



Finding a political solution for phasing out dental amalgam in Germany

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Executive summary

Mercury

Mercury and its compounds pose a risk to the environment and human health due to their toxicity. A major source of human exposure and contamination of soil and water is the use of mercury in dentistry and other products, in industrial processes and in the artisanal processing of gold ores, as well as mercury emissions from coal-fired power plants and other sources.

Dental amalgam is a dental filling material made by combining elemental mercury (about 50% of the amalgam) with a variety of metals (silver, tin, copper, etc.). Despite regulatory and other precautions, mercury from dentistry is inevitably released to the environment. When emitted to the atmosphere, mercury may be transported locally, regionally and globally, and is subsequently deposited in the Earth's oceans, lakes, streams, soils, etc. When mercury is deposited into these media, microbial metabolism transforms a portion of it into methylmercury, one of its most toxic forms, which may then be taken up in the food chain.¹

Many nations have severely restricted or banned the use of dental amalgam, while others have eliminated its use in women during their childbearing years, as well as children. Among other important initiatives, the European Union instituted a mid-2018 ban on amalgam use in children, pregnant women, and breastfeeding women, required Member States in 2019 to develop strategies to reduce amalgam use,² and in June 2020 the European Commission received a consultant report regarding the phase-out of all amalgam use in the EU.

The dental challenge

As detailed in this document, all signs are pointing to an EU-mandated phase-out of amalgam in dental use, which remains the most significant use and release of mercury in several Member States. Across the EU, it is estimated that each year approximately 12-24 tonnes of dental mercury become bioavailable, i.e., emitted to the air, discharged into surface waters, discarded in solid waste and/or released to groundwater.³

Given the public authorities' appreciation of the widespread use and release of mercury used in dentistry, the phase-out of dental amalgam in the EU is imminent for several reasons:

- Similar to the conclusions of the BIO Intelligence Service consultant report to the European Commission published in 2012, the Deloitte et al. consultant study (June 2020) carried out for the European Commission recommends a phase-out;

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3514464/>

² https://ec.europa.eu/environment/chemicals/mercury/regulation_en.htm

³ Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020.

- The requirements of the Medical Devices Regulation and the Water Framework Directive are not compatible with the continued use of mercury in dental practice;
- Alternative mercury-free dental filling materials are reliable, cost-effective, and available, as evidenced by the growing number of EU Member States that have phased down or completely phased out dental amalgam use;
- Alternative materials are already used far more often than amalgam, which has been banned in the EU since July 2018 for children and pregnant and breastfeeding women;
- The human health and environmental risks associated with dental amalgam considerably outweigh any risks associated with alternative filling materials;
- Surveys have confirmed strong public support in favour of a European ban on amalgam.

However, due to a long-term reliance on amalgam, unfamiliarity with the mercury life-cycle, lack of experience with modern materials, or a number of other factors, some are reticent to embrace a phase-out in the near term. As such, we are concerned that the inevitable transition to mercury-free dentistry will not be as smooth as it could be, and many dentists could be unprepared for this transition.

Purpose of this document

The purpose of this document is to further examine the valid concerns of the major stakeholders, to provide updates in place of outdated information, and to analyse and present realistic options for the phase-out in order to minimize any uncertainties and ensure that the transition to mercury-free dentistry in Germany is undertaken in a smooth and timely manner. It is anticipated that this document should be of particular interest to the German dental sector, public insurance providers, the Ministry of Environment, the Ministry of Health and various political parties preparing for the 2021 elections. It is also anticipated that this analysis will be of use to other EU Member States as they develop their own strategies for phasing out amalgam use.

Key observations

Key observations of this analysis include:

- The EU ban on the use of dental amalgam for children and pregnant and breastfeeding women laid down in Article 10(2) of the Mercury Regulation is already influencing the shift towards mercury-free materials.
- However, an effective phase-out of amalgam can be obtained only by eliminating state subsidies for amalgam, or directly banning the use of amalgam. For example, eliminating amalgam subsidies in Sweden resulted in a swift transition to mercury-free alternatives.⁴
- Based on the EU consultant report and other regulatory pressures, the question for Germany is no longer if, but when the phase-out will take place.

⁴ Lessons from Countries Phasing Down Dental Amalgam Use, UNEP Chemicals and Waste Branch, United Nations Environment Programme, Geneva, 2016.

- Even though the remaining use of amalgam is less than 10% in Germany, the present statutory health insurance scheme needs to be adapted to the post-amalgam reality.
- The main parties implicated in revising the present scheme are the dentists as represented by the National Association of Statutory Health Insurance Dentists (KZBV), the statutory health insurance companies, and the general public.
- The cost data for fillings agreed some years ago by the Valuation Committee (Bewertungsausschuss) are outdated and should be revised. The result would be that the actual cost of phasing out amalgam use could be significantly lower than that estimated by the umbrella organization of the statutory health insurances (GKV-Spitzenverband), and could be expected to be more than offset by a range of environmental and socioeconomic benefits.
- Many of the findings and recommendations included in this analysis are equally valid for the situations of other countries in Europe.

Basic findings

Based on the above, and assuming a general phase-out of amalgam use, this document suggests a way forward that combines the public need for basic and cost-effective healthcare with the dental practitioner's need to maintain a viable business. It is recommended that the post-amalgam era should respect the following basic requirements:

- Full public reimbursement for basic mercury-free restorations;
- Constraints on the extent of private billing, while maintaining the opportunity for dental practitioners to invoice the patient for treatments exceeding the basic restoration;
- The possibility for dental practitioners to use amalgam only in exceptional cases;
- Limited, if any, additional employer and employee contributions to the public health insurance;
- Measures to accommodate the special needs of the economically disadvantaged part of the population;
- The requirement that dentists maintain and submit to public insurance companies data on the type of material used in each filling;
- The obligation for dental practitioners to continue properly managing all hazardous waste and wastewater.

Three main options integrating those basic requirements have been elaborated and analysed in this report:

- **Option 1:** Full reimbursement of composites in place of amalgams
- **Option 2:** Full reimbursement for single-layer fillings, with an additional fee for multi-layer fillings
- **Option 3:** Full reimbursement only for one- and two-surface fillings, with a fixed reimbursement for larger fillings

Any of these options could probably find political agreement with a modest increase of EUR 200-330 million in the statutory healthcare insurance budget. To put that increase in perspective, it is roughly 10-15% of the 2.3 billion reimbursed specifically for fillings in 2018, and only 2-4% of the EUR 8.4 billion reimbursed for related restoration and surgical services.

Since the decision to adopt one or a combination of these options will be political, the authors decline to express any preference, instead summarizing below the key considerations related to each option.

Option 1: Full reimbursement of composites in place of amalgams

Option 1 refers to a 2018 calculation by the statutory health insurance companies (GKV) that was based on simply replacing all amalgam fillings with composites, the total cost of which (initially estimated by GKV at EUR one billion) would be covered by the public healthcare system.

- In order to determine fair and justified reimbursement rates, dentists and health insurance companies would have to thoroughly analyse and update the cost of appropriate, sufficient and economical treatment of patients with composite fillings, which would probably result in an increased cost for the amalgam ban of EUR 300- 500 million rather than one billion.
- It should be discussed whether to provide a derogation for possible use of amalgam fillings in exceptional circumstances, as was done in Denmark and Sweden.
- For both anterior and posterior fillings, an additional cost regulation (i.e., private billing of the patient by the dentist) should be permitted for special patient wishes and treatment exceeding the basic composite filling.
- Over 90% of all fillings are already mercury-free. Precise data on the filling materials used for basic dental care are not available, but it is known that cheaper and less durable materials are often used. The acceptance of composite fillings as part of basic care will ensure reasonable durability of fillings, which will benefit health insurance companies and consumers alike.
- Although reduced opportunities for private billing are supported by consumer advocates, this aspect of Option 1 could significantly reduce the income of many dental practices. In parallel, however, new billing opportunities are on the increase, such as for partial crowns and CAD/CAM inlays.
- For patients, the full reimbursement of composite fillings would provide some financial relief, following the trend that has already been initiated by the increase in reimbursement rates for dentures.
- This analysis shows that a political agreement on Option 1 could probably be found with a modest increase of about EUR 330 million in the statutory healthcare insurance budget.

Option 2: Full reimbursement for single-layer fillings, with an additional fee for multi-layer fillings

Option 2 was developed by the authors in consultation with expert colleagues. Basically, this option provides for a full public insurance reimbursement of all single-layer fillings – both large

and small – with the opportunity of private billing by the dental practice for any more sophisticated materials such as multi-layer fillings. In the anterior region the insurance reimbursement would completely cover single-layer composites, while in the posterior region the single-layer reimbursement could be for any authorised filling material, although the material may not be matched to the tooth colour unless the patient agrees to private billing by the dentist.

- In contrast to Option 1, Option 2 would provide more opportunities for dentists to apply the additional cost rule (i.e., private billing of the patient by the dentist), which would help to maintain something closer to their current level of income.
- For dentists, Option 2 would be generally a continuation of the current system, while also requiring basic mercury-free materials where amalgams would have previously been placed.
- For health insurance companies as well, this option would be a continuation of the current model, which would incur only minor additional costs.
- Easy-to-process mercury-free filling materials increasingly appear on the market, but for many of these materials the range of colours is limited. Tooth-coloured materials may incur extra costs via private billing.
- Good quality mercury-free filling materials that may be placed as a single layer of one material or a combination of two materials are sufficient, practical and economically feasible for the treatment of all indications in the posterior region.
- Multilayer restorations can still be separately invoiced via the additional cost regulation.
- It should be discussed whether to provide a derogation for possible use of amalgam fillings in exceptional circumstances, as was done in Denmark and Sweden.
- This analysis shows that a political agreement on Option 2 could probably be found with a modest increase of EUR 200-300 million in the statutory healthcare insurance budget.

Option 3: Full reimbursement only for one- and two-surface fillings, with a fixed reimbursement for larger fillings

Option 3 was also developed by the authors in consultation with expert colleagues. Basically, this option provides for a full public health insurance reimbursement for all 1- and 2-surface fillings, as well as a full or reasonable partial reimbursement for fillings of more than two surfaces. In the event of partial reimbursement of fillings of more than two surfaces, dental practices would have the possibility of private billing for the remaining cost.

- Option 3 would directly address the current increasingly burdensome situation where the majority of patients pay between EUR 50 and 100 in extra private billing for various services related to a composite filling in the posterior region. If the rate that is currently reimbursed by health insurance companies were to be converted into a fixed reimbursement, a ban on amalgam would have less of an impact on both health insurance companies and dentists.
- Full public insurance reimbursement of the cost of one- and two-surface fillings, which account for about 70% of all fillings, will considerably ease some of the financial burden on patients. These fillings are generally much less complicated to treat with alternative

filling materials than larger fillings, and an appropriate reimbursement rate should be relatively easy to agree on.

- In the case of larger fillings, interested parties will have to agree on what level of public insurance reimbursement is appropriate. As part of this discussion, it may be considered whether other more durable restoration methods might be indicated for large cavities, such as ceramic inlays or partial crowns, which are becoming cheaper and cheaper thanks to computer-controlled technologies.
- Meanwhile, low-income patients should continue to be entitled to full reimbursement of larger fillings via the hardship clause, as is the case with dentures.
- This analysis shows that a political agreement on Option 3 could probably be found with a modest increase of EUR 200-300 million in the statutory healthcare insurance budget.

Finding a political solution for phasing out dental amalgam in Germany

1 Context

While the timing of any phase-out of dental amalgam in Germany is not yet decided, the phase-out itself appears inevitable because of the Minamata Convention, the EU Mercury Regulation, German (and other EU) national action plan(s) for the phase-down of the use of amalgam, the EU Assessment of the feasibility of phasing out dental amalgam, the EU Water Framework Directive, the EU Medical Devices Regulation, etc. The relevance of each of these is discussed in further detail below, following a brief overview of the broader European situation.

1.1 Dental care in Europe

1.1.1 Utilisation of dental services

The “utilisation rate” of dental services indicates what proportion of the population has contact at least once with a dentist within a given year. Figure 1 shows relatively high utilisation rates over most of northern and central Europe, with somewhat lower rates in eastern and southern Europe. Second only to Ireland in Europe, 81.9% of the German population has contact with a dentist at least once during any given year.

1.1.2 Financing of European healthcare systems

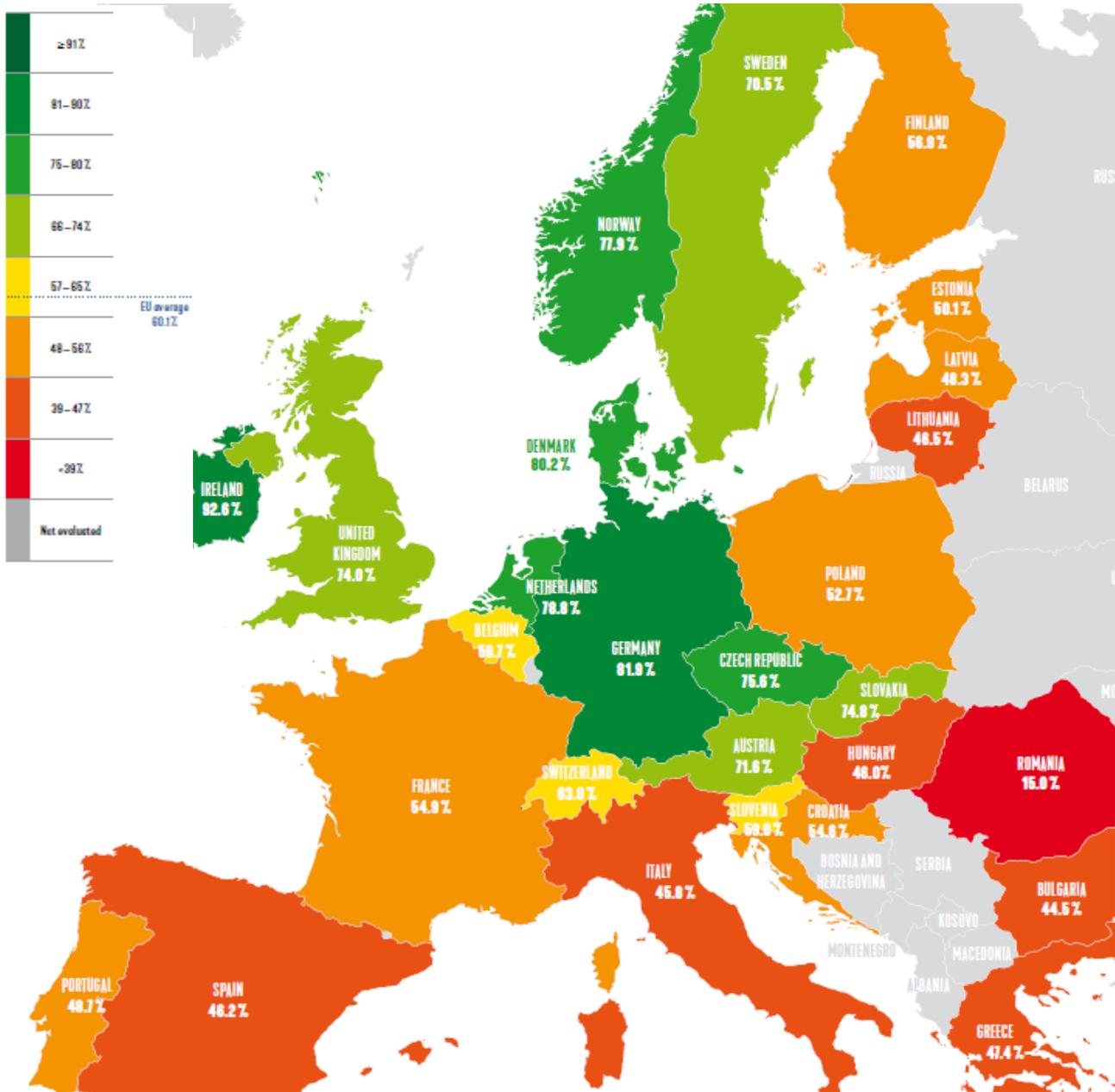
Financing of dental services is structured according to political and regulatory requirements. Two main systems are used in European public healthcare:

- “Beveridge systems” are state systems with a healthcare network of doctors’ practices and hospitals to which all inhabitants have access, and financed through taxes. Systems of this nature are found in the United Kingdom, the Scandinavian countries, Italy and Spain.
- “Bismarck systems” are social health insurance models financed through the social security contributions of insured persons and their employers. There are three variants of this system:
 - standard regional or central insurance (France, Poland, Czech Republic)
 - company/occupational and compulsory regional insurance (Belgium, Austria)
 - systems with a free choice of insurer and competition between insurance providers (Germany, Netherlands, Switzerland).⁵

⁵ Atlas Dental – European Markets: Structures, Challenges and Scenarios, Rebmann Research GmbH & Co. KG, GFDI Gesellschaft zur Förderung der Dental-Industrie mbH, 2018.

A recent consultant report for the European Commission highlights the fact that a large share of adult patients in the EU are required to cover any price differences between dental amalgam and mercury-free restorations at their own expense.⁶

Figure 1. Percentage of the population contacting a dentist at least once in 2018



Source: Atlas Dental – European Markets: Structures, Challenges and Scenarios, Rebmann Research GmbH & Co. KG, GFDI Gesellschaft zur Förderung der Dental-Industrie mbH, 2018.

1.1.3 Germany's statutory health insurance system

The statutory health insurance is the oldest branch of the German social security system. The task of the statutory health insurance companies (GKV) is to maintain, restore and improve the state of health of its insured persons, whereby all insured persons are entitled to the same basic

⁶ Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020.

benefits. In accordance with the solidarity principle, the system is financed by the contributions of its members. In 2019 the number of members paying contributions was over 57 million, and the number of family members co-insured free of charge was more than 16 million.⁷ Thus of the approximately 83 million people in Germany, more than 73 million were insured under the statutory health insurance system. The other 10 million were covered by private insurance arrangements.

The decisive factor with regard to healthcare insurance subsidies or reimbursements is not the individual's risk of illness, but solely the economic capacity of the insured person. There are special regulations for voluntarily insured persons, pensioners, job seekers and recipients of social assistance and unemployment benefits.⁸

In 2018, the total expenditure of the statutory health insurance system amounted to around EUR 240 billion. Unlike in most other countries, people in Germany have the right to free treatment of caries, which can potentially affect anyone. Dental prostheses as well are increasingly subsidised; recently an extra EUR 570 million have been shifted to the budgets of the insurance companies for the reimbursement of dental prostheses.

1.1.4 Dental health in Europe

According to the WHO, there is a high prevalence of dental disease in European countries, especially caries, dental (acid) erosion and periodontal diseases. Depending on the country, between 20 and 90% of 6-year-old children suffer from caries while, on average, between 0.4 and 3.5 teeth of 12-year-old children are damaged. By the time Europeans reach the age of 35 to 40, almost 100% suffer from caries, and in this age group between 10 and 20 teeth are likely to be affected, depending on the country.

Socio-economic factors also heavily influence the prevalence of dental disease. Underprivileged or disadvantaged population groups, who often find it difficult to access dental care, are disproportionately affected by dental disease. These groups also tend to be treated more frequently with dental amalgam than other population groups.^{9,10}

1.1.5 Dental restorations

In 2018, of the approximately 372 million dental restorations carried out annually in the EU28, between 32 and 69 million restorations are estimated to be carried out with dental amalgam (10-19% of the total) and between 304 and 341 million restorations with mercury-free materials (81-90% of the total). Therefore, the vast majority of restorations in the EU28 (now the EU27) are carried out with mercury-free materials, according to the European Commission.¹¹

⁷ https://www.vdek.com/presse/daten/b_versicherte.html

⁸ <https://www.bundesgesundheitsministerium.de/beitraege-und-tarife.html>

⁹ BZÄK/DAJ Study 2016, URL: https://www.bzaek.de/fileadmin/PDFs/grafiken/karies12/dmft_12-J_sw.pdf

¹⁰ WHO (2018): Factsheet on oral health and sugars intake. http://www.euro.who.int/__data/assets/pdf_file/0009/365850/oral-health-2018-eng.pdf?ua=1

¹¹ Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020.

The German national action plan to reduce the use of dental amalgam presented some estimates of the use of amalgam vs. other filling materials in Germany, but noted that there are currently no reliable statistics on this breakdown (see Section 1.4).

According to a BARMER survey, 20% of 3-surface fillings in first molars placed in 2014 were amalgam, as shown in Figure 2.¹²

Figure 2. Relative frequency of materials used for fillings in Germany in 2014

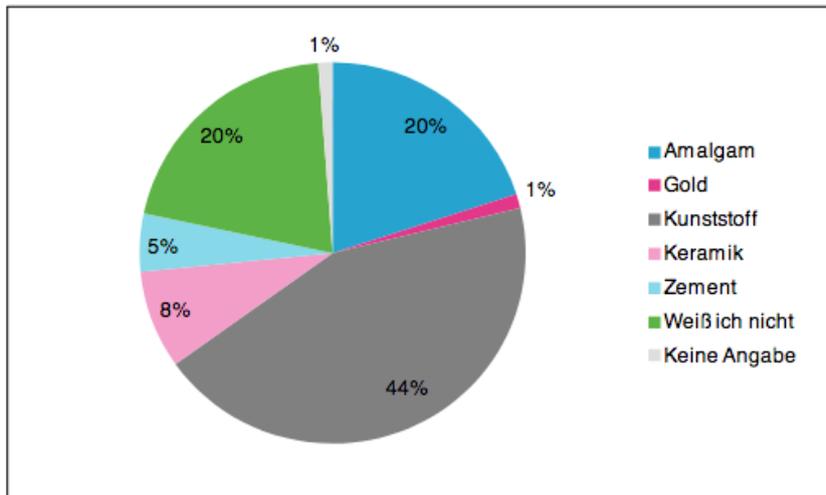


Abbildung 6-14: Verteilung der Antworten bezüglich des verwendeten Füllungs-materials

Source: BARMER GEK Zahnreport 2015

It is estimated that by 2018 only 5-10% of the posterior fillings placed in Germany were amalgam.¹³ In terms of the share of dental amalgam restorations compared to total restorations, Germany is thus in the leading group of EU countries with regard to reducing the use of amalgam. Other EU countries estimated to place less than 10% amalgam fillings include Austria, Belgium, Portugal, Hungary, Italy, Denmark, Estonia, Spain, Finland, Luxembourg, the Netherlands and Sweden.¹⁴

Assuming the preparation of more amalgam than needed for each filling (some amalgam is unused and some is lost during the procedure), it is estimated that an average of about 850 mg of mercury are used per filling,¹⁵ giving overall estimated 2018 demand for dental mercury at the EU28 level of between 26.9 and 58.3 tonnes (average 42.6 tonnes).¹⁶

¹² BARMER GEK Zahnreport 2015; <https://www.barmer.de/presse/infothek/studien-und-reports/zahnreporte/report-2015-38928>

¹³ Deloitte et al., op. cit. Also, despite the lack of statistical evidence, the German federal dentist association (BZAEK) reported that the overall use of dental amalgam had decreased to less than 10% (in terms of market share of dental filling materials sold) already in 2015. This estimate was supported by the German federal government in their national action plan for the phase down of dental amalgam.

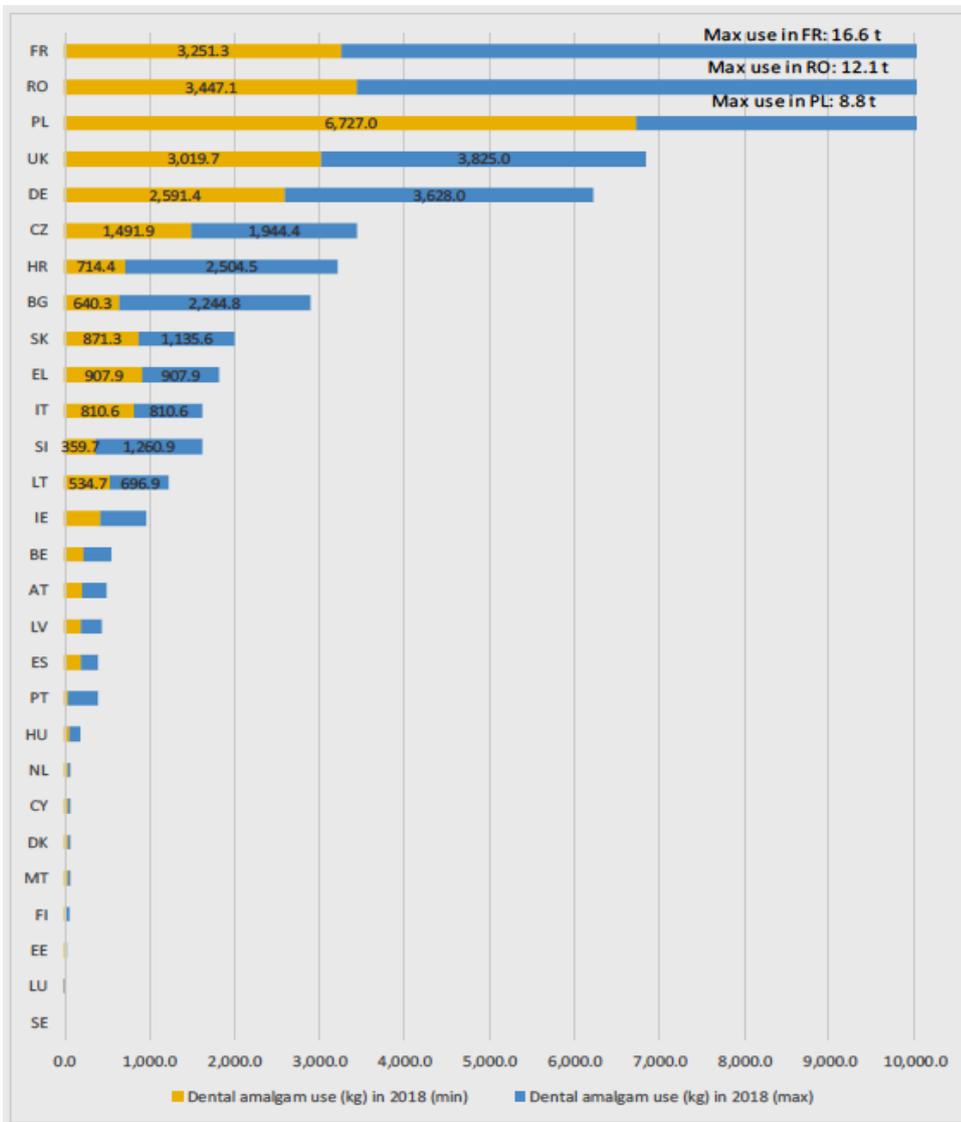
¹⁴ Ibid., p.25.

¹⁵ Some consultants use a lower figure, such as 600 mg mercury per average filling estimated by BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries; http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf

¹⁶ Deloitte et al., op. cit., p.25.

Due to the size of its population, Germany was fifth among the EU-28 in total demand for dental mercury of 2.6-3.6 tonnes, as shown in Figure 3 (with notes clarifying the data in the figure).¹⁷

Figure 3. Estimated annual demand for dental mercury in the EU28 (kg. 2018)



Notes: Despite the indication in the legend of this figure, the text of the consultant report confirms that these quantities represent only the mercury content, and not the weight of the whole amalgam. Moreover, the yellow and blue bars represent minimum and maximum estimates of dental mercury use in each country, and should not be added together as suggested in this figure. Source: Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020, p.26.

1.1.6 Releases of mercury to the environment

Even though a precise measurement of mercury releases from dental use is problematic, the health and environmental risks cannot be ignored. Mercury from dental amalgam is released to

¹⁷ Ibid., p.25.

the environment (air, water and soil) mainly through wastewater, waste disposal, leakages from dental surgeries, cremations and burials.

With regard to potential health effects, the exposure of the general population to mercury occurs mainly due to mercury accumulated in fish and through inhalation (organic mercury, methylmercury), as well as due to direct exposure to dental amalgam (elemental mercury, inorganic mercury). In addition, mercury is released from natural deterioration of amalgam fillings (chewing, brushing, etc.). Dental personnel and patients with amalgam fillings are two groups with higher measured exposure levels.¹⁸

Across the EU, it is estimated that annually approximately 5.2-9.4 tonnes of dental mercury are emitted to the air, 3.5-7.6 tonnes are discharged into the water, and 3.1-6.8 tonnes end up in solid waste and/or in groundwater. The aggregation of these estimates gives 11.8-23.8 tonnes of dental mercury that annually become bioavailable. In addition, it is estimated that annually some 15.0-32.5 tonnes of dental mercury are sequestered or recycled in the EU.¹⁹

1.1.7 Economic impacts of dental mercury releases

The value to the economy and society of phasing out the use of amalgam has already been demonstrated by a number of studies.

In particular, a study conducted for the European Commission by BIO Intelligence Service concluded that, when all environmental and socio-economic aspects are considered, phasing-out the use of dental amalgam is one of the most effective options for protecting human health and the environment.²⁰

Focusing primarily on the U.S. situation but with conclusions equally valid to the EU, an analysis by Concorde East/West Sprl demonstrated that “when the real cost (to the environment and society at large) of amalgam is accounted for, composite turns out to be significantly less costly than amalgam as a filling material.”²¹

Another economic analysis that deserves mention due to its exceptional detail is an accounting of the direct health impacts of mercury emissions from coal-fired power plants in the United States. The authors identified lifetime benefits of USD 1.1 billion per tonne of avoided atmospheric mercury emissions.²² While a direct extrapolation of those findings to the benefits of eliminating dental mercury emissions to the atmosphere should be treated with caution, it nevertheless provides an order of magnitude understanding of the large benefits of phasing out the use of amalgam. Moreover, the lifetime benefits calculated in that paper do not include a number of further benefits relevant to amalgam, such as the health and environmental benefits of avoiding mercury releases to surface waters, groundwater, solid waste and soils.

¹⁸ *Ibid.*, p.15

¹⁹ *Ibid.*, p.47

²⁰ BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries; http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf

²¹ The Real Cost of Dental Mercury, Concorde East/West Sprl for the European Environmental Bureau, the Campaign for Mercury-Free Dentistry and the Mercury Policy Project, March 2012.

²² A. Giang and N. Selin, Benefits of mercury controls for the United States, PNAS, 12 January 2016, vol. 113, no. 2, pp.286–291; www.pnas.org/cgi/doi/10.1073/pnas.1514395113.

Finally, the extensive Deloitte assessment of the feasibility of phasing-out dental amalgam recently carried out for DG Environment of the European Commission concluded that “a general phase-out is both technically and economically feasible.”²³

1.2 Minamata Convention

The Minamata Convention on Mercury was negotiated under the auspices of the United Nations Environment Programme, and is an international treaty with the overall objective to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. The agreement became binding under international law on 18 May 2017 when at least 50 states (including EU Member States) had ratified it, and it entered into force on 16 August 2017.

One of the main focuses of the Minamata Convention is to reduce the use of mercury and mercury compounds in products and manufacturing processes. The Convention also includes measures to control the supply and trade of mercury, including setting limitations on specific sources of mercury such as primary mining. Among other provisions, the Convention provides for financial and technical support to developing countries and countries with economies in transition.²⁴

Under the Minamata Convention Article 4(3) (in conjunction with Annex A, part II), the Parties to the Convention must take measures to phase down the use of dental amalgam, including two or more of the measures from the following list:

- 1) Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration;
- 2) Setting national objectives aiming at minimizing its use;
- 3) Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration;
- 4) Promoting research and development of quality mercury-free materials for dental restoration;
- 5) Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices;
- 6) Discouraging insurance policies and programs that favour dental amalgam use over mercury-free dental restoration;
- 7) Encouraging insurance policies and programs that favour the use of quality alternatives to dental amalgam for dental restoration;
- 8) Restricting the use of dental amalgam to its encapsulated form;
- 9) Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

²³ Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020.

²⁴ <http://mercuryconvention.org/Portals/11/documents/Booklets/COP1%20version/Minamata-Convention-booklet-eng-full.pdf>

1.3 EU Mercury Regulation

For the European Union, the Minamata Convention was integrated into European law via Regulation 2017/852 (the EU Mercury Regulation),²⁵ which stipulates *inter alia* for all EU Member States:

- From 1 January 2019 dental amalgam was to be used only in pre-dosed encapsulated form.
- From 1 January 2019 dental facilities were required to use and properly maintain amalgam separators in order to capture and remove from the wastewater system amalgam and teeth containing amalgam. Separators installed after 1 January 2018 need to provide a retention level of at least 95%, and from 1 January 2021 all other separators must also provide this retention level.
- Dentists must ensure that amalgam waste is managed by authorized waste management organizations.

In addition, the European Parliament and the Member States introduced some measures that went beyond those of the Convention:

- It introduced a ban (with some exceptions) on the use of dental amalgam in children under 15 years and pregnant or breastfeeding women from 1 July 2018.
- Each Member State was required by 1 July 2019 to produce a national plan detailing the measures it intended to implement to phase down the use of dental amalgam. The plan prepared by the German Federal Government is discussed in Section 1.4.
- The Commission was required to assess and report on the feasibility of a phase-out of the use of dental amalgam in the long term, and preferably by 2030, taking into account the national plans required by 1 July 2019, and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care.

1.4 German national action plan for amalgam

In response to the requirement of the EU Mercury Regulation, the German Government published its National Action Plan for the Phase-down of Dental Amalgam (Nationaler Aktionsplan der Bundesregierung zur schrittweisen Verringerung von Dentalamalgam) in July 2019. The action plan highlighted the various laws and measures already undertaken in Germany to address and reduce the impacts of dental mercury on human health and the environment. Among other information, as previously mentioned, the action plan presented some estimates of the use of amalgam vs. other filling materials in Germany, but noted that there are currently no reliable statistics. The estimates cited in the Action Plan were attributed to scattered comments and statements that failed to identify any primary source,²⁶ though these estimates were consistent with occasional consultant reports on the market shares of various dental materials sold in Germany.

²⁵ https://ec.europa.eu/environment/chemicals/mercury/regulation_en.htm

²⁶ Badzio and Hahn 2000, Kommission Umweltmedizin 2007, Staehle 2007, Wolf 2016, Bundesregierung 2018, as cited in the German National Action Plan for the Phase-down of Dental Amalgam.

New and/or reinforced measures cited in the action plan include:

- A continuation of the dental prophylaxis system geared to the principles of prevention and tooth preservation that Germany embarked on already in the 1980s, with a particular emphasis on the prevention of early childhood caries, as well as the oral health of care-dependent people and people with a migration background;
- Ensuring that the curricula of colleges and universities that train dental personnel reflect the call to reduce the use of dental amalgam, mainly via the provision of information on the use of alternative filling materials;
- Ensuring that patients are adequately informed about the options for treating cavities;
- Further minimizing the release of dental amalgam into wastewater systems;
- Monitoring the reduction in the use of amalgam by periodically collecting and publishing data on the percentage of fillings restored with amalgam.

The German National Action Plan for the Phase-down of Dental Amalgam was initially drawn up in July 2019, and was intended to be periodically updated in subsequent years.²⁷ It is anticipated that the Action Plan will be revised and updated before the end of 2020, and it is envisioned that this analysis by the IG Umwelt Zahn Medizin will feed into that new German strategy for phasing out amalgam use.

1.5 European Commission report on phasing out the use of dental amalgam

As mentioned in Section 1.3, the EU Mercury Regulation 2017/852 mandated that each Member State produce by 1 July 2019 a national plan detailing measures to phase down the use of dental amalgam. On the basis of these plans, previous reports to the European Commission²⁸ and other information, the Commission on 17 June 2020 produced a report²⁹ that explores the feasibility of completely phasing out the use of dental amalgam.

After assessing three options for a phase-out of amalgam by 2025, 2027 and 2030, the key findings of the report include:

- Dental amalgam use in the EU is decreasing, and a general phase-out (possibly including exceptions that could take account of patients with special medical needs) is both technically and economically feasible, but with some disruption of insurance systems in some Member States.
- Progressive substitution of dental amalgam with mercury-free materials is expected to continue without a policy intervention at the EU level. However, without a ban, significant amounts of dental amalgam would continue to be used, which would unnecessarily prolong the environmental and health impacts associated with the current use of dental amalgam.

²⁷ Federal Ministry of the Environment, Nature Conservation and Nuclear Safety, 10 July 2019, The German Government's National Action Plan for the Phase-down of Dental Amalgam; <https://www.bmu.de/en/download/the-german-governments-national-action-plan-for-the-phase-down-of-dental-amalgam/>

²⁸ Especially SCHER 2008 (updated 2015), SCENIHR 2008 (update 2015) and BIOIS 2012.

²⁹ Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020.

- The continuation of dental amalgam use could hinder and perhaps reduce the effectiveness of other legislation and measures that target the impacts of mercury, most notably the Water Framework Directive 2000/60/EC that classifies mercury as a priority hazardous substance, Directive 2008/105/EC that sets environmental quality standards for mercury, and the timely implementation of the Minamata Convention.

1.6 EU Medical Devices Regulation

There is ample evidence that the mercury in dental amalgams is far more toxic than any chemicals in the mercury-free alternative filling materials. The European policy regarding toxic compounds/chemicals in products is to always substitute with a less toxic material when no appropriate non-toxic material is available.

The EU Medical Devices Regulation (EU 2017/745), or MDR, comprises a uniform regulation for the marketing of medical devices, with a particular focus on product quality and safety. In general, the technical documentation of a medical device must demonstrate that it is in conformance with the basic safety and performance requirements of the MDR. For Class IIa products (including dental filling materials), the technical documentation must comply fully with the requirements of the “notified body.”³⁰

If the manufacturer of a medical device has a current “approval,” this remains valid as long as the certificate of the notified body was issued on or before 25 May 2021. However, its validity ends at the latest on 27 May 2025 (this is the new date established due to the coronavirus), even if the validity date on the certificate may be later than 27 May 2025.

From 27 May 2025, therefore, specific proof of the biocompatibility of dental filling materials will be required, in conformity with EU regulations. Special requirements apply both for the approval and for the labelling of fillings containing substances that are carcinogenic, mutagenic, or toxic for reproduction (CMR). Dental amalgam was not required to meet these requirements in the past, and there is strong reason to believe that dental amalgam will not be able to meet them after 27 May 2025.

With the introduction of the Medical Devices Regulation, the approval, labelling and safety of mercury-free filling materials will also be further ensured.

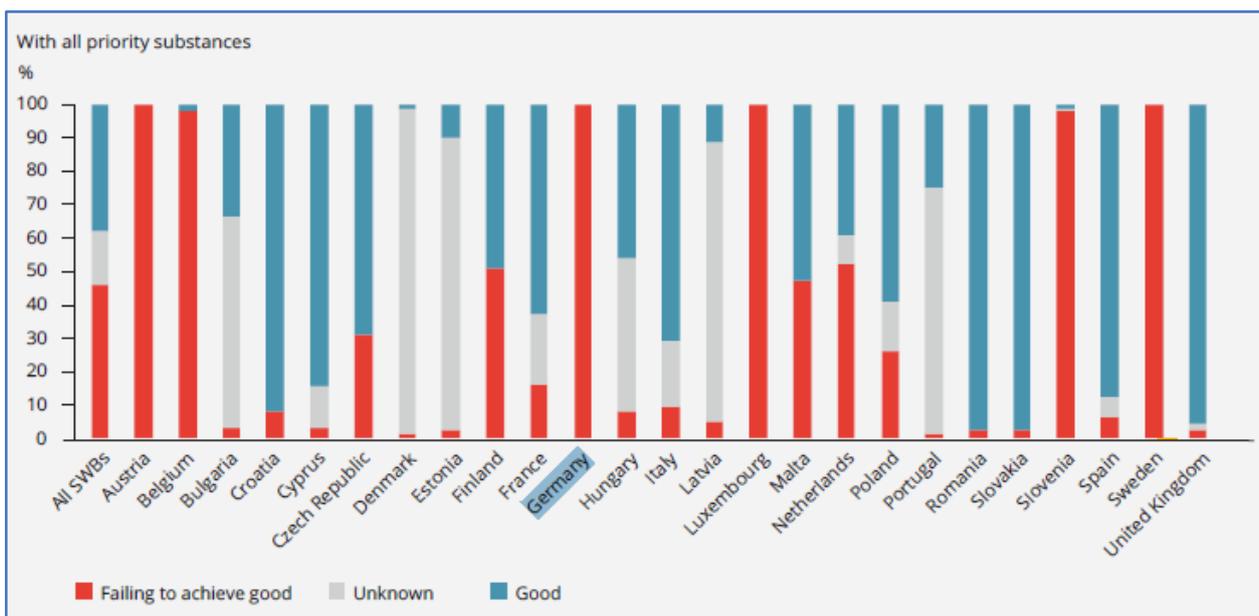
1.7 EU Water Framework Directive

The provisions of the Water Framework Directive (2000/60/EC) and the Environmental Quality Standards Directive (2013/39/EU) are increasingly mainstreamed into sectoral policies requiring further emission reductions. The Water Framework Directive identifies mercury as a Priority Hazardous Substance. The Environmental Quality Standards Directive sets a maximum allowable concentration for mercury in surface water bodies at 0.07 µg/l.

³⁰ A notified body is an organisation designated to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required.

38% of the surface water bodies in the EU meet environmental quality standards (EQSs)³¹ and are therefore in “good chemical status,” while 46% do not achieve good chemical status and 16% have unknown chemical status. In most Member States, a few priority substances account for the poor quality of surface waters, the most common being mercury. Several Member States, including Germany, failed to achieve good chemical status for any of the monitored waterbodies, and therefore extrapolated those results to most of their other surface water bodies, as seen in Figure 4 below. The main pathways leading to failure to achieve good chemical status are atmospheric deposition and discharges from urban wastewater treatment plants, both of which are sources of mercury.³²

Figure 4. Chemical status of all surface water bodies, including ubiquitous, persistent, bioaccumulative and toxic (uPBT) substances



Note: uPBT substances are mercury, polybrominated diphenyl ethers (pBDEs), tributyltin and certain polyaromatic hydrocarbons (PAHs)

³¹ Established in the Environmental Quality Standards Directive 2008/105/EC (as amended by the Priority Substances Directive 2013/39/EU).

³² EEA (2018) European waters. Assessment of status and pressures 2018. Report No 7/2018. <https://www.eea.europa.eu/publications/state-of-water>

2 The German public health insurance companies

The main German public health insurance companies, by number of insured members, are shown in Table 1. There are many others, but these eight account for over half of the population.

Table 1. The main German public health insurance companies in 2019

VERSICHERTE DER GESETZLICHEN KRANKENKASSE 2019		
Krankenkasse	Versicherte	Stand
Techniker Krankenkasse (TK)	10.663.500	01.06.2020
BARMER	8.969.500	01.03.2020
DAK Gesundheit	5.600.000	01.03.2020
AOK Bayern	4.563.000	01.02.2020
AOK Baden-Württemberg	4.508.600	01.03.2020
AOK PLUS	3.368.000	01.03.2020
IKK classic	3.129.100	01.04.2020
AOK Rheinland/Hamburg	3.038.100	01.03.2020

2.1 Financial status

The health insurance system in Germany is currently quite healthy. According to the German Federal Government, the statutory health insurance funds achieved considerable revenue surplus in 2016-2018 and were able to increase their operating funds and reserves to a total of around EUR 21 billion by the end of 2018/2019. The health fund also had a liquidity reserve of around EUR 9.7 billion as of 15 January 2019, as shown in Figure 5.

In explaining the surplus, the Federal Government points to savings due to quality improvements, efficiency gains, the avoidance of sickness and the subsequent avoidance of related healthcare costs. In view of the dynamic revenue growth as compared with the quite moderate increases in expenditure in recent years, it is evident that one can improve the quality of care and reduce costs at the same time. There is reason to believe that this formula can be applied as well to the phase-out of amalgam use.

Figure 5. Evolution of surpluses and reserves of the statutory health insurance funds

1D Finanzreserven von GKV und Gesundheitsfonds



Source: KZBV Yearbook 2019.

2.2 Share of expenses for dental fillings

Figure 6 summarizes the public insurance reimbursements for different categories of dental services in Germany in 2018.

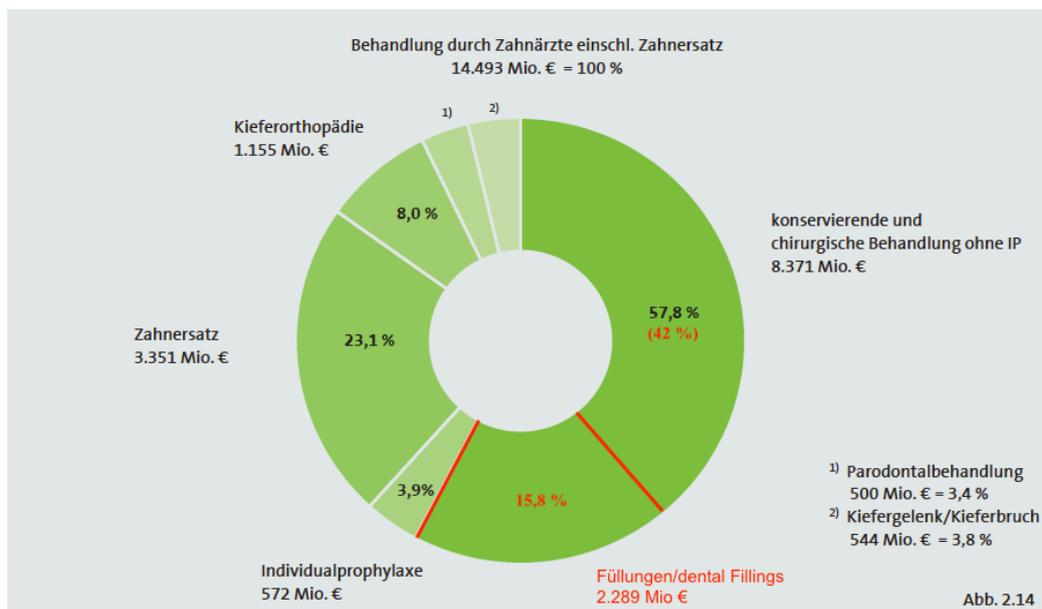
The category for dental restoration and surgical treatment (EUR 8.371 billion in reimbursements) in Figure 6 is further divided into the following sub-categories:

- **fillings** (25.6% of the “restoration and surgical treatment” category)
- examination/consultation (20.2%)
- endodontic services (7.7%)
- tartar removal (6.7%)
- X-rays (6.5%)
- anaesthesia (5.8%)
- IP/FU (5.8%)
- extractions (5.1%)
- local medical treatment/smoothing of tooth edges (3.9%)

Therefore, fillings comprised 25.6% of the “restoration and surgical treatment” category, and about 15.8% (EUR 2.289 Mio) of all public insurance reimbursements for dental services in 2018. Note that the public insurance reimbursements are less than the full cost of dental services, for which we don’t have firm data.

Figure 6. Public insurance reimbursements for dental services in Germany (2018)

GKV: Aufteilung der Ausgaben für zahnärztliche Behandlung 2018 – Deutschland



Source: KZBV Yearbook 2019, with the section for fillings separately calculated and added.

The volume (2018) and evolution (2004-2018) of public insurance reimbursements for these subcategories of dental services are summarized in Figure 7 below. It is worth noting that reimbursements for fillings have declined by nearly 22% during this period of time, ostensibly due to improved preventive dental hygiene.

As further described below, public insurance reimburses some or all of the cost of about 90% of all dental fillings in Germany, and the remaining 10% are covered by private insurance.

2.3 Structure of public health insurance in Germany

The structure and functioning of the public health insurance system in Germany is complex. The main parts of that system that apply to dental services are explained below.

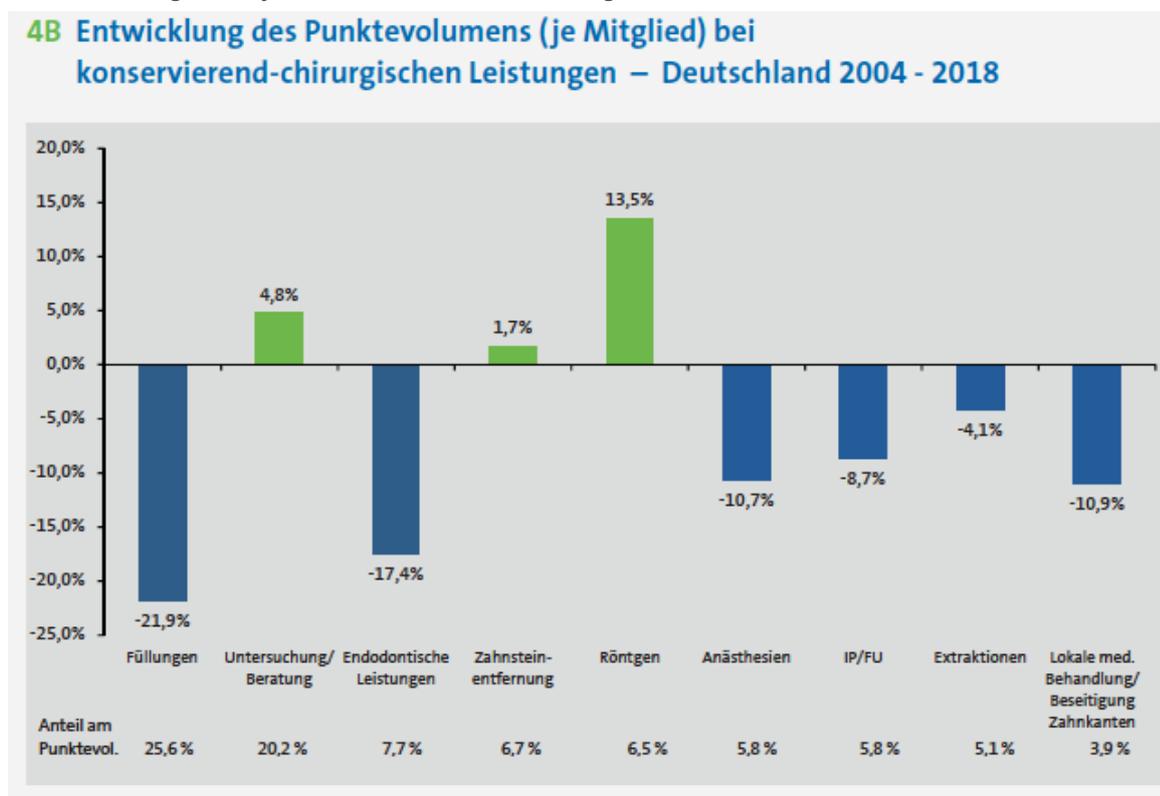
2.3.1 The BEMA – “Bewertungsmaßstab für zahnärztliche Leistungen”

The statutory health insurance companies calculate and base all dental insurance reimbursements on the Bewertungsmaßstab für zahnärztliche Leistungen (BEMA).³³ The BEMA schedule includes all dental services that are at least partially covered by the statutory health insurance funds. It includes not only material costs, but also determines the dentists' fees for the individual treatments. Although some of the broad range of dental treatments are not covered by public insurance, the BEMA subsidizes all medically necessary treatments (“basic care”) for persons insured by the statutory health insurance scheme. It should be mentioned that the reimbursements for one- to three-surface composite filling materials were fixed in 1996, and since that time the evolution of old filling materials and

³³ BEMA, Einheitlicher Bewertungsmaßstab für zahnärztliche Leistungsgemäß § 87 Abs. 2 und 2h SGB V; file:///Users/florianschulze/Downloads/BEMA_20190701-4.pdf

development of new materials have not been formally integrated into the reimbursement schedule, other than a new rate for multilayer fillings in 2018.

Figure 7. Volume (2018) and evolution (2004-18) of German public insurance reimbursements for various categories of dental restorations and surgical treatments



Source: KZBV Yearbook 2019.

The rules and regulations are laid down by a joint committee (Gemeinsamer Bundesausschuss) comprising the KZBV (National Association of Statutory Health Insurance Dentists) and the umbrella organisation of the statutory health insurances (GKV-Spitzenverband). The services included in “basic care” are scientifically reviewed in order to confirm that they are necessary and appropriate.

The reimbursement rates themselves are negotiated and decided in the Valuation Committee (Bewertungsausschuss), whose members are also drawn from the KZBV and the GKV central association.

Regulations under the German Social Security Code ensure that all patients can decide for themselves, for example in the case of filling materials and dental prostheses, which treatment option they prefer after discussion with the dentist. Generally, patients with statutory health insurance can opt for services not included in the service catalogue of their health insurance company, but retain their right to public insurance benefits and only have to bear the additional costs incurred beyond those normally reimbursed by their own health insurance company. All such additional costs are based on an agreement under private law. Starting in 1996, dentists were permitted to invoice any such extra services to the patient in

accordance with regulations under the Gebührenordnung für Zahnärzte (GOZ), the German fee schedule for dentists.³⁴

2.3.2 The GOZ – “Gebührenordnung für Zahnärzte”

The Gebührenordnung für Zahnärzte (Catalogue of Dental Fees), or GOZ,³⁵ which is regulated by the Federal Government, is a catalogue of fee guidelines for a large range of treatments, including treatments that are not covered by the statutory scheme. The GOZ also includes dentist fees. In contrast to the BEMA, however, the GOZ rates do not always include all material costs, in which case these additional consumables may be invoiced separately.

With the GOZ, the time required and degree of difficulty of a treatment are included in the fee guideline, and are reflected in a multiplier of between 1 and 3.5. The 2.3-fold multiplier is considered the standard for private billing. A higher multiplier is relatively common, however, and a lower multiplier is relatively rare.

The fees for dental fillings were last revised on 5 December 2011. Fee guidelines for dentin-adhesive reconstructions such as composites, which were previously included with the fee guidelines for inlays, were added to the GOZ. At the same time the previous fees for inlays were significantly increased and adapted to such procedures as CAD/CAM ceramic inlays.³⁶

When fillings are invoiced according to GOZ items 2050 to 2120, additional fees can be charged for a number of related services such as conserving the exposed vital pulp or removing sharp edges of fillings.³⁷

2.3.3 Additional fee agreements

As mentioned above, for a basic treatment according to GOZ, it is normal to multiply the standard fee by a factor of 2.3. For difficult treatments the factor may be as high as 3.5, and in exceptional cases even higher. If a factor greater than 3.5 is warranted, however, the dentist must also obtain a fee agreement with the patient in advance in accordance with GOZ § 2 paragraphs 1, 2 and 3. Factors as high as 8.2 are sometimes applied. The German

³⁴ <https://www.kzbv.de/kzbv-schnittstellen-bemagoz.media.47f31ca2b4a7aeee25e3aae885d0d766.pdf>

³⁵ Gebührenordnung für Zahnärzte (GOZ) Stand 5 Dezember 2011; file:///Users/florianschulze/Downloads/gebuehrenordnung_fuer_zahnaerzte_2012-5.pdf

³⁶ © BLZK, Referat Honorierungssysteme Gebührenordnung für Zahnärzte, Vergleich GOZ 1988 und Erste Verordnung zur Änderung der Gebührenordnung für Zahnärzte(GOZ)vom 5 Dezember 2011, [https://www.blzk.de/blzk/site.nsf/gfx/goz_vergleich_1988_2012_blzk.pdf/\\$file/goz_vergleich_1988_2012_blzk.pdf](https://www.blzk.de/blzk/site.nsf/gfx/goz_vergleich_1988_2012_blzk.pdf/$file/goz_vergleich_1988_2012_blzk.pdf)

³⁷ Gebührenordnung für Zahnärzte, Kommentar der Bundeszahnärztekammer in Zusammenarbeit mit den (Landes-)Zahnärztekammern Aktualisierter Stand Oktober 2018; <https://www.bzaek.de/fileadmin/PDFs/goz/nov/goz-kommentar-bzaek.pdf>

Dentists' Association has published on its website a ruling with regard to the use of such high factors, which is roughly translated below:³⁸

*A fee agreement based on the **8.2-fold multiplier** may be appropriate as long as it relates to the quality of the dental services provided. A justification of such a high multiplier is not a prerequisite for the agreement to be effective.*

*In proceedings in 2015, the Regional Court of Duisburg determined that a multiplier **higher than 3.5 is in line with the GOZ** because a dentist does not necessarily have to orient his practice operations towards cost-effective treatment, but may also endeavour to guarantee the best possible standard of current dental science through the precision and quality of his services (Regional Court of Duisburg, loc. cit.).*

2.3.4 Arrangements for patients with low income

All German citizens and legal residents are obliged to have health insurance. 90% of all citizens and legal residents claim statutory health insurance, with contributions divided between employers and employees. The other 10% have private insurance.

Unemployed persons who are entitled to social benefits (Hartz IV), recipients of student assistance (BAföG), social welfare recipients, veterans and those qualifying as low-income persons or qualifying for basic old-age security are entitled to free statutory health insurance and thus free basic dental care.

Qualified low-income individuals are also eligible for full reimbursement of prostheses. In 2020 the low-income limit for monthly gross income is set at EUR 1,274. With one dependent in the same household, this limit increases to EUR 1,751.75, and for each additional dependent by another EUR 318.50. "Dependents" in this case are defined as spouses and same-sex partners in accordance with the German Civil Partnership Act (Lebenspartnerschaftsgesetz), as well as children insured under family insurance.³⁹

In the case of basic dental prostheses, all patients not qualifying for free treatment are subsidized at 50% of the cost, with additional possible bonus reimbursements of 20% or 30% of the cost for those who can prove that they have regularly received preventive dental check-ups over five or ten years, respectively. The increased percentage for the bonus is based on a new regulation and takes effect on 1 October 2020 (see section 2.5.) It is possible that a similar bonus system could be applied to reimbursements for large fillings, but that may simply encourage dentists to increase their private billing.

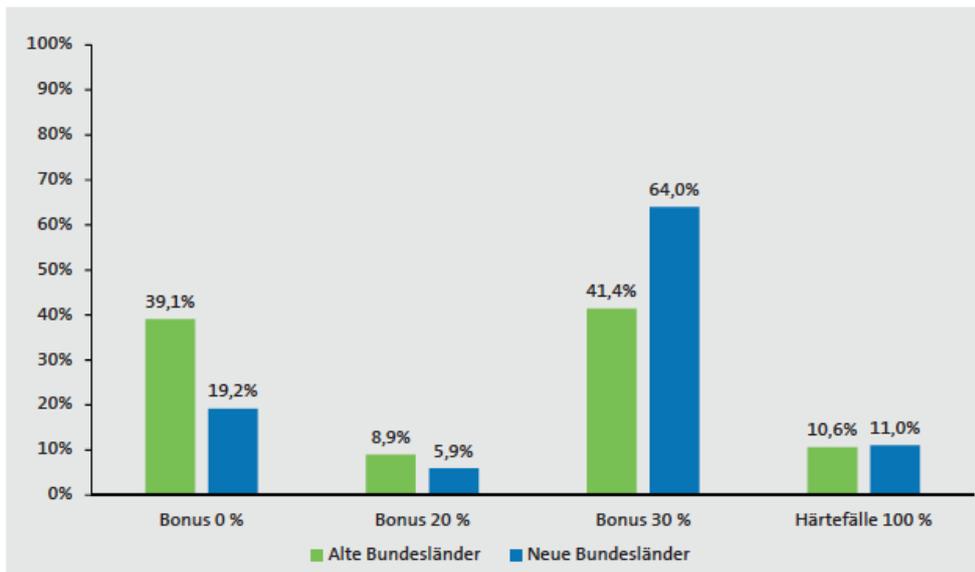
³⁸ Bundeszahnärztekammer, Adequacy of fee agreements, 25 June 2015; <https://www.bzaek.de/goz/urteiledatenbank-goz/urteil/angemessenheit-von-honorarvereinbarungen.html>; and Requirements for an effective fee agreement, 12 October 2017; <https://www.bzaek.de/goz/urteiledatenbank-goz/urteil/anforderungen-an-eine-wirksame-honorarvereinbarung.html>

³⁹ Verbraucherzentrale, Kostenfalle Zahn, Härtefallregelung beim Zahnersatz, Stand 19 February 2020; <https://www.kostenfalle-zahn.de/projekt-kostenfalle-zahn/zahnersatz/haertefallregelung-beim-zahnersatz-12887>

Figure 8 below shows the difference between the old and new Länder with regard to persons getting regular preventive dental check-ups. Only 50% of patients from the old Federal states benefit from the 20% and 30% bonuses as compared with 70% from the new Federal states, suggesting that the latter tend to visit healthcare professionals more regularly.

Figure 8. Differences between patients from old and new Federal states in qualifying for bonuses linked to regular preventive care

4D Aufteilung der über die KZVen abgerechneten Zahnersatzfälle nach Zuschuss-Bonusgruppen – Alte Bundesländer/Neue Bundesländer



Source: KZBV Yearbook 2019.

2.3.5 Supplementary insurance

At the end of 2016, around 15.4 million people (16.6% of those with statutory health insurance) across Germany had supplementary dental insurance. This amounted to a fourfold increase since 2000 and probably reflects common concerns about major dental expenses such as for prostheses. The 2014 household survey of the Federal Statistical Office showed that nearly half of the respondents skipped an otherwise necessary visit to the dentist for financial reasons.⁴⁰

2.4 Effective and efficient dental care

According to the International Dental Federation (FDI), the safety of the patient and the quality of care are dentists' primary concerns. For the public health insurance system, cost is also a key factor, although the system has already demonstrated that reducing costs and improving the quality of care are perfectly compatible. High-quality care and durable dental

⁴⁰ Federal Statistical Office, Household Survey "Living in Europe" (2014), p. 39. https://www.destatis.de/DE/Publikationen/Thematisch/EinkommenKonsumLebensbedingungen/LebeninEuropa/EinkommenLebensbedingungen2150300147004.pdf?__blob=publicationFile

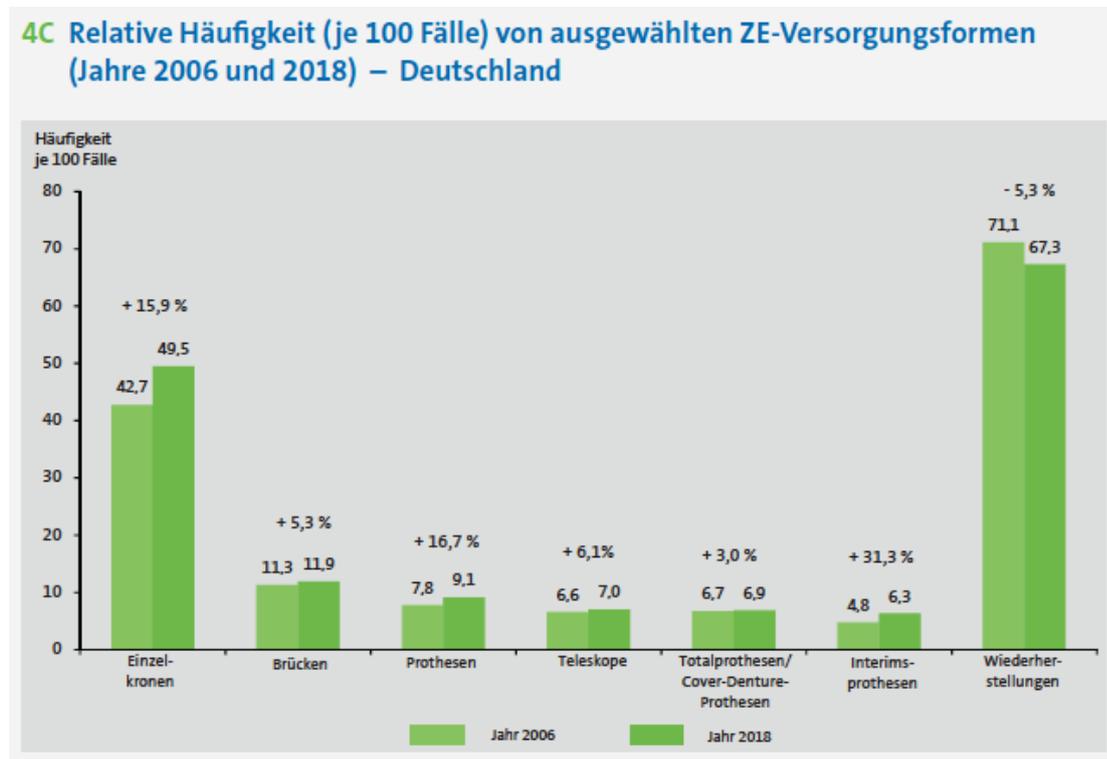
fillings and prostheses reduce the need for return visits and repairs to previously placed fillings and dentures.

2.4.1 Proper incentives

A common problem in dentistry, as in the health care system in general, is that a higher standard of care is not necessarily recognized or rewarded by the healthcare system, while practices with more patients and repeat or follow-up treatment tend to be better rewarded financially.

Although there are no similar data available for repairs to fillings, the last column of Figure 9 below shows a large number of procedures devoted to denture repairs. It is beyond the scope of this analysis to further explore the data on dentures, so we have no explanation for this at present. Nevertheless any incentives that might improve the quality of treatment should be welcomed.

Figure 9. Evolution of public health insurance reimbursements for dental prostheses (2006-18)



Source: KZBV Yearbook 2019.

According to a recent study by the consumer advice centre, many patients felt that certain dental treatments were unnecessary and/or too expensive.⁴¹ According to a review of the Bertelsmann Stiftung's "Weisse Liste" portal 2015, only 62.2% of patients said that their dentist explained the private part of the bill in an understandable way.⁴² According to an assessment of patient concerns in the state dental chambers and associations of statutory

⁴¹ Position paper, The Consumer Advice Centre of North Rhine-Westphalia on the dentistry market, North Rhine-Westphalia Consumer Advice Centre e.V., 13 March 2018.

⁴² Health Spotlight 06/2015, Dentist Reviews. <https://www.bertelsmann-stiftung.de/de/unsere-projekte/weisse-liste/projektnachrichten/spotlight-gesundheit-zahnarztbewertungen/>

health insurance dentists in 2016, cost and legal issues were by far the greatest areas of concern, with the main focus on checking the legality of financial claims and the permissibility of private billing.⁴³ The recommendation of the advice centre was to provide better access to a second opinion about proposed treatments and costs, especially for prostheses.

2.4.2 Quality of care

For preventive, effective and efficient care in dentistry, there is a range of scientific institutions, committees and programs that may be called upon to improve the overall quality of care. They should be given a more active role in the transition to mercury-free dentistry, such is the assessment of what a fair cost for basic fillings should be, or in shaping the future of dental care in Germany. At the same time, the independence and objectivity of the experts engaged in such decisions is critical.

2.4.2.1 Centre for Dental Quality (ZZQ)

The Centre for Dental Quality (ZZQ) is a joint institution of the National Association of Statutory Health Insurance Dentists (KZBV) and the German Dental Association (BZÄK). It was founded in 2000 to support its members in connection with the quality assurance of dental treatments.

2.4.2.2 Institute for Quality and Efficiency in Health Care

The Institute for Quality and Efficiency in Health Care (IQWiG) was established in 2004 by the Federal Joint Committee (G-BA) as a private foundation. IQWiG supports the G-BA in fulfilling its statutory tasks by providing scientific, evidence-based expert opinions.

2.4.2.3 Institute for Quality Assurance and Transparency in Health Care

The independent Institute for Quality Assurance and Transparency in Health Care (IQTiG) was commissioned by the Federal Joint Committee to develop measures for quality assurance and methods to ensure the quality of care in the healthcare system from 2016 onwards, and to participate in their implementation.

2.4.2.4 Continuing dental education

Although all dentists are already obliged to undergo further training under professional law, in 2004 the legislator also obliged professional dentists to undergo further training in the Social Code Book (§ 95 d SGB V). According to this regulation, every professional dentist is obliged to undergo regular professional training, and every five years the dentist must prove to the Association of Statutory Health Insurance Dentists (KZV) responsible for him or her that the dentist has fulfilled this obligation during the past five years.

⁴³ Dental patient consultation, Annual Report 2016, pp. 22-31, http://www.patientenberatung-der-zahnaerzte.de/fileadmin/content/jahresbericht_patientenberatung_2016.pdf

2.4.3 Quality assurance and imaging systems

The KZBV and the statutory health insurance funds have agreed with on an appraisal system. Experts appointed by the health insurance companies and KZVs can review prosthetic, orthodontic and periodontological treatment plans in advance. In addition, they evaluate the quality of treatment in case of suspected problems.

2.4.3.1 Importance of X-rays for quality assurance

If treatment errors are suspected, in compliance with the guidelines of the health insurance companies, the first thing that is usually requested are X-rays from before and after the treatment. In addition, patients are better able to obtain a second opinion with these records.

Digital X-ray systems are increasingly replacing X-ray images, making "classic" X-ray chemistry unnecessary. In the future, artificial intelligence-based programs will increasingly support the dentist in the analysis of X-ray and other diagnostic image files.

2.4.3.2 Need for more transparency about filling materials

As stated in the Federal Government's National Action Plan for the Phase-down of Dental Amalgam, there are no reliable data on the frequency of amalgam use in Germany. In support of the targeted data collection required in 2020,⁴⁴ and in the interest of consumers and health insurers, it is anticipated that dentists will need to specify (in a field to be created on the existing forms) the filling materials or material category used when invoicing for fillings.

2.4.3.3 Importance of quality inspections and reporting

Since the second half of 2019, legally required quality inspections have been carried out nationwide. The associations of statutory health insurance dentists (KZVs) are obliged to check the quality of the services provided through professional dental care on a case-by-case basis using selected random samples. As the KZVs were obliged to submit their most recent reports by the end of April 2020, the quality inspections of dental practices had to be carried out well before that date.⁴⁵

2.4.4 Incentives for improved dental care

Among others, two important incentives for improved dental care that should be further discussed are guarantees and bonus booklets.

⁴⁴ Federal Ministry of the Environment, Nature Conservation and Nuclear Safety, 10 July 2019, The German Government's National Action Plan for the Phase-down of Dental Amalgam; <https://www.bmu.de/en/download/the-german-governments-national-action-plan-for-the-phase-down-of-dental-amalgam/>

⁴⁵ KZBV, Zahnärztliche Qualitätsförderung; <https://www.kzbv.de/zahnaerztliche-qualitaetspruefungen.1298.de.html>

2.4.4.1 Guarantees

Dentists are legally liable for defects in fillings and dentures (§136a para. 4 SGB V). This effectively provides a two-year warranty that one- and two-surface fillings and dentures are to be repaired or replaced free of charge, provided the patient is not at fault for the defect.⁴⁶ Dentists are free to give longer guarantees for fillings or prostheses, but this is rare in practice.

2.4.4.2 Bonus booklets

As described further below, bonuses for dental prostheses are available to policyholders who can prove that they have had regular preventive dental check-ups for the last five or ten years. This incentive for regular visits to the dentist, which could be extended to basic, fully reimbursed fillings, not only contributes to better oral hygiene, which reduces the number of subsequent treatments and insurance reimbursements, but also contributes to the quality of dental care.

2.5 Recent regulatory changes and budgets

The statutory health insurance scheme reported reserves of over EUR 20 billion after the first half of 2019. This corresponds to approximately one month of expenditures and is thus about four times the legally required minimum reserve.⁴⁷

In March 2019 the Appointment Service and Care Act (Terminservice- und Versorgungsgesetz, or TSVG) was passed, and came into force on 11 May 2019. In line with these new regulations, an additional EUR 570 million are to be allocated to treatments for dental prostheses as of 1 October 2020, which is a 17% increase over the total EUR 3.351 billion reimbursements made in 2018. The statutory reimbursements for dental prostheses will be increased from currently 50% to 60%. In addition, bonus reimbursements to policyholders who can prove that they have regularly had preventive dental check-ups for the last five or ten years will rise from 60% and 65% to 70% and 75% respectively.

In light of the healthy financial situation of the statutory health insurance scheme, an added EUR 200-330 million to the scheme's budget to support the transition to mercury-free fillings in Germany should not be out of the question. This is the range of added cost that would cover any of the three options presented in Sections 4, 5 and 6. To put that increase in perspective, it is roughly 10-15% of the 2.3 billion reimbursed specifically for fillings in 2018, and only 2-4% of the EUR 8.4 billion reimbursed for related restoration and surgical services.

⁴⁶ Bundesmantelvertrag, Anlage 13, Beschluss des Bundesschiedsamtes für die vertragszahnärztliche Versorgung vom 13 Dezember 1993 zur Gewährleistung bei Füllungen und Zahnersatz.

⁴⁷ <https://www.bundesgesundheitsministerium.de/presse/pressemitteilungen/2019/3-quartal/finanzergebnisse-20191.html>

3 The dental association and dental professionals

3.1 Status and commitments of dental professionals

The dentist is a key member of the public health service, which operates on the premise that the public has a legal right to basic “free” healthcare, i.e., paid for by society at large. The dentist therefore has a contract with society, but at the same time often operates as an independent business person who therefore needs a level of entrepreneurial freedom. These separate roles can be complementary in some ways but also conflicting in others.

It is not within the scope of this analysis to suggest how all such conflicts might be avoided, but it is important to point out that the imminent ban on the use of amalgam could put a spotlight on the dentist’s role in society, and reopen the debate on the dentist’s role and possible changes in that role. Many professions are dealing with similar issues as a result of technical progress, etc., and such discussions should be welcomed as opportunities to anticipate and plan for the future rather than to simply react to whatever changes may come. These concerns are unfortunately not addressed in the German dentists’ mission statement of 2015:

“The future of the dental profession requires a framework that enables dentists to make diagnostic and therapeutic decisions based on their dental expertise and for the benefit of patients and society. He [or she] needs planning security and entrepreneurial freedom. Compliance with ethical medical principles is an essential prerequisite for this. In doing so, the dentist binds himself [or herself] to public-law obligations by his [or her] own will and thus assumes responsibility for the social challenges. He or she fulfils important tasks related to the common good. He [or she] is neither an official nor a representative of the statutory health insurance companies. He [or she] is an important part of the middle class and ensures growth, training and employment in Germany. The promotion of quality requires appropriate personnel and organizational structures as well as appropriate remuneration. The rationing of resources is detrimental to quality promotion. Concepts that aim to improve the quality of care by means of financial incentives are the wrong way to go.”⁴⁸

Having received authorization to provide professional dental care, the dentist undertakes to treat those insured by the statutory health insurance (GKV) according to the agreed schedule of treatments and reimbursements. The reimbursements provided by the statutory health insurance are subject to the limits set in accordance with § 12 of the Social Security Code, Book 5 (SGB V), according to which the treatments should be sufficient, appropriate and economical, i.e., they should not go beyond what is necessary.⁴⁹

⁴⁸ Mission statement of the German Dentists' Association, the German Society for Dentistry, Oral and Maxillofacial Surgery, and the National Association of Statutory Health Insurance Dentists 2015; file:///Users/florianschulze/Downloads/KZBV-BZAEK_Leitbild_2015_web-1.pdf

⁴⁹ <https://www.kzbv.de/kzbv-schnittstellen-bemagoz.media.47f31ca2b4a7ae25e3aae885d0d766.pdf>

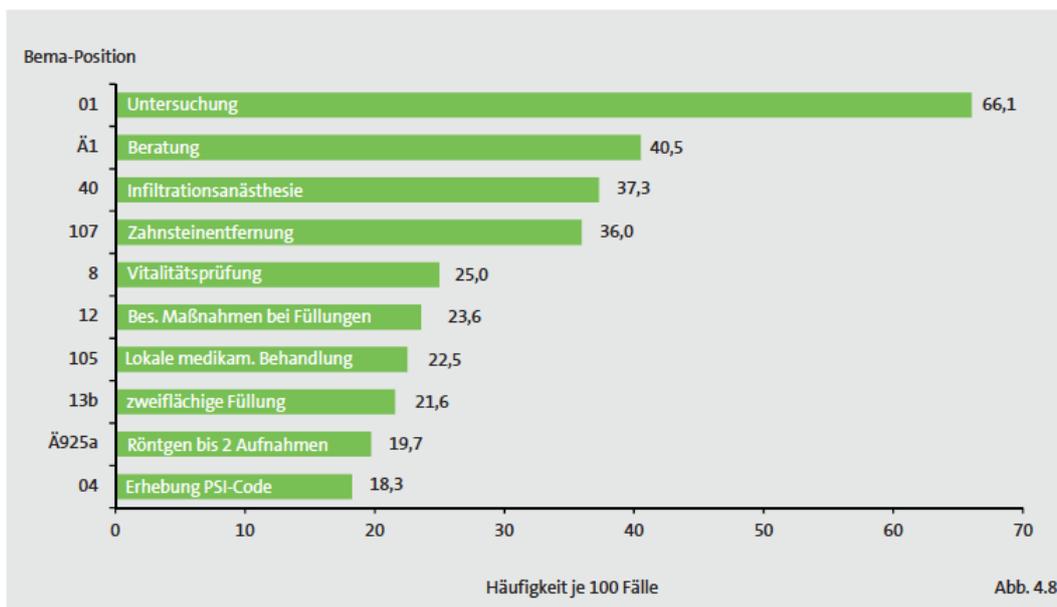
3.2 Private services vs. public insurance coverage

The most common dental restoration and surgical treatments for dental clinics in 2018 are shown in Figure 10 below, and account for the highest share of turnover for dental practices. Most of these treatments involve private invoicing and are related to treatments for dental fillings (49.7 million statutory insurance reimbursements in 2018) and prosthetics (8.9 million statutory insurance reimbursements in 2018). Other treatments contributing significantly to total dental clinic fees in 2018, according to the GOZ, are examinations and consultations, and professional dental cleaning.

Figure 10. The most common restoration and surgical treatments for dental clinics in Germany (2018)

Source: KZBV Yearbook 2019

Positionen mit den höchsten relativen Häufigkeiten im Bereich kons./chir. Behandlung 2018 – Deutschland



Since private fees comprise such a large part of the turnover of dental clinics, it may be assumed that these fees (and the private insurance market) will suffer if amalgam is phased out and composites are fully reimbursed. This is why it may be important in the post-amalgam era for dentists to retain the option of private billing for extra services related to fillings, such as multi-layered materials or ceramic inlays.

It is also interesting that the share of private dental services in the old federal states (ABL) is far higher than the private share observed in the newly-formed German states (NBL). The combined turnover of all German dental clinics may be divided into a public health insurance share of 47,8% in the ABL (and 63,5% in the NBL) and a private share of 52% in the ABL (and 36,5% in the NBL).⁵⁰ This suggests that a significantly higher percentage of patients in the ABL have agreed to pay more for dental services than those in the NBL. This could be due to the better financial situation of patients in the ABL, a higher demand in the ABL for extra services such as aesthetic fillings, or a number of other reasons.

⁵⁰ KZBV Yearbook 2018, Steuerliche Einnahmen-Überschussrechnung je Inhaber 2015 und 2016; <https://www.kzbv.de/kzbv-jahrbuch-2018.media.21f2fd08cc7dbf0c07422eb110f022ea.pdf>

3.3 A call for higher fee rates

In an article in the ZM 2019,⁵¹ Dr. Wolfgang Menke, President of the Bremen Dental Association and Chairman of the Committee for Fee Law of the German Dental Association, called for the standard 2.3 multiplier (discussed in section 2.3.2 of the text) to no longer be routinely used. The full range of multipliers from 1.0 to 3.5 times the basic fee rate could thus be invoiced by dentists without restriction. In other words, Dr. Menke proposed ignoring the previous standard 2.3 multiplier and exceeding it when convenient, even if the difficulty, time or circumstances of a treatment did not warrant a higher multiplier.

Dr. Wolfgang Menke further referred to the time required for various treatments and included a table of fees in which he assumed a target turnover of about EUR 274 per hour for a typical clinic owner or partner⁵² (2015/2016 data, regularly updated by consultant Prognos AG), suggesting that such a turnover is necessary for the success of an average dental clinic.

According to GOZ Statistics, in 2018 the average multipliers used for private invoices for fillings were significantly higher than the standard 2.3. But the GOZ Statistics represented only patients with full private insurance coverage (only about 10% of all patients), where the multiplier must be justified for each treatment, and where some treatments are limited to the standard 2.3 multiplier.

For patients covered by the public health insurance, there are no statistics about the average multipliers used for various treatments, and any elevated rates rely entirely on the agreement with the patient. In the past the dentist was obliged to justify using a multiplier higher than 2.3, but more recently a higher multiplier is more easily justified and may be used by some dentists simply to increase turnover or to cover unrelated expenses.

3.4 Dental practice revenues and private billing

The average annual turnover of the 51,956 independent dental practice owners is around EUR 40,000 per month, depending on whether lab fees are included. One consultant pointed out that private invoicing has become particularly important to overall profitability. They claimed that if a dental practice has less than 50% private contribution to turnover, it can be successful only by engaging with more patients, seeing the same patients more often, or invoicing more per patient than clinics with more than 50% private contribution to turnover.⁵³

The real value of dental practice owner profits declined from the late 1970s to the mid-1990s. Private billing was authorized in 1996,⁵⁴ and turnover and profitability stabilized to some extent, but it was only from about 2005 that turnover trended consistently upward. Between 2005 and

⁵¹ <https://www.zm-online.de/archiv/2019/18/politik/23-fachen-satz-nicht-universell-verwenden/>

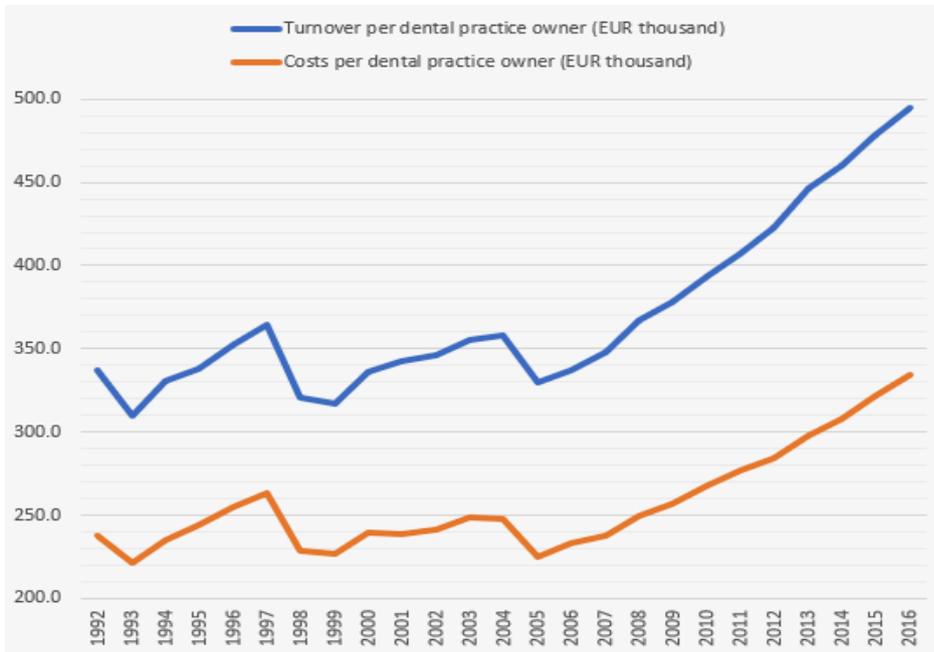
⁵² There may be several owners for any given clinic.

⁵³ <https://www.praxisgruendungen.de/umsatz-einer-zahnarztpraxis/>

⁵⁴ In 1996 an additional cost regulation (i.e., private billing) for tooth preservation was implemented analogous to the already existing additional cost regulation for dental prostheses. Thus persons insured by the statutory health insurance who choose filling alternatives (e.g. ceramic or gold inlays) that go beyond the basic guidelines must bear the additional costs themselves. This was based on a legislative resolution of the German Bundestag in the GKV-Anpassungsgesetz of 19 May 1994 (BR-Drucksache 466/94), which was initially rejected by the Bundesrat, and a petition resolution of the German Bundestag of 29 June 1995.

2016 the increase in average turnover per dentistry owner was 50% and the increase in average profitability was 52%, as summarized in Figure 11, Figure 12 and Table 2 below. This analysis did not attempt to identify the reasons for these increases, which could be due to increased efficiencies derived from ever better restoration materials, increased private billing for modern materials and techniques, ancillary services, etc.

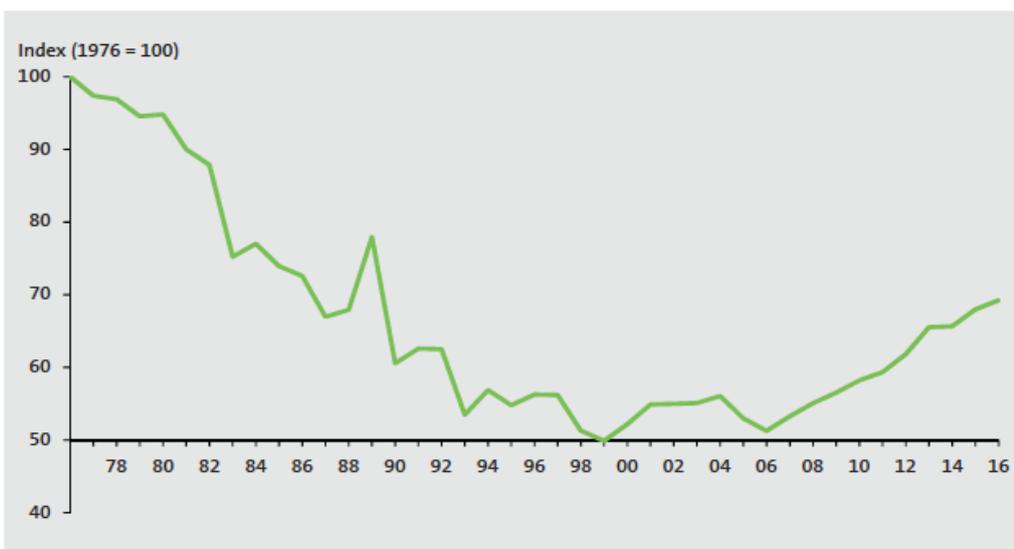
Figure 11. Evolution of turnover and costs per dental practice owner (1992-2016)



Source: Table 2

Figure 12. Evolution of the real value of dental practice profits in the old federal states

**5A Realwertentwicklung des Einnahmen-Überschusses je Praxisinhaber
1976 - 2016 – Alte Bundesländer**



Source: KZBV Yearbook 2019 (<https://www.kzbv.de/kzbv-jahrbuch-2019.media.381dcb7f99745a1edf1e2c179a5624b3.pdf>)

Table 2. Turnover, costs and profits of the average dental clinic owner, 1992-2016

Steuerliche Einnahmen-Überschussrechnung je Praxisinhaber 1992 bis 2016 – Deutschland

Jahr	Umsatz (aus selbst. zahnärztl. Tätigkeit) in €	Verän- derung in %	Kosten (=steuerliche Betriebs- ausgaben) in €	Verän- derung in %	Anteil am Umsatz in %	Umsatz minus Kosten (=steuerlicher Einnahmen- Überschuss) in €	Verän- derung in %	Median des Einnahmen- Überschusses in € bei
Deutschland								
1992	336.715	+ 19,5	237.836	+ 21,9	70,6	98.879	+ 14,1	87.050
1993	309.265	- 8,2	221.270	- 7,0	71,5	87.995	- 11,0	74.840
1994	330.285	+ 6,8	234.598	+ 6,0	71,0	95.687	+ 8,7	82.680
1995	337.691	+ 2,2	244.104	+ 4,1	72,3	93.587	- 2,2	81.130
1996	352.931	+ 4,5	254.606	+ 4,3	72,1	98.325	+ 5,1	85.500
1997	364.672	+ 3,3	263.609	+ 3,5	72,3	101.063	+ 2,8	88.450
1998	321.025	- 12,0	228.352	- 13,4	71,1	92.673	- 8,3	81.950
1999	317.145	- 1,2	226.900	- 0,6	71,5	90.245	- 2,6	77.560
2000	336.602	+ 6,1	239.980	+ 5,8	71,3	96.622	+ 7,1	83.560
2001	342.874	+ 1,9	238.959	- 0,4	69,7	103.915	+ 7,5	92.080
2002	346.575	+ 1,1	241.386	+ 1,0	69,6	105.189	+ 1,2	93.590
2003	355.038	+ 2,4	248.293	+ 2,9	69,9	106.745	+ 1,5	95.360
2004	357.811	+ 0,8	247.359	- 0,4	69,1	110.452	+ 3,5	99.090
2005	330.207	- 7,7	224.605	- 9,2	68,0	105.602	- 4,4	94.150
2006	337.263	+ 2,1	233.348	+ 3,9	69,2	103.915	- 1,6	93.810
2007	348.092	+ 3,2	237.309	+ 1,7	68,2	110.783	+ 6,6	97.680
2008	366.896	+ 5,4	249.627	+ 5,2	68,0	117.269	+ 5,9	103.270
2009	377.840	+ 3,0	256.948	+ 2,9	68,0	120.892	+ 3,1	107.900
2010	393.545	+ 4,2	268.137	+ 4,4	68,1	125.408	+ 3,7	111.980
2011	407.392	+ 3,5	276.981	+ 3,3	68,0	130.411	+ 4,0	116.790
2012	422.363	+ 3,7	283.762	+ 2,4	67,2	138.601	+ 6,3	123.350
2013	446.800	+ 5,8	297.900	+ 5,0	66,7	148.900	+ 7,4	133.800
2014	459.900	+ 2,9	308.200	+ 3,5	67,0	151.700	+ 1,9	136.800
2015	478.700	+ 4,1	321.400	+ 4,3	67,1	157.300	+ 3,7	142.400
2016	495.100	+ 3,4	334.200	+ 4,0	67,5	160.900	+ 2,3	144.000

Steuerlicher Einnahmen-Überschuss = Einkommen vor Steuern
 Grundlagen: Jährliche Kostenstrukturerhebungen der KZBV Tab. 5.1

The NRW consumer advice centre demands that dentistry should not be privatized more than it already is:

Since dentists as service providers,⁵⁵ and health insurance companies as cost bearers⁵⁶ benefit equally from the fact that dental care is heavily privatized, the NRW consumer advice centre believes that a political initiative for more consumer protection in dentistry is necessary. This is because the increasing proportion of private services is not being examined for its benefits and necessity.

⁵⁵ 50.6% of the income of the dental practice owners does not come from reimbursements by the statutory health insurance providers, which is a higher proportion than for doctors, according to the Yearbook of the National Association of Statutory Health Insurance Dentists, 2016, p.118.

⁵⁶ In the statutory health insurance system, expenditure on dentistry in 2015 was only 6.6% of total expenditures, compared to 15% in 1977 and 10.1% in 1997 (Agenda Mundgesundheits der KZBV 2017-2021, p. 29).

3.5 Improved prevention reduces the need for treatment

Regular visits to the dentist for check-ups and professional dental cleaning are encouraged by the incentive of bonus booklets for patients (also discussed in section 2.4.4.2.), which are used to increase public insurance reimbursements for prostheses. Such an incentive for preventive dental care reduces the need for many subsequent costly treatments, and at the same time provides a financial boost to the dentist through more frequent patient visits. Bonus booklets may also be considered as a way for patients to increase public insurance reimbursements for fillings, but they may also encourage dentists to simply increase their private billing.

3.6 Dentists pay for hazardous waste management

The current and historical use of dental amalgam results in the need to separately collect and treat dental amalgam waste as hazardous waste. This mainly includes surplus amalgam waste from sludge accumulated in amalgam separators and chair-side traps and, to a lesser extent, solid waste from the preparation of new amalgam.

The cost of dental amalgam waste disposal for a dental practice in Germany may be up to 600€ per year,⁵⁷ but several disposal companies that appreciate the value of the silver in amalgam waste have been known to offer their services for free, or even pay for this waste.

⁵⁷ Study on the potential for reducing mercury pollution from dental amalgam and batteries, European Commission, 11 July 2012 (p.208): https://ec.europa.eu/environment/chemicals/mercury/pdf/mercury_dental_report.pdf

4 Option 1: Calculation by the statutory health insurance companies

Option 1 refers to a calculation by the statutory health insurance companies (GKV) that was based on simply replacing all amalgam fillings with composites, suggesting that the total cost would be covered by the public healthcare system.

4.1 Understanding the calculation of the statutory health insurance companies

In response to a question on 12 July 2018 in the Bundestag regarding the additional costs for the statutory health insurance companies (GKV) of insured individuals if only alternative dental filling materials were used for amalgam, the Federal Government referred to an estimate of the GKV that the exclusive use of composite fillings would entail extra public insurance reimbursement costs of about **EUR 1 billion per year**.⁵⁸

In arriving at this figure of additional costs, it was assumed that composite fillings were already used as a replacement for amalgam in the molars of pregnant and breastfeeding women, and children under 15 (as well as individuals with kidney failure or suffering from a mercury allergy).⁵⁹ The GKV further assumed that composite fillings would consequently be extended to all persons covered by statutory health insurance (approx. 73 million people in total), and that these costs would be fully reimbursed by the statutory health insurance companies at rates that were already in effect for composites. The additional cost of some EUR 1 billion was calculated as shown in Table 3 below, which requires some explanation:

- The table includes only fillings in posterior teeth (molars) since amalgams are no longer used in Germany for anterior teeth (incisors) fillings;
- The first two columns show the number of fillings reimbursed in 2018 according to the size of the fillings, indicated as the number of surfaces;
- Columns 3 and 4 show the rates and actual reimbursements in 2018 for all posterior fillings covered by statutory insurance, adding up to EUR 1.5 billion;
- The fifth column shows the reimbursement rates that were authorized for composite fillings in 2018; and
- The last column shows the total reimbursements that would be required if all fillings were composite and if all were reimbursed at rates (for composites) in effect in 2018, adding up to EUR 2.5 billion.

The difference (or increased cost) between the actual public insurance reimbursements (EUR 1.5 billion) for posterior fillings in 2018, and the reimbursements that would be required if all fillings were composite (EUR 2.5 billion) comes to EUR 1 billion.

⁵⁸ Antwort der Bundesregierung auf kleine Anfrage im Bundestag vom 12. Juli 2018 – Drucksache 19/3065 – Auswirkungen der Amalgam-Nutzung in der Zahnmedizin auf Mensch und Umwelt; <https://polit-x.de/de/documents/1083252/bund/bundestag/drucksachen/antwort-2018-07-23-auf-die-kleine-anfrage-drucksache-193065-auswirkungen-der-amalgam-nutzung-in-der-zahnmedizin-auf-mensch-und-umwelt>

⁵⁹ Beschluss des Bewertungsausschusses BEMA 13h gültig ab dem 01.07.2018; <https://www.kzv-sh.de/wp-content/uploads/2018/06/Beschluss-Bewertungsausschuss-13h.pdf>

Table 3. Cost calculations for the Option 1 scheme following a ban on the use of amalgam

Surfaces of permanent fillings	Number of reimbursements for molars ¹ in 2018 ² [in Mio.]	Expenses 2018		Calculation of the costs - Option 1 Public Health Insurance	
		Dental amalgam is the basic filling material and is fully reimbursed by the public healthcare system; patients pay extra for more aesthetic alternatives		Full reimbursements for BEMA items 13e-h for composites, which were previously used only in exceptions, are now valid for all insured persons	
		Amalgam		Composite	
		Reimbursement rates BEMA 13 a-d [points converted into EUR ³]	Reimbursements of the public health scheme in 2018 [EUR, Mio.]	Reimbursement rates BEMA 13 e-h [points converted into EUR ³]	Calculated reimbursements of the public health sector [EUR, Mio.]
1	9.26	€34	315	€56	519
2	14.18	€42	596	€68	964
3	6.52	€52	339	€90	587
4/4+	4.2	€62	260	€107	449
Total	34.16		~1.5 bn.		~2.5 bn.

¹ The ratio of fillings for molars compared to incisors is about 70:30 according to the GKV-Spitzenverband.

² 880,000 fillings were invoiced in the 2nd half of 2018 for exceptional cases via BEMA 13 e-h, and are not included in this calculation.

³ Fees are initially set as “points” whose values may vary regionally and are adjusted regularly: ∅ €1,07 in 2018

4.2 Updating the statutory health insurance (GKV) calculation

4.2.1 Updating the statutory reimbursement rates for composites

The recent consultant report to the European Commission, which compared the statutory reimbursements for amalgam and composite fillings in various European countries, questioned whether the German calculation takes into account the decline in the cost of mercury-free fillings in recent years.⁶⁰

In fact, the assumptions behind the calculations in Table 3 above need to be updated since the reimbursement rates for composite fillings with 1-3 surfaces were negotiated long ago in 1996, when it was decided that individuals in Germany with kidney failure or an allergy to mercury were entitled to amalgam-free fillings. These reimbursement rates have not been adjusted since then, despite far-reaching technical improvements in filling materials and the development of durable and cheaper alternatives. Nor were these rates adjusted when a rate for fillings with 4 and more surfaces was added in July 2018.

Moreover, according to a protocol note, the KZBV and the GKV-Spitzenverband agreed in 1996 that the rates for fillings in the posterior region, which are invoiced according to BEMA items 13

⁶⁰ Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020.

e - h, would be reviewed under certain circumstances. As things stand today, paragraph 2 of the note to the minutes still applies, according to which, if invoices under BEMA items 13 e - h comprise “significantly” more than one percent of all posterior fillings, the KZBV and the GKV-Spitzenverband, as negotiating partners at federal level, will review the previous reimbursement rates for BEMA items 13 e - h.⁶¹ The relevant number of fillings is discussed further below.

4.2.2 Updating data on the number of fillings

When the GKV Spitzenverband calculated the costs of an amalgam ban, there were no data available on how many mercury-free fillings had already been placed after the introduction of the ban on amalgam use for pregnant and breastfeeding women, and children under 15. Some of those data are now available, but come with some uncertainty.

In the 2nd half of 2018, 880,000 mercury-free fillings (1.8% of all posterior tooth fillings covered by public health insurance in 2018) were invoiced under the special BEMA items 13 e-h. One could therefore assume that some 1.8 million fillings (3.5%) could be expected to be invoiced under these categories on an annual basis. Following the agreement between the KZBV and the GKV-Spitzenverband on BEMA items 13 e - h, the partners were asked to help ensure that the fillings invoiced would not exceed 1% of the total fillings. This request was reportedly passed on to dentists, who feared that if the limit of 1% of the total posterior fillings was exceeded and a review of the basic reimbursement was carried out, the reimbursement rates might be reduced.⁶² According to the numbers above, in 2018 the 1% hurdle was already exceeded on an annual basis, so the reimbursement rates should soon be reviewed – at the latest when the figures for 2019 are available. Revised reimbursement rates such as those recently implemented in Austria (see section 4.2.3.4) might be considered.

⁶¹ According to Beschluss des Bewertungsausschusses BEMA 13h gültig ab dem 1 July 2018, accessible at <https://www.kzv-sh.de/wp-content/uploads/2018/06/Beschluss-Bewertungsausschuss-13h.pdf>

1) The evaluation committee for dental services assumes that the fillings in the posterior region billable according to BEMA items 13 e, f, g and h are 1% of the total number of fillings. The Evaluation Committee recommends that the KZBV and the Associations of Statutory Health Insurance Dentists, as well as the National Association of Health Insurance Funds and the Regional Associations of Health Insurance Funds and the Substitute Health Insurance Funds establish suitable review procedures to ensure that the stated percentage of 1% is observed.

2) If the percentage is significantly exceeded, the Evaluation Committee and, if necessary, the Extended Evaluation Committee will review the existing evaluation standard.

⁶² Interview with Dr. Wolfgang Eßer, Chairman of the KZBV, BZB Januar/10 Februar 2019, https://www.bzb-online.de/jan19/bzb119_06.pdf

Demographic and healthcare research on the German population suggest that the number of at-risk persons who are currently entitled to composite fillings free of charge under BEMA items 13 e - h is significant. They include primarily:

- About 1 million women who are pregnant or breastfeeding during any 12-month period
- About 10 million children under 15 years of age
- The more seriously ill of the five to six million persons suffering from chronic kidney disease (CKD)⁶³

Figure 13 below shows that the number of fillings placed annually for children under 15 years of age is relatively low, as compared with other age groups.⁶⁴ As confirmed by the German National Action Plan, German children at the age of 12 have an average of only 0.5 carious, missing or filled teeth.⁶⁵ In 2018, public healthcare insurance schemes reimbursed 1.1-1.2 million fillings (and filling repairs)⁶⁶ for about 1.8 million children under the age of 15. Another 48.5 million fillings (and filling repairs) were reimbursed for approximately 19 million older persons insured by public healthcare schemes. This suggests an average of more than 2.5 fillings in 2018 for each of these 19 million patients over 15. This seems perhaps too high an average, but time constraints have prevented us from identifying an alternative explanation.

Meanwhile, the frequency of caries is becoming increasingly polarised, as an ever smaller percentage of insured children are receiving an increasing number of fillings per person. Studies on oral health have shown that socioeconomic status (SES) is a key factor in caries incidence.⁶⁷

Depending on the number of chronic kidney disease patients who might qualify for composite fillings along with the other at-risk groups above, the approximate numbers of fillings placed annually for each at-risk group, and the rough percentage of fillings placed in the posterior region, the number of posterior fillings reimbursed under BEMA items 13 e – h in 2019 may well have exceeded the estimated 1.8 million.

⁶³ In 2018 about 38,000 reimbursements for mercury-free fillings were formally allocated to persons suffering from impaired kidney function or mercury allergies. However, 75,000 persons (2014 data) had stage 5 chronic kidney disease (CKD), requiring continuous ambulatory dialysis, and another 131,000 persons (2014 data) had stage 4 CKD (pre-terminal renal failure), according to A Gandjour, W Armsen, W Wehmeyer, J Multmeier and U Tschulena, Costs of patients with chronic kidney disease in Germany, PLOS ONE, 24 April 2020; <https://doi.org/10.1371/journal.pone.0231375>

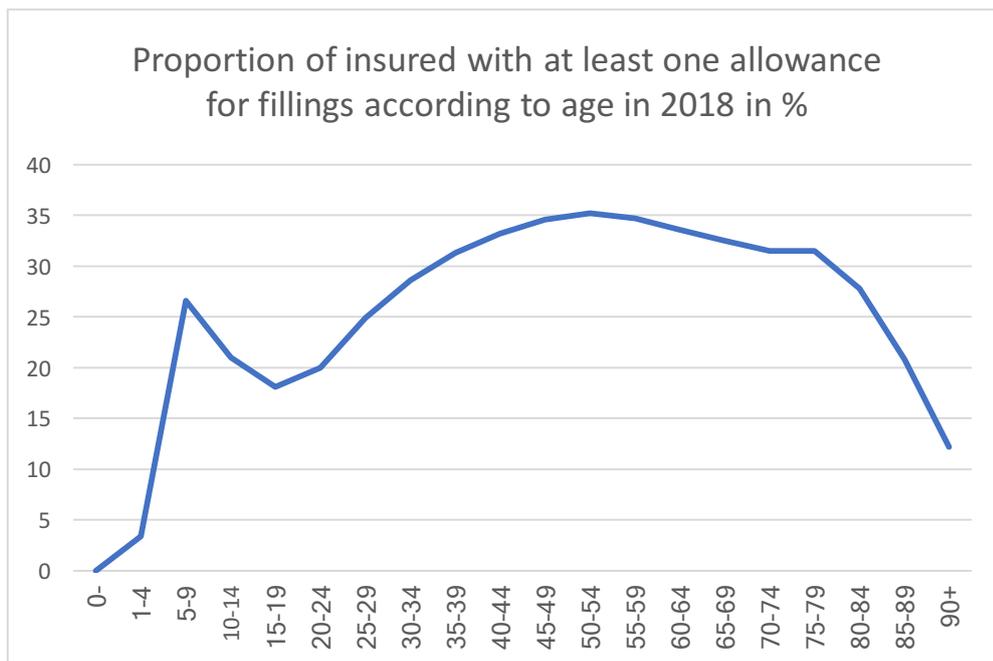
⁶⁴ BARMER Zahnreport 2019: Regelversorgung: Gut bewährt, aber immer seltener; <https://www.barmer.de/presse/infothek/studien-und-reports/zahnreporte/zahnreport-2019-192482>

⁶⁵ Daten & Fakten 2020 – Bundeszahnärztekammer und Kassenzahnärztliche Bundesvereinigung, as cited in the German Government's National Action Plan for the Phase-down of Dental Amalgam, Federal Ministry of the Environment, Nature Conservation and Nuclear Safety, 10 July 2019; <https://www.bmu.de/en/download/the-german-governments-national-action-plan-for-the-phase-down-of-dental-amalgam/>

⁶⁶ According to an extrapolation of data from the Techniker Krankenkasse (largest statutory health insurance provider with over 10 million members), received as the result of a request from IG Umwelt Zahn Medizin: Total invoices for fillings for children under 15 in 2019: 79,565 BEMA items 13 a-d and 83,038 BEMA items 13e-h.

⁶⁷ Mundgesundheitsverhalten von Kindern und Jugendlichen in Deutschland – Querschnittergebnisse aus KiGGS Welle 2 und Trends, *Journal of Health Monitoring* 2018 3(4); DOI 10.17886/RKI-GBE-2018-089; Robert Koch Institut, Berlin.

Figure 13. Percentage of insured persons in Germany reimbursed for at least one filling in 2018



Source: BARMER Zahnreport 2020: Zahngesundheit bei Kindern und Jugendlichen; <https://www.barmer.de/presse/infothek/studien-und-reports/zahnreporte/zahnreport-2020-241610>

4.2.3 Changes in the cost of amalgam vs. mercury-free restorations

4.2.3.1 Cost of placing amalgams vs. mercury-free fillings

As the recent European Commission study⁶⁸ confirmed, the difference in the cost of placing an amalgam vs. a mercury-free filling is mostly related to the time required to place the filling, since the cost of the restoration material is only a fraction of the overall cost. The time required to place a filling is based on training and experience, and these days virtually all dentists in the EU have substantial experience with mercury-free materials. In parallel the technical specifications of mercury-free materials have evolved so that less and less time is required to use many of the materials.

Experience from Sweden has demonstrated that the improvements in the properties of mercury-free dental restoration materials, along with the increased familiarity of dentists in handling these materials, has reduced the time needed to place these fillings to levels that are comparable to the time required to place amalgam fillings.

More than ten years ago, the Swedish Environment Ministry received a signed statement from the Swedish Dental and Pharmaceutical Benefits Agency (TLV) that is responsible for the Swedish dental reimbursement scheme, which concluded that there was “currently no (or minor) time difference to perform Hg-free restorations compared to amalgam.”⁶⁹ Table 4 below breaks down the relevant tasks to show how composite fillings can normally be placed as rapidly as amalgam fillings, and some new materials can be placed even faster than composite. Younger

⁶⁸ Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020.

⁶⁹ BIO Intelligence Service, Study on the potential for reducing mercury pollution from dental amalgam and batteries, European Commission (DG Environment), 2012.

dentists trained at German universities (and many other countries) tend to be more familiar with mercury-free materials, as most of them are no longer taught how to prepare and place amalgam fillings.

Table 4. Time to place an amalgam vs. a composite filling

(0) No difference in time (+) Composite fillings a little faster (++) Composite fillings faster or much faster (-) Amalgam fillings a little faster (- -) Amalgam fillings faster or much faster		
	Task	Time (“+” indicates composite is faster)
a	If needed, dental anaesthesia and cofferdam take the same amount of time.	0
b	Drilling the cavity: Less drilling for composite, a little faster than amalgam.	+
c	If needed, put on matrix strip and wedge.	0
d	Cavity cleaning.	0
e	Underfilling in deep cavities.	0
f	Mix and isolate for amalgam. Etch and bond for composite.	-
g	Place the filling. Mix, insert and pack amalgam. Insert composite and cure with light.	0
h	If needed, take off matrix strip and wedge.	0
i	Model chewing surface and check chewing.	0
j	Polishing the surface of the completed filling. Amalgam should only be polished after 24 hours.	++
Source: Christer Malmström, DDS, Assessment of the feasibility and benefits of non-mercury alternatives to dental amalgam, June 2020.		

4.2.3.2 Durability of composite fillings

The GKV health insurance companies consider composites to be just as durable as amalgam, as confirmed by the studies summarized in Table 5, which shows the survival rates of composite restorations in the posterior region in long-term clinical studies with observation periods of at least 4 years between 1990 and 2015. The durability of composites is further confirmed by the “Recommendations for composite restorations in the posterior region” of the German Society of Dentistry, together with the German Society of Dentistry, Oral Medicine and Orthodontics.⁷⁰ Therefore, it should be expected that the need to replace composite fillings would not be any more frequent than for amalgam.

⁷⁰ DGZ, DGZMK, Guideline for composite restorations in the posterior region, Oct. 2016. Survival rates of composite restorations in the posterior region (1990-2015) - Long-term clinical studies with at least four years observation period. <https://secure.owidi.de/documents/10165/1373255/kompositszblang.pdf/7b1a34a7-ae85-4ace-bc83-0b31bd094fbd>

Table 5. Survival rates of (mostly) composite restorations in the posterior region

Reference	Year	Observation period (years)	Filling material type	AFR (%)
Manhart et al. (not yet published)	2016	10	Bulkfill Composit Hybridcomposit	1,8
Pallesen U, van Dijken JW: A randomized controlled 30 years follow up of three conventional resin composites in Class II restorations. Dent Mater 2015; 31: 1232–1244	2015	30	HybridComposit light-curing 2 Hybridkomposite chemically curing	1,4 1,1/0,8
Pallesen U, van Dijken JW: A randomized controlled 27 years follow up of three resin composites in Class II restorations. J Dent 2015; 43: 1547–1558	2015	27	2 Hybridcomposites light-curing Hybridkomposit chemically curing	1,7/1,8 1,4
van Dijken JW, Pallesen U: A six-year prospective randomized study of a nano-hybrid and a conventional hybrid resin composite in Class II restorations. Dent Mater 2013; 29: 191–198	2013	6	Hybridcomposit Nano-Hybridcomposit	1,7 2,3
van Dijken JW, Pallesen U: Clinical performance of a hybrid resin composite with and without an intermediate layer of flowable resin composite: a 7-year evaluation. Dent Mater 2011; 27: 150–156	2011	7	Hybridkomposit without Lining Technik Hybridkomposit with Lining Technik	2,3 2,0
Da Rosa Rodolpho PA, Donassollo TA, Cenci MS et al.: 22-year clinical evaluation of the performance of two posterior composites with different filler characteristics. Dent Mater 2011; 27: 955–963	2011	22	Hybridcomposit (70vol% Filler) Hybridcomposit (50vol% Filler)	1,5 2,2
Manhart J, Chen HY, Hickel R: Clinical evaluation of the posterior composite Quixfil in class I and II cavities: 4-year follow-up of a randomized controlled trial. J Adhes Dent 2010; 12: 237–243	2010	4	Bulkfill Composit Hybridcomposit Kompomer Underfilling	2,7 0,6 0,2
van Dijken JW: Durability of resin composite restorations in high C-factor cavities: a 12-year follow-up. J Dent 2010; 38: 469–474	2010	12	Hybridkomposit (closed sandwich technique) Hybridkomposit (only Class I Restaurationen)	0,2
Opdam NJ, Bronkhorst EM, Loomans BA, Huysmans MC: 12-year survival of composite vs. amalgam restorations. J Dent Res 2010; 89: 1063–1067	2010	12	Hybridcomposit Amalgam	1,68 2,41
van Dijken JW, Lindberg A: Clinical effectiveness of a low-shrinkage resin composite: a five-year evaluation. J Adhes Dent 2009; 11: 143–148	2009	5	Hybridcomposit Hybridkomposit with Präpolymerisaten (low shrinkage)	2,9 2,1
Lindberg A, van Dijken JW, Lindberg M: Nine-year evaluation of a polyacidmodified resin composite/resin composite open sandwich technique in Class II cavities. J Dent 2007; 35: 124–129	2007	9	Compomer/Hybridcomposit (Open Sandwich Technique) Hybridcomposit	1,0 1,37
van Dijken JW, Sunnegardh-Gronberg K: A four-year clinical evaluation of a highly filled hybrid resin composite in posterior cavities. J Adhes Dent 2005; 7: 343–349	2005	4	Hybridcomposit Calcium aluminate cement	1,9 19
Pallesen U, Qvist V: Composite resin fillings and inlays. An 11-year evaluation. Clin Oral Investig 2003; 7: 71–79	2003	11	Hybridcomposit Composit-Inlays	1,5 1,5
Gaengler P, Hoyer I, Montag R: Clinical evaluation of posterior composite restorations: the 10-year report. J Adhes Dent 2001; 3: 185–194	2001	10	Hybridcomposit	2,58

Note: AFR = Annual Failure Rate

Source: Federlin, M., et al., Kompositrestaurationen im Seitenzahnbereich. S1-Handlungsempfehlung (Langversion). AWMF-Registernummer: 083–028; Stand: Oktober 2016; gültig bis: Oktober 2021. Deutsche Zahnärztliche Zeitschrift, 2017. 72(1): p. 75–82.

The public health insurance company BARMER carried out its own study of the durability of fillings in general based on 2013 data. It concluded that the four-year survival rate (defined as no retreatment or “re-intervention” on the filling during the first four years) for different sizes of fillings was as follows:

- 69.9% survival rate for one-surface fillings
- 74.8% survival rate for two-surface fillings
- 66.6% survival rate for three-surface fillings
- 60.9% survival rate for fillings with more than three surfaces⁷¹

For the majority of fillings (one- and two-surface), this would appear to suggest an annual failure rate (AFR) of about 7%, which is inconsistent with Table 5 above. It is without question that the

⁷¹ BARMER GEK Zahnreport 2015, p.118; <https://www.barmer.de/presse/infothek/studien-und-reports/zahnreporte/report-2015-38928>

technology of restoration materials has greatly advanced during the last seven years and BARMER would no longer find the same AFRs, but there are those who may argue that the lower AFRs of crowns, partial crowns or CAD/CAM inlays for larger fillings may justify their higher cost.

4.2.3.3 Mercury-free fillings require less complex treatment

As the recent European Commission report shows, alternative fillings are less invasive and preserve more healthy tooth substance, which tend to require less complex follow-up treatments in the longer term.⁷² Moreover, when repaired, they are more durable than amalgam fillings.

According to SCENIHR, dental amalgam requires the preparation of larger cavities that are often associated with excessive tooth tissue removal. The World Health Organization (WHO) also states that adhesive resin materials (such as composites) cause less expansion and contraction and allow a longer survival of the tooth.

With regard to reparability, mercury-free restorations and particularly composites can be repaired with a partial replacement when they fail. Composites permit minimal invasive approaches for localised repair. Therefore, the consequences of replacing a failed filling with amalgam – that includes an increase in the depth and width of the cavity – are avoided with the use of composites. Another study concluded that composite fillings have a higher success rate than dental amalgam fillings when repaired. Specifically, the annual failure rate (AFR) after four years of observation was 9.3% for a repaired amalgam filling, and 5.7% for a repaired composite filling.⁷³

4.2.3.4 The example of Austria

Austria provides an example of more realistic statutory reimbursement rates, which were renegotiated in 2018, and were based on the understanding that glass ionomer cements are adequate for use as basic permanent fillings.⁷⁴ As seen in Table 6 below, the Austrian public insurance reimbursement rates for basic mercury-free fillings in posterior teeth are significantly lower (about EUR 20 less for the smaller fillings, and nearly EUR 30 less for a 3-surface filling) than those currently in effect in Germany.

If the Austrian fees for amalgam-free alternatives in the posterior region were introduced in Germany, the added public health insurance cost of an amalgam ban would amount to about **EUR 330 million per year** instead of EUR 1 billion estimated by the GKV assuming exclusive use of composite for all posterior fillings.

⁷² Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020.

⁷³ Niek J.M. Opdam, Longevity of repaired restorations: A practice based study, *Journal of Dentistry* 40 (2012) 829-835

⁷⁴ Austrian Chamber of Dentists, Official Notices, Vienna, 19 June 2018; https://www.zahnaerztekammer.at/fileadmin/content/shared/infocenter/amtliche_mitteilungen/Gesamtvertragliche_Vereinbarungen/AEnderungen_per_1._Juli_2018/Rundschreiben_neue_Vertragsleistungen_190618.pdf

Table 6. German and Austrian statutory reimbursements for basic mercury-free fillings in posterior teeth

Surfaces	Reimbursements for basic mercury-free fillings in the posterior region	
	Germany (composites)	Austria (glass ionomer cements)
1	€56	€37
2	€68	€47
3	€90	€62
4/4+	€107	€99

4.2.3.5 Conclusions regarding the cost of fillings

It must be concluded that current statutory reimbursements for fillings in Germany no longer reflect the reality in the dental clinic. In fact, in at least 16 Member States for which data are available, there is no significant difference (except in the Czech Republic and in Germany) in the level of statutory reimbursement for dental amalgam vs. mercury-free restorations.

The GKV estimate of increased costs after amalgams are phased out should therefore be updated as concerns both the number of posterior fillings that are covered by exceptions, and the reimbursement rates for modern composites.

4.3 The dentists' perspective

For dentists, if composite fillings were to be accepted as the basic standard treatment, this would mean that the dentists' income for fillings would be capped and the additional cost rule could no longer be applied, i.e., they would be prevented from parallel private billing of patients.

As can be seen in Table 7 below, the current income potential for dentists via private billing for fillings is significantly higher than the capped refunds they would receive if all prices were fixed via current BEMA reimbursement rates for basic (amalgam equivalent) treatment. Private billing could bring in an extra EUR 1.1-2.4 billion for dental practices, depending on the multipliers used.

The frequent application of private billing, due to the unpopularity of amalgam (now only 5-10% of all fillings), has become an important economic factor for dentists due to the flexibility of the billing multipliers.

This has enabled the pricing of dental treatments to be somewhat adapted to the income structure of the patient base, which has also compensated for higher fixed costs. However, if one looks at the trends in dentists' incomes, it is noticeable that the average real value of this income has risen significantly since dentists began to take advantage of the additional cost regulation (i.e., private billing) for fillings. As noted previously, the increase in average turnover and profitability per dentistry owner was relatively stable between the 1996 additional cost agreement and 2005; however, between 2005 and 2016 the turnover has increased by 50% and profits by 52%.

A regulation eliminating private billing would significantly reduce the income of many dentists, which is why compromise solutions need to be considered.

Table 7. Cost of mercury-free fillings if private billing permitted

Surfaces of permanent fillings	Number of reimbursements for molars ¹ in 2018 ² [in Mio.]	Potential income from fillings, assumed patients agree on additional payment for alternatives (current demand is at 95%)							
		GKV contribution		Private Liquidation					
		dental amalgam is the basic supply material and is fully reimbursed by the public health care system; patients pay extra for more aesthetic alternatives		Patients who wish to receive services that go beyond basic care conclude a private cost agreement with the dentist. The dentist charges at 2.3 times or 3.5 times the rate according to the GOZ. However, the dentist can also agree a higher rate. There are no statistics on the rates applied for those with statutory insurance without supplementary insurance.					
		Reimbursement rates BEMA 13 a-d [points converted into € ³]	total reimbursements of public health sector in 2018 [EUR, Mio.]	Fees according to the GOZ with incremented rates 2,3 or 3,5 ⁴					
				2,3	Contribution by patients	request for the invoicing of fillings [EUR, Mio.]	3,5	Contribution by patients	request for the invoicing of fillings [EUR, Mio.]
1	9,26	34 €	315	68 €	34 €	630	104 €	69 €	963
2	14,18	42 €	596	72 €	30 €	1.021	109 €	67 €	1546
3	6,52	52 €	339	83 €	31 €	541	126 €	74 €	788
4/4+	4,2	62 €	260	100 €	38 €	420	152 €	90 €	638
Total	34,16		~1,5 bn.			-2,6 bn.			-3,9 bn.

¹ The proportion of fillings for molars compared to incisors is about 70:30 according to the GKV-Spitzenverband

² 880000 Fillings were invoiced for exceptional cases via BEMA 13 e-h and are not included in this calculation.

³ Fees are initially set as "points" whose values may vary regionally and are adjusted regularly: ∅ €1,07 in 2018.

⁴ Without taking into account the business of dentists by setting up their own practice fees which may exceed the GOZ.

4.4 Perspective of the consumer

Contrary to the dentists' perspective above, in a 2018 position paper the Consumer Protection Agency called to limit dentists' private billing practices, especially since the justification of treatment and treatment costs can only be checked with difficulty,⁷⁵ and this fact appears to have been abused by some dentists.

For patients who now pay between EUR 50 and 100 in private billings for most posterior fillings, a full reimbursement for composite fillings would represent a significant financial saving.

4.5 Other options

Of course, apart from Option 1 there are other alternatives for fair pricing of basic care in a post-amalgam Germany.

Based on the need to balance the concerns of public health insurance, dentists and the general public, two other key options for amalgam-free dentistry should be considered. One option

⁷⁵ Positionspapier der Verbraucherzentrale Nordrhein-Westfalen zum Markt der Zahnmedizin Stand: 13 März 2018; https://www.verbraucherzentrale.nrw/sites/default/files/2018-09/2018-03_13-Forderungspapier_Zahnmedizin.pdf

focuses on the restoration material used and the number of layers placed, while the other option is based on the number of surfaces restored:

- **Option 2:** Full reimbursement for single-layer fillings, with an additional fee for multi-layer fillings
- **Option 3:** Full reimbursement only for one- and two-surface fillings, with a fixed reimbursement for larger fillings

Both of these options are elaborated and analysed in Sections 5 and 6.

5 Option 2: Full reimbursement for single-layer, and extra fee for multi-layer fillings

According to Option 2, in anterior teeth only single-layer composite fillings would be covered by the public health insurance companies. In a similar manner, single-layer fillings in posterior teeth would also be fully reimbursed by public health insurance, although these fillings may not necessarily be matched to the tooth colour. Dentists would have the opportunity of private billing for more sophisticated or possibly more durable materials such as multi-layer anterior fillings or aesthetic posterior fillings.

Due to impressive technical advancement in the properties of mercury-free filling materials, the quality of time-saving (and therefore cost-effective) alternative filling materials has improved significantly over the last decade. The main options among single-layer filling materials include:

- **Conventional composites:** light-curing up to 2mm thickness, adhesive technique, suitable for load-bearing restorations
- **Bulk-fill composites:** light-curing up to 4-5mm thickness, adhesive technique, suitable for load-bearing restorations
- **Compomers:** light-curing up to 2mm thickness, adhesive technique, not recommended for certain load-bearing restorations
- **Glass ionomer cements:** self-curing and light-curing up to 4-5mm options, self-adhesive, not recommended for certain load-bearing restorations

Most caries in the posterior region can now be treated with durable single-layer restoration materials. Glass ionomer cements (GIZ), compomers and especially bulk fill composites are perfectly adequate for a functional restoration, and also meet the technical and economic requirements of health insurance companies with regard to their durability (abrasion resistance) and dimensional stability (minimal shrinkage). Numerous dental practices have been using these materials for years.

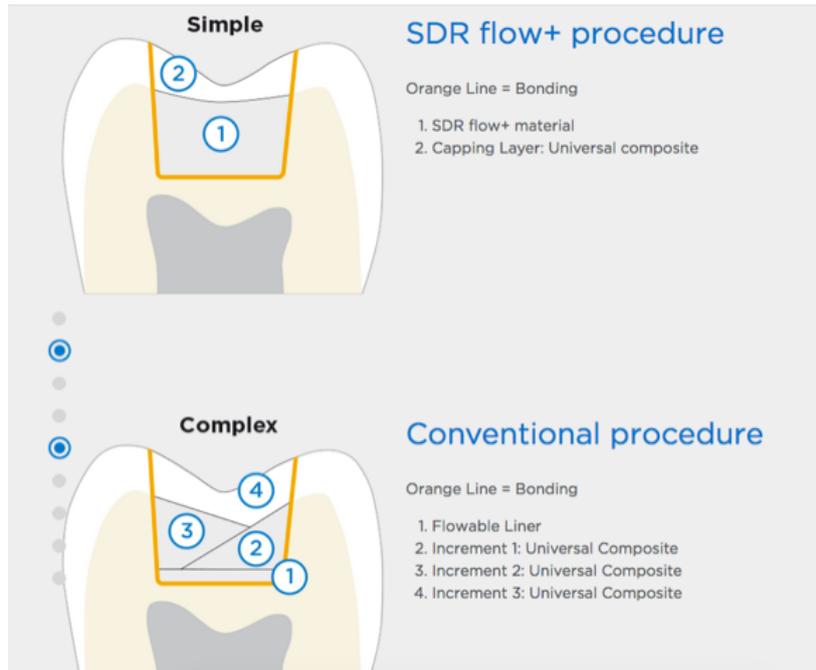
Although it is not clear whether the “Simple” filling in Figure 14 below would be considered a single-layer filling, a common restoration technique is to use a single-layer “underfilling” material (e.g. GIZ) and to cap it with a composite or other finishing material.

In fact, the BEMA order 13 expressly states that all filling procedures include the following steps:⁷⁶

- Preparation of the cavity
- Filling with selected material including underfilling
- Placing of a matrix or using other aids for shaping and polishing the filling

⁷⁶ BEMA Einheitlicher Bewertungsmaßstab für zahnärztliche Leistungsgemäß § 87 Abs. 2 und 2h SGB V
file:///Users/florianschulze/Downloads/BEMA_20190701-3.pdf

Figure 14. Restoration techniques for simple vs. complex fillings



If an underfilling of self-curing GIZ is relatively large, this would not imply a significantly greater cost, but it may take 5-7 minutes to harden properly. If a light-cured GIZ or a bulk-fill material is used, however, the extra material cost could be somewhat greater.

The “single-layer filling” option is further supported by a number of factors, as described below.

5.1 GIZs and compomers are compliant with the GKV standards in most indications for posterior tooth fillings

According to the guidelines of the Joint Federal Committee, basic treatment should be appropriate to the need, should not remove more of the natural tooth substance than necessary, and should be oriented towards prevention. Only tested and approved filling materials should be used, consistent with any medical indications and in accordance with the manufacturer’s instructions for use, and specialist information or circumstances should be taken into account. All indicated filling materials must be able to perform satisfactorily in the posterior region.⁷⁷

⁷⁷ Richtlinie des Gemeinsamen Bundesausschusses für eine ausreichende, zweckmäßige und wirtschaftliche vertragszahnärztliche Versorgung vom 4. Juni 2003/24. September 2003 https://www.g-ba.de/downloads/62-492-78/RL-Z_Behandlung_2006-03-01.pdf

These requirements are already met by several GIZs and compomers for fillings in non-load-bearing posterior teeth. For example, some manufacturer specifications for the glass ionomers and compomers most commonly used in Germany⁷⁸ include:

GC Equis Forte (glass ionomer)

- Class I
- Non-stress Class II
- Stress Class II (isthmus less than half of the intercuspal distance)
- Intermediate restorative
- Class V & root surface restorations
- Core build-up

3M Ketac Molar (glass ionomer)

- Linings for single- and multiple-surface composite fillings
- Core build-up prior to crown placement
- Primary tooth fillings
- Stress-bearing Class I restorations with at least one additional support outside of the filling area
- Stress-bearing Class II restorations when the isthmus is less than half of the intercuspal distance and with at least one additional support outside of the filling area

Dentsply Sirona Dyract Extra (compomer)

- Direct restorations of all cavity classes in anterior and posterior teeth. Cavity width must be less than two-thirds of the intercuspal distance

5.2 GIZ is authorized for all permanent fillings in Austria and Slovakia

In Austria and Slovakia, modern glass ionomer cements have been officially recognized by health insurance companies since 1 July 2018 as the material of choice for the care of children, pregnant and breastfeeding women.^{79,80} The health insurance companies in Austria also require a two-year warranty obligation, as in Germany. This means that if the filling fails within two years, and the patient is not at fault for the failure, the dentist must repair or replace the filling free of charge.

⁷⁸ GfK Consumer Health, Dental, DDM Jahresbericht 2018, Management Report.

⁷⁹ Gesamtvertragliche Vereinbarung gemäß § 343d ASVG abgeschlossen zwischen der Österreichischen Zahnärztekammer (ÖZÄK) und dem Hauptverband der österreichischen Sozialversicherungsträger (HV) (Overall contractual agreement in accordance with § 343d ASVG concluded between the Austrian Dental Association and the Main Association of Austrian Social Insurance Institutions), 19 June 2018.

⁸⁰ Národný plán opatrení Ministerstva zdravotníctva Slovenskej republiky v súvislosti s postupným ukončovaním používania zubného amalgámu (National plan of measures of the Ministry of Health of the Slovak Republic in connection with the phasing out of the use of dental amalgam). The National Action Plan entered into force on 1 July 2019.

5.3 Bulk fill composites as a time-saving option for large cavities

For larger cavities, dentists can now use recognized bulk fill composites, which do not have to be carefully layered as do standard composites, but are placed in a single procedure with no layering. Although they are only available in a limited range of colours or shades, they can achieve most restorations in a time-saving and effective manner. Compared to amalgam fillings, they have only slightly higher material costs.^{81,82}

5.4 Bulk-fill materials, GIZs and compomers already widely used in Germany

Some dental practices have been using durable glass ionomer cement (GIZ) as a fully reimbursed alternative since the 1990s, and have had good experience with this material. They estimate the average durability of more recently developed GIZ at 4-6 years when placed following proper procedures. More and more dental practices use glass ionomer cements for acceptable and inexpensive standard treatment, and defer to amalgam only in special cases. The German health insurance companies are not officially supportive of this material but they are obliged to tolerate it for now, especially as the dentists do not have to indicate in their invoices which filling material was used. However, as long as the insurance companies have not formally accepted glass ionomer cements, compomers and bulk fill composites as alternatives to amalgam fillings, dentists using these materials are working in a legal “grey area.”

When the EU amalgam ban for children, pregnant women and nursing mothers took effect in 2018, the KZBV confirmed that patients and dentists could choose from among all appropriate materials (including GIZs and compomers), and that composite fillings in the posterior region would also be fully reimbursed under the statutory health insurance (GKV) scheme.⁸³

A general comparison of the use of various mercury-free restoration materials in Germany in 2018 is presented in Figure 15 below.⁸⁴ Light-cured composites comprised 60% of the total, but bulk-fill materials and glass ionomers were each responsible for another 13%, and those fractions continue to increase.

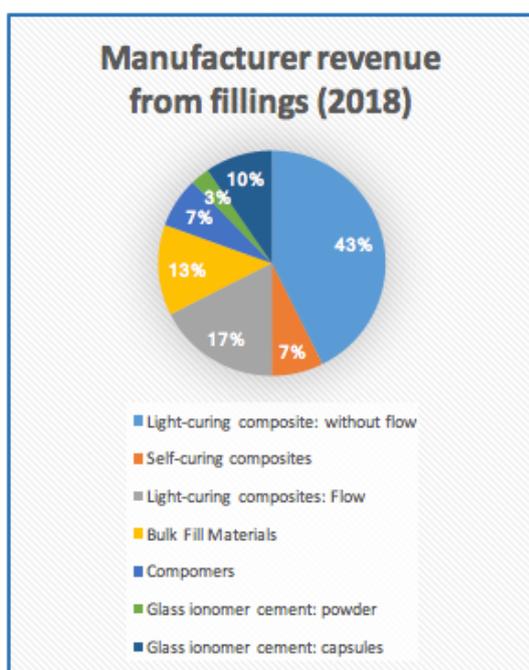
⁸¹ Voco, Three alternatives to amalgam fillings; <https://www.voco.dental/in/service/press/press-area/three-alternatives-to-amalgam-fillings.aspx>

⁸² Passende Amalgam-Alternativen für jeden Patientenbedarf, ZMK, 04 June 2019; https://www.zmk-aktuell.de/fachgebiete/aesthetik/story/passende-amalgam-alternativen-fuer-jeden-patientenbedarf__7743.html

⁸³ <https://www.kzbv.de/pressemitteilung-vom-29-6-2018.1241.de.html>

⁸⁴ GfK Consumer Health, Dental, DDM Jahresbericht 2018, Management Report

Figure 15. Relative use of various mercury-free restoration materials in Germany, 2018



5.5 Perspective of health insurance companies

Under Option 2 the present reimbursement rates for fillings in incisors (BEMA items 13 a-d as shown in the table below under the Current Situation heading) would not change, and the dentist is free to choose any appropriate and economically justified material. However, in order to accommodate dentists' financial concerns with regard to providing mercury-free fillings for molars, our analysis suggests that 10-20% be added to the existing basic insurance reimbursement rates for BEMA items 13 a-d (as shown under the Public Health Insurance heading in the table below) in order to ensure that all single-layer fillings in molars are free of charge to the patient. A 10-20% increase would also cover higher material costs for basic fillings in the posterior region. These new rates could be implemented as BEMA items 13 e-h for molars, and patients who might prefer more aesthetic multi-layer fillings could be invoiced privately by the dentist.⁸⁵

To summarize, studies have shown that modern restoration materials are perfectly adequate and durable for single-layer restorations. As further assurance, in practice, the health insurance companies have various methods of quality assurance (see Part 3).

5.6 Perspective of dentists

It is expected that the ability of dentists to invoice extra private fees for non-amalgam restorations will decrease when the amalgam option – that some patients suspect of being

⁸⁵ Similarly, in Austria the reimbursement by the health insurance companies of a posterior tooth filling with composite instead of glass ionomer cement ("basic treatment") may be reimbursed at 80% of the renegotiated Austrian rate for mercury-free fillings. Ref: <https://ooe.zahnaerztekammer.at/aktuelles/antworten-auf-die-haeufigsten-fragen-zu-den-ab-1-juli-2018-neuen-kassenleistungen/>

harmful to health – is no longer available. For this reason we have suggested above that 10-20% be added to the existing insurance reimbursement rates for BEMA items 13 a-d in order that there should be no charge to the patient for all basic single-layer fillings in molars. A 10-20% increase would also cover higher material costs for basic fillings in the posterior region. However, for patients who may prefer more aesthetic multi-layer composites, inlay fillings, etc., dentists could invoice extra private fees according to the GOZ.

5.7 Perspective of consumers

Under Option 2, patients will appreciate that all basic fillings can be placed free of charge, like dental amalgam used to be. In addition, for those patients who may want multi-layer composite fillings with colour adjustments, etc., these would be readily available for a modest extra fee as agreed with the dentist. A further incentive for patients, if approved by the public insurance companies, could be provided by bonus reimbursements⁸⁶ awarded for regular visits to preventive dental care over five or ten years (similar to the bonus scheme for prostheses).

Table 8 below shows that Option 2 could be provided at an overall cost of EUR 200-300 million per year more than current public insurance reimbursements. The table assesses only the data related to fillings in posterior teeth (molars) since amalgams are no longer used for anterior teeth (incisors) fillings in any case. The extra cost of this option could be covered by a modest increase in contributions. Moreover, as detailed in a separate section of this report, any such increased cost will be offset by the diverse health and environmental benefits due to reducing the amount of dental mercury released to the biosphere.

⁸⁶ With the risk that if dentists can still do private billing via GOZ, they could simply charge more in line with the bonus.

Table 8. Cost calculations for the Option 2 scheme following a ban on the use of amalgam

Sur- faces of per- manent fillings	Number of reim- burse- ments for molars ¹ in 2018 ² [in Mio.]	Current situation		Calculation of the costs - Option 2	
		Dental amalgam is the basic supply material and is fully reimbursed by the public health care system; patients pay extra for more aesthetic alternatives		Public Health Insurance	
		Glass ionomer cements, compomers and bulk-fill composites (only in universal colour) replace dental amalgam as the basic material; patients may pay extra for more aesthetic alternatives			
		Reimburse- ment rates BEMA 13 a-d [points converted into EUR ³]	Total reimbursements of public health sector in 2018 [EUR, Mio.]	BEMA new for molars with approx. 10- 20% adjustment of material costs in EUR [points converted into EUR ³]	New calculation of fees reimbursed by the public health sector [EUR, Mio.]
1	9.26	€34	315	€37-41	343-380
2	14.18	€42	596	€46-50	652-709
3	6.52	€52	339	€58-63	378-411
4/4+	4.2	€62	260	€68-75	286-315
Total	34.16		~1.5 bn.		~1.7-1.8 bn.

¹ The proportion of fillings for molars vs. incisors is about 70:30 according to the GKV-Spitzenverband.

² 880,000 fillings were invoiced in the 2nd half of 2018 for exceptional cases (e.g., children and pregnant or nursing women) via BEMA 13 e-h and are not included in this calculation.

³ Fees are initially set as "points" whose values may vary regionally and are adjusted regularly: Ø €1,07 in 2018.

6 Option 3: Full reimbursement for simpler fillings, and fixed reimbursement for larger fillings

Under Option 3 the public health insurance companies (GKVs) would provide full reimbursement for all 1- and 2-surface fillings, as well as a full or reasonable partial reimbursement for fillings of more than two surfaces. In the event of partial reimbursement of fillings of more than two surfaces, dental practices would have the possibility of private billing for the remaining cost.

The vast majority of fillings invoiced by dentists in Germany via the KZVs are one- and two-surface fillings, amounting to about 70% of all fillings in molars, as shown in the table above. Most of these one- and two-surface fillings can be readily filled with one layer of filling material, and would be provided to the patient free of charge assuming present BEMA item a-b reimbursements are increased by 10-20%, as indicated in Figure 16 below.

Figure 16. Typical one-, two- and three-surface restorations



6.1 Insurance reimbursement for serious tooth damage

Option 3 does not in any way change the public insurance reimbursements in place for prostheses. When a tooth is too damaged to be repaired with basic restoration materials, patients are faced with the choice of either having the tooth extracted, or replacing it with a crown or denture. Apart from full reimbursement for such dental repairs authorized by the statutory health insurance companies in cases of economic hardship, the partial reimbursement for prostheses in past years may have come to hundreds of euro. However, with advances in technology for making and placing crowns and partial crowns, not to mention CAD/CAM inlays, the costs of such alternatives continue to decline.

6.2 Fixed reimbursements for large fillings

The low level of amalgam use in Germany (less than 10% of all fillings) suggests that dentists have practiced a “hidden” additional cost arrangement for many years. As shown in the table below, in 2018 health insurance companies reimbursed the dentist EUR 34-62 for each basic amalgam (or equivalent) filling, depending on the number of surfaces; meanwhile the dentist privately billed an extra EUR 50 to 100 to most patients as they preferred to have a more aesthetic mercury-free filling.

We suggest a fixed subsidy or reimbursement by the public health insurance companies of 40% of the current cost of large fillings, which would imply that full (100%) reimbursement under the hardship regulation would come to EUR 130 for a 3-surface filling and EUR 155 for a 4-surface filling. These rates roughly correspond to the private insurance rates of the GOZ with a multiplier of 3.5 times (€126 and €152). The current guarantee of two years for the durability of one- and two-surface fillings could be extended to fillings with three and more surfaces.

Under Option 3, if dentists and health insurance companies cannot agree on a new full reimbursement rate for large (three and more surfaces) fillings, then a partial reimbursement rate would be fixed,⁸⁷ and dentists could continue to invoice according to the GOZ with the exception of hardship cases, which comprise some 10% of the cases for prostheses.

As seen in Table 9 below, this option would cost the public health insurance scheme about EUR 200-300 million more than currently, with another EUR 326-774 million probably contributed by patients through private fees. The table assesses only the data related to fillings in posterior teeth (molars) since amalgams are no longer used for anterior teeth (incisors) fillings in any case.

6.3 Full refund for the socioeconomically disadvantaged

As with the hardship provision for dental prostheses, low-income persons are entitled to full reimbursement for large fillings.

⁸⁷ It should be noted that in order for full coverage to be provided for patients who qualify, the interested parties would need to agree in advance what the full cost of the filling should be.

Table 9. Cost calculations for the Option 3 scheme following a ban on the use of amalgam

Surfaces of permanent fillings	Number of reimbursements for molars ¹ in 2018 ² [in Mio.]	Current situation		Calculation of the costs: Option 3			
		Dental amalgam is the basic supply material and is fully reimbursed by the public healthcare system; patients pay extra for more aesthetic alternatives		Public Health Insurance		Patients	
		Reimbursement rates BEMA 13 a-d [points converted into EUR ³]	Total reimbursements of public health sector in 2018 [EUR, Mio.]	F1 and F2: calculated according to new BEMA 13 a+b for molars (+10-20%). F3 and F4: BEMA c+d turn into partial contributions. (Dentists invoice fillings or inlays according to the GOZ)	Reimbursed fees of the public health sector, assuming 10% are hardship cases [EUR, Mio.]	F1+F2 fillings are fully reimbursed. F3+F4 require an extra contribution. (Bonus booklet holders and low-income people could have access to further reduced contributions)	Contribution according to GOZ-factor 2.3 or 3.5
1	9.26	€34	315	F1+F2 [points converted into EUR ³] F3+F4 40%/100% in cases of hardship	343 to 380	-	-
2	14.18	€42	596	€37-41	652 to 709	-	-
3	6.52	€52	339	€46-50	301+85	€31-74	182 to 434
4/4+	4.2	€62	260	€52/€130	234+65	€38-90	144 to 340
Total	34.16		~1.5 bn.	€62/€155	~1.7 to 1.8 bn.		~0.3 to 0.8 bn.

¹ The proportion of fillings for molars vs. incisors is about 70:30 according to the GKV-Spitzenverband.

² 880,000 fillings were invoiced in the 2nd half of 2018 for exceptional cases (e.g., children and pregnant or nursing women) via BEMA 13 e-h and are not included in this calculation.

³ Fees are initially set as “points” whose values may vary regionally and are adjusted regularly: ∅ €1,07 in 2018.

6.4 Gold and ceramic inlays

The more expensive gold and ceramic inlays are regarded by the BEMA as “similar” fillings, but the public insurance reimbursement is the same as for less expensive filling materials.

Meanwhile the production of ceramic inlays as shown in Figure 17 is being revolutionized by the new CAD/CAM (computer-assisted design and manufacturing) systems, which have significantly reduced costs and will continue to do so in the future. In Germany, 15-20% of dentists currently use intra-oral scanners, and the trend is rising sharply.⁸⁸

⁸⁸ Atlas Dental European Markets – Structures, Challenges and Scenarios 2018, GFDI mbH; https://www.gfdi.de/ids-2019/Atlas_Dentalstudie_2018_EN.pdf

Figure 17. Typical CAD/CAM inlay fillings



6.5 Advantages for dentists

Dentists can negotiate a more favourable rate for reimbursements from health insurance companies, at least for large fillings. This would ease any financial shock related to the transition to mercury-free fillings.

6.6 Advantages for health insurance companies

The total budget for reimbursing filling costs would remain manageable. Reimbursements for one- and two-surface fillings would probably have to increase by 10-20%, but reimbursements for fillings of three and more surfaces would remain more or less the same since a part of those costs would continue to be borne by the patients.

6.7 Advantages for patients

Low-income patients would continue to receive free dental care. Small fillings (the majority) would remain free of charge, and private fees for large composite fillings would remain within the existing range. Where previously only dental prostheses were subject to partial reimbursement, large fillings would also be partially reimbursed.

6.8 Advantages for politicians

The major remaining use of mercury in the EU would be phased out. The impact of dental mercury on human health and the environment would decline much more rapidly. The voting public would continue to have access to free basic fillings, for small fillings in general and, for low-income persons, also for large fillings.

7 Findings

7.1 Basic requirements for any option

The options for a revised public insurance reimbursement scheme for dental fillings that have been presented in this report focus on the technical details of a needed political agreement between the government, the dental profession and the public as we move into the post-amalgam era. The trade-offs are not insignificant, as the government and public health insurance companies rightly insist on continuing to provide a high level of dental care at a reasonable cost, the public is increasingly concerned by ever-rising private billing for dental treatments, and dental professionals strive to balance their largely entrepreneurial environment with their obligation to public healthcare during a time of rapidly evolving technological change, as well as social and economic uncertainties.

Based on the previous analysis, and assuming a general phase-out of amalgam use, it is recommended that any option for a revised public insurance reimbursement scheme in the post-amalgam era should respect the following basic requirements:

- Full public reimbursement for basic mercury-free restorations
- Constraints on the extent of private billing, while maintaining the opportunity for dental practitioners to invoice the patient for treatments exceeding the basic restoration
- The possibility for dental practitioners to use amalgam only in exceptional cases
- Limited additional employer and employee contributions to the public health insurance
- Measures to accommodate the special needs of the economically disadvantaged part of the population
- The strict requirement for dental practitioners to continue properly managing all hazardous waste and wastewater

Any of these options could probably find political agreement with a modest increase of EUR 200-330 million in the statutory healthcare insurance budget. To put that increase in perspective, it is roughly 10-15% of the 2.3 billion reimbursed specifically for fillings in 2018, and only 2-4% of the EUR 8.4 billion reimbursed for related restoration and surgical services.

The key considerations related to each of the three options are summarized below. Since the decision to adopt one or a combination of these options will be political, the authors do not express any preference among them.

7.2 Option 1: Full reimbursement of composites in place of amalgams

Option 1 reflects a 2018 calculation by the statutory health insurance companies (GKV) that was based on simply replacing all amalgam fillings with composites, the total cost of which would be covered by the public healthcare system. In discussing this option, the following should be considered:

- In order to determine fair and justified reimbursement rates, dentists and health insurance companies would have to thoroughly analyse and update the cost of appropriate, sufficient and economical treatment of patients with composite fillings,

which would probably result in an increased cost for the amalgam ban of EUR 300- 500 million rather than EUR one billion initially estimated by GKV.

- It should be discussed whether to provide a derogation for possible use of amalgam fillings in exceptional circumstances, as was done in Denmark and Sweden.
- For both anterior and posterior fillings, an additional cost regulation (i.e., private billing of the patient by the dentist) should be permitted for special patient wishes and treatment exceeding the basic composite filling.
- Over 90% of all fillings are already mercury-free. Precise data on the filling materials used for basic dental care are not available, but it is known that cheaper and less durable materials are often used. The acceptance of composite fillings as part of basic care will ensure reasonable durability of fillings, which will benefit health insurance companies and consumers alike.
- Although reduced opportunities for private billing are supported by consumer advocates, this aspect of Option 1 could significantly reduce the income of many dental practices. In parallel, however, new billing opportunities are on the increase, such as for partial crowns and CAD/CAM inlays.
- For patients, the full reimbursement of composite fillings would provide some financial relief, following the trend that has already been initiated by the increase in reimbursement rates for dentures.
- This analysis shows that a political agreement on Option 1 could probably be found with a modest increase of about EUR 330 million in the statutory healthcare insurance budget.

7.3 Option 2: Full reimbursement for single-layer fillings, with an additional fee for multi-layer fillings

Option 2 provides for a full public insurance reimbursement of all single-layer fillings – both large and small – with the opportunity of private billing by the dental practice for any more sophisticated materials such as multi-layer fillings. In the anterior region the insurance reimbursement would completely cover single-layer composites, while in the posterior region the single-layer reimbursement could be for any authorised filling material, although the material may not be matched to the tooth colour unless the patient agrees to private billing by the dentist. In discussing this option, the following should be considered:

- In contrast to Option 1, Option 2 would provide more opportunities for dentists to apply the additional cost rule (i.e., private billing of the patient by the dentist), which would help to maintain something closer to their current level of income.
- For dentists, Option 2 would be generally a continuation of the current system, while also requiring basic mercury-free materials where amalgams would have previously been placed.
- For health insurance companies as well, this option would be a continuation of the current model, which would incur only minor additional costs.
- Easy-to-process mercury-free filling materials increasingly appear on the market, but for many of these materials the range of colours is limited. Tooth-coloured materials may incur extra costs via private billing.

- Good quality mercury-free filling materials that may be placed as a single layer of one material or a combination of two materials are sufficient, practical and economically feasible for the treatment of all indications in the posterior region.
- Multilayer restorations can still be separately invoiced via the additional cost regulation.
- It should be discussed whether to provide a derogation for possible use of amalgam fillings in exceptional circumstances, as was done in Denmark and Sweden.
- This analysis shows that a political agreement on Option 2 could probably be found with a modest increase of EUR 200-300 million in the statutory healthcare insurance budget.

7.4 Option 3: Full reimbursement only for one- and two-surface fillings, with a fixed reimbursement for larger fillings

Option 3 provides for a full public health insurance reimbursement for all 1- and 2-surface fillings, as well as a full or reasonable partial reimbursement for fillings of more than two surfaces. In the event of partial reimbursement of fillings of more than two surfaces, dental practices would have the possibility of private billing for the remaining cost. In discussing this option, the following should be considered:

- Option 3 would directly address the current increasingly burdensome situation where the majority of patients pay between EUR 50 and 100 in extra private billing for various services related to a composite filling in the posterior region. If the rate that is currently reimbursed by health insurance companies were to be converted into a fixed reimbursement, a ban on amalgam would have less of an impact on both health insurance companies and dentists.
- Full public insurance reimbursement of the cost of one- and two-surface fillings, which account for about 70% of all fillings, will considerably ease some of the financial burden on patients. These fillings are generally much less complicated to treat with alternative filling materials than larger fillings, and an appropriate reimbursement rate should be relatively easy to agree on.
- In the case of larger fillings, interested parties will have to agree on what level of public insurance reimbursement is appropriate. As part of this discussion, it may be considered whether other more durable restoration methods might be indicated for large cavities, such as ceramic inlays or partial crowns, which are becoming cheaper and cheaper thanks to computer-controlled technologies.
- Meanwhile, low-income patients should continue to be entitled to full reimbursement of larger fillings via the hardship clause, as is the case with dentures.
- This analysis shows that a political agreement on Option 3 could probably be found with a modest increase of EUR 200-300 million in the statutory healthcare insurance budget.