

| | | |
|---|--|---|
| Institution: The University of Manchester | | |
| Unit of Assessment: 3 (Allied Health Professions, Dentistry, Nursing and Pharmacy) | | |
| Title of case study: Optimising patient care for the prevention of dental caries | | |
| Period when the underpinning research was undertaken: January 2010 - December 2016 | | |
| Details of staff conducting the underpinning research from the submitting unit: | | |
| Name(s): | Role(s) (e.g. job title): | Period(s) employed by submitting HEI: |
| Anne-Marie Glenny | Professor of Health Sciences Reader in Evidence based healthcare Senior Lecturer in Evidence based healthcare | 2013 - present 2012 - 2013 2008 - 2012 |
| Helen Worthington | Professor of Evidence Based Care | 2003 - present |
| Jan Clarkson | Professor of Clinical Effectiveness (20%) Honorary Professor | 2013 - present 2010 - 2013 |
| Tanya Walsh | Professor of Healthcare Evaluation Reader in Biostatistics Senior Lecturer in Biostatistics Lecturer in Biostatistics | 2018 - present 2016 - 2018 2012 - 2016 2005 - 2012 |
| Period when the claimed impact occurred: August 2013 - July 2020 | | |
| Is this case study continued from a case study submitted in 2014? N | | |
| 1. Summary of the impact | | |
| <p>Dental caries is a major public health problem in most industrialised countries, causing pain, distress and utilisation of substantial clinical resource. Inequalities in levels of decay still exist. Researchers at the University of Manchester (UoM) have worked with relevant stakeholders, including guideline developers and policy makers (e.g. American Dental Association, Public Health England, National Health and Medical Research Council (Australia)), to directly inform national/international healthcare policy and manufacturing activities, influencing public health, professional and self-care activities for improving oral and general health. Our research focuses on synthesising evidence in areas where there is a clinical need, as identified by healthcare professionals, policy makers or patients.</p> | | |
| 2. Underpinning research | | |
| <p>On a population basis, traditional treatment of oral disease (dental caries and periodontal diseases) is the fourth most expensive chronic disease to treat, according to the World Health Organization (WHO) (global policy document by Petersen et al. <i>Community Dent Oral Epidemiol.</i> 2009; Feb;37(1):1-8). Caries in permanent teeth was the most prevalent condition among all those evaluated in the Global Burden of Disease 2016 study, affecting 2,400,000,000 people (GBD 2016. <i>Lancet</i> 2017; Sep 16;390(10100):1211-1259).</p> <p>Whilst the link between fluoride and the prevention of dental caries dates back to the 1930s, questions regarding the most effective methods of delivering fluoride and the impact on health inequalities and adverse events have continued. From 2010, Glenny, Clarkson, Walsh and Worthington conducted a series of Cochrane reviews at the UoM to provide the most comprehensive, methodologically rigorous summary of the research evidence in this area. We synthesised the findings from both experimental and observational studies using a range of statistical approaches (as relevant to each research question).</p> | | |

Topical fluorides (applied directly to the tooth)

Our reviews provided clear evidence on the role of topical fluorides contained in mouthrinses, gels and varnishes. We demonstrated that fluoride mouthrinse is associated with a large reduction in caries increment in permanent teeth in children and adolescents [1]. Similarly, we demonstrated a large caries-inhibiting effect of fluoride gel in the permanent dentition [2]. A large effect was also seen in the primary dentition, although the evidence was less certain. With regard to fluoride varnish, we showed a substantial caries-inhibiting effect in both permanent and primary teeth [3].

The benefits of using fluoride toothpaste in preventing caries when compared to non-fluoride toothpaste have previously been established. Our review (96 studies, 11,356 participants) demonstrated, using a network-meta-analysis, a dose-response effect of fluoride for decayed, missing or filled surfaces in permanent teeth in children and adolescents [4]. Only fluoride toothpastes with fluoride concentrations of 1,000 ppm and above were found to be significantly better than non-fluoride toothpastes at preventing caries. The results of our review have been used to inform NIHR commissioning briefs, resulting in an NIHR HTA trial (REFleCt, awarded 2017) on the effectiveness of high fluoride toothpaste for the elderly.

Our reviews found limited evidence that starting the use of fluoride toothpaste in children under 12 months of age may be associated with an increased risk of fluorosis [5].

Water fluoridation

Although water fluoridation was found to be effective at reducing caries levels in both deciduous and permanent dentition in children, confidence in the size of the effect estimates is limited by the observational nature of the study designs, the high risk of bias within the studies and, importantly, the applicability of the evidence to current lifestyles, particularly given the majority of water fluoridation studies were undertaken before the widespread use of fluoride toothpaste [6]. There is insufficient evidence to determine whether water fluoridation results in a change in disparities in caries levels across different socioeconomic groups. Findings highlight a lack of information to determine the effect of stopping water fluoridation programmes on caries levels.

There is a significant association between dental fluorosis and water fluoride concentration [6]. Our review demonstrated that for a fluoride level of 0.7 ppm the percentage of participants with fluorosis of aesthetic concern was approximately 12% (95% CI 8% to 17%); 40 studies, 59,630 participants).

3. References to the research

Cochrane Reviews are systematic reviews of primary research in human health care and health policy; they are internationally recognized as the highest standard in evidence-based health care and are invaluable in informing decision-makers.

1. Marinho VC, Chong LY, **Worthington HV, Walsh T**. Fluoride mouthrinses for preventing dental caries in children and adolescents. Cochrane Database Syst Rev. 2016 Jul 29;7:CD002284. doi: [10.1002/14651858.CD002284.pub2](https://doi.org/10.1002/14651858.CD002284.pub2)
2. Marinho VC, **Worthington HV, Walsh T**, Chong LY. Fluoride gels for preventing dental caries in children and adolescents. Cochrane Database Syst Rev. 2015 Jun 15;(6):CD002280. doi: [10.1002/14651858.CD002280.pub2](https://doi.org/10.1002/14651858.CD002280.pub2)
3. Marinho VC, **Worthington HV, Walsh T, Clarkson JE**. Fluoride varnishes for preventing dental caries in children and adolescents. Cochrane Database Syst Rev. 2013 Jul 11;(7):CD002279. doi: [10.1002/14651858.CD002279.pub2](https://doi.org/10.1002/14651858.CD002279.pub2)

4. **Walsh T, Worthington HV, Glenny AM**, Appelbe P, Marinho VC, Shi X. Fluoride toothpastes of different concentrations for preventing dental caries in children and adolescents. *Cochrane Database Syst Rev.* 2010 Jan 20;(1):CD007868. doi: [10.1002/14651858.CD007868.pub2](https://doi.org/10.1002/14651858.CD007868.pub2)
5. Wong MC, **Clarkson J, Glenny AM**, Lo EC, Marinho VC, Tsang BW, **Walsh T, Worthington HV**. Cochrane reviews on the benefits/risks of fluoride toothpastes. *J Dent Res.* 2011; May;90(5):573-9. doi: [10.1177/0022034510393346](https://doi.org/10.1177/0022034510393346)
6. Iheozor-Ejiofor Z, **Worthington HV, Walsh T**, O'Malley L, **Clarkson JE**, Macey R, Alam R, Tugwell P, Welch V, **Glenny AM**. Water fluoridation for the prevention of dental caries. *Cochrane Database Syst Rev.* 2015 Jun 18;(6):CD010856. doi: [10.1002/14651858.CD010856.pub2](https://doi.org/10.1002/14651858.CD010856.pub2)

4. Details of the impact

Context

Fluoride has been used for several decades to prevent tooth decay through a variety of different methods including toothpaste, water, milk, mouthrinses, tooth gels and varnish. Despite being a largely preventable disease, dental caries remains widespread, affecting billions of people worldwide. It is one of the most common reasons for hospital admissions in children. Within this context, our research provides clear evidence that is directly informing national and international healthcare policy on the most effective methods of delivering fluoride.

Pathways to impact

Our synthesised evidence produced by Cochrane Oral Health has had a positive impact through both health professional and patient facing materials. The research played a significant role in ensuring appropriate knowledge transfer from primary studies through to clinical guidelines and policy.

Reach and significance of the impact

1. Optimising patient care through clinical recommendations

Our systematic reviews and their findings have been cited in national and international guidelines by developers, including:

- Public Health England (Delivering Better Oral Health) [A].
- Scottish Dental Clinical Effectiveness Programme (Prevention and Management of Dental Caries in Children) [B].
- American Dental Association (Topical fluoride for caries prevention) [C].
- American Academy of Pediatric Dentistry (Guideline on fluoride therapy) [D].
- National Health and Medical Research Council (NHMRC), Australia (Water fluoridation) [E].
- Royal Australian College of General Practitioners (Guidelines for preventive activities in general practice) [F].

Guidelines and their recommendations, underpinned by our research, have had and continue to have direct impact on patient care. For example, our research underpinned many of the recommendations of Public Health England's 'Delivering Better Oral Health (DBOH): an Evidence-Based Toolkit for Prevention' (2014, updated 2017), including recommendations around what age to start toothbrushing, how often to brush, the fluoride concentration in toothpaste, the role of fluoride varnish and the role of fluoride mouthrinses. DBOH is given to every General Dental Practitioner in England and Wales and as such

influences clinical practice in primary care. DBOH is also informing revisions to the dental contract.

NHMRC, Australia, has utilised our review on water fluoridation to develop advice for the Australian community, health professionals and government [E]. It acknowledged the review to be the highest quality evidence synthesis included in their technical report.

2. Influencing industry

Following the recommendations on toothpaste fluoride concentrations within DBOH, many major manufacturers have increased the concentration of fluoride in children's toothpastes from 550 ppm or less to 1,000 ppm fluoride or more [G]. By 2014, only four types of children's toothpaste could be found that contained low levels of fluoride and none that were fluoride free, reducing access to fluoride toothpastes with sub-optimal fluoride concentrations. Industry stakeholder involvement in the ongoing update of DBOH has confirmed the influence the publication continues to have on product manufacturing [H].

3. Informing political debate

Our research has informed and continues to inform debate regarding the possible (re) introduction of community water fluoridation in the UK. We were consulted to prepare a parliamentary debate (Lord Baldwin, 2015), and were asked to speak at a closed meeting to inform Irish parliamentary decision making (2015).

In 2015, Cochrane Oral Health were asked by the UK Department of Health to provide information about the review and its implications in two UK Parliamentary Questions:

- why systematic scientific reviews, such as Cochrane reviews, adopt 'specific and relatively narrow criteria' (HL395).
- what plans the government had to commission further studies that might meet the criteria of the 2015 Cochrane review *Water fluoridation for the prevention of dental caries*, in the light of findings that "the applicability of the results to current lifestyles is unclear because the majority of the studies were conducted before fluoride toothpastes and the other preventative measures were widely used" (HL396).

Our review on water fluoridation has also been directly cited by decision makers in local authorities (e.g. Hull [I]). Discussions are ongoing.

4. Informing national programmes to improve the oral health of children

In the Eradicating Child Poverty in Wales strategy (2006), the Welsh Government set a target to address oral health inequalities in children by 2020. Their 'Designed to Smile Programme' (based on the Scottish initiative, ChildSmile) has been key to reaching this target. Designed to Smile explicitly cite our research on fluoride concentration in toothpastes [4] to inform their daily toothbrushing schemes [Ji]. In 2018/2019 alone, 1,398 primary schools and nurseries participated in daily toothbrushing schemes, with appropriate fluoride toothpaste [Jii]. Over the past 10 years Designed to Smile has helped achieve a 10% reduction in tooth decay in five-year-old Welsh children, with a 35% (>3,200) reduction in the number of children undergoing dental procedures under general anaesthesia.

5. Sources to corroborate the impact

A. Public Health England. Delivering better oral health: an evidence-based toolkit for prevention. London: Public Health England; March 2017. Available from: <https://www.gov.uk/government/publications/delivering-better-oral-health-an-evidence-based-toolkit-for-prevention>

National guidelines citing our research findings from multiple Cochrane Systematic reviews.

B. Scottish Dental Clinical Effectiveness Programme. Prevention and Management of Dental Caries in Children (2018). Available from <http://www.sdcep.org.uk/published-guidance/caries-in-children/>

National guidelines that cite research findings from multiple Cochrane Systematic reviews.

C. Weyant et al. ADA Topical fluoride for caries prevention: executive summary of the updated clinical recommendations and supporting systematic review. *J Am Dent Assoc.* 2013 Nov;144(11):1279-91 doi: [10.14219/jada.archive.2013.0057](https://doi.org/10.14219/jada.archive.2013.0057)

International guidelines that cite our research findings indicating minimal concerns regarding adverse effects associated with professionally applied topical fluorides.

D. American Academy of Pediatric Dentistry. Guideline on fluoride therapy. *Pediatric Dentistry*, 2014 38(6), 181-4.

https://www.aapd.org/globalassets/assets/1/7/g_fluoridetherapy1.pdf

International guidelines that cite our research findings indicating reduction in caries with increasing fluoride concentration in toothpaste.

E. National Health and Medical Research Council (NHMRC) 2017, Information paper – Water fluoridation: dental and other human health outcomes. Canberra: NHMRC

<https://www.nhmrc.gov.au/about-us/publications/water-fluoridation-dental-and-other-human-health-outcomes>

International guidance that cites our research findings on the effectiveness of water fluoridation. Our review is highlighted as the highest quality synthesis of the evidence included in the document.

F. Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice (9th edition). Victoria: The Royal Australian College of General Practitioners; 2016. Available from:

<http://www.racgp.org.au/download/Documents/Guidelines/Redbook9/17048-Red-Book-9th-Edition.pdf>

International guidelines citing research findings from multiple Cochrane Systematic reviews.

G. Davies GM, Neville J, Jones K, White S. Why are caries levels reducing in five-year-olds in England? *Br Dent J* 2017;223: 515–519. doi:[10.1038/sj.bdj.2017.836](https://doi.org/10.1038/sj.bdj.2017.836)

Ecological study linking PHE support for higher fluoride toothpaste, based on our research findings, to reductions in caries levels in five-year-olds in England.

H. Testimonial from the National Lead for Child Oral Health Improvement, Public Health England, stating that stakeholder engagement with industry confirms that the guideline has

influenced toothpaste manufacturers to reformulate their products to more effectively prevent tooth decay.

I. 'The Benefits of Water Fluoridation to Oral Health', March 2017. Available from

<http://www.hull.gov.uk/sites/hull/files/media/Editor%20-%20Environmental/Benefits%20of%20Water%20Fluoridation.pdf>

This publication demonstrates how our review on water fluoridation is cited by decision makers in local authorities.

J. Documents outlining and evaluating Designed to Smile, a national prevention programme incorporating daily toothbrushing schemes utilising 1,000ppp -1,500ppm fluoride toothpaste.

Ji Designed to Smile - working to improve oral healthcare for children (NICE shared learning database). <https://www.nice.org.uk/sharedlearning/designed-to-smile-working-to-improve-oral-healthcare-for-children>

Jii Iomhair N, Wilson M, Morgan, M. Ten years of Designed to Smile in Wales. *BDJ Team 7*, 12–15 (2020).