Dental Amalgam

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Introduction

1. Dental amalgam is a dental filling material, used to fill cavities caused by tooth decay, and is made from a mixture of different metals, including mercury. It remains one of the range of restorative materials available to dentists, enabling the profession to provide the most appropriate treatment for the individual needs of each patient.
2. There is currently no ideal replacement material that compete with amalgam on speed and ease of placement (and repairment), longevity or cost at present. It remains the material of choice for high-needs patients, for example those presenting with a large number of cavities, and with its antibacterial properties, has a role to play in reducing the risk of secondary caries development. The loss of dental amalgam will likely increase the need for crowns and extractions.
3. There is no evidence that exposure to mercury from amalgam fillings has any harmful effects on health. The mercury in dental amalgam is more stable than methylmercury - the main source of mercury exposure for the majority of the general population - and may be released into the environment through amalgam production and restorations, when placed or removed. Regulations are in place in the UK and EU member states, including the requirement for dental practitioners to use amalgam in pre-dosed encapsulated form and amalgam separators, to prevent mercury exposure to the environment.
4. This paper outlines the status of dental amalgam in the European Union and the UK and sets out the reasons why recent developments at EU level in relation to dental amalgam, should not directly apply to Northern Ireland.

The status of dental amalgam in the European Union

5. On 17 May 2017, the European Parliament and the Council of the European Union passed Regulation (EU) 2017/852 to address the impact of mercury on the environment. In relation to dental amalgam, regulations included the prohibition of its use in the treatment of children under 15 years of age and in pregnant or breastfeeding women except when deemed strictly necessary by the dental practitioner based on specific needs of the patient; the use of dental amalgam only in pre-dosed encapsulated form; and for each Member State to set out a national plan concerning measures to be taken to implement the phase down of the use of dental amalgam. These measures were based entirely on environmental concerns and there is no evidence-based reason to restrict dental amalgam use in either pregnant women or young children on health grounds (Scientific Committee on Health and Environmental Risks, 2008 & Scientific Committee on Emerging and Newly Identified Health Risks, 2008). The Regulation also contained provisions for a feasibility study for the phase-out of dental amalgam in the future. Such a feasibility study was undertaken between August 2018 and June 2020.

6. On the 8 February 2024, the European Council and European Parliament reached a provisional agreement on a proposal to revise the 2017 Mercury Regulation, which would phase out the use of dental amalgam and prohibit its manufacturing, import and export. This agreement is pending at the time of writing (mid-February 2024), ahead of formal adoption by both institutions. The provisional agreement would:
   - Prohibit the use of dental amalgam in the EU from 1 January 2025, except where it is deemed strictly necessary by the dental practitioner to address specific medical needs of the patient.
   - Introduce an eighteen-month derogation for member states where low-income individuals would otherwise be socio-economically disproportionally affected. Member states would have to justify their use of the derogation and notify the European Commission of the measures they intend to implement to achieve phase out of dental amalgam by 30 June 2026.
   - Prohibit the export of dental amalgam from the EU, from 1 January 2025, and introduce a ban on the manufacturing and import of dental amalgam in the EU from 30 June 2026. There will be provision for a derogation to allow the import and manufacturing of dental amalgam for use with patients with specific medical needs.
   - A review of the exemptions for the use of dental amalgam will be performed by the European Commission by 31 December 2029, and will take into account the availability of mercury-free alternatives.

UK position on dental amalgam

7. The UK government has for many years maintained their commitment to work with the dental profession to phase *down* the use of dental amalgam, in the NHS and private dentistry.
8. To support this commitment, the UK along with over 140 other countries signed the Minamata Convention on Mercury, which came into force on the 16 August 2017. The global treaty sets out measures to phase down the use of dental amalgam. In addition, the UK implemented the measures of the EU's Regulation 2017/852 on Mercury, as detailed at paragraph two, on 1 July 2018.
9. Alongside these measures, national plans for the phasing down of the use of dental amalgam -including the Northern Ireland Plan to phase down the use of Dental Amalgam - were published by the four UK nations, and the Department for Environment, Food and Rural Affairs Department (DEFRA) included the reduction of mercury pollution from dentistry as one of the strands in their 25-year environment plan.
10. The Northern Ireland phase down plan sought to ensure a gradual reduction in the use of dental amalgam and recognised the importance of focusing on improving oral health by prevention; promoting research and development of alternative restorative materials and new techniques; and bringing forward changes to service delivery, including a new General Dental Services Contract with targeted preventive interventions, and the further development of Community Dental Services to meet rising population needs. The Plan also recognises the need for appropriate training and experience with new and evolving techniques and materials.

BDA position on dental amalgam

11. The UK dental profession has a longstanding commitment to environmental responsibility and the BDA agrees with the UK position and the measures set out by the Minamata Convention. We believe that the phase down of dental amalgam, at a rate appropriate for each signatory country, to be the best option for public health, particularly considering the

strain on healthcare systems especially in light of the profound impact of the COVID-19 pandemic and the risk of further exacerbating inequalities.

12. Alongside the Council of European Dentists (CED) and the FDI World Dental Federation (FDI), the BDA has maintained that dental amalgam, alongside other restorative materials, must remain available as one of the tools in the armoury of the dental profession for the repair and maintenance of damaged teeth. The BDA advocates that the treating clinician is best placed to discuss with the patient the options available and to achieve valid consent for the treatment offered. Whilst alternative materials do exist, none does currently fully replicate the clinical and economic effectiveness of amalgam. We also agree with the Minamata Convention and the World Health Organization (WHO) that further research is needed on the health and environmental impact of new restorative materials.
13. In addition, all four UK nations need effective preventive strategies, and their incorporation alongside appropriate funding, into health service dentistry, to help address poor oral health, and reduce the need for restorative materials.
14. This position is further demonstrated by the BDA's support of a joint statement by the FDI and the International Association for Dental, Oral, and Craniofacial Research (IADR) at the fifth meeting of the Conference of Parties to the Minamata Convention on Mercury in 2023. This statement, in response to a proposal to adopt 2030 as a phase-out date for dental amalgam, set out the need to maintain the current phase-down model which respects differences in country capacities and guarantees access to oral health and the overall well-being of populations.

Dental amalgam phase down in Northern Ireland

15. The BDA is concerned that in the event the provisional agreement to amend the EU Mercury Regulation is adopted at EU level, the default position is that the amended regulation would have direct application in Northern Ireland under the terms of the Windsor Framework, causing a significant divergence between dental practices/businesses/HSC organisations and patients in NI relative to the rest of the UK.
16. It is imperative that we set out the highly significant impact application of the amended Regulation -particularly the move away from the UK-wide phase-down approach, to an arbitrarily imposed accelerated date for phase-out of dental amalgam in less than a year's time -would have in Northern Ireland.
17. It is our firm belief this issue satisfies the criteria set under Section 8 for an Inquiry by the NIA Windsor Framework Scrutiny Committee and the application of the Stormont Brake to avoid direct application of a ban on dental amalgam from 1 January 2025, as per The Windsor Framework (Democratic Scrutiny) Regulations 2024. Specifically, that the replacement Act in question -the amended Mercury Regulation –Section 8, 2)a)i) *'significantly differs from the content or scope of the EU instrument which it amends or replaces'*, and ii) '*would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist'.*
18. In short, the requisite preparatory focus areas of: prevention, alternative materials/techniques and service reform laid out in the Northern Ireland Plan to phase down Dental Amalgam have not been progressed to the required extent to be in a position to phase-out amalgam from 1 January 25. Dental Services that were devastated by COVID-19 continue to deal with significant patient backlogs, while the Department of Health have only just launched for public consultation their Oral Health Improvement Plans; work on a new GDS contract has stalled, and the service continues to be under immense financial pressures due to rising costs and unviable fees; while dental system reform requires much more work to address significant workforce recruitment and retention issues. Moreover, BSO figures show just how heavily reliant we continue to be on dental amalgam in Northern Ireland.

- BSO/Northern Ireland Health Service statistics for Amalgam fillings in adults from 2015/16-2023/Q2 show a total of 2,641,487 permanent fillings.
- BSO/Northern Ireland Health Service statistics for Permanent Amalgam fillings in Children from 2015/16-2023/Q2 show a total of 366,948 permanent fillings. Non-amalgam accounts for only 82,018. A total of 241,960 are amalgam (the remainder 124,988 accounts for items such as Tunnel Restorations, Composite / Synthetic Resin Fillings, Glass Ionomer / Silicate Fillings etc).

19. These figures for both adults and children in Northern Ireland clearly illustrate the prevalence and reliance on amalgam, and hence the additional burden on already over-stretched and stressed General Dental Services if phase out by 1 January 2025 was required.
20. The essential approach to this issue remains achieving all three key components established in the plan outlined previously. We stress, we are nowhere near the end point of this important area of work, and in some cases, we are only at the very early stages. The Northern Ireland Plan to phase down the use of Dental Amalgam, 2019 advised that the greatest opportunities to continue the phase down in the use of amalgam would be through three broad means – 1. improvement of oral health to reduce the need to use amalgam; 2. the use of new treatment techniques and materials instead of amalgam; and 3. continuing changes in service delivery to better enable the first two means.

Oral Health

21. Despite improvements in oral health, tooth decay is still one of the most prevalent diseases affecting children and young people. The 2018/19 National Dental Epidemiology Oral Health Survey[1] for 5-year-old children in Northern Ireland reported that 31.59% of children sampled had dental decay experience, and of those children, the mean number of teeth that were decayed, missing or filled was 3.86. When compared to the equivalent survey in England, it showed that 5-year-old children in Northern Ireland had both a higher prevalence and severity of decay.
22. Tooth decay also disproportionally affects those in areas of deprivation, with the prevalence of experience of dental decay higher in children from more deprived areas (45.25%) than those from the least deprived areas (16.27%). Children from deprived background also had higher levels of decay.
23. Untreated tooth decay may cause pain, infection and trouble eating, sleeping and missed days from school/work. Those presenting with tooth decay may require extractions or fillings, and it remains the number one reason for child hospital admissions, with over 21,000 extractions carried out on children under general anaesthetic in Northern Ireland in 2019/20. Whilst rates were reduced in 2020/21, this is a reflection of the impact of the COVID-19 pandemic and reduced access to services. The impact extends beyond children, with 34.4% of adults in Northern Ireland, registered with a health service dentist, receiving at least one filling in 2019/20[2].
24. In some situations, and for some patients, the use of dental amalgam will be the only feasible treatment option to best meet the specific clinical circumstances and patient's needs. Examples include when there is an allergy, when it is not possible to obtain adequate moisture control or with more vulnerable patients, such as those with certain disabilities, medical conditions such as dementia, or patients with limited communication ability or health literacy. Without the option to place amalgam fillings, there is a risk that more tooth extractions will be carried out in population groups where composite fillings cannot be placed, further exacerbating oral health inequalities.

[1] National Dental Epidemiology Oral Health Survey - Five year old children in Northern Ireland 2018/19 (2023)

[2] Northern Ireland Statistics and Research Agency (2020). *Family Practitioner Services General Dental Statistics for Northern Ireland Annual Statistics 2019/20*.

25. A major contribution to the phase down of dental amalgam will be approaches that aim to prevent and control oral disease, including oral health promotion and preventive interventions. Consideration needs to be given to the introduction of a package of preventive measures to tackle tooth decay, such as legislative changes to address the marketing and consumption of foods high in sugar, addressing the increasing number of children and young people taking up vaping, water fluoridation and supervised tooth brushing schemes.
26. Whilst the BDA welcomes the development of Children's and Older Person's Oral Health Improvement Plans for Northern Ireland, the prevalence of tooth decay in children in Northern Ireland and percentage of adults requiring fillings indicates the continued need for restorations, alongside oral health prevention measures which will further support and enable the phasing down of dental amalgam.
27. The additional steps to reduce the need for dental amalgam/restorations by rolling out evidence-based, preventative interventions across Northern Ireland aimed at delivering oral health improvements are only at early stages. It will take time for the Oral Health Improvement Plans to be refined, approved and implemented, and crucially, for the benefits to come through.

New treatment techniques & materials

28. As noted in the Northern Ireland Dental Amalgam Plan, *there is currently no ideal replacement material that can be substituted for all clinical scenarios.* Whilst mercury-free alternatives exist, they are less than optimal based on clinical, economic and practical reasons.
29. More research is needed on the health and environmental impact of new restorative materials, as highlighted by the Minamata Convention and the WHO. Consideration must be given to the clinical longevity and cost-effectiveness of new materials, along with an assessment on their safe disposal. Of particular importance is robust data and evidence for the use of alternative materials in difficult clinical conditions, such as areas of high caries, lack of compliance, for example due to medical conditions, and in extended cavities.
30. With alternative material, such as composite fillings, BDA research indicated that the financial impact -notably cost to dental practices -would be much higher, primarily owing to the increased time taken to apply the filling material. The BDA Wimpole Timings Study (April 2023), looking at dental treatment times concluded that composite fillings take on average 7.5 minutes longer to apply for a single surface, and 15 minutes more for multiple surfaces, compared with amalgam fillings. With increased time and costs to independent contractors, it will equate to increased strain on Department of Health to mitigate these costs if amalgam were to be no longer available.
31. In Scotland, the new determination 1 fees rolled out at the end of last year include composite supplements of £10.60 for front teeth and a higher supplement for posterior teeth, although this is only available to particular patients such as pregnant women. Scottish fees are also higher in general than those in Northern Ireland for amalgam fillings, including if you compare the fee for both types of 2 surface fillings with the comparable 1 item code in the Scottish determination.
32. If the current volume of patients requiring amalgam fillings were instead paid using the equivalent codes for children's composite fillings, the NI dental service would be spending £2,649,954.96 more per year (2023 treatment volumes). If this were applied to 2019-20, the most recent 'normal year prior to the COVID-19 pandemic, the additional cost would be even higher at £3,639,476.10. This equates to £7.5 million on the four amalgam filling Item of Service codes currently in place, or a doubling in costs.

33. The difference is also reflected in the private market. BDA research from 2023 into private fees indicates that on average, composite fillings for posterior teeth cost £57.98 more in private practices than amalgam fillings do.
34. We agree with the Dental Amalgam Plan that until more ideal replacement materials are available, the option to use amalgam should remain, and that the pace of phase down will be dependent on the development of new materials, which are as suitable from a clinical, economic and environmental perspective.

Changes in service delivery

35. As documented in our evidence to the Review Body on Doctors' and Dentists' Remuneration (DDRB), the sustainability of health service dentistry in Northern Ireland is already in an unprecedented and deeply precarious situation, where fees bear little correlation with cost to deliver care. A ban on amalgam from January -without full mitigation of associated increased costs associated with material substitution and increased time required -would have a devastating impact on future sustainability of Health Service dentistry for the public, at a time the service urgently needs to be stabilised.
36. The Dental Amalgam Plan advised that a piloted and evaluated capitation-based primary dental care model for a future GDS contract could encourage greater use of preventive interventions, which would support the Plan's first theme of improving oral health. It also noted that consideration would be given to the incorporation of other models of preventive care delivery, within a capitation-based contract.
37. Despite the urgency, little progress has been made in bringing forward a new GDS contract and in securing dental payment reform to ensure health service dentistry is financially viable and put on a sustainable footing.
38. A BDA survey of practice owners in Northern Ireland highlighted the precarious and difficult situation they face on a range of issues – in particular recruitment and retention, stress, motivation and morale and pay. The increasing operating costs at practice level, and the inability to mitigate these costs combined with a failure to apply timely uplifts (or indeed, any uplift at all) has compounded the issues within HS dentistry.
39. There is the additional issue of skills gap. There will need to be training available for the whole dental team should the proposed new regulations take effect in Northern Ireland. Some dental teams will have limited experience in placing post composites, particularly within the Community Dental Service. It could potentially de-stabilise an already over-stretched and under resourced service. This skills gap includes nursing and therapists as well as dentists. Training of all dental teams including CDS and GDS should be available to meet this gap and should be fully funded. Training needs are essential and additional to *the 2019 Dental Amalgam Plan*.
40. We are gravely concerned that unless significant and immediate progress is made, there will be no future for health service dentistry in Northern Ireland, further impacting upon the oral health of the population. Direct application of an amalgam ban with a continued inadequate approach to dental remuneration will worsen the exodus we are already seeing of dentists from a broken, unviable Health Service system which has become financially unviable.

Summary

41. A plan for phase down of dental amalgam in Northern Ireland was published in 2019, as part of a UK-wide approach. This graduated position which aims to put in place the steps to improve population oral health, enact dental system reform and apply a robust approach looking to the emerging data and evidence for the use of alternative, remains the correct

approach. It is our belief that this approach continues to be the considered view of what is required by the four UK Chief Dental Officers and UK government.

42. Direct application of the proposed amendment to the EU's Regulation 2017/852 on Mercury and imposing a ban on dental amalgam in Northern Ireland from 1 January 2025 at a time when amalgam is heavily relied upon as a restoration material, is simply unworkable. It will further destabilise the provision of dental services. The profession is still unrecovered from the COVID-19 pandemic; the preparatory steps outlined in our National Plan have not been fulfilled, and indeed we are only at the early stages of key actions being taken forward.
43. The BDA is committed to a responsible approach being applied to the phase down of dental amalgam, and as such we call on the NI Assembly to make the necessary financial and policy investments into prevention measures that will achieve the oral health outcomes we want to see, invest in dental system reform including a sufficiently incentivised new GDS contract and the requisite dental workforce, particularly in salaried services, and look carefully at the research on new materials, and how they may be embedded seamlessly when considered appropriate by practitioners.
44. The UK dental profession has a longstanding commitment to environmental responsibility, and the BDA agrees with the UK position and the measures set out by the Minamata Convention. We believe that the phase down of dental amalgam, at a rate appropriate for each signatory country, to be the best option for public health, particularly considering the strain on healthcare systems particularly in light of the profound impact of the COVID-19 pandemic and the risk of further exacerbating inequalities.

45. In conclusion, we call on the NI Assembly to utilise powers available to it and apply the Stormont Brake so that the proposed amended Mercury Regulation and a ban on dental amalgam from 1 January 2025 will not directly apply to Northern Ireland.