FEASIBILITY OF PROVISION AND EVALUATION OF SEALANTS FOR CHILDREN HAVING CARIES RELATED DENTAL EXTRACTIONS UNDER A GENERAL ANAESTHETIC

By

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ABSTRACT

Children experiencing caries related dental treatment under general anaesthetic (GA) are vulnerable to relapse, so prevention is paramount. Evidence based pro-active interventions are required to address the preventive needs of this high-risk group and this includes making better use of opportunities offered by the GA encounter.

The principal aim of this research was to develop and undertake a pilot randomised control trial (RCT) to assess the feasibility of provision and evaluate the outcome, of sealing sound permanent molars, during the pre-GA assessment visit, in children requiring caries related extractions under a chair GA. This was supported by a service evaluation on the need for sealants in this cohort and investigating referring practitioners' views and practices on prevention for high-risk children.

Findings identified an unmet need for sealants and found children were at high risk of new caries in permanent molars that were sound at the time of the GA. Sealant placement during the pre-GA assessment appointment was feasible and had the potential to reduce caries incidence in permanent molars. Moving forwards, a definitive multi-centre RCT is justified to further explore delivery of this intervention.

DEDICATION

For my dearest Mummy jaan, Daddy jaan, Bobo and Punay.

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TABLE OF CONTENTS

INTRODUCTION: Structure of thesis 1

CHAPTER 1: BACKGROUND 3

1.1: Dental caries in children 3

1.1.1 - Risk factors associated with caries in children 3

1.1.2 - Prevalence of dental caries in children 4

1.1.3 - Impact of dental caries 7

1.1.4 - Caries prevention: prioritising children needing caries related dental treatment under GA 9

1.2: Caries prevention in children 10

1.2.1 - Approaches to caries prevention - population versus individual 10

1.2.2 - Caries preventive interventions – Overview 11

1.2.2.1 - Oral health counselling 12

1.2.2.2 - Topical fluoride 18

1.2.2.3 - Dental sealants 20

1.2.2.3.1 - *Sealants in permanent teeth* 21

1.2.2.3.2 - *Sealants in primary teeth* 22

1.2.2.3.3 - *Cost effectiveness of sealants* 23

1.2.2.3.4 - *Clinical recommendations on use of sealants* 23

1.2.2.4 - *Sealants versus fluoride varnish to prevent caries on pits and fissures of permanent molars* 24

1.3: General anaesthesia for dental treatment 25

1.3.1 - Options for delivery of dental treatment 25

1.3.2 - Background on use of GA for dental treatment in the UK 26

1.3.3 - Indications for use of GA for dental treatment 27

1.3.4 - Dental GA Services 27

1.3.5 - Benefits and risks of a dental GA 28

1.3.6 – Prevalence and cost of dental GA in the UK 29

1.3.7 - Factors associated with use of GA for dental treatment in children 30

1.3.7.1 - *Deprivation and dental GA* 30

1.3.7.2 - *Ethnicity and dental GA* 31

1.3.7.3 - *Dental fear and anxiety* 32

1.3.7.4 - *Parental anxiety and dental GA* 32

1.3.7.5 - *Experience of dental GA within families* 33

1.3.7.6 - *Self efficacy and oral health related fatalism* 33

1.3.7.7 - *Dental neglect and dental GA* 34

1.3.7.8 - *Service availability and dental GA* 34

1.3.7.9 - *Fluoridation and dental GA* 35

1.3.8 - Repeat dental GA 35

1.3.8.1 - Repeat dental GA incidence 35

1.3.8.2 - Factors associated with a repeat dental GA 36

1.3.8.3 - Reasons for a repeat dental GA 37

1.3.8.3.1 - *Failures in treatment planning* 37

1.3.8.3.2 - *Relapse related to new caries* 38

1.3.9 - Caries prevention following a dental GA 39

1.4: Dental general anaesthesia and caries prevention: Literature review 40

1.4.1 - Literature review methods 40

1.4.2 - Previous research on dental general anaesthesia and caries prevention 43

1.4.2.1 - Observational research on dental GA and caries prevention 63

1.4.2.1.1 - Parental knowledge, attitudes, beliefs and behaviours relating to caries prevention 64

1.4.2.1.2 - Compliance for follow-up appointments after a dental GA 66

1.4.2.1.3 - Oral health support and preventive care for children needing a dental GA 67

1.4.2.1.4 - Dental practitioners' views on prevention for high-risk children 70

1.4.2.2 - Interventional studies to evaluate preventive strategies in patients requiring caries related dental treatment under GA 71

1.4.3 - Literature review summary 73

1.4.4 - Prevention for children requiring a caries related dental GA – rationale for research 75

CHAPTER 2: DEVELOPING PREVENTIVE INTERVENTIONS FOR CHILDREN REQUIRING A CARIES RELATED DENTAL GA 77

2.1 - Introduction 77

2.2 - Background of paediatric dental GA service in Birmingham 77

2.3 - The 'ideal' intervention 79

2.4 - Opportunities to deliver prevention 80

2.5 - Re- appraisal of preventive interventions, as applied to children requiring a caries related dental GA 83

2.5.1 - Oral health counselling 83

2.5.2 - Topical Fluoride 84

2.5.3 - Fissure sealants 84

2.6 - Sealants as part of the GA encounter - rationale 87

2.7 - Developing a caries preventive intervention based on delivering sealants as part of the GA encounter 89

2.7.1 - Background to overall aim and objectives of research 89

2.7.2 - Overall aim and objectives of research 90

2.7.3 - Studies to inform development of a caries preventive intervention based on delivering sealants as part of the GA encounter 91

CHAPTER 3: CLINICAL CASE STUDIES TO ASSESS FEASIBILITY OF PROVIDING SEALANTS AT THE GA EXTRACTIONS VISIT 94

3.1 - Sealants placed under GA 94

3.1.1 - Setting, subject and methods 95

3.1.2 - Outcome 95

3.1.3 - Discussion 96

3.2 - Sealants placed at the GA visit (prior to the GA) 96

3.2.1 - Setting, subjects and methods 97

3.2.2 - Outcome 98

3.3 - Sealants at the pre-GA assessment appointment - a new opportunity 99

CHAPTER 4: SERVICE EVALUATION: PREVENTION IN THE CONTEXT OF CARIES RELATED EXTRACTIONS UNDER GENERAL ANAESTHESIA – AN EVALUATION OF THE USE OF SEALANTS AND OTHER PREVENTIVE CARE BY REFERRING PRACTITIONERS 100

4.1 – Aim ……100

4.2 - Baseline service evaluation on need for sealants, plans for follow up dental care after the GA and views of parents of high-risk children, on use of sealants - Study A 101

4.2.1 – Objectives ……..101

4.2.2 - Setting, subjects and methods ……101

4.2.3 - Results – response rate ……104

4.2.3.1 - Demographic characteristics of sample ……..104

4.2.3.2 - Clinical status of first permanent molars 107

4.2.3.3 - Dental attendance behaviours 109

4.2.3.4 - Parents' opinions on sealants and taking part in a trial 110

4.2.4 - Discussion 111

4.2.4.1 - Methods and limitations 111

4.2.4.2 - Demographics of sample 113

4.2.4.3 - Dental attendance behaviours 114

4.2.4.4 - Unmet need for sealants in first permanent molars 114

4.2.4.5 - Parents opinions on taking part in a trial 115

4.2.5 - Conclusions and recommendations 115

4.3 - Two-year follow-up: an evaluation of caries levels in first permanent molars, use of sealants and other preventive care provided by referring dentists, for children experiencing caries related extractions under GA – Study B 117

4.3.1 - Background 117

4.3.2 - Aim and Objectives 117

4.3.3 - Setting, subjects and methods 118

4.3.3.1 - Clinical examination 121

4.3.3.2 - Parental questionnaire 123

4.3.4 - Results – response rate 123

4.3.4.1 - Demographic characteristics of sample 124

4.3.4.2 - Dental attendance behaviours 126

4.3.4.3 - Preventive support and dental treatment and levels of dental anxiety 127

4.3.4.4 - Parents' views on measures to help improve dental care for their child 128

4.3.4.5 - Caries levels and evidence of sealants at 2 years 128

4.3.5 - Discussion 132

4.3.5.1 - Methods and limitations 132

4.3.5.2 - Demographics of sample 133

4.3.5.3 - Previous dental treatment under GA 134

4.3.5.4 - Dental attendance behaviours 134

4.3.5.5 - Preventive dental care 135

4.3.5.6 - Dental caries 136

4.3.5.7 - Parents' opinions on measures to help 137

4.3.6 - Conclusions and recommendations 137

CHAPTER 5: REFERRING PRACTITIONERS' VIEWS AND PRACTICES ON PREVENTION, FOR CHILDEN UNDERGOING CARIES RELATED EXTRACTIONS UNDER GENERAL ANAESTHESIA IN BIRMINGHAM 139

5.1 - Background 139

5.2 - Aim and objectives 140

5.3 - Methods 141

5.3.1 - Ethics approval 141

5.3.2 - Setting and subjects 141

5.3.3 - Design 141

5.3.4 - Invitation letters and Questionnaires 144

5.3.5 - Data collection, recording and statistical analyses 145

5.4 - Results 145

5.4.1 - Response rate 145

5.4.2 - Demographic characteristics of study sample 146

5.4.3 - Referring practitioners' views and practices on prevention 147

5.4.3.1 - Follow up after GA 151

5.4.3.2 - Preventive advice and treatments 152

5.4.3.3 - Barriers to delivering prevention 153

5.4.3.4 - Views on interventions to prevent caries in high-risk children 153

5.4.3.5 - Comments by referring practitioners 153

5.4.4 - Comparison of differences between GDPs and CDPs - Demographic characteristics and views and practices on follow-up and prevention 154

5.4.5 - Comparison of differences between high and low referrers - Demographic characteristics and views and practices on follow-up and prevention 160

5.5 - Discussion 172

5.5.1 - Study strengths and limitations 172

5.5.2 - Demographics of sample 173

5.5.3 - Follow up procedures, reminders and managing poor attendance 174

5.5.4 - Preventive support for high-risk children 176

5.5.5 - Barriers to delivering prevention 177

5.5.6 - Views on interventions to prevent caries in high-risk children 178

5.5.7 - Recommendations: shared care approach to preventing caries in high-risk children .179

5.6 - Conclusions 183

CHAPTER 6: A PILOT RANDOMISED CONTROLLED TRIAL TO EVALUATE PLACEMENT OF SEALANTS DURING THE GA ASSESSMENT, IN CHILDREN REQUIRING CARIES RELATED DENTAL EXTRACTIONS UNDER A GENERAL ANAESTHETIC 184

6.1 - Background: Sealant placement as part of the pre-GA assessment appointment 184

6.2 - Aim and objectives 185

6.3 - Methods 186

6.3.1 - Ethics approval and registrations 186

6.3.2 – Design 187

6.3.3 - Setting and subjects 187

6.3.4 - Selection criteria 187

6.3.5 - Study procedures - pilot RCT 188

6.3.5.1 - *Triage referrals* 190

6.3.5.2 - *Recruitment - pre-GA assessment visits* 190

6.3.5.2.1 - Eligibility and consent 190

6.3.5.2.2 - Clinical Examination 191

6.3.5.2.3 – Randomisation and allocation concealment 192

6.3.5.2.4 - Sealant group intervention 192

6.3.5.2.5 - Control group procedures 194

6.3.5.2.6 - Management of carious teeth not earmarked for extraction 194

6.3.5.2.7 - Refusals and non-eligibility 194

6.3.5.4 - *Follow up and review* 194

6.3.5.4.1 - Clinical Examination at Follow up/ Review Appointment – 12 and 24 months 195

6.3.5.4.2 - Clinical photographs - 12 and 24 Months 196

6.3.5.4.3 - Structured interview questionnaires - 12 and 24 Months 196

6.3.5.4.4 - Oral Health Related Quality of Life - 24 Months 196

6.3.5.4.5 - Outcome assessor blinding and calibration to assess reliability 197

6.3.5.4.6 - Dental treatment and prevention activity at follow-up appointments 197

6.3.5.5 - *Outcome measures (and their assessment)* 199

6.3.4.6 - *Sample size* 201

6.3.5.7 - *Statistical analyses* 201

6.3.5.8 - *Resources (implementation and research costs)* 201

6.4 - Pilot RCT Results 202

6.4.1 - Participants' flow through the pilot RCT (CONSORT) 202

6.4.2 - Participants' demographic characteristics and dental attendance patterns at baseline 204

6.4.2.1 - Whole group 206
6.4.2.2 - Control versus Sealant group 207
6.4.2.3 - Follow-up at 24 months versus no follow-up at 24 months 207
6.4.3 - Baseline caries prevalence (and evidence of sealants) 210
6.4.4 - Sealants applied at baseline 216
6.4.5 - Follow up results: 24 months 219
6.4.5.1 - Demographic characteristics of participants followed up at 24 months 220
6.4.5.2 - Sealants at 24 months 222
6.4.5.3 - Caries prevalence in permanent molars at 24 months 223
6.4.5.4 - Caries in primary teeth at 24 months 230
6.4.5.5 - Oral symptoms and Oral Health related Quality of Life (OHRQoL) 24 months after GA 231
6.4.5.6 - 24 month follow up Questionnaire - parents' experiences of dental services for their children 239
6.4.5.6.1 - Dental attendance behaviours within 24 months after dental GA 239
6.4.5.6.2 - Preventive advice and treatments in primary care 244
6.4.5.6.3 - Dental treatment received in primary care 247
6.4.5.6.4 - Dental anxiety 249
6.4.5.6.5 - Parents views on advice and interventions to support their child's oral health 250
6.4.6 - Examiner calibration for caries assessment – inter and intra-examiner variation 252
6.5 - Discussion 255
6.5.1 - Discussion of methods: study procedures, design limitations and recommendations for improvement 255

6.5.1.1 - Study design and selection criteria 255
6.5.1.2 - Caries assessment and sealant retention status: ICDAS 256
6.5.1.3 - Examiner training and calibration 257
6.5.1.4 - Radiographs 258
6.5.1.5 - Sealants procedures and acceptability 260
6.5.1.6 - Follow-up questionnaires 263
6.5.1.7 - Oral health related Quality of Life evaluation 265
6.5.1.8 - Clinical Outcome measures 267
6.5.1.9 - Incentives to enhance recruitment and retention of participants 268
6.5.2 - Discussion of results 269
6.5.2.1 - Recruitment and retention 269
6.5.2.2 - Demographic characteristics of study group 270
6.5.2.3 - Previous experience of dental GA 272
6.5.2.4 - Referral source and plans for follow-up after GA 273
6.5.2.5 - Radiographic assessment 274
6.5.2.6 - Examiner training, calibration and reliability 274
6.5.2.7 - Prevalence of caries at baseline 275
6.5.2.7.1 - Caries primary dentition 275
6.5.2.7.2 - Caries permanent dentition 276
6.5.2.8 - Sealants and ‘sealable’ molars at baseline 277
6.5.2.9 – Comparison of Baseline characteristics: Follow-up at 24 months versus no follow-up at 24 months 277
6.5.2.10 - Sealant acceptability (intervention group) 278
6.5.2.11 - Follow-up - 24 months 279
6.5.2.11.1 - Sealants present at 24 months 279

6.5.2.11.2 - Caries prevalence in permanent molars at 24 months 281
6.5.2.11.3 - Caries prevalence in primary teeth at 24 months 283
6.5.2.11.4 - Oral symptoms and Oral health related quality of life (OHRQoL) two years after dental GA 284
6.5.2.11.5 - Oral health behaviours and experience of dental services following - questionnaire strengths and limitations 286
6.5.2.11.6 - Dental attendance patterns 287
6.5.2.11.7 - Prevention delivered following GA by providers outside the study 289
6.5.2.11.8 - Dental treatment received in primary care following GA 291
6.5.2.11.9 - Dental anxiety post GA 292
6.5.2.11.10 - Parents views on advice and interventions to support oral health 293
6.5.2.11.11 - GA use in siblings 294
6.5.2.12 - Discussion of relevant outcomes at 12 months 295
6.5.3 - Can sealing first permanent molars as part of the GA encounter prevent repeat GA? 296
6.5.4 - Pilot study limitations and recommendations for future research 297
6.6 - Pilot RCT Conclusions 300
6.7 – Pilot RCT Recommendations – multi-centre RCT 301

CHAPTER 7: OVERALL CONCLUSIONS (AND RECOMMENDATIONS) .303

LIST OF FIGURES..... xiii

LIST OF TABLES xiv

LIST OF APPENDICES xix

LIST OF ABBREVIATIONS xxi

LIST OF REFERENCES 304

LIST OF FIGURES

Figure 1: Literature search methods on ‘prevention for children requiring caries related dental extractions under general anaesthesia’ 42

Figure 2: Opportunities to deliver prevention as part of the GA care pathway 82

Figure 3: Overview of studies to inform development of a caries preventive intervention based on delivering sealants as part of the GA encounter 92

Figure 4: Two-year post GA service evaluation - procedures for 2-year follow ups and throughput of patients 119

Figure 5: Pilot RCT procedures flow diagram 189

Figure 6: Participants’ flow through the pilot RCT (CONSORT) 203

LIST OF TABLES

Table 1: Caries Prevalence in Children in England (2013) 6

Table 2: Key evidence-based advice on oral health messages 13

Table 3: Observational studies on dental GA and caries prevention 44

Table 4: Interventional studies on dental GA and caries prevention 56

Table 5: Birmingham Dental Hospital Paediatric Dental GA Service Activity: 2017-18 79

Table 6: Benefits (pros) and Limitations (cons) of a preventive intervention based on fissure sealing permanent molars as part of the GA encounter 88

Table 7: Outcomes of sealants applied at GA treatment visit (before GA) 98

Table 8: Baseline service evaluation – codes to record condition/ status of first permanent molars 102

Table 9a: Baseline service evaluation – data on age of sample at GA appointment (children > 5 years) 104

Table 9b: Baseline service evaluation – other demographic characteristics of sample at GA appointment (children > 5 years) 106

Table 10: Baseline service evaluation - condition of first permanent molars at GA appointment 107

Table 11: Baseline service evaluation - prevalence of sound and sealable first permanent molars at GA appointment, by age group 108

Table 12: Baseline service evaluation - dental attendance behaviours before the GA 109

Table 13: Parents' opinions on sealants and on taking part in a trial 110

Table 14: ICDAS II Restorative codes criteria 121

Table 15: ICDAS II Caries codes criteria 122

Table 16: Baseline (2012-13) demographic characteristics for children followed up after 2 years 124

Table 17: Preventive care and dental treatment received by children that visited a dentist within 2 years following GA 127

Table 18: Parents' views on measures they would find helpful to look after their child's teeth 128

Table 19: Untreated caries affecting first permanent molars (FPMs) that were sound at the time of the GA, in patients followed up clinically at 2 years 129

Table 20: Number of first permanent molars affected, in children presenting with untreated caries, two years after the GA 130

Table 21: Untreated caries data for first permanent molars in patients followed up at 2 years 131

Table 22: GDP referral rates to BDH for paediatric caries related dental extractions (2013) 142

Table 23: Demographic characteristics of referring practitioners: responders and non-responders 147

Table 24: Referring practitioners' views and practices on follow-up and prevention for children needing a caries related dental GA 148

Table 25: GDP and CDP - Comparison of demographic characteristics and views and practices on follow-up and prevention 154

Table 26: High and Low referrers (all respondents) - Comparison of demographic characteristics and views and practices on follow-up and prevention 160

Table 27: High and Low referrers (GDS only) - Comparison of demographic characteristics and views and practices on follow-up and prevention 166

Table 28: Techniques used for sealant placement in pilot RCT 193

Table 29: Pilot RCT - Demographic characteristics and dental attendance patterns at baseline - whole group and comparison of control versus sealant 204

Table 30 Pilot RCT – Comparison of demographic characteristics and dental attendance patterns at baseline - follow up versus no follow up at 24 months 207

Table 31 – Pilot RCT - Caries prevalence at baseline (and evidence of sealants) – whole group 210

Table 32 Pilot RCT - prevalence of sound first permanent molars at baseline, in different age groups 211

Table 33 – Pilot RCT - Caries prevalence at baseline (and evidence of sealants) – control versus sealant group 212

Table 34 – Pilot RCT - Caries prevalence at baseline (and evidence of sealants) – follow up versus no follow up at 24 months 214

Table 35 – Pilot RCT – Sealants applied at baseline 216

Table 36 – Pilot RCT – Sealants acceptability based on FIS scores 218

Table 37 - Pilot RCT – Demographic characteristics for participants followed up at 24 months – 'whole group' and control versus sealant 220

Table 38 - Prevalence of sealants at 24 months on permanent molars that were sound at baseline 222

Table 39 - Caries prevalence at 24-months control versus sealant 223

Table 40 - Prevalence of different severities of caries on a child level at 24 months in permanent molars that were present & sound at baseline (SPM_{BL}): control versus sealant 226

Table 41 – Prevalence of different severities of caries on a surface level at 24 months in permanent molars that were present & sound at baseline (SPM_{BL}): control versus sealant 227

Table 42 - Caries prevalence at 24 months in permanent molars that were sound at baseline: surface types affected 229

Table 43 - Pilot RCT - Caries primary teeth at 24 months – control versus sealant 230

Table 44 - Caries primary molars at 24 months – surface types affected 231

Table 45 - Oral symptoms and Oral health related Quality of Life impacts at 24-month follow up: control versus sealant 231

Table 46 - Oral symptoms and Oral health related Quality of Life impacts at 24-month follow up: based on sex 234

Table 47 - Oral symptoms and Oral health related Quality of Life impacts at 24-month follow up: based on ethnicity 235

Table 48 - Oral symptoms and Oral health related Quality of Life impacts at 24-month follow up: based on deprivation 237

Table 49 – Dental attendance behaviours within 24 months after dental GA 240

Table 50 - Dental visits for children that returned to see a dentist within 24-months following dental GA 242

Table 51- Preventive advice and treatments received within 24-months following dental GA 245

Table 52 - Dental treatment received within 24-months following dental GA 247

Table 53: Parents' views (at 24 months) on advice and interventions to support oral health 250

Table 54 - Examiner calibration – inter and intra-examiner variation 254

Table 55 - Pilot RCT on sealant application as part of GA assessment visit: limitations of study methods 297

Table 56 - Recommendations to improve design of future trials on sealant application as part of GA assessment visit 299

Table 57 - Summary of conclusions from pilot RCT to evaluate placement of sealants as part of the GA assessment visit 300

Tables 58 to 66 - 12 month results (in Appendix 25)

Table 58 - Pilot RCT – Demographic characteristics for participants followed up at 12 months – whole group and control versus sealant

Table 59 - Prevalence of sealants at 12 months on permanent molars that were sound at baseline

Table 60 - Caries prevalence at 12-months control versus sealant

Table 61 - Caries prevalence in children at 12 months and 24 months

Table 62 - Caries prevalence based on attendance for 12 and 24 month reviews

Table 63 - Dental attendance behaviours within 12 months after dental GA

Table 64 - Preventive advice and treatments received within 12-months following dental GA

Table 65 - Dental treatment received within 12-months following dental GA

Table 66 - Parents' views (at 12 months) on advice and interventions to support oral health

LIST OF APPENDICES

Appendix 1 – Baseline GA service evaluation CRF 1

Appendix 2 – Baseline GA service evaluation parent questionnaire

Appendix 3 – Two-year post GA follow up service evaluation – parent invitation letter

Appendix 4 – Two-year post GA follow up service evaluation CRF 2

Appendix 5 – Two-year post GA follow up service evaluation – parent questionnaire

Appendix 6 - Referring practitioners' views and practices on prevention – GDP invitation letter

Appendix 7 – Referring practitioners' views and practices on prevention – GDP Questionnaire

Appendix 8 - Referring practitioners' views and practices on prevention – CDP Questionnaire

Appendix 9 – Protocol for pilot RCT on sealants as part of GA assessment visit

Appendix 10 – Pilot RCT NHS Ethics approval letter

Appendix 11 – Pilot RCT participant invitation letter

Appendix 12 – Pilot RCT parent information sheet

Appendix 13 – Pilot RCT child information sheet

Appendix 14 – Pilot RCT parent consent form

Appendix 15 – Pilot baseline CRF 3a

Appendix 16 – Pilot RCT Facial image scale

Appendix 17 – Pilot RCT record of refusals and non-eligibility

Appendix 18 – Pilot RCT participant withdrawals form

Appendix 19 – Pilot follow-up CRF 3b

Appendix 20 – Pilot RCT 12-month parent questionnaire

Appendix 21 – Pilot RCT 24-month parent questionnaire

Appendix 22 – Pilot RCT Oral health related QoL questionnaire

Appendix 23 – Pilot RCT dentist letter for treatment completed

Appendix 24 – Pilot RCT dentist letter for treatment recommended

Appendix 25 – Pilot RCT Summary of Key - Outcomes at 12 months - tables (Table 58 – 66)

Appendix 26 – Paper published in British Dental Journal:

Prevention in the context of caries-related extractions under general anaesthesia: an evaluation of the use of sealants and other preventive care by referring dentists

Abida Raja, Deborah Anne White, Sally Elizabeth Kerr and Thomas Dietrich

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LIST OF ABBREVIATIONS

BASCD - British Association for the Study of Community Dentistry

BCHC NHS Trust - Birmingham Community Healthcare NHS Trust

BDH - Birmingham Dental Hospital

BSPD - British Society of Paediatric Dentistry

CDHS - Child Dental Health Survey

CDP – Community Dental Practitioner

CDS - Community Dental Services

Child-OIDP - Child-Oral Impacts on Daily Performances

CONSORT - Consolidated Standards of Reporting Trials

CRF - case report form

DBOH - Delivering Better Oral Health, an evidence-based toolkit for prevention in England

DCP – dental care professional

dmfs – decayed, missing and filled primary tooth surfaces

dfs - decayed and filled primary tooth surfaces

DMFT - decayed, missing (due to caries), and filled permanent teeth

DMFS - decayed, missing (due to caries), and filled permanent surfaces

FIS - Facial image scale

FPM - first permanent molar

ECC - early childhood caries

GA - general anaesthetic

GDC - General Dental Council

GI - glass ionomer

ICDAS - International Caries Detection and Assessment System

ICCMS - International Caries Classification and Management System

IMD - index of multiple deprivation

IRAS - integrated research application system

LA - local anaesthesia

MCDAS - Modified Child Dental Anxiety Scale

NHS - National Health Service

NICE - National Institute for Healthcare and Clinical Excellence

NIHR - National Institute of Health Research

NRES - National Research Ethics Service

OHE - oral health education

OHRQoL - Oral health related Quality of Life

PCD - professional complementary to dentistry

PCT - primary care trust

PIN - participant identification number

Ppm - parts per million

RCA - Royal College of Anaesthetists

RCS - Royal College of Surgeons

RCT - randomised controlled trial

SDCEP - Scottish Dental Clinical Effectiveness Programme

SD - standard deviation

SDF - silver diamine fluoride

SFPM - sound first permanent molar

SIGN - Scottish Intercollegiate Guidelines Network

SPM_{BL} - permanent molars that were sound at baseline

Std Err – standard error

UK - United Kingdom

US - United States

WHO - World Health Organisation

Wt - weight

INTRODUCTION: Structure of thesis

Dental caries is largely preventable (1) and despite a decline over recent decades in the proportion of children affected in the United Kingdom (UK), inequalities remain, with higher prevalence and severity among certain groups (2). A general anaesthetic (GA) is sometimes required to manage caries, and often involves multiple extractions, especially for younger children (3). Children with experience of dental treatment under GA are vulnerable to further caries and potentially, a repeat GA, which is a procedure never without risk (4). Previous research has helped identify the challenges parents face in supporting their child's oral health (5-7) but suggests the GA experience does not appear to have a significant impact on long term preventive behaviours (5). Therefore, prevention is clearly a priority but unfortunately, support within primary care dental services and by GA providers appears to be inadequate and failing to meet the needs of this high-risk group (6, 8).

Despite reasonable understanding of the factors associated with increased risk of caries in children experiencing a dental GA, relatively few studies have investigated the impact of preventive interventions tailored to address the needs of this high-risk group, indicating scope for more research in this area (9-11). Therefore, the principal aim of this thesis is to identify, develop and evaluate an appropriate intervention to prevent relapse in children requiring a caries related dental GA: crucially, this includes making better use of the opportunity offered by the GA encounter, to deliver preventive treatments, most notably sealants, to potentially hard to reach families.

The thesis describes the steps required to reach this goal and is divided into 7 main Chapters:

Chapter 1 includes a brief background on dental caries and evidence-based interventions for prevention. Key aspects surrounding use of GA in paediatric dentistry are outlined and followed by a review of previous research relating to caries prevention for children with experience of a dental GA.

Chapter 2 explores opportunities available to deliver prevention in this cohort and assesses which preventive treatments might be most appropriate in this setting. The main research questions are identified, and study methods required to address these are considered before presenting the rationale for the planned intervention.

The following 4 chapters describe each of the 4 main aspects investigated and studies that were carried out, which include: clinical case studies to evaluate feasibility of placing sealants as part of the GA extractions visit (Chapter 3), service evaluations on unmet need and use of preventive treatments by referring practitioners (Chapter 4), an investigation of referring practitioners views and practices on prevention for high-risk children (Chapter 5) and finally, a pilot study to evaluate placement of fissure sealants as part of the GA encounter (Chapter 6).

The closing chapter (Chapter 7) draws together the main findings and outlines key conclusions and recommendations for further research.

CHAPTER 1: BACKGROUND

1.1

Dental caries in children:

Dental caries is defined as

"The localised destruction of susceptible dental hard tissues through acidic by-products from bacterial fermentation of dietary carbohydrates"(12).

Caries is multi-factorial, being influenced by a range of physiological, behavioural and wider environmental risk factors, including dietary and oral hygiene practices and socio-economic background (12, 13). Importantly, the disease is preventable and can also be controlled to slow, arrest or facilitate repair of early lesions through remineralisation (1).

Early childhood caries (ECC) refers to an aggressive form of caries in young children and is defined as "*the presence of one or more decayed (non-cavitated or cavitated), missing (due to caries) or filled tooth surfaces in any primary tooth in a child under the age of 6*" (14). This often is related to feeding practices, particularly, frequent consumption of sugary drinks from baby bottles and pacifiers (2, 14).

1.1.1

Risk factors associated with caries in children:

A range of factors can contribute to a child's susceptibility to dental caries, including biological factors (such as oral levels of cariogenic streptococci mutans bacteria and salivary flow rates), exposure to fluoride, dietary and oral hygiene behaviours, through to wider socio-demographic and economic determinants of oral health (12, 15).

The association between deprivation and childhood dental caries is well known, with highest levels of disease presenting in children from the most disadvantaged backgrounds (16, 17). These inequalities are clearly apparent when comparing differences in caries prevalence across different parts of the UK and even more so, when evaluating variations within local authority areas in England (18), with around 40% of variations identified in 5 year olds being attributed to material deprivation (19). Deprivation also influences severity of caries: the most recent Child Dental Health Survey (CDHS) in the UK found that children eligible for free school meals were at least twice as likely to experience 'severe or extensive disease' (20).

Associations between ethnic background and caries experience may be difficult to extract from possible links with socio-economic status and deprivation (21, 22). Earlier studies suggest inequalities might be related to cultural differences in oral health related behaviours, such as diet and oral hygiene practices (23, 24). Bedi *et al*., report higher caries in children from the South Asian continent (especially if their mothers don't speak English) and lowest rates for Afro-Caribbean communities (23). In 2015, caries levels in 5 year olds in the UK, were highest amongst Chinese children, followed by those from an Eastern European or Asian background (19, 25).

1.1.2

Prevalence of dental caries in children:

Dental caries is one of the most prevalent diseases in the world, reportedly affecting 2.4 billion people and 621 million children (26). Untreated caries in permanent teeth is considered to be the most prevalent condition worldwide and caries affecting the primary dentition the 10th most common disease in children (26). In low and middle

income countries, early childhood caries in particular, is growing, due to changes in diet and lifestyles (14) but even in the United States (US), dental caries in children is five times more common than asthma (12).

Caries continues to be the "*most common oral disease affecting children and young people in England*" (18). Since 1973, national surveys of children's dental health in the UK, have been undertaken every 10 years, with the most recent in 2013 (27, 28). Since the 1970's, the oral health of British children has continued to improve, with the number affected by caries declining each year (27). Overall, in the UK, the prevalence of caries throughout the last 40 years, in 5-year olds, had reduced to 41% in 2013 (from 72% in 1973) and to 46% (from 97% in 1973) in 15 year olds (27). Increased use of fluoride (most notably through toothpaste) has been key to this improvement (2). However, despite the decline in caries prevalence in both primary and permanent dentitions, the rate is slowing. Even more importantly, most disease is now confined to a minority of children and the burden of disease within this group is considerable (20, 27). Table 1 summarises the extent of the problem in England. In 2013, almost a third of 5-year old children and nearly half of 8-year olds had experienced decay in their primary dentition (29). Furthermore, 13% of 8 year olds (and 32% of 12 year olds) had experience of caries affecting their permanent teeth (29).

Table 1: Caries Prevalence in Children in England (2013)

Children with obvious decay experience in primary teeth: • 3 year olds* - 12% • 5 year olds - 31% • 8 year olds - 45%
Children with obvious decay experience in permanent teeth: • 8 year olds - 13% • 12year olds - 32% • 15 year olds - 44%
Children with obvious untreated decay in permanent teeth: • 8 year olds - 8% • 12 year olds - 17%

Data from, 2013 UK Child Dental Health Survey (England report) (29) and National Dental Epidemiology Programme for England: oral health survey of three-year-old children 2013 (30)*

Another set of UK wide epidemiological surveys have been undertaken since 1985, co-ordinated through the British Association for the Study of Community Dentistry (BASCD) (25). These are carried out more frequently and include larger samples of a given age group; in 2015, nearly a quarter (24.7%) of 5 year olds in England had experience of tooth decay and amongst those affected, an average of 3 to 4 teeth were involved (31). In 2013, the first ever survey of 3 year olds was carried out, and found that more than 1 in 10 (12%) already had experience of caries by this age (30).

Therefore, despite overall improvements in oral health of children across the UK, levels of disease are still high and there are huge variations across the country: children in the South East of England have better oral health compared to their peers in the

North West (2). At a local authority level, differences are especially noticeable amongst very young children: for example, in 2013, only 2% of 3 year olds in Gloucestershire had experienced caries compared to just over a third (34%) in Leicester (19, 30).

1.1.3

Impact of dental caries:

Oral health is an integral part of general health and enables people to "*eat, speak and socialise without active disease, discomfort, or embarrassment*" (2). For children, good oral health is also fundamental to growth and development (19).

Caries can clearly lead to toothache and is the primary cause of oral discomfort (12), but other negative effects include difficulties with eating, talking, sleeping and socialising. Oral health related quality of life measures are now widely used to evaluate the impact of dental disease (32), and have also been used extensively in children (33, 34). According to the UK CDHS of 2003, toothache was common, but most children did not reportedly experience any problems with their general health or social wellbeing, because of their dental disease (33). However, surveys carried out a decade later found that oral conditions were more likely to have an adverse impact on children's quality of life and these were disproportionately higher for children from deprived backgrounds (34). Other negative consequences of dental caries in childhood include:

- Poor nutrition resulting in poor growth and development and a failure to thrive (35).

- Effects on education and learning through missing school, either due to symptoms or attending dental appointments (2).
- The need for treatment including fillings and extractions. Management of dental disease can increase anxiety about dental treatment, especially if a child's first experience of dental care is an emergency visit to address pain (19). Crucially, some children need to have dental treatment under GA, which entails a small but real risk of life-threatening complications, along with several other negative impacts (3).
- Orthodontic implications: premature loss of primary teeth can cause loss of space and affect alignment of developing permanent teeth, which may require future orthodontic treatment (36, 37).
- Increased caries risk of permanent dentition: experience of caries affecting the primary dentition can be a predictor of caries in permanent teeth, in part due to continuation of unfavourable oral health behaviours, and in some cases, related to infections associated with primary teeth affecting development of underlying successors (38) .
- Negative impacts on parents and carers: some parents report feeling anxious, stressed and guilty about their child's oral conditions (34). Sleep can be disrupted and some need time off work to deal with their child's dental problems (34, 39).
- Financial implications: treatment and management of dental caries has a financial bearing on society (2, 14) Estimates suggest that £3.4 billion each year are spent by the National Health Service (NHS) in England on treating dental disease, with an additional £2.3 billion in the private sector (40).

In the UK, five to nine year olds are reported to experience most disability as a consequence of poor oral health: the average number of hours of healthy life lost due to poor oral health in this age group, are reported to exceed those due to vision impairment or medical conditions, such as diabetes (18).

1.1.4

Caries prevention: prioritising children needing caries related dental treatment under GA

Prevention of dental caries is paramount given the impact the disease can have, on the child, his or her family and society in general. By the age of 5, 10% of children in the UK will have had a tooth extracted and in 1 in 20, this will have been under a GA (11). According to a report by the Royal College of Surgeons (RCS), on 'The State of Children's Oral Health in England', it was "*lamentable*" that so many children need to be admitted to hospital for dental treatment, when "*poor oral health is largely preventable*" (2). Notably, children with previous experience of caries are at an increased risk of caries in the future (1, 38).

Preventive dental care is defined as "*any activity by which an individual avoids the development, progression and reoccurrence of an oral disease"* (8). Clearly, this is necessary for all children (41) but it is important to prioritise those at highest risk, which includes children that need caries related dental treatment under a GA (6, 8, 42). Although experience of a dental GA is recognised by many as a predictor of further caries, as Haworth *et al*. pointed out, it is surprisingly, not currently used in any of the commonly employed caries risk assessment tools (43). However, a dental GA might be

a more reliable predictor of the burden of caries through to adolescence, compared to more commonly recognised risk factors, such as experience of caries in earlier childhood (1, 43)

The next section reviews current caries preventive techniques, as a basis on which to plan interventions to prevent relapse in children following a dental GA.

1.2

Caries prevention in children:

1.2.1

Approaches to caries prevention - population versus individual:

Estimates suggest up to 90% of caries can be prevented (2). Preventive strategies can be implemented at a population level or targeted towards specified groups and individuals, based on their degree of disadvantage (18, 19). However, high risk groups also stand to gain from population approaches: for example, the benefits of water fluoridation are well documented (44), resulting in fewer hospital admissions for caries related extractions in fluoridated areas (45). Examples of targeted caries preventive measures include supervised tooth-brushing in schools and community-based schemes to apply fluoride varnish (18). National oral health programmes, such as Childsmile in Scotland (46) and Designed to Smile in Wales have helped improve access to dental services and reduce oral health inequalities in young children (19). Whilst similar initiatives have been piloted in local authority areas in England, no equivalent schemes have been introduced on a national scale (2). Clearly, population and community focused approaches are important, but children requiring caries related dental treatment

under GA, are a unique group, with an identified risk and complex need, which justifies a more targeted and tailored approach. When assessing a child's risk of caries, previous caries experience is a demonstrated indicator of further disease (1) as too, importantly, is the experience of a dental GA (43, 47).

1.2.2

Caries preventive interventions – Overview:

The key interventions include:

- Brushing teeth with a fluoride toothpaste
- Reducing intake of cariogenic foods and drinks
- Topical fluorides

  and

- Fissure sealants

A wealth of evidence supports these measures, as well as strategies on how they can most effectively be delivered and these form the basis of numerous guidelines and recommendations for dental professionals (1, 48-51).

Delivering Better Oral Health (DBOH): an evidence-based toolkit for prevention in England (first published in 2007), is now in its 3rd edition (50) and comparable guidelines have been produced in Scotland ('*Prevention and Management of Dental Caries in Children*') (51), based primarily on evidence collated by the Scottish Intercollegiate Guidelines Network (SIGN) guideline 138, '*Dental interventions to prevent caries in children*' (1). Policies and guidance from other countries are also mostly supported by a common evidence base (52, 53). However, the DBOH toolkit and Scottish Dental Clinical Effectiveness Programme (SDCEP), both recently

updated to take account of new research, are currently amongst the most widely recognised and readily accessible resources in the UK (50, 51): these include recommendations for standard prevention and enhanced measures for those at increased risk, which clearly should include children with experience of a dental GA.

The remainder of this section on prevention, serves to describe some of the key interventions that can be provided at an individual level. It is beyond the scope of this thesis to evaluate all the scientific research to support each intervention, particularly, as reviews of the evidence are readily accessible elsewhere (1, 50, 51).

1.2.2.1

Oral health counselling

A recognised part of oral health promotion is to deliver oral health information during clinical encounters to enable people to adopt behaviours that support their oral health (54). According to SIGN, the term 'dental brief intervention' refers to

"*dialogue between the clinician and the child or parent/ carer, to support positive dental health behaviour change, as part of an overall package, aimed at improving the patient's oral health*" (1).

This includes tailored advice and instruction on oral hygiene and diet, as well as motivating and supporting families to adopt any necessary actions. For younger children, this will rely on support from parents. Key evidence based oral health advice is outlined in Table 2. Advice needs to be reinforced regularly and more frequently for those at increased risk, who should be recalled every 3 months (55).

Enhanced measures for high-risk children include hands-on tooth-brushing instruction and use of diet diaries to help ensure advice is appropriate and personalised (50-52). Resources on practical evidence-based information on nutrition and oral health are recommended (56, 57).

Table 2: Key evidence-based advice on oral health (50, 51)

Key oral health messages:
• Twice daily toothbrushing (including last thing at night) with an age appropriate concentration (1000-1500ppm) and amount of fluoride toothpaste • Assisted or supervised brushing by a parent/ carer, until a child can brush teeth effectively • Spit out excess toothpaste (instead of rinsing) after brushing • Limit overall consumption and frequency of food and drinks that contain free sugars • Avoid snacking on sugary foods • Drink only milk or water between meals • Use of sugar free medicines (where available)

Despite strong evidence to support behaviours conducive to good oral health, research on strategies that might be employed to effectively deliver this advice is less robust. NICE guidance on oral health promotion in GDP, makes recommendations on oral health messages that should be delivered by dental professionals, but also highlights the poor quality of evidence on effectiveness of some of the methods used to deliver this advice (48). A systematic review on the effectiveness of brief interventions in a dental setting found the quality of studies varied (1): furthermore, many studies

involved adults (rather than children), most relied on self-reporting changes in behaviour and only assessed changes in the short term.

During the late 1990s, a review in the UK, on the scientific evidence for oral health promotion effectiveness, concluded that there was no evidence that oral health promotion activities reduce dental caries, even if changes in oral health knowledge and behaviour were achieved, unless these involved the use of fluoride (58). Furthermore, according to a Cochrane review on one to one dietary intervention delivered in a dental setting, there was limited evidence to suggest this encouraged any change in dietary behaviour (59).

However, several further reviews have been undertaken to determine the circumstances in which oral health promotion in a dental practice setting might be most effective (54, 60-63). Compared to the review published in 1997 (58), a more recent review by Kay and Locker (63), focused on oral health promotion activities that could be delivered in the context of general dental practice (instead of organisational activities), to change individuals' knowledge, attitudes and behaviours to influence their oral health. It was based on the principle that evidence underpinning effective prevention is now well-established (1) and so the priority was to determine 'how' oral health promotion in the dental surgery should be carried out to optimize its effectiveness (63). The evidence available was variable but suggested that oral health promotion based on behavioural and psychological models was more effective for improving oral health, calling for increased emphasis on teaching oral health professionals about health psychology. Verbal advice alone had a positive effect on knowledge, behaviour and gingival health, but the effect was insufficient to impact on caries levels unless the use of fluoride was

included. Written advice (leaflets) promoted oral health knowledge but had limited impact on behaviours and no impact on oral health outcomes. Overall, there was weak evidence to suggest that improvements in knowledge lead to improved oral health behaviour, at least in the short-term. Furthermore, various barriers and facilitators to the successful delivery of oral health promotion in the dental surgery were identified. These include beliefs about oral health promotion held by the 'sender', as well as their communication skills and ability to build therapeutic relationships with their patients (63).

A review to assess the effectiveness of behaviour models for individual oral health promotion identified 32 studies in the areas of: clinical prevention and health education, counselling, models based interventions and motivational interviewing (MI) (54). In summary, traditional 'biomedical' health education approaches were found to be unsuccessful in achieving sustainable improvements in oral health, calling for measures that address personal motivations for preventive behaviour and underlying social determinants of oral health (54).

Health education refers to information and expert advice provision with a passive patient but ignores the underlying factors that cause poor oral health (54). These techniques, which often rely on standardised messages, have failed to achieve sustainable improvements in oral health (64, 65). Programmes based on 'information giving' approaches in clinical settings, have been shown to produce changes in knowledge but with little or no effect on plaque scores or caries levels (60).

Counselling has been defined as targeted and interactive information giving approaches that address individual behaviour, thereby meeting the specific needs of individuals (54). A randomised control trial (RCT) on the effectiveness of oral hygiene, dietary counselling, and non-invasive preventive measures, on reducing caries in children demonstrated less caries in the 'intervention group' (66). However, the results also showed that frequent counselling sessions alone had little effect on oral health habits of the participants, other than increased consumption of xylitol and fluoride lozenges. Furthermore, children in the experimental group had regular application of fluoride varnish applications, which can be expected to contribute to the reduction in caries among this group.

Studies based on psychological models of health behaviour change (including the 'Transtheoretical Model of Behaviour Change' (67) have been shown to be effective in improving adherence to oral hygiene instructions amongst adults with periodontal disease (68) and reducing consumption of carbonated drinks by adolescents (69). The Transtheoretical Model assumes that behaviour change is a dynamic, nonlinear process and describes the stages (pre-contemplation, contemplation, preparation, implementation and maintenance) through which an individual will pass as they adopt a new behaviour or change a current one (67). It provides a framework for understanding the change process itself (which includes an individual's readiness to implement and sustain change), whilst motivational interviewing takes this a step further by providing a means of facilitating this change process (54).

According to the review by Yevlahova and Satur (54), MI interventions were found to be the most effective method for altering health behaviours in a variety of fields,

including asthma, diabetes, heart disease, smoking and substance abuse, with potential to further develop the MI approach within the oral health field. Motivational interviewing is described as an evidence-based, client-centred, practical and personalised counselling approach that is based on the 'Transtheoretical Model of Behaviour Change' (70). It attempts to prepare people for behaviour change by addressing the common problem of "ambivalence about change" and guides individuals on making decisions about why and how to proceed (71). Compared to traditional health education approaches, MI places the individual/ patient in the role of the 'expert' and allows them to decide how to apply information within the context and relevance of their own lives and social circumstances (72).

The use of MI in the oral health field is still relatively new (compared to other areas) and less well understood, but its use is growing and is promising (11, 73, 74). A systematic review on the effectiveness of MI compared to traditional health education suggested MI surpassed conventional approaches in improving oral hygiene behaviours for preschool children but had limited impact on dietary habits (73). However, earlier studies have found that MI interventions can influence parents to adopt and maintain preventive oral health behaviours for young children, including oral hygiene, feeding practices and dental attendance patterns (75-77). After two years, a lower prevalence of early childhood caries was reported in children whose mother had received MI compared to the control group (75, 76). More recently, an exploratory randomised controlled study found some evidence that a MI approach to deliver oral health information to parents of pre-school children in Trinidad had a positive effect on their oral health knowledge, tooth brushing behaviour and oral health fatalism compared to traditional dental health education (71). However, although a community-

based cluster RCT in the US (involving MI counselling plus intensive caries prevention activities for early childhood caries), demonstrated an increase in knowledge, there was no improvement in oral health behaviours or caries increment after 24 months, in young children living in public housing (74). The need for a more intensive and multi-faceted approach was highlighted, to address the complex needs of young children at high risk of caries (74). Despite this, MI has been found to be one of the most effective approaches to altering behaviours and there is potential to further develop this approach within oral health care (54). Indeed, the intervention described by the Dental RECUR trial protocol (Section 1.4.2.2) includes a 'brief negotiated interview' (based on the principles of motivational interviewing) and aims to evaluate if this is more efficacious and cost effective, than 'traditional' preventive advice, for children that have had caries related primary tooth extractions (11).

Finally, it is important to recognise the importance of a common risk factor approach, by working closely with other professionals to achieve a shared objective (1), which might, for example, involve referring children at higher risk to other available sources of support, such as health visitors (18, 51). However, whilst there is support for the incorporation of oral health into general health promotion, it would be important to monitor the outcomes in oral health terms (60).

1.2.2.2

Topical fluoride:

The systemic action of fluoride was previously deemed to be most significant for caries prevention, but the topical effects are now recognised as being more important (78). Topical fluoride, when present in solution at the plaque-enamel interface, acts by

inhibiting de-mineralisation and promoting re-mineralisation, resulting in the formation of fluorapatite crystals, which are more resistant to acid attack (78).

Clearly the most widely used topical fluoride intervention is brushing with fluoridated toothpaste, but another vehicle for topical delivery at home is fluoride mouthwash. Daily (0.05% or 225ppm sodium fluoride) or weekly rinses (0.2%. 900ppm), are available and should be used at a different time to brushing to maximise frequency of exposure to fluoride. Evidence supports regular and supervised use of fluoride mouthwash to prevent caries in permanent teeth, with studies reporting an average of 27% fewer decayed, missing or filled surfaces (79): these benefits are clear in the absence of daily brushing with a fluoride toothpaste but less so if fluoride toothpaste is also being used (1). Despite this, guidelines recommend prescription of fluoride mouthwash for children that are over 8 and have active caries (50).

Topical fluoride varnish is the most widely employed technique for professional use, though other methods include gels, slow releasing fluoride beads and silver diamine fluoride (SDF). SDF is a topical anti-caries medicament derived from silver nitrate and fluoride: it has been available in several countries over many decades and has been shown to be almost twice as effective as fluoride varnish to arrest caries (80, 81). It is considered to be safe, inexpensive and suitable for younger less co-operative children but has limitations, including parental acceptance (related to the associated staining), so is not currently recommended for use in the UK (80-82). Fluoride supplements (drops and tablets) are normally prescribed for their systemic effect (in non-fluoridated areas), but if tablets are sucked before swallowing, they too can provide a topical action.

Professionally applied fluoride varnish, dates back over three decades (83), and is one of the most beneficial methods of maximising availability of topical fluoride (50). Strong evidence supports recommendations for use in all children (over 2 years of age), at least twice yearly and up to four times a year in those at increased risk (1, 50, 51). It is reported to reduce experience of dentine caries by up to 43% in permanent teeth and 37% in primary teeth (83). In its commercial form, sodium fluoride varnish (5%wt, 22,600ppm), is most widely available as Duraphat varnish (Colgate). The varnish adheres to tooth surfaces, for periods of up to 12 hours and provides a slow release reservoir of fluoride (84). Other available products (e.g. Profluorid) are not currently licensed for caries control (50).

Fluoride varnish is simple to apply and does not require meticulous moisture control (unlike, for example, fissure sealants), although removal of gross plaque deposits and drying teeth first can maximise adhesion (50, 51). It is usually well accepted by most patients, including very young (and pre-co-operative) children and cost efficiency can be maximised by training dental nurses in its use (50). Clearly, on an individual level, frequent application relies on regular dental attendance, but community-based fluoride varnish programmes can be used to target children in schools and nurseries (18).

1.2.2.3

Dental sealants:

Sealants were first introduced in the 1960's and are used to protect pits and fissures on occlusal surfaces of posterior teeth from dental caries: they have been described as '*protective plastic coatings, which are applied by a dental care professional, in order to obliterate pits and fissures and remove the sheltered environment, in which caries*

can thrive' (1). They can be applied to permanent or primary teeth and there are two main types of material currently available: resin-based sealants and glass ionomer cements (GI) (85).

1.2.2.3.1

***Sealants in permanent teeth*:**

A wealth of evidence supports the use of sealants as an effective intervention to prevent caries in permanent teeth (1, 85-87). The most recent Cochrane systematic review, to evaluate use of pit and fissure sealants in permanent teeth of children and adolescents was based on 38 trials (7 of which were new to this review), and included the results of studies involving, in total, almost 8000 children aged 5 to 16 years (85). Conclusions drawn from the latest review reinforce earlier evaluations (88-90): there was moderate quality evidence to show that resin-based sealants applied to occlusal surfaces of permanent molars in children and adolescents, can lead to a reduction in caries of between 11 to 51% up to 4 years later. The caries preventive effect was also maintained for longer follow up but the evidence to support this was less robust (85).

Outcomes from studies comparing glass ionomer (GI) with resin-based sealants are inconclusive (85, 91, 92). In the most recent Cochrane review, only 3 studies were used to evaluate GI sealants, so the evidence base was insufficient to report on the effectiveness of this as a sealant material, although resin-based materials were better retained (85). According to a meta-analysis on longevity of different sealant materials, the 2-year retention rate for GI sealants was only 12% (93). However, sealant retention should not be viewed as the most clinically important endpoint, because the caries preventive effects are more relevant (94). This relates to continued release of fluoride

from GI sealants, even after visible loss of the bulk of the material, although evidence to support this claim has been questioned (95).

Sealants should preferably be placed as soon as teeth have erupted sufficiently to allow adequate moisture control (96). Resin sealants are relatively simple to place but are very technique sensitive, as salivary contamination can affect the bond and therefore the retention of the sealant (87). Whilst resin-based sealants are the first-choice material, GI can be used as a temporary sealant when moisture control is compromised, as is the case for partially erupted molars or un co-operative children (51, 94). A simple 'gloved finger' technique has been described to apply sealant in these situations (51).

1.2.2.3.2

***Sealants in primary teeth*:**

Evidence relating to the caries preventive effect of fissure sealants in primary molars is lacking, (97) though some early studies report high retention rates: a randomised split mouth trial on 3-4 year olds found resin based sealants were fully retained in over 70% of primary molars after 2 years (98) and another involving slightly older children (4-7 years) reported even higher retention with flowable composite (95%), though this was only after one year (99). However, retention of GI in primary teeth on young children is poor (100, 101).

Historically, routine application of sealants on primary teeth was not recommended, though they could be considered for high risk children (91, 96, 102). However, support for sealing primary molars appears to be increasing, even though, this is mostly based

on evidence from studies on permanent molars (51, 92). A protocol for a Cochrane systematic review on use of sealants in primary teeth, has recently been published, which should hopefully serve to clarify the evidence base and recommendations for sealing primary molars (103).

1.2.2.3.3

***Cost effectiveness of sealants*:**

Reviews exploring the cost efficiency of sealants on permanent teeth, suggest they are both cost effective, as well as efficacious (91, 104). The cost benefits arise through a reduced need for more invasive and expensive restorative treatments (87). One study in the US analysing the cost utility of sealing first permanent molars concluded that this was the most cost-effective way to prioritise limited resources in lower dental utilisers (105). However, cost efficiency can be further maximised by targeting high-risk patients and utilising appropriately trained dental care professionals (DCP) to deliver sealants (92, 106, 107).

1.2.2.3.4

***Clinical recommendations on use of sealants*:**

Evidence based clinical guidelines in the UK, clearly recommend that children susceptible to caries, should have permanent molars sealed, preferably as soon as they are sufficiently erupted, to allow adequate moisture control (50, 51). Scottish guidance suggests these should be carried out for all children, whilst those at higher risk, should also have their primary molars sealed (51). In contrast, the DBOH toolkit in England only recommends sealants for children that give concern, which includes, patients with active caries (50). Glass ionomer sealants have been advocated for partially erupted

permanent molars and/ or non-compliant children, when moisture control for resin sealants is likely to be compromised (51).

1.2.2.4

***Sealants versus fluoride varnish to prevent caries on pits and fissures of permanent molars*:**

A recent update of an earlier Cochrane review, to compare the effectiveness of these two interventions, found only low-quality evidence to support the superiority of resin sealants over fluoride varnish (108, 109) and weak evidence to suggest that resin-based sealant and fluoride varnish used in combination were more beneficial than fluoride varnish alone (109). Likewise, a community-based trial to compare both interventions in school children in South Wales (110), found no significant difference in the caries preventive effects of biannual application of fluoride varnish compared with application and maintenance of sealants over 36 months. However, evidence-based clinical practice guidelines from the US recommend use of sealants over topical fluoride (86, 87).

This brief account of preventive interventions has outlined the range of evidence-based advice and treatments currently available, and potentially applicable for children that remain susceptible to caries, following a dental GA. The next section review keys aspects of the use of GA for caries management in children and serves a basis on which to identify opportunities to deliver prevention to this high-risk group.

1.3

General anaesthesia (GA) for dental treatment:

1.3.1

Options for delivery of dental treatment:

Clearly, a GA is sometimes the most appropriate option for delivery of paediatric dental care but, given the associated risks, it is important to consider other methods, especially for older children. These include local anaesthesia (LA) with appropriate behaviour management techniques (111) as well as conscious sedation. Many different non-pharmacological behaviour management approaches can be used to facilitate acceptability of treatment with LA only, including tell-show-do, positive reinforcement, modelling and systematic desensitisation (111).

Conscious sedation is

"*A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used should carry a margin of safety wide enough to render loss of consciousness unlikely*" (112, 113).

Conscious sedation includes inhalation sedation as well as oral, transmucosal or intravenous sedation for children older than 12 years (113). Compared to GA, the risks are low, there are increased opportunities to restore teeth (instead of extractions) and it is cheaper (114). However, it may not be suitable for very young children, that lack maturity and understanding to respond to suggestion (115). Use of sedation as an alternative to GA, has increased (112, 113) but no randomised controlled trials (RCTs)

compare sedation with GA for dental treatment in children, calling for well-designed studies, to quantify differences relating to morbidity and cost (116).

1.3.2

Background on use of GA for dental treatment in the UK:

General anaesthesia is defined as,

"*Any technique using equipment or drugs, which produces a loss of consciousness in specific situations, associated with medical or surgical interventions*" (112).

More recently, the term dental general anaesthesia (DGA) has been widely employed to describe the use of GA for provision of dental treatment, and refers to,

"*a pharmacological technique to provide extensive or urgent dental treatment (usually extractions) to children with caries within a hospital setting*" (117).

Historically, dental GA's in the UK were carried out in high street practices (118), but from the mid 1960's, following a decrease in caries, there was a fall in the overall use of GA for dental procedures (112, 119) . Despite this, a hike was observed in the early 1990's, following publication of the Poswillo report, which made more than 50 recommendations to minimise the risk of adverse events (120). In the late 1990's, further guidance from the General Dental Council (GDC) (121) and Royal College of Anaesthetists (RCA) (122) clarified responsibilities for referring practitioners and training requirements for anaesthetists but use of GA for dental treatment was only restricted to a hospital setting from January 2002 (2, 112). Guidance on best possible practice for use of GA in paediatric dentistry in the UK continues to be updated (4, 123).

1.3.3

Indications for use of GA for dental treatment:

The two main indications for use of GA in Paediatric dentistry, are

- A child's inability to cope with dental treatment (due to immaturity or anxiety) that would normally be possible in older (compliant) patients by conventional means (LA and/ or sedation)

or

- To complete complex procedures, where the operator requires the patient to be anaesthetised in order to carry them out (4).

GA may also be necessary when use of LA is contraindicated, due to presence of acute orofacial infections or when previous attempts to use LA or sedation have failed (124). Most often, a dental GA is required to carry out multiple caries related dental extractions in young pre-co-operative, (pre-school age) children or, to provide dental treatment for older children, presenting with a high treatment need and high levels of dental anxiety (3). It may also be necessary for children with special care needs (including learning disabilities or challenging behaviours) or complex medical problems, when examination, assessment and treatment by other methods is not feasible (4, 125). However, a GA can rarely be justified for routine orthodontic extractions in healthy children (4, 126).

1.3.4

Dental GA Services:

The 2 main approaches for delivery of dental care under GA are:

- The exodontia (or extraction only) approach, often referred to as a 'chair' GA

and

- Comprehensive dental treatment, which includes restorations and preventive treatments such as fissure sealants. This is usually required for medically compromised children or those with special care needs and involves a day stay procedure, with oral intubation to protect the airway (3, 124).

Extraction only services are clearly less expensive and thus more widely available (3, 127). Dental treatment under GA can also be provided by Community Dental Services (CDS) but the procedure itself must be carried out within a hospital setting.

1.3.5

Benefits and risks of a dental GA:

A dental GA permits delivery of dental treatment, when other options (including sedation) are inappropriate or might have failed and treatment can be completed in a single visit. Studies suggest high levels of parental satisfaction with the procedure, and some even consider it to be more convenient (3, 128). Dental rehabilitation under GA also has a positive impact on oral health related quality of life (OHRQoL) (129-132).

However, there is universal recognition that a GA is a procedure which is "*never without risk*" (4) and despite a high record of safety (133), the risks of morbidity and even mortality remain (112, 124, 134). Short term complications include nausea, vomiting, headaches, dizziness and a sore throat (124). Pain, bleeding and difficulty eating following extractions have been reported in up to 90% of children (129) and drowsiness was one of the most frequently reported complications, associated with longer day-stay procedures (135). Long waiting lists can lead to further problems in the meantime (136) and the GA experience can also lead to increased levels of dental anxiety (19).

1.3.6

Prevalence and cost of dental GA in the UK:

Despite increased use of sedation, the use of GA for dental treatment in the UK has also been growing and since 1997, has continued to increase annually (2, 137). In 2013-14, approximately 43, 700 children in England, required hospital admission for a caries related GA, but by 2015-16, this had risen to over 60, 000 (2, 3, 19). Rates have been highest amongst 5 to 9 year olds, with hospital admissions for removal of decayed teeth exceeding those for conditions such as tonsillitis (2).

It is important to try to understand why use of GA for dental treatment continues to rise, despite a backdrop of falling levels of disease (119). Reported explanations include: an increase in birth rates, treatment not being sought until caries is too advanced and, inappropriate treatment in primary care (2), which might be related to lack of skills and confidence to treat children (138), inadequate remuneration (139) and poor understanding of guidance on GA referrals (140). A study reporting on dental students' confidence about various dental procedures, found this was lowest for selecting patients for a GA (138).

The cost of providing dental treatment under GA continues to grow: in 2012-13, this was approximately £30 million for England (141) but by 2015-16, had risen to around £50 million (142), with the estimated unit cost for each procedure being around £1200 (47). These figures have been compared to the annual cost of running three secondary schools (14). The cost of a dental GA is almost three times that of providing dental treatment with sedation (143).

1.3.7

Factors associated with use of GA for dental treatment in children:

Certain factors might be linked to increased use of GA, resulting in some groups of children being over-represented. Evidence is limited, but studies suggest deprivation and ethnicity are especially relevant (117).

1.3.7.1

***Deprivation and dental GA*:**

Children from deprived areas are more likely to receive a dental GA (144-147). In 2013, 14% of 8 year olds in the UK eligible for free school meals (and 22% of 12 year olds) had, as reported by parents, received a GA for dental treatment, compared to 6% and 7% respectively for those that weren't (144). In the South West of England, GA admissions are reported to be three times greater in the poorest areas (47).

Obviously, any apparent association between deprivation and GA rates might simply reflect increased levels of dental disease amongst those from the most disadvantaged backgrounds (16, 20). However, a recent study suggests the link between socio-economic background and receipt of a dental GA was "over and above" the effects of age, anxiety, and importantly, disease levels, with children whose parents had never worked or were in routine or manual occupations, being more likely to have had a dental GA (117). However, the prevalence of experiencing a dental GA was also shown to be higher in children who only visit the dentist when having trouble (117). This relationship between deprivation and dental attendance is well observed: in 2013, 27% of disadvantaged children in the UK only went to a dentist when they had trouble, compared to 12% of those from wealthier backgrounds (144). Parents of children from

deprived areas are also more likely to report problems with finding NHS dentists (144).

Thus, differences in families' attitudes towards oral health care, (including dental attendance behaviours), along with difficulties accessing NHS dental care, might in part, account for higher use of GA in children from the most deprived backgrounds. However, inequalities in standard of care received by children from poorer backgrounds have been observed, even when they are regular dental attenders, with some poorer children being more likely to receive extractions, compared to their wealthier counterparts with similar patterns of dental attendance (148).

1.3.7.2

***Ethnicity and dental GA*:**

A child's ethnic background has also been reported as a co-factor for receiving dental treatment under GA (6, 118). Again, any apparent association might simply echo differences in levels of disease, (which in turn, may reflect levels of underlying deprivation), although variations in caries rates amongst children from different ethnic backgrounds, are less clear compared to associations between socio-economic status and caries risk (19, 23). However, varying beliefs and cultural attitudes towards the use of GA for dental treatment can mean that it might be more acceptable amongst some ethnic groups (117, 149).

1.3.7.3

***Dental anxiety and fear*:**

Clearly, as outlined earlier (1.3.3), one of the main indications for use of GA for dental treatment is to provide treatment for very young children (considered to be pre co-operative) or older children, adolescents and adults with heightened levels of anxiety. Dental fear is the most common self-reported indication for referral for a dental GA (150). A questionnaire based survey in Finland (involving patients of all ages, referred for GA) found that 90% of respondents reported having 'dental fear' and in half, this was related to previous negative experiences in dental care (150). Other studies also report young age, dental anxiety and poor co-operation as common factors associated with a dental GA (149, 151). According to Savanheimo *et al*. (2012), the main reason for a dental GA was extreme non-cooperation (65%) followed by dental fear (37%) (151), which calls for increased training of oral health professionals in behaviour management techniques to help support children with dental anxiety (149).

1.3.7.4

***Parental anxiety and dental GA*:**

Parents' anxiety towards dental treatment might also have a bearing on a child's chances of experiencing a dental GA. Not only can this influence a child's caries experience (152) but also levels of dental attendance (153, 154). Irregular attendance denies the child timely management of early caries, as well as preventive interventions, culminating in the need for extractions under GA. As outlined earlier, children that only see a dentist when they have trouble with their teeth are more likely to experience a dental GA (117).

1.3.7.5

***Experience of dental GA within families*:**

According to Deery *et al*. (155), almost half (48%) of parents accompanying children to GA appointments for caries related extractions in Glasgow had, themselves, undergone the same procedure. A Dental Hospital in London found that 47% of parents of children needing a dental GA, reported similar treatment in at least one of their other children (6), which was comparable to the 33-59% familial experience seen in a group of Hospitals in the North-West of England (119).

1.3.7.6

Self-efficacy and oral health related fatalism:

Self-efficacy has been defined as an individual's confidence in determining 'how well he or she can take the actions necessary for producing certain results' and this can be linked to oral health behaviours and oral health status (156). Research on self-efficacy with respect to oral health includes efficacy to manage behaviours such as brushing, dietary habits for children and dental consultations (157, 158).

Mothers' self-efficacy and sense of fatalism about children's oral health can influence engagement in oral health-promoting behaviours and caries risk (159) and studies suggest that parents of children in low socio-economic groups have lower self-efficacy in relation to oral health related behaviours (including dental hygiene and sugar snacking) and these were significant predictors of the development of caries in their children (160). Studies involving parents of children needing dental treatment under GA report fatalistic and defeatist views about their ability to influence their children's oral health (7, 42). Amin *et al*. (2007) found that parents of children experiencing

caries relapse 6 months after a dental GA felt less able to control their child's oral health compared to those that had no relapse (161).

1.3.7.7

Dental neglect and dental GA:

Dental neglect is defined as ''the persistent failure to meet a child's basic oral health needs, likely to result in the serious impairment of a child's oral or general health or development'' (162).

Untreated dental disease can in turn, then sometimes lead to dental disability which is defined as 'dental caries, periodontal disease, dento-alveolar trauma, and other oral conditions left untreated, that substantially limit a child's development and an individual's participation in life activities' (163). Children needing a dental GA have a higher prevalence of extensive caries (164), as well as more behaviour management problems and poor attendance (165). A retrospective records based study in Sweden found that children treated under GA were more often diagnosed with both dental neglect and dental disability compared to matched controls who had not received treatment under GA (163). This included significantly higher caries prevalence and infections due to pulpal necrosis, more extensive treatment needs and problems with behaviour management.

1.3.7.8

***Service availability and dental GA*:**

Availability of and access to GA services can also be expected to impact on geographical differences in GA rates. Studies indicate that variations in use cannot solely be explained by varying disease levels (or a need or demand for services), but

also relate to access to care, including the availability of appropriate alternatives, such as sedation (166). Historically, some services might be provider led as opposed to commissioned, subject to a health needs assessment, resulting in disparities between availability and measured need (119). Waiting times can also vary, with one UK study suggesting a wait of anything between 3 to 84 weeks (167).

1.3.7.9

***Fluoridation and dental GA*:**

Finally, children living in areas with fluoridated water are less likely to require dental treatment under GA (168). Hospital admissions for caries related dental extractions are 59% lower for children living in fluoridated areas, compared to those residing in areas with no added fluoride (45). This is not surprising given that 5 year olds in fluoridated areas have been shown to have less caries than their counter-parts in non-fluoridated areas (19).

1.3.8

Repeat dental GA:

A repeat dental GA refers to the use of GA for delivery of dental treatment on more than one occasion. Clearly, this is something to avoid, given the potential risks, especially as these are higher for a repeat GA (155).

1.3.8.1

Repeat dental GA incidence:

These can vary depending in part, on the demographics of the sample and the type of service being delivered: in England, rates reported between 1997 and 2006 for healthy

children, were 5.6% (137). Guidry *et al*. in the US, also found that about 5% had required a further GA within 4 years, but their sample also includes children that were medically compromised (133). Many dental hospitals across the UK describe repeat GA figures of around 10% (169, 170) but higher rates (12 to 37%), have been recorded in hospitals in the North-West of England (171). The average time between the initial GA and repeat also varies (133): many studies suggest an interval of around two years, though this clearly depends on several factors including the age of the child, any co-morbidities and whether the treatment provided involves extractions only or full mouth rehabilitation (169, 172).

1.3.8.2

Factors associated with a repeat dental GA:

There are circumstances when a GA is the only feasible way of providing treatment and this is especially applicable to children with special care needs (4): medically compromised children have been shown to be four times more likely to require a repeat dental GA (133). Patients that are younger at the time of the first GA are also at higher risk of a repeat (173, 174), and this has been linked with poor co-operation, dysfunctional social circumstances and unfavourable oral health behaviours (175). Demand from parents has also been shown to influence GA delivery: Macpherson *et al*. in Scotland found half of parents would, if necessary, elect for their child to have a repeat GA (149), whilst Harrison and Nutting found only 17% of first time GA's were self-referrals compared to 30% of repeats (172).

1.3.8.3

Reasons for a repeat dental GA:

In broad terms, the two main reasons for a repeat GA, are poor treatment planning, which fails to manage all caries at the time of the first GA, or relapse associated with development of new caries (4).

1.3.8.3.1

***Failures in treatment planning*:**

Failure to manage all caries appropriately at the first GA runs the risk of exposing the child to a repeat procedure (4, 127). Studies suggests a high proportion of children who had been left with untreated dental caries return for a repeat (170, 172), calling for a more aggressive approach to treatment planning to ensure all carious teeth are removed (175).

Children referred for a dental GA should be under the care of a Consultant in Paediatric Dentistry and the treatment should be planned by an appropriately trained and qualified specialist (123, 142, 176). The assessment should include radiographs to help identify caries (177) and for exodontia only services, any restorative treatment (where appropriate) should be carried out prior to the GA (127). Furthermore, centres providing comprehensive care under GA should include facilities to take radiographs whilst the child is unconscious, as without these, a full and comprehensive assessment is not possible (4, 127, 155).

Despite clear recommendations, most children needing a dental GA in the UK are not assessed by a specialist in paediatric dentistry: the majority undergo extractions only, following direct referral from a general dental practitioner (GDP), and without a comprehensive assessment or radiographs (112). This is of concern given that some of these referrals are inappropriate and, most often associated with the need for a repeat GA (140, 171). In contrast, repeat GA rates as low as 1% have been shown to be achievable through specialist or Consultant led services (155, 178).

1.3.8.3.2

***Relapse related to new caries*:**

Unfortunately, a repeat GA is often required to address new caries, which has developed after the initial GA (179-181). This includes caries in permanent teeth, most notably first permanent molars, following caries related extractions of primary teeth (11). A study in Leeds found 72% of the teeth extracted during a repeat GA had been recorded as caries free or unerupted at the time of the first GA (180). Similar relapse rates (79%) were also reported by Almeida *et al*., although a GA was not always necessary to manage new disease (179). Recurrence also depends on the duration of the follow up period: Amin *et al*. (2010) found that 24 % of children had new caries 12 months after their first GA but this had more than doubled (to 53 %) over the following 12 months (182).

1.3.9

Caries prevention following a dental GA:

Clearly, a caries related dental GA "*should be avoided whenever possible*" (120), but there are circumstances when this might be justified (112). If so, radical and aggressive treatment plans (including extraction of all carious teeth), can help tackle the burden of dental disease at the time (4, 123, 127, 142). However, this fails to deal with the potential for new caries to develop after the GA, which calls for increased efforts in terms of prevention (179-181). Preventing relapse after the procedure is paramount, to avoid pain, infection, and adverse impacts on quality of life associated with new caries, as well as to minimise need for further treatment, including a repeat dental GA.

Before developing an intervention tailored to meet the needs of this high-risk group, it is important to review existing research on caries prevention for children requiring dental treatment under GA. This includes an evaluation of strategies and techniques, that have already been employed and can help identify some of the anticipated challenges and how these might be addressed.

1.4

Dental general anaesthesia and caries prevention: Literature review

1.4.1

Literature review methods:

The aim was to review research that focused on prevention for children requiring a caries related dental GA, as this would help plan and develop interventions appropriate to the needs of this high-risk group.

A range of search strategies were used, and these are described below. The databases used were the Science citation index (Web of Science), Medline (OVID), Cochrane, National Institute for Healthcare and Clinical Excellence (NICE) and the University of Birmingham search engine ('Findit@Bham'). The review was first carried out in 2012 and repeated at least annually (until December 2018).

The original search criteria used for the Science citation index, Medline and Findit@bham databases, were:

("general anaesth*" OR "general anesth*")

AND

(extract* OR cari* OR prevent*)

(* = truncation was used to ensure all relevant terms were captured E.g.

extract* to include extract, extraction(s), extracted etc

cari* to include caries, carious etc

prevent* to include prevent, prevention, preventing etc)

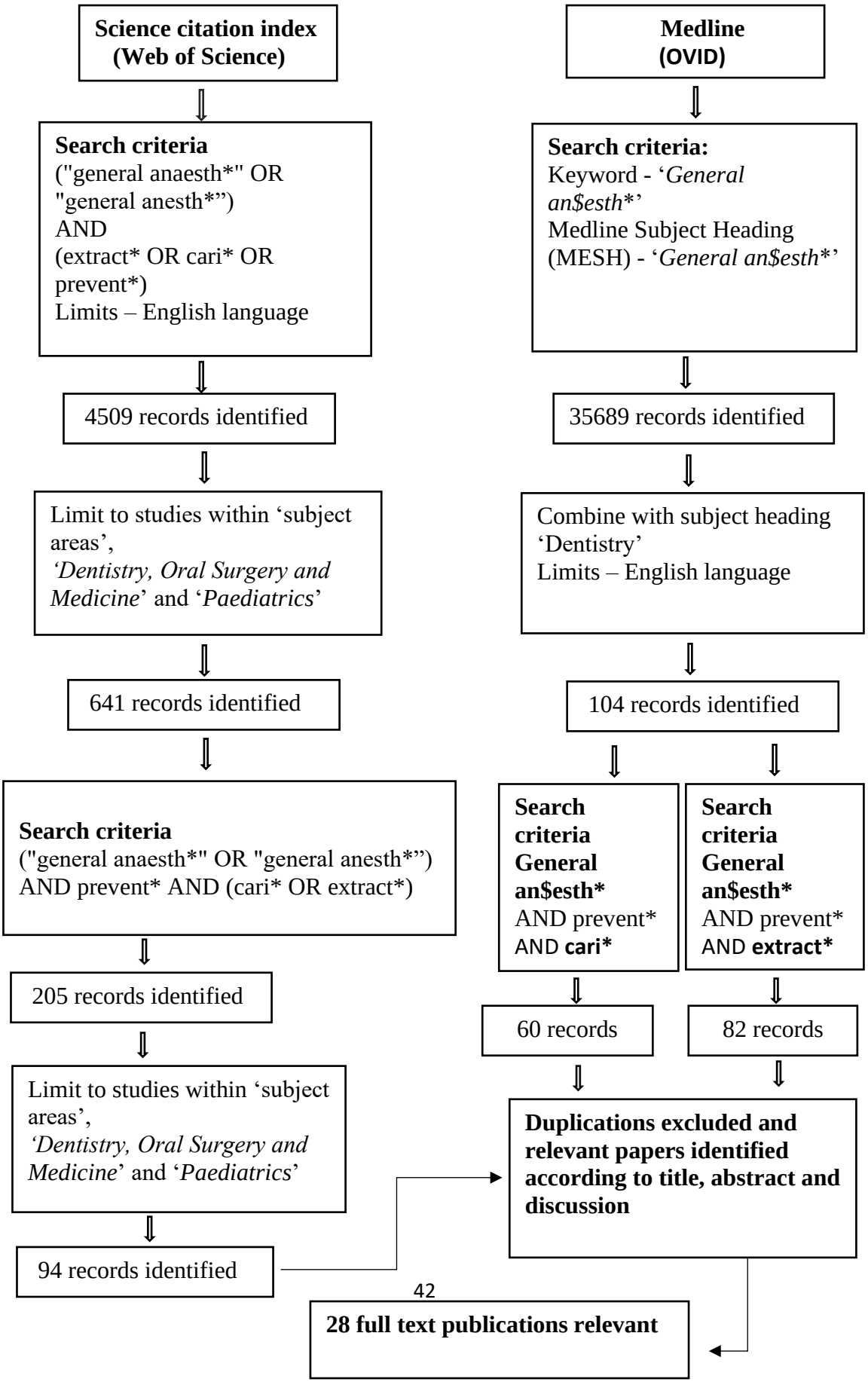
For Medline (OVID), Medline Subject Headings (MESH) were also employed. Figure 1 describes the search criteria in more detail and outlines the number of publications identified. Further to the original search, it was apparent that most papers covering '*preventive aspects of caries related dental extractions under general anaesthesia*' related to either '*caries*', or '*extract*' but rarely both. The key terms, crucial to the search were '***general anaesthesia'*** and '***prevention***', so the search criteria were revised to records that would include '***general anaesthesia***' AND '***prevention***', with either, '***caries***' OR '***extrac***t' (Figure 1).

'Findit@bham' searches a broad range of databases but failed to identify many new relevant papers that hadn't already been found from the other sites. The only Cochrane resource on general anaesthesia for dental treatment was a review comparing sedation versus GA for dental treatment in patients under 18 years (116). A search for '*general anaesthesia in dentistry*' on the NICE database (1.04.18) identified several resources, but most were guidance and policy documents rather than research papers. These include several documents referred to earlier (2, 4, 18, 123, 183).

Papers were reviewed for relevance, according to the: title, abstract, keywords and a brief inspection of the full text (especially the discussion). References were also scrutinised to ensure nothing relevant was missed. Based on this initial review, some items were clearly irrelevant and so were excluded, as too were any duplications.

Figure 1 – Literature search methods on 'prevention for children requiring caries related dental extractions under general anaesthesia'

Last full search (December 2018)



1.4.2

Previous research on dental general anaesthesia and caries prevention:

Most of the selected publications were observational, based on either retrospective data analyses or questionnaires and interviews, with several studies investigating parents' attitudes and behaviours with respect to prevention: these include challenges parents face in supporting their child's oral health and the type of support they may find helpful (6, 7, 42, 161, 175, 184, 185). Other studies focus on preventive input provided by GA centres and referring practitioners, as well as the barriers providers may perceive to delivering care (8, 47, 136).

However, relatively little research exists on prospective interventional studies, designed to investigate outcome of measures to prevent caries in this high-risk cohort (9-11). Indeed, Aljafari *et al*. (2015) on describing the protocol for their RCT (to assess the impact of an oral health education video game for high risk children) highlighted the need for more research in this area (9) and similarly, Pine *et al*., reporting on the protocol for the Dental RECUR trial, suggest no RCTs had previously been published on caries prevention in children with experience of a dental GA (11).

Key features of some of the most relevant studies are summarised in Table 3 (observational) and Table 4 (interventional). Some studies also investigate unrelated aspects of a dental GA but only areas relevant to prevention are included in the review.

Table 3: Observational studies on dental GA and caries prevention				
Title:	**Author(s), year of publication, country:**	**Aim:**	**Setting, subjects, methods**	**Key findings and recommendations**
Reported infant feeding, oral hygiene and dental attendance patterns in children aged 5 years and under referred for extraction of teeth under general anaesthesia (184)	Hunter ML *et al*. 1997 Cardiff, Wales	To assess infant feeding, oral hygiene practices and dental attendance patterns in children referred for caries related dental extractions under GA	• Cardiff Dental Hospital, Paediatric Dentistry Unit • 150 mothers of children aged 5 years and under referred for caries related extractions under GA • Structured interview administered questionnaire prior to GA extractions	• Prolonged feeding from a bottle (including bedtime), high consumption of sweets and unsupervised brushing all contributed to caries in these young children • Primary care dentists need to work with other health professionals to encourage registration with a dentist as soon as possible after birth and provide practical preventive advice to mothers through-out their child's early years

Reasons for repeat dental treatment under general anaesthesia for the healthy child (175)	Sheller B *et al*. 2003 Seattle, USA	To investigate the reasons a healthy child might require a repeat dental GA for early childhood caries	• Children's Hospital, Seattle, USA • Comparison of risk factors between 11 children (receiving 2 GA's) and 9 children (receiving 1 GA) • All children were under 6 years old at initial GA and under 8 years at the repeat GA • Health records (medical and dental) reviewed and structured taped interview questionnaire with parents (at home or Hospital)	• Factors associated with high risk of repeat GA include bedtime bottle, unsupervised brushing, families' dysfunctional social situation, child's poor co-operation in a dental setting, and lack of follow up dental care • Improved outcomes require aggressive treatment of caries at time of GA, pro-active follow up and more oral health education for parents
A qualitative look at parents' experience of their child's dental general anaesthesia (185)	Amin MS, Harrison RL and Weinstein P 2006	To assess parents' experience of their child's dental treatment for early	• Paediatric dental centre with on-site GA facility • Semi-structured open-ended taped interviews (at	Improved oral health behaviours in the short term (reduced sugar consumption and increased frequency tooth-brushing) but

	Canada	childhood caries under GA, including changes in attitudes and behaviours related to their child's oral health	dental centre or child's home) • 11 parents (of children under 6 years) interviewed at post-op review (scheduled 7 to 14 days after GA)	further research required to assess long-term maintenance
A conceptual model of parental behaviour change following a child's dental general anaesthesia procedure (161)	Amin MS and Harrison RL 2007 Canada	To investigate parents' challenges to achieving long term success in maintaining healthy oral health behaviours for their child after a dental GA and compare responses from parents of 'relapse' children (with new	• Paediatric dental centre with on-site GA facility • Semi-structured open-ended taped interviews (at dental centre or child's home) • 26 parents (of children under 6 years) interviewed at varying intervals (up to 12 months) after the GA	• Most parents were unable to maintain long-term positive oral health behaviours, and this was closely associated with their willingness to change • However, 'relapse' parents displayed less favourable oral health attitudes and practices: they were less concerned about their child's teeth, felt less able to

		caries at 6 months) with 'no relapse' children (caries free at 6 months)		influence their child's oral health and were less receptive to oral health advice from professionals
Parental views on delivering preventive advice to children referred for treatment of dental caries under general anaesthesia: A qualitative investigation (7)	Aljafari AK *et al.* 2014 London, UK	To investigate parents' opinions on delivery of oral health advice, determine current oral health behaviours and inform future development of interventions	• King's College Hospital, London • Semi-structured taped interviews with parents at GA assessment appointment • Response rate – 67% (29/ 43) • Children: range 3 to 10 years, mean age 7 years	• Parents had 'basic' oral health knowledge but felt restricted to control their child's oral health • Many claimed to have not received professional oral health advice or fluoride application for their child • Preferred methods to receive advice were through schools, video games or the internet

Why has oral health promotion and prevention failed children requiring general anaesthesia for dental extractions? (42)	Karki AJ, Thomas DR and Chestnutt IG 2011 Cardiff, Wales	To assess previous experience of oral health education, parents' beliefs and practices relating to caries and opinions on measures to prevent it	3 Dental GA Centres, Cardiff • Parental questionnaire administered by a single researcher, at GA treatment appointment • Response rate 96% (198/ 207) • Children: range 2 to 9 years, mean age 6.5 years	• Some parents held inaccurate misconceptions and defeatist views about their child's oral health • Many families had received oral health advice but reported application of topical fluoride was low • Most favoured information leaflets or a website as useful sources of health-related information • There is scope for increased use of fluoride varnish in this high-risk group and further research is required on how this can best be achieved

Why are children still having preventable extractions under general anaesthetic? A service evaluation of the views of parents of a high caries risk group of children (6)	Olley RC *et al*. 2011 London, UK	To assess oral health care received by children attending for caries-related extractions under GA and seek parents' opinions on experiences of dental services and support that might help them care for their child's teeth	Kings College Hospital, London • Interview questionnaire administered at pre-GA assessment appointment, by a single researcher • 108 parents interviewed, 1 declined (100 included in analyses as 8 incomplete) • Children: range 2 to 15 years, mean age 7 years	• Provision of oral health advice and treatments was low, and most parents would welcome further support • Customised preventive interventions are required to meet the needs of this high-risk group
A study of the provision of hospital based dental general anaesthetic services for children in the North West of England: part 1 - a comparison of service	Goodwin M, Sanders C, Pretty IA 2015 North-West of England	An exploration of the differences in dental GA services provided by 6 randomly selected hospitals across the North West of	• 456 patients attending 6 randomly selected hospitals across the North West of England for a dental GA • Questionnaires (self-administered) completed	• Reported discussions on preventive treatments (fluoride varnish and fissure sealants) by GDPs with parents, before the GA, were low and levels of

delivery between six hospitals (119)		England, including an assessment of prevention provided before the GA	by parents (93% response rate) and examination of Hospital clinical records	delivery of prevention also varied across Hospitals • Inconsistencies need to be addressed and opportunities to deliver prevention need to be explored: these include input by referring practitioners before and after the GA, and by GA providers at pre-assessment appointments, prevention clinics or by application of fissure sealants under GA
A study of the provision of hospital based dental General Anaesthetic services for children in the North West of England: Part 2 - the views and	Goodwin M, Pretty IA, Sanders C 2015 North-West of England	Qualitative evaluation of the experiences and opinions of families, referring clinicians and dental GA	• 6 randomly selected hospitals across the North West of England offering dental GA services • Semi-structured recorded interviews conducted by a	• Reinforces earlier findings, in that level and quality of preventive advice and treatment delivered prior to the GA and as part of the GA encounter, varied across

experience of families and dentists regarding service needs, treatment and prevention (136)		providers, on organisation and delivery of dental GA services (including prevention)	single (non-clinical) researcher • 15 parents, 6 primary care referring dentists and 5 operating dental GA clinicians • Interviews conducted at home, dental setting or over the phone	Hospitals and was generally inadequate • Parents requested more support, but some dentists held negative attitudes towards success achievable for this vulnerable group
Preventive aspects in children's caries treatments preceding dental care under general anaesthesia (195)	Savanheimo N and Vehkalahti MM 2008 Helsinki, Finland	To evaluate the preventive aspects of dental care for 'healthy' children receiving a caries related dental GA, during the two years preceding the GA	• Helsinki Public Dental Service (PDS) and Special Oral Health Care Unit (SOHCU) • Retrospective analyses of patient records for children referred from Helsinki PDS to SOHCU	• In the 2 years preceding the GA, children had on average, visited the dentist 5 times, 90% had at least one 'prevention visit', with these accounting for 37% of all visits.

			for comprehensive dental treatment under GA • 102 children (age range 2 – 15)	• Unco-operative children were least likely to receive preventive treatments • Children at high risk of caries had failed to receive the prevention they required • High risk patients failed to respond to 'normal' preventive care so 'intensive' measures were necessary to "cut the cycle of caries" in this resistant group
Five-year follow-up of children receiving comprehensive dental care under general anaesthesia (188)	Savanheimo N and Vehkalahti MM 2014 Helsinki, Finland	To evaluate the preventive dental care received during the 5-years, following a dental GA	• Helsinki PDS and GA provider service • Retrospective analyses of records for children receiving dental treatment	• Nearly all children (97%) received preventive interventions on at least one visit after the GA but measures to address dental

			under GA provided by Helsinki PDS/ GA service • PDS and GA provider have shared records, facilitating data collection • Data analysed for all healthy children attending for dental GA in 2004 • 199 children at baseline (mean age 6.2 years), 188 (94%) followed up after 5 years	anxiety and poor co-operation were inadequate • Increased support with behaviour management (as well as prevention) is required to facilitate on-going routine care
Dental treatment and caries prevention preceding treatment under general anaesthesia in healthy children and adolescents: a	Grindefjord M 2018 Stockholm, Sweden	To compare preventive treatment received by children prior to a dental GA, with prevention	• Stockholm Public Dental Service (PDS) and Eastman Institute (Stockholm dental GA service)	• GA group had received more 'preventive treatment' than the matched 'no GA' control group ($p < 0.001$) but despite this, almost half (48%) of the GA patients

retrospective cohort study (21)		received by children that don't need a GA	• Retrospective data analyses • Children referred from Stockholm PDS to Eastman Institute for dental GA (from January 2006 to October 2007) • 71 healthy children needing dental GA and 213 age and gender matched controls	had not received any prevention at all • Suggests failures in caries risk assessment and targeting prevention to those most in need • Practitioners are encouraged to identify and deliver preventive interventions to children at high risk of caries to reduce the need for GA
Failure on all fronts: general dental practitioners' views on promoting oral health in high caries risk children- a qualitative study (8)	Aljafari AK, Gallagher JE, Hosey MT 2015 London, UK	To explore the opinions and experiences of referring primary care dental practitioners, towards preventive	• King's College, London and GDP practices London • Qualitative (face to face) semi-structured taped interviews with GDPs (from 3 London boroughs)	• Multiple failures on all levels contribute to poor oral health in high caries risk children • GDPs were frustrated by barriers to delivering prevention: these include

		dental care, in high caries risk children needing dental treatment under GA	that referred children for dental GA • 18 GDPs (from 14 different practices) interviewed: 56% male, average age 42 years • High, medium and low referring practices • 51 practices were invited, contact achieved with 21 • Of the 25 GDPs invited to interview, 18 agreed to take part	factors relating to the child, parents, training, funding, poor communication from GA providers in secondary care, as well as wider political and socio-economic determinants • All need to be addressed to achieve better oral health in vulnerable children

Table 4: Interventional studies on dental GA and caries prevention				
Title:	**Author(s), year of publication, country:**	**Aim:**	**Setting, subjects, methods**	**Key findings and recommendations**
Can oral health education be delivered to high-caries-risk children and their parents using a computer game? – A randomised controlled trial (10)	Aljafari AK, Gallagher JE, Hosey MT 2017 London, UK	RCT to compare an oral health education video game with traditional one to one education to deliver oral health advice to high-risk children (and parents), requiring a caries related dental GA: Specific aims were to, evaluate: • Satisfaction and acceptability	• King's College, London • Families of children scheduled for caries related dental GA • Participants recruited at pre-GA assessment clinic from October 2013 to October 2014 • 119/ 177 families consented to take part, 10 later withdrew • Randomised control trial: Study group (55) - child and parent played video game and	• Families (children and parents) reported high levels of satisfaction with both methods of delivery • Immediately after receipt of intervention, there was a significant improvement in identification of unhealthy foods by children in both groups and after 3 months, some positive changes in oral health behaviours were also reported • The computer video game was rated as being equally

		of the intervention (to child and parents) • Effectiveness in improving child's dietary knowledge • Changes in child's oral health related behaviours (diet and tooth-brushing).	received a copy on DVD to play at home Control group (54) - child and parent received oral health education from a dental nurse • Outcomes recorded post-intervention and at 3 months (by phone call or review visit) • Demographics of both groups (computer game and one-to-one) comparable • Children: mean age 6.5 years, wide ethnic range, mostly socially deprived background	as effective as one to one education, but further research was required to assess long term behaviour change
Effectiveness of a preventive recall strategy	Berry EJ *et al*. 2017	RCT to compare 3-month versus 6-	• US, Virginia Commonwealth	• At 6 months, no significant differences were recorded in

for children after dental rehabilitation with general anaesthesia (196)	USA	month frequency interval following caries rehabilitation under GA	University, Paediatric Dental Unit • Families of children (under 6 years) scheduled for caries related GA • RCT: Study group (63) – recalls scheduled at 3 months intervals Control group (67) - recall scheduled at 6 months • At each scheduled recall, both groups received oral health education (using motivational interviewing techniques), prophylaxis and fluoride varnish • Caries risk assessment and dental examination completed at baseline and each scheduled recall	caries incidence between the two groups • However, caries risk assessment levels were lower for children seen for 3 month reviews

			• Recruitment period – July 2014 – January 2016 • Both groups were comparable at baseline	
Outcomes assessment of an intervention strategy to improve parental compliance to follow-up evaluations after treatment of early childhood caries using general anaesthesia in a Medicaid population (197)	Primosch, RE, Balsewich, CM, Thomas CW 2001 Florida, USA	To evaluate an intervention designed to encourage parents of children needing caries management under GA to attend follow up visits	• US, University of Florida Paediatric Dentistry Clinic • Parents of children (under 6 years) scheduled for caries related dental GA • Intervention group (124 children) compared with control group (100 children) not receiving intervention • Intervention – additional pre-operative 'prevention' visit, to deliver oral health	• Poor attendance overall, to follow up appointments: a higher proportion (60%) of the 'intervention' group returned for the one-week review, but fewer attended the 6 month review (31% compared to 42% for control group) • The 'prevention' visit, also failed to have any positive impact on dental health knowledge or oral health behaviours

			education, apply fluoride varnish and stress priority to attend follow up appointments (one week and 6 months after GA) Outcomes at baseline and 6-month review: • Caries levels, plaque, gingival health and streptococcus mutans scores recorded • Parental questionnaires to evaluate oral health related knowledge, values and behaviours	• Improvements in oral health (based on plaque, gingival and streptococcus mutans scores) were recorded but almost 40% had untreated caries, with no statistically significant difference between the intervention and control groups
A new primary dental care service compared with standard care for child and	Pine C *et al*. 2015 UK	To evaluate and compare a dental nurse led oral health	• Multi-centre two-year RCT	PROTOCOL only

family to reduce the re-occurrence of childhood dental caries (Dental RECUR): study protocol for a randomised controlled trial (11)		promotion service (based on motivational interviewing) with 'standard care' to reduce caries relapse in children that have previously experienced caries related extractions	• Dental extraction provider services across UK including, University Dental Hospitals and other secondary care GA centres • Children (5-7 years) scheduled to have caries related primary tooth extractions with LA, inhalation sedation or GA • Intervention – 'brief negotiated interview' (based on motivational interviewing techniques) delivered between recruitment and 6 weeks post extraction followed up by guided on-going prevention in primary care	

			• Assessments – clinical dental examination and questionnaires (parent and child) at baseline, and 1 and 2 year follow-ups • Main outcome measure – dentine caries at 2 years post extraction in any tooth (primary or permanent) that was caries free at baseline • Secondary measures - oral health related behaviours, including use of dental services and opinions on parents' readiness and self-efficacy to change behaviours • Intended sample size – 224 children	

1.4.2.1

Observational research on dental GA and caries prevention (Table 3):

These studies can be categorised in to two broad groups:

1. Studies that explore parental knowledge, attitudes, beliefs and behaviours with respect to caries prevention for children requiring a dental GA.
   Much of the research in this area relies on self-reported data, with it's inherent limitations.

2. Studies to evaluate oral health support and preventive services delivered to high risk children. Again, some are based on parents' perception of care received, whilst others take account of patient records and service data to provide a potentially, more accurate measure of follow up regimes and preventive interventions.
   Studies exploring referring practitioners' views and activity on prevention, are also considered within this group.

Clearly, several studies examine more than one aspect and many have common limitations. For studies based on self-reported data, non responders may hold completely different views and could be considered to be less compliant, given that they fail to respond. Respondents might choose to give answers they believe to be desirable (7, 42, 161, 175, 184) and parents might not be familiar with some types of dental treatment (e.g. fissure sealants, fluoride application), or realise these had been

provided (6, 42). Also reliability of records based data, inevitably depends on the consistency and quality of record keeping (179, 182, 186-188).

1.4.2.1.1

Parental knowledge, attitudes, beliefs and behaviours relating to caries prevention:

Previous studies on parents' behaviours examine oral hygiene, feeding practices, and patterns of dental attendance for children, referred for caries related extractions under GA. A Welsh study interviewing mothers of pre-school children prior to their GA found unfavourable oral health behaviours in most areas (184). Although this study highlighted factors that culminate in the need for a GA, it failed to evaluate any changes in oral health behaviour following the procedure. However, Sheller *et al*., in the US, compared differences in behaviour between parents of children that were attending for their first GA, with those that required a repeat (175). The study sample was small but unfavourable behaviours identified in the repeat group, support risk factors reported by Hunter and Hood, including, prolonged use of a nursing bottle, frequent sugary snacks and unassisted brushing (175).

Further qualitative studies to examine the impact a dental GA might have on modifying parents' attitudes and practices with respect to their child's dental health, suggest parents had adequate knowledge on how to look after their child's teeth and the GA experience appears to instill a more favourable attitude towards oral health (5, 161, 185). However, most parents still believed their ability to influence their child's oral health was limited, and some also reported poor access to dental care services.

Importantly, parents were interviewed only two weeks after the GA, so ongoing maintenance of behaviour change is questionable (185).

Research to compare differences between parents whose children presented with new caries six months after the GA with no relapse families, might help improve understanding of behaviour change over a longer period (161). Relapse parents felt they had less control over keeping their children's teeth healthy and were less receptive to preventive advice from professionals (161). In any case, even six months seems a relatively short interval to confidently predict that children in the no relapse group won't also develop new caries in the longer term. Amin *et al*. describe a theoretical model of behaviour change for high-risk families: potential barriers influncing parent's readiness and ability to change and subsequently, maintain postive oral health behaviours, include parenting strategies, differing cultural beliefs, unhealthy advertising, and significantly, input from dental professionals (5). Whilst some parents welcomed the practical advice offered by professionals, others felt the information was confusing and conflicting (5). Some parents also reported problems accessing dental care for young children (5).

More recent studies on parents' attitudes and practices towards caries prevention (6, 7, 42) reinforce conclusions drawn from earlier work. Most continue to explore preventive input prior to the GA, but also involve parents of older children, which is appropriate, given that GA rates in the UK are highest amongst 5 to 9 year olds (2). Aljafari *et al*. interviewed 29 parents of 3-10 year olds scheduled for caries related extractions under GA at a London Teaching Hospital (7). Most parents understood the importance of good oral hygiene and restricting sugar intake. However, parenting

challenges hampered efforts to keep their children's teeth healthy and most welcomed further support, preferring input through schools, the internet or a child friendly video game (7).

Questionnaire based studies generally support themes emerging from qualitative interviews (6, 42). Karki *et al*. found half of parents would find it difficult to refuse if their child asked for foods that were harmful to their teeth, and a quarter thought it was "*cruel not to give children sweets*"(42). Children's behaviour, pressure from other family members, lack of time and difficulties accessing dental care were amongst the challenges reported by parents completing questionnaires at a Dental Hospital in London (6). Notably, 61% had no plans for continuing dental care for their child following treatment under GA, although it was not clear whether this reflects a failure to take up services that are offered, or a lack of provision. Most parents welcomed more oral health support, including help through nurseries and schools and prevention at the GA assessment appointment (6).

1.4.2.1.2

Compliance for follow-up appointments after a dental GA:

Oral health behaviours discussed above, are based on self-reporting by parents, which may be unreliable, but one behaviour that could be expected to be reported on with greater confidence is attendance for follow-up appointments after the GA. Several studies, suggest recall rates amongst this cohort are generally poor (174, 175, 186, 187, 189-191). A study in the US found less than a third (29%) returned for their 6 month review (190), whilst another suggested only 7% of children requiring a repeat GA, attended review appointents a few weeks after the extractions, compared to 43% of

those attending for their first GA (175). However, higher rates of attendance have been observed, and especially for families that pay for healthcare (187). Time factors, travel difficulties and dis-satisfaction with services are all reported barriers (186) and children without a source of routine care are also less likely to return for follow up (191).

Of greater relevance is any impact that regular attendance might have, on caries relapse. Some studies propose a favourable association between recall frequency and a reduction in new caries (169, 181, 187, 192), whilst others fail to identify any significant relationship (174, 179, 193, 194). Almeida *et al*., found no significant correlation between frequency of recall appointments and caries relapse in children needing a GA in the US, despite intensive advice and preventive treatments being delivered at review visits (179). However, lower attendance has been observed in children that need a repeat GA (169, 192), with one study suggesting irregular dental attenders are four times more likely to have a repeat GA (169).

1.4.2.1.3

Oral health support and preventive care for children needing a dental GA:

It is important to assess the level and types of prevention delivered by dental professionals, including referring practitioners, as well as GA providers. Again, most research in this area centres on activity prior to the GA (6-8, 42, 119, 136, 195), which is still relevant, especially as enhanced prevention for high-risk patients might even avoid the need for a GA. However, evaluation of on-going support to prevent relapse, is equally important (21, 188).

Two thirds (67%) of parents of children needing a dental GA in Wales, claimed to take their child to a dentist at least once a year: most said their dentist had provided oral health advice, but only half reported that they had had been shown how to brush their child's teeth. Less than 10% had received fluoride varnish and only 14% of the 7 to 10 year age group had fissure sealants (42). Infrequent use of fluoride varnish was also reported by parents interviewed by Aljafari *et al*. in London: however, most also claimed, to have never received any kind of oral health advice (7).

Goodwin *et al*., in the North West of England undertook in-depth interviews with a small group of parents, referring dentists and clinicians delivering treatment under GA (136). Most parents felt their dentist had provided basic oral health information but some were very dissatisfied with the support offered. Some dentists expressed concerns about using fluoride varnish and preferred sealants, as a more reliable treatment that could be delivered in one visit. Poor remuneration was a barrier to providing prevention and one respondent simply summed up by stating,
"*The issue really is that I don't think there is a lot of prevention going on in primary care*" (136).

It is useful to examine the preventive care provided by GA dental services in other countries, whilst recognising the limitations in comparability with the NHS in the UK, due to varying healthcare systems. A study in Helsinki investigated service records on preventive care received by children in the 2 years preceding their dental treatment under GA (195). Overall, 'preventive' appointments accounted for 37% of all attendances and 90% of children had received at least one 'prevention visit' in the 2 years leading up to the GA. Further to this, Savanheimo *et al*., went on to also

investigate provision of oral health support after the procedure (188). Nearly all children (97%) received at least one prevention visit during the mean follow up time (which was 4 years) but this was clearly inadequate for high risk patients requiring additional support. A similar study by Grindejford *et al*., (2018), found children scheduled for a GA had received significantly more preventive input compared to those not needing a GA but despite this, almost half (48%) of the GA patients had not actually received any prevention (21).

An investigation in the South West of England used data on NHS activity by GDPs and dental GA services at Bristol Dental Hospital to compare rates of dental extractions under GA in children and the level and type of dental activity provided by GDPs in the same area (47). In summary, nearly 7 children per 1000 needed a dental GA in the year to March 2014. Around 40% of children had not seen a dentist at all during this time and amongst those that did, the level of preventive activity was very low. Less than a fifth (17%) had received application of topical fluoride and only 1.8% had fissure sealants. A significant relationship was found between increased use of fluoride varnish and higher rates of a dental GA, suggesting, as expected, more frequent use of fluoride in the areas with highest disease. Overall, levels of preventive activity by NHS dental practices was reported to be inadequate, highlighting the need for more action to reduce the observed rate of preventable paediatric dental GA's (47).

Research from the US reports lower rates of repeat GA in children that have sealants during their dental rehabilitation under GA (133). However, in the UK, treatment is often limited to extractions, unless a child has special care needs (3) and despite recommendations to increase availability of preventive treatments under GA, this is

unlikely to be feasible, without increased resources (119). Equally, hospitals in the UK lack capacity to follow-up patients after the GA and so most children are discharged back to referring dentists for on-going care (4). Good communication and well organised transfer of care between secondary and primary care providers is essential, to facilitate return to a routine source of dental care (8). However, a study in Yorkshire found no reference to the need for on-going prevention, in over fifty per cent of discharge letters sent to referring practitioners (167).

1.4.2.1.4

Dental practitioners' views on prevention for high-risk children:

One of the most in depth evaluations on practitioners' views on prevention was carried out by Aljafri *et al*. in London (8): this involved semi-structured interviews with GDPs that referred children for a GA, including a mix of high and low referrers. It was apparent that GDPs felt overwhelmed by the scale of the problem and several barriers to delivering prevention were identified, including:

1. High caries prevalence in poorly compliant young children
2. Unfavourable parental attitudes and behaviours towards dental health
3. Socio-economic and cultural differences in local populations
4. Poor NHS remuneration and lack of training
5. Inadequate input by secondary care providers
6. A wider failure of National policy to address the issue.

Previous research also suggests that GDPs might be less willing to spend time, effort and resources on providing preventon to parents with poor motivation, which suggests those most in need of support are least likely to receive it (139).

1.4.2.2

Interventional research on dental GA and caries prevention (Table 4):

Comparatively less research exists on prospective interventions, to prevent caries in this high-risk cohort. Aljafari *et al*. in London, undertook a RCT, to compare use of an oral health education (OHE) video game, with more traditional one to one delivery of OHE by a dental nurse (9, 10). The study involved children scheduled for a caries related dental GA and families were followed up for 3 months, to investigate the acceptability of the intervention, improvements in dietary knowledge and any changes in diet or tooth-brushing behaviours. Immediately after the intervention, children in both groups demonstrated a significant improvement in their ability to identify unhealthy foods, but any long-term impact couldn't be assessed because only 10% of families returned for the 3 month follow up. However, 55% of the 109 families that took part were contacted by telephone after 3 months: a similar proportion of parents in both groups reported positive changes in dietary behaviours, as too did children about their tooth-brushing regime. Clearly, self-reported behaviours can be unreliable, and the quality of the study is further compromised by the high drop-out rate. A longer follow up period would have been more valuable to assess if changes in behaviour were maintained and clinical data to investigate caries relapse would also have been helpful. It was recognised that incentives might have improved attendance for follow-up, but importantly, this study highlights difficulties of trying to target high-risk groups.

Other interventions have been based on increasing frequency of follow up visits (196, 197). Researchers in the US, compared a 3 month versus 6-month preventive recall

strategy for children scheduled for full mouth dental rehabilitation under GA (196). Preventive interventions at each recall visit were identical for both groups, including oral health counselling and application of fluoride varnish. At the 6-month review, caries risk levels were lower for children seen more frequently, but there were no significant differences in caries incidence. Loss to follow up (almost 50%) was again, high and 6 months was inadequate to demonstrate long term caries relapse. Despite this, 3 month recalls were recommended, along with measures to support attendance (196).

Another prospective study in the US, assessed the impact of an additional appointment for preventive therapy and counselling prior to the GA and used questionnaires to investigate parents' knowledge, values and behaviours with respect to their child's oral health (197). Dropout was high: 60% returned for the routine post-operative appointment one week after the GA, but only 31% attended the 6-month review. The additional prevention visit failed to produce any significant improvements in attendance or other oral health behaviours: the group seen for prevention were more likely to return for the routine review one week after the GA, but this was not maintained for the 6-month follow-ups. Also, more than a third (38%) of children seen at 6 months required further dental treatment, although the authors were unable to confirm whether this related to new caries or failed restorations (197).

More recently, the Dental RECUR study protocol describes a multi-centre RCT (in England and Scotland) to evaluate whether a new primary care dental service (based on dental nurse led motivational interviewing), is more efficacious and cost effective, than 'traditional' preventive advice, for children that have had primary teeth extracted

due to caries (11). The study (which was still recruiting at the time of writing) aims to enrol 224 children aged 5 to 7 years: this includes children that have had extractions under GA, but also inhalation sedation, or only LA. Though this trial is not restricted to patients needing a GA, given the young age of the sample, it would be appropriate to assume that many will require a GA. The intervention has been described as the "Dental Recur Brief Negotiated Interview for Oral Health": oral health counselling will be delivered by a trained dental nurse within 6 weeks of the extractions, supported by on-going prevention in primary care. Compared to earlier studies, the 2-year follow-up period is clearly more appropriate to assess long-term development of caries. Most children will be 7 to 9 years of age at the end of the trial, and so any new caries in permanent teeth will most likely be affecting first permanent molars. Practice records and parental questionnaires will be used to collect data but difficulties to recruit and retain high-risk families are anticipated (11).

1.4.3

Literature review summary:

The GA experience has been shown to have a positive emotional effect on parents, which motivates them to take immediate action and implement changes in oral health behaviours in the short term (185), but it does not appear to have a significant impact on long term preventive behaviours (5).

Many children requiring dental treatment under GA are irregular dental attenders (6, 198) and studies also report low attendance to follow up appointments after the GA (174, 175, 186, 187, 189-191). However, any association between frequency of follow

up visits and future caries development following the GA is not conclusive: some studies have found that caries can recur in high risk children despite intensive preventive regimes (174, 179, 193, 194), whilst others suggest that the number of recall visits is related to a lower incidence of relapse (169, 181, 187, 192). However, attendance levels after a dental GA have been strongly associated with the risk of having an unplanned repeat GA, with children who are irregular attenders shown to have four times increased risk (169).

Previous research has helped improve understanding of the challenges parents face in supporting their child's oral health following dental treatment under GA (5, 6, 175) and identified the types of support that might help them to look after their child's teeth (6, 42). Although there appears to be a general under-utilisation of dental services and preventive care amongst this group (169, 181, 186, 198), only limited information exists on the level and type of oral health support that is actually made available to these families, especially in the UK. Overall, provision of preventive treatments in primary care dental services appears to be inadequate (6, 42, 47, 136). However, GDPs also appear to be overwhelmed by the scale of the problem and report a range of barriers to provision of appropriate oral health support (8, 136).

Clearly, children who require caries related dental treatment (most often extractions) under GA continue to be at risk of caries, as well as a potentially avoidable repeat GA, calling for a more structured, proactive and original approach to prevention, to address the needs of vulnerable families (6, 8, 42, 136). Aljafari *et al*. describe the situation as, a "failure on multiple levels" and assign accountability to everyone involved with oral health care, including parents, dental practitioners, GA providers, other health

professionals, and also those responsible for planning local and national policies (8). It is important to target resources for children at greatest risk (42) and Goodwin *et al*., stress the importance of making the most of every opportunity to promote oral health, as per the Government strategy to '*make every contact count*' (136). This has led to recommendations to recruit other health professionals to deliver oral health promotion, and to set up mandatory prevention clinics at GA centres, that parents would be required to attend prior to their child receiving a GA (136).

Given broad recognition for more rigorous, tailored and innovative preventive regimes to minimise caries relapse in this challenging high-risk group, it is disappointing that relatively little research has been carried out to evaluate the impact of any proposed interventions. Indeed, Pine *et al*., on describing the protocol for the 'Dental RECUR' trial, claimed, that at the time of writing, no previous RCT on preventive interventions had been undertaken in children with experience of primary tooth extractions, but even this study was not exclusively restricted to those needing treatment under GA (11). So clearly, there is scope for more research activity in this area. There might be some reluctance to undertake studies with families that are presumed to be hard to recruit and retain (as well as resistant to behaviour change), but this shouldn't discourage further work in this area.

1.4.4

Prevention for children requiring a caries related dental GA – rationale for research:

This review highlights the need to develop and trial more caries prevention strategies, that are specifically designed and tailored to address the challenges posed by children

experiencing dental treatment under GA. Opportunities to facilitate and promote prevention exist through-out the patients' journey to receipt of a dental GA: this includes oral health support in the primary care sector prior to a child being referred to a secondary care setting (GA Centre/ Hospital), the GA encounter itself, through to on-going care, again at a local level, once discharged back to referring practitioners.

However, current efforts (mostly based on traditional approaches to prevention), appear to be either, inadequate and/ or failing, in part, because they don't explicitly address issues related to this group of patients. Most notably, for many families, there appears to be a lack of engagement in attitudes and oral health behaviours that support good dental health, and this crucially, includes poor levels of dental attendance. Therefore, one key aspect to focus on, is to make better use of the opportunity offered by the GA encounter. Capitalising on GA visits (including assessment appointments) is an option that justifies further investigation, given that this encounter allows access to otherwise, hard to reach families.

Furthermore, it is equally important to recognise that most children will be discharged back to referring practitioners, for regular care after the GA. Clearly, isolated interventions by providers in secondary care, are less likely to succeed, without on-going support from local dental teams. Good communication and teamwork are required, which warrants improved understanding of the challenges faced by referring practitioners, with respect to delivering preventive advice and treatments to high-risk children.

CHAPTER 2: DEVELOPING PREVENTIVE INTERVENTIONS FOR CHILDREN REQUIRING A CARIES RELATED DENTAL GA

2.1

Introduction:

Further to a review of preventive methods currently available and better understanding of the difficulties encountered when trying to prevent relapse of caries after a dental GA, the next step, is to explore how existing interventions might most appropriately be utilised, within the context of delivering preventive support to children requiring a dental GA. Research was based at the Birmingham Dental Hospital (BDH), so it would be useful to start by describing the paediatric dental GA service at this unit.

2.2

Background of paediatric dental GA service in Birmingham:

Birmingham was one of the first areas, in the UK, to be fluoridated (over 50 years ago), with just over two-thirds of the population in the West Midlands, having access to fluoridated water (45). Despite this, in 2015, five-year olds in the West Midlands region still had levels of decay comparable to the average for England (23.4%) and rates were even higher in Birmingham (30%) (31).

Birmingham Dental Hospital provides a paediatric dental GA service to the area covered by the Birmingham and Solihull Primary Care Trusts (PCT) Cluster, as well as accepting referrals from the wider West Midlands. This includes an exodontia

(extractions only) service, often referred to as the short ‘chair’ GA (which constitutes the major aspect of the paediatric dental GA service at this Hospital), as well as comprehensive dental treatment (including restorative treatment and sealants) under a longer ‘day stay’ procedure, for children with physical, learning, or behavioural co-morbidities. A small number of general hospitals also provide paediatric dental GA services to support other areas of the West Midlands (including Sandwell, Walsall and Wolverhampton) and the Birmingham Children’s Hospital provides dental treatment under GA for children that are medically compromised.

Each year, around 1600 children (under 17 years) are referred to the BDH for caries related extractions under a chair GA. A retrospective audit of clinical records based on activity during 2000-2005, reports a repeat GA rate of 3.6%, which was considered at the time to be low, compared to rates observed nationally (137, 169, 170). Activity data, based on age, (Table 5), show almost 65% of children attending for a chair GA in 2017-18, were 6 years or older.

Historically, children referred for chair GA extractions, were not required to attend a separate assessment appointment prior to the GA: assessments were completed on the same visit as the extractions and most patients were then discharged back to their referring dentist, without any follow up visits. However, from Spring 2014, the BDH GA Service implemented a separate pre-GA assessment appointment prior to the GA extractions visit.

Table 5:

Birmingham Dental Hospital Paediatric Dental GA Service Activity: 2017-18

Type of GA	Age Band	2017/18 %, (n)
Chair GA (n=1639)	< 5 years	19.8 (324)
	5 years old	16.0 (262)
	6-8 years old	40.5 (664)
	9-16 years old	23.7 (389)
Day Stay GA (n=260)	< 5 years old	0.4 (1)
	5 years old	0.8 (2)
	6-8 years old	11.5 (30)
	9-16 years old	87.3 (227)

2.3

The 'ideal' intervention:

To summarise, the 'ideal' preventive intervention for any child at high-risk of caries, should be:

- Evidence based and clinically effective
- Feasible and simple to undertake
- Acceptable to the child and parent
- Not heavily dependent on compliance or behaviour change by the child or family

- Protect all surfaces of all teeth, but failing that, target those that are most vulnerable to caries i.e. for permanent teeth, occlusal surfaces of first permanent molars (199, 200)

and

- Cost efficient

2.4

Opportunities to deliver prevention:

These include various stages of the GA care pathway. In the UK, children are usually referred by dental practitioners in primary care and following the GA, patients are discharged back to their dentist for on-going care. Most hospitals lack capacity to continue reviewing children in secondary care and the BDH is no exception, though patients with special care needs are sometimes followed up, after comprehensive dental treatment under GA. Based on this, opportunities available to offer support are illustrated in Figure 2 and can most usefully be categorised as:

- Before referral for dental GA - enhanced prevention should be started in primary care dental services (GDS and CDS), as soon as a child is identified as being at high caries risk
- As part of the GA encounter – activity in secondary care services (Hospital/ GA Centre), which could involve intervention at:
  - pre-GA assessment appointments
  - additional scheduled appointments dedicated to prevention
  - the GA extractions visit (specifically, placing fissure sealants whilst child is still awake i.e. before the GA or under GA)
- After the dental GA – including:

- On-going prevention in primary care dental practice, following discharge to referring practitioners

and potentially,

- Follow up visits in secondary care, possibly on under-graduate student teaching clinics

As explained earlier, until Spring 2014, assessments for chair GA extractions at the Birmingham Dental Hospital (BDH) were completed on the same visit as the GA, after which, most patients were discharged back to referring dentists. Therefore, the 'GA encounter' was limited to this single visit. However, since then, patients are seen on a separate visit for the assessment: on this basis, the GA encounter includes a pre-GA assessment appointment and the GA treatment visit.

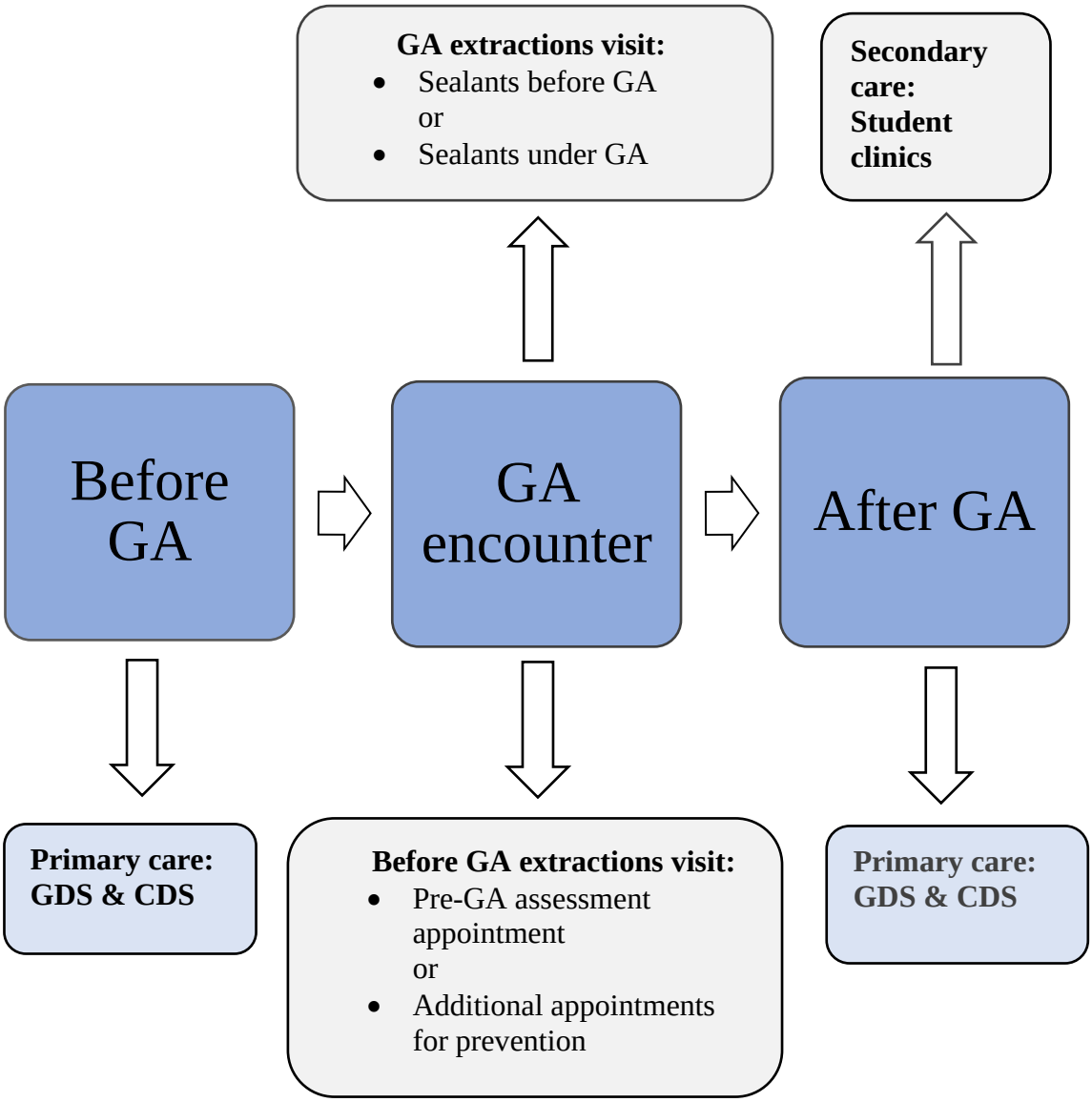


Figure 2 - Opportunities to deliver prevention as part of the GA care pathway

2.5

Re- appraisal of preventive interventions, as applied to children requiring a caries related dental GA:

The next step is to re-evaluate preventive interventions outlined in Section 1.2.2, but within the context of how each could be applied within the GA care pathway, along with due consideration of the difficulties associated with targeting high-risk families.

2.5.1

Oral health counselling:

As already outlined, oral health counselling, based on traditional 'biomedical' health education doesn't necessarily result in a desired change of oral health behaviour (58) unless personal motivations for preventive behaviour and underlying social determinants of oral health are also addressed (54). Furthermore, in high risk families, the GA experience does not appear to have any significant impact on long term preventive oral health practices (161). Even more importantly, oral health advice needs to be regularly reinforced (48, 50), which would most readily be achieved in GDP, where families can be seen for continuing care (both before and after the GA). However, high-risk families are irregular attenders (6, 198), which can clearly undermine efforts to deliver advice.

Another possibility is for GA providers to offer oral health counselling. This could be delivered as part of the pre-GA assessment appointment or the GA treatment visit. Delivering OHE in waiting rooms is another option but might be less effective when linked to GA visits, because parents are more likely to be engaged with advice and

instructions relating to the GA. Families could therefore be invited to attend separate prevention clinics, either before or after the GA. However, given that attendance after the GA has been shown to be poor (175, 190, 198), mandatory attendance on pre-GA prevention clinics has been recommended (119). However, the impact of one-off delivery of oral health advice alone is questionable and would best be supported by practical interventions that are based on stronger evidence, (such as topical fluoride and sealants), at the same time (63). Furthermore, it would be difficult to justify withholding of dental treatment if parents fail to attend mandatory prevention clinics.

2.5.2

Topical Fluoride:

In comparison to oral health counselling, strong evidence supports the caries preventive action of fluoride varnish, on both permanent and primary teeth (1, 83). However, to achieve optimal benefits in high-risk patients, fluoride varnish should be applied every 3 to 4 months, which is clearly not feasible if attendance is poor (6, 198). Equally, one off application as part of the GA encounter is unlikely to help. Therefore, interventions based on frequent application of topical fluoride, and which thus rely on regular attendance, might be unsuitable.

2.5.3

Fissure sealants:

High quality evidence also supports use of pit and fissure sealants on permanent molars (1, 50, 51, 85). Unlike oral health counselling, efficacy does not rely on long term positive behaviour change by the child or parents, and compared to topical

fluoride, sealants have the additional advantage of being applied in a single visit (and thus are more suitable for irregular attenders).

One in 8 children in England, have experienced decay in to dentine in at least one permanent tooth by the age of 8 years, and almost a third (32%) by the time they are 12 (29). The most susceptible sites are occlusal surfaces of permanent molars (199), with caries at this site accounting for most of the decay experienced in permanent teeth, by older children and adolescents (201, 202). Permanent molars are especially vulnerable during their period of eruption, which in some cases, can last up to a year (94, 200).

Children having carious primary teeth extractions are more likely to require removal of first permanent molars due to caries, when they are older (11). Albadri *et al*., found that 40% of children undergoing caries related removal of first permanent molars in Hospital, had previously had primary teeth extracted (203). In England, 5 to 9 year olds are most likely to have a dental GA (2), which overlaps the age group at greatest risk of developing caries in newly erupting molars (110).

It would seem most appropriate for sealants to be carried out in primary dental care, preferably before practitioners refer a child for a dental GA. However, the provision of sealants in GDP in the UK, is low, with only 7% of 8 year olds and 23% of 15 year olds having evidence of sealants (204) and reported use in high-risk groups is also inadequate (42, 47, 119). Barriers to use are comparable to those described for topical fluoride (8, 139, 205, 206): poor patient co-operation might be especially relevant in

children requiring a dental GA and sealants can clearly be more challenging than application of fluoride varnish.

Sealants can also be placed under GA, which clearly overcomes any problems related to compliance and some hospitals provide sealants as part of comprehensive dental rehabilitation under GA (119, 207). Success rates of sealants applied under GA vary, ranging from almost 100% retention after 4 years to two-thirds after only 8 months (207). However, in the UK, dental treatment under GA is usually restricted to extractions only, with comprehensive dental care reserved for children with special care needs or other co-morbidities.

Sealants could however be delivered at other points in the GA encounter, including the pre-GA assessment appointment, as well as the GA treatment visit but before the GA: given low use of sealants in GDP, these options merit due consideration.
This said, it is also important to recognise that sealants have less scope to benefit younger children (with unerupted permanent molars). Some guidelines do recommend sealing primary molars, especially in high risk children, despite weak supporting evidence (51, 92, 102, 103, 208) but interproximal surfaces are more vulnerable in primary teeth, with pit and fissure caries only accounting for around 40% of the total caries experience (103).

2.6

Sealants as part of the GA encounter – rationale:

Strong evidence supports both topical fluoride applications and fissure sealants as effective caries prevention methods (83, 85). However, for children requiring a caries related dental GA, fissure sealants appear to be the most appropriate, on the basis that they can be placed in a single visit and maximise the opportunity to reach high-risk patients as part of the GA encounter.

Table 6 outlines the pros and cons of implementing a preventive strategy based on delivering sealants as part of the GA encounter. Sealants target the most caries susceptible (occlusal) surfaces of the most caries prone teeth (first permanent molars), in the age group (5-9 years) that most often require a dental GA (2). Clearly, sealants don't protect all tooth surfaces and for reasons outlined earlier, any benefits in relation to preventing caries in the primary dentition of younger children are limited (103). It is also important to recognise that sealants provided in the GA setting are only one component of a comprehensive approach, which should preferably include continuing care by local practitioners to maintain sealants, apply topical fluorides and reinforce preventive advice.

Table 6: Benefits (pros) and Limitations (cons) of a preventive intervention based on fissure sealing permanent molars as part of the GA encounter

Potential Benefits - pros:	**Potential Limitations - cons:**
• Evidence based caries preventive intervention • Targets age group (5 to 9-year olds) most often requiring a caries related dental GA • Targets most caries susceptible surfaces (occlusal) of most caries prone teeth (first permanent molars) • Single visit application • Does not rely on a lifestyle change by child/ family • Some guidelines also recommend sealants on primary molars for high caries risk children • Maximises opportunity offered by GA encounter (assessment and/ or treatment visits) to deliver prevention • Resin sealants relatively simple to apply and well received by most children • Glass ionomer sealants can be used if poor co-operation or moisture control compromised • Cost efficiency increased if placed by professionals complementary to dentistry (PCD)	• Fissure sealants fail to prevent caries on all tooth surfaces • Less scope to prevent caries on primary molars, as: ➢ Interproximal surfaces are more vulnerable ➢ Evidence for efficacy of sealants on primary molars less robust • Less scope to benefit younger children (under 6 years), with primary dentition • Sealants can only be applied to teeth that are present and adequately erupted at GA encounter, requiring additional visits to seal newly erupting teeth • Regular follow up and maintenance recommended • Fails to promote holistic approach to improve oral health for patient or siblings (unless supported by on-going oral health counselling) • Difficulties associated with delivery of sealants under a 'chair' GA – increases duration of GA, practical feasibility and risk of compromising airway, cost implications

2.7

Developing a caries preventive intervention based on delivering sealants as part of the GA encounter

2.7.1

Background to overall aim and objectives of research:

Based on a review of the opportunities available to deliver preventive interventions, to children needing caries related extractions under GA, placement of fissure sealants as part of the GA encounter, appears to be the most appropriate option, whilst recognising the importance of on-going support by local practitioners.

As outlined earlier, from Spring 2014, the BDH GA Service introduced a separate pre-GA assessment appointment prior to the GA extractions visit. Until then, the only opportunity to provide sealants as part of the GA encounter, was at the GA extractions visit, at which time, sealants could potentially be applied, either before or during the GA itself.

This research began in 2012 and transcended through the period when local practice at the BDH was modified to adopt a pre-GA assessment visit. The objectives thus indicate the change in practice and reflect interventions based on providing sealants at various steps throughout the GA pathway: these include the GA extractions visit (either before or under GA), as well as during a separate pre-GA assessment appointment.

2.7.2

Overall aim and objectives of research:

Aim:

To inform development of a caries preventive intervention based on delivering sealants as part of the GA encounter.

Objectives:

1. To evaluate feasibility of providing sealants as part of the GA extractions visit, but before the child has their GA.
2. To evaluate feasibility of providing sealants under a chair dental GA for extractions.
3. To establish if there is an unmet need for sealants in children attending for caries related extractions under GA.
4. To explore parents' views on preventive interventions, including placement of fissure sealants as part of the GA encounter.
5. To explore referring dentists' attitudes and practices, towards preventing caries in children experiencing a dental GA, including opinions on placement of fissure sealants as part of the GA encounter.
6. To determine the type of oral health support and preventive dental care children currently receiving in primary care following a dental GA.
7. To investigate caries incidence two years after the GA in first permanent molars that were sound at the time of the GA.
8. To undertake a pilot RCT on the feasibility of provision and evaluation of sealants placed during the pre-GA assessment visit, for children having caries related dental extractions under a GA.

2.7.3

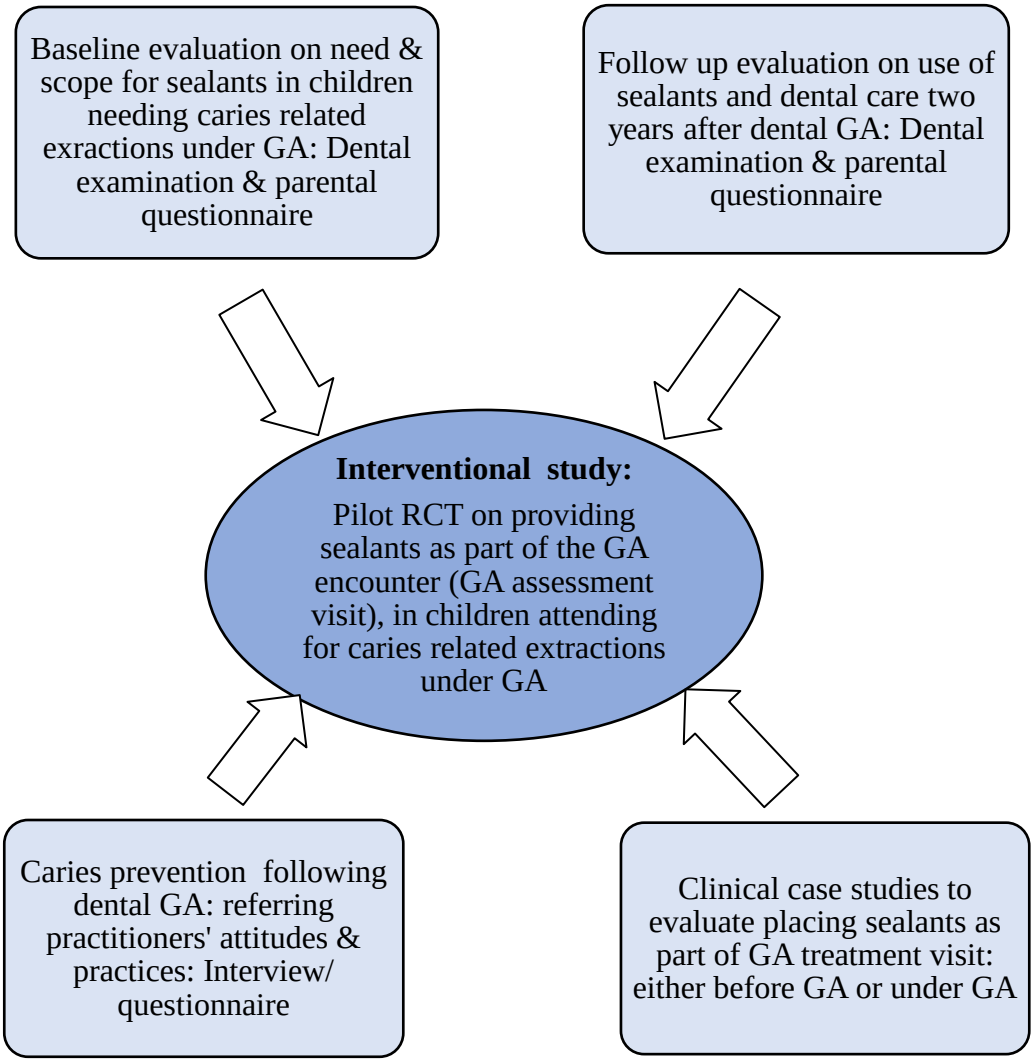
Studies to inform development of a caries preventive intervention based on delivering sealants as part of the GA encounter:

A series of studies were carried out to examine each of the objectives outlined in 2.7.2. These are best described as:

- Preliminary studies, including clinical case studies to evaluate feasibility of placing sealants as part of the GA extractions visit (including before the GA or under GA), service evaluations (using clinical data and parent questionnaires) to assess the need for sealants, and questionnaires to investigate referring practitioners' views and practices, on prevention for high-risk children and
- A pilot RCT on the feasibility of provision and evaluation of sealants placed during the pre-GA assessment visit, for children having caries related dental extractions under a GA.

Figure 3 demonstrates how the preliminary studies interact and serve to plan the pilot RCT.

Figure 3 - Overview of studies to inform development of a caries preventive intervention based on delivering sealants as part of the GA encounter



The next three chapters describe each of the preliminary studies to inform the development and planning of a pilot RCT, on delivering sealants as part of the GA encounter. Chapter 3 outlines clinical case studies, to evaluate feasibility of placing sealants as part of the GA visit, which could be under GA or at the assessment stage. Chapter 4 covers service evaluations (using clinical data and parent questionnaires) to assess the need for sealants in this group and Chapter 5 describes a questionnaire-based study to investigate referring practitioners' views and practices, on prevention for high-risk children.

CHAPTER 3: CLINICAL CASE STUDIES TO ASSESS FEASIBILITY OF PROVIDING SEALANTS AT THE GA EXTRACTIONS VISIT

The next section describes clinical case studies, to evaluate feasibility of placing sealants as part of the GA visit, which could be under GA or at the assessment stage.

3.1

Sealants placed under GA:

As explained earlier, sealants can be placed under GA, but this normally relates to comprehensive dental treatment under day-stay intubation GA, when the airway is secure and so gold standard resin-based sealants, involving use of water spray can be used. However, during a chair GA, patients are not usually intubated, which prevents use of etch and water spray, even with high-speed suction to aspirate and clear secretions. Sealants that are more moisture tolerant (such as glass ionomer, GI) are a possible alternative but achieving adequate moisture control might still be difficult, and extra time required to place sealants during the GA, must also be considered. The Lead Consultant Anaesthetist (Dr Lola Adewale) for the Paediatric Dental GA Service at BDH at the time had reservations about use of water spray under chair GA but was happy for GI to be placed using the simple gloved finger sealant technique (51, 94). This was subsequently carried out for a patient attending for a chair GA at the BDH.

3.1.1

Setting, subject and methods:

GA referral letters to the BDH were triaged by Abida Raja (AR) to identify appropriate patients. As explained earlier, at that time (Summer 2012), pre-GA assessment appointments were not routinely carried out: however, in this situation, parents were invited to attend an assessment appointment prior to the GA, so the procedure could be fully explained and discussed. Informed verbal and written consent were obtained from parents. The patient was an 8-year-old girl referred (in August 2012) for 2 caries related primary tooth extractions and she had 4 sound first permanent molars that justified sealing. Radiographs were available to confirm the caries free status of the teeth to be sealed. Sealants were applied under GA (by AR), but before the extractions, as moisture control was likely to be more difficult after these had been carried out. Fuji triage (a pink coloured dual cure GI sealant that does not require acid etching and thus water spray) was used. No tooth surface preparation was carried out: teeth were dried using cotton wool rolls, sealant was applied with a gloved finger, excess wiped away with a fresh cotton wool roll and then light cured to facilitate setting.

3.1.2

Outcome:

Technically, the sealants were relatively simple, but did add approximately 10 minutes to the duration of the GA, which was significant, given the extractions took only 3 minutes. Throughout the procedure, Dr Adewale had no concerns about the airway but suggested a laryngeal mask might be required if the treatment took any longer. With further experience, the operating time could be expected to be shorter, but it would still take at least 2 minutes to seal each tooth, adding 8 to 10 minutes to the GA, to seal

four molars. The patient was to be followed up 3 months after sealants were applied, but the family failed to attend review appointments.

3.1.3

Discussion:

Clearly, it important to minimise the duration of the GA to avoid any associated risks, but it is also relevant to consider the impact that extra theatre time has on the overall cost-efficiency of service delivery. Levels of activity would inevitably be reduced, which would be difficult to justify, given the long waiting times for a chair GA. It is also important to factor in the additional staff and resources required to deliver sealants as part of the GA: oral surgeons (performing extractions) could place sealants but this would not be cost-effective use of their skills and expertise. This could be improved if PCD such as dental therapists place sealants, but even this approach suggests oral surgeons would be waiting for sealants to be carried out, before moving on to the next patient, compromising overall efficiency and cost-effectiveness. Given the challenges highlighted, placing GI sealants under a chair GA, was not tenable, especially within the constraints of maintaining current levels of GA service activity.

3.2

Sealants placed at the GA visit (prior to the GA):

The other option for delivering sealants as part of the GA exodontia visit, is to place sealants at the assessment stage of the appointment, before patients are anaesthetised for extractions.

This would be a more cost-efficient approach, compared to sealant placement under GA, especially if PCDs apply sealants: there would be no impact on costly theatre time, so capacity to deliver GA services would not be affected and this makes better use of the time that patients might be waiting to go into theatre. Furthermore, for patients with adequate compliance, preferred resin sealants could be placed, although it would still be important to minimise accidental intake of water when washing away etch. However, it must also be recognised that some children might not comply with treatment (especially technically challenging resin sealants), more so as they will be starved (and potentially tired) and are more likely to be anxious shortly before they are due to have extractions.

3.2.1

Setting, subjects and methods:

To assess feasibility of placing sealants in this setting, 4 children undergoing caries related extractions at the BDH (in August 2013) had sealants carried out on the GA treatment visit but prior to the GA. The treatment planned was again discussed and agreed with Dr Adewale and informed verbal and written consent obtained from parents. Table 7 provides further information on the sealants placed, and outcomes, when children were followed up 6 months later. Two children failed to comply for resin-based sealants, so GI was used. For resin sealant, buccal pits on lower molars and palatal fissures of uppers were sealed, in addition to occlusal surfaces.

3.2.2

Outcome (Table 7):

The mean time required to apply 4 sealants for each patient was 20 minutes for GI and 23.5 for resin based. Only 2 families (both patients with resin sealants) could be contacted after 6 months, but outcomes were encouraging, with resin sealant retained on 87.5% (14/16) of all surfaces sealed 6 months earlier, and more importantly, no evidence of caries.

Table 7: Outcomes of sealants applied at GA treatment visit (before GA)

Patient sex/ age	**Teeth sealed & Type of sealant**	**Time required to apply sealants**	**Outcome at 6 months**
Male, 7 years	• 4 first permanent molars • 8 surfaces – 4 occlusal, 2 buccal, 2 palatal • Resin	22 minutes	Sealant fully retained on all occlusal & buccal surfaces, lost on 2 palatal surfaces
Male, 7 years	• 4 first permanent molars • 8 surfaces – 4 occlusal, 2 buccal, 2 palatal • Resin	25 minutes	Sealant fully retained on all surfaces
Male, 9 years	• 4 first permanent molars • 4 surfaces – occlusal • Glass ionomer	20 minutes	Lost to follow up
Female, 8 years	• 4 first permanent molars • 4 surfaces – occlusal • Glass ionomer	20 minutes	Lost to follow up

3.3

Sealants at the pre-GA assessment appointment - a new opportunity:

The clinical cases described, highlight the challenges associated with providing sealants at the GA treatment visit, although placement prior to the GA was clearly less technically demanding than providing sealants under GA. However, implementation (in Spring 2014) of separate 'pre-GA assessment appointments' at the BDH, prior to the GA extractions visit, offered an ideal opportunity to carry out sealants (as part of the GA encounter), overcoming many of the difficulties associated with placing sealants on the same visit as the extractions.

CHAPTER 4: SERVICE EVALUATION: PREVENTION IN THE CONTEXT OF CARIES RELATED EXTRACTIONS UNDER GENERAL ANAESTHESIA – AN EVALUATION OF THE USE OF SEALANTS AND OTHER PREVENTIVE CARE BY REFERRING PRACTITIONERS

4.1

Aim:

To explore the use and scope for fissure sealants amongst children requiring caries related extractions under GA and inform development of a pilot study to evaluate sealant placement as part of the GA encounter.

Two successive observational studies (baseline – Study A and two-year follow-up – Study B) were carried out, involving children (and their parents) attending the BDH, for caries related extractions under a chair GA. These will be described in turn, starting with the baseline evaluation.

4.2

Baseline service evaluation on need for sealants, plans for follow up dental care after the GA and views of parents of high-risk children, on use of sealants – Study A

4.2.1

Objectives:

1. To establish the prevalence of first permanent molars that would be suitable to receive fissure sealants.
2. To investigate dental attendance behaviours before the GA and identify arrangements for follow up dental care after the GA.
3. To seek parents' views on placement of fissure sealants as part of the GA encounter (including before, during or after the GA).
4. To assess ability to contact families after the GA and seek parents' opinions on their child taking part in a trial on caries prevention.

4.2.2

Setting, subjects and methods:

Further to advice from the National Research Ethics Service (NRES), on the need for ethical approval, the study was "deemed as service evaluation", and thus registered with the BDH, Birmingham Community Healthcare NHS Trust (BCHC NHS Trust), registration number: 44.

Children between the ages of 5 to 15 years, that had been referred to BDH for caries related extractions under a chair GA were included. Younger children were excluded, as first permanent molars were unlikely to be erupted.

At the time of this baseline evaluation, patients were not required to attend a separate pre-GA assessment appointment, so the GA extractions were carried out at the child's (usually) first and only visit to the Hospital. At this appointment, a senior clinician undertaking GA assessments, Sally Kerr (SK), collated data on the condition of first permanent molars: options for each first permanent molar are outlined in Table 8. Where possible, teeth were dried with a 3 in 1 syringe: no radiographs were taken for the purpose of the service evaluation, but any available were referred to. A simple tick box case report form, CRF1 (Appendix 1) was used to record data and if appropriate, more than one option could be selected for each molar. However, the 'sound and sealable' option was restricted to teeth that were free from any clinical signs of active caries, including any visual changes in enamel (such as white or brown decalcification) suggestive of early caries.

Table 8: Baseline service evaluation – codes to record condition/ status of first permanent molars
• Unerupted/ partially erupted • Sound and fissure sealable • Carious (including early or suspect lesions) • Restored • Fissure sealed • Hypomineralised &/ or hypoplastic • Scheduled for extraction • Missing (previously extracted) • Other

The first thirty children were also examined by the evaluation lead, Abida Raja (AR) to advise on use of the scoring criteria and assess consistency in recording.

Parents were asked if they would be happy to be contacted by telephone and or for their child to be recalled, up to two years after the GA. Parents were also invited to complete a short, self-administered questionnaire (Appendix 2). Interpreters (booked for the GA assessment) were available to assist parents with language difficulties. The questionnaire assessed dental attendance behaviours, (including whether patients had a follow-up appointment arranged with their own dentist after the GA), as well as parents' views on placement of sealants and taking part in a trial on caries prevention. Post-code and ethnicity data were self-reported (on questionnaires). Post-codes were used to derive index of multiple deprivation (IMD) scores (209), which were then correlated to deprivation deciles.

Sample size:

Data collection was carried out over a period of 6 months, from October 2012 to March 2013. According to BDH service activity data, approximately 600 children, aged 6 years and over, were expected to be referred to the Hospital during this time, so a sample of around 200 patients was considered appropriate, to represent at least a third of the cohort overall.

Data analysis:

Key-point software was used to prepare the CRF and questionnaire, so data entry was carried out by scanning paper forms. Data were analysed using *STATA IC Version 12, (Stata Corp., College Station, USA)* statistical software.

4.2.3

Results – response rate:

A total of 352 patients were examined and 214 parents completed questionnaires (response rate 60.8%).

Nearly three-quarters (73%, n=257) of parents agreed to be contacted after the GA, 15%, (n=53) refused, and the rest were not sure.

4.2.3.1

Demographic characteristics of sample:

Table 9a provides data on age for all children examined at baseline (n=352) and separately for those whose parents completed questionnaires (n=214).

Table 9a: Baseline service evaluation – data on age of sample at GA appointment (children > 5 years)

	Whole group at baseline, data from CRFs (*n*=352)	**Group at baseline that also completed questionnaire (*n*=214)**
Age:		
Mean (SD), range (years)	7.2 (5.2), 5-14	6.8 (1.4), 5-13
% (*n*) for different ages		
5 years	21.9 (77)	24.3 (52)
6	28.4 (100)	27.1 (58)
7	22.7 (80)	22.4 (48)
8	11.9 (42)	12.2 (26)
9	6.3 (22)	5.6 (12)
10	3.7 (13)	3.7 (8)
11	1.4 (5)	1.9 (4)
12	0.9 (3)	0.9 (2)
13	2.0 (7)	1.9 (4)
14	0.9 (3)	0
Total	100 (352)	100 (214)

Data on other baseline demographic characteristics (i.e. sex, ethnicity and deprivation) is restricted to children whose parents completed questionnaires (Table 9b).

The mean age of children was 7.2 years (standard deviation, SD 5.2) and almost 85% were between 5-8 years old: the mean age and distribution for the overall group (352) were comparable with those whose parents completed the questionnaire (214). For the latter, there were a similar proportion of boys and girls and most children were White British (35%) or Asian British Pakistani (40%). Deprivation levels were high with 70% of children falling within the lowest quintile (and 58% within the poorest decile). Ten percent (21/214) had previous experience of dental treatment under GA.

Table 9b: Baseline service evaluation – other demographic characteristics of sample at GA appointment (children > 5 years)

	Group at baseline that also completed questionnaire (*n*=214)
Sex % (n):	
Male	54.2 (116)
Female	45.8 (98)
Ethnicity % (n):	
White British	35.1 (75)
White Irish	0
Other White	1.9 (4)
White & Black Caribbean	1.9 (4)
White & Black African	0.5 (1)
White & Asian	1.4 (3)
Other Mixed	0.5 (1)
Asian British Indian	4.7 (10)
Asian British Pakistani	39.7 (85)
Asian British Bangladeshi	3.7 (8)
Other Asian	0.5 (1)
Black British Caribbean	3.7 (8)
Black British African	0.5 (1)
Other Black	0
Chinese	0.5 (1)
Any other group	2.3 (5)
Declined to answer	3.3 (7)
Index of multiple deprivation (IMD) Decile % (n):	***(n= 206)***
1 – poorest	58.3 (120)
2	12.1 (25)
3	5.3 (11)
4	5.8 (12)
5	7.3 (15)
6	3.4 (7)
7	2.9 (6)
8	2.4 (5)
9	0.5 (1)
10 – richest	1.9 (4)

4.2.3.2

Clinical status of first permanent molars:

Table 10: Baseline service evaluation - condition of first permanent molars at GA appointment

	Whole group at baseline, data from CRFs (*n*=352)	**Group at baseline that also completed questionnaire (*n*=214)**
Condition of at least one first permanent molar: % (n) of children affected * Where appropriate, more than one option could be selected for child (and each molar)		
Sound & 'sealable'	62.5 (220)	58.9 (126)
Caries	8.2 (29)	5.6 (12)
Hypomineralised &/ or hypoplastic	1.1 (4)	0.9 (2)
Filled	1.7 (6)	0
Fissure sealed	1.1 (4)	1.9 (4)
Missing (extracted due to caries)	0.3 (1)	0.5 (1)
Scheduled for extraction (due to caries)	9.4 (33)	7.5 (16)
Other	0	0
None erupted	31.5 (111)	33.6 (72)

Overall, 10.2% (36/352) of children had experience of caries in dentine (which includes untreated caries, filled or missing due to caries) affecting at least one first permanent molar and only 4 patients (1.1%) presented with molars that were already sealed prior to the GA (Table10). Sixty three percent (n=220) had at least one 'sound and sealable' first permanent molar at the time of the GA.

Table 11: Baseline service evaluation - prevalence of sound and sealable first permanent molars at GA appointment by age group

	Age group: years		
	5-15 (352 children)	**6-8 (222 children)**	**5 (77 children)**
Children with at least one 'sound & sealable' first permanent molar % (n)	62.5 (220)	77.0 (171)	16.9 (13)
Children with four 'sound & sealable' first permanent molars % (n)	48.0 (169)	63.5 (141)	9.1 (7)

Of those that had at least one 'sound and sealable' first permanent molar at the time of the GA (n=220), 77% (n=169) had four sealable first permanent molars (Table 11). The proportion of children with sound and sealable first molars varied by age: of the 222 children aged 6 to 8 years, 77% (n=171) had at least one sealable first molar, 82% (n=141) of whom had four sealable first molars.

4.2.3.3

Dental attendance behaviours:

Table 12: Baseline service evaluation - dental attendance behaviours before the GA

Referral source (213 respondents)	**% (n)**
General dental practice	77.9 (166)
Community dental practice	16.4 (35)
Other &/ or self-referral	5.6 (12)
Visits to dentist before GA (212 respondents)	
Only when trouble	26.9 (57)
Occasional check-ups – less than once every 6 months	26.9 (57)
Regular check-ups - at least once every 6 months	46.2 (98)
Plans for follow up after GA (214 respondents)	
Have appointment booked with dentist	15.4 (33)
Will wait to hear from dentist	28.5 (61)
Will contact dentist in 3 months	28.5 (61)
Will contact dentist in 6 months	16.4 (35)
No plans/ not sure	11.2 (24)

Most (78%) referrals had been made by a GDP and almost half (46%) of parents reported taking their child to a dentist for regular check-ups (at least once every 6 months). However, around a quarter (27%) had check-ups less frequently and a similar number only sought care if their child was experiencing problems. At the time of GA extractions, only 15% (n=33) of children had an appointment already booked to see their dentist after the GA.

4.2.3.4

Parents' opinions on sealants and taking part in a trial:

Table 13: Parents' opinions on sealants and on taking part in a trial

	Parents' response on sealants (214 respondents) (%, n)		
	Yes	**No**	**Not sure**
Would like child to have sealants	89.3 (191)	8.4 (18)	2.3 (5)
	Parents' response on questions relating to taking part in a trial (210 respondents) (%, n)		
	Yes	**No**	**Not sure**
Plan to stay at current home address	77.6 (163)	4.8 (10)	17.6 (37)
Agree to take part in a trial	50.0 (105)	25.7 (54)	24.3 (51)
Opinions on incentives if not willing to take part in a trial (n=105)	8.6 (9)	51.4 (54)	40.0 (42)

Most (89%, n=191) parents wanted their child to have sealants (Table 13): 8% (n=18) did not want their child to have sealants and the remainder were unsure. Of those who wanted sealants, 53% (n=102) preferred for these to be placed under GA, 31% (n=59) at the Hospital but not during the GA and 16% (n=30) chose to have sealants at their usual dentist.

Table 13 also outlines parents' opinions on questions relating to taking part in a trial: 210 parents responded to questions in this area. Most families (78%) had no plans to move home within the next 3 years but only half (n=105) of parents were happy for their child to take part in a trial. Of those that refused or were not sure, only 9% indicated they might be more likely to take part if offered an incentive, such as travel expenses.

4.2.4

Discussion:

Each year, around 1600 children are referred to the BDH for caries related extractions under a chair GA: over 60% are 6 years or older, which implies that many may have erupted first permanent molars, that justify sealing. This baseline service evaluation shows that, at the time of the GA extractions, a large proportion of children presented with first permanent molars that were suitable for sealing but had not been sealed, signifying a potentially unmet need for sealants in this high-risk group.

4.2.4.1

Methods and limitations:

The criteria used to indicate status of first permanent molars were clearly quite basic, in comparison to well established caries diagnostic tools, such as the surface specific International Caries Detection and Assessment System (ICDAS) (210). However, for the purpose of this evaluation, a custom-made tool, designed to identify whether each first permanent molar was caries-free and suitable for sealing, was considered more appropriate. Other conditions were also recorded, but the key objective was to identify

teeth that were suitable for sealants. Also, it was important to simplify data collection and minimise any extra time spent on this, given that children were due to have GA extractions on the same day.

Data were collected by a single examiner (SK), which eliminates scope for inter-examiner variation. SK received appropriate training and guidance on application of the customised first permanent molar codes (from AR), who also examined the first thirty children to assess consistency in recording. The possibility of intra-examiner variation remains and is recognised.

The questionnaire was designed to address aims that were specific to this service evaluation, and so no existing validated tool could be used. Prior to commencing the service evaluation, feedback on the questionnaire, was sought from a small (n=14) group of parents, further to which minor modifications were made, most notably, a short explanation to describe sealants was included. It was initially designed to be administered as a structured interview and was delivered as such (by AR) for the first 30 participants. However, it was not feasible for AR to undertake this on a regular basis and no other suitable members of staff could be recruited to carry this out. Therefore, the questionnaire was adapted so it could be self-administered and handed out to parents at the GA appointment. The response rate (61%) was relatively low, so views expressed might not be representative of the entire group. Limitations of self-reported data are also recognised, in that parents' ability to recall information can be unreliable and some might feel obliged to give responses they consider desirable.

Data on ethnicity and deprivation (based on post-codes) were self-reported and thus limited to families that completed the questionnaire (Table 9b). In hindsight, post-code data (and the child's sex) could have been obtained for all children, by referring to Hospital clinical records: ethnicity was not, as a routine, recorded, but the other two items were. On reflection, consideration was given to recovering records to seek this information but by that time, this was difficult, as many paper records had been archived.

4.2.4.2

Demographics of sample:

Most patients were 7 years of age at the time of the GA, suggesting they were representative of the national picture of children requiring GA extractions in the UK (6, 7, 42, 118, 180). However, given that children under 5 years were excluded, the cohort overall will almost certainly be younger. The sex distribution was also comparable to that identified in other studies (6, 118, 147, 180). Birmingham has high levels of deprivation, with 40% of the population residing in areas that lie within the poorest decile (211) but nearly 60% of the group referred for GA lived in the poorest socio-economic areas, lending support to the widely reported association between deprivation, caries and a child's risk of a caries related dental GA (16, 47, 147, 212). The ethnic background of children presenting for GA extractions might simply reflect the ethnic profile of the local population, as around 40% of children in Birmingham are from an Asian background (211). However, differences in caries experience between varying ethnic groups might also be a factor (23, 212).

4.2.4.3

Dental attendance behaviours:

Only 46% of children were reported to be regular attenders. This is similar to attendance behaviours reported in some previous studies (6), but unfavourable compared to others (42), suggesting on-going dental attendance after the GA, in the group investigated, is even less likely. Even though the majority (94%) of children had been referred for GA by a primary care dental practitioner, only 15% had an appointment booked to see their dentist for a follow-up after the GA. This does not necessarily imply that dentists were not planning on recalling children after the GA, but would appear to be so, given that almost half (45%) of parents were expecting to arrange a recall appointment themselves. High caries risk children need to be followed up more frequently to deliver enhanced prevention (50, 55), which is clearly not feasible if reviews are not scheduled accordingly.

4.2.4.4

Unmet need for sealants in first permanent molars:

At the time of the GA appointment, a large proportion of children had caries free first permanent molars that were suitable for sealing. However, only 1% had evidence of sealants. This was lower than the national prevalence of sealants (7% of 8-year olds) (204), whereas rates amongst children needing a dental GA would have been expected to be much higher.

Even though almost half of parents questioned claimed to be regular dental attenders, most children had not yet had their first permanent molars sealed by referring practitioners. It was evident that most (89%) parents wanted their child to have

sealants: although around half preferred these be carried out under GA, suggesting concerns about compliance or possibly reflecting the convenience of having all treatment completed at the same time. Whilst recognising that dentists might be planning to place sealants after the GA, it would seem more appropriate for these to have been carried out beforehand, given that families may not return to see their dentist after the GA (198) and even if they do, children might be more anxious, as a result of the GA experience. Furthermore, some might already have caries affecting first permanent molars by the time they return to see their dentist.

4.2.4.5

Parents opinions on taking part in a trial:

Most families had no plan to move over the next three years, signifying they would be contactable if recruited on to a trial. However, only half of parents were happy for their child to take part in a study, supporting the perception that high-risk families are hard to recruit and potentially unreliable study volunteers (9, 11). It was surprising that most parents were not persuaded to re-consider based on the offer of incentives (213).

4.2.5

Conclusions and recommendations:

There is an unmet need for fissure sealants in children attending for a caries related dental GA at the BDH. At the time of the GA, many 6-8-year olds had first permanent molars that were suitable for sealing but had not been sealed, despite most children being registered with a dentist and parents happy for their child to have sealants. Therefore, the GA encounter in secondary care could present an opportunity to deliver fissure sealants to high-risk patients.

Procedures to follow-up children in primary care after the GA also appear to be inadequate. Further studies are required to evaluate preventive advice and treatments provided by referring practitioners and to establish the longer-term incidence of caries in permanent molars that were sound at the time of the GA.

The two-year follow up evaluation (described in the next Section – 4.3) serves to address some of these issues, as well as investigate other aspects that relate to developing an intervention based on providing fissure sealants as part of the GA encounter. However, these baseline findings suggest it may be difficult to recruit high-risk families to take part in a trial.

4.3

Two-year follow-up: an evaluation of caries levels in first permanent molars, use of sealants and other preventive care provided by referring dentists, for children experiencing caries related extractions under GA – Study B

4.3.1

Background:

Key conclusions drawn from the baseline evaluation (study A) serve as the foundation for this two-year review, in that:

- Many children (over 6 years) had first permanent molars that were suitable for fissure sealing but had not been sealed at the time of the GA,
- Many parents wanted their child to have sealants,
- Most children had been referred for the GA by a GDP,

yet,

- Most did not have an appointment to see their dentist after the GA extractions or plans to return to see their dentist within 3 months of the procedure,

all indicating an unmet need for fissure sealants, on first permanent molars, in this high-risk group.

4.3.2

Aim:

To review children two years after caries related extractions under GA, and who at that time, had at least one caries free first permanent molar.

Objectives:

To evaluate,

1. Prevalence of fissure sealants on first permanent molars that were suitable for sealants at the time of the GA.
2. Two-year incidence of caries in first permanent molars that were caries free at the time of the GA.
3. Oral health support and treatment received in primary care within the 2 years following the GA.
4. Views of parents on measures they might find helpful to prevent further caries in their children's teeth.
5. Ability to contact families two-years after the GA and assess rates of attendance for a follow up appointment.

4.3.3

Setting, subjects and methods:

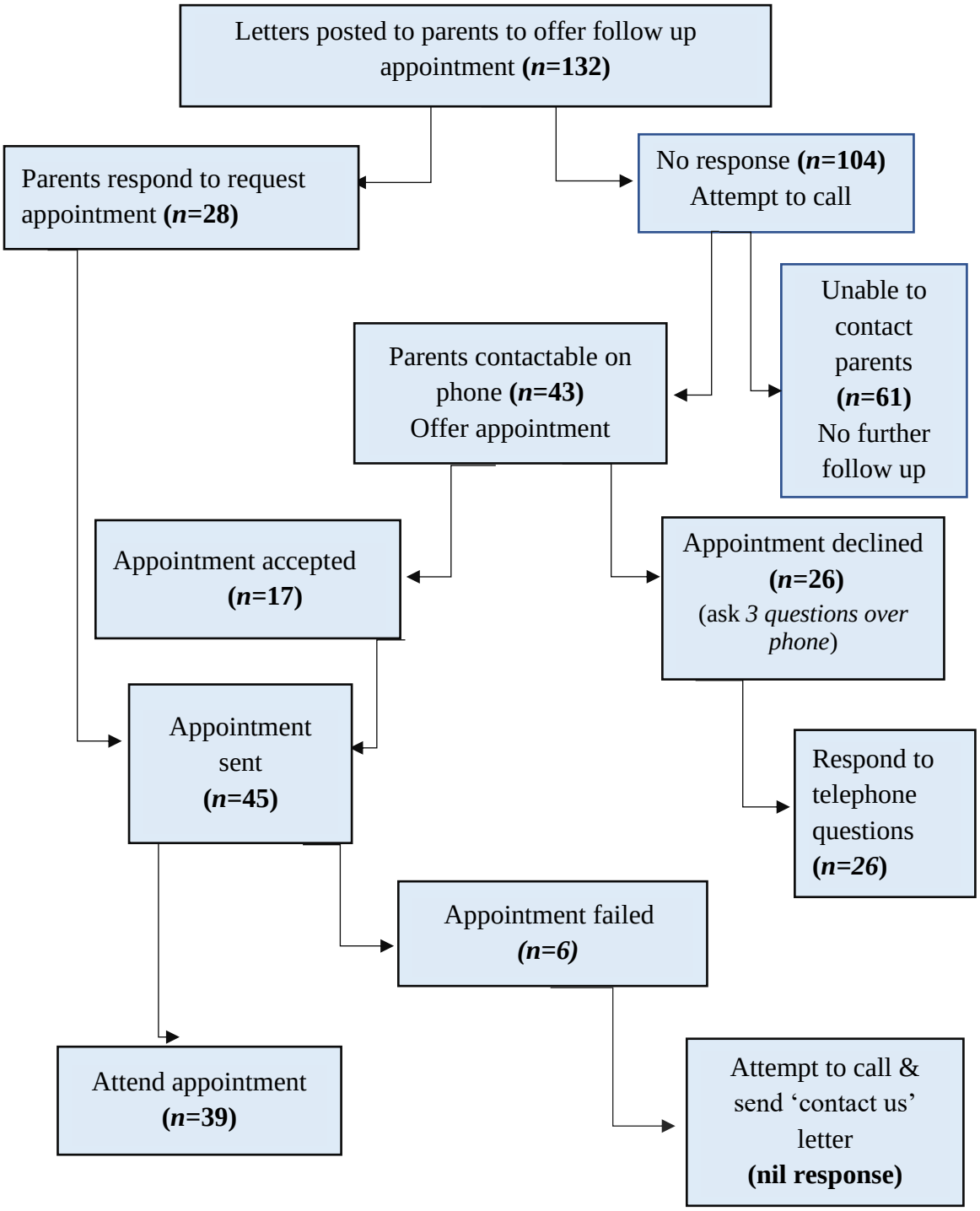
According to NRES, this study was "deemed as service evaluation" and so was registered with the BDH (BCHC NHS Trust), registration number: 178.
Case report forms (CRF1) from the baseline evaluation were used to identify families to be followed up. These were children that had undergone caries related extractions under a chair GA, at the BDH two years earlier and who at that time, had at least one first permanent molar that was identified as suitable for fissure sealing. Only children whose parents had agreed at the time of the GA, to be contacted afterwards, were included.

Figure 4 outlines the procedure for the follow-up schedule and the number of families involved at each stage.

Figure 4

Two-year post GA service evaluation - procedures for 2-year follow ups and throughput of patients

n = number of families/ children



Letters were sent to parents to offer a follow up/ review appointment at the BDH and invite them to contact the Hospital (by phone or e-mail) to indicate whether they wanted an appointment (Appendix 3). Where possible, non-responders were followed up with a phone call (by AR). Parents declining an appointment were invited to answer a short set of questions over the phone, to establish:

- if their child had been back to see a dentist after the GA
- whether parents would have found it helpful to have received a follow-up appointment at the BDH a few weeks after the GA

and,

- experience of repeat GA in this child and/ or dental GA within siblings

Failed appointments were followed up with a phone call and/ or contact us letter. Records were kept of the numbers that accepted/ refused a follow up appointment, failed to attend or were not contactable by phone (Figure 4). All study related administration was completed by AR.

Reviews were carried out on paediatric dentistry under-graduate (year 4) student clinics, mostly at the BDH but also at a Community Dental Clinic (Richmond Primary Care Centre, Stechford, Birmingham), where students under-take outreach placements. The evaluation lead (AR) supervised students at both sites.

At follow up visits:

a. A clinical dental examination was undertaken (by AR) to assess caries experience and evidence of sealants in first permanent molars

and

b. Parents completed a questionnaire

4.3.3.1

Clinical examination:

Teeth were washed and dried using a 3 in 1 syringe and a ball ended probe used to remove soft debris and check for presence of sealants. The presence or absence of caries and caries related treatment (including evidence of sealants), on first permanent molars, was recorded using the ICDAS (International Caries Detection and Assessment System) (210): this is an internationally recognised evidence-based caries assessment tool, which standardises classification of the stages of carious lesions, based on their clinical visual appearance (214). The first digit of the surface specific two-digit ICDAS code refers to the restorative or sealed status of the tooth surface (Table 14) and the second specifies different severities of caries (Table 15). The examiner (AR) had previously completed online training on use of ICDAS.

Table 14: ICDAS II Restorative codes criteria

ICDAS Restorative code (1st digit of 2-digit ICDAS score)	**Restorative code descriptor**
0	Unrestored or unsealed
1	Sealant, partial - sealant that does not cover all pits and fissures on a tooth surface
2	Sealant, full - sealant that covers all pits and fissures on a tooth surface
3	Tooth coloured restoration
4	Amalgam restoration
5	Pre-formed metal/ stainless steel crown
6	Porcelain, gold, PFM crown or veneer
7	Lost or broken restoration
8	Temporary restoration

Table 15: ICDAS II Caries codes criteria

ICDAS Caries code (2nd digit of 2-digit ICDAS score)	**Caries codes descriptor**
0	Sound tooth surface
1	First visual change in enamel, lesion non-cavitated and seen only when tooth is dry
2	Distinct visual change in enamel, lesion non-cavitated, seen when wet and dry
3	Enamel breakdown but no dentine visible
4	Dentinal shadow, not cavitated into dentine
5	Distinct cavity with visible dentine (less than 50% of tooth surface)
6	Extensive distinct cavity with visible dentine (more than 50% of tooth surface &/ or pulp involved)

Categories of caries reported on, were:

- Any caries – ICDAS codes 1-6
- Dentine caries - ICDAS codes 4, 5, 6
- Severe caries - ICDAS codes 5, 6

Radiographs were taken if clinically justified. Data was recorded on case report forms (CRF2 - Appendix 4).

Dental students delivered oral hygiene instruction and dietary advice and if appropriate, topical fluoride application and sealant placement were offered. Alternatively, parents could choose to return to their child's usual dentist for preventive interventions and any other outstanding treatment. Letters were sent to dental practitioners and where relevant, these included a request for completion of any remaining treatment.

4.3.3.2

Parental questionnaire:

Parents were invited to complete a structured interview questionnaire (Appendix 5), administered by AR, to evaluate:

i. Preventive dental care and treatment the child had received during the 2 years after the GA extractions, and
ii. Parents' views on measures they would find helpful to look after their children's teeth.

Ethnicity (self-reported) and post code data, were recorded on CRF2.

Follow up visits were completed from October 2014 to June 2015.

Data were entered onto excel spread sheets, which were then transferred to *STATA IC Version 12, (Stata Corp., College Station, USA)* statistical software, for calculation of appropriate summary statistics.

4.3.4

Results – response rate:

Figure 4 shows parents' response to the invitation for a review appointment, through to the number of children attending for follow up. Clinical (paper) records were requested from the Medical Records Department at BDH for children that fulfilled the inclusion criteria (n=219). Two searches recovered 132 clinical files (60%): on this basis, invitation letters for a follow-up appointment were sent to 132 parents. Overall, contact (by letter or phone) was achieved with 54% (n=71) of families for whom records were available. Of these, 63% (n=45) accepted the follow-up invitation, of which, 87%

(n=39) attended. On this basis, 55% (39/71) of children whose parents could be contacted and 30% (39/132) of children for whom records were available after 2 years, attended the review appointment.

Thus overall, data was available for 65 children:

- 39 clinical follow ups (CRF2 and interview questionnaire)
- 26 telephone question responses (3 short questions)

Sixty-nine percent (n=27) were accompanied to the review appointment by their mothers, and twenty eight percent (n=11) by fathers: no child was accompanied by both parents. One child was brought by a grandparent (which had previously been consented for by the parent). All spoke adequate English and were confident to complete the interview questionnaire.

4.3.4.1

Demographic characteristics of sample:

Table 16: Baseline (2012-13) demographic characteristics for children followed up after 2 years

	Followed up at 2 years		
	Phone call only *(n=26)*	**Clinical reviews only (*n=39*)**	**Phone call & clinical reviews (*n=65*)**
Age: (years) Mean (SD), range	6.7 (1.1) 5-9	6.9 (1.0) 5-9	6.8 (1.4) 5-9
% (*n*) for different ages			
5 years	15.4 (4)	5.1 (2)	9.2 (6)
6	38.5 (10)	33.3 (13)	35.4 (23)
7	26.9 (7)	33.3 (13)	30.8 (20)
8	11.5 (3)	20.5 (8)	16.9 (11)
9	7.7(2)	7.7 (3)	7.7 (5)

Sex % (n):			
Male	50.0 (13)	51.2 (20)	50.8 (33)
Female	50.0 (13)	48.8 (19)	49.2 (32)
Ethnicity % (n):	***(n=8)***	***(n=39)***	***(n=47)***
White British	12.5 (1)	20.5 (8)	19.2 (9)
White & Asian	0	2.6 (1)	2.1 (1)
Other Mixed	0	0	0
Asian British Indian	0	2.6 (1)	2.1 (1)
Asian British Pakistani	50.0 (4)	59.0 (23)	57.5 (27)
Asian British Bangladeshi	25.0 (2)	7.7 (3)	10.6 (5)
Other Asian	0	0	0
Black British Caribbean	12.5 (1)	2.6 (1)	4.3 (2)
Any other group	0	2.6 (1)	2.1 (1)
Declined to answer	0	2.6 (1)	2.1 (1)
No children were: White Irish, Other White, White & Black Caribbean, White & Black African, Black British African, Other Black or Chinese			
Index of multiple deprivation (IMD) Decile % (n):	***(n=25)***	***(n=37)***	***(n=62)***
1 – poorest	40.0 (10)	70.3 (26)	58.1 (36)
2	20.0 (5)	10.8 (4)	14.5 (9)
3	8.0 (2)	0	3.2 (2)
4	12.0 (3)	5.4 (2)	8.1 (5)
5	8.0 (2)	8.1 (3)	8.1 (5)
6	4.0 (1)	5.4 (2)	4.8 (3)
7	0	0	0
8	8.0 (2)	0	3.2 (2)
9	0	0	0
10 – richest	0	0	0

Table 16 outlines demographic characteristics at baseline for the sample of children followed up either by completion of telephone questions (n=26) or attending a follow-up appointment (n=39). On this basis, most children were 8 to 9 years old by the two-year review and there was an even distribution of boys and girls. Almost 60% of those attending the follow up appointment were Asian British Pakistani and just over 20%

were White British. No families had moved home since the GA. Most (70%) children fell within the lowest decile, representing the highest level of deprivation.
One child in the sample followed up (n=65) had undergone a dental GA prior to the baseline GA extractions but none had required a further GA since then. However, 20% (n=13), of parents reported that at least one sibling had also had extractions under a GA.

4.3.4.2

Dental attendance behaviours:

Overall, 74% (48/ 65) of children were reported to have been back to see a dentist within the 2 years following the GA. Of the 39 children attending for review, 92% (n=36) had been referred for the GA by a primary care dental practitioner, but only two-thirds (67%, n=26) returned to see a dentist afterwards and for all, this was 6 months or longer after the GA. Of these (n=26), almost three quarters (n=19) claimed to have a check-up once every 6 months, 19% (n=5) once a year and the remainder (n=2) only saw a dentist when having 'trouble'. Most children (96%, n=25) saw a GDP but 1 child (4%) was seen within the CDS.

Procedures for organising check-ups varied: for those receiving a check-up since the GA, 50% (12/24) had received a 'contact us letter' from their dentist, a quarter (n=6) had received an appointment and the remainder (25%) had not received any notification, so it was left to parents to contact their dentist when they thought a check-up was due. Fifty eight percent (n=14) received reminders (text, phone call, letter), once an appointment had been booked.

4.3.4.3

Preventive support and dental treatment received and levels of dental anxiety:

Table 17: Preventive care and dental treatment received by children that visited a dentist within 2 years following GA (n= 26)

Preventive care/ dental treatment received	**% (*n*)**
Oral hygiene advice	84.6 (22)
Diet advice	76.9 (20)
Advice on importance of prevention to avoid repeat GA	38.5 (10)
Teeth polished	19.2 (5)
Fluoride varnish	15.4 (4)
Fissure sealants	3.9 (1)
Fillings	19.2 (5)
Extractions	3.9 (1)
Radiographs	3.9 (1)
Other	0

Table 17 outlines preventive care and types of dental treatment received in the 2 years following the GA. Almost 40% believed their dentist had emphasised the importance of prevention to minimise the need for a further dental GA.

Amongst children that had been back to a dentist following the GA (n=26), just over a quarter (27%, n=7) of parents felt their child was anxious and 2 believed this anxiety had impacted on delivery of treatment. Only one parent (out of 7) thought their dentist had tried to address the anxiety and this was using communication and behaviour management techniques. None had provided or referred the child for treatment under sedation.

4.3.4.4

Parents' views on measures to help improve dental care for their child:

Table 18: Parents' views on measures they would find helpful to look after their child's teeth (39 responses)

Type of oral health support	**Yes, helpful % (*n*)**
Help with finding a 'child friendly' dentist	33.3 (13)
More frequent check-ups	41.0 (16)
Appointment reminders	61.5 (24)
Advice from allied health professionals (e.g. dieticians, GP surgeries)	12.8 (5)
Programs in school	38.5 (15)
Oral health leaflets	41.0 (16)
Oral health DVDs	15.4 (6)
Online resources – dental websites	10.3 (4)
Other	2.6 (1)

Nearly two-thirds (62%), requested a reminder about dental appointments and 41% would have welcomed more frequent dental check-ups. Oral health education leaflets and programmes delivered through schools were more highly favoured than online resources or DVDs and a third requested help with finding a 'child-friendly' dentist. All parents, (n=65), including those responding to the telephone questions, were asked if an appointment to bring their child back to the Dental Hospital, for a review a few weeks after the GA, would have been helpful: just over half (54%, *n*=35) felt it would.

4.3.4.5

Caries levels and evidence of sealants at 2 years:

According to data from the baseline evaluation (Study A), 37 out of the 39 children followed up at 2 years (Study B), had 4 sound and sealable first permanent molars at

the time of the GA. However, two children had caries in some but not all their first permanent molars and this was taken into consideration when measuring caries incidence in the sample, two years later. None of the sample followed up at 2 years, had evidence of sealants prior to the GA extractions.

Table 19: Untreated caries affecting first permanent molars (FPMs) that were sound at the time of the GA, in patients followed up clinically at 2 years

	Patients (n=39) with at least one affected FPM:	**FPM teeth (n=154) affected:**	**FPM surfaces (n=770) affected:**
Type/ severity of caries (ICDAS codes)	**% (*n*)**	**% (*n*)**	**% (*n*)**
Any caries (ICDAS codes 1-6)	64.1 (25)	47.4 (73)	11.9 (92)
Untreated dentine caries (ICDAS codes 4-6)	33.3 (13)	16.9 (26)	4.3 (33)
Untreated severe caries (ICDAS codes 5-6)	23.1 (9)	12.3 (19)	3.2 (25)
Totals	39 patients	154 teeth	770 surfaces

Tables 19 shows levels of untreated caries, affecting first permanent molars that were sound at baseline. Of the 39 children examined at 2 years, two thirds (n=25) presented with some degree of caries (ICDAS 1-6), one third (n=13) with dentine caries (ICDAS 4-6) and one quarter (n=9) with severe dentine caries (ICDAS 5-6) in at least one first permanent molar. Of the 154 first permanent molars that had been sound and sealable at the time of the GA appointment, 17% (26 teeth) had untreated caries involving

dentine two years after the GA and 12% (19 teeth) had 'severe' caries (ICDAS codes 5 and 6).

Table 20: Number of first permanent molars (FPMs) affected, in children presenting with untreated caries, two years after the GA

	Children affected, % (n)	
	Children (n=25) with FPMs with 'any' caries (ICDAS codes 1-6)	**Children (n=13) with FPMs with 'untreated dentine' caries (ICDAS codes 4-6)**
Total number of carious first permanent molars (n = 1 to 4) per child		
1 FPM affected	12.0 (3)	38.5 (5)
2 FPMs affected	24.0 (6)	30.8 (4)
3 FPMs affected	32.0 (8)	30.8 (4)
4 FPMs affected	32.0 (8)	0

Table 20 shows how many first permanent molars were affected in children presenting with caries two years after the GA. Of the 25 children presented with clinical signs of 'any' caries (ICDAS 1-6) in at least one first permanent molar, almost two-thirds (64%, n=16), had 3 or more first permanent molars affected. Among the 13 children presenting with caries into dentine in at least one first permanent molar, 62% (n=8) had at least two molars affected.

Table 21: Untreated caries data for first permanent molars (FPMs) in patients followed up at 2 years – surface types affected

	Surface type affected			
	Total surfaces affected (number)	**Occlusal % (n)**	**Buccal and palatal % (n)**	**Interproximal % (n)**
Type/ severity of caries (ICDAS codes)				
Any caries (codes 1-6)	92 surfaces	75.0 (69)	20.7 (19)	4.3 (4)
			Buccal / **Palatal /lingual**	
			13 / 6	
Untreated dentine caries (codes 4-6)	33 surfaces	66.7 (22)	21.2 (7)	12.1 (4)
			Buccal / **Palatal /lingual**	
			6 / 1	

Occlusal surfaces were most frequently affected (Table 21).

Two children (5%) presented with clinical evidence of sealants in first permanent molars. Three children had fillings in at least one first permanent molar, but these could only be considered as new restorations (since the GA) in two cases (representing 5% of the sample) because one child had presented with the same restorations prior to the GA. Experience of caries into dentine for all permanent teeth was reported on using the sum of the decayed, missing (due to caries) and filled teeth (DMFT) and surfaces (DMFS) indices. ICDAS codes 4, 5 and 6 were used to record the D (decay component) to signify caries into dentine (215). The mean DMFT and DMFS were 0.9 and 1.1 respectively, and all caries experience in the permanent dentition was confined to permanent molars.

4.3.5

Discussion:

Previous studies mostly focus on preventive support prior to a GA, rather than ongoing care afterwards (6, 7, 42, 136), so this evaluation draws attention to the type of support provided by referring practitioners, following the GA. Also, use of clinical data provides a measure of caries levels two years after GA extractions, and a more reliable indication of use of sealants in this high-risk group.

Referring dentists are reported to deliver preventive advice following extractions under GA, but there is an unmet need for preventive treatments i.e. fluoride varnish and sealants. Most children identified as having sealable first permanent molars at the time of their GA extractions, had not received sealants in primary care during the two-year period since the GA. Furthermore, the two-year incidence of caries in first permanent molars that were sound at the time of the GA, was high.

4.3.5.1

Methods and limitations:

The proportion of children that could be followed up after 2 years was low: Based on case report forms (CRF1) from the baseline service evaluation (Study A), dental records for 219 patients were requested from the Medical Records Department, but only 132 files were accessible: the remainder could not be found, with the possibility they might have been archived. Therefore, from the outset, it was not possible to contact around 40% of the target group. Patient records have since been transferred to an electronic system, which should facilitate any future efforts to maintain contact with patients (as well as participants in a trial). Just over half (55%) of parents that could be

contacted brought their child to the follow up appointment, which was reasonable, given that many might already have a dentist.

The questions were tailored to address specific aims and so there was again, no validated tool to refer to, other than a similar assessment by Olley *et al*., in London (6). However, the questionnaire was piloted on a small group of parents (n=9): feedback was positive, and no significant revisions were necessary. Parents' ability to recall information (especially, from two years previously) could be questionable. However, responses on provision of sealants were validated by comparison with clinical data, which suggested reasonable agreement from both sources. In hindsight, it would have been useful to collect further information from parents that had agreed to undertake the very short telephone questionnaire.

Clinical assessments were undertaken by a single examiner, which eliminates scope for any inter-examiner differences. Whilst the validity of ICDAS scoring for early caries (codes 1 and 2) might be questionable, dentine caries can be reported on with more confidence. Besides, some patients were also examined by other clinicians (on teaching clinics), which helped verify reported data and where justified, radiographs were also taken. On reflection, it could have been useful to also record caries levels in primary teeth two years after the GA.

4.3.5.2

Demographics of sample:

The sample followed up were, in most respects, comparable to the entire group at baseline 2 years earlier (Study A): most children were around 7 years of age at the

time of the GA (6, 7, 42, 118) and the sex distribution was also similar to that reported in previous studies (6, 118, 147).

However, it was surprising that over two-thirds (70%) of those that attended the 2 year follow-up, fell within the poorest socio-economic decile, as one could assume that this was the group least likely to return (144). Furthermore, children from an Asian ethnic background were also better represented in the group attending the follow up appointment. This contrasts with previous studies, that report poor attendance within ethnic minority families, relating to apparent barriers to seeking dental care, such as language difficulties and cultural differences (216).

4.3.5.3

Previous dental treatment under GA:

None of the children followed up had required more than one GA, compared to nearly 10% of children in the baseline sample (Study A). This could suggest that those at highest risk were least likely to return for a review appointment. However, 20% of parents reported experience of GA in at least one of their other children. These figures support findings by Aljafari *et a*l., where 14% of parents reported use of GA for dental treatment in another child (7). Other studies report much higher experience (up to 59%) of siblings requiring a dental GA, calling for more pro-active prevention to break the vicious cycle of poor dental health within families (6, 119).

4.3.5.4

Dental attendance behaviours:

Of the families that had been back to see a dentist after the GA, three-quarters of parents stated this was for regular check-ups, compared with 46% at the baseline

evaluation, suggesting families that came to the two-year review, were more likely to be regular attenders and better motivated. Attendance at post GA follow up clinics, has been shown to be poor, in both CDS and Hospital settings (175, 186, 198).

Over 90% of children attending the two-year review, had been referred for the GA by a primary care dental practitioner, but only two-thirds returned to see a dentist after the GA. In all cases, this was 6 months or longer after the GA, which fails to comply with recommendations for more frequent recall schedules, for children at increased risk of caries (55). Topical fluoride application up to 4 times a year is advised for high-risk patients (50, 51), which is clearly not feasible if children are only reviewed once every 6 months.

The process for organising check-ups varied, with responsibility to arrange recalls mostly being left to parents. Whilst recognising the need to improve efficiency and minimise time lost through failed appointments, more pro-active and tailored procedures are justified to follow up vulnerable patients, to ensure they are not 'lost in the system'. It was encouraging that over half (58%) of parents received a reminder once an appointment had been arranged, though this is presumed to be routine practice and not specifically to target high caries risk children.

4.3.5.5

Preventive dental care:

Since most children at the 2-year follow up were co-operative for dental treatment (as reported by parents), the low use of fluoride and sealants in this group, is unacceptable and unfortunately supports findings from similar studies (6, 42). This supports recommendations for increased use of both fissure sealants and fluoride varnish in children at high risk of caries (42, 136). In recent years, there has been a modest

increase in the use of fluoride varnish by dental practitioners (for e.g. a 20% increase from 2014-15 to 2015-16) but provision of fissure sealants during a similar period, has only grown by 11% (204). Levels of oral health counselling provided were more encouraging and again, support findings from previous research (6, 7, 42). However, information on the type and quality of advice delivered was not sought, so the impact of simple preventive advice alone, on high risk groups may be limited (58), unless based on psychological models of health behaviour change (67).

4.3.5.6

Dental caries:

There appears to be little consensus on the ICDAS II codes to be used to record the decay, D-component of the DMF index: codes 5 and 6 appear to have undisputed support with less certainty for codes 3 and 4. For the purpose of this evaluation, codes 4, 5 and 6 were used to represent dentine caries and comparable cut-off points have also been used in other caries research studies (215, 217).

The reported caries experience in first permanent molars, since the two years after the dental GA, was high. One third of children in the group followed up 2 years after the GA, had untreated caries into dentine in at least one first permanent molar: this does not bode well when compared with findings from the most recent UK National CDHS (28), which reports that one in ten children (9%) at the age of 8 years had untreated dentine caries. Additionally, the mean number of permanent teeth with obvious decay experience (DMFT) at 0.9, was three times that (0.3) reported for 8-year olds in England (29). Not surprisingly, the well-established observation of occlusal surfaces of permanent molars being most vulnerable to caries, was reinforced (199, 200).

4.3.5.7

Parents' opinions on measures to help:

Opinions on measures that might help parents to look after their child's teeth were wide ranging. Many (61%) would have welcomed a reminder about dental appointments and 41% requested more frequent check-ups, apparently suggesting these families are more motivated to visit dentists than is often perceived. Earlier work also shows most parents would like to receive support to prevent tooth decay in their children, with the most popular methods including use of the internet, video games or through schools (6, 7, 42). Use of digital online media is very common, so it was surprising that only 10% of parents in the sample questioned chose the internet as a means of receiving oral health information.

4.3.6

Conclusions and recommendations:

Oral health support and preventive care following caries related extractions under GA in the sample of children followed up at BDH, appear to be inadequate, with an unmet need for topical fluorides and fissure sealants. This is despite the fact that many children are reported to be regular dental attenders and apparently, not unduly apprehensive about dental treatment. Furthermore, two years after the GA, the incidence of caries in first permanent molars that were sound at the time of the GA, is of concern.

More must be done to prevent further caries in children at high risk, following dental extractions under GA. Oral health counselling *per se* is unlikely to succeed, so more rigorous efforts are required, to optimise delivery of evidence-based caries preventive interventions, to hard to reach families.

The GA encounter in secondary care offers an opportunity to reach susceptible children. However, on-going care relies on continued support at a local level, which at present, falls mostly on activity by dental practitioners in primary care. Feedback from referring dentists might help identify and better understand the reason(s) that underpin current deficits in care for high-risk children, including the unmet need for sealants.

CHAPTER 5: REFERRING PRACTITIONERS' VIEWS AND PRACTICES ON PREVENTION, FOR CHILDEN UNDERGOING CARIES RELATED EXTRACTIONS UNDER GENERAL ANAESTHESIA IN BIRMINGHAM

5.1

Background:

Clearly, prevention is a priority for children at high-risk of caries, which includes those requiring dental extractions under GA. A range of evidence based preventive interventions exist to help address this need: guidance on delivering prevention in primary care is widely available and describes enhanced measures necessary for those most at risk (50, 51). Furthermore, children in the UK are eligible for free NHS dental care and parents are encouraged to register children with a GDP, from as young as the age of one (218, 219).

However, preventive activity by dental practitioners in primary care appears to be inadequate. NHS Service data, interviews with parents and feedback from dentists, all indicate that preventive input falls short of the level required and fails to meet the needs of vulnerable children (6, 8, 42, 47, 136). This is disappointing, given that dental teams in primary care would seem best placed to deliver prevention, both before and after the GA, as referrals are usually made through primary care and most children are discharged to their usual dentist for on-going care following treatment. Barriers to promotion of oral health by GDPs include poor patient compliance, parents' attitudes and behaviours with respect to oral health, as well as inadequate remuneration for preventive activity (8, 139, 220).

When developing an intervention to prevent caries in high-risk children, it is important to establish the level of preventive care currently provided by referring practitioners, as well as, ascertain the views of dentists towards proposed measures. Furthermore, following dental treatment under GA, most patients will rely on continuing support from their local dental practitioner, so close collaboration and teamwork between secondary and primary care providers is essential, to help achieve the most favourable long-term outcomes.

5.2

Aim and objectives:

Aim:

To investigate views and practices of primary care dental practitioners in Birmingham, on prevention, for children they have referred for caries related dental extractions under GA.

Objectives:

To explore,

- Recall procedures to follow up and review patients after the GA
- Provision of preventive advice and treatments (including fluorides and fissure sealants) for high-risk children
- Barriers to delivery of preventive support in primary care
- Views on interventions to enhance prevention for high risk children (including fissure sealants as part of the GA encounter)
- Differences in views or practices between GDS and CDS practitioners and between high and low referrers

5.3

Methods:

5.3.1: Ethics approval

Further to consultation with NRES, it was advised that NHS approvals would not be required for this study. However, ethics approval was sought and secured from the University of Birmingham (13.05.13): Study registration number ERN_12-0828.

5.3.2: Setting and subjects

Primary care dentists i.e. General Dental Practitioners (GDPs) and Community Dental Practitioners (CDPs) in Birmingham, who had referred children to the Birmingham Dental Hospital (BDH) for caries related dental extractions under GA in 2013.

5.3.3: Design

Structured e-mail questionnaire.

Referral data were used to collate a list of GDPs that had referred children to the BDH for dental extractions under GA, from January to December 2013.

Table 22:
GDP referral rates to BDH for paediatric caries related dental extractions (2013)

Number (n) of referrals made by a single GDP in 2013	Number of GDPs making 'n' referrals	GDPs' referral rates	Total number of GDP referrers
1	130	***Infrequent (<3 referrals per year)***	187
2	57		
3	20	***Low (3-5 referrals per year)***	48
4	16		
5	12		
6	3	***Moderate (6-9 referrals per year)***	9
7	2		
8	2		
9	2		
10	4	***High (10 or > referrals per year)***	26
11	1		
12	2		
13	1		
14	1		
15	1		
18	3		
19	1		
20	1		
21	1		
26	2		
27	1		
29	1		
30	1		
32	1		
44	1		
49	1		
52	1		
56	1		

Data on referrers was available for 1191 of the 2228 referrals received in 2013 and of these, 1096 referrals had been made by 270 dental practitioners within Birmingham. The remainder were from other regions of the wider West Midlands. The average number of referrals made by each Birmingham practitioner, during 2013, was 4 (1096/ 270), with a range of 1 to 56 referrals. Based on referral rates, practitioners were categorised as high, moderate, low or infrequent referrers (Table 22):

- High – 10 or more referrals per year (26 GDPs)
- Moderate – 6 to 9 referrals per year (9 GDPs)
- Low – 3 to 5 referrals per year (48 GDPs)
- Infrequent – less than 3 referrals per year (187 GDPs)

CDPs in Birmingham were sent an e-mail to establish if they had made any paediatric GA referrals to the BDH, in 2013: all (n=28) responded, of whom 75% (n=21) reported they had. The researcher (AR) works within the Birmingham Community Dental Service, so it was relatively easy to gather this information.

Purposive sampling was used to reflect views and practices from a range of practitioners with differing referral patterns: all high (26) and low (48) referring GDPs were invited to take part, but all (21) CDPs were included (irrespective of the number of referrals made), given the comparatively small number of CDPs overall: data on the number of children referred by individual CDPs was subsequently sought as part of the questionnaire.

5.3.4: Invitation letters and Questionnaires

Invitation letters were posted to GDPs (Appendix 6) and these were followed up two weeks later, by a phone call from the researcher (AR), to establish if they agreed to take part. At the outset, a semi-structured telephone interview questionnaire was to be employed, but only 4 GDPs consented to this. Of the remainder (n=70), most (68/70) refused due to time constraints and practical difficulties with arranging a mutually convenient time for the interview but were willing to complete and return a questionnaire.

The questionnaire was revised so it could be self-administered, before piloting on 5 GDPs that had experience of referring children for a dental GA but were not included in the study sample. Further to minor revisions in the layout of questions, the questionnaire (Appendix 7) was sent via e-mail to all GDPs that had previously agreed to complete it (n=68) and to the target sample of CDPs in Birmingham (Appendix 8).

The questionnaire, using a combination of closed and open questions was structured to gather data on 4 key areas:

- Recall procedures to review children following a dental GA
- Preventive advice and treatments (including fluorides and fissure sealants) for high-risk children
- Barriers to delivery of oral health support and prevention
- Views on interventions to enhance prevention for high risk children (including fissure sealants as part of the GA encounter)

Four weeks after sending the first questionnaire, non-respondents were contacted (by e-mail or phone call) and a further 6 weeks allowed for receipt of completed questionnaires.

5.3.5: Data collection, recording and statistical analyses

Data collection was carried out over 4 months between February to May 2014.

For anonymity, participant identification numbers (PIN) were allocated to each respondent.

Records were kept on the number (and reasons) for refusals and the number of non-respondents.

Responses to closed questions were coded and data entered on to STATA spreadsheets. All data entry was completed by AR. Summary statistics were calculated, as appropriate, using *STATA IC Version 12, (Stata Corp., College Station, USA)* statistical software.

Responses to open ended questions were reported on separately.

5.4

Results:

5.4.1

Response rate:

Overall, the response rate was 78.9% (75/95).

Almost 70% (18/26) of high-referring GDPs, 81% (39/48) of low-referring GDPs and 86% (18/21) of CDPs, completed questionnaires.

Four GDPs (2 high and 2 low referrers) had previously taken part in the telephone interview: these responses were subsequently transferred to the self-administered questionnaire survey and comments from the interview recorded separately.

Only 2 practitioners (both low referring GDPs) refused to complete the questionnaire, all other non-respondents (8 high-referring GDPs, 7 low-referring GDPs and 3 CDPs) failed to return survey forms, despite 2 reminders.

5.4.2

Demographic characteristics of study sample:

Demographic characteristics of responders and non-responders were similar (Table 23). Overall, there was an even distribution of male and female dentists, the mean time since qualification was 16 years (range 3 to 39 years) and just over half (55%) were practising in the poorest areas of Birmingham. Three-quarters (76%) of respondents were GDPs and one quarter CDPs (24%).

Table 23: Demographic characteristics of referring practitioners: responders and non-responders

	Responders (n=75)	**Non-responders (n=20)**	**P-value**
Sex: % (n) Male Female	 52.0 (39) 48.0 (36)	 55.0 (11) 45.0 (9)	 0.81[1]
Years since qualification: Mean (SD) Range	 16.2 (9.3) 3 - 39	 15.8 (7.9) 4 - 30	 0.83[2]
Practice area deprivation levels (based on postcode): % (n) Poorest decile: Other deciles:	 54.7 (41) 45.3 (34)	 50.0 (10) 50.0 (10)	 0.71[1]
Type of practitioner: % (n) GDP CDP	 76.0 (57) 24.0 (18)	 85.0 (17) 15.0 (3)	 0.39[1]

Statistical tests:

1 - Pearson's chi squared

2 - Two sample t tests

5.4.3
Referring practitioners' views and practices on prevention:

Overall views and practices (of all respondents, n=75), on follow-up and prevention for children needing caries related dental extractions under GA, are summarised in Table 24.

Table 24: Referring practitioners' views and practices on follow-up and prevention for children needing a caries related dental GA

(all respondents, n=75)

Follow up and preventive activity	**Reported level of activity: % (n)**
Follow-up procedures after GA:	
Are appointments for follow-up after GA 'booked'? Yes	17.3 (13)
If Yes (n=13), timing of appointment: • Within 1 month of GA • Between 1 to 3 months of the GA • Within 3 to 6 months of the GA • Other	15.4 (2) 53.8 (7) 30.8 (4) 0
If No (n=62), are parents advised to 'contact' to arrange follow-up appointment after GA? Yes	40.3 (25)
If Yes (n=25), timing of appointment: • Within 1 month of GA • Between 1 to 3 months of the GA • Within 3 to 6 months of the GA • Other	24.0 (6) 36.0 (9) 40.0 (10) 0
Reason(s) for follow-up visit: *(More than one response may apply)* *(n=38)* • Review healing • Complete outstanding treatment • Caries prevention	47.0 (18) 45.0 (17) 100.0 (38)
Main reason for follow-up visit: • Review healing • Complete outstanding treatment • Caries prevention	3 (1) 0 97 (37)

Recall protocols, reminders and managing failed appointments:	
If not followed up after GA (n=37), are patients in due course, 'recalled'? Yes *If Yes (n=31), how are 'recalls' arranged?* *(More than one response may apply)* • Appointments sent in the post • 'Contact us' letters sent in the post • Advised to contact the practice when check-up 'due'	83.8 (31) 58.1 (18) 48.4 (15) 29.0 (9)
Are appointment 'reminders' sent? Yes *If No (n=6), are 'reminders' sent for children that have had a dental GA?* Yes *If reminders are sent (n=69), what methods are used?* *(More than one response may apply)* • Reminder letters sent in post • Text message • Phone calls • Other	92.0 (69) 16.7 (1) 39.1 (27) 86.9 (60) 55.1 (38) 5.8 (4)
What procedures are used to manage failed appointments? *(More than one response may apply)* *(n=75)* • Await contact • Send 'Contact us' letters sent • Further appointment sent • Phone call to re-appoint • Other *Does procedure for managing failed appointments differ for children that have had a dental GA?* Yes	 29.3 (22) 61.3 (46) 20.0 (15) 66.7 (50) 10.7 (8) 8.0 (6)

Prevention:	
Does practice have a • *Dental therapist?* Yes	20.0 (15)
• *Hygienist?* Yes	16.0 (12)
What preventive interventions are used for children that have experienced a caries related dental GA? *(More than one response may apply)* *(n=75)*	
• Oral hygiene instruction • Diet advice • Topical fluoride • Fissure sealant • Prescription of high fluoride toothpaste • Prescription of fluoride mouth rinse • Other	100.0 (75) 100.0 (75) 98.7 (74) 76.0 (57) 73.3 (55) 24.0 (18) 2.7 (2)
Which members of the dental team deliver preventive advice and treatments? *(More than one response may apply)* *(n=75)*	
• Dentist • Dental therapist (if available, n=15) • Hygienist (if available, n=12) • Dental nurse	94.7 (71) 100.0 (15) 91.7 (11) 48.0 (36)
Do you feel that you/ your practice could do 'more' to help prevent further caries in patients that you have referred for extractions under GA? (n=75) Yes	36.0 (27)
Barriers to prevention in high-caries risk children needing a dental GA: ***(More than one response may apply)*** ***(n=75)***	
• Time	49.3 (37)

• Financial (resources, staff, remuneration) • Patient compliance e.g. for fissure sealing) • Parents poor motivation (e.g. irregular attenders, unreceptive to advice given) • Other	13.3 (10) 77.3 (58) 89.3 (67) 5.3 (4)
Views on proposed interventions: (n=75)	
Prevention plan in discharge letter: • Unhelpful • Neither helpful/ unhelpful • Somewhat helpful • Very helpful *Patients followed-up in CDS &/ or Dental Hospital:* • Unhelpful • Neither helpful/ unhelpful • Somewhat helpful • Very helpful *Fissure sealants placed as part of the 'GA encounter':* • Unhelpful • Neither helpful/ unhelpful • Somewhat helpful • Very helpful	 14.7 (11) 36.0 (27) 37.3 (28) 12.0 (9) 9.3 (7) 13.3 (10) 41.3 (31) 36.0 (27) 8.0 (6) 8.0 (6) 30.7 (23) 53.3 (40)

5.4.3.1

***Follow up after GA*:**

On considering follow-up procedures after a GA, less than a fifth (17%) of practitioners booked review appointments and of the remainder, only 40% (25/62) advised parents to contact the practice to arrange a follow-up appointment. The timing

of visits varied but, around 60% recommended children should be reviewed within 3 months of the GA and for all, the main reason for the review visit was for prevention.

Exploring recall protocols for dentists that failed to specifically follow-up children after the GA, over 80% (31/37) did recall patients in due course, with a mean interval of 5.3 months. A variety of methods (including appointment letters, contact us letters and text messages) were used to arrange appointments. Most practices (92%) had systems in place to remind patients about scheduled appointments: the majority (86%) used a text messaging service, but letters, phone calls and e-mails were also employed. Of the 6 practices that did not send reminders, only 1 reported targeting reminders for children that had received a dental GA.

A range of measures were employed to manage patients that failed to attend. Overall, only 20% sent a further appointment. More often, contact us letters (61%) were posted or parents called to re-schedule visits (67%). Only 8% (n=6) of practitioners used more pro-active measures to target and follow-up failed appointments for children that had a dental GA.

5.4.3.2

***Preventive advice and treatments*:**

All respondents claimed to provide oral hygiene instruction and dietary advice and only 1 failed to apply fluoride varnish. Overall, three-quarters (76%) provided fissure sealants and/ or prescribed high fluoride toothpaste (73%) but less than a quarter (24%) issued prescriptions for fluoride mouthwash. Preventive advice was most often delivered by dentists (95%), but only half (48%) of dental nurses. A fifth of practices/

clinics employed a dental therapist and slightly fewer (16%) had a hygienist, most of whom (100% therapists, 92% hygienists) delivered advice on prevention.

5.4.3.3

***Barriers to delivering prevention*:**

Just over a third (36%) of dentists surveyed felt they '*could do more*' to prevent caries in children following a dental GA.

Patient related factors, namely the child's compliance for treatment (77%) and families' motivation towards prevention (89%) were more often cited as barriers to delivery of oral health support, compared to time (49%) or financial reasons (13%).

5.4.3.4

***Views on interventions to prevent caries in high-risk children*:**

Considering practitioners' views on interventions to enhance prevention for high caries risk children: provision of sealants as part of the GA encounter or recalling patients in secondary care/ CDS were more popular, compared to inclusion of caries prevention plans in discharge letters sent to referring practitioners following the GA (Table 24).

5.4.3.5

***Comments by referring practitioners*:**

Survey responses described in Table 24 quantify practitioners' views and behaviours but qualitative data (based on feedback from practitioners taking part in the interview, n=4, and comments recorded on paper questionnaires) provide more in-depth understanding of some of the key issues.

A selection of these are included below:

- *"I'm not sure there's much that we can do, it's the same families over and over again"*
- "*One of the biggest issues with us is poor attendance, the only reason I have time to talk with you this morning is that a family of four haven't turned up"*
- *"I personally feel we're doing the best we can, it's the type of patients we see, most are high caries risk"*
- *"We're definitely using more fluoride varnish than we used to, so that should help, it's better than just giving advice or handing out leaflets"*
- *"The problem is some patients just don't listen; it might be better coming from you guys at the Dental Hospital"*
- *"Yes please, any input from the DH would be welcome!"*

5.4.4

Comparison of differences between GDPs and CDPs - Demographic characteristics and views and practices on follow-up and prevention:

Table 25:
GDP and CDP: Comparison of demographic characteristics and views and practices on follow-up and prevention

Demographic characteristic	**GDS (n=57)**	**CDS (n=18)**	**P-value**
Sex: % (n) Male Female	 65 (37) 35 (20)	 11 (2) 89 (16)	<0.001[1]
Years since qualification: Mean, (SD)	14.8 (9.0)	20.9 (9.0)	0.014[2]

Practice area deprivation levels (based on postcode): Poorest decile: % (n) Other deciles: % (n)	54 (31) 46 (26)	56 (10) 44 (8)	0.93[1]
	Reported level of activity: % (n)		
Activity	**GDS (n=57)**	**CDS (n=18)**	**P-value**
Follow-up procedures after GA:			
Are appointments for follow-up after GA 'booked'? Yes	11 (6)	39 (7)	0.006[1]
If Yes, timing of appointment: • Within 1 month of GA • Between 1 to 3 months of the GA • Within 3 to 6 months of the GA • Other	17 (1) 50 (3) 33 (2) 0	14 (1) 57 (4) 29 (2) 0	0.97[1]
If No, are parents advised to 'contact' to arrange follow-up appointment after GA? Yes	41 (21)	36 (4)	0.77[1]
If Yes, timing of appointment: • Within 1 month of GA • Between 1 to 3 months of the GA • Within 3 to 6 months of the GA • Other	19 (4) 33 (7) 48 (10) 0	50 (2) 50 (2) 0 0	0.17[1]
Reason(s) for follow-up visit: (More than one response may apply) • Review healing	44 (12)	55 (6)	0.57[1]

• Complete outstanding treatment • Caries prevention	48 (13) 100 (27)	36 (4) 100 (11)	0.51[1] -
Main reason for follow-up visit: • Review healing • Complete outstanding treatment • Caries prevention	 4 (1) 0 96 (26)	 0 0 100 (11)	 0.52[1]
Recall protocols, reminders and managing failed appointments:			
If not followed up after GA, are patients in due course, 'recalled'? Yes	100 (30)	14 (1)	<0.001[1]
If Yes, how are 'recalls' arranged? *(More than one response may apply)* • Appointments sent in the post • 'Contact us' letters sent in the post • Advised to contact the practice when check-up 'due'	 60 (18) 47 (14) 30 (9)	 0 100 (1) 0	 0.23[1] 0.29[1] 0.52[1]
Are appointment 'reminders' sent? Yes	93 (53)	89 (16)	0.58[1]
If No, are 'reminders' sent for children that have had a dental GA? Yes	0	50 (1)	0.12[1]
If reminders are sent, what methods are used? *(More than one response may apply)* • Reminders sent in post	 38 (20)	 59 (10)	 0.80[1]

• Text message	83 (44)	94 (16)	0.26[1]
• Phone calls	53 (28)	59 (10)	0.67[1]
• Other	8 (4)	0	0.24[1]
What procedures are used to manage failed appointments? (More than one response may apply)			
• Await contact	39 (22)	0	0.002[1]
• Send 'Contact us' letters sent	53 (30)	89 (16)	0.006[1]
• Further appointment sent	19 (11)	22 (4)	0.79[1]
• Phone call to re-appoint	68 (39)	61 (11)	0.57[1]
• Other	4 (2)	33 (6)	<0.001[1]
Does procedure for managing failed appointments differ children that have had a dental GA?			
Yes	0	33 (6)	< 0.001[1]
Prevention delivered:			
Does practice have a • *Dental therapist?*			
Yes	7 (4)	61 (11)	<0.001[1]
• *Hygienist?*			
Yes	21 (12)	0	0.034[1]
What preventive interventions are used for children that have experienced a caries related dental GA?			
• Oral hygiene instruction	100 (57)	100 (18)	-
• Diet advice	100 (57)	100 (18)	-
• Topical fluoride	98 (56)	100 (18)	0.57[1]
• Fissure sealant	74(42)	83 (15)	0.40[1]
• Prescription of high fluoride toothpaste	74 (42)	72 (13)	0.90[1]
• Prescription of fluoride mouth rinse	25 (14)	22 (4)	0.84[1]
• Other	4 (2)	0	0.42[1]

Which members of the dental team deliver preventive advice and treatments?			
• Dentist	93 (53)	100 (18)	0.25[1]
• Dental therapist (if available)	100 (4)	100 (11)	-
• Hygienist (if available)	92 (11)	n/a	-
• Dental nurse	49 (28)	44 (8)	0.73[1]
Do you feel that you/ your practice could do 'more' to help prevent further caries in patients that you have referred for extractions under GA? Yes	37 (21)	33 (6)	0.79[1]
Barriers to prevention in high-caries risk children needing a dental GA:			
• Time	56 (32)	28 (5)	0.036[1]
• Financial (resources, staff, remuneration)	16 (9)	6 (1)	0.27[1]
• Patient compliance e.g. for fissure sealing)	82 (47)	61 (11)	0.059[1]
• Parents poor motivation (e.g. irregular attenders, unreceptive to advice given)	89 (51)	89 (16)	0.94[1]
• Other	0	22 (4)	<0.001[1]
Views on proposed interventions:			
Prevention plan in discharge letter:			
• Unhelpful	12 (7)	22 (4)	0.45[1]
• Neither helpful/ unhelpful	40 (23)	22 (4)	
• Somewhat helpful	37 (21)	39 (7)	
• Very helpful	11 (6)	17 (3)	

Patients followed-up in CDS &/ or Dental Hospital:			
• Unhelpful	2 (1)	33 (6)	<0.001[1]
• Neither helpful/ unhelpful	12 (7)	17 (3)	
• Somewhat helpful	40 (23)	44 (8)	
• Very helpful	46 (26)	6 (1)	
Fissure sealants placed as part of the 'GA encounter':			
• Unhelpful	2 (1)	28 (5)	<0.001[1]
• Neither helpful/ unhelpful	5 (3)	17 (3)	
• Somewhat helpful	28 (16)	39 (7)	
• Very helpful	65 (37)	17 (3)	

Statistical tests:

1 - Pearson's chi squared

2 - Two sample t tests

Almost 90% of practitioners in the CDS were female, compared to only a third (35%) in GDS (P < 0.001) and they were also more likely to have been qualified for longer (P = 0.014).

Compared to GDPs, dentists working in the CDS were more likely to schedule follow-up appointments after the GA (P = 0.006), although the ones that did not were less likely to subsequently recall patients (P < 0.001). CDPs were also more pro-active in pursuing patients that failed appointments, including children that had experienced a dental GA (P < 0.001), instead of waiting for families to contact to re-schedule.

Although community dentists less often cited time as a barrier to delivering prevention (P = 0.036), other barriers were encountered, notably around a quarter of CDPs (28%, n=5) included a comment to explain that prevention was not provided because patients were discharged back to referring GDPs after the GA.

When considering opinions towards interventions proposed to prevent caries in high-risk children, compared to GDPs, CDPs were less likely to perceive placement of sealants as part of the GA encounter, or recalling patients within CDS or Hospital services after the GA, as helpful interventions ($P < 0.001$).

Dentists working in the CDS had greater access to a dental therapist ($P < 0.001$) but were less likely to work with a hygienist ($P = 0.034$).

5.4.5

Comparison of differences between high and low referrers - Demographic characteristics and views and practices on follow-up and prevention:

Table 26:
High and Low referrers (all respondents): Comparison of demographic characteristics and views and practices on follow-up and prevention

Demographic characteristic	**High referrers (n=42)**	**Low referrers (n=33)**	**P-value**
Sex: % (n) Male Female	 55 (23) 45 (19)	 48 (16) 52 (17)	0.59[1]
Years since qualification: Mean, (SD)	 14.9 (8.5)	 17.9 (10.2)	0.16[2]
Practice area deprivation levels (based on postcode): Poorest decile: % (n) Other deciles: % (n)	 62 (26) 38 (16)	 45 (14) 55 (18)	 0.16[1]
Type of practitioner: **GDP: % (n)** **CDP: % (n)**	 76 (32) 24 (10)	 76 (25) 24 (8)	 0.97[1]

Activity	Reported level of activity: % (n)		
	High referrers (n=42)	**Low referrers (n=33)**	**P-value**
Follow-up procedures after GA:			
Are appointments for follow-up after GA 'booked'? Yes	12 (5)	24 (8)	0.16[1]
If Yes, timing of appointment:			
• Within 1 month of GA	0	25 (2)	0.27[1]
• Between 1 to 3 months of the GA	80 (4)	38 (3)	
• Within 3 to 6 months of the GA	20 (1)	38 (3)	
• Other	0	10 (1)	
If No, are parents advised to 'contact' to arrange follow-up appointment after GA? Yes	41 (15)	40 (10)	0.97[1]
If Yes, timing of appointment:			
• Within 1 month of GA	33 (5)	10 (1)	0.40[1]
• Between 1 to 3 months of the GA	33 (5)	40 (4)	
• Within 3 to 6 months of the GA	33 (5)	50 (5)	
• Other	0	0	
Reason(s) for follow-up visit: (More than one response may apply)			
• Review healing	55 (11)	39 (7)	0.32[1]
• Complete outstanding treatment	50 (10)	39 (7)	0.49[1]
• Caries prevention	100 (20)	100 (18)	-

Main reason for follow-up visit: • Review healing • Complete outstanding treatment • Caries prevention	0 0 100 (20)	6 (1) 0 94 (17)	0.29[1]
Recall protocols, reminders and managing failed appointments:			
If not followed up after GA, are patients in due course, 'recalled'? Yes	82 (18)	87 (13)	0.69[1]
If Yes, how are 'recalls' arranged? *(More than one response may apply)*			
• Appointments sent in the post	61 (11)	54 (7)	0.69[1]
• 'Contact us' letters sent in the post	50 (9)	46 (6)	0.83[1]
• Advised to contact the practice when check-up 'due'	22 (4)	38 (5)	0.33[1]
Are appointment 'reminders' sent? Yes	93 (39)	91 (30)	0.76[1]
If No, are 'reminders' sent for children that have had a dental GA? Yes	0	33 (1)	0.27[1]
If reminders are sent, what methods are used? *(More than one response may apply)*			
• Reminders sent in post	38 (15)	39 (12)	0.98[1]
• Text message	97 (38)	71 (22)	0.002[1]
• Phone calls	51 (20)	58 (18)	0.57[1]
• Other	3 (1)	10 (3)	0.20[1]

What procedures are used to manage failed appointments? *(More than one response may apply)* • Await contact • Send 'Contact us' letters sent • Further appointment sent • Phone call to re-appoint • Other *Does procedure for managing failed appointments differ children that have had a dental GA?* Yes	 31 (13) 67 (28) 21 (9) 69 (29) 10 (4) 5 (2)	 27 (9) 55 (18) 18 (6) 64 (21) 12 (4) 12 (4)	 0.73[1] 0.28[1] 0.73[1] 0.62[1] 0.72[1] 0.24[1]
Prevention delivered:			
Does practice have a • *Dental therapist?* Yes • *Hygienist?* Yes *What preventive interventions are used for children that have experienced a caries related dental GA?* • Oral hygiene instruction • Diet advice • Topical fluoride • Fissure sealant • Prescription of high fluoride toothpaste • Prescription of fluoride mouth rinse • Other	 14 (6) 14 (6) 100 (42) 100 (42) 100 (42) 79 (33) 74 (31) 31 (13) 5 (2)	 27 (9) 18 (6) 100 (33) 100 (33) 97 (32) 73 (24) 73 (24) 15 (5) 0	 0.16[1] 0.65[1] - - 0.26[1] 0.56[1] 0.92[1] 0.11[1] 0.20[1]

Which members of the dental team deliver preventive advice and treatments?			
• Dentist	90 (38)	100 (33)	0.068[1]
• Dental therapist (if available)	100 (6)	100 (9)	-
• Hygienist (if available)	100 (6)	83 (5)	0.30[1]
• Dental nurse	57 (24)	36 (12)	0.074[1]
Do you feel that you/ your practice could do 'more' to help prevent further caries in patients that you have referred for extractions under GA? Yes	40 (17)	30 (10)	0.36[1]
Barriers to prevention in high-caries risk children needing a dental GA:			
• Time	43 (18)	58 (19)	0.21[1]
• Financial (resources, staff, remuneration)	7 (3)	21 (7)	0.075[1]
• Patient compliance e.g. for fissure sealing)	83 (35)	70 (23)	0.16[1]
• Parents poor motivation (e.g. irregular attenders, unreceptive to advice given)	93 (39)	85 (28)	0.26[1]
• Other	5 (2)	6 (2)	0.80[1]
Views on proposed interventions:			
Prevention plan in discharge letter:			
• Unhelpful	7 (3)	24 (8)	0.13[1]
• Neither helpful/ unhelpful	36 (15)	36 (12)	
• Somewhat helpful	40 (17)	33 (11)	
• Very helpful	17 (7)	6 (2)	

Patients followed-up in CDS &/ or Dental Hospital:			
• Unhelpful	10 (4)	9 (3)	0.15[1]
• Neither helpful/ unhelpful	7 (3)	21 (7)	
• Somewhat helpful	38 (16)	45 (15)	
• Very helpful	45 (19)	24 (8)	
Fissure sealants placed as part of the 'GA encounter':			
• Unhelpful	7 (3)	9 (3)	0.66[1]
• Neither helpful/ unhelpful	5 (2)	12 (4)	
• Somewhat helpful	31 (13)	30 (10)	
• Very helpful	57 (24)	48 (16)	

Statistical tests:

1 - Pearson's chi squared

2 - Two sample t tests

At the outset, BDH referral data were used to identify high and low referrers, so that purposive sampling could be used to capture responses from practitioners with different referral patterns. However, service records failed to include all referrals made and so self-reporting by practitioners (via the questionnaire) was anticipated to provide a more reliable assessment of referral rates. Furthermore, self-reported rates were potentially more relevant, as they would reflect practitioners' views on prevention, based on their perceived level of referral activity.

For analyses, 'high and moderate' and 'low and infrequent' referrers were grouped, resulting in two categories:

- High referrers – 6 or more referrals per year
- Low referrers – 5 or less referrals per year

For the first round of comparisons according to referral activity, all respondents, irrespective of their area of practice (GDP or CDP) were included (Table 26). High referrers were more likely (62%) to practice in the most deprived areas, compared to low referrers (45%), although this variation was not statistically significant. Also, no significant differences were apparent with respect to opinions or practice, other than high referrers were more likely to send text reminders for appointments (P = 0.002).

To exclude any influence that working within the GDS or CDS might have on opinions and activity, the same areas were compared for high and low referrers that only worked within the GDS (Table 27).

Table 27:
High and Low referrers (GDS only): Comparison of demographic characteristics and views and practices on follow-up and prevention

Demographic characteristic	**High referrers (n=32)**	**Low referrers (n=25)**	**P-value**
Sex: % (n) Male Female	 69 (22) 31 (10)	 60 (15) 40 (10)	0.49[1]
Years since qualification: Mean, (SD)	 14.3 (8.5)	 15.4 (9.7)	0.66[2]
Practice area deprivation levels (based on postcode): Poorest decile: % (n) Other deciles: % (n)	 59 (19) 41 (13)	 48 (12) 52 (13)	 0.39[1]

Activity	Reported level of activity: % (n)		
	High referrers (n=32)	**Low Referrers (n=25)**	**P-value**
Follow-up procedures after GA:			
Are appointments for follow-up after GA 'booked'?			
Yes	9 (3)	12 (3)	0.75[1]
If Yes, timing of appointment:			
• Within 1 month of GA	0	33 (1)	0.51[1]
• Between 1 to 3 months of the GA	67 (2)	33 (1)	
• Within 3 to 6 months of the GA	33 (1)	33 (1)	
• Other	0	0	
If No, are parents advised to 'contact' to arrange follow-up appointment after GA?			
Yes	41 (12)	41 (9)	0.97[1]
If Yes, timing of appointment:			
• Within 1 month of GA	33 (4)	0	0.15[1]
• Between 1 to 3 months of the GA	25 (3)	44 (4)	
• Within 3 to 6 months of the GA	42 (5)	56 (5)	
• Other	0	0	
Reason(s) for follow-up visit: *(More than one response may apply)*			
• Review healing	53 (8)	33 (4)	0.30[1]
• Complete outstanding treatment	53 (8)	42 (5)	0.55[1]
• Caries prevention	100 (15)	100 (12)	-

Main reason for follow-up visit: • Review healing • Complete outstanding treatment • Caries prevention	0 0 100 (15)	8 (1) 0 92 (11)	0.25[1]
Recall protocols, reminders and managing failed appointments:			
If not followed up after GA, are patients in due course, 'recalled'? Yes	100 (17)	100 (13)	-
If Yes, how are 'recalls' arranged? *(More than one response may apply)*			
• Appointments sent in the post	65 (11)	54 (7)	0.55[1]
• 'Contact us' letters sent in the post	47 (8)	46 (6)	0.96[1]
• Advised to contact the practice when check-up 'due'	24 (4)	38 (5)	0.38[1]
Are appointment 'reminders' sent? Yes	91 (29)	96 (24)	0.43[1]
If No, are 'reminders' sent for children that have had a dental GA? Yes	0	0	-
If reminders are sent, what methods are used? *(More than one response may apply)*			
• Reminders sent in post	38 (11)	38 (9)	0.97[1]
• Text message	97 (28)	67 (16)	0.004[1]
• Phone calls	45 (13)	63 (15)	0.20[1]

• Other	3 (1)	13 (3)	0.21[1]
What procedures are used to manage failed appointments? (More than one response may apply)			
• Await contact	41 (13)	36 (9)	0.72[1]
• Send 'Contact us' letters sent	56 (18)	48 (12)	0.54[1]
• Further appointment sent	25 (8)	12 (3)	0.22[1]
• Phone call to re-appoint	69 (22)	68 (17)	0.95[1]
• Other	3 (1)	4 (1)	0.86[1]
Does procedure for managing failed appointments differ children that have had a dental GA? Yes	0	0	-
Prevention delivered:			
Does practice have a • *Dental therapist?* Yes	3 (1)	12 (3)	0.19[1]
• *Hygienist?* Yes	19 (6)	24 (6)	0.63[1]
What preventive interventions are used for children that have experienced a caries related dental GA?			-
• Oral hygiene instruction	100 (32)	100 (25)	-
• Diet advice	100 (32)	100 (25)	0.25[1]
• Topical fluoride	100 (32)	96 (4)	0.39[1]
• Fissure sealant	78 (25)	68 (17)	0.80[1]
• Prescription of high fluoride toothpaste	75 (24)	72 (18)	0.051[1]

• Prescription of fluoride mouth rinse	34 (11)	12 (3)	0.20[1]
• Other	6 (2)	0	
Which members of the dental team deliver preventive advice and treatments?			
• Dentist	88 (28)	100 (25)	0.067[1]
• Dental therapist (if available)	100 (1)	100 (3)	-
• Hygienist (if available)	100 (6)	83 (5)	0.30[1]
• Dental nurse	59 (19)	36 (9)	0.080[1]
Do you feel that you/ your practice could do 'more' to help prevent further caries in patients that you have referred for extractions under GA?			
Yes	41 (13)	32 (8)	0.50[1]
Barriers to prevention in high-caries risk children needing a dental GA:			
• Time	50 (16)	64 (16)	0.29[1]
• Financial (resources, staff, remuneration)	6 (2)	28 (7)	0.025[1]
• Patient compliance e.g. for fissure sealing)	91 (29)	72 (18)	0.067[1]
• Parents poor motivation (e.g. irregular attenders, unreceptive to advice given)	94 (30)	84 (21)	0.23[1]
• Other	0	0	-
Views on proposed interventions:			
Prevention plan in discharge letter:			
• Unhelpful	3 (1)	24 (6)	0.049[1]
• Neither helpful/ unhelpful	38 (12)	44 (11)	

• Somewhat helpful • Very helpful	44 (14) 16 (5)	28 (7) 4 (1)	
Patients followed-up in CDS &/ or Dental Hospital: • Unhelpful • Neither helpful/ unhelpful • Somewhat helpful • Very helpful	0 6 (2) 38 (12) 56 (18)	4 (1) 20 (5) 44 (11) 32 (8)	0.14[1]
Fissure sealants placed as part of the 'GA encounter': • Unhelpful • Neither helpful/ unhelpful • Somewhat helpful • Very helpful	0 3 (1) 25 (8) 72 (23)	4 (1) 8 (2) 32 (8) 56 (14)	0.44[1]

Statistical tests:

1 - Pearson's chi squared

2 - Two sample t tests

Again, high referrers were more likely to send text reminders (P=0.004). However, they were less likely to consider cost as a barrier to delivering prevention (P=0.025) and more inclined to favour inclusion of prevention plans in discharge letters (P=0.049).

5.5

Discussion:

5.5.1

Study strengths and limitations:

The response rate (almost 80% overall) was acceptable and the sample includes a range of GDPs, CDPs and high and low referrers. Demographic characteristics of responders and non-responders were comparable, suggesting the dentists that took part were representative of the wider group. The response rate compares favourably to other research involving dental practitioners, although direct associations might be inappropriate, given that some studies were interview based and more qualitative (8, 221). Poor response rates have previously been related to time pressures and difficulty arranging interviews (8, 139, 221), which clearly was also an issue encountered in the present study, and as a result, self-completed questionnaires were used instead of interviews. Bias related to respondents feeling obliged to give answers that are desirable or professionally acceptable is recognised.

Whilst appreciating the benefits of qualitative research (to improve depth of understanding on key issues) (222), the quantitative (questionnaire) techniques employed still serve to identify overall views and practices from a relatively larger sample. Also, 4 practitioners agreed to be interviewed, so opinions expressed during these helped to inform and revise the questionnaire and practitioners were encouraged to leave comments on questionnaires. Furthermore, the sample size supports sub-group analyses to compare differences in opinions or activity between GDPs and CDPs, as well as high and low referrers.

On reflection, it might also have been useful to establish if practitioners worked in both GDS and CDS, to explore variations according to working in different services. Dental therapists and hygienists could have been included in the study sample, as they were clearly contributing to delivery of prevention. Post-graduate training and qualifications have been shown to have a positive impact on enforcing preventive care, so further information on respondents' levels of training, may have also been helpful (220).

5.5.2

Demographics of sample:

Overall, there was an even distribution of male and female dentists, which reflects the pattern for the current UK workforce (223). CDPs were more likely to be female and to have been qualified for longer. Over half of those surveyed were working in the poorest parts of Birmingham, which can be expected to have highest levels of caries (16) and, referral rates for a dental GA (144-147). Less than 20% of responding practices employed a dental therapist or hygienist and the former were more likely to work in the CDS: these rates were higher compared to the national picture, where therapists and hygienists represent only around 10% of registered dental professionals (223). However, practices in the most deprived parts of Birmingham were least likely to employ PCDs, suggesting areas with the highest levels of disease were least well served by members of the dental team, that might be most appropriate to meet their needs (224).

5.5.3

Follow up procedures, reminders and managing poor attendance:

There are no conclusive associations between frequency of follow up visits and caries relapse in children following a dental GA (169, 179, 181, 187, 192), but on balance, intensive preventive procedures are indicated, given that children who are irregular attenders have been shown to have four times increased risk of an unplanned repeat GA (169). It was therefore important to explore current practice in this area, as well as measures used to support attendance and follow up patients that don't attend.

Overall, less than a fifth of dentists scheduled appointments to review children following the GA: this compares with 15% of parents in the baseline service evaluation (page 103), reporting that their child had an appointment booked to see their dentist after the GA. Clearly, the cohort of practitioners in this study are unlikely to be identical to the practices parents were referring to in the service evaluation but these findings do confirm low rates for follow-up after a GA. Of the 57% of dentists that followed children up (either by sending appointments or advising parents to contact the practice) after the GA, around 60% recommended reviews should be arranged within 3 months of the extractions (which supports the frequency of recalls required to deliver 'enhanced' prevention (50, 51, 55) and it was encouraging that for the majority, this was the main reason for the review appointment. However, this also means that at least 40% of this high-risk group were not receiving support.

Overall, 80% of practices (GDS and CDS) had general systems in place to recall patients in due course, which would include children that have had a GA, but again, this also suggests that 20% of this vulnerable group are not receiving any on-going support. Community dentists were more likely to schedule follow-up appointments

after the GA ($P = 0.006$), but those that didn't were less likely to subsequently recall patients ($P < 0.001$): respondents explained that review appointments were only arranged for children that were 'registered' CDS patients, which mostly referred to children with special care needs. However, patients referred to the Service by GDPs were discharged back to their family dentist, on the understanding that on-going reviews would be provided within GDS.

Most (92%) practices sent reminders, which was favourable compared to the 58% of parents reporting receipt of reminders in service evaluation B. Studies suggest poor attendance at follow up clinics after a GA, in both CDS and Hospital settings (175, 186, 190, 198), signifying a need for increased efforts to encourage attendance. However, only 1 respondent targeted reminders for high risk patients, suggesting any measures to encourage attendance were based on improving efficiency, rather than offering support to vulnerable families. There was some disparity in reminder protocols reported by CDPs, which was unexpected, given that all clinicians worked in the same Service: it later transpired that procedures varied within different localities.

A range of measures were employed to manage patients that failed to attend but overall, only 20% of practices sent a further appointment. Whilst recognising that practitioners cannot afford to lose time on failed visits, this also means that families that are least likely to book another appointment (on receipt of a 'Contact us' letter), might not be receiving the extra support they need. CDSs also have commitments to fulfil service contracts and improve efficiency but may be better placed to accommodate poor attenders. CDPs were more pro-active in pursuing failed appointments for high-risk children, instead of simply waiting for families to contact to

re-schedule. Several CDPs commented on following organisational policies and procedures on ‘Safeguarding children that were not brought’ to appointments, which involved contacting schools and liaising with other health and social care professionals.

5.5.4

Preventive support for high-risk children:

All practitioners reported that they gave preventive advice and most also applied fluoride varnish: for the latter, frequency of delivery was not explored but findings on timing of recall intervals suggest this was rarely four-times a year, as is recommended for children at highest risk (50). Only 15% of parents surveyed in the two-year post GA service evaluation B could recall their child having fluoride applied: recall bias might be a factor, but this might also suggest over-estimates of the level of activity reported by practitioners. Equally, there was huge disparity between the relatively high reported use of fissure sealants (77%), compared to less than 5% of children presenting with sealants, based on evidence (including clinical examinations) from the earlier service evaluations.

According to the 2013 UK CDHS, 27% of 8 year olds in England, were reported to have received ‘preventive treatment to teeth’ (144): only 7% of 8 year olds had evidence of sealants (204) and despite increasing use of fluoride varnish in the UK, rates of application overall, remain low (47, 204, 225). The comparatively high levels of preventive care reported in this survey might reflect efforts to target prevention to vulnerable children, which supports findings from some other studies, indicating children with caries are more likely to be offered preventive advice and treatment (139,

226). However, results from the service evaluations again suggest possible over-reporting by practitioners. Very few dentists reported prescribing a fluoride mouthwash, compared to high fluoride toothpaste, even though both are recommended for 'older' high-risk children (50). One respondent explained that "*it was easier to encourage patients to switch to a different toothpaste instead of expecting them to start using a mouthwash as well*".

Unlike some other studies, the questionnaire didn't attain adequate detail on the content of preventive advice provided, which in hindsight, would have been useful, given that the quality has been shown to vary (205, 221, 226, 227). It was interesting to discover that male dentists were more likely to delegate oral health counselling to nurses, which supports research suggesting female dentists were more likely to engage in prevention (227) and a comment made by a male practitioner in Threllfall *et al*.'s survey, "*It's the nurses that do that, not me*" (139). Several CDPs in our study suggested that therapists were "*better at giving advice*" and "*more up to date with current messages*". Employment of a hygienist has been shown to shift practice from being disease centred to health focused (228) and delegating preventive care to PCDs including appropriately trained dental nurses, could clearly also improve efficiency (107).

5.5.5

Barriers to delivering prevention:

Findings support previously reported challenges to promoting oral health in high-risk families, including poor cooperation and negative attitudes towards good oral health (8, 229). Children with least co-operation have been found to receive least preventive

treatments (195) and dentists are reportedly more inclined to offer advice to affluent and motivated parents (139).

Time factors and inadequate remuneration for delivering prevention appeared to be less important compared to some previous investigations (8, 139, 206, 220). In this study, CDPs were less likely to perceive time as a barrier, compared to GDPs, which probably reflects the role of the CDS, in which additional time is available to treat children that require more support. Dentists working in environments with less time pressures have been shown to be more willing to treat children, which is presumed to include preventive treatments, such as sealants (229). A recent review on the future of the oral workforce for England highlights need for appropriate financial support to encourage dentists to dedicate more time to children (223).

5.5.6

Views on interventions to prevent caries in high-risk children:

Overall, providing sealants as part of the GA encounter or recalling patients in secondary care and/ or CDS were more popular, than including caries prevention plans in discharge letters. The response towards all 3 interventions was more positive amongst high referrers, indicating any type of support was welcome by this group. Delivering sealants as part of the GA encounter was the most popular intervention, which supports views of parents from the baseline evaluation in 2012, which found that most of the parents wanting their child to have sealants, would prefer to have these carried out at the GA visit.

Other studies highlight inadequate communication and low levels of preventive input by GA providers (8, 167), calling for more shared responsibility between primary and secondary care sectors. A survey of dental GA providers in Yorkshire and Humber found over half failed to mention the need for further preventive care in discharge letters sent back to referring dentists (167).

5.5.7 Recommendations: shared care approach to preventing caries in high-risk children

Dental teams in the primary sector could be expected to be best placed to deliver preventive support throughout the GA journey: timely preventive interventions, tailored to meet the needs of high-risk children might mitigate the need for a dental GA in the first place and on-going support to prevent relapse (and potentially a repeat GA), after the procedure, is equally important. However, this in turn, relies on improving access to care and promoting attendance among high-risk families, which has been shown to be poor (175, 186, 198) as well as making full use of the skill mix offered by the whole dental team (223).

Clearly, closer partnerships between referring practitioners and GA providers are also required, to share responsibility and integrate care. To this end, care pathways for children needing a dental GA have been developed and describe the process that should be followed when children are referred for GA, which involves collaboration between Hospital, Community and General Dental services (142). These also help identify opportunities to provide treatment with sedation (or possibly even LA only) avoiding the need for a GA.

Most practitioners appear to recognise their responsibilities and duty of care (227) but would welcome practical support to deliver the level of activity necessary (8, 139, 206, 220). Changes in commissioning of paediatric dental care have been recommended, including introduction of remuneration systems that promote prevention in primary care and encourage dentists to dedicate more time and resources to treating children (223). A decade ago, the Steele Report signified the need to prioritise preventive activity in NHS GDS, recommending local initiatives and pilot schemes to reform and incentivise best practice in primary care (230).

Innovative arrangements to deliver prevention to susceptible groups need to be explored and evaluated and good practice shared (230). Within the West Midlands and Birmingham, there is scope for closer collaboration between GA providers (which includes Hospital and Community services) and GDS (231) and to this end, several recommendations can be made, based in part, on interventions that were proposed in the study questionnaire. These include:

1. <u>Highlighting the need for caries prevention in all GA correspondence, including referral forms and discharge letters</u>

This could be relatively simple to implement and the most practically feasible of the initiatives suggested. In 2016, there was a change in practice at the BDH, in that, a sentence (provided below) to highlight the need for on-going prevention, was included in all letters sent to referring practitioners, on discharging patients after their GA:

"*This child is **high caries risk** and we would recommend carrying out intensive preventive treatment and advice together with regular recalls in line with the DBOH toolkit*".

This was not as a direct consequence of the study findings but nevertheless, is a positive step towards improving support for high-risk children, and might help remind practitioners about their duty of care to provide preventive activity after the GA. This revised practice has not been evaluated but use of pop up electronic reminders and displaying flow-charts on 'best practice for prevention' in dental surgeries, have previously been shown to increase preventive activity (232).

Similarly, practitioners could be obliged to complete a checklist of conditions (relating to provision of preventive care), on GA referral forms, to confirm that appropriate oral health advice has been provided and preventive treatments carried out (or at least attempted) before making the referral. Information on follow up arrangements relating to continuing care after the GA could also be sought. The quality of orthodontic referrals have been shown to improve with the use of proformas, so similar techniques might promote preventive activity amongst GA referrers (233).

2. <u>Streamline GA care pathways with closer collaboration between Hospital, Community and General Dental Services</u>

Dentists responding to the survey welcomed the idea of patients being recalled to the BDH or within the CDS after the GA and feedback from parents (Service evaluation B) also suggests around half would be happy to attend reviews at the Hospital. On

reflection, changes to service contracts would be required to support any additional activity, which would not be feasible without appropriate funding. However, "student clinics" (both at the Hospital and outreach placements in the CDS) offer a possible source of on-going care.

A review of dental GA care pathways was recently undertaken (as part of a wider review of CDS) and emphasised a need to focus on prevention, as well as increase availability of sedation services (as an alternative to GA) within local CDS (231). Closer partnership and better communication between Hospital, Community and GDS, can help all services to work together to support families before, during and after the GA experience.

3. Delivering preventive interventions as part of the 'GA encounter'

Given that high-risk families have been shown to be poor attenders for routine care (175, 186, 198), any intervention that can be delivered as part of the GA encounter, warrants further consideration. At the present time, the GA assessment visit would appear to provide the most appropriate opportunity to intervene. The suggestion of placing sealants at this appointment, was clearly well received by survey respondents, which adds further incentive to continue to work on developing this proposal.

5.6

Conclusions:

According to self-reported practice, dentists in primary care in this study provide a range of caries preventive interventions for high-risk children, including fluoride varnish and fissure sealants. However, procedures to follow-up and review patients, after a dental GA, appear to be inadequate (especially in GDS), which could undermine any efforts to deliver preventive advice and treatments. Dentists would welcome more oral health input from GA providers. Given that patient centred barriers, such as compliance and parental motivation (including poor attendance) were common, initiatives that maximise the opportunity provided by the GA encounter in secondary care would seem most appropriate.

CHAPTER 6: A PILOT RANDOMISED CONTROLLED TRIAL TO EVALUATE PLACEMENT OF SEALANTS DURING THE GA ASSESSMENT, IN CHILDREN REQUIRING CARIES RELATED DENTAL EXTRACTIONS UNDER A GENERAL ANAESTHETIC

6.1

Background: Sealant placement as part of the pre-GA assessment appointment

In Spring 2014, Birmingham Dental Hospital introduced a separate pre-GA assessment appointment prior to the GA extractions visit. This offered an ideal opportunity to carry out sealants (as part of the GA encounter), overcoming many of the problems associated with placing sealants on the same visit as the GA. Children are less likely to be hungry, tired or anxious, as they would not be scheduled to have extractions on the same day. Resin sealants (involving etch/ water spray) could be placed with increased confidence as swallowing water would no longer be hazardous and parents are less likely to be focused on their child's GA, and thus potentially more receptive to oral health counselling.

It was therefore possible to pilot an intervention based on placement of sealants during the GA assessment appointment: this would serve to assess the feasibility of the procedure and inform the planning of a definitive randomised controlled trial (RCT), to investigate the effectiveness of providing sealants in this setting.

6.2

Aim and objectives:

Aim:

To undertake a pilot RCT to compare sealant versus no sealant, placed on sound permanent molars, during the pre-GA assessment visit, in children scheduled for caries related dental extractions under a chair general anaesthetic.

Objectives:

To evaluate,

1. Recruitment and retention of participants.
2. Feasibility and acceptability of placing sealants in this setting.
3. Sealant retention rates during the two-year study period.
4. Two-year incidence of caries in permanent molars that were sound and suitable for fissure sealants at the time of the pre-GA assessment appointment.
5. Oral health related Quality of Life (OHRQoL) two years following caries related extractions under GA.
6. Oral health support (including preventive advice and treatment) provided by referring practitioners, within the 2 years following the dental GA.
7. Differences in caries levels, OHRQoL and receipt of oral health support in primary care, between the sealant and control groups.

6.3

Methods:

A protocol was developed to undertake a pilot RCT on delivering sealants as part of the GA assessment visit (Appendix 9).

6.3.1

Ethics approval and registrations:

- NHS research ethics approval was obtained (through the integrated research application system IRAS) from South Birmingham NRES Committee: West Midlands in June 2014.

REC reference: 14/WM/1007, IRAS project ID: 148667 (Appendix 10)

Approval for amendments to:

- Include an OHRQoL assessment at the 2-year follow-up

  and

- Reimburse travel expenses for participants (£40 shopping voucher) on attending the 24 month review,

were obtained on 28th July 2016 (Amendment number: SA#01)

The study was sponsored by the University of Birmingham.

- Local NHS permissions (Research and Development approval) were obtained from the National Institute of Health Research (NIHR) Clinical Research Network: West Midlands Consortium and BCHC NHS Trust.
- The study was also registered on a publicly accessible database (ClinicalTrials.gov), registration number NCT02443896.

6.3.2

Design:

A two-arm two-year non-blinded pilot RCT.

6.3.3

Setting and subjects:

The target group were children (age 5 to 15 years) referred to the BDH for extraction of carious teeth under a chair GA and who had at least one caries free ('sound and sealable') permanent molar at the GA assessment appointment.

Recruitment of families (children and parents/ guardians) and application of sealants were carried out at the BDH but some families were subsequently seen at a Community Dental Clinic (Richmond Primary Care Centre, Stechford) for the follow up/ reviews.

6.3.4

Selection criteria:

Children were eligible to be recruited to the study if they fulfilled all the inclusion criteria and none of the exclusion criteria.

These were as follows:

Inclusion criteria

- Age 5 to 15 years
- Birmingham residents (based on postcode)
- Co-operative to a clinical dental examination

- Scheduled for at least one caries related dental extraction under a chair GA at the BDH
- Have at least one permanent molar that is caries free and suitable for fissure sealing
- Accompanied by an adult that has legal capacity to give informed consent to take part in the pilot study

Exclusion criteria

Patients who at the pre-GA assessment visit presented with:

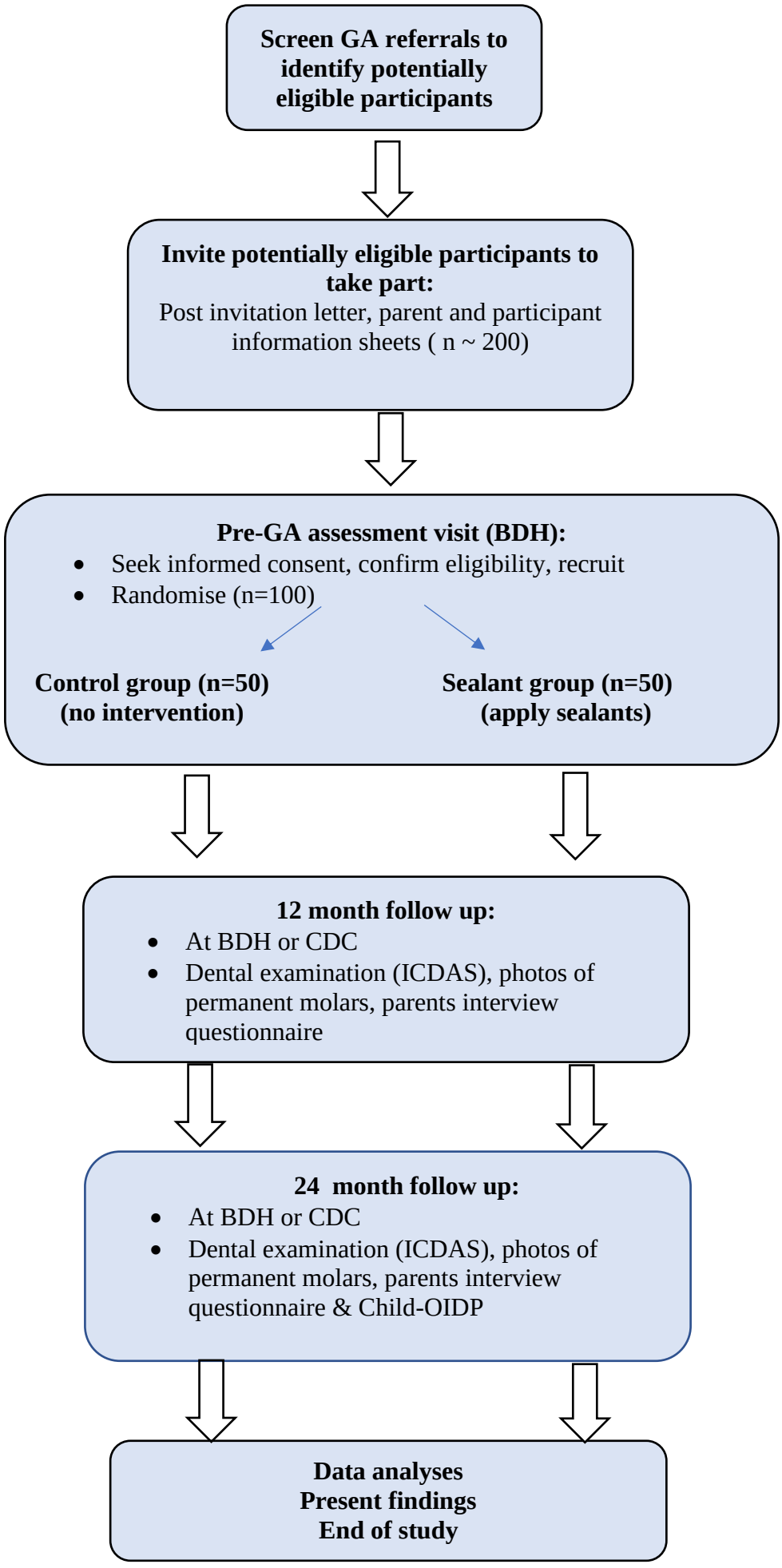
- Signs of a systemic illness (e.g. coughs, colds, chicken pox) that might preclude placement of sealants
- Oral symptoms (e.g. pain, swelling) that would preclude sealant placement
- Parents unable to confirm (with a reasonable degree of confidence) that they would be contactable and able to attend for review during the 2 years duration of the study

6.3.5

Study procedures - pilot RCT:

The pilot RCT design and procedures are illustrated in Figure 5 (page 189).

Figure 5: Pilot RCT procedures flow diagram (page 189)



6.3.5.1

***Triage referrals*:**

Referrals were triaged by the principal investigator (AR), to identify children that were potentially eligible for inclusion, based on: age, postcode and reason for extractions. Invitation letters (Appendix 11) and parent/ child information sheets (Appendix 12 and 13) were sent separately to documents relating to the GA visits and posted a few weeks in advance of the assessment appointment, to give parents time to reflect on taking part. All study related administration was completed by AR.

6.3.5.2

***Recruitment - pre-GA assessment visits*:**

6.3.5.2.1

Eligibility and consent*:*

Patients underwent the routine pre-GA assessment (including dental examination and if justified, radiographs) before discussing the study. Most GA assessments were carried out by a single clinician (SK), although others were involved on ad hoc sessions. Parents of children considered to be eligible, were asked if they would be agreeable to see AR to discuss taking part.

If they agreed, this discussion was carried out within the Paediatric Department. If appropriate, children were also included in the conversation and a further information leaflet provided if the one sent in the post had been lost. If the parent(s) and child agreed to take part, informed written consent was obtained and a copy of the signed consent form (Appendix 14) given to parents.

A basic dental examination was then carried out, to establish if the child had at least one sound permanent molar.

6.3.5.2.2

Clinical examination:

As part of the study, a more detailed baseline clinical dental examination was undertaken by a single examiner (AR), which involved visual and tactile examination of all teeth. A 3 in 1 syringe was used to wash and dry teeth and a ball ended (blunt tip) probe used to remove soft debris and check for presence of sealants. The presence or absence of caries and caries related treatment (including evidence of sealants) was recorded using the ICDAS (210, 214) (Tables 14 and 15 – ICDAS II restorative and caries codes – page 115 and 116). Radiographs were not taken for study purposes but any available (as part of the GA assessment) were referred to.

Categories of caries reported on, were:

- Any caries - ICDAS codes 1-6
- Enamel caries - ICDAS codes 1, 2, 3
- Dentine caries - ICDAS codes 4, 5, 6

- Early caries - ICDAS codes 1, 2
- Established caries - ICDAS codes 3, 4
- Severe caries - ICDAS codes 5, 6

All demographic and clinical data (and other relevant baseline information, such as whether the patient was registered with a dentist*)* were recorded on case report form 3a

(Appendix 15). A unique PIN was allocated to each participant and, subsequently used for data recording and analyses.

6.3.5.2.3

Randomisation and allocation concealment:

A 1:1 computer generated online randomisation programme ('sealedenvelope.com') utilising block randomisation was used to randomise participants to the Control group (no intervention) or Sealant group (sealants applied), with 50 children in each group. Allocation concealment was applied in that randomisation was carried out immediately prior to providing sealants for children in the intervention group.

6.3.5.3.4

Sealant group intervention:

Where possible, all caries free, sound and fully (or adequately) erupted permanent molars were sealed. Occlusal fissures and where appropriate, buccal pits (on lowers) and palatal pits/ fissures (on uppers) were also sealed.

Where patient compliance (and moisture control) were adequate, a resin-based sealant (Helio-seal F) was used as the first-choice material.

Where patient compliance was compromised (and moisture control more challenging as a result), a glass ionomer (GI) sealant (Fuji triage) was placed.

The same products (resin: Helio-seal F and GI: Fuji triage) were used throughout the study to minimise variation related to different materials.

All sealants were applied by a single operator (AR) and in accordance with the manufacturer's instructions and recommended techniques (Table 28).

Table 28: Techniques used for sealant placement in pilot RCT (51, 94, 234)

Resin sealants	**Glass ionomer sealants**
• Obvious debris & gross plaque deposits removed by washing tooth using 3 in 1 syringe • Moisture control achieved using combination of saliva ejectors, cotton wool rolls and/ or dry guards • Surfaces to be sealed, etched for 30 seconds (33-37% phosphoric acid gel) • Etch washed away (minimum 20 seconds) using high speed aspirator close to tooth • Surfaces to be sealed dried using 3 in 1 syringe until surface appeared frosty – avoid moisture contamination • Sealant applied using a dycal applicator or blunt probe (metal instrument preferred over brush to avoid air bubbles) • Light cured for 30-40 seconds • Integrity and retention assessed with probe & if defective, corrected	• Obvious debris & gross plaque deposits removed by washing tooth using 3 in 1 syringe • Small amount of GI sealant placed on tip of 'gloved' index finger & small amount of petroleum jelly (Vaseline) on tip of middle finger • If possible, surfaces to be sealed wiped dry with cotton wool roll • Sealant applied to surface to be sealed by firmly applying fingertip with GI on to tooth surface. Held in place for approximately 2 minutes • Swiftly covered with Vaseline (on middle finger) to prevent moisture contamination • Light cured for 30-40 seconds (dual cure) • Gross excess removed, where possible, with hand instruments

The time required to apply sealants was recorded.

Children were asked to report on the acceptability of the treatment by selecting a face from a 'Facial Image Scale' (FIS) (Appendix 16), before and after sealants were placed.

Data on sealants applied (teeth/ surfaces sealed, material used, time required) were recorded on the Baseline CRF 3a (Appendix 15), as too were the FIS scores selected by children.

6.3.5.3.5

Control group procedures:

Children in the control group were subject to the current standard of preventive care in the secondary and primary sector. Sealants were not applied as part of the study.

6.3.5.3.6

Management of carious teeth not earmarked for extraction:

For both groups (sealant and control), carious teeth that were not earmarked for extraction were managed as per the routine standard of care: if appropriate, parents were offered treatment on under-graduate student clinics and/ or patients were referred to their dental practitioner for completion of any outstanding restorative treatment.

6.3.5.3.7

Refusals and non-eligibility:

Records were kept on the number of refusals (including reasons) and on the numbers that consented but failed to fulfil the eligibility criteria (Appendix 17).

6.3.5.4

Follow up and review:

Participants were reviewed at 12 months and 24 months after randomisation.

Follow ups were mostly carried out at the BDH, but a small number of participants (at the 12-month stage) were seen at a Community Dental Clinic (Richmond Primary Care Centre, Stechford, Birmingham) instead. Appointments were posted at least 2 weeks in advance and where possible, followed up by a telephone call (by AR) to remind parents of the appointment. A further appointment was sent if the first was failed (followed, where possible, by another phone call reminder). If the second 12-month appointment was also missed, no further contact was made until the scheduled 24-month review. However, if a second 24-month appointment was missed, parents were, if possible, called (by AR), to establish why. Responses were recorded on a Withdrawals form (Appendix 18).

Shopping vouchers (value £40) were provided to reimburse travel expenses for parents attending the 24-month review. This incentive was introduced shortly before commencing the 24- month follow ups (after obtaining appropriate Ethics approval for a substantial amendment).

All study related administration and phone calls were completed by AR.

6.3.5.4.1

Clinical Examination at Follow up/ Review Appointments - 12 and 24 Months:

The procedure for the clinical examination was identical to that used at baseline and completed by the same (AR) single examiner: caries status was assessed using the ICDAS and radiographs only taken if clinically justified (but not for study purposes). Retention of sealants was reported as fully intact, partially intact or lost.

All data were recorded on follow-up case report forms 3b (Appendix 19).

6.3.5.4.2

Clinical photographs - 12 and 24 Months:

Where possible, clinical photographs were taken of all permanent molars, so these could be assessed by a calibrated ICDAS examiner, to help substantiate reported clinical findings: this aspect will be discussed in more detail when covering 'Outcome assessor blinding'. Photographs were taken within the Clinical Illustration Department at the BDH: Trust protocols on consent for clinical photography were followed.

6.3.5.4.3

Structured interview questionnaires - 12 and 24 Months:

Structured interview questionnaires (12 month - Appendix 20 and 24 month - Appendix 21) were used to collect information on parents' experiences of dental services for their children, following the GA, along with measures they might find helpful to look after their teeth. Where appropriate, children were also encouraged to be involved. Questionnaires were administered by AR.

6.3.5.4.4

Oral Health Related Quality of Life - 24 Months:

At the 24-month review, OHRQoL was assessed using the Child-Oral Impacts on Daily Performances (Child-OIDP) scale (235, 236), along with separate questions relating to specified oral symptoms. The OHRQoL questionnaire (Appendix 22) was administered by AR.

6.3.5.4.5

Outcome assessor blinding and calibration to assess reliability:

Given the nature of the intervention (presence of sealants), blinding was clearly difficult to achieve. Furthermore, the follow-up examiner (AR) completed all the study administration (including contacting parents to schedule recalls) and had also delivered the intervention, so was more likely to know which group participants were in.

Therefore, in order to assess reliability of reported findings at follow-up, clinical photos were taken to record the status of permanent molars. A trained and calibrated ICDAS examiner (Kate Cullotty, KC) was asked to report on a 1 in 10 sample of photos and the observations compared with clinical data collected by AR. AR also reported on the same set of photographs, so a comparison of these scores with data from earlier clinical examinations, also served to provide some measure of intra-examiner reproducibility (for AR).

6.3.5.4.6

Dental treatment and prevention activity at follow-up appointments:

12-month review/ follow up visit

There was an understanding that children in both groups would be subject to the current standard of preventive care in the primary sector.

Preventive interventions (i.e. sealants or topical fluoride) were not provided at the 12-month follow-up appointment: this means that, for the sealant group, sealants identified as lost or defective were not replaced.

However, evidence of caries and/ or symptoms were managed appropriately. Where necessary, dental treatment was offered (on undergraduate student clinics) and/ or patients were referred to their dental practitioner for this to be carried out. Where a child was registered with a dentist, a letter was sent to dental practitioners to advise of any treatment that had been undertaken (Appendix 23) and/ or to request completion of outstanding treatment (Appendix 24). This included a recommendation for radiographs (where justified) if these had not been taken as part of the review.

24-month review/ follow up visit

At this (final) study visit,

- Preventive advice and if appropriate, preventive interventions (i.e. sealants and/ or topical fluoride) were offered to all participants (sealant and control group). This included sealants on teeth that may have erupted since the baseline examination.
- In the sealant group, lost or defective sealants were, if appropriate, replaced.

Parents could opt to attend under-graduate student clinics for these interventions, or if preferred, a letter was sent to their dental practitioner to request the necessary preventive care.

Any outstanding needs for dental treatment were managed, as per the 12-month review visit, described earlier.

6.3.5.5

Outcome measures (and their assessment):

1. Recruitment and drop-out rates

   Based on,

   a. Exclusions relating to not meeting the inclusion criteria or declining to participate
   b. Subsequent withdrawals

   Where possible, withdrawals were followed up to determine the reason(s).

2. Feasibility and acceptability of intervention

   Children's compliance and acceptability for sealant application was assessed in 3 ways:

   a. By recording the type of sealant (material and technique) used - the GI gloved finger technique signified poor co-operation.
   b. By recording the time required to place sealants (also reported as the 'average time for four sealants per child')
   c. By comparing FIS scores selected by children, before and after sealant placement.

3. Sealant retention status (sealant group)

   By reporting on the proportion of sealants (placed as part of the study) that were fully intact, partially intact or lost at the 12 and 24 month reviews.

4. Caries incidence (after 1 year and 2 years) in permanent molars that were identified as sound and sealable at the baseline examination.

For both intervention (sealant) and control groups, this includes:

a. The proportion of children with experience of caries into dentine in at least one permanent molar.
b. The proportion of children with untreated caries into dentine in at least one permanent molar.

Note: the presence or absence of caries and caries related treatment (including evidence of sealants), were recorded for all surfaces of all teeth (primary and permanent) using the ICDAS. However, primary outcome measures were restricted to permanent molars that were identified as sound and sealable at the baseline examination.

5. OHRQoL two years following caries related extractions under GA, as based on the Child-OIDP scores (and specified oral symptoms) selected by children.

6. Preventive dental care provided by primary care dental practitioners 'outside' the study, during the 2 years following the GA extractions.

   Assessed by,

   a. Structured interview questionnaire to record parents' experience of preventive advice and treatment received, following the GA extractions
   b. Recording sealants at the follow up clinical examinations, that were not present at baseline or carried out as part of the pilot study.

Parents opinions on measures they might find helpful to take better care of their children's teeth were also assessed (using the questionnaire).

6.3.5.6

Sample size:

The target sample size for the pilot study was 100 participants: 50 in the intervention 'sealant' group and 50 in the 'control' group. This was a feasibility study and thus, a formal power calculation was not required, but it was anticipated that 100 participants would provide robust data on recruitment and retention, and variations in outcome measures.

6.3.5.7

***Statistical analyses*:**

Data entry was completed by AR. Summary statistics were calculated, using *STATA IC Version 12, (Stata Corp., College Station, USA)* statistical software.

Statistical analyses were performed to compare outcomes for the control and intervention groups (including reporting of P values) but it is recognised that this was a pilot and feasibility study and thus any reported differences should be interpreted with caution (237). Intention to treat (ITT) analyses were performed for all participants in the sealant group, regardless of whether sealants were placed. Two sample t tests were used to compare continuous variables and Pearson's chi squared for categorical data. Intra and inter-examiner reliability of caries assessment were assessed using Cohen's kappa.

6.3.5.8

***Resources (implementation and research costs)*:**

No external funding was sourced for this study. Costs involved with implementing the intervention (sealants) were contained within normal NHS service delivery. Shopping

vouchers to reimburse travel expenses for parents attending the 24-month review and administration costs were funded through a University of Birmingham research budget.

6.4

Pilot RCT Results:

6.4.1

Participants' flow through the pilot RCT (CONSORT):

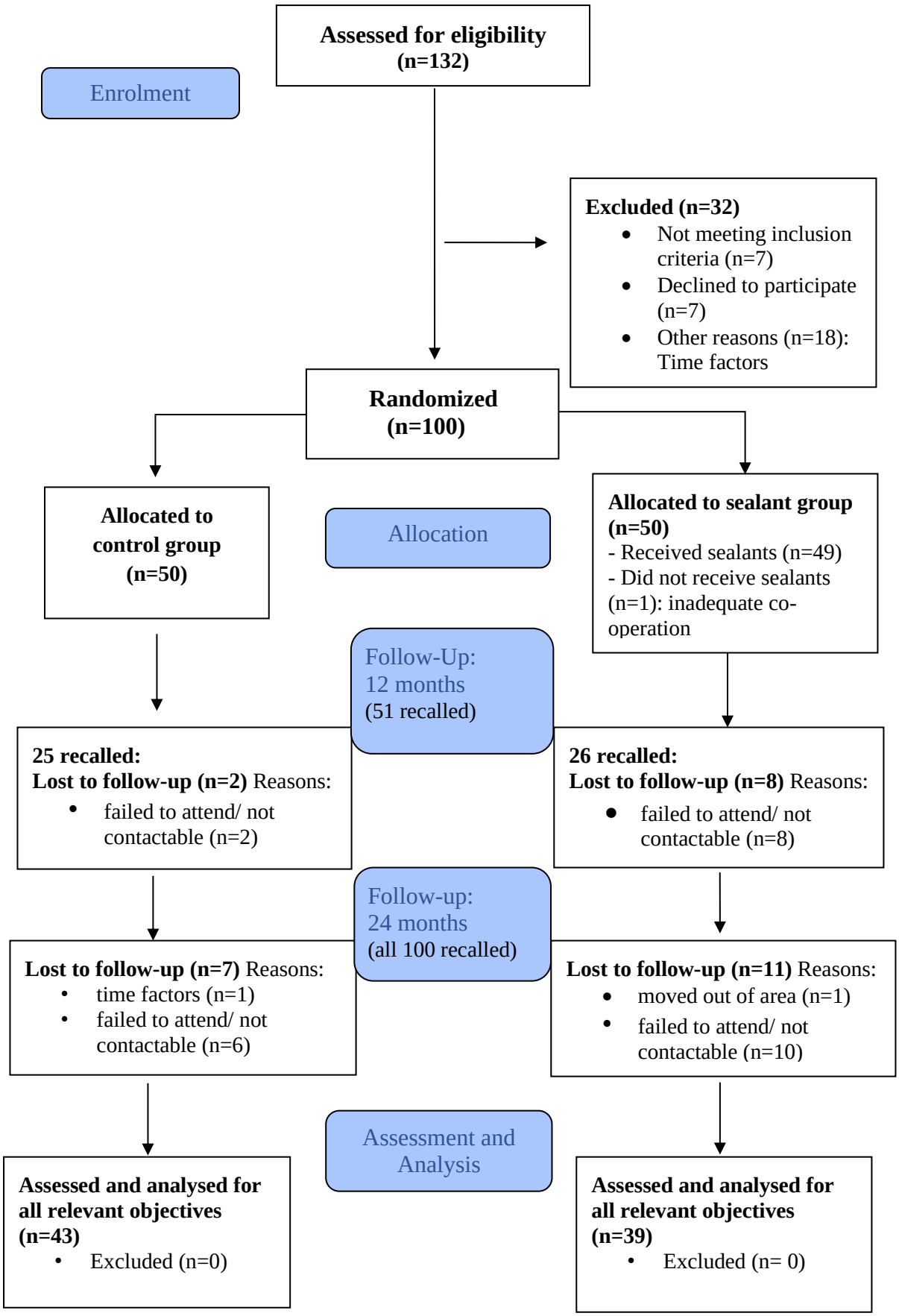
Participants' flow through the pilot RCT, in line with CONSORT guidelines (237), is illustrated in Figure 6 (page 203).

Recruitment was carried out August 2014 - March 2015.

12 month reviews were completed August 2015 - December 2015. Only 51participants could be recalled at 12 months (please refer to section 6.4.5 and Appendix 25).

24 month reviews were completed August 2016 – May 2017.

Figure 6: Participants' flow through the pilot RCT (CONSORT)



6.4.2

Participants' demographic characteristics and dental attendance patterns at baseline:

Table 29: Pilot RCT - Demographic characteristics and dental attendance patterns at baseline – whole group and comparison of control versus sealant

	Whole group (n=100)	**Control (n=50)**	**Sealant (n=50)**
Baseline characteristic			
Age, years:			
mean (SD)	7.7 (1.7)	7.5 (1.7)	7.8 (1.6)
range	5 -14	6 – 14	5 – 14
% (n) for different ages:			
5	1 (1)	0	2 (1)
6	23 (23)	32 (16)	14 (7)
7	31 (31)	28 (14)	34 (17)
8	22 (22)	20 (10)	24 (12)
9	12 (12)	10 (5)	14 (7)
10	5 (5)	4 (2)	6 (3)
11	2 (2)	2 (1)	2 (1)
12	2 (2)	2 (1)	2 (1)
14	2 (2)	2 (1)	2 (1)
	% (n)	**% (n)**	**% (n)**
Sex:			
Male	56 (56)	52 (26)	60 (30)
Female	44 (44)	48 (24)	40 (20)
Ethnicity broad:			
White	30 (30)	22 (11)	38 (19)
Asian	45 (45)	52 (26)	38 (19)
Black	14 (14)	14 (7)	14 (7)
Other	11 (11)	12 (6)	10 (5)
Ethnicity specific:			

White British	28 (28)	22 (11)	34 (17)
White Other	2 (2)	0	4 (2)
White British Caribbean	5 (5)	6 (3)	4 (2)
Other Mixed	1 (1)	2 (1)	0
Asian British Indian	5 (5)	8 (4)	2 (1)
Asian British Pakistani	36 (36)	38 (19)	34 (17)
Asian British Bangladeshi	1 (1)	2 (1)	0
Other Asian	3 (3)	4 (2)	2 (1)
Black British Caribbean	7 (7)	8 (4)	6 (3)
Black British African	7 (7)	6 (3)	8 (4)
Chinese	1 (1)	2 (1)	0
Other	4 (4)	2 (1)	6 (3)
Index of multiple deprivation (IMD) Decile:			
1 – poorest	60 (60)	64 (32)	56 (28)
2	15 (15)	10 (5)	20 (10)
3	10 (10)	10 (5)	10 (5)
4	2 (2)	2 (1)	2 (1)
5	5 (5)	6 (3)	4 (2)
6	3 (3)	4 (2)	2 (1)
7	2 (2)	2 (1)	2 (1)
8	1 (1)	0	2 (1)
9	2 (2)	2 (1)	2 (1)
10 – richest	0	0	0
IMD score: mean (SD)	5168.1 (6250.0)	5150 (6050)	5187 (6505)
Registered with a dentist:			
Yes	100 (100)	100 (50)	100 (50)
No	0	0	0
Not sure	0	0	0
Type of dentist:			
GDP	95 (95)	94 (47)	96 (48)
CDS	5 (5)	6 (3)	4 (2)
Referral source:			
GDP	87 (87)	86 (43)	88 (44)
CDS	13 (13)	14 (7)	12 (6)
Appointment booked with referring dentist after GA:			

Yes No Not sure	3 (3) 91 (91) 6 (6)	2 (1) 90 (45) 8 (4)	4 (2) 92 (46) 4 (2)
Prevalence previous dental GA: Yes No	 12 (12) 88 (88)	 10 (5) 90 (45)	 14 (7) 86 (43)

6.4.2.1

Whole group (Table 29):

The average age was 7.7 years and the range (5 – 14 years), reflects the study eligibility criteria, in that children under 5 were excluded. Most participants were 6 to 8 years old, with a comparable number of boys (56%) and girls (44%).

Asian children (mostly Pakistani) were, as a collective ethnic group, the most widely represented (45%), followed by White children (mostly British), who accounted for almost one-third (30%). Sixty percent of participants were resident in the poorest areas of Birmingham, and none belonged to the richest 10% of the local population.

All children were registered with a dentist, the vast majority (95%) with a GDP and the remainder with a CDP. All GA referrals had been made through primary dental care, mostly from GDP. However, the number of referrals sent through the CDS (n=13) were higher than would be expected from the numbers that were apparently registered with a CDP (n=5). Most children (91%) had no follow-up appointment booked to see their dentist after the GA and 12% had previous experience of a caries related dental GA.

6.4.2.2

Control versus Sealant group (Table 29):

In most respects, the control and sealant groups were very similar. The mean age was 7.5 and 7.8 years respectively and there was again, a comparable distribution of boys and girls in both groups. Levels of deprivation were also similar and although Asian children accounted for a higher proportion of the control group, these differences were not statistically significant. Dental attendance behaviours before the GA and referral source were similar for both groups.

6.4.2.3

Follow-up at 24 months versus no follow-up at 24 months:

Table 30: Pilot RCT – Comparison of demographic characteristics and dental attendance patterns at baseline - follow up versus no follow up at 24 months

	Followed up (n=82)	**Not followed up (n=18)**	**P-value**
Baseline characteristic			
Age, years:			
mean (SD)	7.6 (1.6)	7.8 (1.9)	0.67[2]
range	6 – 14	5 – 14	
% (n) for different ages			
5	1 (1)	0	0.13[1]
6	24 (20)	17 (3)	
7	28 (23)	44 (8)	
8	26 (21)	6 (1)	
9	9 (7)	28 (5)	
10	6 (5)	0	
11	2 (2)	0	
12	2 (2)	0	
14	1 (1)	6 (1)	
	% (n)	**% (n)**	

Sex:			
Male	51 (42)	78 (14)	0.04[1]
Female	49 (40)	22 (4)	
Ethnicity broad:			
White	27 (22)	44 (8)	0.045[1]
Asian	51 (42)	17 (3)	
Black	13 (11)	17 (3)	
Other	9 (7)	22 (4)	
Ethnicity specific:			
White British	26 (21)	39 (7)	0.36[1]
White Other	1 (1)	6 (1)	
White British Caribbean	4 (3)	11 (2)	
Other Mixed	1 (1)	0	
Asian British Indian	6 (5)	0	
Asian British Pakistani	40 (33)	17 (3)	
Asian British Bangladeshi	1 (1)	0	
Other Asian	4 (3)	0	
Black British Caribbean	7 (6)	6 (1)	
Black British African	6 (5)	11 (2)	
Chinese	1 (1)	0	
Other	2 (2)	11 (2)	
Index of multiple deprivation (IMD) Decile:			
1 – poorest	62 (51)	50 (9)	0.32[1]
2	12 (10)	28 (5)	
3	7 (6)	22 (4)	
4	2 (2)	0	
5	6 (5)	0	
6	4 (3)	0	
7	2 (2)	0	
8	1 (1)	0	
9	2 (2)	0	
10 - richest	0	0	
IMD score: mean (SD)	5443 (6742)	3917 (2976)	0.35[2]
Registered with a dentist:			
Yes	100 (82)	100 (18)	-
No	0	0	
Not sure	0	0	

Type of dentist:			
GDP	95 (78)	94 (17)	0.90[1]
CDS	5 (4)	6 (1)	
Referral source:			
GDP	88 (72)	83 (15)	0.61[1]
CDS	12 (10)	17 (3)	
Appointment booked with referring dentist after GA:			
Yes	4 (3)	0	0.71[1]
No	90 (74)	94 (17)	
Not sure	6 (5)	6 (1)	
Prevalence previous dental GA:			
Yes	12 (10)	11 (2)	0.90[1]
No	88 (72)	89 (16)	

Statistical tests:

1 - Pearson's chi squared

2 - Two sample t tests

Baseline characteristics for children that were lost to follow-up, compared with those that attended at 24-months, were again, mostly similar and are shown in Table 30. However, significant differences were apparent with respect to sex and ethnicity, in that more boys (78%, n=14) were lost to follow up (P = 0.04), and Asian children (51%, n=42) were better represented in the group that returned (P = 0.045). Also, 62% of children (n=51) in the group followed up fell within the poorest decile compared to only half of those that failed to return (n=9) but this difference was not statistically significant.

6.4.3

Baseline caries prevalence (and evidence of sealants):

Table 31

Pilot RCT - Caries prevalence at baseline (and evidence of sealants) – whole group

Baseline caries prevalence (and evidence of sealants)	
	Whole group (n=100)
Carious teeth scheduled for XGA: mean number (SD) range	 3.8 (2.3) 1 - 10
***Children with carious permanent teeth scheduled for XGA*:** % (n)	 5 (5)
Caries experience permanent teeth:	
Children with dentine caries experience in a permanent tooth:* (D $_{4\text{-}6}$MF>0)** % (n) ***DMF(T): mean (SD)	 6 (6) 0.2 (0.7)
Caries experience permanent molars:	
Children with dentine caries experience in at least one permanent molar, **(D $_{4\text{-}6}$MF>0)** % (n) ***Children with dentine caries experience in a first permanent molar,*** % (n) ***Children with dentine caries experience in a second permanent molar,*** % (n)	 6 (6) 6 (6) 2 (2)
Untreated dentine caries permanent molars:	
Children with untreated dentine caries in at least one permanent molar,	

(D_{4-6}>0) % (n) ***Children with untreated dentine caries in a first permanent molar,*** % (n) ***Children with untreated dentine caries in a second permanent molar,*** % (n)	5 (5) 5 (5) 2 (2)
Children with at least one permanent molar, missing due to caries, % (n)	1 (1)
Sound permanent molars:	
'Sound' permanent molars (first & second) per child, 'Sound' = all visible surfaces ICDAS 00: mean (SD) ***'Sound' first permanent molars per child:*** mean (SD)	3.8 (0.7) 3.7 (0.8)
Children with at least one fissure sealed permanent molar: % (n)	0

Table 32
Pilot RCT - prevalence of sound first permanent molars at baseline, in different age groups

	Age (years)		
	5 (n=1 child)	**6-8 (n=76 children)**	**9 -15 (n=23 children)**
Children with four 'sound' first permanent molars % (n)	0	88.2 (67)	60.9 (14)

Radiographs, taken as part of the GA assessment, were available for a fifth (21%) of children at baseline. Table 31 describes caries prevalence at baseline for the whole group.

The mean number of teeth scheduled for extraction in each child, was 3.8, (range 1 to 10): these were mostly primary teeth, but 5 children had caries related permanent tooth extractions. Six percent (n=6) had experience of dentine caries in a permanent tooth: all experience of caries in permanent teeth was confined to permanent molars. Five children presented with untreated dentine caries in a permanent molar: this mostly involved first permanent molars (FPMs), but second permanent molars were also affected in 2 cases.

The mean number of sound permanent molars (ICDAS codes of 00 for all surfaces) in each child was 3.8 and given the average age of the sample at baseline, it was not surprising that the majority of these were FPMs. Based on the inclusion criteria, all participants had at least one caries free permanent molar, but Table 32 shows that 6-8 year olds were most likely to have four sound FPMs. Notably, no children at baseline had evidence of sealants.

Table 33

Pilot RCT - Caries prevalence at baseline (and evidence of sealants) – control versus sealant group

Baseline caries prevalence (and evidence of sealants)		
	Control (n=50)	**Sealant (n=50)**
Carious teeth scheduled for XGA: mean number (SD) range	 4.1 (2.4) 1 - 10	 3.6 (2.3) 1 - 9

Children with carious permanent teeth scheduled for XGA: % (n)	4 (2)	6 (3)
Caries experience permanent teeth:		
Children with dentine caries experience in a permanent tooth: (D $_{4\text{-}6}$MF>0) % (n) ***DMF(T):*** mean (SD)	6 (3) 0.2 (0.8)	6 (3) 0.1 (0.7)
Caries experience permanent molars		
Children with dentine caries experience in at least one permanent molar, **(D $_{4\text{-}6}$MF>0)** % (n) ***Children with dentine caries experience in a first permanent molar,*** % (n) ***Children with dentine caries experience in a second permanent molar,*** % (n)	6 (3) 6 (3) 2 (1)	6 (3) 6 (3) 2 (1)
Untreated dentine caries permanent molars:		
Children with untreated dentine caries in at least one permanent molar,* (D $_{4\text{-}6}$>0)** % (n) ***Children with untreated dentine caries in a first permanent molar, % (n) ***Children with untreated dentine caries in a second permanent molar,*** % (n)	4 (2) 4 (2) 2 (1)	6 (3) 6 (3) 2 (1)

Children with at least one permanent molar, missing due to caries, % (n)	2 (1)	0
Sound permanent molars:		
'Sound' permanent molars per child, ***'Sound' = all visible surfaces ICDAS 00*** mean (SD) ***Sound first permanent molars per child:*** mean (SD)	3.7 (0.7) 3.7 (0.8)	3.8 (0.8) 3.6 (0.9)
Children with at least one fissure sealed permanent molar: % (n)	0	0

Table 34

Pilot RCT - Caries prevalence at baseline (and evidence of sealants) – follow up versus no follow up at 24 months

	Followed up (n=82)	**Not followed up (n=18)**	**P-value**
Carious teeth scheduled for XGA: mean number (SD) range	3.8 (2.4) 1 - 10	3.9 (1.9) 1 - 7	0.82[2]
Children with carious permanent teeth scheduled for XGA: % (n)	4 (3)	11 (2)	0.19[1]
Caries experience permanent teeth:			
Children with dentine caries experience in a permanent tooth: ($D_{4-6}MF>0$) % (n)	4 (3)	17 (3)	0.035[1]

DMF(T): mean (SD)	0.1 (0.6)	0.4 (1.2)	0.063[2]
Caries experience permanent molars:			
Children with dentine caries experience in at least one permanent molar, ***(D $_{4-6}$MF>0)*** % (n)	4 (3)	17 (3)	0.035[1]
Children with dentine caries experience in a first permanent molar, % (n)	4 (3)	17 (3)	0.035[1]
Children with dentine caries experience in a second permanent molar, % (n)	1 (1)	6 (1)	0.23[1]
Untreated dentine caries permanent molars:			
Children with untreated dentine caries in at least one permanent molar, **(D $_{4-6}$>0)** % (n)	4 (3)	11 (2)	0.19[1]
Children with untreated dentine caries in a first permanent molar, % (n)	4 (3)	11 (2)	0.19[1]
Children with untreated dentine caries in a second permanent molar, % (n)	1 (1)	6 (1)	0.23[1]
Children with at least one permanent molar, missing due to caries: % (n)	0	6 (1)	0.032[1]
Sound permanent molars:			

'Sound' permanent molars per child, ***'Sound' = all visible surfaces ICDAS 00*** mean (SD) ***'Sound' first permanent molars per child:*** mean (SD)	3.8 (0.7) 3.7 (0.7)	3.6 (0.8) 3.5 (1.0)	0.38[2] 0.36[2]
Children with at least one fissure sealed permanent molar: % (n)	0	0	-

Statistical tests:

1 - Pearson's chi squared

2 - Two sample t tests

There were no differences in caries prevalence between the control and sealant groups at baseline (Table 33). However, on comparing the groups that did and did not return for the 24 month follow up (Table 34), the group lost to follow up were more likely to have experience of caries in dentine in permanent molars.

6.4.4

Sealants applied at baseline:

Table 35 – Pilot RCT – Sealants applied at baseline

Sealants applied at baseline:
Children: • 50 children randomised to sealant group • 49 received sealants • 1 refused (poor co-operation)
Number of teeth & surfaces sealed: • 181 molars

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- 335 surfaces:
  - 54% (181) occlusal surfaces
  - 46% (154) buccal &/ or palatal surfaces

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Molars per child:

- Mean (SD) – 3.6 (1.0)
- Range - 1 to 7
- Median – 4.0

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Surfaces per child:

- Mean (SD) – 6.7 (2.3)
- Range - 1 to 14
- Median – 8.0

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Sealant material:

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Resin:

- 44 children
- 163 molars
- 316 surfaces (163 occlusal)

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Glass ionomer:

- 5 children
- 18 molars
- 19 surfaces (18 occlusal)

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Overall, 49 children received sealants, 1 refused

- Resin – 88% (44)
- Glass ionomer – 10% (5)
- No sealant – 2% (1)

Of children that received sealants (n = 49),

- Resin – 89.8% (44)
- Glass ionomer – 10.2% (5)

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Procedure time:

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- Range - 12 to 29 mins (for 1 to 7 molars)
- Mean (SD) procedure time for 4 molars if 4 or > teeth sealed (38 patients) – 20.7 mins (3.4)

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Forty-nine (out of 50) children in the intervention group had sealants applied but one child was not compliant (Table 35).

The mean number of molars sealed in each child was 3.6, but the number of surfaces were clearly greater, because where appropriate, buccal pits (on lower molars) and palatal fissures (on uppers) were also sealed.

Most had resin sealants (90%) but the remainder had GI due to insufficient co-operation to achieve adequate moisture control. No participant had both types of sealants.

The procedure time was 12-29 minutes depending, on the most part, on the number of teeth sealed, although the average time required to seal four molars was around 20 minutes.

Table 36:
Pilot RCT – Sealants acceptability based on Facial Images Scale (FIS) scores

Sealant acceptability: FIS scores 		
	Before placement (n=49)	**After placement (n=49)**
FIS scores: **Mean (SD)** **Median**	 2.0 (1.1) 2.0	 1.6 (1) 1.0
FIS scores % (n): **1** **2** **3** **4** **5**	 49 (24) 18 (9) 22 (11) 8 (4) 2 (1)	 67 (33) 18 (9) 8 (4) 0 6 (3)

Using FIS scores to evaluate acceptability of sealants (Table 36), almost half were '*not at all worried*' before the procedure, and after application, this had increased to two-thirds (67%). However, the proportion that were '*very worried*' also increased from 2% at the start, to 6% afterwards. Sealant placement was generally well accepted with a mean FIS score of 2 before placement and 1.6 after placement.

6.4.5

Follow up results: 24 months

One key outcome measure was to assess caries incidence in permanent molars (that were caries free at baseline) two years after the GA, but reviews after 12 months were also planned, in part to measure caries development at this earlier stage, but more so, to maintain contact with families, in case of a high loss to follow-up by the time of the 24-month review.

Unfortunately, due to unforeseen circumstances, the researcher (AR) had to take a leave of absence, during the 12-month follow-up period, and so it was not possible to review all participants at that time. Around half were completed and families that could not be seen were where possible, called, to update contact details and establish if the child had any symptoms or any other reason to justify a review. No problems were reported, so parents were advised that an appointment would be sent for the 24 month review.

Therefore, comprehensive results are only presented for the 24-month reviews, which, in any case, was the preferred endpoint for the study. However, Appendix 25 provides a summary of key findings at the 12-month stage , especially as these now also serve as a useful comparison of any differences in outcomes, between children that were followed up twice during the study period, compared to those that were only seen after 24 months.

6.4.5.1

Demographic characteristics of participants followed up at 24 months:

Table 37:

Pilot RCT – Demographic characteristics for participants followed up at 24 months – whole group and control versus sealant

	All children seen at 24 months (n=82)	**Control group (n=43)**	**Sealant group (n=39)**
Age, years:			
mean (SD)	9.7 (1.7)	9.4 (1.4)	10.1 (1.9)
range	7 - 16	8 - 14	7 - 16
% (n) for different ages:			
7	1 (1)	0	3 (1)
8	21 (17)	30 (13)	10 (4)
9	29 (24)	28 (12)	31 (12)
10	28 (23)	26 (11)	31 (12)
11	9 (7)	7 (3)	10 (4)
12	4 (3)	5 (2)	3 (1)
13	4 (3)	2 (1)	5 (2)
14	4 (3)	2 (1)	5 (2)
16	1 (1)	0	3 (1)
Sex: % (n)			
Male	51 (42)	47 (20)	56 (22)
Female	49 (40)	53 (23)	44 (17)
Ethnicity broad: % (n)			
White	27 (22)	21 (9)	33 (13)
Asian	51 (42)	58 (25)	44 (17)
Black	13 (11)	12 (5)	15 (6)
Other	9 (7)	9 (4)	8 (3)
Ethnicity specific: % (n)			
White British	26 (21)	21 (9)	31 (12)
White Other	1 (1)	0	3 (1)
White British Caribbean	4 (3)	5 (2)	3 (1)
Other Mixed	1 (1)	2 (1)	0
Asian British Indian	6 (5)	9 (4)	3 (1)
Asian British Pakistani	40 (33)	42 (18)	38 (15)

Asian British Bangladeshi	1 (1)	2 (1)	0
Other Asian	4 (3)	5 (2)	3 (1)
Black British Caribbean	7 (6)	7 (3)	8 (3)
Black British African	6 (5)	5 (2)	8 (3)
Chinese	1 (1)	2 (1)	0
Other	2 (2)	0	5 (2)
Index of multiple deprivation (IMD) Decile: % (n)			
1 – poorest	62 (51)	65 (28)	59 (23)
2	12 (10)	12 (5)	13 (5)
3	7 (6)	5 (2)	10 (4)
4	2 (2)	2 (1)	3 (1)
5	6 (5)	7 (3)	5 (2)
6	4 (3)	5 (2)	3 (1)
7	2 (2)	2 (1)	3 (1)
8	1 (1)	0	3 (1)
9	2 (2)	2 (1)	3 (1)
10 – richest	0	0	0
IMD score: mean (SD)	5443 (6742)	5235 (6403)	5671 (7176)
Siblings experience of dental GA: % (n)			
Yes	23 (19)	26 (11)	21 (8)
No	77 (63)	74 (32)	79 (31)

Table 37 describes demographic characteristics of participants that were followed up at 24 months and compares any variation between the control and sealant groups. The average age was 9.7 years with a similar proportion of boys and girls. Asian children were most widely represented (51%, n=42) and accounted for almost twice as many as the next largest group (White, 27%, n=22). Over 60% (n=51) of children attending belonged to the most deprived decile and almost a quarter (23%, n=19) of parents reported that at least one of their other children had also received a dental GA. There were no significant differences between the intervention and control groups.

6.4.5.2

Sealants at 24 months:

Table 38: Prevalence of sealants at 24 months, on permanent molars that were sound at baseline (SPM_{BL})		
	Control group (n=43 children)	**Sealant group (n=39 children)**
Child with at least one sealed SPM_{BL} % (n):	11.6 (5)	94.9 (37)
Sealants retained after 24 months (sealant group only), surfaces % (n):		93.5 (244/ 261)
<u>Sealant Quality</u> (*restricted to surfaces with some sealant in situ*):		
Sealant quality: all surfaces,		
Part retained % (n): Fully retained % (n):	58.3 (7) 41.7 (5)	17.6 (43/244) 82.4 (201/244)
Sealant quality: occlusal surfaces,		
Part retained % (n): Fully retained % (n):	58.3 (7) 41.7 (5)	16.2 (21/130) 83.8 (109/130)
Sealant quality: buccal/ palatal surfaces, (*sealant group only*)		
Part retained % (n): Fully retained % (n):	-	19.3 (22/114) 80.7 (92/114)
<u>Resin v GIC</u> (*sealant group only*):		
Sealant retained after 24 months, on surfaces sealed at baseline: % (n)		

• GI • Resin		27.3 (3 out of 11) 96.4 (241 out of 250)

Almost 12% of children in the control group had evidence of at least one sealant at the 24-month review (assumed to have been provided in primary care) and almost 95% of participants in the study intervention group, still had at least one sealant in situ.

Of the sealants retained (244) in the intervention group, 82% (201) were fully retained (compared to 42% of sealants identified in the control group). For sealants provided as part of the study, resin sealants were better retained than GI. Sealant retention on occlusal and smooth (buccal and palatal) surfaces was comparable.

6.4.5.3

Caries prevalence in permanent molars at 24 months

Table 39: Caries prevalence at 24-months: control versus sealant

Caries prevalence at 24-months: control versus sealant			
	Control (n=43)	**Sealant (n=39)**	**P-value**
All permanent teeth *(includes teeth that were present but not sound at baseline and any that had erupted within the 2-year study period)*			
Children with dentine caries experience in a permanent tooth, **($D_{4-6}MF>0$):** **% (n)**	41.9 (18)	15.4 (6)	0.005[1]
DMF(T): mean (SD)	0.7 (1.1)	0.2 (0.8)	0.006[2]

Children with dentine caries experience in at least one permanent molar, ($D_{4-6}MF>0$): % (n)	41.9 (18)	15.4 (6)	0.005[1]
Children with untreated dentine caries in at least one permanent molar, ($D_{4-6}>0$): % (n)	34.9 (15)	5.1 (2)	<0.001[1]
Permanent molars that were present & sound at baseline (SPM_{BL}):			
Children with dentine caries experience in at least one SPM_{BL}, ($D_{4-6}MF>0$): % (n)	41.9 (18)	0	<0.001[1]
Children with untreated dentine caries in at least one SPM_{BL}, ($D_{4-6}>0$): % (n)	32.6 (14)	0	<0.001[1]
Permanent molars (SPM_{BL}) per child with dentine caries experience, ($D_{4-6}MF>0$): mean (SD)	0.7 (1.0)	0	<0.001[2]
Permanent molars (SPM_{BL}) per child with untreated dentine caries, ($D_{4-6}>0$): mean (SD)	0.5 (0.8)	0	<0.001[2]
SPM_{BL} surfaces per child with dentine caries experience, ($D_{4-6}MF>0$): mean (SD)	0.9 (1.2)	0	<0.001[2]
SPM_{BL}) surfaces per child with untreated dentine caries, ($D_{4-6}>0$): mean (SD)	0.6 (1.0)	0	<0.001[2]

Statistical tests:

1 - Pearson's chi squared

2 - Two sample t tests

Table 39 compares caries prevalence in permanent molars in the two study groups at 24 months. When reporting on all permanent teeth (which includes teeth that were present but not sound at baseline and any that had erupted within the 2 year study period), the control group had significantly more experience of caries in dentine (P = 0.005): almost 42% (n=18) of control group children had a DMFT of greater than zero, compared to 15% (n=6) in the sealant group. All experience of caries affecting dentine in permanent teeth, was confined to permanent molars. The control group also had higher levels of untreated dentine caries than the sealant group (35%, n=15 children in control group and 5%, n=2 children in sealant group, P < 0.001).

However, when restricting analyses to permanent molars that were present and sound at baseline (i.e. no experience of caries, restored or unrestored), these differences were even greater: no children in the sealant group had experience of dentine caries in a permanent molar, compared to 42% (n=18) in the control group (P < 0.001) . The mean number of teeth affected in each control group participant was 0.7 and there were, again, significant differences in levels of untreated dentine caries between the two groups (33%. n=14 children in control group compared to none in the sealant group, P < 0.001 - Table 39).

Table 40: Prevalence of different severities of caries on a child level at 24 months in permanent molars that were present & sound at baseline (SPM_{BL}): control versus sealant			
	Control (n=43)	**Sealant (n=39)**	**P-value**
Any caries (ICDAS codes 1-6)			
Child with at least one SPM_{BL} affected by Any caries: % (n)	77 (33)	64 (25)	0.21[1]
Child with at least one first permanent molar affected by Any caries: % (n)	77 (33)	62 (24)	0.14[1]
Child with at least one second permanent molar affected by Any caries: % (n)	0	5 (2)	0.13[1]
Untreated dentine caries (ICDAS codes 4, 5, 6)			
Child with at least one SPM_{BL} affected by Untreated dentine caries: % (n)	33 (14)	0	<0.001[1]
Untreated severe caries (ICDAS codes 5, 6)			
Child with at least one SPM_{BL} affected by Untreated severe caries: % (n)	14 (6)	0	0.015[1]

Statistical test:

1 - Pearson's chi squared

Table 41: Prevalence of different severities of caries on a surface level at 24 months in permanent molars that were 'present & sound' at baseline (SPM_{BL}): control versus sealant			
	Control (n=43 children)	**Sealant (n=39 children)**	**P-value**
Any caries (ICDAS codes 1-6)			
SPM_{BL} surfaces per child affected by Any caries mean (SD)	3.3 (2.9)	1.4 (1.5)	<0.001[2]
First permanent molar surfaces per child affected by Any caries mean (SD)	3.3 (2.9)	1.3 (1.4)	<0.001[2]
Second permanent molar surfaces affected by Any caries mean (SD)	0	0.2 (0.7)	0.14[2]
Early caries (ICDAS codes 1, 2)			
SPM_{BL} surfaces per child affected by Early caries mean (SD)	2.2 (2.2)	1.2 (1.3)	0.018[2]
Cavitated enamel caries (ICDAS code 3)			
SPM_{BL} surfaces per child affected by Cavitated enamel caries mean (SD)	0.6 (1.1)	0.2 (0.5)	0.062[2]
Enamel caries (ICDAS codes 1, 2, 3)			
SPM_{BL} surfaces per child affected by Enamel caries mean (SD)	2.7 (2.7)	1.4 (1.4)	0.008[2]

Untreated dentine caries (ICDAS codes 4, 5, 6)			
SPM_{BL} surfaces per child affected by Untreated dentine caries mean (SD)	0.6 (1.0)	0	<0.001[2]
Untreated severe dentine caries (ICDAS codes 5, 6)			
SPM_{BL} surfaces per child affected by Untreated severe dentine caries mean (SD)	0.2 (0.6)	0	0.032[2]
Dentine caries experience			
SPM_{BL} surfaces per child with experience of dentine caries mean (SD)	0.9 (1.2)	0	<0.001[2]

Statistical test:

2 - Two sample t tests

Tables 40 and 41 illustrate prevalence of different severities of caries present at 24 months: this can be reported on child, tooth or surface levels. However, caution must be exercised on interpreting findings based on specific ICDAS caries codes (1 to 6), on anything other than a 'surface' level, because more than one caries code can be applicable to a single tooth or patient. Therefore, in table 40 (which compares caries between the two groups on a 'child' level), severity is restricted to three cumulative stages: 'any' (ICDAS codes 1-6), 'dentine' (ICDAS codes 4-6) and 'severe' (ICDAS codes 5-6) caries respectively. According to this, there was no significant difference in the proportion of children in each group that had 'any' caries (77%, n=33 children in control group and 64%, n=25 children in sealant group, P = 0.21), which includes ICDAS codes 1, 2, 3, representing the earlier stages of caries confined to enamel

(Table 40), but the mean number of surfaces affected was higher in the control group (control group = 3.3 surfaces, sealant group = 1.4 surfaces, P < 0.001 - Table 41).

Table 42: Caries prevalence at 24 months in permanent molars that were sound at baseline: surface types affected

	Surface type affected			
	Total surfaces affected (number)	**Occlusal surfaces % (n)**	**Buccal/ palatal surfaces % (n)**	**Interproximal (mesial/ distal) surfaces % (n)**
'Type' of caries (ICDAS codes)				
Any caries untreated (codes 1-6)	223	62.3 (139)	36.3 (81)	1.3 (3)
			Buccal n=33 / Palatal n=48	
Untreated dentine caries (codes 4-6)	32	90. 6 (29)	3.1 (1)	6.3 (2)
Dentine caries experience	63	74.6 (47)	11.1 (7)	14.3 (9)

Table 42 shows that overall, most caries affected occlusal surfaces, with 90% of untreated dentine lesions involving occlusal fissures, compared to only 6% of interproximal surfaces (Table 42). However, more than a third of buccal/ palatal surfaces presented with 'any caries' (which includes early lesions).

6.4.5.4

Caries in primary teeth at 24 months:

Table 43:
Pilot RCT – Caries prevalence in primary teeth at 24 months – control versus sealant

Caries primary teeth at 24 months – control versus sealant			
	Control (n=43)	**Sealant (n=39)**	**P value**
Children with dentine caries experience in a primary molar, ($d_{4-6}f>0$): % (n)	44 (19)	31 (12)	0.38[1]
Children with untreated dentine caries in a primary molar, ($d_{4-6}>0$): % (n)	33 (14)	24 (9)	0.21[1]
Primary molar surfaces per child affected by untreated dentine caries, ($d_{4-6}>0$): mean (SD)	1.3 (2.4)	0.6 (1.1)	0.094[2]

Statistical tests:

1 - Pearson's chi squared

2 - Two sample t tests

Table 43 compares caries levels in primary teeth (that were sound at the time of the GA) in the two study groups, at 24 months. All experience of caries affecting dentine in primary teeth was confined to primary molars. A higher proportion of control group children had experience of and/ or untreated dentine caries in at least one primary molar at 24 months and the mean number of surfaces affected was also greater but, these differences were not statistically significant (Table 43).

Table 44: Caries primary molars at 24 months – surface types affected

	Surface type affected % (n) (Total surfaces affected = 81)		
	Occlusal	**Buccal and palatal**	**Interproximal**
Primary molars with dentine caries experience at 24 months:	49.4 (40)	17.3 (14)	33.3 (27)

Table 44 shows that only one third (33.3%) of surfaces with experience of caries in dentine were interproximal.

6.4.5.5

Oral symptoms and Oral Health related Quality of Life (OHQoL) 24 months after GA:

Table 45: Oral symptoms and Oral health related Quality of Life impacts at 24-month follow up: control versus sealant

	Whole group followed up at 24 months (n=82)	**Control (n=43)**	**Sealant (n=39)**	**P-value**
Oral symptoms reported in past 3 months: % (n)				
Toothache	24 (20)	19 (8)	31 (12)	0.20[1]
Sensitivity	50 (41)	40 (17)	62 (24)	0.047[1]
Bleeding or swollen gums	39 (32)	40 (17)	38 (15)	0.92[1]
Broken tooth	5 (4)	5 (2)	5 (2)	0.92[1]
Mouth ulcers	30 (25)	28 (12)	33 (13)	0.59[1]

Bad breath	46 (38)	47 (20)	46 (18)	0.97[1]
At least 'one' oral symptom in past 3 months: **% (n)** *Yes* *No*	 88 (72) 12 (10)	 88 (38) 12 (5)	 87 (34) 13 (5)	 0.87[1]
Oral impacts reported in past 3 months: **% (n)**				
Difficulty eating: *- Not at all* *- A little* *- A fair amount* *- A lot* ***Difficulty speaking:*** *- Not at all* *- A little* *- A fair amount* *- A lot* ***Difficulty cleaning teeth:*** *- Not at all* *- A little* *- A fair amount* *- A lot* ***Difficulty sleeping:*** *- Not at all* *- A little* *- A fair amount* *- A lot* ***Felt 'different' e.g. irritant, upset:***	 83 (68) 12 (10) 4 (3) 1 (1) 96 (79) 4 (3) 0 0 71 (58) 26 (21) 4 (3) 0 94 (77) 4 (3) 1 (1) 1 (1)	 84 (36) 12 (5) 2 (1) 2 (1) 95 (41) 5 (2) 0 0 65 (28) 30 (13) 5 (2) 0 91 (39) 7 (3) 0 2 (1)	 82 (32) 13 (5) 5 (2) 0 97 (38) 3 (1) 0 0 77 (30) 21 (8) 3 (1) 0 97 (38) 0 3 (1) 0	 0.71[1] 0.62[1] 0.50[1] 0.18[1]

- Not at all	71 (58)	77 (33)	64 (25)	0.26[1]
- A little	23 (19)	21 (9)	26 (10)	
- A fair amount	4 (3)	0	8 (3)	
- A lot	2 (2)	2 (1)	3 (1)	
Difficulty smiling, laughing, showing teeth:				
- Not at all	87 (71)	91 (39)	82 (32)	0.44[1]
- A little	6 (5)	5 (2)	8 (3)	
- A fair amount	5 (4)	5 (2)	5 (2)	
- A lot	2 (2)	0	5 (2)	
Difficulty doing schoolwork:				
- Not at all	95 (78)	95 (41)	95 (37)	0.51[1]
- A little	4 (3)	2 (1)	5 (2)	
- A fair amount	1 (1)	2 (1)	0	
- A lot	0	0	0	
Difficulty enjoying being with other people:				
- Not at all	94 (77)	95 (41)	92 (36)	0.57[1]
- A little	5 (4)	5 (2)	5 (2)	
- A fair amount	1 (1)	0	3 (1)	
- A lot	0	0	0	
At least one oral impact % (n)				
Yes	52 (43)	53 (23)	51 (20)	0.84[1]
No	48 (39)	47 (20)	49 (19)	
Impact of oral condition on everyday life in past 3 months: % (n)				
- Not at all	60 (49)	65 (28)	54 (21)	0.58[1]
- A little	37 (30)	33 (14)	41 (16)	
- Somewhat	0	0	0	
- A fair amount	2 (2)	2 (1)	3 (1)	
- A great deal	1 (1)	0	3 (1)	

Statistical test:

1 - Pearson's chi squared

Prevalence of oral symptoms in children followed up after 2 years was high, with 88% reporting at least one problem (Table 45): symptoms reported most often were sensitivity, bad breath, and bleeding or swollen gums (Table 45).

Table 46: Oral symptoms and Oral health related Quality of Life impacts at 24-month follow up: based on sex

	Sex		
	Male (n=42)	**Female (n=40)**	**P-value**
Oral symptoms reported in past 3 months: % (n)			
Toothache	17 (7)	33 (13)	0.095[1]
Sensitivity	48 (20)	53 (21)	0.66[1]
Bleeding or swollen gums	38 (16)	40 (16)	0.86[1]
Broken tooth	5 (2)	5 (2)	0.96[1]
Mouth ulcers	26 (11)	35 (14)	0.39[1]
Bad breath	36 (15)	57 (23)	0.048[1]
At least 'one' oral symptom in past 3 months: % (n)			
Yes	83 (35)	93 (37)	0.20[1]
No	17 (7)	7 (3)	

Oral impacts:			
Oral impacts reported in past 3 months ***At least one oral impact in the last 3 months*** ***% (n)***			
Yes *No*	52 (22) 48 (20)	53 (21) 48 (19)	0.99[1]
Impact of oral condition on everyday life in past 3 months: % (n)			
- *Not at all* - *A little* - *Somewhat* - *A fair amount* - *A great deal*	69 (29) 29 (12) 0 0 2 (1)	50 (20) 45 (18) 0 5 (2) 0	0.12[1]

Statistical test:

1 - Pearson's chi squared

Table 47: Oral symptoms and Oral health related Quality of Life impacts at 24-month follow up: based on ethnicity					
	Ethnicity				
	White (n=22)	**Asian (n=42)**	**Black (n=11)**	**Other (n=7)**	**P-value**
Oral symptoms reported in past 3 months: % (n)					
Toothache	32 (7)	21 (9)	36 (4)	0	0.26[1]
Sensitivity	45 (10)	55 (23)	45 (5)	43 (3)	0.85[1]
Bleeding or swollen gums	27 (6)	48 (20)	27 (3)	43 (3)	0.35[1]

Broken tooth	0	5 (2)	0	29 (2)	0.017[1]
Mouth ulcers	32 (7)	24 (10)	45 (5)	43 (3)	0.46[1]
Bad breath	36 (8)	52 (22)	27 (3)	71 (5)	0.18[1]
At least 'one' oral symptom in past 3 months: % (n)					
Yes	82 (18)	93 (39)	73 (8)	100 (7)	0.17[1]
No	18 (4)	7 (3)	27 (3)	0	
Oral impacts:					
Oral impacts reported in past 3 months					
At least one oral impact in the last 3 months % (n)					
Yes	45 (10)	55 (23)	45 (5)	71 (5)	0.63[1]
No	55 (12)	45 (19)	55 (6)	29 (2)	
Impact of oral condition on everyday life in past 3 months: % (n)					
- *Not at all*	64 (14)	64 (27)	36 (4)	57 (4)	0.76[1]
- *A little*	32 (7)	31 (13)	64 (7)	43 (3)	
- *Somewhat*	0	0	0	0	
- *A fair amount*	5 (1)	2 (1)	0	0	
- *A great deal*	0	2 (1)	0	0	

Statistical test:

1 - Pearson's chi squared

Table 48: Oral symptoms and Oral health related Quality of Life impacts at 24-month follow up: based on deprivation			
Deprivation level			
	Poorest decile (n=51)	**Other deciles (n=31)**	**P-value**
Oral symptoms reported in past 3 months: % (n)			
Toothache	20 (10)	32 (10)	0.20[1]
Sensitivity	41 (21)	65 (25)	0.040[1]
Bleeding or swollen gums	39 (20)	39 (12)	0.96[1]
Broken tooth	6 (3)	3 (1)	0.59[1]
Mouth ulcers	35 (18)	23 (7)	0.23[1]
Bad breath	51 (26)	39 (12)	0.28[1]
At least 'one' oral symptom in past 3 months: % (n)			
Yes	86 (44)	90 (28)	0.59[1]
No	14 (7)	10 (3)	
Oral impacts:			
Oral impacts reported in past 3 months			
At least one oral impact in the last 3 months % (n)			
Yes	59 (30)	29 (9)	0.009[1]
No	41 (21)	71 (22)	

Impact of oral condition on everyday life in past 3 months: % (n)			
- *Not at all*	71 (36)	42 (13)	0.024[1]
- *A little*	29 (15)	48 (15)	
- *Somewhat*	0	0	
- *A fair amount*	0	6 (2)	
- *A great deal*	0	3 (1)	

Statistical test:

1 - Pearson's chi squared

There were no significant differences in the likelihood of experiencing at least one oral symptom based on study group, sex, ethnicity or deprivation (Table 45, 46, 47, 48). However, some oral symptoms were more prevalent in certain demographic groups (Tables 46, 47, 48): girls were more likely to experience bad breath (57%, n=23 girls, 36%, n=15 boys, P = 0.048) (Table 46) and children from ethnic backgrounds other than White, Asian or Black were more likely to have a fractured tooth (P = 0.017), although the numbers overall were small (Table 47). Children from the poorest 10% of the population were less likely to complain of sensitivity (41%, n=21 children, P = 0.040 - Table 48) but the sealant group reported sensitivity more frequently than the control group (62%, n=24 sealant group children, 40%, n=17 control group children, P = 0.047 - Table 45).

Considering the impact of oral problems on quality of life, just over half (52.4%) of children questioned had experienced at least one negative impact (Table 45). There were no clear discrepancies in the frequency of reporting for differing types of impact, but difficulty cleaning teeth and 'feeling different' were most prevalent (Table 45).

There were no significant differences in the likelihood of experiencing at least one oral impact based on sex or ethnicity (Tables 46, 47), but the prevalence was higher in children from the poorest backgrounds (59%, n=30 children in poorest decile, 29%, n=9 children in other deciles, P = 0.009 - Table 48).

6.4.5.6

24 month follow up questionnaire – parents' experiences of dental services for their children:

6.4.5.6.1

Dental attendance behaviours within 24 months after dental GA (Tables 49 and 50):

Table 49: Dental attendance behaviours within 24 months after dental GA

	Whole group followed up at 24 months (n=82)	**Control (n=43)**	**Sealant (n=39)**	**P-value**
Did child visit a dentist before GA? % (n)				
- *Yes*	100 (82)	100 (43)	100 (39)	-
- *No*	0	0	0	
- *Not sure*	0	0	0	
Type of dentist % (n)				
- *GDP*	95 (78)	91 (39)	100 (39)	0.16[1]
- *CDP*	4 (3)	7 (3)	0	
- *Hospital*	1 (1)	2 (1)	0	
If yes, frequency of attendance: ***82 responses*** **% (n)**				
- *Only when having trouble*	12 (10)	19 (8)	5 (2)	0.12[1]
- *Irregular check-ups (< once a year)*	7 (6)	9 (4)	5 (2)	
- *Regular check-ups (at least once a year)*	81 (66)	72 (31)	90 (35)	
- *Not sure*	0	0	0	
Has child visited a dentist since GA? % (n)				
- *Yes*	85 (70)	88 (38)	82 (32)	0.42[1]
- *No*	15 (12)	12 (5)	18 (7)	
- *Not sure*	0	0	0	

Reasons for non-attendance: ***(> 1 response may apply)***				
% (n)				
- No problems	50 (6)	40 (2)	57 (4)	0.56[1]
- Did not receive any appointments or reminders	58 (7)	60 (3)	57 (4)	0.92[1]
- Check-ups not a priority	8 (1)	20 (1)	0	0.22[1]
- Any other reason	5 (4)	7 (3)	3 (1)	0.35[1]
- No specific reason	8 (1)	20 (1)	0	0.22[1]
Responses to specific reasons for non-attendance: ***(> 1 response may apply)***				
% (n)				
- Difficulty taking time off work	8 (1)	0	14 (1)	0.38[1]
- Difficulty taking time off school	33 (4)	20 (1)	43 (3)	0.41[1]
- Transport issues	8 (1)	20 (1)	0	0.22[1]
- Language barrier	0	0	0	-
- Other young children to look after	25 (3)	20 (1)	29 (2)	0.74[1]
Have family failed a scheduled appointment?				
% (n)				
- Yes	25 (3)	20 (1)	29 (2)	0.93[1]
- No	58 (7)	60 (3)	57 (4)	
- Not sure	17 (2)	20 (1)	14 (1)	
Is child anxious about visiting the dentist?				
% (n)				
- Yes	40 (33)	44 (19)	36 (14)	0.46[1]
- No	59 (48)	56 (24)	62 (24)	
- Not sure	1 (1)	0	3 (1)	

Statistical test:

1 - Pearson's chi squared

All children returning for the 24-month review, had seen a dentist before the GA. For most (81%), this was for regular check-ups (at least once a year) and 85% had been back to see a dentist within the 2 years following the extractions. Amongst the few that failed to return to a dentist, no specific reason took precedence, but over half suggested this was because their child had not experienced any problems, or no appointment had been sent. One third reported 'time off school' as a reason for non-attendance (more so than 'time off work' for parents) and especially so in the sealant group. One quarter felt that caring for other children made dental attendance more difficult, but none reported language difficulties as a barrier to attending. There were no statistically significant differences between control and sealant groups.

Table 50: Dental visits for children that returned to see a dentist within 24-months following dental GA (n=70)

Dental visits for children that returned to see a dentist within 24-months following dental GA (n=70)				
	Whole group (n=70)	**Control (n=38)**	**Sealant (n=32)**	**P-value**
Did child return to the same dental practice after the GA?				
% (n)				
- *Yes*	87 (61)	82 (31)	94 (30)	0.13[1]
- *No*	13 (9)	18 (7)	6 (2)	
- *Not sure*	0	0	0	
If different, has the 'new' dentist been made aware of the GA?				
%(n)				
- *Yes*	50 (5)	38 (3)	100 (2)	0.29[1]
- *No*	40 (4)	50 (4)	0	
- *Not sure*	0	0	0	
Type of dentist:				

% (n) *- GDP* *- CDS* *- Hospital* *- Not sure*	 95 (66) 4 (3) 1 (1) 0	 90 (34) 8 (3) 2 (1) 0	 100 (32) 0 0 0	 0.16[1]
How soon after the GA did the child first visit a dentist? **% (n)** *- Within 3 months* *- Between 3 to 6 months later* *- After about 6 months* *- Between 6 to 12 months later* *- More than 12 months later* *- Not sure*	 20 (14) 11 (8) 33 (23) 20 (14) 14 (10) 1 (1)	 21 (8) 16 (6) 18 (7) 18 (7) 24 (9) 3 (1)	 19 (6) 6 (2) 50 (16) 22 (7) 3 (1) 0	 0.025[1]
Reason for first dental visit after having teeth taken out? **% (n)** *- Check-up* *- Complete outstanding treatment* *- Toothache, problems* *- Other* *- Not sure*	 96 (67) 0 3 (2) 1 (1) 0	 95 (36) 0 5 (2) 0 0	 97 (31) 0 0 3 (1) 0	 0.24[1]
How are dental check-ups normally arranged? **% (n)** *- Dental practice sends appointment (e.g. letter or text)* *- Dental practice sends reminder to prompt parent to arrange appointment* *- Parent arranges appointment* *- Other* *- Not sure*	 17 (12) 53 (37) 19 (13) 11 (8) 0	 26 (10) 47 (18) 21 (8) 5 (2) 0	 6 (2) 59 (19) 16 (5) 19 (6) 0	 0.055[1]

Does dental practice send appointment reminders? % (n) - *Yes* - *No* - *Not sure*	 64 (45) 36 (25) 0	 71 (27) 29 (11) 0	 56 (18) 44 (14) 0	 0.20[1]

Statistical test:

1 - Pearson's chi squared

Of those that saw a dentist after the GA (Table 50), most returned to the same dental practice attended previously, although this doesn't imply, they saw the same dentist. For the few that went to a different practice, all sealant group parents said their new dentist was aware of their child's experience of a dental GA, compared to only 38% in the control group, but these differences were not statistically significant (P = 0.29). Half of children in the sealant group went back after about 6 months but there was a wider range within the control group, with similar proportions (around 20%) returning earlier or later than this. Overall, a fifth saw a dentist within 3 months of the GA (Table 50). For most (95%), the main reason for the initial visit to a dentist after the GA was for a routine check-up. Just over half of parents had received notifications to advise them to contact their practice to arrange a check-up and nearly two-thirds of families had received reminders for scheduled appointments.

6.4.5.6.2

Preventive advice and treatments in primary care (Table 51):

Table 51: Preventive advice and treatments received within 24-months following dental GA

Preventive advice and treatments received within 24-months following dental GA				
	Whole group followed up at 24 months (n=70)	**Control (n=38)**	**Sealant (n=32)**	**P-value**
Have the parent &/ or child received: Yes, % (n)				
- Oral hygiene instruction	76 (53)	79 (30)	72 (23)	0.49[1]
- Dietary advice	66 (46)	68 (26)	63 (20)	0.60[1]
- Advice on importance of prevention to avoid repeat GA	11 (8)	16 (6)	6 (2)	0.21[1]
Have the family received advice on: Yes, % (n)				
- Frequency & timing of tooth-brushing	47 (33)	53 (20)	41 (13)	0.32[1]
- Fluoride content of toothpaste	26 (18)	26 (10)	25 (8)	0.90[1]
- Spit & not rinse	7 (5)	8 (3)	6 (2)	0.82[1]
- Reducing frequency of sugary foods & drinks	40 (28)	45 (17)	34 (11)	0.38[1]
Has child received tailored tooth-brushing demonstration/ instruction? Yes, % (n)	9 (6)	13 (5)	3 (1)	0.14[1]

Would you rate the advice given as 'helpful'? ***(54 responses)*** **% (n)** - *Yes* - *No* - *Not sure*	 69 (37) 15 (8) 17 (9)	 74 (23) 16 (5) 10 (3)	 61 (14) 13 (3) 26 (6)	 0.28[1]
Do parent &/ or child report positive behaviour change as a result of advice received? ***(54 responses)*** **% (n)** - *Yes* - *No* - *Not sure*	 54 (29) 24 (13) 22 (12)	 65 (20) 19 (6) 16 (5)	 39 (9) 30 (7) 30 (7)	 0.18[1]
Fluoride varnish Yes: % (n)	17 (12)	24 (9)	9 (3)	0.11[1]
Fissure sealants Yes: % (n)	7 (5)	11 (4)	3 (1)	0.23[1]

Statistical test:

1 - Pearson's chi squared

Three-quarters (76%) of respondents reported receiving oral hygiene instruction, and two-thirds (66%) dietary advice, by a dental practitioner outside the study, following the GA. Most could recall advice on frequency and timing of brushing and to control consumption of sugary foods and drinks but not to explicitly reduce frequency of intake. Some comments recorded by parents (a selection of which are included below) suggested the advice received was often rudimentary:

- *It was quite basic really, cut down on the fizzy drinks and sweets*

- *To be honest, nothing we don't already know, it's just getting him to do it that's the problem*
- *It wasn't really anything new except about drinking through a straw, but the regular reminders help*

Only 7% could remember advice about spitting instead of rinsing after brushing and a similar proportion (9%) had received practical tailored demonstrations or instruction on brushing teeth. Only 11% of parents had been advised on the importance of prioritising prevention for their child, to minimise the risk of a repeat GA. Notably, many (69%) of parents described the advice they had received as, 'helpful' and just over half (54%) claimed to have changed behaviour as a result.

According to parents, 17% of children had fluoride varnish applied and 7% had received sealants. More control group children had received fluoride varnish and sealants compared to the intervention group and their parents were more likely to report that their dentist had highlighted the importance of preventing a repeat GA. However, these differences were not statistically significant.

6.4.5.6.3

Dental treatment received in primary care:

Table 52: Dental treatment received within 24-months following dental GA

Dental treatment received within 24-months following dental GA				
	Whole group followed up at 24 months (n=70)	**Control (n=38)**	**Sealant (n=32)**	**P-value**
Type of dental treatment: % (n)				

Scale &/ or polish	16 (11)	18 (7)	13 (4)	0.50[1]
Fillings	29 (20)	37 (14)	19 (6)	0.095[1]
Extractions	4 (3)	5 (2)	3 (1)	0.66[1]
Radiographs	14 (10)	21 (8)	6 (2)	0.078[1]
Other	0	0	0	-
Did child have a local anaesthetic (for fillings &/ or extractions)? % (n)				
- *Yes*	30 (7)	35 (6)	17 (1)	0.39[1]
- *No*	70 (16)	65 (11)	83 (5)	
- *Not sure*	0	0	0	
Was child anxious about having dental treatment? % (n)				
- *Yes*	43 (30)	47 (18)	32 (12)	0.46[1]
- *No*	57 (40)	53 (20)	68 (20)	
- *Not sure*	0	0	0	
If anxious, did this prevent planned treatment being completed? % (n)				
- *Yes*	37 (11)	39 (7)	33 (4)	0.76[1]
- *No*	63 (19)	61 (11)	67 (8)	
- *Not sure*	0	0	0	
If anxious, did dentist provide help to reduce anxiety?				
- *Yes*	70 (21)	72 (13)	67 (8)	0.56[1]
- *No*	27 (8)	22 (4)	33 (4)	
- *Not sure*	3 (1)	6 (1)	0	
If yes, what measures were offered to reduce anxiety:				

(> 1 response may apply)				
% (n)	86 (18)	77 (10)	100 (8)	0.141
- Behaviour management	0	0	0	-
- Sedation	24 (5)	31 (4)	13 (1)	0.34[1]
- Referral to Community Dental Service	0	0	0	-
- Referral to Hospital Dental Service	5 (1)	8 (1)	0	0.42[1]
- Referral for GA	0	0	0	-
- Other				

Statistical test:

1 - Pearson's chi squared

Overall, almost 30% had received fillings but only 14% had radiographs taken. Of children that had required restorations or extractions, only 30% could recall having a local anaesthetic. A higher proportion of control group children had received radiographs and restorations, but the differences were not statistically significant.

6.4.5.6.4

Dental anxiety (Table 49 and Table 52):

Overall, 40% of parents felt their child was anxious about visiting a dentist (Table 49), and of those that had required further treatment since the GA, 43% were reportedly anxious about having this completed (Table 52). Amongst this group, just over a third (37%) of parents claimed the level of anxiety had impacted on delivery of planned treatment. Whilst many (70%) believed their dentist had offered help to reduce the anxiety, for most, this was restricted to behaviour management techniques. None had

offered sedation, but a quarter (more so in the control group), had referred children to Community Dental Services where, for some, treatment with inhalation sedation had been carried out. One child, in the control group, had been referred for a repeat GA.

6.4.5.6.5

Parents views on advice and interventions to support their child's oral health:

Table 53: Parents' views (at 24 months) on advice and interventions to support oral health

Parents' views (at 24 months) on advice & interventions to support oral health				
	Whole group followed up at 24 months (n=82)	**Control (n=43)**	**Sealant (n=39)**	**P-value**
Would you like further <u>advice</u> on how to look after your child's teeth? % (n)				
- *Yes*	68 (56)	70 (30)	67 (26)	0.96[1]
- *No*	29 (24)	28 (12)	31 (12)	
- *Not sure*	2 (2)	2 (1)	3 (1)	
If yes, how would you like to receive this advice? *(could select > 1 option)* % (n)				
- *From a dental professional*	79 (44)	80 (24)	77 (20)	0.78[1]
- *From other health professionals*	2 (1)	3 (1)	0	0.35[1]
- *Through child's school*	38 (21)	47 (14)	27 (7)	0.13[1]
- *Information leaflets*	20 (11)	27 (8)	12 (3)	0.16[1]
- *DVDs*	16 (9)	23 (7)	8 (2)	0.11[1]
- *Internet/ online resources*	18 (10)	20 (6)	15 (4)	0.65[1]
- *Other*	0	0	0	-

Which, if any of these measures would you find helpful to <u>access</u> regular dental care for your child? *(could select > 1 option)* % (n)				
- *Help with finding a 'child friendly' dentist*	11 (9)	16 (7)	5 (2)	0.11[1]
- *More frequent check-up appointments*	11 (9)	16 (7)	5 (2)	0.11[1]
- *Appointment reminders*	38 (31)	30 (13)	46 (18)	0.14[1]
- *Translation services*	2 (2)	2 (1)	3 (1)	0.94[1]
- *Dental 'mobiles' at school*	34 (28)	37 (16)	31 (12)	0.54[1]
- *Other*	0	0	0	-
Would a follow-up appointment at the BDH a few weeks after the GA have been helpful? % (n)				
- *Yes*	60 (49)	67 (29)	51 (20)	0.29[1]
- *No*	33 (27)	28 (12)	38 (15)	
- *Not sure*	7 (6)	5 (2)	10 (4)	

Statistical test:

1 - Pearson's chi squared

Overall, two-thirds of parents welcomed further advice on how to look after their child's teeth. Most preferred to receive advice directly from a dentist (or other dental professional), but input from schools was also popular compared to some other suggestions. Only a fifth supported the use of online resources.

When evaluating opinions on practical measures to improve access to regular dental care, 11% requested help with finding a 'child friendly' dentist, suggesting most were

satisfied with their existing practitioner. However, over a third felt that appointment reminders would be of benefit and a similar proportion welcomed the idea of dental treatment being delivered on mobile units at schools. For most, translation services were not a priority, which supports the fact that none of the parents had previously cited language difficulties as a barrier to accessing dental services.

Control group parents were more likely to favour preventive advice through schools, as well as help with seeking a new dentist and more frequent check-up appointments, but any variations were not statistically significant.

Overall, 60% would have welcomed a review appt at the Dental Hospital, a few weeks after the GA, but based on parents' comments, it became apparent that for most, this was viewed as an opportunity to 'check' on healing of extraction sites instead of reinforcing prevention.

6.4.6

Examiner calibration for caries assessment – inter and intra-examiner variation (Table 54):

Levels of agreement (surface specific) were reported for the 1st digit restorative ICDAS code (specifying variations in recording of partly retained sealants, fully retained sealants and restorations) and separately for the 2nd digit caries diagnosis ICDAS code. For the latter, levels of agreement were described for:

- the full range of caries scores (0, 1, 2, 3, 4, 5, 6)
- for caries free surfaces (0), versus enamel caries (scores 1, 2, 3) versus dentine caries (scores 4, 5, 6)

and

- to simply differentiate between surfaces with (scores 4, 5, 6) and without (scores 0, 1, 2, 3) dentine caries.

The kappa statistic (ƙ) is derived by comparing observed levels of agreement between two examiners, with the hypothetical probability of agreement due to chance (238). A kappa score of 0 indicates the amount of agreement that would be expected by chance, where as a value of 1 indicates 'perfect' agreement (238).

High levels of inter and intra-examiner agreement were observed for the pilot study, both for restorative/ sealant codes as well the different stages of caries (Table 54).

Table 54: Examiner calibration – inter and intra-examiner variation								
	Inter-examiner kappa co-efficient (KC photos versus AR photos)				**Intra-examiner kappa co-efficient (AR clinical versus AR photos)**			
	Expected agreement %	Achieved agreement %	Kappa score	Std Err	Expected agreement %	Achieved agreement %	Kappa score	Std Err
1st digit ICDAS restorative code - Part sealant, full sealant, restoration								
Unweighted Weighted	43.61 67.70	78.00 91.00	0.6099 0.7214	0.0642 0.0788	45.32 65.65	93.00 97.67	0.8720 0.9321	0.0790 0.0889
2nd digit ICDAS caries codes:								
Caries codes 0 – 6								
Unweighted Weighted	36.29 65.49	73.00 92.20	0.5762 0.7740	0.0538 0.0745	42.50 67.61	92.00 98.20	0.8609 0.9444	0.0576 0.0777
Sound/ enamel caries/ dentine caries								
Unweighted Weighted	41.71 73.89	83.00 94.00	0.7084 0.7702	0.0725 0.0782	46.51 64.51	97.00 98.50	0.9439 0.9577	0.0752 0.0819
Sound versus dentine caries								
Unweighted Weighted	72.07 85.60	93.00 96.00	0.7222 0.7494	0.0934 0.0946	75.90 75.90	98.00 98.00	0.9170 0.9170	0.0997 0.0997

6.5

Discussion:

6.5.1

Discussion of methods: study procedures, design limitations and recommendations for improvement

6.5.1.1

Study design and selection criteria:

The options were parallel groups (sealant and control), which is what was used, or a split mouth design. Both have been used in fissure sealant trials: the most recent Cochrane review on sealants evaluated 11 parallel group studies and 27 split mouth designs (85) but the latter might be more appropriate when comparing different materials instead of sealant versus no sealant.

First permanent molars normally erupt between 6 to 8 years of age but might be present in children as young as 5 (239), who were therefore included. These teeth are most susceptible to caries within 1 to 1.5 years of their eruption, making this the most appropriate time to place protective sealants (1, 94). However, older children also benefit from sealants: placement might be easier due to better compliance and some will have potentially sealable second permanent molars (96).

The key indicator for high caries risk (and thus eligibility for inclusion) was for the child to require at least one caries related extraction under GA. Obviously, several factors are linked to caries risk, including diet, oral hygiene, fluoride use, social and medical history,

and importantly, past caries experience (12, 13). The standard used was deemed appropriate, on the basis that even a single carious tooth, would result from a culmination of one or more of these underlying factors. Furthermore, even though a range of more elaborate caries risk assessment tools are available, there is little consensus on which are most effective (1). British guidelines recommend sealants for children with caries affecting 2 or more primary tooth surfaces (dmfs > 2) (240), which is comparable to the benchmark used for the pilot and previous trials have also recommended sealants on the basis of similar levels of disease (85, 241).

Children with at least one sealable permanent molar, were eligible to take part, although it would clearly have been more beneficial, to seal all four molars at the same time. However, the earlier service evaluations (Study A) found that most children were likely to present with more than one first permanent molar and many with, four (Table 11). Other trials have also recruited children that only had 1 sealant placed at the start of the study, but teeth erupting throughout the study period were also subsequently sealed (110, 242). This was not proposed for the pilot because it was important to investigate outcomes, when children would be subject to the usual standard of preventive care in primary practice.

6.5.1.2

Caries assessment and sealant retention status: ICDAS

The ICDAS was used to assess and diagnose caries: this is a valid and reliable caries assessment detection system, which has been widely adopted for use in both population and clinical research (214) and the associated International Caries Classification and Management System (ICCMS) facilitates translation of research findings to clinical practice, with particular emphasis towards a prevention orientated approach (243).

Most studies reporting on retention of sealants have used similar scoring systems (85) though some have opted to use modifications of the Simonsen scale, which reports on a tooth, as opposed to surface level (207). Researchers reporting on caries relapse following a GA have used modified versions of ICDAS (196), as too did the last UK Child Dental Health Survey, which should support comparison of caries levels in the pilot sample with the national picture (238).

6.5.1.3

Examiner training and calibration:

The examiner (AR) completed ICDAS training, using online resources (210), but it was not feasible to attend a formal training or calibration exercise prior to commencement of data collection. Given that all clinical assessments, at baseline and follow ups, were completed by the same examiner (AR), this clearly eliminates the scope for any inter-examiner variation. However, to provide some measure of the validity and reliability of reporting on caries data, a trained and calibrated ICDAS examiner (KC) subsequently reported on 100 clinical photographs, of permanent molars, that were taken as part of the study, so these could be compared with clinical data recorded by AR. Intra-examiner reproducibility was also assessed by comparing AR's scores for the same set of photographs, with the scores originally recorded from clinical examinations. Other researchers have also made use of clinical photos to evaluate intra-examiner variations (207, 244) . Clearly, it would have been preferable for AR to undertake training and calibration before commencing data collection and this would obviously be a recommendation for a future definitive trial, involving multiple examiners.

6.5.1.4

Radiographs:

No radiographs were taken for study purposes but any available as part of the GA assessment were referred to. These serve to,

1. Identify further caries, that would either, require restoration prior to the GA, or warrant extraction (most likely primary teeth)

and

2. Confirm that permanent molars considered suitable for sealing (based on visual inspection), had no occult caries.

Radiographs can assist caries diagnosis in both primary and permanent teeth and are especially valuable to identify proximal lesions affecting broad contact areas between primary molars (51). A radiographic assessment is also recommended, when assessing a child for a dental GA, although this is not frequently done (155, 170, 245). Bite-wing radiographs can help identify dentine caries in permanent molars, especially occult lesions that might not be detectable on visual inspection, but they are less reliable for diagnosing early occlusal caries (234, 246). Furthermore, there appears to be no clear consensus on recommendations for radiographs prior to fissure sealing: the British Society of Paediatric Dentistry (BSPD) suggest sealants should be based on a "*thorough clinical examination, supported by radiographs, if appropriate*", and when there is "*real doubt about the caries status of a susceptible site*" (240). However, other key policies on sealants, fail to offer guidance on radiographic assessment prior to sealing (87, 92). Only 3 of the studies reviewed by Cochrane (85) include a radiographic assessment, which might also be difficult to implement as part of community based sealant programmes, such as those delivered in schools (18, 247).

Radiographs are not routinely taken as part of the GA assessment process at the BDH. The Paediatric GA exodontia service is delivered by the Oral Surgery Department and so there was an obligation for study procedures to comply with standard practice. Furthermore, by the time parents saw AR to discuss taking part in the pilot, GA extractions had already been treatment planned and consent obtained. It was therefore inappropriate to carry out a radiographic assessment (as part of the study) at this stage, especially if the findings were likely to impact on treatment plans that had already been agreed.

Irrespective of whether radiographs were available to evaluate the presence of early caries, a wealth of evidence now supports a non-restorative biological caries management approach, to seal early lesions or suspect fissures (51, 234, 248, 249). Sealants are less destructive than restorations and can slow down or even arrest progression of incipient lesions (87, 234). Non-cavitated occlusal carious lesions (including those with radio-lucencies extending in to one third of the depth of dentine) have also been shown to benefit from sealants (234), suggesting it may be permissible to inadvertently seal in caries that has not been identified on radiographs.

However, to achieve the most favourable outcomes using minimally invasive techniques, it is important to regularly review patients and maintain defective or suspect sealants (234, 249). Pilot participants were anticipated to be irregular attenders that might not return for on-going care. In view of this (and the fact that, for many, radiographs were not available to confirm the caries free status of teeth earmarked for sealing), strict criteria were employed to select teeth to seal as part of the pilot study: only surfaces deemed to be 'sound' (ICDAS score 0) on clinical examination, were sealed, and any with clinical signs of early caries (ICDAS 1, 2) were excluded.

6.5.1.5

Sealants procedures and acceptability:

Technique:

A standardised technique was used according to the type of material (resin or GIC) and all sealants were placed by a single operator (AR). This minimised scope for variations in operating conditions to influence the outcome.

Clinical techniques for resin sealants have been widely reviewed (87, 92, 234, 250) and include consideration of: the need for chairside assistance to facilitate moisture control, isolation techniques including use of rubber dam, cleaning surfaces prior to sealing, acid etch agent concentrations and etching times, and the use of bonding agents. Although most manufacturers recommend cleaning teeth prior to etching, there appears to be no difference in retention of sealants based on whether surfaces are polished using a handpiece or simply cleaned using a toothbrush (250). Furthermore, etching has been shown to remove plaque, so unless teeth are covered by excessive debris, there is no longer a need to clean teeth prior to sealing (234). Use of bonding agents to enhance retention, especially when moisture control is compromised, have been advocated (87, 234). However, this introduces an additional step in the procedure, which may be inappropriate for children that are already less compliant, suggesting a GI sealant might be more suitable (94, 234).

Sealant maintenance at 12 months:

Sealants should be regularly reviewed and maintained, with the frequency of recall intervals dependent on a child's caries risk (55, 96, 251). Bearing this in mind, there would have been an expectation for defective sealants to be replenished or replaced at the 12-

month reviews. However, this was not done, as it was important to evaluate outcomes when children were subject to current levels of preventive support by referring practitioners in primary care, and without any further interventions in secondary care. Obviously, active caries if identified, was managed accordingly.

Caries risk for teeth with defective sealants is considered to be no greater than for those that have never been sealed (234, 252), which helps justify the decision not to replenish defective sealants at the 12 month review. Understandably, there might be concerns about inadequate sealants trapping cariogenic plaque and making surfaces more prone to caries. However, a systematic review to compare the risk of caries in teeth that have lost some or all sealant, with those that have never had sealants, found the caries risk after 4 years, in teeth with defective sealants, was less than or equal to those that had never been sealed (252). This suggests, sealants should still be provided, even when patients are not expected to return for on-going care and maintenance (87, 234, 250).

Sealant acceptability:

A range of scales can be used to assess dental anxiety in children, but a review on these concluded, there was no single 'gold standard' measure, to fulfil the criteria for an 'ideal scale', based on validity, reliability and versatility (253). The 'Modified Child Dental Anxiety Scale' (MCDAS), is designed to evaluate children's perceptions on a set of dental procedures (254): children respond to questions relating to specific dental interventions, by selecting a score of 1 (relaxed or not worried) to 5 (extremely worried), based on the level of anxiety perceived: the faces version of the MCDAS assigns faces to the numerical scores (254).

However, the Facial image scale (FIS) (255), might be more appropriate when assessing a child's anxiety in relation to a specific type of treatment or intervention, particularly if responses are recorded, immediately before and then following treatment. The FIS is a valid measure for assessing dental anxiety in a broad age range of children and is simple and quick to administer (255). Children choose a face from a 3 or 5 point scale: using only 3 faces (with a neutral response in the middle), has been recommended, especially for very young children, (253) but a 5 point scale, was used for the pilot study to cater for the wider age group.

Chestnutt *et al*. also used a FIS to assess children's response to sealants, along with recording adverse reactions (such as crying and gagging) and parents perceptions on the procedure (242). Another study reporting on acceptability of fissure sealants used questionnaires to investigate children's views on 5 specific aspects of the sealant experience including, how easy the procedure was, the taste, how sealants felt, was the procedure explained and would they be happy to have it done again (256). Similar depth of detail was inappropriate for the pilot study, especially as children had already undergone their GA assessment on the same appointment.

However, to augment assessment of sealant acceptability, the time required to apply sealants was also recorded, as well as the material/ technique used, with GI signifying patient compliance was poor. Only molars that were fully or adequately erupted were included in the study, so use of GI sealants was based on the child's co-operation, as opposed to problems achieving moisture control for partially erupted teeth.

On reflection, it would have been useful to also measure dental anxiety amongst children in the control group, to provide a comparison of baseline dental anxiety levels between both groups and this would be recommended for a future trial. In this case, anxiety should be assessed before randomisation, as the prospect of having treatment might lead to heightened anxiety levels for children in the sealant group.

6.5.1.6

Follow-up questionnaires:

The main objective of the structured interview questionnaire (at the 12- and 24-month reviews), was to evaluate parents' experiences of dental services for their children, and investigate oral health support provided by referring practitioners, following the GA extractions.

The key areas explored were:

- Dental attendance patterns
- Barriers to seeking dental care
- Support offered by primary care dental providers to facilitate regular check-ups and attendance
- Delivery of oral health advice, preventive interventions and dental treatment
- Reported dental anxiety and support provided to manage this

  and,
- Parents' opinions on measures to help them access dental care for their child and look after their teeth

A combination of open and mostly, closed questions were used, and where appropriate, children were actively encouraged to contribute to discussions, as previous research suggests responses from children can be valid and reliable (257, 258). Tailored questions

were used, to address specific objectives, and so there were no pre-existing validated tools to refer to, other than a similar assessment by Olley *et al*., in London (6). Some questions evolved from the questionnaire that was used for the two-year post GA service evaluation (Study B) and others were loosely based on themes reported in similar studies (6, 7, 42), as this would facilitate comparisons with previous research in this area. Patterns of dental attendance reflected categories used for the UK CDHS, to provide an insight on how the study sample relates to the national picture (144). However, key priorities were to establish how soon children returned to see a dentist after the GA extractions, and thereafter, the frequency of on-going review appointments, given that high-risk children should be seen more regularly (50, 51, 55). Both questionnaires (12 and 24 month) were very similar, but the latter was more comprehensive.

Unfortunately, it was not feasible to pilot the questionnaire, with parents of children that had previously had a dental GA, as it was not standard practice to see these families again for a review. However, a small group (n=11) of parents were invited to feedback on the lay-out and clarity of the questions: 5 were parents of children attending for GA extractions and the remainder were being seen for routine dental appointments in the Paediatric Department. Further to consultation, only minor revisions were required, most notably, related to simplifying some of the terminology.

6.5.1.7

Oral health related Quality of Life evaluation:

There is now wide recognition that health can no longer be defined simply as ‘the absence of disease’, but instead refers to “a complete state of physical, mental, and social well-being” (259)

Health and equally, oral health, can impact on quality of life and oral health related quality of life (OHRQoL) has thus been described as, "*a standard of the oral tissues, which contributes to overall physical, psychological and social well-being, by enabling individuals to eat, communicate and socialise, without discomfort, embarrassment or distress and which enables them to fully participate in their chosen social roles*" (260).

OHRQoL tools are now widely used in oral health research, including studies involving children and have also been used to investigate the impact that dental treatment under GA might have on children and their families (129-132). Assessment of a child's OHRQoL can be based on direct child reported measures or proxy outcomes as reported by parents' evaluations of the impact of poor health on their child's well-being. However, a recent systematic review on changes in children's OHRQoL following caries rehabilitation under GA, found that only one study involved child-reported assessments, whereas all others relied on the views of parents (131). The impact of a child's oral health and treatment under GA, on other family members has also been assessed using measures such as the Family Impact Scale (260).

The proposal to measure OHRQoL as part of the pilot study, was only introduced at the two-year follow up and ethics approval (for a substantial amendment) was obtained, prior to implementing this change. Clearly, it would have been more valuable to have also assessed this at baseline, so any changes in OHRQol following the GA could be compared and this would be a recommendation for a definitive trial. Despite this, any differences between control and sealant groups after the GA could be measured and this also allowed us to assess feasibility of using an OHRQoL tool in this particular cohort.

Several OHRQoL tools have been designed and validated for use specifically for children and these include the Child Perception Questionnaire (CPQ), the Early Childhood Oral Health Impact Score (ECOHIS), Pediatric Oral Health-Related Quality of Life (POQL), Child Oral Impacts on Daily Performances (Child-OIDP), and the Child Oral Health Impact Profile (COHIP) (258). An account of the available measures is beyond the scope of this thesis, and in any case, reviews of the most widely used instruments are readily available Genderson *et al*. (258).

Employing an existing validated scale and preferably one that had been widely used in previous studies, was deemed most appropriate, so based on the sample age-group, the most appropriate options were the CPQ or Child-OIDP (258). Further to seeking advice from Dr. Georgios Tsakos (University College Hospital, London), the Child-OIDP was employed, on the basis that this is a widely used self-reported measure, which has been validated for use in children in the UK and importantly, was also used for the most recent Child Dental Health Survey (34, 235, 236).

The Child-OIDP records the severity of the negative impact of oral conditions on 8 key aspects of children's daily living, over the preceding 3 months: these include difficulties with eating, speaking, cleaning teeth, smiling, relaxing, emotional stability, completing schoolwork and social interaction. For each of these aspects of daily living, the options available are, '*not at all', 'a little', 'a fair amount'* or *'a lot'* (34, 235, 236).
Furthermore, as recommended by Dr Tsakos, two other measures were included, to mirror the OHRQoL evaluation used in the national CDHS (34):

First, children were asked to respond to a global rating (single item) question on OHRQoL, to assess the overall impact that oral conditions might have had on their daily life, by asking:

"In the past 3 months, how much did the condition of your teeth and mouth affect your everyday life?"

Possible responses for each option were*: not at all, a little, somewhat, a fair amount* or *a great deal.*

and

Second, in terms of specific oral symptoms*:*

"In the past 3 months have you had: toothache, a sensitive tooth, bleeding or swollen gums, a broken tooth, mouth ulcers or bad breath?"

Responses for each option were *'yes'* or *'no'.*

6.5.1.8

Clinical Outcome measures:

The two main clinical outcome measures: two-year caries incidence in permanent molars that were caries free at the time of the GA extractions, and retention of sealants applied, were analogous to measures adopted by many other sealant trials (85).

The 2 year follow up time-scale was selected further to careful consideration of longer and shorter periods: whilst studies with longer follow up periods can be expected to provide a more robust evaluation of the caries preventive effect of sealants, these also run the risk of higher drop-out rates and so a balance must be achieved. Many previous sealant trials have also opted for a 2 year follow up period (85). Berry *et al*., reporting on the effectiveness of different recall frequencies to prevent caries relapse in children following GA, recommend

a two-year follow up period would be ‘ideal’, to evaluate interventions in this cohort (196), which is also the interval proposed by the RECUR trial (11).

6.5.1.9

Incentives to enhance recruitment and retention of participants:

Incentives, such as travel expenses or shopping vouchers can be used to encourage people to take part (and remain) in trials (10, 11, 196, 213). At the outset, this was not deemed necessary, especially as financial rewards were not reported to be important amongst parents responding to questions on incentives, in the baseline evaluation (page 105). Furthermore, families that agreed to take part were anticipated to benefit from:

- A 1 in 2 chance of having sealants applied at the GA assessment
- A review after 12 and 24 months with the opportunity to have treatment on student clinics

  and
- Preventive interventions (including fluoride varnish and sealants, if appropriate), at the 24 month review.

However, by the 24-month reviews, the BDH had moved to a new site (away from the City Centre), so an incentive to help reimburse travel expenses was now justified.

6.5.2

Discussion of results:

6.5.2.1

Recruitment and retention:

It was encouraging that only a fifth of exclusions at the outset, related to parents declining to take part in a study, whilst most were due to time constraints on the day. Delays were related to the fact that only one investigator was recruiting families and providing the intervention, which calls for multiple examiners and operators in any future trials. In a trial investigating an oral health education video for high-risk children, one third of parents refused to take part: this was also related to the fact that recruitment was being carried out by a single researcher but language difficulties were another factor (10): these were not a barrier for the pilot study, because where necessary, interpreters were available to translate for the GA assessment. The uptake was higher than anticipated according to the baseline service evaluation (Study A), when only half of parents said they would be happy for their child to be involved in a study.

The retention rate (of 82% after two years), also compares favourably with other trials involving high-risk participants, which are reported to be low as 10% after a period of only 3 months (7). Furthermore, any loss to follow-up was mostly related to problems with contacting families, as opposed to families dropping out. A study in the US highlights difficulties associated with contacting patients several years after a dental GA and found that only a quarter responded to a postal survey (186): however, unlike the pilot study, no incentives were offered, and families were not expecting to be contacted, which might help explain the poor returns. Higher retention rates have been reported for clinical trials on

fissure sealants (85), but many of these are likely to involve participants that are lower risk and potentially more reliable.

Parents had been offered the opportunity to attend reviews at a Community Dental Clinic, especially in view of anticipated difficulties to travel to the new Dental Hospital, which was outside of the City Centre: the clinic was close to an acute general hospital and served by good public transport links. However, most parents opted to be seen at the Dental Hospital, suggesting the Community site might only have been convenient for families living close to that clinic. The impact of shopping vouchers is debatable: clearly, financial incentives had no influence on recruitment or on attendance at the 12 month follow ups, (which was comparable to the 24 month reviews), as at that stage, no vouchers were provided. However, appointment letters for 24 month reviews did notify parents that shopping vouchers would be given to families that attend, suggesting these may have influenced attendance at this stage.

Nevertheless, it is important to recognise that almost one fifth (18%) of participants were lost to the 2 year follow-up, so the children seen might not be representative of the entire group. This said, the groups that did and did not return for the 2 year review were in most respects, comparable.

6.5.2.2

Demographic characteristics of study group:

Children under 5 years were excluded, so direct comparison with National statistics or local studies might not be appropriate, especially because some others also involve specific age groups (10, 42). Despite this, the group under investigation was analogous to the

cohort observed in our earlier service evaluation (Study A), which in turn was representative of the wider population of children attending for dental GA in the UK (2, 6, 7, 118, 147). Most children were clustered within the 6 to 8 year bracket, again supporting the national picture (2) and importantly, reinforcing the fact that these are the age group most likely to benefit from sealants.

The ethnic profile reflects the general ethnic pattern of school children in Birmingham (211). As a joint ethnic group, the highest proportion (45%) of children recruited to the pilot study were from an Asian background (mostly Pakistani), followed by White (mostly British) accounting for 30%. As discussed previously, this could simply be demonstrative of the multi-cultural profile of the local population, but it might also reflect differences in caries levels between varying ethnic groups (261). Inequalities in caries experience might be attributable to cultural differences in oral health related behaviours, with higher levels of disease reported in children from South East Asia (23, 262). Among 5 year olds in the UK, highest levels of caries prevalence and severity were found in Chinese children, followed by those from an Eastern European and Asian background (19, 25). Other studies report a variety of ethnic profiles for children attending for dental GA, reflecting the diverse and dynamic demographics of the catchment area (6, 7, 118). For the pilot study, significantly more Asian children returned for follow up, which again mirrored findings from our service evaluation in 2014 (Study B). This contradicts traditional perceptions of poor attendance within ethnic minority families (216), and as discussed earlier, might be indicative of changing dental health behaviours amongst younger generations.

Post code data were used to calculate IMD scores, which are based on a variety of socio-economic factors, including income, employment, education, housing and health (263).

Levels of deprivation were high and again, corroborate findings from earlier evaluations, as well as other evidence, suggesting children from deprived areas are more likely to receive a dental GA (144-147, 261). Karki *et al*. found over two thirds of children needing a dental GA in Cardiff, lived in areas classified as being in the two most deprived quintiles (42) and a recent study in Wolverhampton found that 70% of 2 to 3 year olds referred for GA, were living in the two poorest deciles (261). Nine per cent of pilot study participants fell within the more affluent half of society, supporting the fact that children from wealthier backgrounds are not immune to a dental GA (47).

6.5.2.3

Previous experience of dental GA:

Twelve percent of the baseline sample had previous experience of a dental GA, which corroborates the 10% repeat rate reported in the baseline service evaluation two years earlier (Study A): this is similar to some other UK hospitals (169, 170) and favourable compared to others, reporting rates as high as 37% (171). Clearly, several factors impact on levels of repeat GA, including the demographic background of the local population, caries prevalence of children in the catchment area, as well as variations in the type of service delivered (119, 171). It was encouraging that none of the children followed up had required a further GA during the two-year study period, although one child was scheduled for a repeat GA after the 24 month review.

6.5.2.4

Referral source and plans for follow-up after GA:

All children were registered with a primary care dentist, mostly (95%) a GDP. However, registration alone does not imply regular attendance, so in hindsight, it would have been helpful to obtain more information, at the time of recruitment, about frequency of attendance. A higher proportion of referrals had been made via the CDS (than would be expected from the numbers that were apparently registered with a CDP), suggesting that some of the CDS referrals represented secondary referral (for a GA), for patients that had originally been referred to the CDS by local GDPs. Incidentally, Birmingham CDS (and related services in Sandwell, Dudley and Walsall) also provides a paediatric dental GA service (delivered through regional general hospitals), separate to the service at the BDH.

Initial assessment in the CDS provides an opportunity to explore other options for delivery of treatment, such as conscious sedation (264), as well as to deliver enhanced preventive advice and interventions. This stage of the GA care pathway justifies further exploration and has been subject to a recent review of service delivery and development within the CDS, which recommends closer collaboration between the BDH and CDS (231).

Most children had no scheduled follow-up appointment to see their dentist after the GA, though this does not strictly imply that arrangements were not in place to recall these patients: according to our investigation on referring practitioners' views and practices for prevention (Chapter 5), only 17% reported 'booking' appointments to review children after the GA, but a further 40% advised parents to contact the practice to arrange a review, which was often within 3 months.

6.5.2.5

Radiographic assessment:

Reasons for not taking radiographs as part of the pilot study were discussed earlier. It has been suggested that anxious children might lack compliance for radiographs but a study involving children requiring GA extractions, found only a tenth experienced any difficulty (127).

At baseline, radiographs were only available for around 20% of participants: notably, for twice as many children in the sealant group compared to controls. It is difficult to speculate on the reasons for this difference, though it cannot be attributed directly to the study given that radiographs had been taken prior to recruitment. In any case, increased access to radiographs for children in the intervention group was particularly helpful, to exclude the possibility of occult caries in teeth that were earmarked for sealing (234).

6.5.2.6

Examiner training, calibration and reliability:

The pilot study examiner (AR) calibrated against a recognised examiner (KC), using clinical photos that had been taken as part of the study. Other researchers (reporting on retention rates of fissure sealants placed under GA) have also used photos to evaluate inter and intra-examiner reproducibility (207). KC was not able to score on the ICDAS caries code of 1 (on the basis that most photos were of teeth that had not been dried). Furthermore, KC was experienced in undertaking epidemiological dental health surveys, so it was recognised that she might under-score compared to the clinical scores recorded by AR. Assessment of intra-examiner variability (for AR), was based on comparing clinical

scores, with those recorded by examining photos, so some degree of variation was again expected.

Notwithstanding limitations in the calibration exercise, high levels of inter and intra-examiner agreement were observed. The lowest kappa scores applied to inter-examiner agreement for the full range of caries codes (0 to 6), but this was not surprising, given the difficulties rating scores 1 and 2 using photos, due to (as mentioned earlier) not being able to dry teeth. Reported levels of agreement were comparable to those recorded in the latest UK CDHS (238) and many of the sealant trials included in the most recent Cochrane review (85).

6.5.2.7

Prevalence of caries at baseline:

6.5.2.7.1

Caries primary dentition:

The mean number of teeth extracted in each child was 3.8 and most were primary teeth: this compares with 4.2 teeth in a retrospective investigation of children undergoing GA exodontias in Leeds (169) and 3.1 in a similar analysis in Wolverhampton (118). Caries affecting the primary dentition is a well-established predictor of caries in permanent teeth (11, 38), which signifies a need for enhanced prevention to protect the secondary dentition (50, 51).

6.5.2.7.2

Caries permanent dentition:

At baseline, six percent of the sample already had experience of caries into dentine in a permanent molar, which support recommendations to prioritise use of sealants in this cohort (11, 203). However, caution is required on trying to compare baseline disease levels in the group under study, with reported caries prevalence in permanent teeth, on a national scale (or with any other studies), because children recruited did not represent all patients referred for a dental GA: children with experience of caries in all permanent molars were excluded, so caries prevalence in the permanent dentition in the study sample can be expected to be lower than the overall group referred for GA.

Our service evaluation in 2012, did provide some measure of experience of dentine caries in first permanent molars amongst children attending for a dental GA (Study A): despite the bespoke codes used, the proportion of children affected (10.2%) was as predicted, slightly higher compared to the pilot RCT sample. This said, a child's experience of dentine caries in a permanent molar (6%) in the pilot sample, was actually very similar (5.7) to baseline levels reported in Chestnutt *et al*.'s, trial to compare sealants and fluoride varnish (110).

6.5.2.8

Sealants and 'sealable' molars at baseline:

It was disappointing that none of the children taking part in the study already had sealants and none of the exclusions were related to '*pre-existing sealants on all FPMs'*. This substantiates the low use of sealants reported in earlier service evaluations.

Clearly, providing sealants as part of the GA encounter, would be most effective if all four first permanent molars can be sealed at the same time and 81% of the sample did have four 'sealable' molars. Obviously, in younger children, teeth that erupt after the GA will remain susceptible, so this calls for measures to secure on-going care after the GA. One option is closer collaboration with primary care practitioners, possibly by including a request in discharge letters, for referring dentists to provide sealants once further teeth erupt.

6.5.2.9

Comparison of Baseline characteristics: Follow-up at 24 months versus no follow-up at 24 months:

Both groups were generally comparable, but a relatively higher proportion of girls, and children from an Asian background, attended the follow-up appointment. Children from the most deprived backgrounds were also better represented in the group that returned for follow-up, though the difference was not statistically significant. This again, supports observations from the service evaluation exercise (Study B). Further to that, it is interesting to note that, researchers reporting on GA exodontias in Helsinki, found that 'immigrants' attended the postoperative review visit more often than 'non-immigrants' (188).

However, patients not seen for follow-up had higher baseline levels of experience of dentine caries affecting their permanent dentition (P = 0.035). This suggests decay rates reported at 24 months could be expected to be even higher if these children had been seen. Given that irregular attenders are more likely to experience caries relapse following a GA (181, 187), as well as requiring a repeat GA (169), reducing the risk of further caries in this sub-group, is obviously the greatest challenge.

6.5.2.10

Sealant acceptability (intervention group):

Using three separate methods to assess 'acceptability' of sealants, it was clear that the procedure was generally well received by most children. Only one child (out of 50) failed to comply and most demonstrated adequate compliance for technically challenging resin sealants. The average time required to seal four molars (approximately 20 minutes) was, in the experience of the operator, comparable to the normal time needed to place four sealants in a relatively co-operative patient. The most relevant and reliable measure of acceptability from the patients' perspective was based on the FIS scores selected by children, which again suggested, the intervention was generally well received.

Importantly, levels of compliance observed in the pilot sample, were higher than expected, given these children had been referred for dental treatment under GA. A study in Sheffield also found that most children coped well with sealants despite anticipated difficulties related to increased anxiety (256). Not forsaking the fact that extractions are obviously more challenging than sealants, this does suggest that some patients might not require a GA for extractions and may manage to have treatment with conscious sedation or possibly only LA (with appropriate behaviour management techniques). This calls for an appraisal

of the assessment process and care pathway for children referred for GA, to ensure all other alternatives are considered (264-266).

6.5.2.11

Follow-up - 24 months:

6.5.2.11.1

Sealants present at 24 months:

Sealants identified in the control group at follow-up, serve as the most appropriate measure of the overall prevalence of sealants, in high risk children that have experienced a dental GA. On this basis, 12% had at least one sealant after 2 years, (which were assumed to have been placed in primary care) and compares with 5% amongst children that were reviewed 2 years after their GA, in the earlier service evaluation (Study B).

Interestingly, the control group had more sealants at follow-up, compared to when they were recruited on the study. Several reasons might help explain why more sealants were apparently provided after the GA: children will be older and so potentially more compliant, though one could also argue that some may be more anxious as a result of the GA experience. Also, some parents might be prompted to ask their 'family dentist' about having sealants, as a result of increased awareness of the procedure, due to taking part in the study.

Sealant rates in the pilot sample are slightly higher than the national average (7% of 8 year olds in England) (204) but are still low, considering the group under study are at high risk

of caries. Other studies also suggest low use of sealants for vulnerable children: Albadri *et al*., found only 5% of children with first permanent molars earmarked for caries related extraction, had evidence of sealants (203).

Retention rates for sealants applied as part of the study, were analogous to those reported in other sealant trials: in the latest review by Cochrane, 80% complete retention at 24 months, was recorded for 7 out of 10 studies (85). Outcomes similar to our pilot were reported in Chestnutt *et al*.'s study to compare sealants versus fluoride varnish, but the follow-up period was longer (36 months) (110). Given that many sealant effectiveness studies are based on sealants on occlusal surfaces, there is a possibility that the relatively high retention rates observed in the pilot, could reflect better retention relating to sealants placed on buccal pits and palatal fissures. In the operator's experience, these surfaces are comparatively easier to seal and so more likely to be retained. To exclude any potential bias related to this, retention rates for occlusal, buccal and palatal surfaces were reported on separately, which showed similar levels of retention for all three.

Results serve to confirm recognised poor retention of glass ionomer sealants, when compared to their resin counterparts, although improvements have been reported, since the introduction of higher viscosity GI materials (94). However, it is important to recognise that sealant retention is only a "*surrogate endpoint*" (94, 234), whilst the true effectiveness of sealants is more usefully measured by their scope to prevent caries and in this respect, GI might be equally beneficial as resin (85, 94, 234).

Sealants provided as part of the study, appeared to be of a higher standard, compared to sealants placed in primary care (i.e. those identified in the control group). However, direct

comparisons may be inappropriate, as operating conditions (including patient co-operation), for sealants provided in primary care are not known. Furthermore, there is a possibility that sealants placed as part of the trial might have been replenished or replaced by outside practitioners, though this seems unlikely, given that only one parent in the intervention group could recall sealants being provided in primary care.

6.5.2.11.2:

Caries prevalence in permanent molars at 24 months:

As explained earlier (6.3.5.7), this was a pilot study and thus P values that have been reported to compare outcomes should be interpreted with caution. Clearly, the number of observations were also provided to enable any estimate of effect to be inferred within the context of this being a pilot study.

Keeping this in mind, at 24 months, there were significant differences in caries experience in permanent molars, between the intervention and control groups. This was observed in the subset of permanent molars that were present and sound at baseline but also apparent when including molars that had experience of dentine caries at baseline or had erupted during the 2-year study period.

Five percent (n=2) of children in the sealant arm had untreated caries in at least one permanent molar at 24 months, which was caries that had previously been identified at baseline. Clearly, any failure to treat caries during the 2-year study period could be related to the possibility that patients had not returned to see their dentist. However, according to parents, the 2 children affected had seen a dentist following the GA and neither were unduly anxious, suggesting apparent failures in providing treatment, as opposed to parents not seeking care.

Nine percent of 8 year olds in the UK (8% in England) have a permanent tooth/ teeth with untreated dentine caries (28, 29). At 24 months, a third of children in the control group had untreated dentine caries in at least one permanent molar that was caries free at baseline (compared to none in the sealant group). These findings demonstrate the very high-risk of caries in children experiencing a dental GA and highlight the potential benefits achievable through sealants. It is also worth noting that caries levels identified were identical to those observed in the 2 year post GA service evaluation (Study B). Similar decay rates have also been observed in other studies reporting on caries prevalence in high-risk children (11), with a study in Wales suggesting 40% had caries in at least one first permanent molar by the age of 10 (216). Not surprisingly, our results confirmed that occlusal surfaces of permanent molars were most vulnerable to caries (199, 200).

Based on Cochrane reviews, resin sealants applied to first permanent molars in children aged 5 to 10 years, could be expected to reduce a 2-year caries incidence of 40%, down to 6.3% (85). However, no new caries in dentine was identified in the intervention group, suggesting the benefits achieved surpassed the best that could have been forecast. Whilst this outcome was very encouraging, caution is required before making recommendations on the generalisability of these findings, given that this was a pilot study and also that equally high success rates might not be as readily achievable in less favourable non-study operating conditions. The quality of sealants and overall outcomes are presumed, in part, to be related to the clinical skill and experience of the operator (AR), especially in providing sealants for less co-operative children.

On evaluating the prevalence of 'any' caries at 24 months (which includes earlier stages of caries, confined to enamel), it became apparent that the sealant group were not completely un-susceptible to caries, as on this basis, there was no significant difference in the proportion of children in each group, with early lesions affecting enamel. Almost two-thirds of 15 years olds examined as part of the 2013 UK CDHS presented with caries into enamel, highlighting a need to ensure these early lesions are not allowed to progress (20). Sealants have been shown to slow down or even arrest incipient lesions and so, a maintenance programme, involving replacement of defective sealants, along with sealing new early lesions, would be most appropriate (87, 234). Fourteen percent of children in the control group had evidence of 'severe' caries (ICDAS codes 5, 6) affecting a permanent molar, which compares with 15% of 15 year olds nationally (20). The extent of severe disease in the pilot sample was of concern, especially because the children affected were younger (mean age 9 years).

6.5.2.11.3

Caries prevalence in primary teeth at 24 months:

Though caries levels in the primary dentition were higher in the control group compared to the sealant group, these differences were not statistically significant. This suggests children in both groups were at comparable risk of caries and so it follows that rates of decay in permanent molars in the intervention group, could have been expected to be similar to the control group, if they had not been sealed.

In primary molars, interproximal surfaces have been shown to be more vulnerable, with pit and fissure caries only accounting for around 40% of the total caries experience (103).

However, within the pilot sample, two-thirds of caries in primary molars affected occlusal, buccal or palatal surfaces, suggesting these surfaces could also be sealed.

6.5.2.11.4

Oral symptoms and OHRQoL two years after dental GA:

Clearly, it would have been more useful to assess OHRQoL at baseline, as well as at follow up, to compare any changes resulting from dental treatment under GA and so, it might be inappropriate to compare our findings against studies that report on changes in OHRQoL, associated with dental rehabilitation under GA (131). However, evaluating OHRQol post GA still serves to assess the feasibility of using an OHRQoL tool in this particular study group and helps to provide an insight into any differences in oral symptoms and impacts, based on demographic characteristics and according to whether children had sealants. It would also be appropriate to compare pilot data on OHRQoL with the latest CDHS (which used similar tools) (34), to help identify differences between high-risk children and the general population. Clearly, for future trials, pre and post GA assessment of OHRQoL would be recommended, to better demonstrate changes as a result of the GA experience.

The mean age of children surveyed for the pilot sample was 9.7 years: the prevalence of experiencing at least one oral symptom was high (87%) compared to the national picture, where 55% of 8 year olds reported oral symptoms in the last 6 months (34). Sensitivity, bad breath, and bleeding or swollen gums were most frequently reported by pilot study participants, compared to toothache, other pain in the mouth and bad breath, in the national survey (34). The higher prevalence of bleeding or swollen gums might reflect poorer levels of oral hygiene in the study group and in hindsight, an assessment of plaque scores at

follow up might have been helpful. The CDHS reported more pain related problems amongst children from the lowest socio-economic groups: in contrast to this, lower levels of sensitivity were reported by pilot participants from the most deprived backgrounds. However, the sealant group were more likely to report sensitivity, which was also surprising, given that caries rates were clearly lower in the intervention group and sealed teeth could be expected to be less sensitive. However, reported sensitivity could also be related to other causes, including non-carious tooth surface loss, such as erosion.

Approximately half (52%) of the pilot group reported an adverse impact of oral conditions on their quality of life, which was comparable to the prevalence found in 12 and 15-year olds nationally (34). Overall, physical impacts, such as difficulty eating were common, but '*feeling different, irritated or upset because of teeth*' was also frequent, highlighting the impact that poor oral health can have on a child's psychological and social well-being. Children in the National survey were older than the pilot sample, which might help explain why they were more likely to '*feel embarrassed to smile or laugh*' because of their teeth. Higher prevalence of negative impacts of oral conditions on quality of life, were observed in children from poorest backgrounds, which serves to reinforce nationally recognised inequalities associated with deprivation (34).

6.5.2.11.5

Oral health behaviours and experience of dental services following GA - questionnaire strengths and limitations:

Limitations associated with self-reported data are widely recognised. Respondents might feel obliged to offer responses they believe to be correct and desirable; some might not fully understand the questions and/ or struggle to remember information, especially when this dates back over two years. However, the questionnaire was administered by the study lead (AR) who was able to explain any terms, especially relating to different types of dental treatment. Karki *et al*., reporting on the preventive needs of children requiring a dental GA in Wales, suggested self-reported data should be verified by checking against GDS records, although this was beyond the scope of their study (42). Goodwin *et al*., exploring differences in GA service delivery in the North West of England, did attempt to collect information from both sources, but found that dental referral notes were frequently inadequate and could not be used to validate parents' responses (119). For the pilot study, data on provision of sealants, was verified by equating parents' answers with clinical data (collected as part of the study), based on which, there appeared to be good agreement from both sources.

All parents attending the 2-year follow-up completed questionnaires, representing 82% of the original sample. Given the high-risk study group, this is encouraging and compares favourably with some other studies, involving a similar cohort (7, 186). Other surveys have achieved higher response rates, though these mostly relate to on spec interviews and/ or questionnaires, delivered at GA assessment appointments, instead of relying on families to return for follow-up (6, 42). Nevertheless, it is still important to recognise that the parents surveyed (n = 82) might hold very different opinions to those (n = 18) that were not seen.

Finally, where appropriate, children were also encouraged to contribute to the questionnaire: in hindsight, their responses could have been recorded separately, but this said, most children were not actively involved. This supports findings from another study on evaluating experiences of a dental GA, which found that many parents didn't want their child to answer questions and when they did agree, very few children elected to take part (136).

6.5.2.11.6

Dental attendance patterns:

Overall, 81% reported that their child had a check-up at least once a year before the GA, which is higher than levels reported (73%) in the baseline service evaluation in 2012 (Study A). For the pilot study, categories for frequency of dental check-ups were simplified (to 'at least once a year' and 'less than once a year'), to facilitate comparison with the 2013 UK CDHS (144). On this basis, the proportion seeing a dentist for check-ups (as opposed to only when having trouble) was similar to the general population (27) and higher compared to levels reported for other vulnerable children: 67% of children experiencing a dental GA in Wales were reported to have yearly checks (42), whilst 40% of a similar cohort in London only attended if having trouble (6). Children in the sealant group were more likely to have an annual check-up, suggesting these families might be better motivated with more favourable oral health behaviours, but the difference was small and not statistically significant.

Eighty five percent of respondents, had taken their child back to see a dentist within two years of the GA, and given that all were previously registered with a dentist, this supports

claims suggesting that patients are more likely to return for post-operative care if they have a 'dental home' (191). No single reason stood out for those that failed to attend, although '*no dental problems*' and '*not being sent for*', were frequently cited. Some failed to attend due to time off school: previous studies report poorer attendance amongst school-aged children compared to younger age groups (195), which reinforces the value of taking advantage of the GA encounter, to provide sealants. Overall, 15% (n = 12) had not received any dental follow-up since the GA, which is of concern, given their high-risk of experiencing further disease and points to a need for increased efforts by primary care practitioners to facilitate and support attendance.

Among the small number that registered with a different practice after the GA, it was interesting to find that (according to parents), all 'new' dentists for children in the sealant group, were, apparently aware of the child's experience of a dental GA, compared to only 38% in the control group. This is hard to explain so, on reflection, it would have been useful to ask parents '*how the new dentist had become aware of the child's GA experience*', and to also find out why they had changed dentists.

At baseline, most children had no scheduled follow-up appointment, to see their dentist after the GA, which supports findings from the preliminary service evaluation in 2012 (Study A). As discussed earlier, this does not imply that arrangements had not been made to recall these children. Leading on from this, it was interesting that a fifth of those followed up at 2 years, had in fact, seen a dentist within 3 months of the GA. This supports responses from referring practitioners in the survey on follow-up practices after a GA, which found that more than half had systems in place to review patients after the GA but less than a fifth booked follow-up appointments at the time of referral (page 145). This also

highlights shortfalls in data collected at baseline, in that simply asking parents about 'pre-booked' review appointments after the GA, gave limited information on follow-up procedures that might actually be in place.

Around half of the sample received contact us letters to prompt them to book a recall and a higher proportion (almost two-thirds) received appointment reminders. However, relying on parents of at-risk children, to arrange timely reviews is at best, optimistic, whereas action by dentists to schedule visits and follow-up those that do not attend would seem more appropriate. Children in the control group were more likely to be sent appointments (instead of contact-us letters), as well as reminders, possibly reflecting increased efforts on the part of practitioners, to target children at greatest risk.

6.5.2.11.7

Prevention delivered following GA by providers outside the study:

For children that had seen a dentist within 2 years of the GA, three-quarters had received oral hygiene instruction and two-thirds, dietary advice. According to the latest UK CDHS (144), 55% of 8 year olds in England, had received advice on oral care: whilst it is encouraging that the high-risk pilot sample were more likely to receive advice compared to the general population, up to a third were still missing out. Other studies evaluating preventive advice for children needing a dental GA, report similar levels of activity to the pilot sample, but these relate to advice offered before the GA, rather than on-going support after the extractions (6, 42).

Compared to our survey on referring dentists' practice on delivering prevention for high-risk children (Chapter 5), the parent questionnaire for the pilot RCT provided more detail

on the type of advice given. Observations support previous research, which suggests the content and quality of advice is often inadequate (6, 7, 42, 136, 221). Less than 10% of parents could recall advice about '*spit not rinse*' after brushing, which was considerably lower than the 29% reported by Karki *et al*. back in 2008 (42): this is disappointing given that (by 2016-17), practitioners would be expected to have increased awareness of the DBOH toolkit (50).

Failure of parents to remember specific advice does not necessarily imply this had not been given, but this in turn, clearly questions the value of advice alone, as a means of preventing caries. As discussed earlier, evidence supporting positive change in oral health behaviours through one to one counselling, is weak, with favourable outcomes reliant on several factors, including the quality of advice given, as well as the recipient's readiness to change (1, 48, 58, 71). Overall, only a tenth of parents believed their dentist had highlighted the importance of prevention, to reduce the chances of their child needing a repeat dental GA, suggesting practitioners need to be more forthright to ensure parents understand the risks associated with GA, along with what they can do to prevent new disease.

Provision of topical fluoride and fissure sealants was low, and confirmed levels reported elsewhere (6, 42). Less than 20% had received fluoride varnish and even fewer (7%) parents could recall their child having sealants. Parents' responses on sealants served to support findings from clinical data, which improves the reliability of findings, compared to some earlier studies (6, 42). Twenty seven percent of 8 year olds in England, are reported to have received 'preventive treatment to teeth' (144), so in this respect, high-risk children in the pilot study appear to be lagging behind their national counterparts, which is, not acceptable. Clearly, increased efforts are needed to target preventive treatments for high

risk children, given the stronger evidence base for these interventions, compared to oral health advice alone (1, 48, 50, 51, 63).

6.5.2.11.8

Dental treatment received in primary care following GA:

Overall, only 14% of children followed up, had radiographs taken in primary care during the 2 years since their GA. This confirms low use of radiography for caries diagnosis in children in GDP in the UK (245, 246) and fails to meet guidelines recommending shorter intervals to aid caries assessment in high risk children (51, 177). Almost a third had received fillings, which was similar to levels of restorative treatment reported by parents in the national survey (144). A higher proportion of control group children had undergone radiographs, as well as restorations, reflecting higher decay rates in this group.

Amongst children that had received fillings or extractions, only 30% could recall having a local anaesthetic. It would be inappropriate to speculate on clinical circumstances, which would determine the need for LA, as this would be influenced by the type of restoration, as well as the child's compliance. However, practitioners' level of skill and experience might also impact on the use of LA, with studies showing that GDPs, when compared to paediatric dentists, are less likely to use LA in children (267). Also, high stress levels have been reported by dentists administering LA to young or anxious children (268).

6.5.2.11.9

Dental anxiety post GA:

According to parents, 40% of children expressed anxiety about visiting a dentist. Many felt their dentist had offered help to address their child's anxiety, but in most cases, this was limited to behaviour management techniques. No GDPs had offered to provide sedation, but a quarter had referred patients to the CDS, where for some, treatment with inhalation sedation had been carried out. These figures compare with 6% of parents of 8 year olds in England, reporting use of sedation for their child's dental treatment (144).

However, latest guidelines on 'Standards for conscious sedation in provision of dental care' (176), include additional recommendations, which could potentially further reduce availability of sedation services in GDS. The importance of on-going acclimatisation and behaviour management for children after a dental GA are well recognised (188). Shared care between GDPs and CDSs could help achieve the best possible outcomes, by providing routine care (including enhanced prevention and acclimatisation) at local practices, supported where necessary, by the opportunity for treatment under sedation in specialised services with appropriate facilities (142, 231).

As explained earlier, it would have been useful to assess baseline levels of dental anxiety, for all children in the study (instead of only the sealant group), so the post GA evaluation, helps in some way, to address this limitation. At baseline, most children in the intervention group were not unduly anxious and were compliant to have sealants. In contrast, 40% of parents at the 2 year follow up described their child as being anxious about visiting a dentist, with no significant differences between the control or sealant groups. Several reasons might explain the apparent heightened levels of anxiety reported after the GA: post

GA anxiety was based on parents' perceptions of their child's anxiety (as opposed to self-reporting by children), so parents' might hold different opinions on their child's compliance. Also, some children might be more anxious in a GDP setting (compared to when they were seen in the Hospital Paediatric Department) or may have become more fearful as a result of the GA experience.

6.5.2.11.10

Parents views on advice and interventions to support oral health:

Only two-thirds of parents welcomed further advice on how to look after their child's teeth, suggesting the remainder were either confident with what they already knew and/ or they were not concerned about preventing further decay. Comments made by parents suggest the former reason was more likely, but this gives cause for concern, given that most were not familiar with key oral health messages, such as '*spit not rinse*' (50). Direct advice from a member of the dental team was most popular, followed by input through schools, which implies parents have more faith in appropriately trained professionals, instead of relying on leaflets or DVDs. The low preference for websites supports findings from the 2 year post GA service evaluation (Study B), which, as discussed earlier, was unexpected given the now widespread use of online resources.

Only 11% of those questioned requested help with finding a 'child friendly' dentist, suggesting most parents were happy with their current practitioner: this again was surprising, in view of the reported levels of dental anxiety and inadequate access to sedation services. Despite the fact that high-risk families are normally poor attenders (174, 175, 186, 187, 189-191), a relatively high proportion welcomed the opportunity for a review appointment at the Dental Hospital. However, most parents saw this is an

opportunity to check healing of the extraction sites, as opposed to it being a visit dedicated to prevention. Funnily, the response to this question could have been influenced by the use of shopping vouchers to encourage attendance: as one parent joked, "*if I get vouchers for coming in, I'll bring him in every week!".* On reflection, it would have been useful to also seek parents' views on attending prevention clinics prior to the GA and/ or receiving preventive interventions as part of their pre-GA assessment visit.

6.5.2.11.11

GA use in siblings:

Nearly a quarter of parents responding to the 24 month questionnaire, reported that at least one of their other children had also received a dental GA, though it wasn't clear if this was before, and/ or after the GA for the child taking part in the study. This is relatively low compared to some studies, which suggest around half of children referred for GA had siblings needing the same treatment (6, 119), but still, calls for measures to also address preventive needs of other family members. In this respect, the GA assessment visit, could be utilised to promote positive oral health for the whole family, by providing advice, as well as organising on-going care for siblings if they are not already registered with a dentist.

6.5.2.12

Discussion of relevant outcomes at 12 months:

As explained previously, only some children were followed up at 12 months and outcomes for these are summarised in Appendix 25 (Tables 58 – 66).

GI sealants appeared to perform better in the short term, with 100% retained at 12 months (compared to less than a third after 2 years) but these results should be viewed with caution, given that these sealants were all in one patient (Table 59). Nearly 12% of the control group had at least one sealant at the 24 month review, but none had evidence of sealants after 12 months, which could imply sealants were not, as is recommended, being placed as soon as possible after teeth had erupted (96, 269).

Control group participants had higher rates of untreated caries into dentine, at the 12-month review (Table 60) but the differences at this stage, were not statistically significant. The control group did have significantly higher rates of 'any' caries, (including early lesions) after 12 months, compared to the sealant group, (Table 60), but these differences were no longer significant by the time of the 24 month reviews, suggesting children with sealants continue to be at risk of developing caries in the longer term (Table 40).

Considering experience of dental care following the GA, relatively fewer children had returned to see a dentist, by the 12-month review, compared to those seen at 24 months. Also, fewer parents at this stage, reported receipt of oral hygiene instruction or dietary advice by providers outside the study. This is surprising, as parents could be expected to more readily remember advice received within 12 months (rather than 24 months) and in any case, it would seem more pertinent for oral health counselling to have been delivered soon after the GA instead of years later.

6.5.3

Can sealing first permanent molars as part of the GA encounter prevent repeat GA?

Dental GA is most often required for extraction of carious primary teeth (118, 170): pilot study findings support this observation, as only 5 out of the 100 participants were undergoing permanent tooth extractions. However, a study to evaluate reasons for extraction of first permanent molars in children referred to Hospital, found that 70% were due to caries and over half required a GA (203). Furthermore, researchers in Leeds report extraction of both primary and permanent teeth as part of unplanned repeat GAs, with 60% of children having at least one first permanent molar extracted at the second GA (169).

One child in the control group did require a further GA after 2 years and this was for extraction of carious first permanent molars as opposed to primary teeth. As none of the children in the sealant group had new caries into dentine in permanent molars (at 24 months), it would be appropriate to assume that sealants could have prevented caries in first permanent molars in this patient and thus avoid the need for a repeat GA. On this basis, it would be reasonable to suggest that providing sealants as part of the GA encounter, could, to some extent, help to prevent another GA. Irrespective of this, sealants clearly provide benefits in terms of preventing symptoms (pain and infection) associated with carious permanent teeth, as well as reducing any orthodontic complications resulting from unplanned extractions (270).

However, it is important to recognise that sealants provided as part of the GA encounter only protect teeth that are adequately erupted at that time, leaving others susceptible unless they can also be sealed once they come through. Furthermore, as explained earlier, repeat GAs often relate to caries relapse affecting the primary dentition (169, 170), signifying a

need for interventions to also prevent caries in primary teeth. In this respect, at 24 months, two-thirds of caries in primary molars in the pilot sample affected occlusal, buccal or palatal surfaces, suggesting sealants could also help protect these teeth.

6.5.4

Pilot study limitations and recommendations to overcome these:

All research has its limitations and this study was no exception. Problems related to the methodology and study procedures were discussed earlier (6.5.1) and these are summarised in Table 55. Based on these, Table 56 outlines recommendations to improve the design and quality of related research in the future, some of which are discussed in further detail below.

Table 55:

Pilot RCT on sealant application as part of GA assessment visit: limitations of study methods

Study methods limitations:
• Number of children excluded from study due to previous experience of caries in all erupted permanent molars was not recorded • Assessment of dental anxiety at baseline was restricted to participants receiving sealants • OHRQoL at baseline was not assessed • Study examiner had not calibrated before commencement of data collection • Difficulties associated with single researcher: ○ Missed opportunities for recruitment as busy with other participants

- Increased detection bias of group allocations/ sealants at follow-up, due to being involved in all study activities (recruitment, providing intervention, administration and reviews)
- Unplanned absence resulting in failure to follow up all participants at 12 months

With respect to baseline caries levels in permanent teeth, the study sample was not entirely representative of all children referred for GA, because patients with caries affecting all permanent molars (including early lesions), were excluded. As previously mentioned, children with early caries could, in future, be included (if radiographs were available) but it would still be useful to record the number of children excluded (because they already had experience of dentine caries affecting all molars), to provide a better assessment of overall caries prevalence in permanent teeth, in children referred for GA.

Dental anxiety should be assessed for all participants at baseline (instead of only children receiving sealants), to compare any differences between the intervention and control groups. This could be based on a combination of FIS images selected by children, along with parents' opinions on their child's level of dental anxiety.

Equally, it would be more helpful to measure OHRQoL both before, as well as after extractions under GA, to evaluate any differences resulting from the GA experience. Furthermore, this could be assessed at regular intervals through-out the study follow up period, depending on the frequency of recalls.

Clearly, many limitations were related to the fact the pilot was executed, on the most part, by a single investigator, and these include: missed opportunities to recruit participants due to the researcher being busy with other families, detection bias through an increased

likelihood of knowing which group participants belong to, as well as unplanned absence from work, resulting in a failure to undertake all the 12 month reviews. Multiple examiners would help address these difficulties and this is further discussed in the next section, as too is the recommendation to undertake a multi-centre clinical trial, based on the findings of the pilot.

Table 56:

Recommendations to improve study procedures:

Recommendations to improve study procedures:
• Record number of children excluded from study due to previous experience of caries in all existing permanent molars • Assess dental anxiety at baseline for all participants (sealant and control groups) • Assess OHRQoL at baseline and re-evaluate after GA, at regular intervals through-out study follow up period • Explore use of social media (e.g. create a study website or facebook page) to maintain contact with families and minimise loss to follow up • Consider sealing pre-molars and primary molars as part of intervention • Under-take a multi-centre RCT with multiple calibrated examiners, in part, to minimise problems encountered by single researcher for pilot study

6.6

Pilot RCT Conclusions:

Table 57:

Summary of conclusions from pilot RCT to evaluate placement of sealants as part of the GA assessment visit

Key conclusions:
• Recruitment and retention of 'high-risk' participants is possible • There is an unmet need for sealants in high caries risk children • Sealant placement as part of the pre-GA assessment visit is feasible • Children remain at high risk of new caries in permanent molars after the GA • Sealant placement during the pre-GA assessment may reduce caries incidence in permanent molars • Caries preventive effects of resin and GI sealants are comparable, despite poor retention of GI sealants • Preventive activity (including oral health advice and interventions) by providers outside the study, after the GA, appears to be inadequate

Further to caries related extractions under GA, children are at high-risk of developing new caries in permanent molars that were sound at the time of the GA. Despite this, use of sealants by referring practitioners in vulnerable children is low. Placing sealants as part of the GA assessment visit, is feasible and well received by most children and may reduce the incidence of caries in this susceptible group. Preventive activity by providers outside the study, following the GA, falls short of what would be expected to meet these patients' needs. High-risk families are willing to take part in a trial and can be reliable participants.

These conclusions reinforce findings from previous research, which highlights failings in delivery of prevention to vulnerable young patients (6-8, 42). To date, very few RCTs have involved children at high-risk of caries (10, 11). However, this study has shown that vulnerable families can be engaged to take part in research, which can facilitate development of appropriately tailored interventions, to help address the specific challenges associated with delivering prevention to this notoriously high-risk group.

6.7

Pilot RCT recommendations – multi-centre RCT

Based on the pilot findings, further research can be recommended to evaluate the effectiveness of the intervention. A multi-centre RCT could also serve to investigate aspects not considered by the pilot study, as well as address some of the limitations. It is important to recognise that the encouraging outcomes observed in the pilot study, might be less readily achievable in less favourable operating conditions. Multiple clinicians working in different clinical settings, with varying facilities, equipment, materials and chairside support, are all likely to influence outcomes. Better understanding of any impact these factors might have, along with an assessment of the health economics and cost effectiveness of the intervention proposed are required, prior to consultation with commissioners and reaching decisions on implementing a change in practice (104).

A definitive trial would address limitations of the pilot study that were related to a single investigator undertaking most of the study procedures (Table 55 and 56). Obviously, a training and calibration exercise would be required to measure agreement between multiple examiners. A formal power calculation would also be required (using data from the pilot

study, on recruitment and retention levels and caries incidence), to estimate the sample size for a definitive trial.

It might also be useful to further evaluate any difference between the use of GI and resin as sealant materials, by including from the outset, an additional intervention group that have only GI sealants: in essence, a 3-arm trial with 2 intervention groups (resin sealant or GI sealant) and the control group. GI sealants offer benefits in terms of being easier to apply (and thus better tolerated by younger anxious patients) (94) and pilot study findings serve to support the potential caries preventive effects of GI sealants despite poor retention rates (85, 91, 92). Furthermore, premolars and primary molars could also be sealed.

CHAPTER 7: OVERALL CONCLUSIONS (AND RECOMMENDATIONS)

Following caries related dental extractions under GA, children remain at high risk of relapse affecting permanent molars that were sound at the time of the GA. There is an unmet need for sealants in this cohort, despite most children being registered with a dentist, but the GA encounter in secondary care offers an opportunity to provide sealants to this high-risk group.

Findings from the pilot study have shown that sealant placement as part of the pre-GA assessment visit is feasible and well received by most children and may reduce caries incidence in this susceptible group. Furthermore, vulnerable families were found to be reliable study participants. Moving forwards, a definitive multi-centre trial to evaluate the effectiveness of the intervention, is recommended.

Procedures to follow-up children in primary care after the GA and preventive activity by practitioners outside the study appear to be inadequate. Referring dentists mostly expressed patient focused barriers, such as co-operation and parents' motivation (including poor attendance) to delivering prevention, reinforcing the value of taking full advantage of the opportunity provided by the GA encounter. Dentists welcomed more preventive input from GA providers.

However, all stages of the GA care pathway provide an opportunity to deliver prevention and, in this respect, closer collaboration between referring practitioners and GA providers is required, to help share responsibility and integrate care.

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APPENDIX 1 - Baseline GA service evaluation CRF 1

Service evaluation on condition of first permanent molars in XGA children

Birmingham Dental Hospital

To be completed for patients age 5+

Date of GA appt……

P number: [ ]

Pt age: [ ]

For each tooth, please mark X in relevant box

(Please cross all that apply)

Status of first permanent molars:

	Unerupted /partially erupted	***Sound & fissure sealable***	***Carious***	***Filled***	***Already FS***	***For XGA***	***Missing (previously extracted)***	***Hypoplastic***	***Other***
UR6 (16)									
UL6 (26)									
LL6 (36)									
LR6 (46)									

For ‘sound and fissure sealable’, please include even if not fully erupted (i.e. > ¾ crown erupted is ok)

APPENDIX 2 - Baseline GA service evaluation parent questionnaire

Baseline GA service evaluation parent questionnaire

Birmingham Dental Hospital

Section 1:

Ques 1:

Has your child had teeth taken out under a General Anaesthetic before?

[ ] Yes [ ] No [ ] Not sure

Ques 2:

Who referred (sent) your child to the Dental Hospital to have teeth taken out? (please cross one box only)

[ ] General Dental Practice

[ ] Community Dentist

[ ] Children's Dept at Dental Hospital

[ ] Self-referral (by you)

[ ] Other

Ques 3:

How often does your child normally visit the dentist?

(please cross one box only)

[ ] Never been to a dentist until now

[ ] Only when having trouble

[ ] Occasionally i.e. for a check up at least once a year

[ ] Regularly i.e. for a check up at least once every 6 months

[ ] Other

Ques 4:

Do you plan to take your child to a dentist after the teeth are taken out?

(please cross one box only)

[ ] Yes – have appointment already booked

[ ] Yes – will wait to receive an appointment from own dentist

[ ] Yes – will make an appointment with own dentist for child to have a check-up in 3 months

[ ] Yes - will make an appointment with own dentist for child to have a check-up in 6 months

[ ] No – don't plan to take child to see a dentist in future

[ ] Other

Section 2: Fissure sealants

Please read the following notes carefully before you answer this question

Fissure sealants are protective plastic coatings placed on the chewing surfaces of some back teeth to help prevent tooth decay. They are usually applied to permanent back teeth around 6 years of age and protect the tooth surface by keeping food & debris out of the grooves. They ae simple & quick to apply: the tooth is cleaned, liquid sealant is applied with a brush and then set hard with use of a special light.

Please note:

Unfortunately, we are not able to offer to seal your child's teeth at the Dental Hospital at the present time.

Even so, can you please answer the following question as we would welcome your views to help us plan future services.

Question 5:

Would you like your child to have fissure sealants at the Dental Hospital on the day that he/ she attends to have teeth taken out under a GA?

(Please cross one box only for your preferred choice)

[ ] - Yes, while he/ she is asleep to have teeth taken out

[ ] - Yes, while he/ she is awake i.e. before the teeth are taken out

[ ] – No, I would prefer to take my child back to my own dentist to have sealants

[ ] – No, I don't want my child to have fissure sealants

[ ] – Other …….

Section 3: Follow up

The next set of questions are to help us find out how easy it is for us to contact you in the future and how you would feel about bringing your child back to see us to have his/ her teeth checked

Ques 6:

Do you plan to stay at your current home address for the next 3 years?

[ ] Yes [ ] No [ ] Not sure

Ques 7:

Would you be happy for us to contact you in the future (up to 2 years after the dental GA) to ask some questions about your child's dental health and/ or to offer a review appointment?

[ ] Yes [ ] No [ ] Not sure

We are planning a study to find ways to prevent further tooth decay in children that have needed to have teeth taken out under a GA.

Families taking part in this trial would be asked to bring their child back to the Dental Hospital so their child's teeth can be checked.
We are not asking you to take part in a trial but would still like you to answer the following questions to help us find out how you feel about this.

Ques 8:

Would you be happy to take part in a study to help find ways to prevent further tooth decay in children that have had teeth taken out under a GA?

[ ] Yes [ ] No [ ] Not sure

If you have answered No or Not sure,

Would you be more willing to take part if offered an incentive such as travel expenses?

[ ] Yes [ ] No [ ] Not sure

Please indicate your child's ethnic group by marking the relevant box below:

[ ] White British

[ ] White Irish

[ ] Other White background

[ ] White and Black Caribbean

[ ] White and Black African

[ ] White and Asian

[ ] Other Mixed background

[ ] Asian or Asian British Indian

[ ] Asian or Asian British Pakistani

[ ] Asian or Asian British Bangladeshi

[ ] Other Asian background

[ ] Black or Black British Caribbean

[ ] Black or Black British African

[ ] Other Black background

[ ] Chinese

[ ] Any other ethnic group

[ ] Decline to answer

Thank you very much for completing the Questionnaire.

If you have any further comments, please enter below.

APPENDIX 3 – Service evaluation B invitation to recall letter

Children's Department
Birmingham Dental Hospital
St Chad's
Queensway
Birmingham B4 6NN

Dental General Anaesthetic Follow up Appointment (Date)

Dear Parent/ Guardian

Patient name:
Dental Hospital registration number:

Our records show that approximately two years ago, your child was seen at the Birmingham Dental Hospital to have a decayed tooth/ teeth taken out under a general anaesthetic (GA).

We are offering you the opportunity to bring your child back to the Dental Hospital for a follow up. This will allow us to check the condition of his/ her teeth including any new teeth that might have come through since your child was last seen at the Hospital. If problems are found, we may be able to offer dental treatment on one of our undergraduate dental student clinics.

We will also provide advice on how you can best care for your child's teeth as well as other measures to prevent tooth decay, such as applying a fluoride varnish to the teeth.

We would encourage you to attend even if your child is already registered with a dentist.

If you would like to be sent an appointment, please contact the Dental Hospital by sending an e-mail to:

Please write 'GA Follow up' in the subject box and include the information listed below in your e-mail:

- **Your Child's Full Name and Dental Hospital Registration Number (see top of letter)**
- **Your Name, Address and Phone number.**

Alternatively, please call to leave a message with our paediatric secretary.

Yours Sincerely

Miss A Raja (Dentist)
Paediatric Department

APPENDIX 4 – CRF1

Evaluation of caries levels in first permanent molars and use of sealants, two years after caries related extractions under GA - CRF 1

Date completed..... **BDH/ CCDS Clinic attended**.....

P number **Age** **DOB**

Gender M F

Ethnicity code (self-reported): **Postcode**

Dental chart: Enter ICDAS Codes (for treatment and caries)

Upper Right **Upper Left** **Lower Right** **Lower Left**

	6		6	
D				D
O				O
M				M
B				B
L				L

	6		6	
D				D
O				O
M				M
B				B
L				L

Outcome:

No treatment required [ ] **Refer to dentist for treatment** [ ] **Book student clinic** [ ]

APPENDIX 5

Evaluation of oral health support and treatment received in primary care within the 2 years following the GA

Interview Questionnaire **Date completed:**

P number:

Person interviewed:

Please tick all that apply

Mother [ ] Father [ ] Other [ ] please specify .....

Introduction:

We would like to find out more about the dental care children receive after they have had decayed teeth taken out under a general anaesthetic (GA).

We would therefore like to ask you some questions about this. These should take no longer than about 15 minutes.

We should stress there are no right or wrong answers.

Furthermore, we can assure you the information you provide will remain confidential and will not affect the care that your child receives.

For all questions, tick one box only unless specified

Ques 1:

Did you take your child to a dentist (outside the Dental Hospital) **before** he/ she had teeth taken out under the GA?

Yes [ ] No [ ] Not sure [ ]

Ques 2:

Have you taken your child to a dentist **since** he/ she had teeth taken out under the GA?

Yes [ ] No [ ] Not sure [ ]

If No/ Not sure to both Ques 1 and 2 → go to Ques 3:

If Yes to Ques 1 but No/ not sure to Ques 2→ go to Ques 4a:

If Yes to Ques 1 and Yes to Ques 2→ go to Ques 5:

If No/ Not sure to Ques 1 and Yes to Ques 2→ go to Ques 5:

Ques 3:

Is there any particular reason why your child hasn't seen a dentist?

Record comments:

→ Go to Ques 13

Ques 4a:

Do you think you might have missed any appointments (i.e. cancelled them or failed to attend)?

Yes [ ] No [ ] Not sure [ ]

Ques 4b:

Is there any particular reason why your child hasn't been back to see a dentist?

Record comments:

→ Go to Ques 13

Ques 5:

What type of dentist does your child normally see?

[ ] General Dental Practice (i.e. High street or family dentist)

[ ] Community Dentist

[ ] Dental Hospital

[ ] Not sure

Ques 6:

Does this dentist know that your child has had teeth taken out under a GA (*explain to parent that this dentist might have referred the child for the GA but if not, has parent told him/ her that child has had teeth taken out under GA*)?

Yes [ ] No [ ] Not sure [ ]

Ques 7:

Since having the teeth taken out under GA, how often does your child normally visit the dentist?

[ ] for a check-up at least once every 3 months

[ ] for a check-up at least once every 6 months

[ ] for a check-up at least once every 12 months

[ ] for a check-up but less than once a year

[ ] no check - ups, only take child to dentist when having trouble **(→ *go to Ques 10*)**

[ ] other (*please specify*) **(→ *go to Ques 10*)**

[ ] not sure **(→ *go to Ques 10*)**

Ques 8:

How are your child's dental check- up appointments usually arranged?

[ ] dental practice sends appointment (e.g. letter or text)

[ ] dental practice contacts you (letter, text, phone call) to remind you to make an appointment

[ ] you contact the dental practice when you think check-up is due

[ ] other (*please specify*)

[ ] not sure

Ques 9:

Does the dental practice send you reminders (letters, phone calls, e-mails or text messages) to help you remember your child's appointment?

Yes [ ] No [ ] Not sure [ ]

→ go to Ques 11.

Ques 10:

Has your child been to see a dentist within the last 12 months?

Yes [ ] No [ ] Not sure [ ]

If Yes → go to Ques 11

If No/ Not sure → go to Ques 12a

Ques 11:

During the last 12 months, has your child's dentist (or a member of the dental team) provided any of the following items of advice or care? *Tick all that apply*

[ ] Advice about tooth brushing

[ ] Advice about a healthy diet (avoiding sugary foods/ drinks)

[ ] Explained about importance of preventing decay to avoid your child having another GA to have teeth taken out

[ ] Polish teeth

[ ] Application of fluoride varnish to teeth

[ ] Dental sealants (plastic coatings) on teeth

[ ] Fillings

[ ] Extractions (teeth taken out)

[ ] X-rays

[ ] Other (specify)

Ques 12a:

Is your child anxious (worried or scared) about dental treatment?

Yes [ ] No [ ] Not sure [ ]

If Yes → go to Ques 12b

If No/ not sure → go to Ques 13

Ques 12b:

Has your child's anxiety about dental treatment stopped the dentist from carrying out treatment that was planned?

Yes [ ] No [ ] Not sure [ ]

Ques 12c:

Has your child's dentist and/ or a member of the team offered any measures to help reduce this anxiety?

Yes [ ] No [ ] Not sure [ ]

If Yes, please expand on these and record below:

Ques 13:

Which, if any of the following measures would you find useful to help you to look after your child's teeth? *Tick all that apply*

[ ] Help with finding a 'child-friendly' dentist

[ ] To receive more frequent check-up appointments with your child's current dentist

[ ] Letters, phone calls, e-mails or text messages to remind you about your child's dental appointments

[ ] Advice from other health professionals e.g. health visitor or dietician

[ ] Information through your child's school, including tooth-brushing programmes at school

[ ] Information leaflets about caring for children's teeth

[ ] DVDs about caring for children's teeth

[ ] Internet site about caring for children's teeth

[ ] Any other support (*please specify*)

Ques 14:

Would you have found it helpful to have had an appointment to bring your child back to the Dental Hospital for a review (check up) a few weeks after the teeth were taken out under the GA?

Yes [ ] No [ ] Not sure [ ]

Ques 15:

Do you have any other children that have had teeth taken out under a GA?

Yes [ ] No [ ] Not sure [ ]

Thank you very much for completing the interview
Do you have any questions or comments you would like to add?

APPENDIX 6

Birmingham Dental Hospital
St Chad's
Queensway
Birmingham B4 6NN

GDP name
Practice address

Date

Re: Caries prevention for children requiring dental extractions under GA

Dear

First, please let me introduce myself. My name is Abida Raja: I am a Community Dentist based in Birmingham and Clinical Lecturer in Paediatric Dentistry at the University of Birmingham School of Dentistry. I am undertaking a study to investigate ways to prevent further caries in children that have had caries related extractions under a general anaesthetic (GA).

One of my aims is to try to establish the level of preventive care that these patients currently receive in primary dental practice.

Our records indicate that you have referred children to the Birmingham Dental Hospital for extractions under GA and so it would be very helpful to obtain your views on caries prevention in this group of patients.

I would therefore be most grateful if you would be agreeable to take part in a short telephone interview (in the form of a structured questionnaire). I am hoping to phone your practice within the next two weeks in order to arrange a mutually convenient time for me to call again to carry out the interview. This should take no longer than about 15 minutes**:** the questions do not relate to any specific patients and the data will not be identifiable to your practice or to you as an individual when presenting findings

I would very much appreciate your help with this but if you choose not to take part, could you please send me an e-mail to let me know ( ).

Furthermore, please feel free to contact me (again by e-mail) if you have any queries or you would like me to send you a list of the questions beforehand.

Thank you very much for your anticipated support.

Yours Sincerely

Miss A Raja
Community Dentist and Clinical Lecturer in Paediatric Dentistry

APPENDIX 7

Questionnaire: Caries prevention following caries related extractions under GA
GDP
Participant ID:

Interview Questions:

1. *In the past year, how many patients (aged under 16 years) have you referred to the Birmingham Dental Hospital (BDH) for caries related extractions under a GA?*
   Please select one of the following responses.

   [ ] Less than 3 [ ] 3-5 [ ] 6-9 [ ] 10 or more

Unless otherwise specified, the remainder of the questions relate to children (under 16 years) that you have referred for caries related extractions under a GA.

2. *When making the referral, do you normally **book** an appointment to review/ follow up the patient at your Practice after the GA?*
   Please select one response.
   [ ] No → go to Ques 3
   [ ] Yes → go to Ques 4a

3. *When making the referral, do you normally advise parents to contact your Practice to arrange a review/ follow up appointment for their child to see you after the GA?*
   Please select one response.
   [ ] No→ go to Ques 6
   [ ] Yes → go to Ques 4b

4a. *How soon after the 'anticipated' GA do you book an appointment for the patient to be seen?*

Please select one response.
[ ] Within 1 month of the GA
[ ] Between 1 to 3 months of the GA
[ ] Within 3 to 6 months of the GA
[ ] Other – please specify

Please go to Ques 5a

4b. How soon after the GA do you advise parents that they should arrange an appointment for their child to return to see you?

Please select one response.
[ ] Within 1 month of the GA
[ ] Between 1 to 3 months of the GA
[ ] Within 3 to 6 months of the GA

[ ] Other – please specify

Please continue to Ques 5a

5a. What *is the purpose of the 'review/ follow up' visit?*
From the following responses, please indicate all that apply:

[ ] Review healing of extraction socket(s)
[ ] Complete outstanding treatment
[ ] Caries prevention

5b. *Which <u>one</u> of the aforementioned is the 'usual' reason or normally the 'priority' for the review appointment?*

Please select only one response.
[ ] Review healing of extraction socket(s)
[ ] Complete outstanding treatment
[ ] Caries prevention

Please go to Ques 7a

6. *Do you normally 'recall' these patients in due course?*
Please select one response

No [ ] Yes [ ]

If No → go to Ques 7a
If Yes → please continue

What is the 'usual' interval between recall visits .....

How are recalls administered?
From the following responses, please indicate all that apply:
[ ] Appointments sent in the post
[ ] 'Contact us' letters sent in the post
[ ] Parents advised that they need to contact the Practice/ Clinic for a check-up in due course

<u>Unless specified</u>, the next group of questions relate to the general appointment systems within your Practice and so are <u>applicable to all patients</u>.

7a. *Do you normally (as a general routine) 'remind' patients about their appointment to help improve attendance?*
Please select one response.

No [ ] (go to Ques 7b) Yes [ ] (go to Ques 7c)

7b. *If no, do you target 'reminders' for children that have had caries related extractions under a GA?*
Please select one response.

No [ ] (go to Ques 8) Yes [ ] (go to Ques 7c)

7c. *If yes, which of the following methods do you use:*
From the following responses, please indicate all that apply:

[ ] reminders sent in post
[ ] text reminders
[ ] phone calls to remind
[ ] other (please specify)

8. *How do you manage patients that fail to attend appointments?*
From the following responses, please indicate all that apply:

[ ] Await contact
[ ] Send 'contact us' letters
[ ] Send a further appointment
[ ] Phone patient to re-appoint
[ ] Other (please specify)

9. *Does your procedure for managing failed appointments differ in any way for children that have had caries related extractions under GA?*
Please select one response.

No [ ] Yes [ ]

If Yes, please elaborate:

Does your practice have a:

[ ] Dental therapist
[ ] Hygienist

The remainder of the questions relate specifically to children that have had caries related extractions under GA.

10a. *What measures, if any, (in appropriate situations) do you employ to prevent caries in this group of patients?*
From the following responses, please indicate all that apply:

[ ] Oral hygiene instruction
[ ] Dietary advice
[ ] Topical fluoride varnish application
[ ] Fissure sealant placement
[ ] Prescribe high strength fluoride toothpaste
[ ] Prescribe fluoride mouth rinse
[ ] Other (please specify)

10b. *Which members of the dental team provide preventive advice/ treatment for these patients?*
Please indicate all that apply:

[ ] Dentist
[ ] Dental therapist
[ ] Hygienist
[ ] Dental nurse

11a. *Do you feel that you/ your practice could do 'more' to help prevent further caries in patients that you have referred for extractions under GA?*

No [ ] Yes [ ]

If yes, please elaborate:

11b. *Which (if any) of the following factors do you see as a barrier to preventing caries in this group of patients?*
From the following responses, please indicate all that apply:

[ ] Lack of time
[ ] Cost factors
[ ] Unco-operative patients (e.g. for fissure sealing)
[ ] Parents not motivated (e.g. irregular attenders, unreceptive to advice given)
[ ] Other (please specify)

12. *The final set of questions relate to your thoughts towards some proposed interventions to prevent caries in children that you refer for extractions under GA.*
The possible responses for each intervention are:
Very helpful Some-what helpful Neither helpful/ unhelpful Un-helpful

Please select one response for each intervention:

12a. *Following the GA, discharge letter you are sent from Dental Hospital to include a 'plan for caries prevention' (including preventive advice, 3 monthly topical fluoride application and possibly fissure sealant application) for you to implement at your Practice.*

[ ] Very helpful [ ] Some-what helpful [ ] Neither helpful/ unhelpful [ ] Unhelpful

Any comments?

12b. *Following the GA, patients to be followed up and recalled in Community Dental Service and/ or at the Dental Hospital.*

[ ] Very helpful [ ] Some-what helpful [ ] Neither helpful/ unhelpful [ ] Unhelpful

Any comments?

12c. *If applicable, patients to have fissure sealants carried out at the BDH (potentially at the GA assessment appointment).*

[ ] Very helpful [ ] Some-what helpful [ ] Neither helpful/ unhelpful [ ] Unhelpful

Any comments?

13. *Do you have any general comments/ questions regarding this topic or study that you would like to make?*

Thank you very much for your time.

Please return to:
Miss A Raja, Dental Dept, Richmond Primary Care Centre, 299 Bordesley Green East, Stechford, Birmingham B33 8TA
Or
E-mail:

APPENDIX 8

Questionnaire: Caries prevention following caries related extractions under GA
CDS
Participant ID:

Interview Questions:

1. *In the past year, how many patients (aged under 16 years) have you referred to the Birmingham Dental Hospital (BDH) for caries related extractions under a GA?*
   Please select one of the following responses.

   [ ] Less than 3 [ ] 3-5 [ ] 6-9 [ ] 10 or more

Unless otherwise specified, the remainder of the questions relate to children (under 16 years) that you have referred for caries related extractions under a GA.

2. *When making the referral, do you normally **book** an appointment to review/ follow up the patient at your Clinic after the GA?*
   Please select one response.
   [ ] No → go to Ques 3
   [ ] Yes → go to Ques 4a

3. *When making the referral, do you normally advise parents to contact your Practice to arrange a review/ follow up appointment for their child to see you after the GA?*
   Please select one response.
   [ ] No→ go to Ques 6
   [ ] Yes → go to Ques 4b

4a. *How soon after the 'anticipated' GA do you book an appointment for the patient to be seen?*
Please select one response.
[ ] Within 1 month of the GA
[ ] Between 1 to 3 months of the GA
[ ] Within 3 to 6 months of the GA
[ ] Other – please specify

Please go to Ques 5a

4b. How soon after the GA do you advise parents that they should arrange an appointment for their child to return to see you?
Please select one response.
[ ] Within 1 month of the GA
[ ] Between 1 to 3 months of the GA
[ ] Within 3 to 6 months of the GA
[ ] Other – please specify

Please continue to Ques 5a

5a. What *is the purpose of the 'review/ follow up' visit?*
From the following responses, please indicate all that apply:

[ ] Review healing of extraction socket(s)
[ ] Complete outstanding treatment
[ ] Caries prevention

5b. *Which <u>one</u> of the aforementioned is the 'usual' reason or normally the 'priority' for the review appointment?*

Please select only one response.
[ ] Review healing of extraction socket(s)
[ ] Complete outstanding treatment
[ ] Caries prevention

Please go to Ques 7a

6. *Do you normally 'recall' these patients in due course?*
Please select one response

No [ ] Yes [ ]

If No → go to Ques 7a
If Yes → please continue

What is the 'usual' interval between recall visits .....

How are recalls administered?
From the following responses, please indicate all that apply:
[ ] Appointments sent in the post
[ ] 'Contact us' letters sent in the post
[ ] Parents advised that they need to contact the Clinic for a check-up in due course

<u>Unless specified</u>, the next group of questions relate to the general appointment systems within your Clinic and so are <u>applicable to all patients</u>.

7a. *Do you normally (as a general routine) 'remind' patients about their appointment to help improve attendance?*
Please select one response.

No [ ] (go to Ques 7b) Yes [ ] (go to Ques 7c)

7b. *If no, do you target 'reminders' for children that have had caries related extractions under a GA.*
Please select one response.

No [ ] (go to Ques 8) Yes [ ] (go to Ques 7c)

7c. *If yes, which of the following methods do you use:*
From the following responses, please indicate all that apply:

[ ] reminders sent in post
[ ] text reminders
[ ] phone calls to remind
[ ] other (please specify)

8. *How do you manage patients that fail to attend appointments?*
From the following responses, please indicate all that apply:

[ ] Await contact
[ ] Send 'contact us' letters
[ ] Send a further appointment
[ ] Phone patient to re-appoint
[ ] Other (please specify)

9. *Does your procedure for managing failed appointments differ in any way for children that have had caries related extractions under GA?*
Please select one response.

No [ ] Yes [ ]

If Yes, please elaborate:

Does your clinic have a:

[ ] Dental therapist
[ ] Hygienist

The remainder of the questions relate specifically to children that have had caries related extractions under GA.

10a*. What measures, if any, (in appropriate situations) do you employ to prevent caries in this group of patients?*

From the following responses, please indicate all that apply:

[ ] Oral hygiene instruction
[ ] Dietary advice
[ ] Topical fluoride varnish application
[ ] Fissure sealant placement
[ ] Prescribe high strength fluoride toothpaste
[ ] Prescribe fluoride mouth rinse
[ ] Other (please specify)

10b. *Which members of the dental team provide preventive advice/ treatment for these patients?*
Please indicate all that apply:

[ ] Dentist
[ ] Dental therapist
[ ] Hygienist
[ ] Dental nurse

11a. *Do you feel that you/ your service could do 'more' to help prevent further caries in patients that you have referred for extractions under GA?*

No [ ] Yes [ ]

If yes, please elaborate:

11b. *Which (if any) of the following factors do you see as a barrier to preventing caries in this group of patients?*
From the following responses, please indicate all that apply:

[ ] Lack of time
[ ] Cost factors
[ ] Unco-operative patients (e.g. for fissure sealing)
[ ] Parents not motivated (e.g. irregular attenders, unreceptive to advice given)
[ ] Other (please specify)

12. *The final set of questions relate to your thoughts towards some proposed interventions to prevent caries in children that you refer for extractions under GA.*
The possible responses for each intervention are:
Very helpful Some-what helpful Neither helpful/ unhelpful Un-helpful

Please select one response for each intervention:

12a. *Following the GA, discharge letter you are sent from Dental Hospital to include a 'plan for caries prevention' (including preventive advice, 3 monthly topical fluoride application and possibly fissure sealant application) for you to implement at your Clinic.*

[ ] Very helpful [ ] Some-what helpful [ ] Neither helpful/ unhelpful [ ] Unhelpful

Any comments?

12b. *Following the GA, patients to be followed up and recalled within the CDS or at the Dental Hospital.*

[ ] Very helpful [ ] Some-what helpful [ ] Neither helpful/ unhelpful [ ] Unhelpful

Any comments?

12c. *If applicable, patients to have fissure sealants carried out at the BDH (potentially at the GA assessment appointment).*

[ ] Very helpful [ ] Some-what helpful [ ] Neither helpful/ unhelpful [ ] Unhelpful

Any comments?

13. *Do you have any general comments/ questions regarding this topic or study that you would like to make?*

Thank you very much for your time.

Please return to Abida Raja (by e-mail or post)

Richmond Primary Care Centre, Dental Dept, 299 Bordesley Green East, Stechford, Birmingham B33 8TA

APPENDIX 9

PROTOCOL VERSION 2.0 (18/07/16) with amendments
A Raja

Title:

A pilot study to investigate the use of pit and fissure sealants in children requiring caries related dental extractions under a chair general anaesthetic (GA).

Study personnel and contact details:

Chief/ Principal Investigator:
Miss Abida Raja
PhD student (Part time Clinical Lecturer in Paediatric Dentistry and Community Dentist)
School of Dentistry
Birmingham Dental Hospital
5 Mill Pool Way
Edgbaston
Birmingham
B5 7EG

Tel:
E-mail:

Academic supervisors:

Professor Deborah White
University of Birmingham School of Dentistry
St Chad's
Queensway
Birmingham B4 6NN

Tel:
E-mail:

Professor Thomas Dietrich
University of Birmingham School of Dentistry
St Chad's
Queensway
Birmingham B4 6NN

Tel:
E-mail:

Background:

Dental caries (tooth decay) is a preventable disease. However, despite overall improvements in children's oral health in the UK in the last few decades, the decline in caries prevalence in the primary dentition (milk teeth) has plateaued.[1]

A general anaesthetic (GA) is sometimes required to carry out dental treatment in children (especially pre co-operative young children in need of multiple extractions). However, in view of the fact that a GA is a *"procedure which is never without risk",* its use should be avoided wherever possible and especially more than once.[2, 3]
In spite of this, the number of children (aged 16 years or under) referred to hospital for extraction of carious teeth under general anaesthesia, has been reported as increasing by 66% in England between 1997 and 2006.[4] Furthermore, the frequency of repeat GA for caries related extractions is also relatively high.[3,5, 6, 7, 8] A study at one London Dental Hospital found that 47% of parents whose children required caries related extractions under GA reported previous dental treatment under GA in their children or child's siblings.[9] Provision of dental treatment under GA also has considerable health care cost implications.[9]

One factor associated with GA repetition is poor treatment planning with studies indicating that a high proportion of children who had been left with untreated dental caries at the first GA return for a repeat.[3, 5] However, other research suggests that a repeat GA is often required to address new caries.[6, 10] A study in Leeds found that 72% of the teeth extracted during a 'repeat GA' had been recorded as caries free or unerupted at the time of the first GA.[6]

This signals the need for a more proactive approach to prevention to address the needs of this high risk group.[5, 6, 9, 11] The GA experience has been shown to have a profound emotional effect on parents, which motivates them to take immediate action and implement changes in oral health behaviours[12] but it does not appear to have a significant impact on long term preventive behaviours.[13] Many children requiring dental treatment under a GA are irregular dental attenders.[9, 14] and studies also report low attendance to follow up appointments after the GA: this includes recall in a University hospital setting[15] and in Community Dental Service clinics, despite parents previously asking for this kind of local support.[14] The pattern of a child's dental attendance after a dental GA has been shown to be strongly associated with the risk of having an unplanned repeat GA, with those who are irregular attendees having a four times increased risk.[16]

Previous research attempts to understand the challenges parents face in supporting their child's oral health following dental treatment under GA[9, 13, 17] and to identify the type of support they would like to help look after their child's teeth.[9, 18] Although it would appear that there is a general under-utilisation of dental services and preventive care amongst this group[14, 15], only limited information exists on the type and extent of oral health support that is actually made available to this high risk group: a survey of dental GA providers in Yorkshire and Humber[19] did report that over half of these providers failed to mention the need for further preventive care in discharge letters sent back to referring dentists and Olley *et al.*[9] found that 61% of parents had no plans for continuing dental care for their child following treatment under GA, although what is not clear from this study is whether this represents a failure to take up services that are offered or a lack of provision. This suggests that there is still a

need to try to establish what oral health support is currently made available to prevent further caries development in children following extractions under GA. This should help to identify any gaps in provision of care and inform decisions on developing further interventions.

In summary, children who require caries related extractions under a GA are a high risk group with a high dental need.[5] It has been suggested that the best outcomes following dental treatment under GA could result from aggressive treatment of caries, active follow up and education of parents.[17] Clear evidence based measures do exist to prevent dental caries, including the use of fluorides, pit and fissure sealants, dietary counselling and brushing teeth using toothpaste containing an appropriate amount of fluoride.[20]The challenge is to develop ways to deliver these measures to this notoriously high risk and vulnerable group: accounting for the fact that many of these families are irregular attendees with unfavourable oral health related attitudes and behaviours and the children often have poor co-operation to dental treatment.

Studies have shown that the majority of detectable incremental caries in the permanent teeth of children is found on the pits and fissures of molar teeth.[21]In Canadian 8 year olds, 95% of caries or restorations affecting first permanent molars were found in pits and fissures.[22] This therefore suggests a need to target caries prevention at the "most susceptible tooth surfaces in the most susceptible members of the population"[23], which undoubtedly includes children that require caries related extraction of deciduous teeth under a GA. The primary aim of a trial currently underway in South Wales[23] is to compare the clinical effectiveness of two evidence based measures used to prevent dental caries in first permanent molars: pit and fissure sealants and fluoride varnishes. Both these measures have a role to play in children experiencing dental extractions under GA but given the 'unfavourable attitudes and behaviours' of this high risk group, it would seem more appropriate to focus on the use of sealants (as a one off measure) in these children as opposed to 3 monthly application of topical fluoride, which would rely on parents bringing their children back for regular follow up visits.

Pit and Fissure Sealants (PFS)

Sealants were introduced in the 1960's to protect pits and fissures on the occlusal (chewing) tooth surfaces from dental caries: they have been described as coatings which are applied by a dental care professional in order to obliterate pits and fissures and remove the sheltered environment in which caries can thrive.[24] They can be applied to permanent (secondary) or deciduous (primary) teeth and there are two main types of material currently available: resin based sealants/ composites and glass ionomer cements.

<u>Sealants in permanent teeth</u>

A Cochrane systematic review to evaluate the use of pit and fissure sealants in the permanent teeth of children and adolescents showed that after 4.5 years, the sealed permanent molars of children aged 5 to 10 years had over 50% reduction in decay on occlusal surfaces compared to teeth without sealant.[25] One study with longer follow up showed that after 9 years, only 27% of sealed tooth surfaces were decayed compared to 77% of tooth surfaces without sealant.[25] This review was updated and republished in 2013.[26]The conclusions drawn were similar to earlier reviews i.e.

compared to a control without sealant, resin based sealants prevented caries in first permanent molars in children aged 5 to 10 years: if 40% of control tooth surfaces (400 per 1000) were assumed to develop caries during the 2 year follow up period, applying a resin based sealant would reduce this proportion to 6.3% (63 per 1000). Similarly, if the assumed risk for controlled teeth was 70% (700 per 1000 tooth surfaces), the corresponding risk for sealed teeth at 2 years would be 19% (190 per 1000 tooth surfaces) The caries preventive effect was also maintained for longer follow up but the quantity and quality of the evidence was reduced. With respect to glass ionomer sealants, there was insufficient evidence to determine whether glass ionomer sealants did prevent caries compared to no sealant at 24 month follow up. [26]The review concluded that sealants are effective in children at high risk of caries but the relative effectiveness of different types of sealants remains to be established.

A study in the US analysing the cost utility of sealing first permanent molars concluded that this was the most cost-effective way to prioritise limited resources in lower dental utilisers.[27]

Another systematic review[28] supports the above findings, concluding that the literature strongly supports the placement of sealants on permanent molar teeth as both cost effective and efficacious in the prevention of caries. The results of studies comparing resin based (RB) and glass ionomer cement (GIC) sealants in permanent teeth were again mixed, depending on whether regular or reinforced GIC sealants were tested.[29, 30, 31, 32, 33] The best retention rates were obtained with the RB sealants but it was suggested that if the retention problems associated with GIC sealants could be resolved, there may be advantages to these through the release of fluoride. It has also been suggested that GIC sealants through their fluoride release, can prevent the development of caries, even after the visible loss of sealant material.[34] Azarpazhooh and Main recommend that additional research is required in this area and RB sealants should be preferred until such time as GIC sealants with better retention capacity are developed.[28]

The Department of Health evidence based 'toolkit for prevention'[20] recommends that children susceptible to caries should have their permanent molars sealed with resin sealant. Sealants should preferably be placed as soon as the selected teeth have erupted sufficiently to allow adequate moisture control.[35]The clinical procedure for placement of resin sealants is relatively simple but is technique sensitive. Salivary contamination of as little as half a second can affect the bond and therefore the retention of the sealant.[24] In view of this, the Scottish Dental Clinical Guidelines on the Prevention and Management of Caries in Children[36] describe a very simple procedure which involves applying GIC sealant to permanent molars using a 'gloved finger'. Whilst it is acknowledged that RB sealants are the first choice material, it is suggested that GIC can be used as a temporary sealant if co-operation is poor or where there are concerns about moisture control.

Sealants in primary teeth

Few studies have looked at the effectiveness of pit and fissure sealants at preventing caries in primary teeth. A systematic review published in 2003 reported that the evidence regarding the caries preventive effect of fissure sealants in primary molars was incomplete.[37] One randomised split mouth trial involving children aged 3-4 years reported complete retention of RB sealants in over 70% of primary molars after 2 years.[38] Another split mouth trial involving children aged 4-7 years reported complete sealant retention in primary molars of 77.5% with RB sealant and 95% with flowable composite after one year.[39] However, retention of GIC sealant in primary teeth on young children tends to be poorer than that reported for RB sealant.[40, 41]
The general consensus regarding primary molars is that routine application of sealants is not recommended but they may be considered for selected high caries risk children.[28, 42, 43]

The Use of Sealants in Children Needing Caries Related Extractions under a Chair GA

Each year, around 2000 children (under 16 years) are referred to the Birmingham Dental Hospital (BDH) for caries related extractions under a chair GA. Service data shows that 64% of these children are aged 6 years and over (71% 5 years and older), implying that many of them may have first permanent molar teeth, which are 'sealable'. A service evaluation project has found that 77% of 5 to 15 year olds seen for GA extractions at the BDH, had at least one 'sound and sealable' first permanent molar at the time of the GA and in 77% of these, all four first permanent molars were 'sound and sealable' (82% of 6 to 8 year olds had four 'sealable' first permanent molars). Surprisingly, just over half (54%) of the 5 year olds studied also had four 'sealable' first permanent molars. A parallel study using a questionnaire to collect parents' views on sealants and dental attendance behaviours showed that the majority of parents would want their child to have sealants: (46% preferred their child to have sealants applied during the GA for extractions, 23% just before the GA and 17% opted to have sealants applied by their family dentist: 181 responses). Furthermore, 47% claimed to be regular dental attendees (228 responses).
It is therefore surprising (and somewhat disappointing) to find that most of these high risk children had not yet had their first permanent molars sealed by referring dental practitioners.
We accept there is a possibility that dentists might be planning to do sealants after the child has had the extractions: however, it would seem more appropriate for these to have been done prior to the GA extractions in view of the fact that patients may not return to see their dentist after the GA and even if they do, the child is likely to be less co-operative as a result of the GA experience. Furthermore, the questionnaire referred to earlier also found that only 16% of children had an appointment booked to see their dentist after the GA (and only 27% of parents had plans to take their child back to see a dentist within 3 months of the GA), suggesting that most of these children are unlikely to access services within the time frame when it would be most effective for sealants to be applied.
These findings would suggest there is an unmet need for sealants in high risk children requiring a GA for caries related extractions.

Therefore, one option worth exploring is for these children to have sealants carried out at the Dental Hospital: technically, this could be done:

- on a separate 'assessment' appointment prior to the GA visit
- as part of the GA visit (either shortly before or actually during the GA)

or

- on a follow up appointment after the extractions.

Until recently, children seen at the Dental Hospital for chair GA extractions were assessed on the same visit as the procedure and the majority of patients were then discharged back to their dentist without any follow up visits. Therefore, the only opportunity to carry out the sealants was to do these as part of the GA visit (either before the GA or during the GA itself).

Sealants as part of the GA visit:

Pit and fissure sealing under a GA is already carried out in some GA centres.[44] However, this normally forms part of a comprehensive programme of dental rehabilitation under intubated GA and is usually restricted to patients that are medically compromised or have special care needs. When the patient is intubated, the airway is secure and this allows placement of the 'gold standard' RB sealants using the acid etch and water spray technique. However, during a 'chair' GA (when the patient is not normally intubated), the conditions for sealing are potentially far more challenging: time will be restricted, the airway will not be as secure and moisture control remains a problem. This therefore warrants modified approaches, in particular to try to avoid the use of etch/ water spray that could risk the airway and so, the GIC gloved finger technique (outlined earlier) may be more appropriate.
A preliminary feasibility exercise to test the 'practicality' of applying PFS during the GA was carried out at the BDH: this found that it is technically possible to place GIC sealants under a chair GA, with the procedure adding approximately 10 minutes to the GA time for applying 4 sealants on one patient. It would obviously be quicker to apply a fewer number of sealants (although this intervention would not be as 'clinically effective' if all four first permanent molar teeth were not erupted and ready to be sealed at the same time). Furthermore, one would expect the procedure to take less time with more experience.

However, aside from the desire to keep the length of the GA as short as possible (for the well-being and safety of the patient), it is important to consider the impact that this additional 'theatre time' has on the cost-efficiency of this intervention. In view of the extra time required to apply sealants, it is inevitable that it would not be possible to see as many patients as are currently being seen during each GA session.

The alternative is to focus on placing sealants as part of the GA visit but just prior to the GA rather than during. This would be more cost-effective as it makes better use of the time that patients are waiting to go into theatre and so should allow the usual number of patients to be seen. Although additional staff would be required to carry out the sealants, it is still likely to be more cost-effective for suitably skilled dental care professionals (e.g. dental therapists) to apply the sealants rather than oral surgeons carrying out the procedure during theatre time (with all the associated costs). Furthermore, this could potentially allow the use of 'gold standard' resin sealants if patients are co-operative. The downside is that some children might not comply with treatment (in particular, the technically more challenging resin sealants), especially as

they will be starved and also more likely to be anxious shortly before they are due to have extractions. Having said this, one can assume that most children should allow placement of GIC sealants (which is a relatively 'easy' procedure).

Sealants as part of a pre- GA assessment visit:

The Dental Hospital has plans to implement a new procedure (in the spring of 2014), which involves assessing patients on a separate appointment prior to the GA extraction visit. This provides an ideal opportunity to place sealants: patients won't be starved and are less likely to be anxious and similarly, parents should be more relaxed and able to understand the treatment proposed.
Furthermore, if children are not compliant to sealant placement (even under these more favourable conditions), this may signify a possible need in some cases to explore the role of sealant application during the GA itself.

It is important to acknowledge that the intervention proposed (i.e. sealing permanent molars in children requiring caries related extractions under chair GA as part of the pre-GA assessment appointment) is of little benefit to children that don't have 'sealable' permanent molar teeth and so this includes the majority of patients under the age of 5 years. Although the literature does support the placement of sealants in deciduous molars, the supporting evidence is limited and retention of GIC sealants in particular, tends to be poor. Furthermore, pit and fissure caries contribute only about 40% of the total caries experience in deciduous teeth[45,] with interproximal caries being the main problem: therefore, the impact of fissure sealants alone in reducing caries is likely to be less for deciduous teeth than for permanent. In spite of this, fissure sealing deciduous molars in younger children may be an option worth exploring in due course.

For the time being, however, this research intends to focus on the feasibility and potential benefit of delivering an evidence based caries preventive procedure (i.e. pit and fissure sealants in permanent molars) to a high caries risk group (i.e. 5 to 15 year olds requiring caries related extractions under a chair GA) in a convenient, acceptable and potentially achievable manner (i.e. as part of the pre - GA assessment appointment).

Aim:

To assess the feasibility and inform the planning of a proposed definitive randomised controlled clinical trial (RCCT) to investigate the efficacy of sealing permanent molars during the pre-GA assessment visit, in children (aged 5 to 15 years) requiring caries related extractions under a chair GA.

Objectives:

1. To provide data on:
   - recruitment rate
   - retention levels (i.e. drop-out rate)
   - caries increments and sealant retention (i.e. clinical data)

to help inform the sample size and follow up time period for the definitive RCT.

2. To test the feasibility and acceptability of the study procedures and data collection tools (as indicated by completion rates and data quality) for the definitive trial.

3. To provide data on dental treatment provided during the study follow up period by 'providers' outside the study.

4. To assess oral health related Quality of Life (OHRQoL) two years following caries related extractions under GA and investigate the impact that sealant placement may have on this.

Methodology:

Study design

A randomised controlled pilot study to compare sealant versus no sealant to prevent caries on the permanent molars of children requiring caries related dental extractions under a chair GA.

Setting and Study population

The target population is children (aged 5 to 15 years) that attend the Birmingham Dental Hospital for extraction of carious teeth under a chair GA and who have at least one 'sealable' permanent molar tooth.
The intervention (pit and fissure sealants) will be carried out at the BDH but participants may also be seen in Community Dental Clinics (CDCs) for review.

Selection criteria

Children will be considered 'eligible' to be recruited to the study if they fulfil all the inclusion criteria and none of the exclusion criteria.
These are as follows:

Inclusion criteria

- Children that are to have extraction of at least one carious tooth under a chair GA at the BDH
- Birmingham residents (as indicated by post code of home address)

At the pre GA assessment visit, these children must:

- Be aged 5 to 15 years
- Be co-operative to a clinical dental examination
- Present with at least one permanent molar tooth that is 'sound and sealable'
- Be accompanied by an adult that has legal capacity to give informed consent

Exclusion criteria

Patients who at the pre-GA assessment visit present with:

- Signs of a systemic illness (e.g. coughs, 'colds', chicken pox) that might preclude placement of sealants
- Oral symptoms (e.g. pain, swelling) that would preclude sealant placement
- Parents unable to confirm (with a reasonable degree of certainty) that they would be contactable and able to attend for review during the 2 years duration of the study (e.g. because of plans to move)

Study Procedure

Referrals to the GA Department (for GA extractions) will be screened by the Principal investigator (PI).
Parents/ legal guardians of children identified as 'potentially eligible' for inclusion (based on some of the selection criteria outlined above) will be invited to participate in the study.
An invitation letter and parent/ participant (child) information sheets (Appendix 1, 2, 3) will be posted to potential participants shortly after (i.e. within a week) of sending the pre-GA assessment appointment. We have opted to post the study literature separately to the GA information to avoid supplying parents with too much information in one letter, which might confuse them.
Pre-GA assessment appointments are normally posted well in advance of (i.e. several weeks before) the actual assessment appointment (in view of the long waiting times for GA extractions). This will therefore allow study literature to be posted at least 1 week in advance of the scheduled pre-GA assessment appointment.

***Pre-GA assessment visits**:*

Patients will undergo a routine assessment (including a clinical dental examination) by the GA 'clerking' dentist.
Parents of children considered as 'potentially eligible' (i.e. presenting with potentially sealable permanent molars) will be asked if they would be agreeable to see the PI so that she can explain about the study.
The PI will discuss the study with parent(s) and where appropriate, the child and answer any queries they may have. Another information leaflet will also be provided in case the one sent in the post has been mislaid.
If the parent(s) and child agree to take part, informed written consent will be obtained (Appendix 4). A copy of the signed consent form will be given to parents.

Following this, the PI will confirm/ refute eligibility by carrying out:
- a 'simple' clinical dental examination
and
- a short interview with parents/ legal guardians.

Clinical Examination:
Once eligibility is confirmed, participants will undergo a detailed baseline clinical dental examination (by the PI).
This will involve a standard visual and tactile examination of clean and dry teeth. A 3 in 1 syringe will be used to wash and dry the teeth and a ball ended (blunt tip) probe will be used to remove soft debris and check for minor cavitations or the presence of sealants.
Where possible, all surfaces of all teeth will be examined - caries, restorations and sealants will be recorded.
Caries status will be assessed using the ICDAS[46] and data will be recorded on charts designed for this purpose.

Radiographs will not be taken unless clinically necessary.

All clinical data (and other relevant information such as whether or not the patient is registered with a dentist*)* will be recorded on a case report form (Baseline CRF).
Participants will be allocated a unique study Participant Identification Number (PIN) to be used for data recording and analysis.

Randomisation:
Participants will be randomised to the intervention i.e. Sealant or Control group. Block randomisation will be used.

Sealants Procedure:
All 'sealable' permanent molars will be sealed: Occlusal fissures and where appropriate, buccal pits (on lower molars) and palatal pits (on upper molars) will be sealed.
If patient compliance is adequate, a resin based sealant will be used as the first choice material.
If patient compliance is compromised, a glass ionomer (GIC) sealant will be employed, if possible.
GIC will also be where adequate moisture control for a resin sealant is compromised.
Where possible, the same brand of sealant (whether resin or GIC) will be used throughout the study to minimise any potential variation caused by the use of different sealants. Sealants will be applied in accordance with manufacturer's instructions and the technique routinely used by the PI.

The time required to apply the sealants will be recorded.
The acceptability of the procedure from the child's perspective will be assessed by asking patients to select a face from a 'Modified Child Dental Anxiety Scale' (MCDAS)[47, 48] before and after treatment to express how they feel. (Appendix 5)
The validity and reliability of the MCDAS (faces version) has been evaluated for use in children.

Details of all treatment provided will be documented on the Baseline CRF, as too will the data collected to assess the acceptability of the procedure.

Children that lack co-operation for placement of even GIC sealants will not be allocated to the control group to avoid any possibility of selection bias.
Intention to treat (ITT) analyses will be performed for all participants in the sealant group, regardless of whether or not sealants were placed.

For all participants (sealant and control group), carious teeth that are not earmarked for extraction will be managed as per the routine standard of care: where necessary, we will offer to provide dental treatment on undergraduate student clinics and/ or the patient will be referred back to their dental practitioner for this to be carried out.

Refusals and non-eligibility:
Records will be kept on the number of refusals and the number that consented but failed to fulfil the eligibility criteria.

***Follow up and Review*:**

Participants will be reviewed at 12 months and 24 months (after the baseline examination).

Reviews will be carried out at the BDH or at one of the Community Dental Clinics (CDCs) in Birmingham.

A review appointment will be sent out at least 2 weeks in advance of the scheduled visit. This will be followed up by a telephone call (by the PI) to remind participants of the appointment and to answer any queries.

For participants that fail to attend the 12 month review appointment, a second appointment will be arranged (followed, where appropriate by a phone call reminder).
If this appointment is also missed, the participant will be contacted again for the 24 month review.
For participants that fail to attend the 24 month review appointment, a second appointment will be arranged (followed, where appropriate by a phone call reminder).
If the second 24 month review appointment is also missed – the PI will where possible, telephone parents of non-attendees to establish the reason(s) for failure to attend and/ or withdrawal. Responses will be recorded on a Withdrawals form (Appendix 6).

Clinical Examination at Follow up/ Review Appointments:

At the follow up visit, a detailed clinical examination will be carried out (by the PI).
The procedure will be identical to the one used for the baseline clinical dental examination.
Where possible, all surfaces of all teeth will be examined.
Radiographs will not be taken unless clinically necessary.
Caries status will be assessed using the ICDAS.

Retention of sealants (for the sealant group) will be reported on the basis of these being fully intact, partially intact or lost.

Data will be recorded on case report forms, (Follow up CRF).

Structured interview questionnaires:

A structured interview questionnaire (Appendices 7 and 8) will be used to collect information on parents' experiences of dental services for their children, following the GA extractions. Children will be welcome to input too.
This will be administered by the PI.

Outcome assessor blinding:
As far as possible (i.e. practicable), the outcome assessor i.e. PI will be blinded about which arm of the study a participant belongs to.
However, it has to be acknowledged that it is virtually impossible to achieve 'complete' blinding, in part because the presence of intact sealants will alert the assessor to the likelihood that the participant belongs to the sealant group. Furthermore, in view of the fact that the PI is involved in providing the intervention (i.e. applying sealants), there is a small possibility that she may recollect some of the patients on whom these were carried out.
Therefore, in order to verify the validity of the outcome data (and thus minimise detection bias), all permanent molars will be photographed. A specialist in paediatric dentistry will be asked to examine and report on a sample of the photographs and the observations will be compared with those of the PI. The photographs should also allow an assessment to be made of intra-examiner reproducibility. Informed verbal and written consent for clinical photography will be obtained using Birmingham Community Healthcare NHS Trust Clinical Photography Consent Forms. A copy of the signed consent form will be given to parents.

Measures specific to each review:
At the 12 month review/ follow up visit*:*

- Preventive interventions (i.e. sealants or topical fluoride) will not be offered to any of the participants
- For the sealant group, sealants identified as lost or defective will not be replaced.

If a child presents with symptoms (pain, sepsis) or evidence of caries, these will be managed appropriately. Where necessary, operative dental treatment will be provided (on undergraduate student clinics) and/ or the patient will be referred back to their dental practitioner for this to be carried out. Where a child is registered with a dentist, a letter will be sent to the dental practitioner to inform them of any treatment that has been undertaken (Appendix 9) and/ or to request the treatment that is indicated (Appendix 10).

At the 24 month review/ follow up visit:

- Preventive advice and if appropriate, preventive interventions (i.e. sealants and/ or topical fluoride) will be offered to all participants (sealant and control group). This includes sealants on teeth that may have erupted since the baseline examination.
- In the sealant group, lost or defective sealants may also be replaced if this is still appropriate.

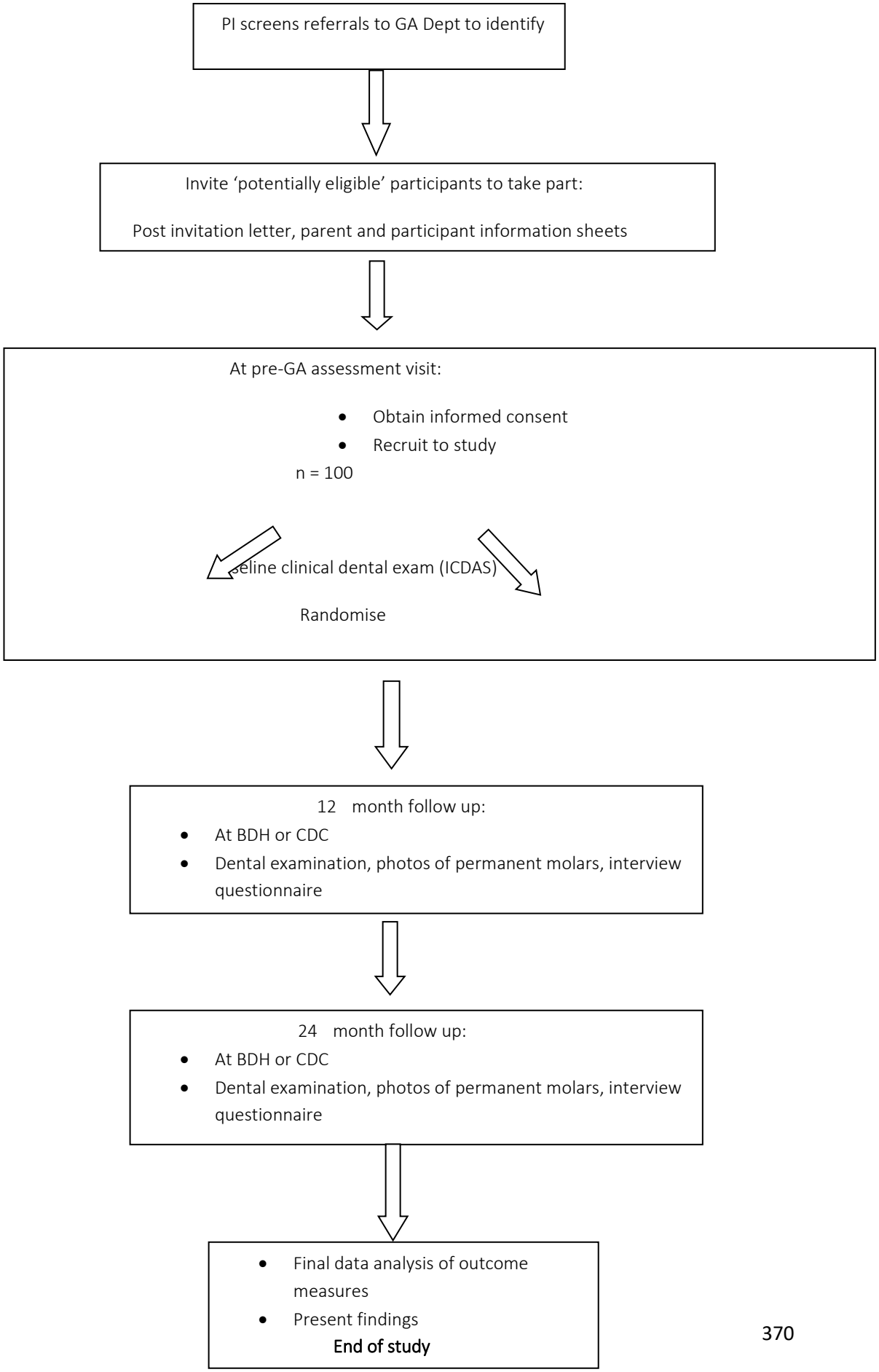
Operative treatment needs in both groups will be managed as per the 12 month review visit.

In addition, oral health related Quality of Life (OHRQoL) will be measured using the Child-Oral Impacts on Daily Performances (Child-OIDP).[49]
(Appendix 11)
This has been shown to be a reliable & valid instrument to measure oral health related quality of life in school aged children. It has been widely used in paediatric oral health research, & so should allow a useful comparison of our findings with other studies.

Withdrawals:

Participation is entirely voluntary and participants are free to withdraw at any time.
The number of withdrawals will be recorded and where possible, these will be followed up (by the PI phoning parents of non-attendees) to establish the reasons for withdrawal. This information will be recorded on a designated 'withdrawals form' (Appendix 6).

Flow diagram of pilot study



Outcome measures:

7. Recruitment and drop – out rates
   The measures used to assess these will be:
   c. The proportion (and number) of 'potentially eligible' children whose parents do not give consent to participate in the pilot study.
   d. The proportion (and number) of participants that subsequently withdraw from the pilot study.

   Where possible, withdrawals will be followed up to determine the cause.

8. Treatment acceptability
   The child's compliance and acceptability for sealant application will be assessed in 3 ways:
   d. By recording the type of sealant (material and technique) used i.e.
      Use of the GIC gloved finger technique will signify that the child lacked co-operation for resin sealants.
   e. By recording the time required to complete the procedure (reported as an average time per sealant for each child if multiple teeth are sealed).
   f. By using the MCDAS before and after sealant placement to assess the child's perspective of the procedure.

9. Sealant retention status
   This outcome will be restricted to the intervention (sealant) group and will report on the proportion (and number) of sealants that are fully intact, partially intact and lost at follow up.

10. Caries incidence (after 1 year and 2 years) in permanent molars that were identified as 'sound and sealable' at the baseline examination.
    Note: the presence or absence of caries and caries related treatment (including evidence of sealants), will be recorded for all surfaces of all teeth using the ICDAS system. However, the primary outcome measures will be restricted to permanent molars that were identified as 'sound and sealable' at the baseline examination.

11. Care provided by referring dentists during the 2 years following the GA extractions.
    This will be assessed in 2 ways:
    c. By using a structured interview questionnaire to record experiences of dental services following the GA extractions.
    d. By identifying dental treatment, (in particular sealants) at the follow up clinical examinations, that was not present at the time of the baseline examination or carried out as part of the pilot study.

12. Oral health related quality of life two years after the extractions under GA, as assessed using the Child-OIDP.

Sample Size:

No formal power calculation is presented for this feasibility and pilot study. The target sample size for the pilot study is 100 participants (50 in the intervention 'sealant' group and 50 in the control group). This should give robust data on recruitment and retention as well as on the variability of the outcome measures.

Statistical analysis:

Summary statistics will be calculated as appropriate using statistical software (STATA). Intra and inter-examiner reliability of caries assessment will be assessed using Cohen's kappa. No formal hypothesis testing will be performed, consistent with the character of this feasibility and pilot study.

Data management, data protection and confidentiality:

Throughout the study, consideration will be given to the implications of the Data Protection Act 1998 and Caldicott arrangements (as required by Birmingham Community Healthcare NHS Trust's Confidentiality/ Data Protection and Information Security Guidelines).

The NHS Confidentiality: Code of conduct will be followed.

Advice will be sought from the Information Governance and Caldicott team prior to obtaining Caldicott approval.

Adverse events:

Although we anticipate the risk of any adverse events associated with this research study to be minimal, any untoward occurrences will be managed and reported according to local Trust policy.

Resources needed:

We do not intend to source any external funding for this study as most of the required resources will be secured locally through the Service (NHS/ University). However, we may consider 'requesting' sealant materials from relevant dental companies if we encounter difficulty in maintaining a constant supply of the materials we have opted to use.

1. **Clinical Time**

Principal investigator*:*

- Identify and recruit patients for pilot study, carry out sealants: anticipate 5 children (intervention or control group) will be recruited per session, equating to the need for ~ 20 sessions to recruit the target sample size (over 5 months)
- Carry out all follow up assessments for pilot study (staggered over 24 months).

Undergraduate BDS student teaching clinics:
Undergraduate BDS students will (if appropriate and under supervision) carry out dental treatment, for participants identified as needing treatment at the 12 and 24 month reviews.
This will be as part of their clinical training in paediatric dentistry.
Facilities (including nursing support, equipment and materials) will be made available as part of the UG training experience.

2. **Equipment and materials associated with sealing**
    - Chair/ unit space and dental nurse assistance for application of sealants – intervention preferably to be delivered in Children's Department.
    - Equipment, instruments, sealant materials.
    - Camera equipment for clinical photography: PI has access to this equipment, both at Dental Hospital and in Community Dental Service.

3. **Administrative time and resources:**
Stationery, printing, photocopying, postage, administrative staff support.
PI time for entering data, analysing results and writing up report/ publications.

Sponsor:

The University of Birmingham will act as the sponsor for this study.

Research Governance and Ethical Considerations:

R and D approval (Research and Development) and full NHS ethics approval (from the Local Research Ethics Committee) will be sought prior to commencing the study.

Dissemination and publication:

The results of the study will be published, preferably as research papers in peer reviewed academic journals.
The results may also be presented at scientific meetings and conferences (e.g. British Society of Paediatric Dentistry).

Benefits and Generalisability:

In the long term, this research intends to benefit a vulnerable group of children at high risk of developing dental caries.
If the proposed 'definitive' randomised control trial shows that sealant application (on permanent molars) as part of the pre-GA assessment visit is a practical and effective measure to prevent caries, this intervention could potentially be implemented in dental GA centres throughout the country. We could also consider extending the measure to include sealant application on other vulnerable teeth (including premolars and possibly even deciduous molars in younger children).
Furthermore, cost-efficiency could be maximised by deploying appropriately trained and skilled dental care professionals (i.e. dental therapists), to carry out sealants.
The data collected should also help to establish what oral health support is currently made available to prevent further caries in children following extractions under GA. This should help to identify any gaps in provision of care and inform decisions on developing further interventions.

Key responsibilities of study personnel:

Chief investigator

To develop, manage and co-ordinate the study. This includes:

- Protocol preparation
- Preparation of all related documents (participant information sheets, consent forms, structured interview questionnaires, case report forms, letters to dentists)
- Seeking and obtaining approvals (ethics, R and D, sponsorship)
- Registering the study as required by
- Ensuring adequate resources are available to implement the study
- Analyse data (with support from academic supervisors)
- Prepare reports and research papers for publication (with support from academic supervisors)
- Ensuring the study is conducted, monitored and reported as agreed in the protocol

Principal investigator

To carry out much of the ground-work for the study and ensure that the procedures agreed in the protocol are followed by all staff involved with the research.
Specific tasks include:

- Identify potential participants, recruit and obtain informed (written) consent
- Carry out baseline dental examinations

- Carry out sealants for intervention group
- Carry out dental examinations at 12 and 24 month reviews
- Carry out or arrange clinical photography at 12 and 24 reviews (after securing appropriate consent)
- Administer structured interview questionnaires
- Enter data on to secure password protected database

Academic supervisors

To provide support throughout the study and in particular with developing the protocol, seeking approvals, analysing results (including statistical) and disseminating the findings.

Proposed time-frame:

Mid July 2014 to end of December 2014:
Identify and recruit participants for pilot study

Mid July 2015 to end of December 2015:
12 month follow up of pilot study participants

February 2016 to June 2016:
Inter-rim data analysis and report

Mid July 2016 to end of December 2016:
24 month follow up of pilot study participants

January 2017 to December 2017:
Final data analysis and report
Completion of PhD thesis
Prepare research papers

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APPENDIX 10

Pilot RCT NHS Ethics approval letters – please see separate documents

APPENDIX 11

Paediatric Department
Birmingham Dental School
St Chad's
Queensway
Birmingham B4 6NN

Letter addressed to:
Parent/ Guardian of 'Child's name'
Address

Date: (*to enter*)

Study title: Sealants for children having decayed teeth extracted under general anaesthesia

Dear Parent/ Guardian

We are carrying out a study to look at ways of preventing tooth decay in children's teeth, especially children that need to be asleep (i.e. have a general anaesthetic, GA) to have teeth taken out.

We are inviting you/ your child to take part because your child needs to have a decayed tooth/ teeth taken out under a GA.

You should have already received a separate letter to tell you about your child's GA assessment appointment.

We would be grateful if you could read the enclosed information sheet prior to this appointment. There is also a separate (child-friendly) information sheet, which your child might like to read or you can go through it with them.

If you require more information or have any questions about the study, please feel free to discuss these with me at the GA assessment visit. Alternatively, you can in the meantime, contact me by telephone or e-mail (please see below for contact details).

Although we would very much appreciate your help with this, participation is entirely voluntary.

Please do attend the GA assessment appointment (whether or not you decide to take part in the research study) as the assessment needs to be done before we can see your child to take the teeth out.

Yours Sincerely

Miss Abida Raja
Study Dentist

Telephone:
E-mail:

APPENDIX 12

Information sheet for Parents/ Guardians

Study title: Sealants for children having decayed teeth extracted under general anaesthesia

We are inviting your child to take part in a research study. However, before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Therefore, please take the time to read the following information carefully and discuss it with others if you wish. Do ask us if there is anything that is not clear, if you would like more information or if you have any questions.

There is a separate information leaflet (written in a child-friendly manner) enclosed with this letter. Your child might want to read this or you can go through it with them.

What is the purpose of this study?

Children that need to have a general anaesthetic (GA) i.e. they need to be asleep to have decayed teeth taken out, are at risk of developing further decay in their remaining teeth, including permanent (adult) teeth that come through later. This study is about preventing new decay in children's teeth, following removal of decayed teeth under a GA.

One way to help stop tooth decay in back teeth (especially permanent teeth) is to carry out 'sealants'.

Dental sealants are protective plastic coatings placed on the chewing surfaces of some back teeth to help prevent tooth decay. They are usually put on permanent back teeth when they have just come through (and are still free from decay) and protect the tooth surface by keeping food and plaque out of the grooves. They are simple and quick to apply: the tooth is cleaned, liquid sealant is put on with a brush and then set hard using a special light. No drilling is involved and no injection is needed.

Sealants were first introduced in the 1960s and there is lots of scientific evidence to show that they help prevent tooth decay.

They are normally put on by dentists or members of their team in dental surgeries and clinics. Your dentist may have talked to you about these or your child may even have already had them.

However, many children miss out on having sealants – this might be because they don't visit the dentist regularly or may be too anxious to have them done. Also, some dentists don't offer or provide this treatment.

We therefore want to see if it would be helpful for children that are at a high risk of getting tooth decay (and this includes those that need to have decayed teeth taken out under a GA) to have sealants put on when they come to the Dental Hospital. We especially want to find out if placing sealants before the child has any decayed teeth taken out can help, because some children might not go back to a dentist after the teeth are taken out.

If you have access to the internet, you might want to find out more about sealants by looking at the following websites:
https://www.dentalhealth.org/tell-me-about/topic/children-s-teeth/pit-and-fissure-sealants

http://www.child-smile.org.uk/parents-and-carers/fissure-sealant.aspx

Why has my child been asked to take part?

We are sending this information to parents of children that are due to have a decayed tooth/ teeth taken out under a GA at the Birmingham Dental Hospital. We plan to contact approximately 200 parents.

Your child's teeth will be checked as part of the routine procedure for the GA assessment appointment. After this, we will know whether or not your child may be suitable to take part.

Do we have to take part?

No. It is up to you and your child to decide whether or not you would like to take part. If you agree to take part, you are free to withdraw at any time and without giving a reason. A decision not to take part or to withdraw at any time, will not affect the standard of your child's dental care.

What will happen if we agree to take part?

Once you have agreed to take part, you will be asked to sign a consent form.
You will be given a copy of the signed consent form and the information sheet to keep.

The research dentist will ask you some simple questions to find out if your child is suitable to take part and examine your child's teeth in more detail. We will record information on a special form. X-rays will not be taken as part of the research study although we would look at any that might have been taken as part of the routine GA assessment procedure.

In this study: half of the children will have sealants put on and half won't. We will then compare the two groups to find out if sealants make a difference. For the comparison to be fair, we need to try to make sure that there is no difference between the children in the two groups that are being compared. We will therefore need to 'randomly' select which children are to have sealants applied – this means that neither we nor you can choose which group your child will fall into. In order to put people into groups by random – we use a pile of sealed envelopes: only half of these will have a slip to say sealants are to be done. Your child therefore has a 1 in 2 chance of having sealants.

If your child is selected to have sealants, these will be done at the GA assessment appointment. The research dentist will do the sealants:
To do sealants, the tooth is cleaned, a gel is applied for about 30 seconds, this is washed away with water and the tooth dried before putting the liquid sealant on, which

is then set hard using a special light. No drilling is involved and no injection is needed. This normally takes less than 5 minutes per tooth and the whole procedure will probably take no longer than about 20 minutes.
If your child is unable to cope with this treatment, we can try a simplified version of the technique using a different type of sealant material, although this is considered to be less effective than the usual procedure.
To help find out how your child has coped with the treatment, we will use a special child-friendly chart (based on pictures of happy and sad faces) – we will ask your child to choose a face just before and immediately after the treatment to let us know how they feel.

Whether or not your child was chosen to have sealants:
An appointment will be arranged for your child to come back to the Dental Hospital, to have the decayed teeth taken out as planned, under a GA.

After having teeth out, you will be asked to bring your child back to the Dental Hospital (or a Community Dental Clinic closer to where you live, if that is more convenient) for a review. We will need to see you twice during the 2 year study period – the first review will be about a year after having the teeth taken out and the second will be about 2 years after the teeth were taken out.

At both review visits:

- Your child's teeth will be checked by the research dentist. No x-rays will be taken as part of the research study – these will only be taken if this is likely to benefit their routine dental care.
- We will take photographs of your child's back teeth to help keep a record of the condition of these teeth. Your child will not be identifiable (as these are only photos of the teeth).
- We will ask you some questions to help us find out about any other dental treatment your child has received since he/ she had teeth taken out.

When we check your child's teeth at the 1 year and 2 year review appointments:

- If problems are found, we will offer to arrange for any necessary dental treatment to be carried out.
  We will either offer appointments on our dental student clinics for this to be done or you may choose to return to see your family dentist for the necessary treatment.

At the 2 year review:

- We will provide advice on how you can best care for your child's teeth and put a fluoride varnish on the teeth to help prevent decay. If your child was not chosen to have sealants at the start of the study, this is something that we may still be able to do, as long as the teeth are free from decay. We may also repair any worn sealants if needed.

If your child is registered with a dentist for his/ her routine dental care, you will be advised to continue to see them as usual, throughout the two year duration of the study and after it ends. Your dentist is free to provide all the usual dental care they would normally provide throughout the study period.

What will I have to do?

Once you have agreed for your child to take part in the study, we will ask you to sign a consent form.

After the assessment visit, you will bring your child back to the Dental Hospital, as planned, to have his/ her decayed teeth taken out under GA.

After having teeth out, you will be asked to bring your child back to the Dental Hospital (or a Community Dental Clinic) for a review, twice during the 2 year study period – the first one will be about a year after having the teeth taken out and the second will be about 2 years after the teeth were taken out.

At both review visits: we will ask you some questions to help us find out about any other dental treatment your child has received since he/ she had teeth taken out.

Are there any possible disadvantages/ risks of taking part?

Sealants are not a new treatment – they are safe and already used by many dentists.

Most children cope well when having sealants applied but if your child is very anxious and unable to accept the procedure (even the 'simplified' form), we would abandon the treatment so as not to upset him/ her.

A possible disadvantage is that you will need to bring your child back to the Dental Hospital (or a Community Dental Clinic) twice during the two year study period for a review.

Are there any possible benefits of taking part?

When sealants are applied to teeth, they help to prevent tooth decay.
At the start of the study, your child has a 1 in 2 chance of having sealants applied to some of his/ her permanent (adult) back teeth.

At the 1 year and 2 year review appointments:
Your child's teeth will be thoroughly checked and if problems are found, we can arrange for any necessary dental treatment to be carried out.

Furthermore, at the 2 year review: we will provide advice on how you can best care for your child's teeth and put a fluoride varnish on the teeth to help prevent decay. If your child was not chosen to have sealants at the start of the study, this is something that we may still be able to do, as long as the teeth are free from decay.

Finally, by agreeing to take part in the study, you are helping to find out how we can best care for children with similar dental problems in the future.

What if new information becomes available in the future?

During the course of a research study, we may get useful new information. If this happens, we will let you know and discuss how it may affect your child's care.

What happens when the research study stops?

If your child is registered with a dentist, we will encourage you to continue to take him/ her back to your dentist for routine check-ups and treatment.

If your child is not registered with a dentist:

- We will encourage you to do this so that your child sees a dentist regularly for check-ups and treatment.
- Alternatively, we may be able to offer routine check-ups and treatment on our dental student clinics.
- If your child is very anxious about dental treatment, we may in exceptional circumstances, be able to arrange routine care with a child friendly dentist in one of our Community Dental Clinics.

What happens to the results of the research study?

The results will be analysed and published in dental journals. These are normally read by dentists and their staff.
The findings may also be presented at scientific meetings and conferences, where they can be shared with other health care professionals and researchers.
You or your child will not be identified in any report or publication.

Will my child's taking part in the study be kept confidential?

Your details and your child's details and study information will be kept confidential.

Only key people who have a need or right to know will be aware that you are taking part in the study: this includes members of the study team and possibly people from regulatory authorities who sometimes wish to check that the study is being carried out correctly.

We do not intend to tell your child's dentist (if he/ she is registered with one) that you are taking part in the study. However, we may contact your child's dentist following the 1 and/ or 2 year reviews, to let them know of any dental treatment required and/ or any treatment that we carry out.
You, however, are welcome to let your child's dentist know (at any time) that he/ she is taking part in the study.

Who is organising and funding the study?

This study is being organised and funded by the University of Birmingham School Of Dentistry and the Birmingham Dental Hospital (which is part of the Birmingham Community Healthcare NHS Trust).

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the South Birmingham Local Research Ethics Committee.

Whom do I contact if I have any questions and/or concerns or I require further information?

If you have any queries, please contact the study dentist:

Miss A Raja (Study dentist and PhD student)
Paediatric Department,
Birmingham Dental School, St Chads, Queensway, Birmingham B4 6NN
Tel:
E-mail:

Academic supervisors:

Professor Deborah White (Birmingham Dental School)
Tel:
E-mail:

Professor Thomas Dietrich (Birmingham Dental School)
Tel:
E-mail:

You can also contact the Customer Services Department of Birmingham Community Healthcare NHS Trust if you would like to receive some general advice about taking part in research.
Tel:

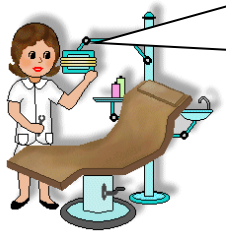
Thank you for taking the time to read this information

APPENDIX 13

Information sheet for Children

For younger children: parents may choose to read this sheet to/ with their child

Project title: Stopping holes in children's teeth



Hello
My name is Abida Raja and I'm a dentist.
I'm doing something called a 'research project'.

What does research mean?



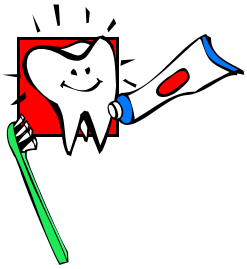


Research is a way we try to find out the answers to questions.

Why are you doing this research project?

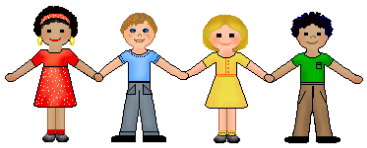


To find out how we can help stop children getting holes in their teeth.



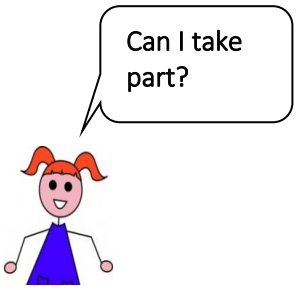
Who can take part?



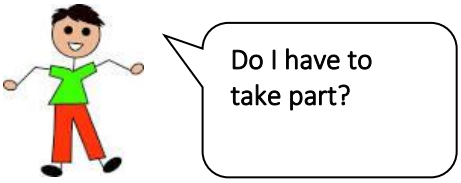


Children that need to come to the Dental Hospital to have some bad teeth taken out while they are asleep but who also have some new big (grown up) teeth that we want to keep healthy.

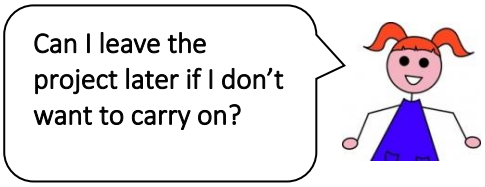




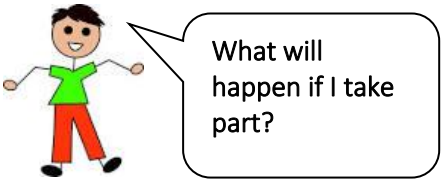
You might be able to.
You are the right age and you also need to have some bad teeth taken out. We would need to check your mouth to see if you have any new big teeth before we can tell you if you can take part and we also need to speak to your parents or the adult that takes care of you.



No, you don't have to take part. It's up to you and your parents to decide and we won't mind if you don't.



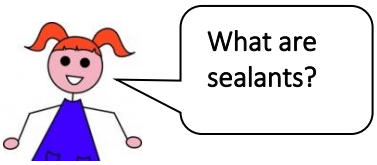
Yes, that's fine. We won't mind.



When you come to the Dental Hospital, a dentist will count and check your teeth (a lot like when you go to see a dentist for a 'check up').

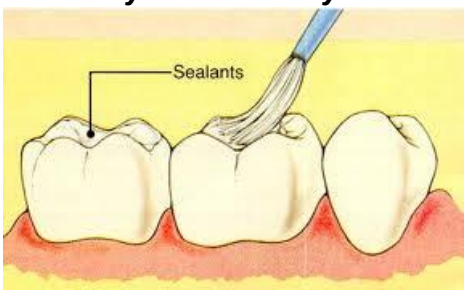


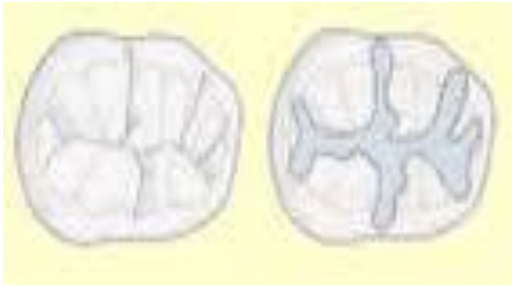
You won't be having any teeth taken out on this day. That will be on a different day.
Some children will then be 'picked' to have something called 'sealants' painted on their grown up back teeth to try to keep them healthy. Neither we nor you can choose who has the sealants. We will use a pile of envelopes to decide who has them – half the envelopes will contain a slip of paper that says 'sealant'. This means that half of the children taking part will have them and half won't.

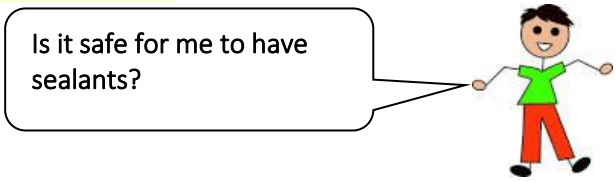




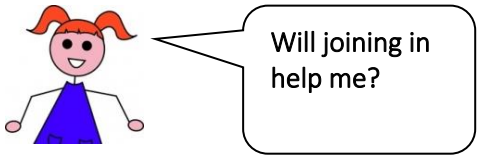
Sealants are a varnish that we can paint onto teeth. We wash the teeth, dry them, paint the varnish on and set this with a special light. The sealants are white so you can't really see them, you can't taste them and they don't hurt.



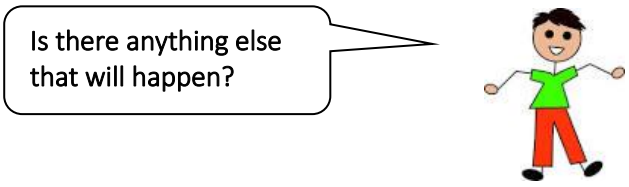




Yes. Sealants are a safe treatment and lots of children have them already. Most children are fine having sealants. However, if you are worried or upset about having them done, you don't have to carry on.
Also, the project has been checked by a special group of people called an 'Ethics Committee'.



If you are picked to have sealants put on your teeth, these can help to keep them healthy.
Even if you don't get picked now, you might still be able to have them done when you are a bit older although we can't promise.



If you are picked to have sealants, we would like to find out what you think about them.
To help us do this, we will show you some pictures of faces just before and just after you have the sealants done and ask you to pick a face to tell us how you feel.

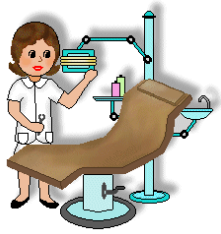


Also, we will want all the children that take part (including the ones that don't have sealants) to come back and see us again when they are a bit older so we can check their teeth and see how they are. We will also take some photos of your back teeth.





You can speak to your parents or the person that looks after you.
You can also ask them to contact me if you have any questions.



Thank you for looking at this form.

Miss Abida Raja (Project Dentist)
Children's Department
Birmingham Dental School
St Chads
Queensway
Birmingham B4 6NN
Tel: [redacted] *E-mail:* [redacted]

APPENDIX 14

Participant Identification Number for this study:

CONSENT FORM

Study title: Sealants for children having decayed teeth extracted under general anaesthesia

Name of Researcher: Miss Abida Raja

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated ***[DATE]*** (version ***[VERSION NUMBER***]) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that participation is voluntary and that I or my child can withdraw at any time without giving any reason, and without this affecting my child's dental care or legal rights. ☐

3. I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from the University of Birmingham, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to these records. ☐

4. I agree for my child to take part in the above study. ☐

Name of Parent or Legal guardian **(Please PRINT name and give title e.g. Mr/ Mrs/ Ms/ Miss)**	**Date**	**Signature**
Child's Name **(Please PRINT)**	**Date**	**Child's signature** ***(if child wishes to sign)***
Name of person taking consent	**Date**	**Signature**

APPENDIX 15

Pilot Baseline CRF 3a

Date completed | | | |

Examining Dentist (PI)..... Nurse (initials).....

							P number

Date of consent: | | | | MH checked | |

Personal Details:

			DOB			AGE

M	F	Gender (circle)

Ethnicity code (self-reported): | | | | | | | | | | Postcode

Dental chart: Enter ICDAS Codes (for treatment and caries)

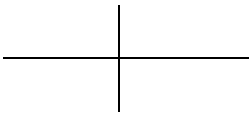
	8	7	6	E/5	D/4	C/3	B/2	A/1	A/1	B/2	C/3	D/4	E/5	6	7	8	
D																	D
O																	O
M																	M
B																	B
L																	L

Upper Right **Upper Left**

	8	7	6	E/5	D/4	C/3	B/2	A/1	A/1	B/2	C/3	D/4	E/5	6	7	8	
D																	D
O																	O
M																	M
B																	B
L																	L

Lower Right **Lower left**

Chart teeth for XGA:



Selection criteria: ***(tick if apply, cross if don't)***

Inclusion criteria:

- **Age 5 to 15 years**
- **Birmingham resident (as per postcode)**
- **Co-operative for dental exam**
- **Minimum of one carious tooth for XGA year review**
- **Minimum of one 'sealable' permanent molar**

Exclusion criteria:

. Signs of systemic illness

. Oral symptoms

. Unable to attend 2

Study PIN

Tick one box only unless specified

Participant accompanied by: *tick all that apply*

Mother ☐ Father ☐ Other ☐ (specify).....

XGA referral source:

Self ☐ GDP ☐ CDS ☐ Dental Hospital ☐ Other ☐

(specify).....

Previous XGA:

Yes ☐ No ☐ Not sure ☐

Registered with dentist:

Yes ☐ No ☐ Not sure ☐

If Yes: GDP ☐ CDS ☐ Hospital ☐

Have appt with dentist after XGA:

Yes ☐ No ☐ Not sure ☐

Radiographs available: Yes/ No (circle)
If applicable: enter details in box
(Views, date taken, report):

Randomisation number

Tick study group: **Sealant** ☐ **Control** ☐

If SEALANT:
Chart which teeth/ surfaces and specify type (R = resin, GIC = glass ionomer cement)

Upper right **Upper left**

	7	6	6	7	
Occ					Occ
Pal					Pal

Lower right **Lower left**

	7	6	6	7	
Occ					Occ
Buc					Buc

Time required to apply sealants:

Start time **End time**

Total time required to apply sealants (mins) | | |

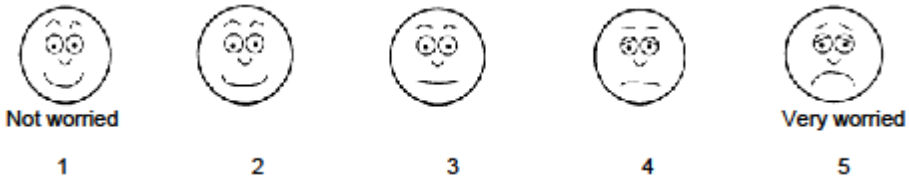
FIS pre-treatment: (circle) **1 2 3 4 5**

FIS post treatment: (circle) **1 2 3 4 5**

APPENDIX 16

Facial image scale
Procedure:

Before sealants:
Explain sealant procedure to child in 'lay' child friendly terms and demonstrate instruments used (PI, dentist)
Following this, ask child to select a face to describe how they feel.



A4 size LAMINATE of pictures to be shown to child

Carry out sealants.

After sealants:
Immediately following treatment, ask child to select a face (using same scale) to describe how they feel.

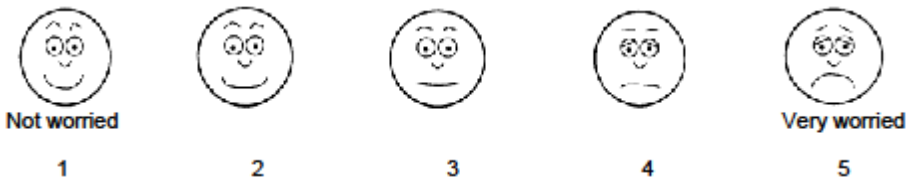
Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5



APPENDIX 17

Pilot RCT record of refusals and non-eligibility

Inclusion criteria:

- Age 5 to 15 years
- Birmingham resident (as per postcode)
- Co-operative for dental exam
- Minimum of one carious tooth for XGA
- Minimum of one 'sealable' permanent molar

Exclusion criteria:

- Signs of systemic illness
- Oral symptoms
- Unable to attend review

P number	**Reason for not taking part** ***Egs:*** ***Don't fulfil selection criteria (see above)*** ***Decline to take part (please record reason)***

APPENDIX 18

Reception staff:
On receipt of a withdrawal, please complete Section One of this form and then pass this on to the study dentist (Miss Abida Raja, Paediatric Department, Birmingham Dental Hospital)
Section One:

Name/ job title of person receiving/ reporting withdrawal.....

Date of withdrawal..... Study PIN: | | | |

Withdrawal requested by: *please tick all that apply*

Parent/ guardian [ ] Participant [ ] Other (please specify) [ ].....

Withdrawal method: *please tick one box only*

Telephone [ ] In person [ ] Other (please specify) [ ].....

Section Two: Withdrawal follow - up (to be completed by study dentist)

Date completed.....

Person interviewed: *tick all that apply*

Parent/ guardian [ ] Participant [ ] Other [ ] (please specify) .....

No interview [ ]

Interview method:

Telephone [ ] In person (i.e. at review appointment) [ ]

Reason(s) for withdrawal: *tick all that apply*

[ ] Change of address

[ ] Inconvenient to attend for follow up (enter details).....

[ ] Child anxious

[ ] Other (enter details) .....

[ ] No reason given

[ ] Participant DNA 12 and 24 month reviews and not contactable

[ ] Participant DNA 24 month review and not contactable

Where possible, ask parent/ guardian

"Is there anything we could have done/ could do to encourage you/ your child to stay in the study"?

APPENDIX 19

Pilot Baseline Follow up – CRF 3b

12 or 24 month review (circle)

Date of review..... Site: BDH ☐ CDC ☐

Specify clinic.....

Examining Dentist (PI).....

Assisting nurse (initials) .....

Enter Participant Details:

☐☐☐ Study PIN ☐☐ Age

Participant accompanied by: *tick all that apply*

Mother ☐ Father ☐ Other ☐ (specify).....

Registered with dentist:

Yes ☐ No ☐ Not sure ☐

If Yes: GDP ☐ CDS ☐ Hospital ☐

Tick on completion:

MH checked ☐ Clinical photos taken ☐ Interview questionnaire completed ☐

Dental chart: Enter ICDAS codes (for treatment and caries)

Upper Right Upper Left

	8	7	6	E/5	D/4	C/3	B/2	A/1	A/1	B/2	C/3	D/4	E/5	6	7	8	
D																	D
O																	O
M																	M
B																	B
L																	L

Lower Right Lower Left

	8	7	6	E/5	D/4	C/3	B/2	A/1	A/1	B/2	C/3	D/4	E/5	6	7	8	
D																	D
O																	O
M																	M
B																	B
L																	L

Sealant chart:

Upper right Upper left

	7	6	6	7	
Occ					Occ
Pal					Pal

Lower right Lower left

	7	6	6	7	
Occ					Occ
Buc					Buc

Dental treatment required:

Outcome:

No treatment required ☐ Refer to dentist for treatment ☐ Book on student clinic ☐

APPENDIX 20

Study title:

Sealants for children having decayed teeth extracted under general anaesthesia

Interview Questionnaire: 12 month review

Study | | | | **PIN:** **Date completed:**

Person interviewed: *tick all that apply*

Mother [ ] Father [ ] Other [ ] please specify

Introduction (PI):

We would like to find out more about the type of dental care provided by dentists to children after they have had decayed teeth taken out under a general anaesthetic (GA).

We would therefore like to ask you some questions about this. These should take no longer than about 15 minutes.

We should stress there are no right or wrong answers.

Furthermore, we can assure you the information you provide will remain confidential and will not affect the care that your child receives.

For all questions, tick one box only unless specified

Ques 1:

Did you take your child to a dentist (outside the Dental Hospital) **before** he/ she had teeth taken out under the GA?

Yes [ ] No [ ] Not sure [ ]

Ques 2:

Have you taken your child to a dentist **since** he/ she had teeth taken out under the GA?

Yes [ ] No [ ] Not sure [ ]

If No/ Not sure to both Ques 1 and 2 → go to Ques 3:

If Yes to Ques 1 but No/ not sure to Ques 2→ go to Ques 4:

If Yes to Ques 1 and Yes to Ques 2→ go to Ques 5a:

If No/ Not sure to Ques 1 and Yes to Ques 2→ go to Ques 6:

Ques 3:

Is there any particular reason why you haven't taken your child to a dentist?

Record comments:

→ Go to Ques 13

Ques 4:

Do you think you might have 'missed' any appointments (i.e. cancelled or failed to attend)?

Yes [ ] No [ ] Not sure [ ]

→ Go to Ques 13

Ques 5a:

Is this the same dentist and/ or dental practice that your child went to before having the teeth taken out?

Yes [ ] No [ ] Not sure [ ]

If No to Ques 5a→ go to Ques 5b

If Yes or Not sure to Ques 5a → go to Ques 6

Ques 5b:

Is there any particular reason why you took your child to a different dentist and/ or dental practice after the teeth were taken out?

Record comments

Ques 5c:

Does the new dentist know that your child has had teeth taken out under a GA (Have you told him/ her?)?

Yes [ ] No [ ] Not sure [ ]

Ques 6:

What type of dentist does your child normally see?

[ ] General Dental Practice (i.e. High street or family dentist)

[ ] Community Dentist

[ ] Dental Hospital

[ ] Not sure

Ques 7:

How soon after having the teeth taken out, did your child first visit a dentist?

[ ] Within 3 months

[ ] Between 3 to 6 months later

[ ] After about 6 months

[ ] Between 6 to 12 months later

[ ] Not sure

Ques 8:

What was the purpose of this first visit after having teeth taken out (*what was it for*)?

[ ] Check up

[ ] Treatment

[ ] Emergency visit as child having problems

[ ] Not sure

Ques 9:

How are your child's dental check- up appointments normally arranged?

[ ] dental practice sends appointment in post

[ ] dental practice sends you a letter reminding you to make an appointment

[ ] you contact the dental practice when you think check up is due

[ ] not sure

Ques 10:

Does the dental practice send you reminders (letters, phone calls or text messages) to help you remember your child's appointment?

Yes [ ] No [ ] Not sure [ ]

Ques 11:

During the last 12 months, has your child's dentist (or a member of the dental team) provided any of the following items of advice or care? *Tick all that apply*

[ ] Advice about tooth brushing

[ ] Advice about a healthy diet (avoiding sugary foods/ drinks)

[ ] Explained about importance of preventing decay to avoid your child needing to have another GA to have teeth taken out

[ ] Teeth cleaned (scale &/ or polish)

[ ] Application of fluoride varnish to teeth

[ ] Dental sealants (plastic coatings)

[ ] Fillings

[ ] Extractions (teeth taken out)

[ ] X-rays

[ ] Other (specify)

Ques 12a:

Is your child anxious (worried or scared) about dental treatment?

Yes [ ] No [ ] Not sure [ ]

If Yes → go to Ques 12b

If No/ Not sure → go to Ques 13

Ques 12b:

Has your child's anxiety about dental treatment stopped the dentist from carrying out treatment that was planned?

Yes [ ] No [ ] Not sure [ ]

Ques 12c:

Has your child's dentist and/ or a member of the team offered any measures to help reduce this anxiety?

Yes [ ] No [ ] Not sure [ ]

If Yes, ask to expand on measures offered and record comments:

Ques 13:

Which, if any of the following measures would you find useful to help you to look after your child's teeth? *Tick all that apply*

[ ] Help with finding a 'child-friendly' dentist

[ ] More frequent check up appointments with your child's dentist

[ ] Letters to remind you about your child's dental appointments

[ ] Phone calls to remind you about your child's dental appointments

[ ] Text messages to remind you about your child's dental appointments

[ ] Information leaflets about caring for your child's teeth

[ ] DVDs about caring for your child's teeth

[ ] Any other support (please specify)

Thank you very much for completing the interview

Do you have any questions or comments you would like to add?

APPENDIX 21

Study title:

Sealants for children having decayed teeth extracted under general anaesthesia

Interview Questionnaire: 24 month review

Study | | | | **PIN:** **Date completed:**

Person interviewed: *tick all that apply*

Mother [ ] Father [ ] Other [ ] please specify

Introduction (PI):

We would like to find out more about the dental care children receive after they have had decayed teeth taken out under a general anaesthetic (GA).

We would therefore like to ask you some questions about this. These should take no longer than about 15 minutes.

We should stress there are no right or wrong answers.

Furthermore, we can assure you the information you provide will remain confidential and will not affect the care that your child receives.

For all questions, tick one box only unless specified

Ques 1:

Did your child go to a dentist (outside the Dental Hospital) **before** he/ she had teeth taken out under the GA?

Yes [ ] No [ ] Not sure [ ]

If yes:

How often did he/ she visit a dentist?

[ ] Only when having trouble

[ ] For check -ups but not regularly (i.e. less than once a year)

[ ] For regular check –ups (i.e. at least once a year)

[ ] Other (*please specify*)

[ ] Not sure

Ques 2:

Have you taken your child to a dentist (outside the Dental Hospital) **since** he/ she had teeth taken out under the GA?

Yes [ ] No [ ] Not sure [ ]

If No/ Not sure to Ques 2 → go to Ques 3:

If Yes to Ques 1 and Yes to Ques 2→ go to Ques 5a:

If No/ Not sure to Ques 1 and Yes to Ques 2→ go to Ques 5c:

Ques 3:

Is there any particular reason why your child hasn't been to see a dentist?

Record comments (& tick options if applicable – tick all that apply)

Options:

[ ] No toothache/ dental problems (apart from problems that resulted in GA)

[ ] Did not receive any appointments or reminders

[ ] Didn't think check-ups were important/ necessary

[ ] Other (*please specify*)

[ ] No specific reason

Ques 4a

Have any of the following been part of the reason why your child hasn't been to see a dentist?

Tick all that apply:

[ ] Difficulty taking time off work (parent)

[ ] Difficulty taking time off school (child)

[ ] Transport difficulties

[ ] Language difficulties

[ ] Other young children to look after

Ques 4b

Do you think you might have been sent an appointment but 'missed' it (i.e. cancelled or failed to attend)?

Yes [ ] No [ ] Not sure [ ]

Ques 4c

Is your child anxious (worried or scared) about visiting the dentist or having dental treatment?

Yes [ ] No [ ] Not sure [ ]

→ ***Go to Ques 13***

Ques 5a:

Is this the same dental practice (surgery/ clinic) that your child went to before having the teeth taken out?

Yes [ ] No [ ] Not sure [ ]

If No to Ques 5a→ go to Ques 5b

If Yes or Not sure to Ques 5a → go to Ques 5d

Ques 5b:

Is there any particular reason why you took your child to a different dental practice (surgery/ clinic) after the teeth were taken out?

Record comments

Ques 5c:

Does the 'new' dentist know that your child has had teeth taken out under a GA? (Have you told him/ her?)

Yes [ ] No [ ] Not sure [ ]

Ques 5d:

Who <u>usually</u> takes 'XX' to visit the dentist? (re-phrase for older children, '*who normally accompanies'*)

[ ] Mother

[ ] Father

[ ] Other (please specify)

Would you be fairly confident to provide answers for the next set of questions, which are about your child's visits to see a dentist?

Yes [ ] No [ ]

Only proceed if respondent reasonably confident to provide information requested.

If not → go to Ques 13.

Ques 6:

What type of dentist does your child normally see?

[ ] General Dental Practice (i.e. High street or family dentist)

[ ] Community Dentist

[ ] Dental Hospital

[ ] Not sure

Ques 7:

How soon after having the teeth taken out, did your child first visit a dentist?

[ ] Within 3 months

[ ] Between 3 to 6 months later

[ ] After about 6 months

[ ] Between 6 to 12 months later

[ ] More than 12 months later

[ ] Not sure

Ques 8:

What was the purpose of this first visit after having teeth taken out (*what was it for*)?

[ ] Check up – ***proceed to ques 10***

[ ] Complete outstanding treatment

[ ] Emergency visit as child having problems

[ ] Other (*please specify*)

[ ] Not sure

Ques 9:

Has your child had a 'routine' dental check-up since having the teeth taken out?

Yes [ ] No [ ] Not sure [ ]

If Yes → go to Ques 10

If No or Not sure → go to Ques 12

Ques 10:

How are your child's dental check- up appointments normally arranged?

[ ] Dental practice sends appointment (e.g. letter or text)

[ ] Dental practice contacts you (letter/ text/ phone call) to remind you to make an appointment

[ ] You contact the dental practice when you think check up is due

[ ] Other (*please specify*)

[ ] Not sure

Ques 11:

Once a dental appointment has been arranged, does the dental practice send you reminders (letters, phone calls, e-mails or text messages) to help you remember your child's appointment?

Yes [ ] No [ ] Not sure [ ]

Ques 12:

Since having the teeth taken out, has your child's dentist (or a member of the dental team) provided any of the following items of advice or care? *Tick all that apply*

[ ] Advice about tooth brushing

[ ] Advice about a healthy diet (avoiding sugary foods/ drinks)

If Yes to either of above:

Can you recall any of the key points you were told about?

Record comments & tick boxes below if applicable:

If not covered, ask about each specific item & tick appropriate box:

Comments:

Has a dentist or member of the team: *Tick all that apply*

[ ] Explained about importance of preventing decay to avoid your child needing to have another GA to have teeth taken out in the future

[ ] Advised on brushing last thing at night & one other time of the day

[ ] Advised on the type of toothpaste to use (fluoride content)

[ ] Advised to spit out & not rinse after brushing

[ ] Demonstrated tooth-brushing i.e. shown you & or your child how to brush his/ her teeth?

[ ] Advised on reducing the frequency (number of times) that your child has sugary foods/ drinks

Was the advice you were given helpful?

Yes [ ] No [ ] Not sure [ ]

Do you feel you/ your child have followed any of this advice & changed behaviour as a result of it?

Yes [ ] No [ ] Not sure [ ]

Since having the teeth taken out, has your child had any of the following carried out?

Tick all that apply

[ ] Teeth cleaned (scale & polish)

[ ] Fluoride varnish applied to teeth

[ ] Fissure sealants (plastic coatings) placed on teeth

[ ] Fillings

[ ] Dental extractions (taken teeth out)

[ ] X-rays

[ ] Other (*specify*)

If fillings or extractions, ask

Did your child have a local anaesthetic (injection) for any of the above treatment (such as fillings, extractions)?

Yes [ ] No [ ] Not sure [ ]

Is your child anxious (worried or scared) about having dental treatment?

Yes [ ] No [ ] Not sure [ ]

If No/ Not sure → go to Ques 13

If Yes, did this stop the dentist from carrying out any treatment that was planned?

Yes [ ] No [ ] Not sure [ ]

Did your child's dentist and/ or a member of the team offer any measures/ techniques to help reduce this anxiety?

Yes [ ] No [ ] Not sure [ ]

If No/ Not sure → go to Ques 13

If Yes, ask to expand on measures offered and record (*tick options*) including comments:

[ ] Behaviour management techniques (friendly manner, demonstrating instruments, acclimatisation)

[ ] Inhalation sedation e.g. laughing gas/ happy air (at local dentist)

[ ] Referral to Community Dental Service

[ ] Referral to Hospital Dental Service

[ ] Referral for GA

[ ] Other (*please specify*)

Ques 13:

Do you have any other children that have had teeth taken out under a GA?

Yes [ ] No [ ] Not sure [ ]

Ques 14:

Which, if any of the following measures would you find useful to help you to look after your child's teeth?

Further advice on how to keep your child's teeth healthy?

Yes [ ] No [ ] Not sure [ ]

***If Yes**, how would you like to receive this advice? (tick all that apply)*

[ ] From a dental professional i.e. dentist, hygienist/ therapist, nurse (at the dental surgery)

[ ] From other health professionals e.g. health visitor, dietician

[ ] Through your child's school

[ ] Information leaflets

[ ] DVDs

[ ] Internet site

[ ] Other (*please specify*)

Help with accessing dental care:

Which, if any of these measures would you find helpful to access dental care for your child? (tick all that apply)

[ ] Help with finding a 'child-friendly' dentist

[ ] To receive more frequent check up appointments with your child's current dentist

[ ] Letters, phone calls, e-mails or text messages to remind you about your child's dental appointments (*specify preferred option*)

[ ] Appointments at weekends or in the evening

[ ] Translation services (*if ticked, specify language*) .....

[ ] Dentist visits child's school to provide treatment on a mobile dental unit (explain, parents may be required to attend for some types of treatment e.g. use of L.A i.e. injections or extractions)

[ ] Any other support (*please specify*) .....

Would you have found it helpful to have had an appointment to bring your child back to the Dental Hospital for a review (check up) a few weeks after the teeth were taken out under GA?

Yes [ ] No [ ] Not sure [ ]

Thank you very much for completing the interview
Do you have any questions or comments you would like to add?

APPENDIX 22

Study title:

Sealants for children having decayed teeth extracted under general anaesthesia

Oral Health related Quality of Life Interview Questionnaire:
24 month review

Study | | | | **PIN:** **Date completed:**

We would like to find out more about the ways in which the mouth & teeth can affect how we feel. We would therefore like to ask you some questions about this. These should take no longer than about 10 minutes.

Please remember, this is not a test and there are no right or wrong answers.

Questions based on Child – OIDP (Child Oral Impacts on Daily Performances)

Possible responses:

0 – Not at all

1 – A little

2 – A fair amount

3 – A lot

"In the <u>past 3 months</u>, have you, because of problems with your teeth or mouth"...

[ ] Had difficulty eating

[ ] Had difficulty speaking

[ ] Had difficulty cleaning your teeth

[ ] Had difficulty relaxing (including sleeping)

[ ] Felt different (for example being more impatient, irritated, easily upset)

[ ] Had difficulty smiling, laughing and showing your teeth without being embarrassed

[ ] Had difficulty doing your schoolwork (for example, going to school, learning in class, doing your homework)

[ ] Had difficulty enjoying being with other people (for example, going out, visiting friends).

"In the <u>past 3 months</u>, how much did the condition of your teeth & mouth affect your everyday life?"

[ ] Not at all

[ ] A little

[ ] Somewhat

[ ] A fair amount

[ ] A great deal

"In the <u>past 3 months</u> have you had"…

a) toothache: yes/ no

b) a sensitive tooth: yes/ no

c) bleeding or swollen gums: yes/ no

d) a broken tooth: yes/ no

e) mouth ulcers: yes/ no

f) bad breath: yes/ no

yes/ no – delete as appropriate

Thank you very much for answering these questions.

Do you have any comments or questions you would like to add?

APPENDIX 23

Paediatric Department
Birmingham Dental School
St Chad's
Queensway
Birmingham B4 6NN

Tel:

Letter addressed to:
Dentist or surgery name, Practice/ Clinic address

Date: (*to enter*)

Dear (*Dentist name*)

Re: *Patient details (Name, DOB, address, BDH registration number)*

We understand *XX* is registered with you for his/ her routine dental care.

As you may be aware, *XX* had some carious teeth extracted under a chair general anaesthetic (GA) at the Birmingham Dental Hospital in (*enter month/ year*).

At that time, *XX* was recruited onto a research study investigating caries prevention in children required caries related extractions under GA.

As part of this study, *XX* attended for a review (follow up) on (*enter date*)**.**
The clinical findings noted at this visit are summarised below:

Enter summary of clinical findings

Arrangements have been made for the necessary dental treatment to be provided on our undergraduate dental students 'paediatric dentistry' clinic.
However, we would be grateful if you could continue to see *XX* for his/ her routine dental care.
We hope this meets with your approval but please feel free to contact us should you have any queries.

Yours Sincerely

Miss A Raja
Clinical Lecturer in Paediatric Dentistry
University of Birmingham School of Dentistry

E-mail:

APPENDIX 24

Paediatric Department
Birmingham Dental School
St Chad's
Queensway
Birmingham B4 6NN

Tel:

Letter addressed to:
Dentist or surgery name, Practice/ Clinic address

Date: (*to enter*)

Dear (*Dentist name*)

Re: *Patient details (Name, DOB, address, BDH registration number)*

We understand *XX* is registered with you for his/ her routine dental care.

As you may be aware, *XX* had some carious teeth extracted under a chair general anaesthetic (GA) at the Birmingham Dental Hospital in (*enter month/ year*).

At that time, *XX* was recruited onto a research study investigating caries prevention in children required caries related extractions under GA.

As part of this study, *XX* attended for a review (follow up) on (*enter date*)**.**
The clinical findings noted at this visit are summarised below:

Enter summary of clinical findings

We would be most grateful if you could arrange to see *XX* at your earliest convenience to provide any necessary treatment.

We hope this meets with your approval but please feel free to contact us should you have any queries.

Yours Sincerely

Miss A Raja
Clinical Lecturer in Paediatric Dentistry
University of Birmingham School of Dentistry

E-mail:

APPENDIX 25:

Outcomes at 12-month follow-up:

Results at 12 months are summarised below and shown in Tables 58 – 66.

Table 58: Pilot RCT – Demographic characteristics for participants followed up at 12 months – whole group and control versus sealant

Demographic characteristics for participants followed up at 12 months				
	All children seen at 12 months (n=41)	**Control group (n=23)**	**Sealant group (n=18)**	**P-value**
Age, years: **mean (SD)** **range** % (*n*) for different ages 6 7 8 9 10 11 15	 8.5 (1.6) 7.0-9.0 2 (1) 27 (11) 27 (11) 24 (10) 12 (5) 5 (2) 2 (1)	 8.3 (1.2) 7.0-9.0 0 35 (8) 22 (5) 26 (6) 13 (3) 4 (1) 0	 8.7 (2.0) 8.0-9.0 6 (1) 17 (3) 33 (6) 22 (4) 11 (2) 6 (1) 6 (1)	 0.41[2] 0.62[1]
Sex: % (n) Male Female	 63 (26) 36 (15)	 52 (12) 48 (11)	 78 (14) 22 (4)	 0.091[1]
Ethnicity broad: % (n) White Asian Black Other	 27 (11) 51 (21) 12 (5) 10 (4)	 17 (4) 61 (14) 13 (3) 9 (2)	 39 (7) 39 (7) 11 (2) 11 (2)	 0.426[1]
Ethnicity categories: % (n) White British White Other White British Caribbean Other Mixed	 24 (10) 2 (1) 2 (1) 2 (1)	 18 (4) 0 (0) 4 (1) 4 (1)	 33 (6) 6 (1) 0 0	 0.481[1]

Asian British Indian	10 (4)	13 (3)	6 (1)	
Asian British Pakistani	34 (14)	35 (8)	33 (6)	
Asian British Bangladeshi	2 (1)	4 (1)	0	
Other Asian	5 (2)	9 (2)	0	
Black British Caribbean	7 (3)	9 (2)	6 (1)	
Black British African	5 (2)	4 (1)	6 (1)	
Chinese	0	0	0	
Other	5 (2)	0	11 (2)	
Index of multiple deprivation (IMD) Decile % (n):				
1 – poorest	58 (24)	57 (13)	61 (11)	0.762[1]
2	15 (6)	13 (3)	17 (3)	
3	15 (6)	13 (3)	17 (3)	
4	0	0	0	
5	5 (2)	4 (1)	6 (1)	
6	5 (2)	9 (2)	0	
7	2 (1)	4 (1)	0	
8	0	0	0	
9	0	0	0	
10 – richest	0	0	0	

Statistical tests:

1 - Pearson's chi squared

2 - Two sample t tests

Table 58 describes demographic characteristics of participants that were followed up at 12 months and compares any variation between the control and sealant groups. Overall, the average age was 8.5 years, and almost twice as many boys attended (compared to girls), unlike the 24-month reviews, when more boys were lost to follow up. Asian children were again, most widely represented in the group that returned, and especially those from a Pakistani background. These trends were apparent in both the intervention and control groups.

Table 59:
Prevalence of sealants at 12 months on permanent molars that were sound at baseline

Data on sealants applied at baseline, for children followed up after 12 months (n=18) **Sealants applied:** • 18 children • 67 teeth • 126 surfaces • 1 child had GI sealants (2 teeth, 3 surfaces), all others resin sealant		
Prevalence of sealants (on permanent molars that were sound at baseline, SPM_{BL}) in children followed up after 12 months (n=18)		
	Control group (n=23 children)	**Sealant group (n=18 children)**
Child with at least one sealed SPM_{BL} (%, n):	0	94 % (17)
Sealant retained (part or full), after 12 months on surfaces sealed at baseline (*sealant group only*) % (n):	-	97 % (122/126)
<u>Resin v GIC</u> (*sealant group only*): Sealant retained after 12 months, on surfaces sealed at baseline: % (n) • GI • Resin		100 % (3 out of 3) 97 % (119/ 123)

At 12 months, overall retention for sealants applied as part of the study, mirrored outcomes after 24 months: 95% of children in the intervention group, still had at least one sealant in situ and 97% of surfaces sealed had evidence of sealants (full or part) (Table 59), compared to 94% after 24 months (Table 38 – page 222).

Table 60: Caries prevalence at 12 months: control versus sealant			
	Control (n=23)	**Sealant (n=18)**	**P-value**
All permanent molars (includes teeth that were present but not 'sound' at baseline and any that had erupted within the 2-year study period)			
Children with dentine caries experience in at least one permanent molar, ($D_{4-6}MF>0$) % (n)	17 (4)	6 (1)	0.25[1]
Children with dentine caries experience in at least one first permanent molar, ($D_{4-6}MF>0$) % (n)	17 (4)	6 (1)	0.25[1]
Children with untreated dentine caries in at least one first permanent molar, ($D_{4-6}>0$) % (n)	17 (4)	0	0.063[1]
Permanent molars that were present & sound at baseline:			
Any caries (ICDAS codes 1-6)			
Child with at least one permanent molar affected by Any caries % (n)	70 (16)	39 (7)	0.05[1]
Child with at least one first permanent molar affected by Any caries % (n)	70 (16)	33 (6)	0.021[1]

Child with at least one second permanent molar affected by Any caries % (n)	0	6 (1)	0.25[1]
Dentine caries (ICDAS codes 4, 5, 6)			
Children with dentine caries experience in at least one first permanent molar ($D_{4-6}MF>0$) % (n)	17 (4)	0	0.063[1]
Children with untreated dentine caries in at least one first permanent molar ($D_{4-6}>0$) % (n)	17 (4)	0	0.063[1]
Untreated severe caries (ICDAS codes 5, 6)			
Child with at least one first permanent molar affected by Untreated severe caries % (n)	4 (1)	0	0.37[1]

Statistical test:

1 - Pearson's chi squared

All experience of caries affecting dentine in permanent teeth, was confined to permanent molars (Table 60). On considering teeth that were sound at baseline, control group children had significantly higher rates of 'any' severity of caries (70%, n=16 control group children, 39%, n=7 sealant group children, P = 0.05), which includes early caries. They also had higher rates of untreated caries into dentine, compared to their sealant group counterparts but the difference, at this stage, was not statistically significant.

Table 61: Caries prevalence in children at 12 months and 24 months			
	12 months (n=41)	**24 months (n=82)**	**P-value**
Children with dentine caries experience in at least one permanent molar, ($D_{4-6}MF>0$) % (n)	12.2 (5)	29.3 (24)	0.002[1]
Children with untreated dentine caries in at least one first permanent molar, ($D_{4-6}>0$) % (n)	9.8 (4)	20.7 (17)	0.001[1]
Children attending 12 and 24-month reviews (n=38):			
Children with dentine caries experience in at least one permanent molar, ($D_{4-6}MF>0$) % (n)	13. 9 (5)	33.3 (12)	0.001[1]
Children with untreated dentine caries in at least one first permanent molar, ($D_{4-6}>0$) % (n)	10.5 (4)	17.9 (7)	0.002[1]

Statistical test:

1 - Pearson's chi squared

Table 61 compares caries incidence in permanent molars for children at 12 months and 24 months: of the 41 children seen 12 months after the GA, 12.2% (n=5) had experience of caries involving dentine and 9.8% (n=4) had untreated caries into dentine. This compares with 29.3% (n=24) and 20.7% (n=17) respectively for the 82 children seen at 24 months. Therefore, twice as many children had untreated dentine

caries and almost three times as many had experience of dentine caries in permanent molars, at 24 months, compared to 12 months. Clearly, the children seen at both reviews were not identical, but these differences also hold true when comparisons are restricted to children that attended both reviews (n=38, Table 61).

Table 62: Caries prevalence based on attendance for 12 and 24 month reviews

	Attending 12 & 24 months (n=38)	**Attending 24 months only (n=44)**	**P-value**
Children with dentine caries experience in at least one permanent molar, ($D_{4-6}MF>0$) % (n)	31.6 (12)	27.3 (12)	0.669[1]
Children with untreated dentine caries in at least one first permanent molar, ($D_{4-6}>0$) % (n)	18.4 (7)	22.7 (10)	0.631[1]

Statistical test:

1 - Pearson's chi squared

No significant differences in caries prevalence were apparent between children that attended both (12 and 24 month) reviews and those that were seen only at 24 months (Table 62).

Tables 63 - 66 outline responses to questionnaires completed at 12 months (n=40).

Table 63: Dental attendance behaviours within 12-months following dental GA
(40 parents completed questionnaires)

	Whole group (n=40)	**Control (n=22)**	**Sealant (n=18)**	**P-value**
Did child visit a dentist before GA? **% (n)**				
- *Yes*	100 (40)	100 (22)	100 (18)	-
- *No*	0	0	0	
- *Not sure*	0	0	0	
Has child visited a dentist since GA? **% (n)**				
- *Yes*	57 (23)	55 (12)	61 (11)	0.68[1]
- *No*	43 (17)	45 (10)	39 (7)	
- *Not sure*	0	0	0	
If not, have family failed a scheduled appointment? ***(17 responses)*** **% (n)**				
- *Yes*	6 (1)	0	0	0.22[1]
- *No*	94 (16)	100 (10)	86 (6)	
- *Not sure*	0	0	14 (1)	
If child has seen a dentist after GA, was it the same dental practice? **(*23 responses*)** **% (n)**				
- *Yes*	96 (22)	100 (12)	91 (10)	0.29[1]
- *No*	4 (1)	0	9 (1)	
- *Not sure*	0	0	0	
If different, does the 'new' dentist know about the GA? ***(1 response*)** **%(n)**				

- Yes	100 (1)	-	100 (1)	-
- No	0		0	
- Not sure	0		0	
Type of dentist: % (n)				
- GDP	100 (40)	100 (22)	100 (18)	-
- CDS	0	0	0	
- Hospital	0	0	0	
- Not sure	0	0	0	
How soon after the GA did the child first visit a dentist? (*23 responses*) % (n)				
- Within 3 months	13 (3)	25 (3)	0	0.26[1]
- Between 3 to 6 months later	13 (3)	17 (2)	9 (1)	
- After about 6 months	48 (11)	42 (5)	55 (6)	
- Between 6 to 12 months later	26 (6)	17 (2)	36 (4)	
- Not sure	0	0	0	
Reason for first dental visit after having teeth taken out? (*23responses*) % (n)				
- Check-up	100 (23)	100 (12)	100 (11)	-
- Complete outstanding treatment	0	0	0	
- Toothache, problems	0	0	0	
- Not sure	0	0	0	
Does dental practice send appointment reminders? (*23 responses*) % (n)				
- Yes	70 (16)	92 (11)	45 (5)	0.053[1]
- No	26 (6)	8 (1)	45 (5)	
- Not sure	4 (1)	0	9 (1)	

Statistical test:

1 - Pearson's chi squared

All children had been to a dentist before the GA but only 57% (n=23) had been back to see a dentist within the 12 months following the extractions. Of these, most (96%, n=22) returned to the same dental practice. Around half (48%, n=11) were seen 6 months after the GA, with approximately a quarter earlier and a similar proportion (26%) later than this interval (Table 63). In all cases, the main reason for the initial visit to a dentist after the GA was for a routine check-up. Amongst those that had not been back to a dentist, no parents believed they had missed appointments (Table 63).

Table 64: Preventive advice and treatments received within 12-months following dental GA

	Whole group followed up at 12 months (n=23)	**Control (n=12)**	**Sealant (n=11)**	**P-value**
Have parent &/ or child received: Yes, % (n)				
- *Oral hygiene instruction*	48 (11)	42 (5)	55 (6)	0.54[1]
- *Dietary advice*	35 (8)	33 (4)	36 (4)	0.88[1]
- *Advice on importance of prevention to avoid repeat GA*	9 (2)	8 (1)	9 (1)	0.95[1]
- *Fluoride varnish*	0	0	0	-
- *Fissure sealants*	0	0	0	-

Statistical test:

1 - Pearson's chi squared

Table 65: Dental treatment received within 12-months following dental GA				
	Whole group followed up at 12 months (n=23)	**Control (n=12)**	**Sealant (n=11)**	**P-value**
Type of dental treatment: % (n)				
Scale and polish	0	0	0	-
Fillings	13 (3)	17 (2)	9 (1)	0.59[1]
Extractions	0	0	0	-
Radiographs	0	0	0	-
Other	0	0	0	-
Was child anxious about having dental treatment? % (n)				
- *Yes*	22 (5)	25 (3)	18 (2)	0.69[1]
- *No*	78 (18)	75 (9)	82 (9)	
- *Not sure*	0	0	0	
If anxious, did this prevent planned treatment being completed? (*4 responses*) % (n)				
- *Yes*	50 (2)	0	100 (2)	0.046[1]
- *No*	50 (2)	0	0	
- *Not sure*	0	0	0	
If anxious, did dentist provide help to reduce anxiety? (*4 responses*) % (n)				
- *Yes*	75 (3)	50 (1)	100 (2)	0.25[1]
- *No*	25 (1)	50 (1)	0	
- *Not sure*	0	0	0	

Statistical test:

1 - Pearson's chi squared

Only half (48%) had received oral hygiene instruction, and a third (35%), dietary advice, by a dental practitioner outside the study, within the 12 months, following the GA (Table 64). None had received fluoride varnish or fissure sealants (Table 64) and overall, minimal dental treatment had been provided (Table 65). A fifth of the sample (22%,) were anxious about visiting a dentist, and for 2 children, this had impacted on delivery of necessary treatment (Table 65).

Table 66: Parents' views (at 12 months) on interventions to support oral health

	Whole group followed up at 12 months (n=40)	**Control (n=22)**	**Sealant (n=18)**	**P-value**
Interventions considered to be 'helpful', parents could select > 1 option, % (n):				
- *Help with finding a 'child friendly' dentist*	28 (11)	32 (7)	22 (4)	0.50[1]
- *More frequent check-up appointments*	20 (8)	27 (6)	11 (2)	0.20[1]
- *Appointment reminders (letter)*	10 (4)	9 (2)	11 (2)	0.83[1]
- *Appointment reminders (phone call)*	25 (10)	23 (5)	28 (5)	0.71[1]
- *Appointment reminders (text)*	40 (16)	27 (6)	56 (10)	0.069[1]
- *Leaflets on oral health*	13 (5)	14 (3)	11 (2)	0.81[1]

- *DVDs on oral health*	20 (8)	14 (3)	28 (5)	0.27[1]
- *Any other support*	5 (2)	9 (2)	0	0.19[1]

Statistical test:

1 - Pearson's chi squared

On considering interventions to support oral health for their child, text messages (40%) were the preferred method for appointment reminders and just over a quarter (28%) welcomed help with finding a 'child friendly' dentist (Table 66).

APPENDIX 26 – BDJ paper

Prevention in the context of caries-related extractions under general anaesthesia: an evaluation of the use of sealants and other preventive care by referring dentists

Abida Raja, Deborah Anne White, Sally Elizabeth Kerr and Thomas Dietrich

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Link to paper:

https://www.nature.com/articles/s41415-019-0729-1