

Irish Dental Association response to Dental Council's revised draft code of conduct relating to infection prevention and control

31st January 2014

Principles informing our response

The IDA recognises the ethical obligations that dentists have to protect their patients and staff. Irish dentists have a very good cross infection control record and support guidelines that are appropriate, clear, concise, enforceable, practical, financially viable and evidence based.

We support the approach stated by the Dental Council in its submission on new legislation to replace the Dentists Act, 1985. The Council in its submission states that "standards must be transparent, **fair, balanced and evidence based** to allow a level of engagement that will lead to improved patient safety and quality of service". (emphasis ours)

Given the potential impact of what is being proposed, we believe there is an onus on the Dental Council to produce evidence to support changes in existing policy rather than on stakeholders to show evidence to refute propositions unsupported by evidence.

There is a profound responsibility on policy makers, including the Dental Council, to be fully cognisant of the impact on patient attendance and oral health caused by increasing regulatory burden and the consequent onus on dental practices to pass on the costs of such extra operating requirements to patients and the inevitable impact on dental attendance and oral health.

We suggest that a full **patient impact assessment (PIA)** should be undertaken by the Dental Council before proceeding further. This should set any perceived risks (i.e. evidence based risks) against the consequences of extra regulatory burden on attendance and oral health gain.

In undertaking this PIA, we suggest the following operational principles:-

- Recommended changes should be evidence based.
- A baseline level of risk and incidence should be quantified and compared with the level of risk and incidence in areas where systems have already been adopted.
- Current expense, initial and ongoing in maintenance, materials and time should be quantified.
- Future expense, initial and ongoing in maintenance, materials and time should be quantified.
- Increased expense in initial, ongoing, maintenance, materials and time should be justified.
- The likely decrease in treatment uptake because of increased expense should be quantified.
- The likely decrease in number of single-handed practices and possible increase in corporate practices and the effects of these, if any, on general dental practice and

possible implications of a decreased number of suppliers for accessibility and cost to the consumer and uptake of treatment should be quantified.

- The Assessment should consider whether proposed changes will deliver an increased quality of service to the consumer at a reasonable cost for that increase.
- It should consider if the application of current theoretical optimal standards is financially, socially, and locally appropriate.
- It should consider the acknowledgement of current theoretical optimal standards while accepting the application of acceptable standards.

Commentary

We are unclear as to the reason why the group which has prepared this draft for the Dental Council has chosen to suggest such radical changes to existing requirements.

In the limited time available to us to research this matter, we believe that the provisions being suggested are far in excess of those obtaining in the rest of the European Union. Given the potential impact of what is being proposed, we believe there is an onus on the Dental Council to produce evidence to support changes in existing policy rather than on stakeholders to show evidence to refute propositions unsupported by evidence.

We are seriously concerned at the absence of any compelling evidence to demonstrate any level of risk necessitating such radical changes or evidence which supports the thrust of the changes being proposed. It is our belief that the only sure result of implementing the changes proposed will be to further jeopardise the viability of dental practices, to force ensuing costs to be passed on to patients and to seriously diminish the oral health of the nation as attendance dwindles.

Therefore, we call on the Dental Council to set aside the draft as published and to engage in a proper and meaningful fashion with all stakeholders to review policy in a manner which can be justified according to risk and viability and with the aim of ultimately enhancing the oral health of the nation guided by appropriate quality and patient safety standards.

Amalgam separation is an environmental issue and we do not see the relevance of this in a cross infection control guideline. We are concerned that the general public may misconstrue inclusion here as a patient safety issue, warning about exposing patients to amalgam, as opposed to waste separation direction.

Context

It is important to set the current context for Irish dentistry before proceeding further with respect to the capacity of the profession to develop oral health and to examine the current oral health status of the nation.

A recent survey conducted on behalf of the Irish Dental Association (IDA) on attitudes to dentists and dental health (November 2013) offers a valuable picture of the state of our oral health today. It found that annual attendees are much more likely to be middle class females under 44 years.

Frequency of dental visits shows a strong age pattern, declining sharply from 45 years on. The correlation between visit frequency and social grades is confirmed by the much higher frequency among those with private medical and dental insurance.

The survey suggests that the economic crisis has had an influence on dental health attendance. The Irish Dental Association (IDA) estimates that the State has removed €400m in dental support from the general public over the past four years in tax relief, cuts to the PRSI scheme and cuts to the Medical Card scheme, amounting to approximately €100m per annum.

Overall, 23% have been attending the dentist less frequently since 2010 – in population terms this equates to 760,000 adults. This rises to 26% of those with a medical card; and to 28% of occasional visitors to the dentist (every 2-5 years). Even one in six (16%) of the most regular visitors of the dentist have been attending less often since 2010. According to the survey of 750 adults, which was carried out by Behaviour and Attitudes on behalf of the Irish Dental Association, 46% of Irish people are spending less on dental health while 41% rarely if ever think of visiting the dentist.

The IDA survey also provides some insight into self-assessment of oral health. Three out of five people (61%) said that they understand very well what they need to do at home to maintain oral health. Practically all Irish adults surveyed considered their teeth and gums to be in good health (82%) and beyond that looking good too (86%).

However, a study on the oral health of Irish adults (Whelton et al., 2007) shows that the frequency of twice daily brushing ranges from a high of 71% for 35-44 year olds, to 68.5% for 16-24 year olds to just over 50% for people over 65 years.

The same study showed that less than one fifth (18%) of young adults were found to have healthy gums. This dropped to 8% for adults aged between 35 and 44 and 7% for those over 65 (Whelton et al., Oral Health of Irish Adults, 2007).

Irish dietary habits are often not conducive to good oral health. A Eurobarometer Report on Oral Health (Special Eurobarometer 330, February 2010) showed that Irish people topped the European Union league for consuming biscuits and cakes often (28% reported eating them often, compared to the EU average of 18%). A HBSC 2001-02 survey (Health Behaviour in School Children) showed that 41 percent of 15 year old girls and nearly 49% of 15 year old boys drank a soft drink every day, putting Ireland near the top of a sugary drinks table for 34 countries. Fifteen year olds topped the table for eating sweets every day.

In a 2012 pan European survey carried out in seven countries (Smiling Europe Campaign, complementing the Platform for Better Oral Health in Europe) over 42% of Irish adults reported that they do not have all of their teeth.

Capacity

In the absence of any mitigating supports^[1] being made available, the ability of dentists to absorb the costs associated with changes being proposed is a critical concern. As the Council will be aware dentists are one of the only health professions^[2] which do not receive any

financial support from the state. Dentists rely solely on their own self-generated funds to set up in practice and adhere to increasing regulatory costs.

A recent survey (May 2013) of Irish dentists undertaken by the Irish Dental Association reveals that in the previous two years, the income of a majority of dentists decreased with the majority suffering a decrease of between 20 and 40%. It is hardly surprising that for all the obvious reasons above, we estimate that at least 1,500 jobs have been lost in dentistry over the past three years.

We estimate that for many individual dentists full implementation of the changes being proposed by the Dental Council would entail once-off capital costs of over €20,000, ongoing maintenance costs of around €5,000 per annum and significant additional employment costs (perhaps another €25,000 per annum). Clearly this would render many practices unviable and lead to a significant reduction in capacity with inevitable access difficulties for greater numbers of patients who will face greater distances to travel for care or who will have to endure longer waiting times for treatment.

Massive state support is provided to dentists in Northern Ireland in the form of grants and pensions which leaves dentists in this state, particularly those close to the border, at a significant disadvantage. To reiterate, dentists in the Republic of Ireland do not receive a single cent toward the running of their practices.

As dentists rely entirely on generating attendance and income to cover costs (and most of these costs are fixed or state controlled), it is no surprise in these difficult times that with falling attendances dental practices are closing and we estimate there have been 1,500 redundancies in the sector in the past couple of years. Again this won't be noticed in the same way as the closure of a high profile multinational but the effects are just as real. Equally, entire classes of dental graduates are forced to emigrate for the lack of viable opportunities (and not because of any professional control on numbers which simply does not exist).

In view of all these indicators, there is a particular responsibility on policy makers, including the Dental Council, to be fully cognisant of the impact on patient attendance and oral health caused by increasing regulatory burden and the consequent onus on dental practices to pass on the costs of such extra operating requirements to patients and the consequent impact on dental attendance and oral health.

We formally request that a full patient impact assessment is undertaken by the Dental Council before proceeding further which sets any perceived risks (i.e. evidence based risks) against the consequences of extra regulatory burden on attendance and oral health gain.

Comments on the draft received

In reiterating our strongly held view that the Council should pause and review the submissions received and to commission a proper patient impact assessment before proceeding further, we offer the following observations on the draft received (*referred to as Version 4, dated October 1st 2013*).

1.2 Reference is made to section 4.8 - there is no s4.8 in the draft we received. This section also provides a reference. It would be very helpful if scientific references to were provided for

this entire document. This would ensure that readers understand fully the argumentation for any new proposals

1.3 The text in this section is vague- not clear which international guidelines are envisaged. We are unclear as to the meaning in the phrase “practice systems and process for non-compliance”? Is “non-compliance” a typographical error? Please provide more information and references for international guidelines.

1.4 Evidence should be requested for immune status of employees. With respect to TB , Measles, VZ, Mumps and Tetanus this may be very difficult to get in writing. Immune status for TB, measles, Mumps and Tetanus would require blood tests – is it being suggested these would be taken before employment? The US Center for Disease Control (CDC) notes that it is not possible to become immunised against Hepatitis C.

Some individuals may not display a positive result to immunisation testing even after vaccination. The following section is adapted from 2005 HIV health care workers document – we note that the Department of Health is undertaking further research on this topic and we are aware of revised guidance issued recently by the GDC (UK) in regard to HIV positive status and the practice of dentistry. We respectfully suggest that the Council should pause and await the imminent guidance from the Department of Health and consider any such recommendations along with the revised guidance from the GDC before proceeding further.

The draft received gives definitions but offers no guidance regarding as to who is allowed to carry out procedures and what is the relevance of infection status. Section 1.4 proposes that immunization status should be a condition of employment for the dental team. However, certain individuals will not respond to e.g. Hepatitis B vaccination and therefore will not be immune despite having received the vaccine. If the proposed code is followed, these individuals could potentially be excluded from practice.

There has been much valuable work done regarding this issue generally within the HSE and with the full participation by staff representative bodies and we suggest that existing policies should be reviewed and considered in tandem with the revised guidance expected from the Department of Health before making any recommendations on such a difficult subject.

2.1- The text received suggests that “all reusable equipment must be accompanied by manufacturer’s instructions detailing decontamination procedures for the equipment”- this is not feasible or possible for all reusable equipment including old equipment that is currently in use. This is a supplier and staff training issue. Once staff are trained in sterilisation of a piece of equipment, then we suggest there is no need to have this information “accompanying” equipment.

The phrase decontamination is used in addition to sterilisation and we wonder if this is intentional; if so, definitions are needed.

2.2 – The text suggests that "instruments should be carried in a secure container if transported out of the dental surgery"

What is considered a secure container? This step may result in increased handling of instruments into and out of containers which would increase risk of injury as opposed to carrying on a tray as is the norm.

Washer Disinfectors

Section 2.3 states that washed disinfectors must be used for cleaning instruments. No evidence base is presented to support this recommendation and there is no evidence to show that the current recommendation of using an ultrasonic cleaner is unsafe or presents any risk to patients.

We suggest that an acceptable regime should encompass the use of validated ultrasonic cleaning followed by manual cleaning with heavy duty gloves prior to use of an autoclave. This should be recognised as an acceptable standard.

The code states that a separate decontamination room is only required for a new practice. However, the requirement for a washer disinfectant is de facto requiring all surgeries to have separate room as washer disinfectors are not suitable for use in a surgery due to the heat and noise generated and most surgeries would not have the space to accommodate them. Therefore, as many existing surgeries, both in the private and public sector, may not have the space to expand to accommodate a separate sterilization room, some surgeries will close as a result of this proposed requirement. This will particularly be an issue in more remote rural areas where there are small stand-alone clinics and will exacerbate the already significant problem of access to services in these areas.

The requirement for washer disinfectors is out of line with the requirements in the UK and elsewhere. The considerable costs associated with the purchase, validating and maintenance of this equipment will put dentistry in Ireland at a considerable competitive disadvantage compared to other jurisdictions, with no proven benefit in terms of patient safety.

The code states that washer disinfectors “must” be used but refers to the use of autoclaves as being “the method of choice” for sterilization and states that Type B vacuum autoclaves “should” be used. This wording indicates that the requirements around washer disinfectors is actually more stringent than the requirements in relation to the use of autoclaves. Again, this would appear to be at variance with international standards e.g. in the UK, USA (CDC guidance).

2.3- Disinfection is possible through chemical or thermal methods. The “most effective method” varies and this depends on what item you are cleaning- e.g. washer disinfectors are less reliable than manual cleaning of dental cements/ ultrasonic cleaners are better for cleaning endodontic files.

A number of studies are particularly relevant (full references available on request) as follows.

Franz A, University of Vienna- “It could be shown that in contrast to the proposed test soils of the EN 15883-5, the used reference substances of the dental practice could not be removed by the washer-disinfectant. Removal of these reference substances was only possible after manual or ultrasonic cleaning. Conclusions: Since blood plays a subordinate role as a contaminant of instruments during conservative-prosthetic dental treatments, testing of the cleaning efficacy of the washer-disinfectant with test soils according to the proposals of the EN 15883-5 is not representative in this discipline of dentistry. Most of the materials used in dental practice can only be removed manually or with the help of the ultrasound bath.”

Perijkaki K, University of Manchester- "Comparing the test groups, the files that had been cleaned ultrasonically had significantly less debris than those cleaned in the washer disinfectors."

Ebner, University Hospital Freiburg- "In hospitals, medical instruments are usually cleaned and disinfected in a washer/disinfector. However, it is not efficient for small hospitals or general practitioners to purchase such machines as they would not be working to capacity. We investigated the possibility of cleaning and disinfecting medical equipment in a conventional household dishwasher modified to achieve a temperature of 71 degrees C. For this purpose we contaminated screws with different test soils containing either bacterial (100 screws) or viral (106 screws) suspensions. Test organisms were re-isolated from 2% of the screws after bacterial contamination and 4.7% of those with viral contamination. In both cases we found dishwasher-processing to be a suitable means of disinfecting medical instruments."

Assaf, BDJ, endodontic files cannot be totally cleaned using a washer disinfectors

Ultrasonic cleaners are also better at reducing vCJD risk if fluid is changed regularly. Washer disinfectors are more expensive to validate- horse blood and albumin etc.

In the UK (ref HTM105) it is a best practice recommendation to have one, not mandatory. It is only best practice because it is possible to validate. Where is the evidence that using a washer disinfectors increases patient safety or employee safety?

A typical washer disinfectors cycle is 50 minutes. This means more practice will need more instruments and staff time increasing costs.

A washer disinfectors could cost more than €10,000 initially. Costs per annum per washer are approximately €500-€800 + vat for one test to validate. Consumables for daily testing will be c. €500 per annum. These are prohibitive costs for changes which we believe are not warranted when it is more appropriate to set out acceptable standards instead.

2.4- Which daily and weekly tests are being recommended? Normal daily test is a washer efficacy test using soiling agent and adds to costs. As mentioned above, soils used are not appropriate for dental materials. How often is periodic and who is a competent person? If being tested daily what is the need for weekly tests? Who calibrates the washer disinfectors? No definition of period of test. Surely validation period should be defined by manufacturer's instructions.

2.5 Is the use of ultrasonic cleaners optional? What does "periodically tested" mean?

2.6 Does a written protocol make manual cleaning more effective; is manual cleaning mandatory?

2.7. The text states that storage of sterile wrapped instruments is allowable for up to a year. Again, no evidence is presented for this apparently arbitrary time-scale. The scientific evidence shows that the time for which the instruments are stored is not the critical issue, rather the focus should be on ensuring that the integrity of the wrapping material is intact prior to use. For example, in one study wrapped instruments were found to still be sterile after 30 months, provided that the wrapping was intact.

Also, what evidence is there that using the washer disinfectors first is safer? Staff could be injured while loading washer disinfectors also. Surely this is a theoretical risk? Also,

instruments contaminated with cements etc. may become harder to clean after washer disinfectant. If there are contaminants under the cements etc. which the washer disinfectant will not remove, manual cleaning will then be carried out to remove this with exactly the same risk, before the instrument goes back into the washer disinfectant?

Preparation and Packaging

2.8 - Please explain packaging instructions? Recording the date and cycle number for every instrument is an unenforceable standard and will introduce a huge amount of paperwork. This suggestion seems to be influenced by surgical protocol where instruments are introduced into a sterile environment and can be traced later if patients are found later to be infected with vCJD etc. Is this really a necessary step for a dental practice?

Most instruments in a dental practice are used multiple times every day and due to their expense dentists do not store large quantities. If instruments can be stored for up to one year, it should be sufficient that all instruments in the surgery are taken out, sterilised and repackaged once per year minimum. It is reasonable to make this track and trace best practice but not a minimum standard. Without linking this information to the patient, this is a pointless process.

Finally, subject to the comments above, we suggest it would be desirable to insert the word 'preferably' before "under magnification....."

Sterilisation

2.9- What are "headpieces"? This instruction is not possible as we cannot effectively sterilise against prions which are pathogenic and can survive temperatures of up to 2000 degrees! We suggest remove the phrase "all known pathogens".

Regarding the phrase "Most instruments," what other methods of sterilisation does the Dental Council deem acceptable for which instruments? Again we suggest a change to "Preferably under magnification".

2.10- What is "high quality water"? (potable? <500cfus?) We would ask that the Council would provide evidence basis and references.

Types of Autoclave

2.11 & 2.12- Why the favouritism to B class? S class are just as acceptable and in fact may have more evidence to prove their effectiveness for specific loads. "Manufacturer's instructions" this goes for B class and all other equipment we use and is not necessary to state this.

Can dental handpieces be sterilised effectively? Please provide evidence for this. We draw your attention to the following statement in HTM 105- "In some instances, the decontamination process may not generate full sterilization, for example in the reprocessing of dental handpieces;"

2.13- The document states that unwrapped instruments from Type N cycle must be used immediately and not stored, yet 2.18 says they must be used within the day. Does immediately mean within one day?

2.14 Validation costs up to €1000 plus annual service costs €500 plus parts. What is a competent person? Who measures and enforces competency? Weekly tests and daily tests are surely unnecessary if autoclave self-monitors and reports faults. It is not clear what happens if a dentist buys his equipment from overseas. Furthermore, testing periods are not defined.

Storage

2.17 Again, we draw attention to the cost of track and trace printer - €250 plus labels. Hospitals now use etched instruments and are scanned through and stored on patients file. The suggested recommendations are not feasible in dentistry due to cost. Regarding the suggestion that stored instruments could be left for one year - surely this depends on the type and quality of packaging used?

Local Decontamination Units / Areas

2.19- We submit there is no compelling evidence for separate decontamination units. This is the kernel of our objection to the thrust of this document. Rather than setting out **acceptable standards** to apply now and setting out best practice standards to which dentists can aspire over the longer term, the document is setting out standards for new practices which would apply immediately in the case of newly constructed surgeries and immediately create a two tier set of standards which will only cause confusion and unnecessary alarm.

The 2013 version of HTM 01-05 describes specific benchmarks by which specific compliance with essential quality requirements and best practice can be achieved. Where new practices are commissioned or contemplated, it is advised that full best practice provisions be utilised "**wherever reasonably practicable.**" (emphasis ours)

Subject to the above, we believe care needs to be taken as to use of the phrase 'new practices' when it is intended to refer to a new building rather than a change of ownership.

2.20 What does inaccessible to the public mean if it is in a surgery?

Design of decontamination area

2.21 Cost of air flow control? Please provide evidence of benefit to patient.

Waste Management

3.2- References relevant legislation, this should be done for other areas of this document to explain thought process.

3.5- Definition of clinical waste- example- what differentiates a plastic cup used at a water cooler and one used in a dental surgery? Or the tissues a patient uses to blow their nose in the waiting room and the one used to wipe their mouth in the surgery?

3.7. Reference is made to inspection without further necessary elaboration on who would undertake such an inspection.

Amalgam

We reiterate the point that provisions relating to amalgam should not be contained in guidance on infection control as this will only serve to suggest risk when no obvious risk exists.

3.8 We again draw attention to the lack of any suggested legal obligation on dentists to use an amalgam separator. The cost of separators is not insignificant and **a five year lead-in would be advisable for any changes which may be deemed acceptable or best practice rather than essential requirements.**

3.12 We ask whether dentists can give back extracted teeth with amalgam to patients. How will patient dispose of them? Where is the concept of cross infection control if the patient can walk out the front door with contaminated waste to show their friends?? What legal obligations does the patient have regarding disposal of this clinical waste? Dentists can save on their waste disposal costs by handing all extracted teeth back to patients who can do with them what they please, even if they have amalgam. Can we also hand them removed amalgam fillings or empty capsules?

3.13- Who is a manufacturer of hazardous waste?

Dental Practice requirements

3.18- How can a dentist ensure a company complies with all relevant legislation? Surely this is the responsibility of the licensing body. We suggest that a dentist can only ensure the waste contractor is licensed to carry and dispose of biomedical waste.

3.19 We are unclear as to the documentation required and by whom it is proposed that inspections would be undertaken

3.20 Again, by whom would a “risk assessment” be carried out and to what standard?

Standard Precautions

Hand Hygiene

4.2 We are unclear as to which standard the Council is advocating.

Personal Protective Equipment

4.3 We wonder if use of a gown, mask, goggles and shield is necessary.

4.7 The text suggests that "...dental unit output water can be heavily contaminated with microorganisms which enter patients' mouths during dental instrumentation. This water.....exposing staff and patients to high densities of bacteria and bacterial endotoxins" While this is possible, it could make alarming reading for a sensitive member of the public or a journalist looking for an angle - better to leave out this detail/unnecessary explanation and stick to the other sentences in the paragraph.

This section does not address legionella and some advice would be appreciated.

Training and Education

5.1 Reference is made to "on-going training". This is a vague term. What standard is required and who is it to be run by?

Risk Assessment / Audit and Standards

6.1 This provision is very vague with regard to "risk assessment." Who carries this out and to what standard? Again, how long is "periodic".

6.3 Whom is it intended would carry out these inspections?

[1] The level of support offered to dentists in the UK is notable in this regard. In the financial year 2008/09 £5million was made available by the Scottish Government for dental practice improvements, specifically aimed at decontamination. In a move to try and reduce the costs to practices the Scottish Government also set up a national procurement contract that covered decontamination equipment. In 2007 the Northern Ireland Assembly announced specific funding of £1.5million 'to help dentists meet the increasing costs of complying with cross-infection control standards.' In England, payments to NHS dentists are said to take account of extra practice costs associated with HTM 105. Also, when the guidance was introduced a small number of local Health Boards in England did decide to provide washer-disinfectors free of charge to all the NHS contracted practices in their area. Some Health Boards also provided direct funding to a small number of practices on a one off basis in areas where they wanted to retain NHS services.

[2] Whereas the State spends €3.6 billion annually building, staffing and equipping hospital medicine within the HSE, no such assistance is provided for dental care in the community. Likewise, before a penny is spent on caring for medical card patients, GMS doctors in general practice can receive up to €100,000 per annum in grants towards employing nurses,

secretaries, practice managers and where they are located in remote rural locations while pension payments are also available to doctors.