became effective from October 2012) increased the legal threshold of concentrations of H₂O₂ in dental bleaching products (abbreviated here to DBPs) for use in adults over the age of 18 to a maximum of 6% H₂O₂ – it had previously been 0.1%. It should be noted that this would be equivalent to about 18% carbamide peroxide – about one third of the much more stable carbamide peroxide is released slowly as the reactive H₂O₂.

There were many limitations imposed in the Cosmetic Directive: for instance, DBPs with concentrations between 0.1–6% of H₂O₂ can only be supplied to 'dental practitioners' (the role as defined in Directive 2005/36/EC), and the first use of the product must take place within a dental practice and be overseen by a dental practitioner. However, the Cosmetic Directive continued to

enforce the limit of 0.1% concentration of H₂O₂ in bleaching products for use in persons under 18 years old and at that very low concentration it is useless for bleaching teeth.

The arguments really hinge around two points: the categorisation of DBPs as ‘cosmetic products’; and the limiting of H₂O₂ concentrations to 0.1% when used on younger patients – regardless of the huge evidence base for the safety and efficacy of night guard vital bleaching with 10% carbamide peroxide in a customised mouth guard. This ban exists in spite of the serious social and psychological effects of discolouration on the individual child, the (understandable) concerns of the parents or carers, or good old-fashioned clinician’s responsibilities in seeking to solve the problems of serious dental discolouration.

So, when faced with managing discoloured teeth in anyone under the age of 18, even when this has been caused by fluorosis (Figure 1), trauma, tetracycline, amelogenesis imperfecta (AI) or various other congenital or acquired problems, the dentist is limited by the current EC directive to 0.1% H₂O₂ concentration products, which is completely useless for bleaching teeth and that’s the end of it. Dentists needn’t worry themselves with the overwhelming evidence proving the long-term safety of higher concentration products, 1,2 nor should they be surprised by the apparently magical change in the safety profiles of bleaching products of concentrations up to 6% H₂O₂ when patients cross the threshold of 18 years of age. Furthermore, dentists should agree that the gold-standard concentration for a DBP (10% carbamide peroxide, releasing about 3.4% H₂O₂, held within a customised mouth guard), though proven to be safe in the long term, 3 would not be safe for patients aged 17 years and 11 months but would somehow be safe for them a month later. This is ludicrously unscientific and farcical.



Figure 1a Young patient presenting with brown fluorosis.



Figure 1b The same patient following 10% carbamide peroxide bleaching to treat the discolouration.

How did dental bleaching products end up being classified as ‘cosmetic products’?

Excellent question, and perhaps to some people there is nothing strange or noteworthy about this classification. After all, many businesses – some of them dental but many of them in the beauty industry – have flourished by offering whiter, brighter ‘Hollywood teeth’ to adults with the inclination and the cash to have them, which would be perceived by many as a mainly ‘cosmetic’ use of DBPs.

EC Directive 2011/84/EU adapted reference 12 in part 1 of annex 3 of the previous cosmetic directive 76/768/EEC so that it explicitly referred to ‘tooth whitening or bleaching products’

(previously it was 'oral hygiene products' 4) as a field of application and/or use of substances that contain 'hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide.' 5 DBPs have been assimilated into this category, along with hair care mixtures and mouth rinses, but no legal or scientific justification for including DBPs within reference 12 was provided either at the time of forming directive 76/768/EEC in 1976 or even when revising the entry in the Cosmetic Directive of 2011. It is worth noting that the UK government supported this change in legislation specifically to catch carbamide peroxide within its remit as, previously, only hydrogen peroxide was specified.

The alternative classification available to DBPs under European regulation is that of medical devices. Among other changes, in the context of this article, this would allow for products with higher concentrations of H₂O₂ to be supplied in the UK, and potentially enable their appropriate use for patients of all ages when under dental supervision.

Council Directive 93/42/EEC (hereafter Medical Devices Directive) 6 defines medical devices as:

any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

diagnosis, prevention, monitoring, treatment or alleviation of disease,

diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

investigation, replacement or modification of the anatomy or of a physiological process,

control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

The key phrase in the description above is 'application intended by the manufacturer'. So, although we might enjoy a principled debate on whether or not DBPs should be classified as 'cosmetic', in fact it is the intended purpose as defined by the manufacturer that really decides if a DBP should be classified legally as a cosmetic product or a medical device.

Surely, the consequence of this is that each individual DBP must be examined on its own merits and its specific intended use should be the deciding factor for its classification? If a DBP is indicated for the treatment of severe intrinsic tooth discolouration, like that caused by serious dental trauma or by fluorosis, for example, then it seems reasonable to consider the product to have a medical purpose (ie treatment of a disease or handicap) and, logically, it ought then to be classified as a medical device. However, if a DBP is indicated to just improve the superficial appearance of teeth temporarily or transiently, without taking into account any pathological, physiological or degenerative condition, it could be classified as a cosmetic product. Pragmatic clinicians would suggest it could be both medical and cosmetic, depending on clinical circumstances. The nitpicking regulatory lawyers suggest it has to be regulated as one or the other.

Here is one interesting exploration of the 'intended use' argument. A customised mouth guard that, by law, has to be made from an impression of the patient's teeth and is customised for their use only, is classified as a medical device under the Medical Devices Directive (MDD). If an unbranded 10% carbamide peroxide, which is a generic antiseptic (in other words, not branded as a product for bleaching teeth) and which is listed as such under Martindale's Pharmacopoeia and The British

Pharmacopoeia, is then used within the mouth guard, the MDD clearly states that 'any accessory that is used with a medical device is converted by virtue of it being used with a medical device into being a medical device in its own right'. The unbranded 10% carbamide peroxide gel therefore could be considered an accessory under the MDD, and in this particular usage becomes a medical device itself, thereby changing its regulatory environment.

However, this is a grey area and, as mentioned later in this article, Dental Protection advise that the bleaching product would probably still fall under the auspice of the Cosmetic Products (Safety) (Amendment) Regulations 2012 (CPSAR), and therefore remain bound by the 0.1% concentration rule when treating under-18s. This has not been tested so far and no doubt opinion on this will shift a bit, depending on which of the protection or indemnifying societies one is speaking to at the time. One thing seems sure, however, and that is that any sensible indemnifying organisation would probably rather defend a dentist who undertook a non-destructive procedure such as bleaching (having explained all the options of treating serious discolouration in someone under 18 to the patient, parents/guardian or carers to obtain their 'appropriate consent') than a dentist who did multiple porcelain veneers or some other destructive procedure to a child's teeth as an alternative, but apparently legal, method of dealing with their serious dental discolouration.

The picky lawyers would probably contend that they could not give valid consent to the use of an 'illegal bleaching product' but that could be countered by saying that the unbranded carbamide peroxide is a generic antiseptic and is listed as such in Martindale's and other pharmacopoeias and in this case it was not branded as a bleaching product.

As an interesting historic aside, carbamide peroxide used to be the antiseptic oxygenating treatment of choice in the First World War for 'trench mouth' (now known as Vincent's infection or acute necrotising ulcerative gingivitis, ANUG). Trench mouth was particularly common in the trenches because of a lack of dental cleaning, lots of smoking and understandable stress. The oxygen-releasing antiseptic carbamide peroxide was the only treatment available for it.

So, as we can see, even the 'intended use' approach isn't foolproof. Certainly, it seems to have been lost on some law-making bodies within the member states of the European Union. Take, for example, the decision of the UK House of Lords.

In 2001, the House of Lords dismissed an appeal from Optident Ltd and Ultradent Inc, 7 who sought to place the bleaching product Opalescence, which contains 10% carbamide peroxide, under the regime of the MDD rather than under the Cosmetic Directive. This was so Optident Ltd could supply the Ultradent-manufactured product in the UK. If it remained classified as a cosmetic product then its H₂O₂ level (10% carbamide peroxide, releasing 3.4% H₂O₂) was far in excess of the 0.1% concentration allowed under the Cosmetic Directive, and it would therefore be illegal to supply it. Optident and Ultradent won the High Court case on all four contested points and the product was declared a medical device and not a cosmetic product. Interestingly, safety was not even discussed seriously in court as the UK government never contested the view that the Opalescence product, when used with a customised mouth guard, was safe.

Eventually, the Court of Appeal reversed Mr Justice Laws (now Lord Laws) decision and the matter was then appealed to the House of Lords, who ruled against Optident Ltd and Ultradent Inc, thereby re-classifying Opalescence as a cosmetic product, and therefore making it illegal to supply in the UK. Lord Slynn of Hadley stated in judgement: 7

The important consideration however is not the effect but the intended purpose which is of relevance. It seems to me clear that the purpose here was to change or restore appearance. I would

accordingly like the unanimous Court of Appeal accept that Opalescence here is within the Cosmetics Directive. That in my view makes it unnecessary to decide whether it is also alternatively within the Medical Devices Directive [...] It does not seem to me that it is a product used for the treatment or alleviation of disease. In some cases it is simply dealing with the effect of disease by changing appearance. Nor am I persuaded by the suggestion that Opalescence is used to treat or alleviate or to compensate for a 'handicap' within the meaning of Article 1.2 of the MDD. Darker teeth may be less attractive than sparkling white teeth but it does not seem to me that they constitute a 'handicap' within the meaning of this Medical Devices Directive.

That somewhat bizarre judgement followed on from the Court of Appeal judgement, which included such gems as 'the dental bleaching material was not "implanted" within the tooth when it was being used for inside/outside bleaching because it was washed out afterwards'. Of course, the bleaching carbamide peroxide material is implanted every few hours within the tooth as well as being held within the tray overnight when doing inside/outside bleaching. 8 That is why the inside/outside technique is spectacularly successful in dealing with dead discoloured teeth. Carbamide peroxide is implanted and sealed within the tooth for many days with one version of 'the walking bleach' approach.

Sadly for patients and their dentists, these particular law lords (bless their limited clinical understanding) failed to grasp the basic 'implanted within the tooth argument'. If they had understood it properly and agreed that it was implanted within the tooth during either of the inside/outside process or walking bleach processes it would have put 10% carbamide peroxide bleaching material used in either process way back under the remit of the MDD. The author refers you to the title of this article – this point of law inhibits dentists from using probably the most effective treatments known today for managing dead discoloured teeth in patients under 18 (Figure 2).



Figure 2a Young patient presenting with a discoloured non-vital tooth.



Figure 2b The same patient following inside/outside bleaching to treat the discolouration.

Perhaps inevitably, this ruling put the cat among the pigeons. The Department of Health (DH) was bombarded by various dentists and different organisations for clarification on dentists' legal position regarding dental bleaching. At that time the DH's position was that 'dentists can bleach discoloured teeth in any legal way provided the parent or the patient gives their consent'.

In 2001, the author wrote on a number of occasions to Dame Margaret Seward, stating:

You cannot reconcile your previous job of being President of the General Dental Council – whose job it is to protect patients – with your present job as Chief Dental Officer of the UK Department of Health, which is now directly, or indirectly, responsible for patients having their teeth damaged because dentists are prohibited from effectively bleaching a patient's discoloured teeth.

The courteous reply from Dame Margaret included this paragraph: 9

Firstly may I say we are sympathetic to the clinical dental advantages to bleaching teeth compared with other techniques which require removal of tooth structure. I understand that my predecessor has indicated that dentists are allowed to use techniques of external and of internal bleaching teeth in any way provided that the patient or their carer agrees. These techniques themselves are not illegal! The highly publicised legal case revolved around the supply of these products and whether they are medical devices or cosmetic products. It is the Government's view that they are cosmetic products. Notwithstanding that the Department of Health would not seek to interfere with a dentist's therapeutic decision to utilise a bleaching technique where a dentist considers this to be in the best interests of the patient's overall oral health care.

Dame Margaret's advice therefore was subtly different to DH's previous position because her statement was that dentists could bleach teeth in any way (ie the word 'legal' got quietly dropped). You'll also notice that Dame Seward confirms the 'government's view is that they are cosmetic products', which by treating all DBPs as being the same, fundamentally ignores the principle of intended use.

The result of this legal morass was a rather messy and unsatisfactory sort of professional stand-off between dentists and regulators during which many dentists bleached teeth with a variety of unbranded products, containing varying concentrations of H₂O₂. Most dentists did not flout that they were doing so and in return most of the trading standards authorities chose to turn a blind eye to dental bleaching, even when carried out by non-dentists quite blatantly in shopping malls and beauty salons. No dentists were prosecuted successfully for bleaching teeth, although there were some instances of commercial companies supplying the bleaching products being harassed and sometimes prosecuted, with varying outcomes, if the H₂O₂ concentrations in the bleaching products supplied by them exceeded 0.1%.

As we know now, dentists can help adult patients who have discoloured teeth by legally utilising DBPs with concentrations of up to 6% H₂O₂ under the Cosmetic Directive. But we also know that the same directive still prohibits their use above 0.1% concentration in patients under 18 years old. So it's time to address the elephant in the room: are higher concentration products such as 10% carbamide peroxide safe to use in under-18s, and are there suitable alternatives to them as treatments for serious dental discolourations in this age group?

Are bleaching products safe? Is there a good reason to limit hydrogen peroxide concentrations to 0.1% in under-18s?

There is overwhelming scientific evidence that dental bleaching is safe if done with proven, effective night guard vital bleaching using low concentration (eg 10%) carbamide peroxide in a customised mouth guard. 10,1 There have been numerous randomised double-blind controlled clinical trials 11–14 showing safety and efficacy, which were deemed sufficient for some bleaching products (10% carbamide peroxide in a customised mouth guard) to gain the stringent American Dental Association (ADA) Seal of Approval available since 1994. 15

There is also lots of practical evidence available from millions of dental bleaching treatments worldwide that have been carried out with night guard vital bleaching with 10% carbamide peroxide in dental practices that show there were no significant adverse long-term problems using this technique. Temporary sensitivity, which ceases within a couple of days of stopping bleaching, is the commonest reported side effect. If there were any significant long-term problems with the bleaching of young patients' or adolescents' teeth, one would be well aware of any such problems from the dental literature, or via our learned friends in the ever-helpful legal community. However, apart from transient sensitivity in some cases, these have not been reported in the past 20 years in any age group and even then this temporary, transient dental sensitivity has to be set against the undoubted success of the bleaching in millions of cases.

In spite of all that irrefutable body of evidence of safety and effectiveness at dealing with discoloured teeth, this treatment is still prohibited for patients under 18 years of age. Incidentally, there is no such restriction in the litigation-orientated USA where over-the-counter bleaching products with over 10% H₂O₂ are on open sale in pharmacists and supermarkets without any age restriction and without any dental examination, diagnosis or other professional dental input at all prior to their use.

It seems somewhat perverse to many that dentists are being exhorted continually by various UK regulatory and academic authorities to 'use evidence-based dentistry' and yet when there is overwhelming evidence of safety, efficacy, appropriateness and lack of significant side effects for dental bleaching (when undertaken with low concentration carbamide peroxide in a customised tray), dentists are told not to use it in under-18s. Close your eyes and one can hear the asses braying from here.

In terms of safety and efficacy it should be appreciated that, in spite of some crazy, unsubstantiated advertising claims by dubious manufacturers for higher concentrations and daft light activation techniques, 10% carbamide peroxide is still the gold standard and is the only one with ADA approval. 15 There is nothing obvious in the safety profile or chemistry of carbamide peroxide or of low concentration hydrogen peroxide agents (under 6%), that would make dental bleaching products unsafe at, say, 17 years and 11 months but suddenly safer at age 18. 16

It may be reassuring for some cautious clinicians to know that dilute hydrogen peroxide is in widespread use in head and neck surgery, including being used for debriding large open head and neck wounds. Given the historic use of dilute hydrogen peroxide following major surgery around vital large blood vessels in the neck, an article by Patel et al, published in the British Dental Journal in 2010, 9 questioned why there is still a perceived safety issue with the clinical use of very dilute hydrogen peroxide released from carbamide peroxide when one is dealing with the much harder tissues of enamel and dentine in the mouth. The correct answer is there doesn't appear to be any scientific reason at all for this unfounded concern. If there were, it would not be being used quite freely by head and neck surgeons following major 'commando operations' where it is applied as an oxygenating antiseptic in order to clean wounds around the head and neck. Surely this has to be a much more dangerous area to apply any oxygenating chemical than the external hard surfaces of calcified teeth, even in young people.

This is especially the case when one considers that low concentration viscous gels are used, allowing the slow release of low concentration 3.5 % hydrogen peroxide from 10% carbamide peroxide. This viscosity helps to retain the mouth guard even on incompletely erupted teeth and helps to protect the gel from being inactivated by the salivary peroxidase or salivary catalase, which are the ubiquitous protective salivary enzymes that inactivate any hydrogen peroxide immediately that

might leak out from the bleaching tray. Red blood cells within the mucous membranes of the mouth and the dental pulps also inactivate any hydrogen peroxide immediately on contact, courtesy of the peroxidase contained in erythrocytes. 1,16 In effect the sticky antiseptic bleaching gel works mainly because it is held in a protective customised mouthguard while it is being used on children or adolescents teeth because often there has not been full gingival maturation at that age.

It is perhaps worth remembering that the original discovery of the bleaching effects of carbamide peroxide came about in the 1960s. A number of clinicians, including a 'paedodontist' and an orthodontist, noted the bleaching colour change as a side effect when the gel was being used within orthodontic retainers to help improve gingival health after orthodontic treatment with removable appliances had resulted in gingival proliferation problems in adolescents. 17

An argument based on that historical perspective could probably be used again now in patients with discolouration who are under 18. In other words, one might contend that one was just using the generic antiseptic carbamide peroxide gel as a treatment within the customised tray for gingival health reasons (because many patients have inflamed gingival tissues as well as having discoloured teeth) and provided the patient or their child consented to accept the risk of the teeth becoming lighter in colour as a side effect of treating the gum problems in that way, it would just be an accidental side effect of the primary intention of its use...

What's the alternative to bleaching with hydrogen peroxide products?

Given the ongoing controversies about legality, the overwhelming evidence for efficacy and safety, and ultimately the pressure from patients and parents to 'do something' to mitigate the discolouration problems, the idea of micro abrasion using hydrochloric acid and pumice would appear to offer a convenient way out of this difficult situation. After all, Theodore Croll, who popularised micro abrasion in 1989, was a 'paedodontist'. 18

However, micro abrasion involves gambling with the destruction of variable amounts of enamel based on an 'educated' guess about the depth of the discolouration. Micro abrasion probably removes about 200 microns or more of invaluable, albeit discoloured, enamel whereas bleaching with 10% carbamide peroxide, which has a neutral pH, removes practically no enamel. 19

Sadly, when micro abrasion is employed it often makes the enamel on which it is used look like ground glass at the end of the treatment (Figure 3). This is an appearance which has been termed 'abrosion', an expression coined to reflect the combination of abrasion (due to the pumice) and erosion (due to the hydrochloric acid) involved in the products.



Figure 3a Young patient presenting with discoloured incisors.



Figure 3b The same patient during micro abrasion under rubber dam.



Figure 3c The same patient following the procedure; note the ground glass appearance of the teeth.

'Mega abrasion' – as the name implies – is not a benign or reversible procedure for teeth and removes a lot more of the discoloured but invaluable enamel.

18% hydrochloric acid is obviously highly acidic and is much more chemically dangerous than carbamide peroxide. In young people the acid and pumice have to be very well controlled to avoid splattering the material onto areas other than the teeth (especially avoiding any danger to the eyes) at every stage. Its use requires that a rubber dam be applied effectively and held in position on tapering, not fully erupted teeth, which is not that easy. Furthermore, cooperation needs to be pretty well guaranteed prior to undertaking this destructive procedure.

An alternative surface removal approach, rather than using acid and pumice, which tends to have a pan-labial flattening of the surface effect, involves the very gentle use of a multi-fluted tungsten carbide bur such as a Jet friction grip 7901 in a high speed handpiece. This can be used by running it in the direction of spin of the bur, with a feather-light touch, to very gently remove only the isolated, superficially discoloured areas. This, however, is only a useful alternative in carefully selected cases and requires a well-trained operator as it is still controlled destruction.

However, enamel never returns once it is removed, even if done so very gently. Enamel is not a renewable resource so the casual removal of it for quasi-legal reasons, particularly when it might be being done by clinicians who are largely protecting their own particular interests, remains very dubious from an ethical or moral standpoint.

This has been going on for years. Surely there's a reason for it being like this?

Some clinicians may perceive that the relevant UK government departments have had a long-standing obsession about controlling dental bleaching and dentists' treatment prescription patterns. There seems to be a choice of two possible motivations for this behaviour: one is in relation to public safety and another is related to the possible financial consequences of dental bleaching.

Is it about public safety?

Possibly yes and probably no. Yes, in the sense that, by classifying bleaching agents under the Cosmetic Directive, the public at large are, in theory at least, prevented from buying various products containing more than 0.1% hydrogen peroxide over the counter in pharmacies or supermarkets in the UK. Dental bleaching involves chemical oxidation and this is an irreversible, deep process. If bleaching is carried out improperly, or carried out properly but on unsuitable candidates eg when the discolouration was actually being caused by untreated serious caries, the public could be put at risk of damaging their appearance or oral and gingival tissues – but only if very high concentrations were to be used.

Additionally, the Cosmetics Directive requires that consumer safety be addressed via labelling and other 'market-orientated' protections. Readers may remember a rare case report in the mid 1990s of a 16-month-old child who died after accidentally swallowing an awful lot of 3% hydrogen peroxide solution. So, arguably, using the Cosmetic Directive to prevent the free sale of bleaching agents to the public with concentrations in excess of 0.1% H₂O₂ is possibly a good idea. However, they can

buy hydrogen peroxide in any chemist or hair product supplier. Any half-savvy teenager with a smart phone can get the material over the Internet easily or from various websites in the UK or America – as pretty well everyone who wants to obtain the bleaching gel knows. Indeed, there are several UK-based companies flagrantly supplying concentrations of well over 6% hydrogen peroxide or the equivalent in carbamide peroxide in various brands. It might be worth emphasising that the crime, in theory under the Cosmetic Directive, is to supply an illegal cosmetic product containing more than 0.1% H₂O₂ to under-18s. However, if a dentist were just to supply a customised mouth guard made from an impression of the young patient's teeth that, in itself, would not be illegal. If the parent or adolescent patient were somehow to source the 10% carbamide peroxide by themselves, possibly just by typing '10% carbamide peroxide' into a well-known search engine, and if they were to acquire the bleaching gel and then use it properly within the mouth guard, it would work and then who could blame the dentist? However, as Dan Fischer, a practising American dentist and the owner of Ultradent, said to the author the night before the Opalescence trial started: 'UK dentists should not be forced to skulk around in the undergrowth in order to help their patients'.

The author doesn't want to risk repeating himself but, of course, the Cosmetics Directive also compromises public safety if it forces perhaps well-meaning or misguided clinicians to undertake destructive processes to treat serious tooth discolouration in under-18s rather than utilising a scientifically proven, safe, effective and non-destructive bleaching process.

Is it about money and control?

To many interested observers this regrettable situation has developed partly because of the potential financial consequences of providing dental bleaching under the NHS. This is understandable, even though they have never openly admitted it. If bleaching were to be regulated as a medical device then there could be pressure to fund it under the great and glorious NHS in certain circumstances. This pitches a number of 'rights' against one another. The individual young patient has a right to have the scientifically proven, most effective treatment for their discoloured teeth. Dentists have a right to be allowed to provide that treatment for seriously discoloured teeth without fear of being imprisoned for six months or be fined £5,000, or both, for supplying an illegal cosmetic product. The UK government clearly has a right to control spending in the NHS and to limit spending to those things that it deems to be priorities. So whose rights trump whose in this difficult arena?

However, were dentists to provide porcelain veneers instead of bleaching teeth, that biologically dubious and irreversible treatment would be paid for by the state in the case of many young people. So even the cost argument has not been thought through sensibly or thoroughly. The earlier the reparative cycle starts, the greater the likelihood of progressively more destructive procedures being required during the young person's life. Porcelain veneers are not permanent. One study on porcelain veneers placed in the general dental services showed that only about half were present at ten years. 21

Those also partly responsible for this unsatisfactory state of affairs include various commercial interests, some of whom would benefit financially if the bleaching products were available to a wider group of consumers/patients. Many multinational companies have products that they would want to supply over the counter such as happens in America and other countries. Sadly, it appears that many of those involved from a regulatory perspective appear not to be particularly concerned with the consequences of whatever their financial or other controlling motives might be on individual younger patients with serious discolouration.

What would happen to a dentist who broke the rules?

The CPSAR and Cosmetics Directive are very explicit about not using concentrations above 0.1% H₂O₂ in under-18s. Even if bleaching products were classified as medical devices, Dental Protection advise that they would still be bound under the CPSAR.

A dental practitioner (or indeed anyone else administering or providing bleaching agents to the those under 18) would be in breach of the CPSAR if the bleaching products had a concentration higher than 0.1% on a patient under the age of 18.

Dental Protection Limited have issued a position statement on tooth whitening (a deprecated term as discussed earlier) that explains the risks and consequences of breaching the rules. 22 In summary, the maximum penalty is a sentence of imprisonment not exceeding six months or a fine of £5,000, or both, and the dentist could be investigated and prosecuted by the local authority or Trading Standards, and potentially be called to a fitness-to-practise hearing by the GDC.

Of particular interest in the Dental Protection statement is the following: 22

The GDC's Position Statement on Tooth Whitening, dated 31 October 2012, 23 sets out that if the GDC receive information or a complaint that a registrant is [...] in breach of the Regulations, the registrant may face fitness to practise proceedings and can expect the matter to be referred to the relevant Trading Standards department.

The unfortunate consequence of the GDC having taken this stance is that a registrant who accepts a patient for treatment in either of the categories below could potentially face fitness to practise proceedings whether they follow the law and ignore the patient's best interests, or whether they protect the patient's best interests and break the law instead.

Those readers who have made it this far will notice that Dental Protection seem to be as despondent about common sense prevailing in this unhelpful scenario as the author has been throughout this article. Incidentally, Dental Protection also offer advice to dentists who wish to provide treatment to under-18s that would breach the regulations 22 – the author suggests you read it if you are tempted – you'll find it, rather tellingly, under the heading 'Ethical Dilemma' in their position statement.

The heart of the matter

The GDC is charged with protecting patients of all ages and it urges all members of the dental team 'to put patients' interests first'. However, following that advice when trying to manage effectively discolouration problems of varying severity in young patients now creates ethical, moral and legal conflicts for many dentists in general practice as well as those working within university and/or hospital dental departments or the community dental services.

It is the author's experience that there are some dentists working within paediatric dentistry departments that are taking the view that they should do whatever 'the lawyers' tell them to do and are therefore not bleaching seriously discoloured teeth in under-18s and have decided to 'toe the line' of the EU, the UK government, their university, their trust or their department in these matters. They appear to be behaving in this way even when it results in outcomes in managing serious dental discolouration that they would not consider acceptable, let alone optimal, if their own child, or that of a near relative or friend, happened to be the one with the serious discolouration problem.

At the very least this is ethically questionable and appears to be a self-protectionist approach. This is perhaps understandable, even reasonable, behaviour. However, one can't avoid the sinking feeling that this could lead to dereliction, or abrogation, of their higher duty of care to do the best for

younger patients, which ought to be the dominant, or pre-eminent, duty in this multiply conflicted area. Indeed, adopting such an approach may itself, rather perversely, conflict with the GDC's Standards for the Dental Team, 24 which was issued by the GDC in 2013. Paragraph 1.4.1 states that 'you must take account of patient's overall health, their psychological and social needs, their long-term oral needs and their desired outcomes'.

Younger people with badly discoloured teeth are often in a distressed, vulnerable position and their interests may not be being protected effectively or adequately by vagaries in their clinicians' approaches and questionable policies.

If you recall Lord Slynn of Hadley's comment in regard to the 2001 Optident case: 'Darker teeth may be less attractive than sparkling white teeth but it does not seem to me that they constitute a "handicap" within the meaning of this Medical Devices Directive'.⁷ The author would be surprised if any really caring, sensible dentist would hold this view today, especially when a young patient suffering from brown fluorosis, trauma, tetracycline, congenital or other problems, is sitting in front of them. Though the young patient might understand the reasons for the discolouration of his or her teeth, it is often a different story among their peer group, where discolouration can be readily perceived as showing a lack of 'dental grooming' or 'personal hygiene'. It is recognised that discolouration (amongst other dental problems) can be a major cause of bullying and unhappiness in young people^{25,26} and the notion of it merely being 'less attractive', as Lord Slynn put it over a decade ago, is a rather flippant dismissal of serious issues to do with a young person's 'overall health, their psychological and social needs'.²⁴ One hopes that, if such a debate were to occur now, Lord Slynn would have a more enlightened view but the authors would not bet on it. When you go to law you get the law – not common sense or professional dental care.

The author hopes that many dentists would, but for fear of legal or disciplinary consequences to themselves, prefer not to destroy sound, albeit discoloured, tooth tissue by managing discolouration through other, more destructive means such as micro or mega abrasion, veneers, crowns or post crowns. The GDC urges us to consider the long-term health of our young patients after all but has done very little to resolve the issues inherent in their stated positions. The conundrum is if dentists don't look after young patients' best interests by bleaching seriously discoloured teeth they get in to trouble. If they do go ahead with bleaching even after discussions and with all options having been explained in detail, having gained written consent and, as part of this, supply an illegal cosmetic product, they could end up facing a GDC fitness-to-practise committee. And still people tell Irish jokes...

It seems bizarre to many concerned dental clinicians, who are faced with these discolouration problems in real young patients on a regular basis, that some anonymous lawyers and faceless civil servants are adamant that their position on dental bleaching and how it should be regulated was, and is, the only possible valid view. It seems even dafter that these lawyers and bureaucrats want to define and control what is 'medical' or 'cosmetic' when dealing with serious dental discolouration problems in many young persons that they have never even bothered to meet.

It also seems stupid that they ignore all the readily available evidence of physical damage that results to discoloured teeth from traditional aggressive abrasion techniques, veneer preparations or post crowns – none of which are biologically neutral in the longer term for these young vulnerable patients.

Finally, with the author not being the sort to miss an opportunity to re-heat a previous article, what would you do if it were your own child with the serious discolouration problem?²⁷ If, in response to

a pleading parent asking why you will not carry out a scientifically proven safe, effective treatment for their child's seriously discoloured teeth, you answer 'I care more about my job, my bosses' orders, departmental and trust policies, my personal interests and safety, and a European cosmetics directive, than I do about your child's wellbeing' how would that sound to them or indeed to anyone in wider society? How can such an attitude be squared with the ethical and professional responsibilities of a supposedly caring profession?

Perhaps if a clinician's judgement mattered a bit more, and bureaucracy mattered a bit less, we could draw a line under this and go about treating patients, regardless of their age, using the best scientific evidence available and the least destructive methods at our disposal.

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