Developing a Decision Aid for Paediatric Dental Sedation or General Anaesthesia

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Abstract

The aim of this thesis was to develop a decision aid for young patients faced with the decision to have dental treatment with inhalation sedation, intravenous (IV) sedation or general anaesthesia (GA).

A series of qualitative interviews were undertaken with patients aged 10-16 years, who had already undergone dental treatment with sedation or GA, and their parents/guardians. The data collected from these interviews were used to inform the content of a draft decision aid, which was presented to a focus group of expert clinicians and to former patients and their parents/guardians in a further series of interviews. Following further revisions, the decision aid was tested with patients who were faced with the decision to undergo dental treatment with inhalation sedation, IV sedation or GA. Patients, aged 10-16 years, and their parents/guardians were recruited from the Liverpool University Dental Hospital and randomly assigned to two groups. Patients assigned to the control group received routine clinical counselling prior to making a treatment decision, whereas patients assigned to the intervention group received routine clinical counselling and the decision aid prior to making a treatment decision. Patients and parents/guardians in both groups received a questionnaire measuring decisional conflict and knowledge. Patients' questionnaires also included a measure of dental anxiety. Patient attendance throughout the care pathway was also monitored.

Significantly higher knowledge was associated with the use of the decision aid when compared to standard care. The decision aid had no significant impact upon measures of anxiety or decisional conflict. Findings suggest that it may not be feasible to deliver the decision aid in secondary care. Further research is required to determine the feasibility of implementing the decision aid in a primary care setting and to explore the impact of the decision aid on attendance, compliance with treatment and participation in the decision-making process.

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List of Abbreviations

CBT	Cognitive Behavioural Therapy
CI	Confidence Interval
DALI	Decision Aid Library Inventory
DCS	Decisional Conflict Scale
GA	General Anaesthesia
IHS	Inhalation Sedation
IV	Intravenous
IPDAS	International Patient Decision Aids Standards
LA	Local Anaesthesia
MCDAS	Modified Child Dental Anxiety Scale
NHS	National Health Service
OHQoL	Oral Health Related Quality of Life
SD	Standard Deviation
SE	Standard Error
SMOG	Simple Measure of Gobbledygook

Presentations and Publications

Development of a decision aid for paediatric dental sedation
Oral presentation
SAAD
Autumn Symposium
Drugs: the Good, the Bad and the Ugly
London, England, UK
13th September 2014

Decision aids in paediatric dental sedation
Poster presentation
The British Society of Paediatric Dentistry
Annual Scientific Meeting
Evolution or revolution
London, England, UK
18th-19th September, 2014

Evaluation of a paediatric dental sedation decision aid
Poster presentation
International Association for Dental Research
General Session & Exhibition
Boston, Massachusetts, USA
11th-14th March, 2015

Use of a decision aid for children requiring dental sedation: a pilot study
Oral presentation
International Association of Paediatric Dentistry
The Voice of the Child
Glasgow, Scotland, UK
1st-4th July, 2015

Hulin, J. 2014. Decision aids in paediatric dental sedation: Helping children choose what is right for them, *SAAD Digest,* 30.

A journal article detailing the entire development process and pilot evaluation of the decision aid will also be submitted to a journal in paediatric dentistry.

Chapter One: Introduction

Dental fear or anxiety can be a barrier to successful dental treatment for children and young people (Aartman et al., 2000; Townend et al., 2000; Moore and Brodsgaard, 2001; Folayan et al., 2003). When the patient cannot be managed using behavioural management techniques and local anaesthesia (LA), they are often referred for treatment with sedation or GA. There are now a variety of sedation techniques available for patients, however findings relating to which agents, dosages and regimens are the most effective are inconclusive (Lourenco-Matharu et al., 2012). Furthermore, there is a paucity of evidence comparing the effectiveness of GA with the various sedation techniques available (Lyratzopoulos and Blain, 2003; Ashley et al., 2012). Considering these findings, it could be suggested that the decision to undergo dental treatment with sedation or GA can be viewed as a preference sensitive decision. This is a term used to describe decisions in which there are no 'right' or 'wrong' choices and the decision is more based upon the individual's personal values (Wennberg et al., 2002). When there are various justifiable options available, and when these various options hold different benefits and risks, which may vary in appeal to different patients, the use decision aids are encouraged (Stacey et al., 2014)

Decision aids are tools which provide information about the treatment options available, the procedures involved and the related benefits, risks and uncertainties. They also encourage patients to recognise their personal values attached to the options available and aid the communication of these values to health care professionals and others involved in the decision-making process.

These tools have been developed for a wide array of healthcare decisions and recent evidence suggests that they may benefit the patient in terms of reducing decisional conflict and increasing knowledge and involvement in the decision-making process (Stacey et al., 2014). However, the majority of the decision aids developed to date have focused on decisions faced by adult patients and there have been few utilised in decisions within dentistry. The aim of this research is to develop the first decision aid to be used by children and young people faced with the decision to undergo dental treatment with inhalation sedation, intravenous sedation or general anaesthetic.

The thesis is structured as follows:

Chapter Two includes a narrative review of the literature, which considers the use of sedation and GA in paediatric dentistry, the concept of shared decision-making in healthcare and the related impact of decision aids. The potential barriers and facilitators of implementing shared decision-making and decision aids in clinical practice are also explored. Finally, attitudes towards shared decision-making and decision aids are considered, along with their role in paediatric healthcare. Chapter Two concludes by describing the rationale behind the current research and the related aims, objectives and choice of methods.

Chapter Three describes the initial stage of the decision aid development process. This includes detailing the methods used in a series of interviews with former patients and parents/guardians, the related findings and the subsequent development of the draft decision aid.

Chapter Four describes the second stage of the development process. This stage involved the presentation of the draft decision aid to expert clinicians and patients who had already undergone dental treatment with sedation or GA and their parents/guardians. This methods used in this stage of the study, the findings and the final development of the decision aid are presented.

Chapter Five describes the pilot evaluation of the decision aid, which evaluated the impact of the decision aid on measures of decisional conflict, knowledge and anxiety. The feasibility of implementing and evaluating the decision aid in a secondary care setting is also explored.

Chapter Six brings together the findings from the development and pilot evaluation of the decision aid and discusses the main conclusions from the research and the related implications and recommendations for future research and clinical care.

The PhD candidate's academic background is based primarily within psychology, having previously completed a BSc in psychology and an MSc in psychological research. During these postgraduate studies, experience of applying a psychosocial approach towards research within oral health was gained through working on separate systematic reviews focusing on the psychosocial impact of undergoing orthognathic

treatment and of cleft lip and palate in adults. Following this, the candidate was given the opportunity to apply the skills gained through postgraduate studies in a clinical setting, working as a research assistant on several research projects for the Neurology Psychotherapy Service at the Royal Hallamshire Hospital. This role primarily involved the recruitment of patients, the administration of various psychometric tests and the statistical analysis of quantitative data.

Chapter Two: Literature Review

2.1 Paediatric dental sedation and general anaesthesia

2.1.1 Background

Due to developments in paediatric healthcare, there has been a rise in the number of potentially painful or stressful procedures that may necessitate the use of anaesthesia or sedation (NICE, 2010). In paediatric dentistry, particularly demanding treatment, such as multiple extractions, may be treated under GA. However, due to high costs, reduction in services and concerns regarding the morbidity and mortality associated with a dental GA, alternative pharmacological methods have been sought. Notably, these include a variety of sedation techniques, which have become increasingly prominent when treating anxious dental patients. Thus, there are a number of options available to children and young people (Lourenco-Matharu et al., 2012). Within the UK, two of the most common approaches used in sedation in paediatric dentistry are inhalation sedation (nitrous oxide) and IV sedation. However, a nationwide review of sedation techniques in paediatric dentistry reported that sedatives are also administered intranasally, rectally, intramuscularly, submucosally or transmucosally (Lourenco-Matharu et al., 2012). Furthermore a wide range of drugs were used across trials, with 28 different drugs or combinations of drugs being reported. Inhalation sedation involves administering a mixture of nitrous oxide and oxygen through a nosepiece, whereas IV sedation involves the delivery of sedatives through an injection into the patient's arm or the back of their hand. Although the patient remains conscious in both these approaches, the sedatives most commonly associated with IV sedation have been shown to cause amnesia, meaning the patient may not remember the entire treatment procedure (Lourenco-Matharu et al., 2012). The drugs used for treatment with GA are also usually delivered through an injection into the patient's arm or the back of their hand, however in some instances can be delivered as a gas that is delivered through a mask. When undergoing treatment with GA, patients remain a controlled state of unconsciousness; therefore patients will be unaware of the treatment while it is taking place.

Hospital Episode Statistics (HES) have suggested that on average there are 29,676 cases of dental treatment under GA every year (Moles and Ashley, 2009), however equivalent rates for treatment under sedation in dentistry are not currently known, as not all

episodes of treatment are recorded through the HES. When defining levels of sedation the terms such as minimal, moderate, conscious or deep sedation are often used. The term most commonly employed in dentistry is conscious sedation, which is defined as a: '*Drug-induced depression of consciousness, similar to moderate sedation, except that verbal contact is always maintained with the patient.'* (NICE, 2010, p.5).

Alternative approaches to the management of dentally anxious children and young people include a number of psychological strategies, including an increased focus on the use of the five areas approach of cognitive behavioural therapy (CBT) (Williams and Garland, 2002). This approach proposes that the most suitable intervention will be dependent upon the factors which contribute to the patient's anxiety, with the five areas including the individual's life situation, thoughts, emotions, physical symptoms and behaviour. It is thought that these five areas are interrelated, often causing a vicious cycle of anxiety, and this cycle can be broken through targeting the appropriate area. For example, if a child is exhibiting avoidance behaviour then it may be suitable to employ such techniques as 'graded exposure', which involves exposing the individual to stimuli or situations that may provoke anxiety on a gradual basis. In these instances the concept of a fear hierarchy is introduced, with patients required to be exposed to stimuli which they are less fearful of first, before gradually moving on to more challenging stimuli or situations. However, although there is some support for the effectiveness of these interventions as an alternative method to sedation and GA in the management of anxiety, there remain several challenges preventing the routine provision of CBT within dentistry (Porritt et al, 2012). These challenges include the high costs and long waiting lists associated with the referral of patients to such services and the reluctance of dentists to implement such techniques, on some occasions due to a lack of confidence in their own ability in the delivering such interventions.

One of the predominant reasons for accessing sedation or GA services for children and young people is the experience of dental caries, with recent figures suggesting that in 2013, 31% of children, aged 5 years old, and 45% of children, aged 8 years old, were recorded as having obvious decay experience in their primary teeth (Holmes et al., 2015). When considering decay in permanent teeth, findings show that 13% of 8 year olds had obvious decay experience and 32% of children had obvious decay experience at the age of 12. Obvious decay experience in permanent teeth in young people aged 15 years was 44%. In addition to this it is suggested that the prevalence of decay in young

people is related to areas of deprivation, with the risk of extensive tooth decay associated with individuals situated in more deprived areas. For example, it has been reported that 20% of young people aged 15 experience severe tooth decay in the highest deprived areas, whereas only 8% of 15 year olds experience severe decay in the areas classed as least deprived within England (Holmes et al., 2015).

When considering rates of dental anxiety, parental reports taken from The Child Dental Health Survey show that between 29% of 12 year olds and 22% of 15 year olds were rated as being moderately to extremely anxious (Holmes et al., 2015). In contrast, self-reports suggested that 63% of 12 year olds and 54% of 15 year olds were moderately anxious about visiting the dentist. Furthermore, 14% of 12 year olds and 10% of 15 year olds were classified as extremely dentally anxious. It was also found that these dentally anxiety may be related to attendance, with higher percentages of extremely anxious12 year olds (21%) and 15 year olds (31%) stating they would only visit the dentist if they had significant trouble with their teeth or that they had never been to the dentist when compared to 12 year olds (14%) and 15 year olds (16%) who were classified as having low anxiety (Holmes et al., 2015).

When consulting the current guidelines for conscious sedation in dentistry, a child is defined as an individual under the age of 12, with individuals aged 12-16 years more commonly referred to as young people (Royal College of Anaesthetists, 2015). In line with these definitions it is advised that although the provision of conscious sedation in the form of inhalation sedation can be administered for all ages, the use of midazolam, which is the recommended drug for intravenous sedation, should usually only be provided for young people above the age of 12. However, it is recognised that individual differences in psychological and physical maturity also have to be taken into account when applying these broad guidelines. In contrast, the provision of GA for dental treatment has been deemed suitable for children and young people of all ages (Adewale et al., 2011).

The importance of providing written and verbal information for both patients and those with parental responsibility has also been stressed in recent guidelines on the use of conscious sedation and GA in dentistry (Adewale et al., 2011; Royal College of Anaesthetists, 2015). It is suggested that such information should include details regarding the treatment options available, the related benefits and risks and also

instructions relating to pre- and post-operative procedures. These procedures include the need for appropriate escorts on the day of the treatment and arrangements relating to the provision of transport to and from the dental hospital. Particular importance is also placed on the provision of guidelines relating to pre-operative fasting. In relation to dental treatment under GA, it is suggested that the patient abstains from eating six hours prior to the appointment and abstains from drinking two prior hours prior to the appointment. The reasoning behind this relates to the fact that reflexes may temporarily halt during treatment under GA, which puts the patient at risk from vomiting or regurgitation, which could affect their breathing. However, in relation to conscious sedation, the need for pre-operative fasting is still under debate, with arguments suggesting that it is unclear when the point of loss of reflex lies. Current guidelines from NICE propose that fasting is not required for inhalation sedation with nitrous oxide or for moderate sedation when verbal contact is maintained with the health professional. However it is also noted that individual risk factors of aspiration must also be taken into account and clinicians who exclude pre-operative fasting should be able to justify their decision (NICE, 2010).

The importance of recovery and discharge procedures has also been highlighted in current guidelines on dental GA and conscious sedation (Adewale et al., 2011; Royal College of Anaesthetists, 2015). In relation to dental GA, it is stated that the responsibility of discharging the patient should lie with the attending clinicians, however, it is also stated that this responsibility can be delegated to recovery staff. In relation to conscious sedation it is suggested that the responsibility for discharge should lie solely with the sedationist. It is also stated that each patient should be assessed individually in accordance with the set criteria. In relation to conscious sedation this criteria states that:

- The patient is orientated in time, place and person.
- Vital signs are stable and within normal limits for the patient. Respiratory status is not compromised.
- Pain and discomfort have been addressed.
- Where relevant, haemostasis has been observed.
- The cannula, where inserted, has been removed.
- The responsible escort is present and arrangements have been made for supervision as advised by the seditionist.

- Written and verbal postoperative instructions appropriate for both the sedation and the dental treatment have been given to the patient and escort/carer.
- Advice has been given regarding precautions in the post-sedation period. This must be related to the dental treatment and the use of any local analgesia, the type of sedation and their duration. The precautions should include not drinking alcohol, operating machinery, driving or making important decisions for a specified period of time.
- Arrangements for postoperative analgesia have been made where appropriate.
- Arrangements are in place for out-of-hours advice.

(Royal College of Anaesthetists, 2015, p.9)

The above guidelines were developed and for both children and adults undergoing treatment with conscious sedation. Therefore certain guidelines relating to drinking alcohol, operating machinery and driving may not be directly applicable to young patients. In relation to dental treatment under a GA, the following criteria for discharge are proposed:

- Conscious level should be consistent with the child's preoperative state.
- Cardiovascular and respiratory parameters should be stable.
- Pain, nausea, vomiting and surgical bleeding should be minimal.
- Mobility should be at a preoperative level.
- A responsible adult must be present to accompany the child home (this adult must be able to give the child his / her undivided attention during the journey home).
- Suitable transport home should have been arranged.

(Adewale et al., 2011, p.42)

Clearly there are reasons, other than patient or parent preference, that must be considered when determining the most appropriate pharmacological adjunct to support children requiring dental treatment. The safety of the patient is paramount in any intervention. Children present with a variety of medical and behavioural conditions which may ultimately dictate whether GA or sedation is the preferred option from a purely clinical point of view. For example, anaesthetic concerns about children who are morbidly obese or who have severe cardiac or respiratory conditions may lead clinicians to advocate the option of conscious sedation rather than GA. Conversely, there may be

parents who would prefer their child to have treatment under sedation, but the surgically demanding nature of the planned procedure makes a GA the preferred option from the clinician's point of view. There are also children with behavioural conditions, such as severe autism or learning disabilities, which make a sedation option unrealistic. An area of potential conflict between patient and clinician may present when a fit and healthy teenager requests simple orthodontic extractions of non-carious premolars under GA because they are too anxious to accept LA. In this instance, most clinicians would be unwilling to offer the GA option because of the risk: benefit discrepancy. They would wish to support the child to have, what may be considered cosmetic-related treatment, under sedation or other techniques such as cognitive behaviour therapy. This thesis assumes the overall ethos that patients have choice in their decision to undergo sedation or GA, but the fundamental caveat remains that the clinician's assessment of the patient's fitness to undergo one of these procedures has to take precedence over patient preference in some instances.

2.1.2 Efficacy of conscious sedation techniques

Within healthcare, efficacy is defined as how well a treatment or intervention produces the desired result in ideal and controlled situations (Revicki and Frank, 1999). The purpose of dental sedation is to relieve anxiety and manage behaviour to a level at which the patient can successfully receive the required treatment. Therefore the efficacy of dental sedation techniques is usually measured in terms of patient's behaviour, completion of treatment, postoperative anxiety and frequency of adverse events (Lourenco-Matharu et al., 2012). When considering the efficacy and relative efficacy of different sedation techniques for children undergoing dental treatment, a systematic review found that no firm conclusions could be drawn (Lourenco-Matharu et al., 2012). It was considered that this failure to draw firm conclusions was due to the lack of relevant studies available and the poor quality of design and reporting across studies (Lourenco-Matharu et al., 2012). For example, of the initial 159 potentially suitable studies identified, only 36 randomised control trials were included in the final review. In addition, the quality of the evidence available in these trials was deemed as poor, with crucial information regarding patient characteristics, such as weight or gender, frequently unreported. Difficulties in determining whether the trials had sufficient statistical power to detect significant differences was also noted, with power calculations either not implemented or reported in the published data on an irregular basis.

A further problem when trying to draw conclusions from previous research was the heterogeneity across studies in terms of the methods being used. For these reasons the authors divided the trials into three groups including placebo studies, dosage studies and comparison studies. However despite grouping trials together, heterogeneity of outcome measures and the tools used made it difficult to conduct a meta-analysis of the data within these sub-categories. When comparing the impact of sedation techniques against placebos, nine studies could be identified. Of these studies, the use of oral midazolam was most frequently reported (Gallardo et al., 1984; Kapur et al., 2004; Wan et al., 2006; Isik et al., 2008a; Mortazavi et al., 2009). Further studies researched the impact of nitrous oxide (Nathan et al., 1988; Veerkamp et al., 1993), chloral hydrate and intramuscular meperidine (McKee et al., 1990). Ages of the patients include in these studies ranged from 4 to 11 years. The only data available which could be combined by meta-analysis was derived from trials comparing the impact of oral midazolam with a placebo (Gallardo et al., 1984; Kapur et al., 2004; Isik et al., 2008a; Mortazavi et al., 2009; Wan et al,. 2006). This meta-analysis was conducted in relation to the relative impact of oral midazolam and the placebo on behaviour, with all studies employing the use of the Houpt behaviour scale (Houpt et al., 1985) or other comparable scales. As not all scales used across the studies included in the review were identical, a standardized mean difference was reported. In this instance, there was some evidence of improved behavior following the provision of oral midazolam in comparison to the effect of the placebo across all trials, with a standard mean difference of 2.98 and 95% confidence intervals (CI) of 1.58 to 4.37. However, this evidence was deemed as weak, with notable heterogeneity identified across studies, in relation to the outcome measures and doses used.

Two studies, noted as being at a high risk of bias, assessed the impact of nitrous oxide in comparison to the use of a placebo (Nathan et al., 1988; Veerkamp et al., 1993). Weak evidence from both these studies suggested that anxiety was significantly reduced for participants receiving nitrous oxide in comparison to the placebo. The one study examining the use of chloral hydrate was reported at being at a high risk of bias and no significant differences were found between groups in relation to behavior (Moore, 1984). One group in the study received chloral hydrate, whereas the opposing group received the placebo. However both these groups also received nitrous oxide during treatment. Finally, a further study reported that the use of intramuscular meperidine did significantly increase compliant behaviour when compared to the use of a placebo

(McKee et al., 1990). However, incidents of nausea and vomiting were more frequent in the merepidine group, with over a third of patients (38%) experiencing such side effects.

The review identified seven studies which focused on comparable dosage levels in sedation procedures. In this instance, the most frequently reported procedure employed was the use of intranasal midazolam, with four separate studies identified (Al-Rakaf et al., 2001; Lee-Kim et al., 2004; Lam et al., 2005; Shashikiran et al., 2006). One study included reported that a 0.5mg/kg dosage significantly improved behaviour in comparison to 0.4mg/kg and 0.3mg/kg and also suggested that per-operative fasting had no impact upon behaviour (Al-Rakaf et al., 2001). In contrast, a further study reported no significant differences in behaviour between groups receiving either 0.3mg/kg intranasal midazolam or 0.7mg/kg oral midazolam, but patients were sedated for significantly longer periods of time when receiving oral midazolam. No significant differences in behaviour were also reported in one study comparing identical doses (0.2mg/kg) of intranasal midazolam to intramuscular midazolam, however, recovery time was reported as being shorter for the intranasal participants (Shashikiran et al., 2006). A further study examining the same dosages did report that behaviour was better when midazolam was used as premedication (Lam et al., 2005). However, these findings can be questioned as only 23 patients took part in the study.

A further study found that behaviour was not significantly different between patients receiving oral midazolam (0.5mg/kg) and rectal midazolam (0.35mg/kg), however, patients were more accepting of oral administration (Aydintug et al., 2004). One study using the Ramsey sedation score, reported that patients who received 0.75mg/kg or 1mg/kg were significantly more sedated than patients receiving either 0.2mg/kg or 0.5mg/kg and that inadequate sedation was noted more frequently in the groups receiving 0.2mg/kg (12 out of 14 patients) when compared to the groups receiving 0.75kg/mg (3 out of 13 patients) (Isik et al., 2008b). Inadequate sedation was noted for 5 out of 13 patients in both groups receiving either 0.5mg/kg or 1mg/kg. It is clear, when appraising data from trials focusing on dosage levels in sedation procedures, an evidence-base for optimum protocols was lacking. For example, although intranasal midazolam was evaluated in four of the studies included, differences in dosages used across studies again made it difficult to draw any conclusions (Al-Rakaf et al., 2001; Lee-Kim et al., 2004; Lam et al., 2005; Shashikiran et al., 2006).

The review by Lourenco-Matharu and colleagues (2012) included twenty studies which compared various different sedatives and modes of delivery. The patients' age range in these studies was from one to ten years and varying outcomes were measured. The most frequently addressed sedative was ketamine, with seven of the studies included in the review investigating its use in comparison to alternative methods. One study reported that both ketamine and midazolam were acceptable methods of sedation when delivered intranasally, in a study comparing these two methods with the use of sufentanil (Abrams et al., 1993). In this instance, sufentanil was associated with deep sedation and oxygen desaturation. Improved behaviour was reported for the use of ketamine in comparison to midazolam or propofol (Rai et al., 2007) and for the combined use of rectal ketamine with midazolam when compared to ketamine alone (Roelofse et al., 1996a). A further study by the same authors, found subjective ratings of sedation, made by the operating dentist, were significantly increased for the use of ketamine when compared to groups receiving standard oral premedication, which included a combination of trimeprazine, physeptone and droperidol. Additional research also suggested that subjective ratings of sedation by the dentist were significantly more favourable in relation to the combined use of ketamine and midazolam in comparison to a combination of trimeprazine and methadone, although incidents of vomiting and hallucinations were noted in the group that received ketamine and oral midazolam.

Two studies, in which all patients also received nitrous oxide, examined the impact of oral ketamine in comparison to oral meperidine/promethazine (Alfonzo-Echeverri et al., 1993) and to a combination of oral ketamine and promethazine (Bui et al., 2002). The former study found no significant differences between groups in relation to behaviour, however, significantly higher incidences of vomiting were reported for the oral ketamine group. In contrast, better behaviour was reported by Bui and colleagues (2002) for the group solely receiving ketamine. Incidences of vomiting were only recorded in this group however, with nearly a third of patients experiencing such side effects.

Five of the included studies examined the impact of chloral hydrate/hydroxyzine in comparison to other sedatives, with all of these studies being reported of being at a high risk of bias. Significant reductions in crying and movement were noted when comparing chloral hydrate//hydroxyzine with chloral hydrate (Avalos-Arenas et al., 1998), however differences were diminished at the time of receiving LA and completion of treatment was noted for all patients. Two studies, in which all participants also received nitrous

oxide, failed to report any differences in behaviour when comparing chloral hydrate/hydroxyzine with oral triazolam (Meyer et al., 1990) or in levels of sedation when comparing chloral hydrate/hydroxyzine with chloral hydrate, delivered orally or rectally (Moody et al., 1986). A further study, in which all participants had planned to receive nitrous oxide, compared chloral hydrate/promethazine with meperidine/promethazine (Sams et al., 1993). No significant differences were reported in relation to treatment time or completion rates, however significantly reduced measures of crying and movement were recorded for the chloral hydrate//hydroxyzine group.

Comparisons of oral midazolam to other agents were reported in three of the studies included in the review. One of these studies determined that sedation was improved significantly when oral midazalom was used with nitrous oxide, in comparison to the sole use of nitrous oxide (Baygin et al., 2010). However no significant differences were recorded when comparing oral midazolam to hydoxine or a combination of midazolam and ketamine. A further study also reported that levels of sedation were significantly improved for groups receiving midazolam/ketamine or midazolam/tramadol in comparison to groups receiving zolpidem and zolipdem with tramadol (Koirala et al., 2006). Finally, shorter recovery times were reported in association with midazolam in comparison to triclofos and promethazine, with significantly better sedation associated with the midazolam and triclofos groups (Singh et al., 2002).

Three separate outcome measures were used to assess the impact of sevoflurane across three studies. One study reported that the use of sevoflurane with nitrous oxide resulted in significantly more effective sedation than nitrous oxide alone (Lahoud et al., 2001). Two related studies examined the impact of sevoflurane combined with nitrous oxide and IV midazolam in comparison to IV midazolam alone and IV midazolam with nitrous oxide (Averley 2004a et al., Averley, 2004b et al.). Both studies demonstrated that treatment completion was higher in groups receiving sevoflurane (83% and 93%) than groups receiving IV midazolam with nitrous oxide (73% and 80%) and IV midazolam alone (50% and 54%). One study compared the use of midazolam with diazepam when both were administered rectally, with significantly higher levels of agitation reported in the diazepam group (Jensen et al., 1999).

As noted previously, a similar lack of data and conflicting findings across studies comparing different methods of sedation also made it impossible to determine the potential clinical and patient benefits of each approach. Furthermore, many of these studies were limited to comparisons being made between the types of drugs as opposed to the methods of administration. It can also be noted that this review focused mainly on outcomes relating to the behaviour of the patient, with a distinct lack of evidence provided in relation to patient-centred outcomes such as satisfaction with treatment and oral health related quality of life (OHQoL).

2.1.3 Conscious sedation versus general anaesthesia

A paucity of data is also evident in a recent review focusing on comparisons between GA and sedation for dental treatment in children, in which no randomised control trials could be identified, leading the authors to conclude that no studies were suitable for inclusion (Ashley et al., 2012). A similar lack of high level evidence was also reported in a review looking specifically at whether inhalation sedation could be viewed as an effective alternative for children deemed to need dental treatment under GA. In this review it was determined that seven previous papers met the study inclusion criteria (Lyratzopoulos and Blain, 2003). However, once again none of these studies included the use of randomised control trials, with all studies providing 'level three' evidence, which refers to research including cohort and case-control studies. The most frequent outcome reported in these seven studies was treatment effectiveness, with all seven studies reporting on either the completion or acceptance of treatment (Hallonsten et al., 1983; Edmunds and Rosen, 1984; Crawford, 1990; Blain and Hill, 1998; Shaw et al., 1996; Berge, 1999; Shepherd and Hill, 2000). Four studies included in the review defined effectiveness as treatment completion (Edmunds and Rosen, 1984; Crawford, 1990; Shaw et al., 1996; Blain and hill, 1998; Shephard and Hill, 2000), whereas the two Scandinavian studies included defined effectiveness in relation to the acceptance of treatment (Hallonsten et al., 1983) or the completion of treatment without side effects (Berge et al., 1999). From these findings, it was suggested that inhalation sedation was an effective alternative to GA in 83-97% of the samples included. It was also concluded that effectiveness was especially high in the studies involving orthodontic patients (90-97%). This was attributed to the fact that orthodontic patients are usually older, of higher social class and more likely to attend treatment frequently. The range of patient ages included in the samples in the studies was often unclear, however, it was apparent that both adults and children were included across the studies, with one study including

participants with a very wide age range of 3-76 years (Edmunds and Rosen, 1984). Mean ages of patients in the other studies reported included 10.7 years (Shaw et al., 1996), 7.8 years (Crawford, 1990), 7.63 years (Blain and Hill, 1998) and 11.9 years (Shepherd and Hill, 2000).

Further outcomes reported in the review included morbidity, satisfaction, cost, number of visits and average time taken for treatment (Lyratzopoulos and Blain, 2003). With regards to morbidity, only one study compared side effects associated with inhalation sedation with those of GA (Shepherd and Hill, 2000). The findings from this study showed that there was significantly lower incidence of morbidity in the patient group undergoing inhalation sedation in comparison to GA. Three further non-comparative studies also reported that 5-13% of patients experienced minor side effects such as nausea/vomiting and headaches following treatment with inhalation sedation (Hallonsten et al., 1983; Shaw et al., 1996; Berge, 1999). Further findings, focusing solely on morbidity following a dental GA, suggest that the most frequently noted side effects following treatment were sleepiness (84%), pain (74%) and feeling weak (68%), with 21% of the patients experiencing nausea (Atan et al., 2004). This study investigated the impact of GA on 121 patients aged 6-16 years old and employed the use of structured interviews conducted face-to-face or via telephone at various time-points. These time points were within 12, 36, 72 and 148 hours following treatment. Similar rates of morbidity have also been recorded in a study looking at the differential impact of a dental GA operation on anxious or dental phobic patients and intellectually or physically impaired patients (Enever et al., 2000). Findings from this study suggested that rates of morbidity were similar in both groups, with incidences of nausea or vomiting being reported by 20% of the participants and unexpected drowsiness being reported in 13% of the cases included. Research has also suggested that there may be a correlation between anxiety and morbidity following dental treatment under GA (Hosey et al., 2006). This study reported findings from 407 patients ranging from 2 to 15 years who on average were rated as more dentally anxious than the population norm. With regards to morbidity this study found that 16% of patients experienced nausea following treatment, 5% vomited, 28% felt drowsy, 7% experienced headaches and 53% had a sore mouth. These reports of morbidity were collected 24 hours and seven days following treatment and the frequency of symptoms were used to test for correlations between morbidity and anxiety. In contrast, a study looking at morbidity associated with IV sedation found that vomiting or nausea only occurred on 23 (0.4%) occasions in

a study including a total of 6,209 cases over a 14 year period (Rodgers and Rodgers, 2011). In this study presnycope was the most common event, with it being reported in 40 cases (0.6%).

Qualitative accounts of postoperative morbidity following dental treatment under GA have also been reported (Rodd et al., 2014). This study implemented the use of video diaries and supplementary semi-structured interviews with ten children, aged 6-11 years, to explore the impact of a GA for dental treatment on these young patients. Findings from this study suggested that patients were particularly concerned with the functional impact of treatment. In these instances patients reported how the discomfort and bleeding associated with eating often limited their diet, leading to sensations of hunger. Nausea and vomiting were once again highlighted as an issue throughout the interviews, with patients also raising issues regarding the pain associated with the use of a cannula, an aspect of treatment not all patients were prepared for. Although this study did hold some limitations in relation to the fact that only white British children were included in the research, the majority of who were female, this was the first and one of the only studies to date, to explore such issues in detail from the child's perspective. Furthermore, the findings from this study also highlighted the potential benefit patients could gain from the greater provision of clinical information and greater involvement in the decision-making process.

In relation to satisfaction following sedation and GA, three studies were included in the review by Lyratzopoulos and Blain (2003), with findings from two comparative studies suggesting that both parents and children were significantly more satisfied following treatment under inhalation sedation when compared to GA (Blain and Hill, 1998; Shepherd and Hill, 2000). High reports of satisfaction (97%) with inhalation sedation were also reported in a prospective study including patients and parents who had already experienced dental treatment under GA (Shaw et al., 1996). In comparison, a more recent study looking at satisfaction following dental treatment under GA for 102 children reported that 76% of parents were 'very satisfied' and 19% were 'moderately satisfied' (Savanheimo et al., 2005). Patients included were aged up to 16 years, with 39% of the sample under the age of 3 years. A similar study also reported that 99% of parents of children undergoing treatment with GA rated it as an overall positive experience with 98% stating that their expectations were met (Acs et al., 2001). However, 36% of parents suggested they would consider an alternative method, if even

if the number of treatment sessions increased. The reasons for this may relate to the higher morbidity and mortality rates associated with GA, or more practical issues relating to recovery time following treatment. The impact this could have on absence from school could be considered an issue, however this would seem unlikely when considering that the average age of the sample was 3.6 years.

In relation to time, six of the seven studies included in the review by Lyratzopoulos and Blain (2003) reported the average time per visit. Two studies found that time taken receiving treatment was significantly longer for inhalation sedation in comparison to GA (Blain and Hill, 1998; Shepherd and Hill, 2000). However the total time taken to manage patients, including recovery time was greater for GA (153.7 minutes) than inhalation sedation (37.5 minutes) in one of the studies (Shepherd and Hill, 2000). Other studies reported that inhalation sedation can take between 22 and 44 minutes per session (Hallonsten et al., 1983; Crawford, 1990; Shaw, et al., 1996; Berge, 1999). Findings from the review also suggested that inhalation sedation involved significantly lower costs in comparison to GA (Shaw et al., 1996; Blain and Hill, 1998) and the number of visits ranged from between 1.03 to 2.09 per patient in five of the included studies (Hallonsten et al., 1983; Edmunds and Rosen, 1984; Blain and Hill, 1998; Berge, 1999; Shepherd and Hill, 2000). When considering the cost effectiveness of alternative sedation measures, results have been conflicting. For example, it was reported that GA was a more cost effective option when comparing a sample of 22 children undergoing treatment with GA with a conscious sedation estimation model (Lee et al., 2001). Cost estimation models are mathematical algorithms or parametric equations that can be implemented to estimate the costs or benefits of a service or product. The study included a panel of four experts in conscious sedation and GA in order to obtain values in the cost estimation model that could not be gathered from existing data. Other authors have reached opposite conclusions, stating that conscious sedation in a primary care setting incurred lower costs than treatment under GA in a hospital setting (Jameson et al., 2007). Furthermore, it could be claimed that through the inclusion of costs in addition to salary costs alone, this latter study provides a more comprehensive analysis of the cost-effectiveness of conscious sedation techniques in comparison to GA.

2.1.4 The need for patient-centred measures

As well as exposing the lack of high level evidence, an appraisal of previous research has also highlighted issues relating to the measures used to assess the efficacy of sedation procedures (Lourenco-Matharu et al., 2012). For example, when comparing the efficacy of various conscious sedation techniques, it was reported that the most frequent outcome measure used was the behaviour of the patient, with other measures often focusing on clinician reports of immobility and the quality of the sedation. This has led to suggestions that more patient-centred outcomes such as satisfaction and oral health related quality of life (OHQoL) are required in future research. For instance, measures of satisfaction were only reported in two comparative studies when reviewing the use of inhalation sedation as a replacement for dental treatment under GA (Lyratzopoulos and Blain, 2003). Furthermore, although a recent systematic review has determined that children's' levels of OHQoL significantly improve following dental treatment under GA (Jankauskiene and Narbutaite, 2010), there is a paucity of research comparing alternative methods of sedation which include similar measures. Furthermore, it should be noted that all studies included in the systematic review included parental reports of OHQoL, failing to take the patients' perspectives into account. In addition, heterogeneity of measurement tools used to assess OHQoL throughout studies once again makes it difficult to compare findings.

It is also proposed that changes in anxiety need to be addressed more comprehensively in future research. For example, previous studies which have implemented pre- and post-operative measures suggest that post-operative anxiety is significantly lower in children and parents who undergo treatment with inhalation sedation in comparison to GA (Arch et al., 2001). It has also been reported that midazolam may be a more effective sedation technique than nitrous oxide when considering measures of anxiety through levels of salivary cortisol (Pereira-Santos et al., 2013). However, when considering the wider evidence base, although pre-treatment measures of anxiety have often been recorded, post-treatment measures have been largely overlooked. There are also broader questions that may be raised regarding what can be considered an appropriate study design when testing such interventions. For example, the review conducted by Lourenco-Matharu, and colleagues (2012) chose to exclude crossover trials from their final analysis, due to the impact that previous treatment sessions may have on future appointments (Veerkamp et al., 1995). However, it could be suggested that one purpose of sedation in paediatric dentistry would be to reduce dental anxiety

levels, eventually enabling children to undergo treatment without sedation or GA. Furthermore, the timing of such measures should also be considered more carefully, as a recent study exploring of anxiety levels shortly after dental treatment under GA actually found an increase in patient anxiety when compared to baseline measures (Cantekin et al., 2014). It could therefore be suggested that post-operative measures of anxiety at several time points following dental treatment under sedation or GA would be beneficial to see how levels of anxiety may vary over time.

2.1.5 Preference sensitive decisions

As well has having clear implications for future research, the above findings and the wide range of procedures available highlight that patient and parent decisions to undergo treatment with either GA or sedation can be viewed as 'preference sensitive' (Wennberg et al., 2002). This term describes decisions in which the ratio of benefit to harm is unclear or is dependent upon the patient's individual values. In such instances it could be concluded that the decision often requires a more detailed discussion of the options available, and the relative harms, benefits, probabilities and scientific uncertainties (O'Connor et al., 2003). A proposition also supported by NICE guidelines, which state that good communication between healthcare professionals and patients is essential (NICE, 2010). To encourage such discussion, a shared decision-making model of consultation is often encouraged, with the use of patient decision aids perhaps being pivotal in the implementation of such services.

2.2 Shared decision-making

2.2.1 Background

Historically, a paternalistic approach to medical decision-making has been prominently adopted in healthcare. This approach assumes that the patient should remain passive in the decision-making process and it is the physician's sole responsibility to choose the most appropriate course of treatment (Parsons, 1957; Roberts and Krouse, 1990). This stance is often regarded to have been related to the availability of treatment options at the time and the implied medical knowledge and experience held by physicians (Charles et al., 1999a; Charles et al., 1999b). For instance, prior to the 1980s, the availability of alternative treatment options was often scarce in comparison to recent decades, with a single unparalleled direction for care often existing in the majority of medical encounters. Furthermore, it was also believed that as the physician holds the relevant

expertise and knowledge, the decision should ultimately lie with them. Ethical guidelines of the time also supported the principle that it is a physician's duty to always act in the best interests of the patient (Lomas and Contandriopoulous, 1994). This would appear to imply that the patient's participation in such decision-making processes is largely unneeded.

However, in recent decades, a rapid shift away from the paternalistic approach to healthcare has developed, with the concept of shared decision-making becoming prominent in medical care. This term was first formally introduced in 1982 in a report entitled 'Making Health Care Decisions', which was produced by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research. It has been suggested that this development was related to increased variations in treatment patterns across healthcare, with more alternatives becoming available to the patient. In addition, for a number of illnesses these varying options each held differing benefits and costs (Kasper et al., 1992). As a result, this made the decisional process increasingly complex for physicians.

At the same time, an increased understanding of, and focus on, consumer knowledge and rights also encouraged patients to be more involved in the decision-making process (Haug and Lavin, 1983; Charles and DeMaio, 1993). This increased awareness was also reflected in new laws and guidelines outlining the notion of informed consent and the rights of patients to be made aware of all treatment options available to them (Charles et al., 1997). In the US, this awareness could also be related to concerns about the increased costs of healthcare and the efficiency of services provided. Such concerns led to physicians becoming further accountable for their patient-based decisions (Katz et al., 1997).

2.2.2 The three stages of shared decision-making

The most frequently cited definition of shared decision-making was developed in a series of papers looking at the role of shared decision-making in the treatment of life-threatening illnesses (Charles, et al, 1997; Charles et al 1999a; Charles et al., 1999b). In an attempt to clearly define their concept of shared treatment decision-making, Charles and colleagues focused on a framework comparing the shared decision-making process with two other commonly cited models: the informed model (Charles et al., 1997) and the paternalistic model (Emmanuel and Emmanuel, 1992). Through incorporating these

three separate approaches into a single framework, Charles and colleagues also attempted to demonstrate the significance of flexibility in the decision-making process. In order to differentiate between the alternate approaches, the three models were primarily discussed in relation to three separate stages of the decision-making process defined as 'information exchange', 'deliberation' and 'deciding on the treatment to implement' (Charles et al., 1999a; Charles et al., 1999b).

The term 'information exchange' relates to the type, amount and direction of information, and whether the flow of information is considered to be one-way or two-way. When defining the paternalistic approach to decision-making, the flow of information is seen as being predominantly one-way, with the physician portraying the minimum amount of medical information by law to the patient. The informed model also portrays similar characteristics in terms of the flow, direction and type of information. However, it suggested that as opposed to simply delivering the minimum amount of information required by law, the physician should provide all the relevant medical information available to enable the patient to make an informed choice regarding treatment. Similarly, the shared decision-making framework, also suggests that all relevant information should be conveyed to the patient in the initial stage of information exchange. However, unlike the previously discussed models, the shared decision-making framework implies that the type of information discussed should concern both medical and personal issues. Furthermore, it also requires the flow of information exchange to be a two-way process, with the patient providing information regarding their own knowledge of the illness and potential treatments, along with relevant personal values and beliefs that may impact upon the ultimate decision for treatment.

The 'deliberation' phase of treatment decision-making focuses on the continued discussion of treatment preferences available and differs across models in regards to who is involved in this process. In the paternalistic approach the patient is excluded from the deliberation process, with the physician left to deliberate the potential benefits and risks of alternate treatment options either alone or with the consultation of other clinicians. In contrast, the informed models state that the physician should have no input in the deliberation process, with the patient and potential others, such as family members, being the only people involved in the discussion of treatment preferences. This once again ties to the overall concept of informed decision-making, which

proposes that the clinician's role is simply to provide the relevant medical and scientific knowledge that will enable the patient to reach a decision. When discussing the deliberation stage in regards to shared decision-making models, it is proposed that both the physician and patient should have an active role in this phase of the decision-making process, with input from potential relevant others also deemed as appropriate. In accordance with this perspective it is proposed that the final stage of deciding which treatment to implement should also involve both the patient and physician. Thus both parties would work together in reaching an agreement on which treatment will most benefit the patient's overall well-being. From a paternalistic approach it is clearly stated that the physician alone is best suited to make this final decision on which treatment to implement. Whereas the informed model ultimately suggests that the responsibility rests on the patient alone.

Despite the growing importance placed upon shared-decision-making in healthcare, there are still concerns over the practical applications of such models. Central to these concerns include questions over the generalisability of the shared decision-making framework to different patient-physician encounters, with the original Charles et al model being developed specifically in the context of life-threatening diseases (Charles et al., 1997). In an attempt to apply the features of shared decision-making to a broader context Murray and colleagues (2005) examined how this process may apply to general practice. They concluded that overall, this original framework could be successfully adapted with the core components of the process applicable to general practice (Murray et al., 2005). However, it must be noted that these findings were presented on a purely conceptual basis, still leaving concerns over the broad applicability of shared-decision-making. This issue has also been addressed recently through the proposal of a simplified model for introducing shared decision making in clinical practice, which include three steps defined as 'choice talk' 'option talk' and 'decision talk' (Elwyn et al., 2000). 'Choice talk' relates to informing the patient of the available options, 'option talk' relates to providing further information about the options and 'decision talk' refers to the exploration of patient preferences and reaching a decision. However, it is unclear whether the application of this model has been supported by empirical evidence. It has also been noted, somewhat ironically, that a shared definition of shared-decision-making still fails to exist (Makoul and Clayman, 2006). This conclusion was reached following a review of 428 articles relating to the concept of shared decision making. In this instance, it was reported that only 39% of these studies included a conceptual definition

of shared decision-making. Furthermore it was reported that only two of the thirty one concepts used to define shared decision-making, appeared in more than half of the studies included. These concepts related to patient values or preferences (67%) and the inclusion of options (50.9%).

One of the most frequently cited alternate definitions of shared decision-making (10%) was reported in research which employs the term informed shared decision making to define decisions that are shared by both the patient and healthcare professional and informed by the best level of evidence available (Towle and Godolphin, 1999). This definition also highlights the importance of sharing information about the patients' values as well as the risks and benefits associated with the treatment options available. In addition to this, the research also proposed steps which could be used to implement shared decision making, which include the establishment of patients' preferences for involvement in the decision-making process and their information preferences, identifying the choices available and agreeing on a treatment plan. It can be noted that these steps and the concepts included in the model are very closely related and in some instances identical, to the concepts used to define shared decision-making by Charles and colleagues (Charles et al., 1997). An alternate model of shared decision-making proposed by Elwyn and colleagues (1999) was also cited in 10% of the studies included in the review, however it was once again unclear how this differed from the alternate definitions discussed, with the steps to shared decision-making developed by Towle and colleagues (1999) also being cited in this research. Furthermore, it was recognised that the shared decision-making model proposed by Charles and colleagues (1997) was the most frequently applied and clearly defined model used throughout the literature, with this model included in 21% of the studies which reported conceptual definitions of shared decision-making.

Despite these acknowledged limitations, research towards patient preferences and continuing developments in the range of available treatments imply that a focus upon shared decision-making should persist (Guadagnoli and Ward, 1998). To this end, more research is needed in order to build upon the potential barriers and facilitators of such practice, as recently outlined in a systematic review of healthcare professionals' perceptions of shared decision-making (Legare et al., 2008b). Furthermore, research which examines the physician's desire to engage in such processes would also prove valuable; particularly when discussing how recently developed shared decision-making

aids may be applied in different clinical settings. These issues will be explored more thoroughly in Sections 2.3.5 and 2.3.6.

2.3 Decision aids

2.3.1 Background

In an attempt to increase patient participation in the medical decision-making process, various decision aids and tools have been developed (Stacey et al., 2014). These aids aim to encourage such participation through providing the patient with in depth information regarding the treatment options available, while also considering the patient's personal values attached to these options. Such tools are believed to offer a necessary alternative to health educational materials frequently provided throughout healthcare, which although providing relevant information, fail to include the patient in the decision-making process. According to the International Patient Decision Aids Standards (IPDAS) Collaboration there are three specific features of decision aids that aim to prepare a person for active participation in the decision-making process (IPDAS, 2005a). Firstly, they provide facts about an individual's health condition, the options for treatment and the related costs, benefits and uncertainties. Secondly they aid people to recognise their own values associated with the various potential treatments and related outcomes and uncertainties. Finally, they aid people in the communication of such values with the health care practitioner and valued others such as family and friends. In addition, it is also stated that the purpose of these decision aids is not to advise individuals to choose certain options in favour of others, and that they should be treated as a supplement to the decision-making process and not as a replacement for counselling.

2.3.2 Effectiveness of decision aids

Due to the widespread development of decision aids and the variability in many of these tools, the IPDAS collaboration also attempted to develop a related quality criteria framework (IPDAS, 2005b; Elwyn et al., 2006). This was achieved through inviting a sample consisting of 212 individuals from 14 different countries to serve on a voter panel. Of the original sample invited a total of 122 agreed to take part; including 21 patients, 10 health professionals, 14 policy makers and 77 researchers. In accordance with this framework a review on the effectiveness of decision aids was recently published (Stacey et al., 2014), focusing on the attributes of the 'choice' and the

'decision process' as the primary outcomes that map onto the IPDAS criteria (IPDAS, 2005b; Elywn et al., 2006). In this instance, attributes of the 'choice' relate to evidence suggesting that decision aids can increase congruence between the selected treatment option and the features that are most valued by the informed patient. Attributes of the 'decision process' relate to evidence suggesting that decision aids improve the patient's recognition that a decision needs to be made; the patient's understanding of the options and their features; the patient's understanding that values impact upon the decision and clarification of which features are most important to the patient. In addition, the study also examined the impact of decision aids on such outcomes as decisional conflict, satisfaction, the proportion of patients undecided, health status, quality of life, anxiety, depression, healthcare costs, consultation length and litigation rates.

In relation to the attributes of the 'choice', the review of findings for publications from 1966 to 2012 appears to indicate that one of the largest effects of decision aids is the impact on the patient's knowledge of the options available and associated outcomes (Stacey et al., 2014). Patients' knowledge was assessed in relation to the information included in the decision aids, with the number of correct responses converted to percentages across studies. The review identified a total of 56 studies assessing knowledge, with 42 of these studies included in a meta-analysis of the data. Results from this analysis suggested that patients who used decision aids had significantly higher knowledge scores on average than those receiving usual care (Mean Difference=13.34%, 95% CI=11.17 to 15.51). Six of the fourteen studies which could not be included in the analysis, also reported significantly higher levels of knowledge for groups receiving a decision aid, compared to groups who received standard care (Partin et al., 2004; Hamann et al., 2006; Watson et al., 2006; Nagle et al., 2008; Trevena et al., 2008; Evans et al., 2010). Four of these studies reported greater knowledge for those who viewed a decision aid in relation to prostate and colorectal cancer screening and testing (Partin et al. 2004; Watson et al. 2006; Trevena et al. 2008; Evans et al. 2010). Participants included in these four studies ranged in age from 40-75 years and were all male. The other studies that could not be pooled reported significantly higher knowledge in relation to viewing a decision aid on options for schizophrenia treatment (Hamann et al., 2006) and prenatal testing (Nagle et al., 2008). Sample sizes for these six studies ranged from 107 to 1,851.

The remaining eight studies that could not be pooled reported varying effects of

knowledge. For example, one study assessing decisions relating to treatment options for diabetes found that although knowledge was increased if administered during the consultation, these differences were diminished if the decision aid was presented prior to this (Weymiller et al., 2007). A further study, looking at screening options for diabetes, also found significant differences between intervention and control groups (Mann et al., 2010). A study of a decision aid relating to breast cancer risk and genetic counselling also failed to find a significant impact on knowledge (Miller, 2005). In contrast, a further two studies including entirely female patients, found that there was a significant increase in knowledge over time for participants who viewed decision aids in relation to mammography screening (Mathieu et al., 2007) and breast reconstruction (Heller et al., 2008). Neither of these studies reported significant increases in knowledge for those who received standard care. The remaining two studies included in the review, which also included entirely female participants, reported significant increases in knowledge for both intervention and control groups receiving information regarding the treatment of menopausal symptoms (Legare et al., 2008a) and significant increases in knowledge of breast cancer prevention for those who received a decision aid (Ozanne et al., 2007). However, follow-up data showed that this increase in knowledge did return to baseline scores. It should also be noted that these findings derived from a pilot trial of the decision aid and only included 15 participants in each group; therefore there may not have been sufficient power to detect significant differences between groups.

A further systematic review, focusing specifically on decision aids developed for menopausal symptom management, proposed that decision aids had an inconsistent impact upon knowledge (Carpenter et al., 2011). However these conflicting findings may be explained by the paucity of literature focusing specifically on menopausal symptom management. This study included a total of 15 trials which assessed treatment options including natural health products or hormone therapy. Of the 15 trials included, there were four trials which were not included in the systematic review by Stacey and colleagues (2014). Two of these trials, conducted by the same research group, reported significant increases in knowledge following the use of a web-based decision aid in comparison to standard care (Saver et al., 2007). In contrast, a decision aid relating to hormone therapy for females with mobility impairments found significant increases in knowledge for both those who received the decision aid and those who did not (Becker et al., 2009). Finally, significant increases in knowledge were also reported in a study researching the impact of a decision aid relating to the use of natural health products for

the management of menopausal symptoms. However, the fact that the design failed to include a control group and only 24 females took part, suggests these results should be approached with caution (Menard et al,. 2010).

In relation to the attributes of the decision process, Stacey and colleagues also reported that decision aids can help reduce patients' decisional conflict (Stacey et al., 2014). Decisional conflict is described as the perceived level of uncertainty regarding a planned course of action. The traditional Decisional Conflict Scale (DCS) (O'Connor, 1993), includes five separate subscales which measure whether patients feel they are informed, they are clear about personal values, they are supported, they are certain about the best choice they have made an effective decision. The overall scale and subscales are converted into scores ranging from 1-100. Overall, 28 studies assessing total decisional conflict were analysed, with a mean difference of -6.22 being reported when comparing the use of decision aids to standard care (95% CI=-8.00 to -4.44). Of the studies that could not be pooled, results were contrasting, with four studies suggesting that decisional conflict was significantly lower for those who received the decision aid in comparison to standard care and three studies reporting no difference between groups. The three studies that failed to report a difference in decisional conflict all examined decision aids relating to cancer treatment and screening options (Krist et al., 2007; Ozanne et al., 2007; Leighl et al., 2011). Two of the four studies that reported a significant difference, also reported results on decision aids relating to cancer screening and testing (Schwartz et al, 2009; Smith et al., 2010), with the other studies reporting decreases in decisional conflict in relation to diabetes (Weymiller et al., 2007) and bariatric surgery (Arterburn et al., 2011). A further study, looking at healthcare decisions relating to breast cancer prevention, actually reported significantly more decisional conflict in participants who viewed the decision aid in comparison to standard care (Fagerlin et al., 2011a). The main effect of decision aids on decisional conflict noted in the review by Stacey and colleagues (2014) relates to lower scores on the two sub-scales which suggest that decision aids leave patients feeling more informed and clearer about personal values. In this instance, analysis of 22 studies that compared the use of decision aids to standard care reported a mean difference for the uniformed subscale of -7.26 (95% CI=-9.73 to -4.78). Analysis of 18 studies included in the review also reported a mean difference of -6.09 (95% CI=-8.50 to -3.67), in relation to scores on the values clarity subscale.

Further outcomes reported in association with attributes of the decision process, in the review by Stacey and colleagues (2014), included the impact of decision aids on communication between the patient and healthcare professional and participation in the decision-making process. In this review, eight studies were identified, with seven of these studies suggesting that improved communication was associated with use of a decision aid in comparison to standard care. Four of these studies included the use of the OPTION scale to assess communication (Weymiller et al, 2007; Montori et al; 2009; Mullan et al, 2009; Hess et al., 2012). This is a generic scale which has been developed to examine the overall decision-making process in relation to all healthcare decisions and is completed by independent assessors (Elwyn et al., 2003). These four studies assessed decisions relating to chest pain (Hess et al., 2012), osteoporosis (Montori et al,, 2009), and diabetes (Weymiller et al., 2007; Mullen et al., 2009). Further measures of communication also included the proportion of patients who had discussed the risks of heart disease (Sheridan et al., 2006) and tube feeding options with healthcare professionals (Hanson et al., 2011). Finally, agreement between healthcare professionals and patients was also recorded as an indicator of good communication in two studies looking at the impact of decision aids on healthcare decisions relating to the treatment of respiratory infections (Legare et al., 2011) and menopausal symptoms (Legare et al., 2003). One study reporting greater agreement for the group who received the decision aid in comparison to standard care (Legare et al., 2003), whereas the other study failed to report significant differences between groups (Legare et al., 2011). A further study included in the review assessed the level of informed decision-making in relation to the use of a decision aid for decisions relating to prostate cancer screening (Myers et al., 2011). Although more informed decision-making was reported for those who received the decision aid in relation to standard care, it is unclear how this relates directly to communication between patients and practitioners. Levels of informed decision-making in this instance were analysed from audio recordings of consultations.

In relation to participation in the decision-making process, 14 studies which compared the use of decision aids to standard care were pooled for analysis in the review. The results suggested that decision aids did reduce passive patient involvement in the decision-making process (relative risk = 0.66, 95% CI=0.53 to 0.81). Such increased participation is key in the implementation of shared decision-making throughout healthcare. Contrasting findings were reported for some studies that could not be pooled for analysis, with three separate studies related to cancer screening and treatment in

adult males (Allen et al., 2010; Rubel et al., 2010; Leighl et al., 2011), and one study related to in vitro fertilisation (van Peperstraten et al., 2010) suggesting that the decision aid did not impact upon patient involvement when compared to standard care. In addition, feelings of being involved were also significantly higher when exposed to a decision aid in two studies reporting findings relating to depression (Loh et al., 2007) and schizophrenia (Hamann et al., 2006). Similar conclusions were also reached in a systematic review of the literature focusing specifically on the use of decision aids for prostate cancer screening (Volk et al., 2007). Here it was suggested that decision aids can often lead patients to desire a more active role in the decision-making process.

Further outcomes relating to the decision-making process were also reported in relation to the proportion of patients who remained undecided about their healthcare decision. Pooled data from 18 studies suggested that decision aids do significantly decrease the proportion of individuals who are undecided in comparison to standard care (relative risk = 0.59, 95% CI=0.47 to 0.72). A further study recorded whether patients remained undecided, using one item ranging from 0-100, with a score of hundred suggesting that the individual had made their decision. (Kasper et al., 2008). In this instance no differences were identified between groups in relation to decisions regarding multiple sclerosis. However the reliability and validity of the single item measure used can be questioned.

The review by Stacey and colleagues (2014) also reported findings relating to whether decision aids impact upon treatment choice. Pooled data from 15 studies suggested that the use of decision aids leads to a decrease in the number of individuals opting for major elective surgery when compared to standard care (relative risk=0.79, 95% CI=0.68 to 0.93) The studies included in this analysis were associated with a variety of decisions relating to surgical options for heart disease, cancer, weight loss**,** menorrhagia and fibroids. Analysis of nine studies comparing choice for prostate-specific antigen screening also found that the decision aid reduced rates of screening for men in comparison to standard care (relative risk=0.87, CI=0.77 to 0.98). Further studies relating to the uptake of screening in relation to colon cancer, genetic testing, mammography, prenatal testing, chest pain and diabetes are also reported in the review. However, a lack of sufficient data often meant firm conclusions could not be drawn. Variable effects were also noted for studies examining the impact of decision aids on choices regarding the use of medication for a variety of healthcare decisions. Whether

treatment choice should be viewed as an appropriate outcome measure for the use of decision aids can be debated however, when considering the fact that decision aids are usually prescribed for preference sensitive decisions, in which the choice is based upon the patients' individual values. Furthermore, it should be noted that 35% of the studies included in the review reported findings on the participants preferred option as opposed to actual choice.

In terms of health outcomes the most frequently reported measure included in the systematic review by Stacey and Colleagues was anxiety, with this concept being measured by 26% of the total studies included in the review. The majority of these studies (63%) reported measures of anxiety using the 20-item Stait Trait Anxiety Inventory (STAI) (Spielberger**,** 1984). Nineteen studies in the review measured the impact of a decision aid on anxiety within thirty days of the stage of the intervention. From these nineteen studies only three studies noted a significant impact on anxiety (Green et al., 2004; Montgomery et al., 2007; Protheroe et al., 2007). In this instance, significant reductions in anxiety were reported for adult women faced with decisions regarding birthing options (Montgomery et al., 2007) and treatment of menorrhagia (Protheroe et al., 2007) in comparison to standard care. . However, when considering the latter study, the fact that a relatively short follow up period was employed meant that some patients may not have received treatment at the point of final data collection. Therefore, it is difficult to determine whether these reductions were maintained, as it could be expected that levels of anxiety may increase closer to the time when the patient is scheduled to receive treatment. Although Green and colleagues (2004) reported significant reductions in anxiety for low-risk women considering genetic testing for breast cancer susceptibility, results also showed that high-risk patients receiving standard care displayed significantly reduced rates of anxiety. The remainder of studies included in the review failed to report a significant impact of decision aids on anxiety at one, three, six and twelve months post consultation. Non-significant differences were also reported for nine studies measuring the impact of decision aids on depression and for seven studies measuring regret. It could be suggested that such limited effects on health outcomes could be expected when considering that for the majority of treatments implementing the use of decision aids, a single 'best' option in terms of health outcomes does not usually exist.

Limited effects were also noted in relation to patient satisfaction with the treatment

option chosen and the actual decision-making process itself. In relation to choice, 15 studies were identified which examined the impact of the decision aid in comparison to standard care. Results from 12 of these studies failed to report a significant impact of decision aids on satisfaction with choice in comparison to standard care. However, of these studies, only three reported significantly higher satisfaction in relation to the use of a decision aid. These three studies investigated decisions relating to breast reconstruction (Heller et al., 2008), blood donation (Laupacis et al., 2006) and childbirth (Montgomery et al., 2007). Furthermore, only five of the fourteen studies included reported significantly greater satisfaction with the decision-making process for those exposed to decision aids (Barry et al., 1997; Kennedy et al., 2002; Laupacis et al., 2006; Schroy et al., 2011; Hess et al., 2012). Finally, two of three studies reported significantly greater satisfaction with preparation for the decision-making process when receiving decision aids on knee pain (Fraenkel et al., 2007) and lung transplantation (Vandemheen et al., 2009). Contradictory findings and limited evidence also made it impossible to reach firm conclusions relating to the impact of decision aids on decisional satisfaction in two separate reviews of the literature focusing on trials of decision aids for menopausal symptom management and prostate cancer screening (Volk et al., 2007; Carpenter et al., 2011). However, it has been hypothesised that the limited impact on satisfaction could be explained through the high levels of satisfaction already displayed by patients receiving usual care and the fact that individuals may find some form of psychological comfort in conveying satisfaction with their chosen treatment, rather than raising doubts as to whether they made the correct choice (Gruppen et al., 1994; Stacey et al., 2014).

Finally, when considering the widespread implementation of decision aids, the impact of such tools on the healthcare system in relation to costs and resource use must also be considered. In relation to this, studies researching the use of decision aids for men with benign prostatic hypertrophy (Murray et al., 2001a) and for women considering hormone replacement therapy (Murray et al., 2001b), found that although there was no difference in resource use between decision aids and usual care, a significant increase in cost was incurred when the decision aids involved the use of video disk systems (Murray et al., 2001a, Murray et al., 2001b). However, when substituted with low cost internet access no such differences in cost were reported. Furthermore, a separate study also reported that the use of decision aids with nurse coaching ($1566) and decision aids alone ($2026) both produced lower mean costs than usual care ($2751) (Kennedy et al.,

2002). In contrast, a further two studies failed to demonstrate any significant difference in overall treatment costs (Vuorma et al., 2003) and costs per patient from the perspective of the NHS (Montgomery et al., 2007). When considering the impact of decision aids on consultation length, six recent studies failed to find any significant differences in consultation length when comparing decision aids to usual care (Whelan et al., 2003; Krist et al., 2007; Loh et al., 2007; Ozanne et al., 2007; Weymiller et al., 2007; Vodermaier et al., 2009). Although other studies do suggest that the use of decision aids may increase consultation length by an average of 6-23 minutes (Bekker et al., 2004; Thomson et al., 2007), conflicting findings once again suggest that the use of certain decision aids may actually reduce consultation length (Green et al., 2004). Although this lack of data and conflicting results make it difficult to gain a conclusive overview of the potential impact of decision aids on healthcare costs and resources, initial findings appear to suggest that even in cases when decision aids have failed to reduce expenditure and consultation length, they do not frequently increase such factors either. Consequently, it could be suggested that the implementation of decision aids can still be justified when considering the potential benefits that can be gained in relation to increased patient knowledge and reduced decisional conflict at no additional cost. However, further research towards the impact such tools have on the healthcare system should still be encouraged to determine if this is the case.

2.3.3 Detailed versus simple decision aids

When determining the effectiveness of decision aids, issues such as heterogeneity of design must also be considered. For instance, there are currently 646 patient decision aids registered in the Decision Aid Library Inventory (DALI) (Ottawa Hospital Research Institute, 2015), with considerable variations noted in terms of format (e.g. video, web-based, CD-ROM, print, audio based) and decision type. In an attempt to address this matter and potentially begin to determine which attributes of decision aids may be most effective, Stacey and colleagues decided to conduct a secondary analysis of the literature, with comparisons being made between detailed and simple decision aids (Stacey et al., 2014).

The authors concluded that limited effects were evident for both knowledge and decisional conflict. In terms of knowledge, analysis of 19 studies reported that there were small but significant findings that groups who received detailed decision aids demonstrated greater knowledge of the treatment options than those who received more

simple decision aids (Mean Difference=5.52%; 95% CI=3.90 to 7.15). Following analysis of 17 studies, the authors also reported that detailed decision aids had a limited effect on reduced decisional conflict in comparison to more simple decision aids (Mean Difference=-1.7795% CI=- 2.64 to -0.91). However, further analysis suggests that this difference is non-significant. The only other support for the use of more detailed decision aids derived from two separate studies which suggested detailed decision aids led to greater satisfaction with choice of fibroid treatment (Solberg et al., 2010) and with the decision-making process associated with prenatal testing (Hunter et al., 2005). However, a further six studies failed to identify any impact of the level of detail included in the decision aids on satisfaction (Rothert et al., 1997; Deyo et al., 2000; Deschamps 2004; Schapira et al., 2007; Kuppermann et al., 2009; Raynes-Greenow et al., 2010). In addition to this, no significant differences were found across numerous studies investigating the impact of detail on choice for screening. These included studies relating to decisions on prostate-specific antigen screening (Schapira et al., 2000; Myers et al., 2005; Myers et al., 2011) cancer genetic screening (Wakefield et al., 2008a; Wakefield et al., 2008b; Wakefield et al., 2008c) and prenatal screening (Hunter et al., 2005; Leung et al., 2004). A further study examining to the use of a decision aid for decisions relating to hormone therapy also failed to find differences relating to choice between groups receiving a detailed or simple decision aid. It was also reported that the level of detail had no impact on adherence (Rothert et al., 1997; Deschamps et al., 2004; Trevena et al., 2008), regret (Goel et al., 2001; Wakefield et al., 2008a; Wakefield et al., 2008b; Wakefield et al., 2008c; Kupperman et al., 2009), confidence (Rothert et al., 1997) or length of consultation time (Myers et al., 2011).

However, when considering these findings, it should be noted that the review by Stacey and colleagues failed to define what constitutes a ‘detailed’ or ‘simple’ decision aid, with a heterogeneity across studies in terms of what information was included or excluded. Furthermore, it was often unclear as to how the more ‘simple’ decision aid was actually different to standard care. For example the ‘simple’ version, as defined by Stacey and colleagues, included in a study on prenatal testing was actually an educational booklet provided by the California Department of Health Services (Kuppermann et al., 2009).

2.3.4 Essential decision aid components

Despite the aforementioned lack of evidence relating to the relative impact of detailed or simple decision aids, further findings reported in the review by Stacey and colleagues (2014) do provide some indication of some the essential components of decision aids. For example, in relation to risk perceptions, it was reported that if outcome probabilities were included in the decision aid, more accurate appraisals of potential benefits and costs were made patients. These findings derived from 19 studies pooled for analysis (relative risk = 1.82, CI=1.52 to 2.16), with accurate risk perceptions being measured as a percentage of participants whose responses matched the scientific evidence available. A further four studies that could not be pooled in the analysis reported that the use of decision aids in general, when compared to standard care, can increase accuracy of risk perceptions (Weymiller et al., 2007; Mathieu et al., 2010; Smith et al., 2010; Hanson et al., 2011). One study looking at genetic counselling and breast cancer risk failed to identify a significant impact of a decision aid on accuracy of risk perceptions (Miller et al., 2005).

Further attempts to establish the fundamental components of decision aids have centred on the use of value clarification methods (Abhyankar et al., 2011; Fagerlin et al., 2013). Values clarification refers to the aspect of a decision aid that attempts to help an individual clarify their relevant attitudes towards the risk-benefit trade-offs associated with choosing various options. These techniques are often divided into either implicit or explicit approaches. Implicit values clarification techniques often employ the use of decision boards or attribute tables in an attempt to present the relevant information in a manner that clearly displays all available options and the associated outcomes. The patient is also encouraged to examine their attitudes towards these options. An explicit approach also presents the information in a manner that displays the relevant options but also includes techniques that require the patient to explicitly engage with the information. This usually requires the patient to rate the personal importance of varying outcomes through techniques ranging from simple Likert or visual analogue scales to more complex procedures such as the standard gamble method. The standard gamble method is a technique that is used to measure the strength of an individual's preferences for certain outcomes when under uncertainty (Gafni, 1994). For example, patients may be asked to decide whether they would rather remain in poor health for an additional number of years, or undergo a procedure which could restore the patient to a full health, but could also lead to immediate death.

Once again, findings from a review by Stacey and colleagues (2014) suggested, following analysis of 13 studies, that the inclusion of an explicit values clarification exercise did significantly increase the chances of patients choosing a treatment option that was congruent with their own values (relative risk = 1.51, 95% CI=1.17 to 1.96). However, it should be noted that only one of the studies included in this analysis directly addressed the impact of including an explicit values clarification exercise (Mathieu et al., 2010), with the majority of the remaining studies forming comparisons between decision aids and standard care, without controlling for other potential contributing features of the decision aid.

A review of the literature focusing on the overall impact of values clarification methods did suggest that the inclusion of these exercises could have a positive impact on the decision-making process, however these findings were limited (Fagerlin et al., 2013). For example, in relation to treatment for breast cancer, Abhyankar and colleagues (2011) determined that value clarification techniques are in fact an essential component of effective patient decision aids and that the use of explicit techniques resulted in lower ambivalence than the use of implicit value clarification techniques. However, although this does give some insight into the essential elements of decision aids, the fact that the study only presented findings from a sample of healthy women making hypothetical choices indicates that the conclusions reached must be approached with caution. Furthermore, only one of the five studies included in the review which included measures of decisional conflict, found that the inclusion of value clarification methods reduced decisional conflict (Montgomery et al., 2003). This study, which looked at decisions relating to hypertension treatment, also reported that increased knowledge is associated with the inclusion of value clarification methods. However, it should be noted that the decision aid being tested took between 45-60 minutes to complete and would therefore be unsuitable to implement in a standard consultation. This impact on knowledge was not mirrored in three other studies in the review which looked at decisions relating to prostate cancer screening (Frosch et al., 2008a), vasectomy (Labrecque et al., 2010) and genetic testing (Lerman et al., 1997). Furthermore, it was difficult to draw any firm conclusions due to the lack of data and heterogeneity of methods used, with only 13 studies included in the final review. It is therefore clear that although research may be growing in reference to the key components of decision aids, findings are still limited. Further enquiry is required to establish how these various components may be applied in different formats and whether the impact of these

components may differ between decision type, populations and clinical context.

2.3.5 Barriers and facilitators

When discussing the use of decision aids in medical practice, the potential barriers and facilitators to implementing shared decision-making must also be reviewed. A comprehensive understanding of such issues from the health professionals' perspective was recently addressed in a systematic review of the literature (Legare et al., 2008). This review included 38 studies with a total of 3,231 participants. The healthcare decisions being assessed varied considerably across trials, with study groups including oncologists, psychologists, social workers, nurses, gynecologists, respirologists, surgeons and pharmacists. The majority of the studies focused on healthcare decisions relating to adults, however there was some evidence of child involvement. For example, one French study focused on how paediatric residents involved children in the decision-making process, with results failing to explain for variations in clinicians' attitudes towards child involvement (André et al., 2005). The majority of the studies included in the review used qualitative methods (n=21), with 11 studies using quantitative methods and six implementing a mixed methods design. Data were collected via interviews in 16 of the included studies, via focus groups in 13 studies and through questionnaires in 15 studies. Five studies also used observations to collect data. Findings from the review suggested that time constraints were the most frequently reported barriers to the implementation of shared decision-making, with this being cited in 22 of the included studies.

Similar concerns have also been identified more recently in research exploring healthcare professionals' views on two computer-based decision aids used for women facing decisions regarding method of delivery in pregnancy (Rees et al., 2009) and in research focusing on the perceptions of physical and rehabilitation medicine physicians in the Netherlands (van Til et al., 2010). More specifically, it was also reported that time constraints can frequently be divided into two separate categories for a range of medical decisions (Graham et al., 2007). These include the actual time required to implement shared decision-making during the consultation and the time needed to initially access the decision aids and to provide this information to the patient. Results from a cross-sectional survey considering patients' views on shared decision-making also highlighted a lack of time in consultations as a potential barrier (Caress et al., 2005). However, although this issue was frequently cited, as mentioned previously, the evidence as to

whether decision aids have a significant impact upon time compared to usual care remains inconclusive (Stacey et al., 2014).

The second most frequently reported barrier to the use of decision aids was the lack of agreement about the applicability of shared decision-making due to the diverse characteristics of patients (Legare et al., 2008b). This was reported in 18 of the 38 studies included. Similarly, the third most reported barrier was a lack of agreement about the applicability of shared decision-making due to the clinical situation. In this instance, the term clinical situation refers to the patient's healthcare condition and the decision being made. For example it has been reported that healthcare professionals may be unwilling to implement shared decision-making or the use of decision aids if the healthcare problem was severe and therefore held potentially greater consequences or if the healthcare condition required urgent attention (Elwyn et al., 1999). This was cited in 16 of the 38 studies included. In addition, the fourth and fifth most cited barriers were perceived patient preferences for decision-making that were not consistent with a shared decision-making model together with a lack of agreement with the component of shared decision-making which suggests asking patients about their preferred role in decision-making. Related themes were also reported more recently in a study assessing the feasibility of implementing four patient decision aids for decisions relating to early stage breast cancer treatment (Silvia et al., 2008). Here it was found that perceived patient readiness and attitude towards involvement in shared decision-making was a key barrier to the implementation of decision aids in clinical settings. A further study investigating the use of decision aids in rehabilitation medicine also concluded that the characteristics of the patient and the clinical process could act as barriers to the practice of shared decision-making (van Til, et al., 2010). As a result of these findings it has been proposed that health professionals may be screening a priori patients most suited to the shared decision-making process (Legare et al., 2008b). This is particularly concerning when considering previous findings that imply physicians are unable to consistently predict patients' preferences for involvement in the decision-making process (Bruera et al., 2002). Following on from this, it was suggested that interventions may be best suited to target the patient directly in order to ensure that shared decision-making can be successfully implemented into practice (Holmes-Rovner et al., 2000).

Lack of self-efficacy and familiarity with the concept of shared decision-making were also reported as perceived barriers to shared decision-making in the review of the

literature (Legare et al., 2008b). Training programmes for physicians relating to the practice of shared decision-making was identified as a potential strategy to overcome such barriers (Elwyn et al., 2004). One study included in the review, which focused on physicians perceptions of three separate decision aids also suggested that ensuring that decision aids remain up to date and of a high quality could be a potential issue when implementing shared decision-making (Graham et al., 2003). This regular review and updating of the decision aids is particularly crucial when considering the pace at which new evidence and new treatment alternatives become available (O'Connor et al., 1998a; O'Donnell et al., 2006). The development of standardised quality criteria has been noted as a potential method to overcome such barriers (IPDAS, 2012). Other reported barriers in recent research included conflicting recommendations from various health professionals, computer illiteracy, language barriers, lack of physician awareness, and organisational issues (Caress, et al., 2005; Graham, et al., 2007; Silvia, et al., 2008; van Til, et al., 2010).

The most frequently cited facilitator of shared decision-making was the motivation of the health professionals (Legare, et al., 2008b), this being cited in 23 of the 38 studies included in the latest review. In addition, 16 of the 38 studies included reported that key facilitators also included the clinician's perceived impact of shared decision-making on both patient outcomes and the clinical encounter itself. More specifically, there was a perception that shared decision-making and decision support tools will improve both these factors. Other noted facilitators included positive perceptions regarding the usefulness or practicality of shared decision-making, the compatibility of patients' preferences fitting the shared decision-making process, and the characteristics of the patient (Legare, et al., 2008b). These findings clearly imply that the attitudes of clinicians towards the potential impact of decision support tools and shared decision-making are vital in the successful implementation of such practice. However, as noted by Legare, how exactly to improve such attitudes remains undetermined. Furthermore, as suggested previously, empirical evidence regarding the impact of shared decision-making on health outcomes such as quality of life remains inconclusive (Legare, et al., 2008b; Stacey et al., 2014). However, there is consistent evidence to suggest decision aids and shared decision-making does have a positive impact on patient knowledge and on the actual decision process itself through reducing levels of decisional conflict (Stacey, et al., 2014). These findings may be crucial in helping develop more positive attitudes towards the potential outcomes of shared decision-making and the use of

decision aids.

More recent studies also reported that structural and organisational factors continue to have an impact in facilitating shared decision-making (Caress, et al., 2005; Rees, et al., 2009). These factors included having a sufficient amount of time during consultations and appropriate distribution channels. Qualitative analysis of data collected from a collaborative study of physicians and patients (Lown et al., 2009) also indicated that adequate levels of trust and respect in the doctor-patient relationship are crucial in facilitating the use of decision aids and shared decision-making. It is clear that many of these factors identified in relation to implementing shared decision-making were reported as both barriers and facilitators. It has therefore been suggested that this issue perhaps warrants a more detailed examination in future research, with greater use of qualitative methods being used to explore these issues further (Gravel et al., 2006).

A recent review also investigated the potential barriers and facilitators to shared decision-making from the patients' perspective (Joseph-Williams et al., 2014). This review included a total of 44 studies spanning a wide array of healthcare decisions. Once again, the concept of time was reported as a significant barrier to the implementation to shared decision-making, with suggestions that time constraints often failed to provide the opportunity for patients to ask questions or discuss treatment options in further detail (Fraenkel and McGraw 2007; Frosch et al., 2012). Furthermore, it has been suggested that patients did not want to engage fully in the decision-making process if clinicians appeared hurried (Beaver et al., 2005; Entwistle et al, 2008). In addition to this, continuity of care was also highlighted as a further factor that was out of the patients' and clinicians' control, with this being addressed in 15 of the 44 studies included. In this instance it was suggested that if too many clinicians were involved in the care pathway, patients were less likely to engage in shared decision-making (Sainio et al., 2001; Doherty and Doherty, 2005), particularly if the clinicians were unfamiliar to the patients (Skea et al., 2004; Bastiaens et al., 2007; Entwistle et al, 2008). Features of the environment (7/44) were also deemed as a potential barrier, with high levels of noise potentially disrupting the decision-making process (Park and Song, 2005; Ruan and Lambert, 2008).

As reported from the health professionals' perspective (Legare et al, 2008b), characteristics of the clinician (35/44) and patient (29/44) one again played a role in the

facilitation of shared decision making from the patients' perspective. It was noted that clinicians who adopted an authoritarian attitude to the consultation often hindered the shared decision-making process, with characteristics of the patient, including poor health (Sainio et al., 2001; Caress et al., 2002; Doherty and Doherty, 2005; Park and Song, 2005; Belcher et al., 2006; Bastiaens et al., 2007, Kelsey et al., 2007; Ekdahl et al., 2011; Larsson et al., 2011) and cognitive impairments (Caress et al., 2002, Caress et al., 2005, Larsson et al., 2011) also having a detrimental impact. In addition to this, it was reported that the age of the patient may also effect the interaction between patients and clinicians, with younger patients potentially feeling they were not able to be involved in the decision-making process (van Staa, 2011). Potential power imbalances (36/44) between the patient and clinician could also have a negative impact on the shared decision-making process, with reports suggesting that patients may be less willing to engage because they assume they should remain passive and that the clinician holds the relevant expertise to make the decision on their behalf (Avis, 1994; Nordgren et al., 2001; Caress et al., 2005; Doherty and Doherty, 2005; Ekdahl et al., 2011; Aasen et al., 2012).

Patients also reported that the characteristics of the healthcare decision itself may impact upon shared decision-making, with embarrassing or sensitive topics potentially hindering the sharing of information from both parties. Furthermore, it was suggested that trust could act as both a barrier and facilitator for shared decision-making. For instance, high levels of trust in the clinician's ability may lead patients to take a withdrawn role in the decision-making process (Adler et al., 1998; Agard et al., 2004), whereas increased trust could also facilitate the sharing of information between both parties (Belcher et al., 2006; Fraenkel et al., 2007; Entwistle et al, 2008; Lown et al., 2009; Peek et al., 2010). It has also been suggested in 30 of the 44 included studies that patients may be reluctant to be involved in the decision-making process because they are unaware that they have a choice in treatment (Avis, 1994; Cohen and Britten, 2003; Clover et al., 2004; Skea et al., 2004; Beaver et al., 2005; Fraenkel et al., 2007; Entwistle et al., 2008,). Finally, reports have suggested that the provision of information about the options available plays a key role in facilitating shared decision-making (27/44), with patients often feeling they can't engage in the decision-making process because they are not aware of the options available. These latter findings lend further support for the role of decision aids in encouraging the implementation of shared decision making.

2.3.6 Attitudes towards shared decision-making and decision aids

As motivation of health professionals was frequently recognised as a facilitator towards the use of shared decision-making, it seems logical to consider practitioners' general attitudes towards the use of decision aids and shared decision-making. Recent studies suggest that, overall, practitioners generally hold positive attitudes towards involving patients in the decision-making process and report high levels of comfort in implementing such practice (Edwards and Elwyn, 2004; Floer et al., 2004b; Edwards et al., 2005; Rees, et al., 2009; van Til, et al., 2010; Caldon et al., 2011; Fiks et al., 2011). These findings were derived from both quantitative and qualitative analysis of physicians' views and spanned a number of health decisions relating to breast cancer surgery, caesarean section, Attention Deficit Hyperactivity Disorder (ADHD) and general practice. However, despite demonstrating positive attitudes towards the practice of shared decision-making, some reservations were noted. One such reservation was a concern that as there is already a wealth of information and support available to patients, the use of decision support tools may simply be adding unnecessary information and support. Furthermore, some clinicians raised concerns that decision support interventions may actually result in 'information overload', which may have a negative impact on the decision-making process (Caldon, et al., 2011). Worries over whether the use of such tools may actually de-value the role of health professionals were also noted. In addition, one study reported that although the majority of a sample of paediatricians had favourable attitudes towards shared decision-making in relation to the treatment of ADHD, 73 % viewed it simply as a method to persuade parents to choose the clinician's preferred treatment option (Fiks et al., 2011).

When considering attitudes towards the use of decision aids, patient reports on shared decision-making must also be addressed. A review of publications focusing on patients' desired involvement in decision-making reported that patients do want to be part of the decision-making process, especially when various options exist (Guadagnoli and Ward, 1998). Similar attitudes have also been noted in more recent investigations of patients' attitudes towards shared decision-making (Rothenbacher et al., 1997; Stewart et al., 2000; Davison et al., 2002; Floer et al., 2004a; Janz et al., 2004; Kremer et al., 2007). More specifically, research on patients' preferences has also helped determine the precise role patients wish to play in shared decision-making. Here, it has been proposed that although patients do not desire to have an autonomous or consumerist role in decision-making, they still want to have a comprehensive understanding of the disease,

the options available and the relative risks and benefits associated with these various options (Deber, 1994; Charles et al., 1999b; Elwyn et al., 2001; Coulter, 2002; Deber et al., 2007).

Nevertheless, despite such support for involving patients in the decision-making process, conflicting findings imply that the patient's desired level of involvement may actually depend upon other variables (Arora and McHorney, 2000; McKinstry, 2000; Levinson et al., 2005). For instance, it has been reported that age, social class, education and gender may all be associated with preferred levels of involvement. Overall, younger, more educated female patients and patients of a higher social status, appear to prefer a more active role in the process (Rothenbacher, et al., 1997; Arora and McHorney, 2000; Stewart, et al., 2000; Janz, et al., 2004). However, these findings remain inconclusive (Stewart, et al., 2000; Janz, et al., 2004; Kremer, et al., 2007). This suggests further studies are necessary which should focus on how decision aid outcomes may vary according to socio-demographic characteristics and other factors including the stage of decision-making and the medical decision being made.

2.4 Shared decision-making in paediatric healthcare

2.4.1 Background

In recent decades, the importance of including children and young people in medical decision-making has been acknowledged, with the Convention Rights of the child leading this global shift in attitudes towards how children are perceived in healthcare settings (The United Nations Children's Fund, 1989). This movement towards the inclusion of children and young people has also been documented more recently on a national level, with the Department of Health in England stating that children *"should be encouraged to be active partners in decisions about their health and care, and, where possible, be able to exercise choice" (*Department of Health, 2003, p9). In addition to this, the growing literature on the impact of shared decision-making and patient decision aids on such aspects as increased patient knowledge and reduced decisional conflict (Stacey et al., 2014) has offered further support to the integration of shared decision-making in paediatric settings. More research investigating the potential impact of shared decision-making on healthcare decisions involving young people is therefore warranted.

In line with such proposals, research has recently been published on the impact of shared decision-making with children with special healthcare needs (Fiks et al., 2012a; Fiks et al., 2012b). In this instance two related studies reported longitudinal analysis of data from young people aged 5-17 who had special health care needs. These data were obtained from between 12,810 and 14,828 households in the US and spanned over two years. In this instance shared decision-making was assessed using seven items included on the Medical Expenditure Panel Survey, which were derived from the aforementioned model of shared decision-making proposed by Charles and colleagues (1997). Findings from these data suggested that increased shared decision-making was associated with improved behavioural health for children classified as behaviourally impaired (Fiks et al., 2012b). It was also reported that increased shared decision-making with children with special healthcare needs was associated with lower healthcare costs and utilisation (Fiks et al, 2012a). However, these findings were potentially limited by the fact that the data collected in relation to shared decision-making was based on household reports as opposed to direct observations. Furthermore, it is not clear on whether the relationship between shared decision-making and behavioural impairment is due to the fact that patients were more likely to become involved in the decision-making process as they became less behaviourally impaired. The potential positive impact of shared decision-making with children and young people was also noted in a study reporting the impact of a computerised decision aid on oral contraceptive use in adolescent patients (Chewning et al., 1999). In this study it was reported that the decision aid resulted in increased knowledge, greater confidence in the efficacy of the oral contraceptive and a higher percentage of compliance for young women who stated their intentions to use oral contraceptives at their first consultation. Significant increases in knowledge were also demonstrated one year following the initial consultations.

However, despite such support for the use of shared decision-making and decision aids in paediatric settings, when compared to the literature focusing on the impact of shared decision-making on adults, the volume of research is scarce. Furthermore, the majority of studies conducted in paediatric settings appear to focus solely on the involvement of the parent in the decision-making process (Dunn et al., 1998; Merenstein et al., 2005; Wroe et al., 2005; Ossebaard et al., 2010; Golnik et al., 2012). The paucity of an ethos in decision-making in paediatric healthcare is also noted when viewing the Decision Aid Library Inventory (Ottawa Hospital Research Institute, 2015). In this instance only 35 out of the available 646 decision aids focus explicitly on paediatric decisions. These

include decisions relating to acne, allergies, ADHD, autism, anticoagulation therapy, bone infection, bone marrow transplantation, circumcision, immunization, cochlear implants, cystic fibrosis, depression, diabetes, diarrhoea ear infections, deafness, psychosis, scoliosis and bed wetting. In addition, the majority of these decisions are again mainly focused towards the parents or carer of the child and their 'proxy' role in the decision-making process. Furthermore, despite meeting the minimal inclusion criteria set by the Ottawa Hospital Research Institute (2014), the scientific evidence regarding the efficacy of these decision aids appears difficult to access. There are also various decision aids available through the NHS Shared Decision Making Programme, however, of the 35 aids available through their website, there is only one decision aid aimed directly at children and their parents/guardians. This decision aid relates to treatment options available for otitis media with effusion. There are currently no other decision aids available which are aimed directly at children and young people in any other clinical context.

2.4.2 Attitudes towards paediatric shared decision-making

Support for the implementation of shared decision-making in paediatric healthcare can also be derived from findings suggesting that many children would prefer to be involved in the decision-making process (Coyne and Harder, 2011). For example, studies have shown that children and young people wish to and are willing to participate in a range of medical decisions, including those relating to diabetes (Dovey-Pearce et al., 2005), cancer (Lewis et al., 1988; Quinn et al., 2011), scoliosis and cystic fibrosis (Angst and Deatrick, 1996). Research suggests that this desired level of involvement does not always imply children and young people prefer an autonomous role in decision-making, but may also require the assistance of others; a key principle to the concept of shared decision-making (Coyne, 2006; Zwaanswijk et al., 2007). Interestingly, there is also some research to suggest that some children and young people may prefer a more passive role in the decision-making process (Knopf et al., 2008). However, these findings simply reiterate the need to take individual preferences into account when starting the decision-making process.

When discussing the involvement of children in shared decision-making the parent's and physician's preferences for such involvement must also be taken into account. Once again it appears opinions on such matters often vary among adults (Ross, 1997; Shemmings, 2000; Coyne and Harder, 2011). In one study, Angst and Deatrick (1996)

observed that varying patterns of parental desired involvement of their child was dependent upon the decision being made and the context of the illness. Here it was suggested that parents of patients with scoliosis often encouraged child participation in the decision-making process, whereas parents of patients with cystic fibrosis were less open to the concept of shared decision-making. In the latter situation it was also found that the parent's views of child involvement depended on factors such as their previous experience of involving their child in medical decision-making and the potential consequences of the decision. In contrast, more recent research has suggested that the majority of parents of children in hospital settings held positive views towards the involvement of their child in the decision-making process (Coyne, 2006). Despite this however, findings suggested that children's' and young peoples' opinions were still not sought as often as they could be.

Interestingly, some findings suggest that parents may be more reluctant to let their child have an active role in the decision-making process due to a belief that they need to protect them from potentially uncomfortable or upsetting situations (Lewis et al, 1988; Coyne and Harder, 2011). These patterns were also evident in a study researching communication with children and young people in a paediatric oncology unit. In this study it was found that parents often managed the amount of information their child received regarding their illness, especially at the point of diagnosis (Young et al., 2003). Furthermore, the young patients in the study often appeared aware that such constraints were being put in place by their parents, something that was not always appreciated by the patient. Further research also reported that even when healthcare professionals attempted to provide children with a more active role in decision-making, protective behaviours from the parent once again prevented such involvement (Tates et al., 2002). It has also been suggested that even when healthcare professionals are receptive to the notion of shared decision-making, evidence of this being practiced remains lacking (Towle et al., 2006). This has led to suggestions that more emphasis should be placed on the training of practitioners and the development of frameworks to ensure they are competent in facilitating shared decision-making with their young patients and families (Towle and Godolphin, 1999; O'Brien et al., 2011)

2.4.3 Competence

A further reason why adults may not advocate the involvement of children in the decision-making process relates to concerns over competence (Coyne, 2006). Support

for such beliefs derives from a study conducted in the 1980s which reported that although children aged 14 or over display similar levels of competence to adults, children who are younger than 14 years do not have the necessary ability to be included in the decision-making process (Weithorn and Campbell, 1982). However, these findings have been scrutinised, suggesting that other factors such as the type of illness, past experiences, education and family background also have an impact upon a child's competence to participate in medical decision-making (Deatrick et al., 2003). These findings are further supported through suggestions that levels of development are not consistently age-related and that children are able to express preferences and opinions on a wide array of subjects (Alderson, 1993; Christensen, 1998; Halpern-Felsher, and Cauffman, 2001; Nova et al., 2005; Alderson et al., 2006; Alderson, 2007). This has led, in turn, to proposals that competence should actually be viewed as situation-dependent and that children and young people cannot be expected to become fully competent in decision-making without having the relative practice and experience of being involved in such situations (Koocher and De Maso, 1990; Coyne and Harder, 2011). This shift in focus away from the age of the individual in relation to competence also coincides with current English Law, which states that consent to medical treatment can be given by children under the age of 16, if they are considered mentally competent (Children Act, 2004).

2.5 Rationale

In summary, the decision for young people to undergo dental treatment with either sedation or GA may be viewed as a preference sensitive decision. When discussing the various dental sedation techniques available for children and young people, a lack of data, conflicting findings and heterogeneity of design have made it impossible to reach firm conclusions on the relative efficacy of these varied approaches. Similar issues are also present when comparing conscious sedation techniques with GA, with these findings suggesting that the decision to undergo treatment with sedation or GA may be more dependent upon the patients' values attached to the options available and the associated benefits and risks. When such preference sensitive decisions exist in healthcare it is often proposed that adopting a shared approach to decision-making may be beneficial. These approaches state that the exchange of information between clinician and patient should be a two-way process, with both medical information and personal values being shared (Charles et al., 1997). In such instances, decisional support tools such as patient decision aids are often implemented in order to encourage involvement

in the decision-making process and to provide further information regarding the options available.

Furthermore, decision aids have been shown to increase patient knowledge, reduce decision conflict, and increase accuracy of risk perceptions and participation in the decision-making process (Stacey et al., 2014). In addition to this, although the development of decision aids designed specifically for children has been limited, research has also shown that young people are willing and able to take a more active role in the decision-making process (Lewis et al., 1988; Alderson, 1993; Christensen, 1998; Halpern-Felsher, and Cauffman, 2001; Dovey-Pearce et al., 2005; Nova et al., 2005; Alderson et al., 2006; Alderson, 2007; Quinn et al., 2011). It is also thought that the provision of further decisional support can also help meet current guidelines regarding the need for the provision of detailed information for both patients and parents undergoing dental Sedation or GA (NICE, 2010; Adewale et al., 2011; Royal College of Anaesthetists, 2015). To date, the use of any decision aid within a paediatric dentistry settings has not been described. The proposed development of a decision aid to support children and young people in their choices between sedation or GA thus seems to be justified. The generic context of the decision would also have wider implications outside of dentistry.

2.6 Aims and objectives

The overall aim of the current study is therefore to develop a patient decision aid to help children and young people make informed choices about having dental treatment with inhalation sedation, IV sedation or GA. It is essential to have a framework to guide the development and evaluation of a decision aid. For the purposes of this research, the study design was based on the initial steps detailed in the development framework proposed in the original IPDAS Collaboration Background Document (IPDAS, 2005a). These stages are as follows:

a) Assessing decisional needs

This involves considering the informational and decisional needs of patients involved in the healthcare decision.

b) Formation of groups to develop and review the decision aid

This stage of the process calls for the formation of groups including experts in the clinical care involved and patients who have experienced the decision-making process

c) Drafting, reviewing and revising the decision aid

This describes the iterative process used to revise the decision aid before completion.

d) Field testing the decision aid with patients

This stage of the study involves testing the decision aid in the clinical care setting and focuses on the feasibility, acceptability and potential impact of the decision aid on patient outcomes.

Detailed on the following page are the specific objectives of the current study in relation to the proposed IPDAS framework, the methods used to meet these objectives and the related chapters these are reported in this thesis (see Table 1).

Table 1**:** *Objectives of the research, their relation to the IPDAS framework and the methods used*

Objectives of the current research	Stages of the IPDAS framework	Methods used	Relevant Chapter
1. To explore what factors are involved, from the young persons' and parents/guardians' viewpoint, when making the decision whether or not to undergo sedation or GA for dental treatment, and subsequently to determine the needs of those involved	a) Assessing decisional needs	Qualitative interviews with former patients and parents/guardians	Chapter Three: Development of The Decision Aid
2. To explore clinicians', patients' and parents/guardians' initial perceptions towards the decision aid	b) Formation of groups to develop and review the decision aid c) Drafting, reviewing and revising the decision aid	Expert Clinician Focus group & Expert patient group interviews	Chapter Four: Further Decision Aid Development and Review
3. To determine the impact of a decision aid for paediatric dental sedation on measures of patients' and parents/guardians' decisional conflict, anxiety, knowledge, attendance and compliance with treatment 4. To determine the acceptability of the decision aid 5. To determine the feasibility of implementing and evaluating a decision aid in a secondary care setting	d) Field testing the decision aid with patients	Between-subjects pilot study	Chapter Five: Evaluation of the Decision Aid

2.7 Strategic choice of methods

The exact methods used to meet these objectives and the reasoning behind their inclusion is detailed below.

2.7.1 Development of the decision aid

2.7.1.1 Qualitative interviews with former patients and parents/guardians

The first objective of the current research was to explore what factors were involved in the decision-making process and to determine the needs of those involved. To address this objective, a series of qualitative interviews were undertaken with patients who had already undergone dental treatment with sedation or GA and their parents/guardians. The findings from these interviews were then used to help inform the content of the decision aid. Semi-structured face-to-face interviews were conducted. A qualitative approach was preferred as it allowed participants to describe their experiences in their own words, while enabling more detailed discussion of certain issues and the development of spontaneous issues which had not previously been recognised. Furthermore, a semi-structured approach was preferred to an unstructured approach as some of the issues of interest had been determined prior to the interview to meet the specific objectives of this stage of the project. These issues had been determined by both the existing literature relating to dental sedation and GA, the barriers and facilitators towards shared decision-making and also by the quality criteria set by the IPDAS collaboration. For example, the development framework proposed by the IPDAS collaboration suggests that as well as the potential consequences; patients also need to be informed of the procedures involved in the treatment options available (IPDAS, 2005a).

2.7.2 Further decision aid development and review

2.7.2.1 Expert clinician focus group

To address the second objective of the current research a focus group was conducted with experts in the clinical care involved including, general dental practitioners who refer patients for sedation, paediatric dentists, dental sedationists and anaesthetists. This focus group involved reviewing the initial draft of the decision aid and was used to gain further knowledge of the informational needs of the clinicians in the decision-

making process. Focus group discussions can be effective when they involve those professionals who work with the population groups who took part in previous interviews. The reason for this is they allow the interviewer to focus on some of the underlying causes of the issues previously raised and help highlight some of the more practical issues involved in the implementation of services. The use of a focus group also allows for more immediate and direct comparisons to be made between participants as they emerge within the group discussion. The opportunity for participants to hear from others can also lead them to reflect more on their own thoughts, leading to a more detailed discussion of the subject matters raised (Ritchie and Lewis, 2003).

2.7.3 Expert patient group interviews

Further interviews with patients and their family members who had already experienced the decision to undergo dental treatment with sedation or GA were conducted. These interviews were implemented to explore the initial patient perceptions towards the decision aid, as stated in the second objective. It was originally intended to present the draft decision aid to the patients and parents/guardians in a focus group. However, due to poor response rates and time constraints it was impossible to arrange a time when all participants could take part. Consequently the three patients and three parents/guardians recruited took part in three separate interviews. This method still allowed an in-depth exploration of the informational and support needs of patients, while also providing initial feedback on the content of the draft decision aid. Once again a semi-structured process allowed the discussion of both pre-determined issues of interest and more spontaneous issues which had not previously been recognised. The inclusion of patients in this second stage of the study was particularly important when reviewing the appropriateness and comprehensibility of the information included in the decision aid prior to pilot testing.

2.7.4 Evaluation of the decision aid

2.7.4.1 Between-subject pilot study

To address objectives 3-5, a pilot evaluation of the effect of the decision aid in terms of changing patient outcomes and experiences within their dental sedation care pathway was conducted. The use of a pilot study is appropriate at this stage of the

research in order to determine the potential feasibility of implementing and evaluating the decision aid in a secondary care setting and to examine the potential impact of the decision aid on patient outcomes. Pilot experiments also allow the research to calculate effect sizes which can then be used to calculate appropriate sample size for future research. For this stage of the study participants who were scheduled to undergo dental treatment with either sedation or GA and their parents/guardians were recruited from Liverpool University Dental Hospital and randomly assigned to either a control or intervention group. The control group received routine clinical counselling prior to making a treatment decision, whereas the intervention group received routine clinical counselling and the decision aid prior to making a treatment decision. The study aimed to compare measures of decisional conflict, anxiety, knowledge, attendance and compliance with treatment between the two groups.

Chapter Three: Development of the Decision Aid

3.1 Introduction

This chapter will introduce the initial development process that has been used to create a patient decision aid for young people and parents/guardians faced with the decision to undergo dental treatment with sedation (inhalation or IV), GA or indeed without any of these options. This includes the initial qualitative interviews conducted with patients and parents/guardians and the subsequent initial development of the draft decision aid. The methods reported in this chapter were designed to contribute to the satisfaction of the following research objective:

1. To explore what factors are involved, from the young persons' and parents/guardians' viewpoint, when making the decision whether or not to undergo sedation or GA for dental treatment, and subsequently to determine the needs of those involved (see Table 1)

3.2 Methodology

The following section will describe the methods used in the interviews with patients and their parents/guardians which formed the first stage of the development process.

3.2.1 Ethical approval and research governance

Ethical approval for the study was obtained from the NRES Committee for Yorkshire and The Humber – Sheffield (13/YH/0142) on 6th August 2013 (Appendix A). Local permission to undertake the study, in terms of research governance, was also obtained from the Sheffield Teaching Hospitals NHS Foundation Trust (STH17248 – 6th August 2013) (Appendix B) and the Royal Liverpool & Broadgreen University Hospitals Trust (4626 – 29th August 2013) (Appendix C).

3.2.2 Sample

The following inclusion and exclusion criteria were adopted:

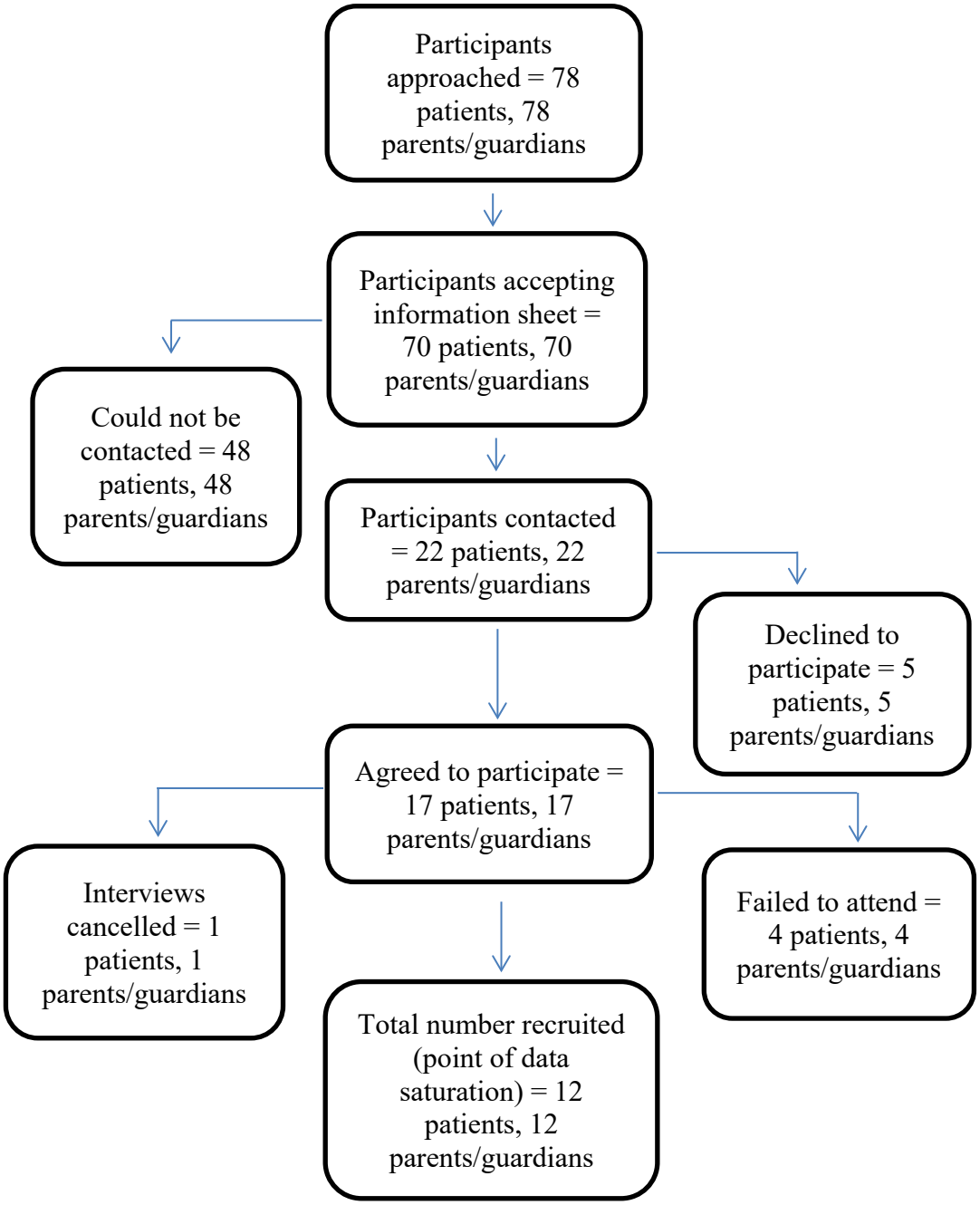
- Inclusion criteria
    - children and young people aged 10-16 years of age at recruitment
    - children who have already undergone dental treatment with either inhalation sedation, IV sedation or GA
- Exclusion criteria
    - any child who needs urgent treatment because of acute symptoms
    - children with severe learning disabilities who lack verbal articulacy
    - non-English speaking children and parents

The age range was informed by the care pathway in place at the Royal Liverpool University Dental Hospital where the decision aid was evaluated in the final stage of the study. Ten years is the youngest age at which young people could be offered the three options of inhalation sedation, IV sedation or GA and 16 years is the age at which patients are discharged from the paediatric dentistry clinic. It was determined that only English-speaking patients and parents were suitable to participate in the study as it was not feasible to employ the use of interpreters. Due to the fact that data were to be collected verbally through interviews, children with severe learning disabilities who lack verbal articulacy were also excluded from the study.

Purposive sampling was employed in an attempt to ensure that the sample included participants with a range of ages, both male and female, of different ethnic groups and with different dental experiences. However as shown in Table 2, only one patient was recruited from an alternate background to White British. This patient described their ethnicity as British Asian. Females were also over-represented in the sample, as 9 of the 12 patients were female. It can also be seen in Table 2 that patients ranged in age from 10-15 years and that five patients were recruited from the Charles Clifford Dental Hospital and seven patients were recruited from the Royal Liverpool University Dental Hospital. With regards to prior treatment, seven of patients had previously had dental treatment with inhalation sedation, three with IV sedation, one with GA and one patient had experiences of dental treatment with both inhalation sedation and GA.

Recruitment commenced on 13th August, 2013 and ended on 10th December, 2013 when data saturation occurred. This occurred after 12 joint interviews with patients (n=12) and family members (n=13). A total of 78 patients and 78 of their parents/guardians were initially approached and invited to take part in the study. Of these, 70 patients and 70 parents/guardians accepted the patient information sheet and agreed to be contacted at a later date. The number of participants that dropped out at each stage of the recruitment process is detailed below (see Figure 1).

Figure 1: *Recruitment process*



The main reason why participants could not be contacted was because many declined to provide contact details, instead stating that they would contact the chief investigator, JH, on the contact number provided on the information sheet. Further reasons why potential participants could not be contacted included the provision of inaccurate contact details and a failure to respond to phone calls, emails or voicemail messages. The sole reason given for declining to take part by parents/guardians was that it was not a convenient time to take part in the study due to work and school commitments. The patient and parent, who arranged an appointment and subsequently cancelled, did so due to a family member's ill health. Of those patients who failed to attend the arranged interviews, 3 parents/guardians could be contacted and the reason given for failing to attend was that they forgot. No subsequent dates for interviews could be arranged.

Table 2: *Characteristics of patients included in the qualitative interviews*

Name	Age	Gender	Ethnicity	Attending Hospital	Previous treatment
WK	14	Female	White British	Charles Clifford Dental Hospital Sheffield	Inhalation sedation
WJL	15	Female	White British	Royal Liverpool University Dental Hospital	IV sedation
GL	15	Female	White British	Charles Clifford Dental Hospital Sheffield	Inhalation sedation
MA	13	Female	White British	Royal Liverpool University Dental Hospital	Inhalation sedation
LJ	12	Female	White British	Royal Liverpool University Dental Hospital	Inhalation sedation
VL	14	Female	White British	Royal Liverpool University Dental Hospital	Inhalation sedation
WA	15	Male	White British	Charles Clifford Dental Hospital Sheffield	Inhalation sedation
SC	13	Female	White British	Royal Liverpool University Dental Hospital	Inhalation sedation and GA
AS	14	Female	British Asian	Charles Clifford Dental Hospital Sheffield	Inhalation sedation
LD	10	Female	White British	Charles Clifford Dental Hospital Sheffield	GA
LK	15	Male	White British	Royal Liverpool University Dental Hospital	IV sedation
WL	15	Male	White British	Royal Liverpool University Dental Hospital	IV sedation

3.2.3 Procedure

Patients were recruited from the Charles Clifford Dental Hospital and the Royal Liverpool University Dental Hospital. Potentially suitable participants were identified by their direct care team at their routine clinic visit. The care team staff were briefed by the chief investigator (JH) regarding inclusion criteria for the study and they introduced interested patients to JH for a more detailed discussion about the study. To facilitate this, JH reviewed clinic schedules to determine if age appropriate patients were due to attend. JH then remained in an unoccupied area of the clinic until introduced to a potential participant. During the initial discussion, patients and parents/guardians were also each given age-appropriate information sheet providing more details of the study (Appendix D). Permission and contact details were sought from the parents/guardians to approach them again in the future about study participation. Patients and parents/guardians were then contacted by JH by telephone, after they had had at least 24 hours to consider whether or not they would like to take part in the research. For those willing to take part, a convenient date and location for the interview to take place were agreed. Written informed consent was obtained from both children and parents prior to the interview (Appendix E). Prior to commencement of this study, JH underwent a period of familiarisation with paediatric dentistry clinics to gain an appreciation of the clinical context, patient care mix, care pathway and booking procedures. This stage was vital in order to gain a better understanding of the vocabulary used to describe the various procedures and attendance status of patients and also to establish rapport with all members of the healthcare team.

3.2.4 Interviews

All interviews were undertaken by JH and took place in a quiet room at the Sheffield or Liverpool dental hospitals. This setting ensured privacy and reduced the potential for participants to be distracted from the interview process or for their responses to be affected by the presence of others not participating in the interview. Interviews began by reiterating the purpose of the research and gaining consent. Participants were also reassured that all data provided would be confidential in an attempt to reduce any potential power imbalances between JH and the child. To ensure anonymity, participants were also given the opportunity to choose a pseudonym. The majority of participants declined this opportunity, therefore the interviewees' initials were used in

reverse order to identify the participants when attributing quotes and characteristics. The fact that the interviews would be recorded using a voice recorder was once again highlighted and the reasons for this were explained to the participants. All conversations were recorded using an Olympus DS-65 Digital Voice Recorder.

Subjects to be covered in the interview were established through the use of a topic guide, with subject areas being developed through previous reviews of the literature, the IPDAS framework (IPDAS, 2005a) and informal conversations with expert clinicians. The use of topic guides helped employ a level of consistency in the data collected between interviews while still enabling the interviewer to expand on areas of particular importance to the participant (Ritchie and Lewis, 2003). The topic guide opened with a general question about the young person's interests (e.g. whether they have any hobbies) in order to make the participant feel comfortable with the interview process, introduce the conversational manner of the interview and encourage participation. This technique is used frequently in research involving young people and children (Mauthner, 1997) and the introduction of this informal tone once again played a key role in reducing the potential power imbalance between JH and the child participant. Attempts to maintain this informal tone included the use of humour throughout the interview process. Further discussion points exploring their previous experience of having dental treatment with sedation or GA and the decision-making process were subsequently introduced. Although questions were primarily aimed at the patients, parents/guardians were also encouraged to contribute throughout the interview, as particular discussion points explored the parent's role in the decision-making process. The topic guide was edited following each interview as new topics emerged, with further emphasis subsequently placed on issues such as the impact of their choice on their type of treatment (e.g. whether teeth would be extracted), the long-term impact of treatment under sedation or GA, the perceived risks, fasting times and waiting times. The original and final version of the topic guides can be found in Appendix F.

Probes and prompts were utilised to try and encourage further elaboration on subject matters of interest. Probes are questions that respond directly to what the participant has just said, whereas prompts usually relate to subject matters that the interviewer wishes to introduce to the interviewee, which may have emerged from the literature

or previous interviews (Ritchie and Lewis, 2003). Following each interview, the participants were de-briefed about the study and given two five pound gift vouchers and relevant travel expenses as a 'thank you' for their participation. At no point in the study were any of the child participants interviewed without a parent or guardian present. The mean average duration of the interviews was 25 minutes (range =18 - 42 minutes).

3.2.5 Data analysis

Interview data were managed and analysed using framework analysis (Ritchie and Spencer, 1994). This method of analysis uses a thematic framework to classify and organise data according to key themes, concepts and categories that emerge from the data (Ritchie and Spencer, 1994).

Framework analysis can be used with various qualitative approaches that have the purpose to develop themes. The main difference between how the framework method is utilised relates to the manner in which the themes are generated. For example when taking a deductive approach to qualitative analysis, themes and codes are usually pre-determined from previous research or existing theories. In contrast, in an inductive approach, themes are not pre-determined and are solely developed through the open coding of raw data. In the context of the current study, a combined approach was employed, as although there were specific issues that the study aimed to explore, unanticipated themes and codes also emerged from the data. The data were analysed in accordance with the stages proposed by Gale and colleagues (2013) in their paper detailing the use of framework analysis in multi-disciplinary health research:

Step one: Transcription

Interviews were recorded and transcribed verbatim. When using framework analysis it is the content of the interviews which is of interest, therefore aspects of the interviews such as pauses were not transcribed.

Step two: Familiarisation with the interview

This stage involves becoming immersed in the raw data through revisiting parts or all of the transcripts or audio recordings. At this stage, notes were made regarding key ideas and initial repetitions and gaps noticed in the data.

Step 3: Coding

Following familiarisation, the transcripts were then coded. This involved re-reading each transcript and assigning descriptive labels to sections of the transcript deemed relevant. This allows data to be easily compared across the individual accounts. The first three transcripts were coded independently by separate members of the research team, JH and ZM, to ensure alternate interpretations of the transcripts were not lost.

Step 4: Developing a working analytical framework

Following coding of the first three transcripts, members of the research team compared the codes which had been assigned to the data and agreed on the codes which were to be used when coding future transcripts. This helped develop an initial analytical framework which continued to change until the final transcript was coded and data saturation occurred.

Step 5: Applying the analytical framework

The analytical framework was then used to code the following transcripts.

Step 6: Charting data into the framework matrix

Following this frameworks were developed for each theme to better organise the analysis and establish patterns within the data. This involved organising the data by category from each transcript, with the inclusion of quotes as illustrations.

Step 7: Interpreting the data

Finally, similarities and differences across the interviews were interpreted to help identify the themes deemed to be important to the decision-making process.

3.3 Results

The following section will report the main themes identified as important in the decision-making process to undergo dental treatment with sedation or GA. In total, nine themes emerged from the data relating to important considerations for the decision-making process (see Table 3). These nine themes will be discussed in turn with quotes used to illustrate the themes.

Table 3: *Important themes in the decision-making process*

Theme	Sub-theme
Method of administration	Cannula/needle
	Mask (smell appearance)
Time	No. of appointments
	Time taken to complete treatment
	Pre-operative fasting
	Recovery time
Perceived side effects and risks	
Treatment type	
Control and communication	Communication with dentist
	Parental presence
Experience of sedation	
Long-term impact	
Information received	
Format	

3.3.1 Method of administration

One of the main themes identified as important in the decision-making process was how the sedatives or general anaesthetic were administered to the patient. Characteristics of needles and masks were cited as influential factors.

> *The problem is, sorry darling, the problem with anything intravenous is that the barrier, the thing that brings the whole thing to a crashing halt is the needle, sticking a needle in her. So if it was intravenous, you wouldn't have the intravenous cannula in so she'd go home with absolutely nothing done. So the thought of GA was just stick a mask over my face, numb me out with gas completely and all the needles come while I'm unconscious.*
>
> *(Father of GL, a 16 year old female who had recently undergone treatment with inhalation sedation)*

The importance of information about the mode of delivery of the sedation and GA is also highlighted through this apparent confusion over how a GA would be administered. GA agents are initially delivered intravenously for most patients at the children's hospital, where this patient's treatment would have taken place. A gas induction would only normally be used for very young children, who may need restraint by a parent/guardian during the induction. A distinction can also be made

with regards to the administration of the LA agent which is injected into the patient's gum and the intravenous administration of sedatives or general anaesthetic through the hand or arm. In this case, some patients who cited a fear of having an injection in the gum as the main reason for being referred to the dental hospital were willing to undergo treatment with IV sedation or GA. This is demonstrated in the extract below, which suggests the use of a cannula when injecting sedatives in the back of the hand was preferable to a needle in the gum. However, the patient had held the view, incorrectly, that the needle for his gum was bigger than the one used in the back of his hand.

> *No, the needle that they put in my gum is bigger. But that needle is only about dead small and it comes in like the little pink slot so it just goes straight in.*
>
> *(LK, a 15 year old male)*

In addition to the site and perceived size of the needles being important to young people, comfort and hygiene factors associated with the nose piece were also key considerations for both parents and children:

> *It was just like a little pig's snout. But he just didn't like it, he wasn't comfortable at all.*
>
> *(WL, 15 year old male who had recently undergone treatment with IV sedation)*

> *The thought of someone else's mouth being on that.*
>
> *(WJL, 15 year old female who had recently undergone treatment with IV sedation)*

The appearance and smell of the nose piece also contributed towards the decision-making process with some patients and parents attaching positive connotations to the mask, in contrast to their preconceptions.

> *And the method of delivery is quite cute as well with the thing over the nose. I thought that was quite nice because it doesn't feel horrible. And I have horrible memories of going to the dentist as a child and having a big black*

rubber smelling gas mask. And of course it doesn't look or feel like that. So as soon as I saw it, I felt better about it as well. So no, I don't think I was worried really.

(Mother of 15 year old female, WJL)

To summarise, these data suggest, that it would be necessary to include detailed information in the decision aid regarding how each method of sedation or GA is typically administered. The data suggests that this information should not only focus on the distinction between the use of a needle or a mask but also include specific information regarding the site of administration, the use of a cannula for IV sedation and GA and also the appearance of the equipment used. It was also apparent that the administration of LA should also be addressed in the decision aid.

3.3.2 Time

The concept of time was a major theme which emerged from the data, with waiting times for appointments and number of visits often playing a role in the decision-making process, particularly for parents/guardians. This related to the fact that multiple appointments were usually required to complete a course of treatment with inhalation sedation or IV sedation when compared to GA, which usually only required a single visit.

Yeah, the only problem that I've found is erm, the dentist asked for a group block of appointments and when they sent it out they only sent out one appointment first and then this time they've only sent out two appointments. So we've still got to wait for the other appointments. Which means that the dental work is taking quite a long time… The way they have it, the length of time is a bit out of line when you're talking about young children's teeth, erm especially when it's her grown up teeth, because obviously a lot of more decay can happen in you know sort of 6, 8 months then what it can if they would have quicker appointments.

(Mother of 13 year old female, MA, who had previously undergone treatment with inhalation sedation)

For patients and parents/guardians, concerns over the time taken to complete treatment also related to a desire to limit the amount of time needed to be taken off school, particularly if treatment interfered with vital stages of the patient's education. The quote below also demonstrates how the recovery period following treatment does have an impact in such instances:

> *Because he's never had a day off school until all these dental treatments. He spent all of his senior school, with not a day off until these 4 times he's had sedation and he's had to take time off. So, that was a major part, the time he'd have to take off school. Because for the general* (GA) *they're saying it'd have to be an extra 2 days, he could take up to a week off. Which is not good because he's about to do his GCSE's, he doesn't need to be taking time off do you.*
>
> *(Mother of LK, 15 year male who had recently undergone treatment with IV sedation)*

Concerns over the length of time patients were required to fast before treatment under a GA were also highlighted during the interviews.

> *I think it is a long time for them. They don't, they don't get it do they, they're starving. So I do think it's a long time for them to go without anything.*
>
> *(Mother of LD, 12 year old female, who had previously undergone treatment with GA)*

These narratives suggested that the decision aid should make clear to patients and parents/guardians that waiting times for appointments and number of appointments are likely to vary depending upon their choice. However, the fact that these variations are unlikely to remain constant meant that the decision aid would have to simply make patients and parents/guardians aware of this matter before referring them to their dentist for further information. As a result of these data, information regarding recovery periods was also deemed as a suitable inclusion in the decision aid and also how these periods impact on when patients can return to school. Specific information regarding pre-operative fasting was also identified as an important inclusion topic in the decision aid.

3.3.3 Perceived side effects and risks

An important concern to arise, particularly from parents' perspectives, was the degree of risk associated with the different procedures. Parents/guardians were most concerned about the potential risks associated with GA, with these often being weighed up against the seriousness of the treatment needed.

> *There's too many dangers. I think it has to be an emergency to be put to sleep. Something a bit more serious than just having a tooth out before I'd be prepared to let them take those, the dangers. I thought it* (inhalation sedation) *was less dangerous than general anaesthetic.*
>
> *(Mother of WK, 14 year old female, who opted to undergo treatment with inhalation sedation)*

Side effects such as nausea, vomiting and drowsiness were also frequently mentioned throughout the interviews, with these minor side effects often being discussed in relation to more practical issues such as transport to and from the hospital. These comments were also related to the previously discussed theme of recovery time following treatment.

> *And it's easier for me because I'm on my own so trying to get him home after the general would be horrendous. It's bad enough now with the taxi, because the taxi driver takes one look and says 'better not be sick in the taxi' so you do have to watch.*
>
> *(Mother of LK, 15 years old male)*

These data suggest that information regarding both minor and major side effects were a necessary inclusion in the decision aid, with the need to present comparable probability rates across the three options.

3.3.4 Treatment type

How the treatment plan differed between the options for sedation or GA also appeared to impact upon the decision-making process. In this instance patients and parents/guardians appeared more reluctant to undergo treatment with GA due the

increased likelihood of having teeth removed and the subsequent effects this would have on the patient's appearance.

> *No, they said that basically erm, if she didn't have the gas and air and she ended up having to come in to have the one where they knock them out erm, she'd have had like some of the fillings done but she'd have had the front teeth extracted. Which would have been a very traumatic sort of thing for her. A 13 year old you know, sort of to be missing two front teeth and ending up with false teeth.*
>
> *(Mother of MA, 13 year old female)*

Potential differences in treatment planning, according to whether treatment is performed under sedation or GA is a complex clinical issue. Nonetheless, findings from this qualitative enquiry suggest that the inclusion of information regarding how treatment may differ in relation to the sedation and GA options available is necessary. However, as changes to the treatment plan may vary markedly between patients, it was once again deemed that the best option would be to raise the issue as a possible area of importance, before referring the patient and parent/guardian to the dentist if they believed they required further information.

3.3.5 Control and communication

A consistent theme throughout the interviews was the concept of control and how this related to the level of consciousness during treatment. For example, patients spoke favourably about being able to communicate to the dentist during treatment under inhalation sedation or IV sedation should they feel any discomfort.

> *I think that it was important that I still had the sort of means to stop anything if I don't feel comfortable. And that was something that was told to me beforehand and while, you know she was doing the dummy run last week you know 'at any point you want to stop you can'. And I think that was a nice thing as well because you know I'm still making decisions.*
>
> *(GL, a 16 year old female)*

Whereas undergoing dental treatment with GA appeared to be associated with a lack of control, which often caused a level of distress for the patient.

> *And when you're asleep you can't see what they're telling you. What you've done to your teeth.*
> *(LJ, 12 year old female who opted for treatment under inhalation sedation)*

This need for control also appeared to extend to parents/guardians, with the data suggesting that parents/guardians are often distressed by not being present during their child's treatment.

> *I'm just not there. I'm just not there, I can't see. I'm not there. If you know what I mean? I'm not there to see what they're doing, I'm not there to hold her hand. I'm not, god forbid and touch wood nothing did ever happen, but if anything did happen and I weren't there. I weren't there to say to her 'you know your mum's here'. I am protective over them, very protective over them since their dad left. So yeah I do get worried when they're not there and I can't see them…*
> *(Mother of LD, a 12 year old female)*

In summary, these findings imply that the level of communication and control the patients and parents/guardians have during treatment should be explained in the decision aid. With regards to patients, it was thought that the most effective way to portray this information was in relation to how levels of consciousness or awareness may differ between the different choices available. The data also suggests that further information regarding parental presence should also be included, as this information could be potentially useful in alleviating any distress at the time of treatment.

3.3.6 Experience of sedation

Patients described the sensation of having treatment under sedation and how it impacted upon their experience of undergoing dental treatment. The following extract is taken from one of the male patient's accounts of undergoing treatment with inhalation sedation.

It does help and it does make things easier, I mean for me anyway it just makes me a lot more relaxed and I think it does kind of help me through the experience. Because, like I am aware of what's going on but it's just kind of, just overall you feel a lot better. And it's not as scary with it.

(WA, a 13 year old male)

Similar terminology was also frequently used when describing treatment under intravenous sedation.

It relaxes me, I'm more comfortable.

(WJL, 15 year old female)

It was clear from the data that the experience of the treatment itself may also play a role in the decision-making process and should therefore be included in the decision aid. These data also emphasised the importance of determining how patients described treatment under sedation in their own words so that the appropriate language could be used when creating the decision aid.

3.3.7 Long-term impact

When describing the benefits of undergoing treatment with inhalation sedation or IV sedation, patients and parents/guardians focused on the potential long-term impact sedation could have on the patient's dental anxiety. The exchange on the following page, between parent and child, highlights the importance of such long term benefits in relation to inhalation sedation.

GL: In hindsight I think it's better because it's helped me get over some things that if you know, I'd have just had the general anaesthetic, then you know.
Father of GL: You'd still have had the phobia.
GL: I'd still have had the phobia.
Father of GL: And I think you're right this has actually moved you forward with that problem as well as getting the work done. So it's had like a double effect hasn't it?
GL: Yeah.

(Exchange between GL, 16 year old female, and her father)

It was also apparent from some accounts how parents/guardians often believed that undergoing treatment with GA may actually have a detrimental effect on their child's fear of undergoing dental treatment.

> *General anaesthetic yeah. But we didn't want to go down that road because when we grow up we've got to go to the dentist. So we got to try and get more happy being there.*
>
> *(Father of LJ, 12 year old female)*

In contrast, some parents/guardians rejected the notion that treatment under sedation had any long-term effect on their child's dental fear but accepted that it still held long-term benefits in enabling treatment to be completed on a regular basis.

> *I don't think it's got her over her fear of dentists but at least she's relaxed enough that she's getting the work done and she's not getting toothaches and things.*
>
> *(Mother of WK, 14 year old female)*

Although, the theme of long-term impact was consistent throughout the data, due to its varying nature, it was difficult to determine how meaningful information could be directly included in the decision aid. However it was clear that this theme could be indirectly addressed through the inclusion of information regarding levels of consciousness and the potential amnesic effects of undergoing IV sedation compared for example, with inhalation sedation.

3.3.8 Information received

A further theme emerging from the data related to the amount of decisional support information provided to patients and parents/guardians, with evidence of contrasting experiences from the data:

> *They gave us plenty of information.*
>
> *(Father of LJ, 12 year old female)*

I mean as it was I was fine but I think for me personally that would have been nice if I had some sort of leaflet or something.

(GL, a 16 year old female)

She just told us, I can't remember anything written can you?

(Mother of WK, 14 year old female)

The above extract also suggests that further opportunities to discuss the treatment options available with healthcare professionals would be beneficial. These data also support the notion that patients and parents/guardians wish to be involved in the decision-making process. Furthermore, suggestions that some patients didn't receive information raises questions over the uniformity in which information is provided to patients.

3.3.9 Format

Data also suggested that opinions differed in regards to the preferred format patients and parents/guardians would have liked to receive this information. For example some data suggested that patients and parents/guardians didn't have a preference with regards to how the information was presented:

I wouldn't have minded.

(Mother of WK, 14 year old female)

However, others felt that the availability of web-based information could be beneficial. This is demonstrated in the following exchange

JH: So would you prefer more internet based information?

Mother of VL: Yeah I would. Because I don't mind reading but I think if they went over a bit more with the parents as well. That would be a good idea when we don't know, when they're saying this is what you could have. Because when the little fella he had general anaesthetic that wasn't sort of, he was having general anaesthetic and there was no discussion about you know how long you could be under and things like that. Because he takes medication as well so not as straightforward as and he's an asthmatic so it's

not as straightforward with anything with him isn't it so. I think that would help more.

(Exchange between JH, the interviewer, and mother of VL, a 14 year old female)

The above extract also suggests that further opportunities to discuss the treatment options available with healthcare professionals would be beneficial. With regards to the provision of more web-based information, these data also suggest that the prospect of developing the decision aid as an online resource was an option that could be considered during the development phase. This issue is explored further in the following section, which details the development of the decision aid, and in Chapter Four, which describes the results of further interviews with patients and parents/guardians.

3.3.10 Summary

In summary, this first stage of the study was crucial in helping to determine which factors are important for young people and parents/guardians when faced with the decision to undergo dental treatment with either inhalation sedation, IV sedation or GA. Furthermore, the apparent confusion and lack of knowledge regarding the sedation and GA options available, shown by both patients and parents/guardians throughout the data, lends further support to the suggestion that additional decisional support is warranted for individuals facing such healthcare decisions. The following section will detail precisely how the main themes emerging from the data were subsequently incorporated into the decision aid.

3.4 Initial decision aid development

The following section will describe the development process used to create the initial decision aid for young people undergoing dental treatment with sedation or GA and their parents/guardians. This chapter will focus on the justification behind the format and content of the decision aid before detailing the separate stages included in the initial draft.

3.4.1 Format

The format of the decision aid was based on the Ottawa Personal Decision Guide (O'Connor et al., 2012) and was designed to be used by patients with their parents/guardians at home in preparation for their pre-sedation or prevention consultation. Patients were also encouraged to bring the decision aid to the consultation to encourage discussion between patients, parents/guardians and the dentist. It has become increasingly popular for such resources to be available through the internet and the potential benefit of such online resources was a theme which emerged from the qualitative interviews with patients and parents/guardians. However, concerns over whether all patients would have access to online resources led to the decision to develop the initial decision aid as an A4 paper booklet. This would thus ensure all patients had access to the decision aid and also increasing the chances of meeting targets in relation to the number of participants recruited.

3.4.2 Content

The content of the decision aid was based upon findings from the qualitative data from children and parents/guardians in the initial stage of the study and in accordance with the quality criteria set by the International Patient Decision Aids Standards (IPDAS, 2005b). The original IPDAS checklist established 64 criteria across 12 separate dimensions with each item on the checklist being defined as present or not. A shorter version of the checklist was subsequently developed, including only the 30 items that were rated highest in the original voting process used to originally establish the quality criteria. This checklist is used to determine the inclusion of decision aids in the Decision Aid Library Inventory (DALI). More recently, the checklist has been adapted to quantitatively assess the quality of decision aids. This recent version is called the International Patient Decision Aids Standards Instrument (IPDASi) and includes a total of 47 items divided into 10 separate dimensions, with each item being rated on a 4-point scale from 1 (strongly disagree) to 4 (strongly agree) (Elwyn et al., 2009). The IPDASi has demonstrated good internal reliability, however it should be noted that the scoring system of the instrument is yet to be finalised. For these reasons and to ensure that the decision aid would qualify for inclusion in the DALI system, the content of the current decision aid was primarily based upon items included in the 30-item checklist (see Table 4).

Table 4: *IPDAS 30-item checklist*

Content
1. The decision aid describes the condition (health or other) related to the decision.
2. The decision aid describes the decision that needs to be considered (the index decision).
3. The decision aid lists the options (health care or other).
4. The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken.
5. The decision aid has information about the procedures involved (e.g. what is done before, during, and after the health care option).
6. The decision aid has information about the positive features of the options (e.g. benefits, advantages).
7. The decision aid has information about negative features of the options (e.g. harms, side effects, disadvantages).
8. The information about outcomes of options (positive and negative) includes the chances they may happen.
9. The decision aid has information about what the test is designed to measure.
10. The decision aid describes possible next steps based on the test results.
11. The decision aid has information about the chances of disease being found with and without screening.
12. The decision aid has information about detection and treatment of disease that would never have caused problems if screening had not been done.
13. The decision aid presents probabilities using event rates in a defined group of people for a specified time.
14. The decision aid compares probabilities (e.g. chance of a disease, benefit, harm, or side effect) of options using the same denominator.
15. The decision aid compares probabilities of options over the same period of time.
16. The decision aid uses the same scales in diagrams comparing options.
17. The decision aid asks people to think about which positive and negative features of the options matter most to them.

Table 4: *IPDAS 30-item checklist (continued)*

18.	The decision aid makes it possible to compare the positive and negative features of the available options.
19.	The decision aid shows the negative and positive features of the options with equal detail.
Development Process	
20.	Users (people who previously faced the decision) were asked what they need to prepare them to discuss a specific decision.
21.	The decision aid was reviewed by people who previously faced the decision who were not involved in its development and field testing.
22.	People who were facing the decision field tested the decision aid.
23.	Field testing showed that the decision aid was acceptable to users (the general public & practitioners).
24.	Field testing showed that people who were undecided felt that the information was presented in a balanced way.
25.	The decision aid provides references to scientific evidence used.
26.	The decision aid reports the date when it was last updated.
27.	The decision aid reports whether authors of the decision aid or their affiliations stand to gain or lose by choices people make after using the decision aid.
28.	The decision aid (or available technical document) reports readability levels.
Effectiveness	
29.	There is evidence that the decision aid (or one based on the same template) helps people know about the available options and their features.
30.	There is evidence that the decision aid (or one based on the same template) improves the match between the features that matter most to the informed person and the option that is chosen.

3.4.3 Features of the decision aid

The following section will describe the separate stages included in developing the initial version of the decision aid and how each of these stages were influenced by the findings obtained from the qualitative accounts of dental treatment under sedation or GA, the IPDAS criteria and previous research on decision aid development and shared decision-making.

3.4.3.1 Introduction to the health care decision

The opening page of the decision aid briefly states why young people may need some form of sedation or GA and introduces the three options of inhalation sedation, IV sedation or GA. This complies with the opening three criteria on the IPDAS checklist relating to the essential content required on a decision aid. These criteria state that the decision aid must describe the healthcare condition relating to the decision, the decision which is required and the related options available to the patient. The original draft of this opening page can be seen in Appendix G.

3.4.3.2 Step one: what do the options involve?

Following on from the introduction, the first step of the decision aid enables the patient and their parent/guardian to compare the positive and negative features of the options available, the information was displayed side-by-side in a question and answer table (see Table 5). This section of the decision aid relates to IPDAS criteria 5-8, 13, 14, 18 and 19.

Table 5: *Original draft of the decision aid: Step one*

	Inhalation sedation ('laughing gas' or 'gas and air')	Intravenous sedation ('IV sedation')	General anaesthetic ('GA' or 'going to sleep')
What does it feel like?	The gas will make you feel relaxed and may make you feel a bit sleepy.	The medicine will make you feel relaxed and may make you sleepy. This medicine usually makes you feel sleepier than 'gas and air' and you won't be able to remember much about what happened afterwards.	The medicine, given by a doctor, will make you fall asleep so you won't feel anything.
How will it be given?	You will breathe in the gas through a little mask that fits over your nose. The mask will not cover your mouth. Below is a picture of the mask. It will not have been used by anyone else before. 	You will be given the medicine through a small plastic tube which is usually put in your arm or the back of your hand. A needle is used to put it in, but it is taken out and only the tube stays in. Before you have the tube you will have cream put on your hand or arm, to make sure it's not sore. The medicine can feel a bit stingy as it travels up your arm but this only lasts a short time.	You will be given the medicine, by a doctor, through a small plastic tube which is usually put in your arm or the back of your hand. A needle is used to put it in, but it is taken out and only the tube stays in. Before you have the tube you will have cream put on your hand or arm, to make sure it's not sore. The medicine can feel a bit stingy as it travels up your arm but this only lasts a short time.

Table 5: *Original draft of the decision aid: Step one (continued)*

	Inhalation sedation ('laughing gas' or 'gas and air')	Intravenous sedation ('IV sedation')	General anaesthetic ('GA' or 'going to sleep')
Will I still be awake?	Yes you will still be fully awake and know what's happening.	Yes but it may feel as though you have been asleep as you won't be able to remember much about what happened.	No, the medicine will make you go to sleep. You will remain asleep until the treatment has finished.
Will I still need a needle in the gum?	Yes, this will happen after you have had the 'gas and air' so you won't worry so much about the injection. This is to numb your tooth or mouth so you don't feel any pain.	Yes, this will happen after you have had needle in the back of your hand so you won't worry so much about the injection.. This is to numb your tooth or mouth so you don't feel any pain.	Yes, you will still have a little injection in your gum but you won't feel it as you will already be asleep.
Are there any side effects?	Usually there are no side effects at all from the treatment. Occasionally, some people might feel a bit dizzy afterwards.	1 in 10 people might have a headache, feel sick or dizzy, or be sick.	When you wake up will feel a bit wobbly and dizzy and about 1 in 3 people who have general anaesthetic feel sick afterwards. Other side-effects also include having a sore throat, feeling cold and shivering. Very occasionally there may be a serious complication with the anaesthetic but this is unlikely if you are fit and well.

Table 5: *Original draft of the decision aid: Step one (continued)*

	Inhalation sedation ('laughing gas' or 'gas and air')	Intravenous sedation ('IV sedation')	General anaesthetic ('GA' or 'going to sleep')
Where will I have my treatment?	You will usually have gas and air at the dental clinic.	You will usually have gas and air at the dental clinic.	You will usually have a GA at hospital.
Can I eat or drink anything before?	You should eat and drink normally, but don't have a big meal just before your appointment.	Depending on where you are having your treatment you may be asked to not eat or drink anything before your appointment. This is something which your dentist will tell you before.	You are usually not allowed to eat or drink anything for at least 6 hours before you have the medicine to put you to sleep. This is something which your dentist will tell you before.

Table 5: *Original draft of the decision aid: Step one (continued)*

	Inhalation sedation ('laughing gas' or 'gas and air')	Intravenous sedation ('IV sedation')	General anaesthetic ('GA' or 'going to sleep')
When can I go home?	You will usually be able to go home straight after your treatment.	You may need to stay at the dentist or hospital until you are ready to leave. This usually takes about 30 - 60 mins but can be longer.	If you are only asleep for a short time you can usually go home after one hour. If treatment takes longer you may need to stay longer but most young people will be able to go home within two hours.
When can I go back to school?	You will usually be able to go straight to back to school if you feel ok.	You will need to take the rest of the day off school after having the treatment. You may need to take more days off school depending on how you feel. This is something you may also have to talk about with your school.	You will need to take the rest of the day off school after having the treatment. You may need to take more days off school depending on how you feel. This is something you may also have to talk about with your school.

The presentation of information in this format was influenced by research showing that decision aids which present information side-by-side are perceived as more balanced than those which present information in alternate formats (Abhyankar et al., 2013). The information given in this section of the decision aid was directly informed by the findings drawn from the qualitative interviews with patients and parents/guardians which are detailed in Chapter Four. The following table demonstrates the relationship between themes discussed in this chapter and the information included in the first draft of the decision aid (see Table 6).

Table 6: *Original information included in step one of the decision aid and associated themes*

Question included in step one	**Influential theme(s) (see Table 3)**
What does it feel like?	Experience of sedation
How will it be given?	Method of administration
Will I still be awake?	Control & communication, long-term impact
Will I still need a needle in my gum?	Method of administration
Are there any side effects?	Perceived side effects and risks
Where will I have my treatment?	No associated themes
Can I eat or drink anything before?	Time
When can I go home?	Time, perceived side effects and risks
When can I go back to school?	Time

As demonstrated in the previous chapter, one of the main themes identified as important in the decision-making process from the qualitative accounts was the method of administration. For these reasons one of the questions listed in the table asked 'How will it be given?' Due to the distinction made by patients between the use of a needle in the hand to administer the sedative or GA and the use of the needle to administer the local anaesthetic in the gum a further column was also added which asked 'Will I still need a needle in the gum?'.

The importance placed upon time, as revealed in the interviews, was also incorporated into the decision aid in this section, with separate rows on this occasion providing more information regarding how long the patient would have to remain in the clinic/hospital following the procedure. Comparative information was also provided about the amount of time the child would need to take off school. Concerns over the amount of time patients were expected to fast before treatment was also considered when developing this section with the question 'Can I eat or drink anything before?' being listed in the table. The original information relating to fasting prior to IV sedation was later replaced (see Appendix D). This was to ensure that the times did not conflict with the fasting times presented in the patient information leaflets provided by the Liverpool Dental Hospital, where the decision aid was to be initially evaluated.

In relation to the prominent theme of control and communication from the qualitative interviews, an item was also added that explicitly stated whether the patient would be awake during treatment and consequently aware of undergoing the procedure. The amnesic effects of IV sedation were also highlighted in this section in relation to parents' concerns over the long-term impact of undergoing dental treatment with sedation and how remembering the procedure may influence their child's dental fear.

Further questions included 'What does it feel like?' and 'Where will I have my treatment?' In relation to the former question, accounts of dental sedation were consulted when attempting to explain the experience of having sedation or GA with phrases such as 'relaxed' and 'sleepy' being used in accordance with the terminology used by patients themselves. Although the latter question was not explicitly stated as a concern in the previous interviews it was felt that it could be important to inform patients that undergoing treatment with GA may result in treatment being provided at a different hospital to the dental hospital.

A further question 'Are there any side effects?' was also included in the decision aid, in relation to the negative impacts associated with some the treatment options. Findings from the qualitative interviews suggested that the main side effects concerning patients and parents/guardians included nausea, vomiting and drowsiness. The risk of something more serious occurring, including death, was also viewed as a

major concern amongst parents/guardians of patients undergoing treatment with GA. When providing information in the decision aid about these factors, IPDAS criteria 8 and 13-15 which relate to chances and probabilities of side effects were particularly applicable. However, following a review of the literature, it was felt that insufficient evidence existed to be able to present accurate probabilities in relation to the side effects associated with inhalation sedation. For these reasons, the initial draft of the decision aid stated that 'There are usually no side effects at all' and that 'Occasionally, some people might feel a bit dizzy afterwards' in regards to inhalation sedation. In relation to IV sedation, more conclusive probabilities were derived from patient information recognised by the Royal College of Anaesthetists which states that '1 in 10 people might have a headache, feel sick or dizzy, or be sick.' However, it should be noted that this sentence was later removed from the decision aid as it was impossible to determine what evidence these probabilities were based on. For these reasons, identical information as included in relation to inhalation sedation was provided.

When discussing the side effects of treatment under GA, more conclusive findings were also available in relation to post-operative nausea allowing the decision aid to state that '1 in 3 people who have general anesthetic feel sick afterwards' (Cruthirds et al., 2013). Approximations could also be made regarding mortality rates following GA, however due to contrasting evidence (Lagasse, 2002; Jenkins and Baker, 2003, Van Der Griend et al., 2011) and the reluctance of parents/guardians to directly discuss death in the previous interviews, the draft decision aid simply stated that 'very occasionally there may be a serious complication with the anaesthetic but this is unlikely if you are fit and well'. This matter was to be discussed further in the second stage of qualitative interviews with clinicians and patients and their parents/guardians. A lack of consistent data regarding side effects also raises broader questions regarding the need for future research into the potential adverse effects of undergoing dental treatment with sedation or GA.

Following the side-by-side display of information in the table, a list of further issues which patients may wish to discuss with their dentist was also included. These items were not originally included in Table 5, as the answers were dependent on a variety of external factors which were not specifically related to treatment choice. The

majority of these items were influenced by the concept of time, which emerged as one of the major themes identified as important in the decision-making process from the previous qualitative accounts. These items included:

- How long you have to wait for your appointment
- The number of appointments you need to have
- How long you have to wait between appointments
- How long you have to wait on the day of your appointment
- The treatment you have: for example, whether you have teeth taken out or not.

3.4.3.3 Step two: which option suits you best?

The second stage of the decision aid involved an exercise which relates to IPDAS criterion 17. This states that the decision aid should ask people to consider the features of each option which matter most to them. To meet this criterion an explicit values clarification exercise was implemented, which asked the patient to note down how important the various negative and positive features of each option were to them on a simple Likert scale ranging from 'not important' to 'very important'. The table then included a suggestion for which may be their 'best' option depending upon how they rated each factor (See Appendix G). The use of such methods is supported by research showing that explicit values clarification techniques actually result in lower ambivalence and decisional conflict when compared to the use of implicit values clarification techniques which do not require the patient to overtly engage in the decision-making process (Abhyankar et al., 2011). The influence that the themes emerging from the previous accounts of dental decision-making had on the information included in this section of the decision aid are once again displayed below (see Table 7).

Table 7: *Original information included in step two of the decision aid and associated themes*

Common reasons included in step two	**Influential theme(s) (see Table 3)**
To be awake when you have treatment?	Control & communication, Long-term impact
To remember what happened?	Long-term impact
Not to have a needle in your hand?	Method of administration
Not to have a needle in your gum?	Method of administration
Not to have a mask on my nose?	Method of administration
Not to have to take time off school?	Time
To be able to eat or drink before your treatment?	Pre-operative fasting
That you're not at the hospital for a long time?	Time
To not have any serious side effects?	Perceived side effects and risks
To not feel sick after treatment?	Perceived side effects and risks
To not have to go somewhere different for treatment?	No associated themes

3.4.3.4 Step three: what else do you need to make your decision?

Following the values clarification exercise, the next stage of the decision aid aims to help the patient and parents/guardians identify their decision-making needs and to determine whether these needs have been met. The first part of this stage included a short multiple-choice quiz, which tested the patients' and parents/guardians' knowledge of the available options for treatment (see Appendix G). Such quizzes are a regular feature in the majority of decision aids included in the DALI system and are used to help the patients and parents/guardians determine if they feel they have sufficient knowledge to allow them to make an informed decision, while also reiterating some of the key facts for each option. The content of these questions was

once again influenced from the themes identified as important in the decision-making process in the previous qualitative interviews (see Table 8).

Table 8: *Original information included in step four of the decision aid and associated themes*

Questions included in step three	**Influential theme(s) (see Table 3)**
1. I will be awake during treatment if I have...	Control & communication, Long-term impact
2. I will need a needle in the hand or arm if I have...	Method of administration
3. 1 in 3 people feel sick after having	Perceived side effects and risks
4. I might be able to go back to school straight away if I have...	Time

The second part of this stage (see Appendix G) then explicitly asks the patient if:

- they feel they have sufficient knowledge and support to make the decision?
- they feel they are clear about the values that matter most to them?
- there is any uncertainty that remains regarding their current choice?

If patients answer ‘no’ to either of these statements, the decision aid then provides additional steps they may want to take to address such issues, such as listing down any questions they still have, suggesting where they may find the answers to these questions and where further support could be gained. This stage of the decision aid once again relates back to one of the original objectives of the decision aid, which is to aid people in the communication of their values with health care practitioners and valued others, which fits closely with the previously discussed concept of shared decision-making.

3.4.3.5 Step four: what are the next steps?

The final stage of the decision aid simply asks the patients to confirm where they currently are in the decision-making process by asking them to tick the appropriate boxes in response to the statements listed below:

- We have decided to have treatment with inhalation sedation ('gas and air')
- We have decided to have treatment with intravenous sedation ('IV sedation')
- We have decided to have treatment with general anaesthetic ('going to sleep')
- I need to discuss the options with:
- I need to read more about my options
- Other, please specify:

This stage once again encourages the patient to explicitly state the potential reasons behind any uncertainty surrounding the decision and the how this can be reduced. This step is purported to encourage the sharing of information and satisfies another key objective of the decision aid which is to ensure the patent is more involved in the decision-making process.

3.4.4 Summary

To summarise, the original draft of the decision aid included a total of six A4 pages (see Appendix G) which included an introduction to the healthcare decision and the options available and four distinct stages which aimed to encourage participation in the decision-making process.

3.5 Discussion

3.5.1 Introduction

The following section will discuss the findings from the initial stage of the decision aid development process. In this section the main themes derived from the qualitative interviews and their influence on the content of the draft decision aid will be discussed in relation to the wider literature on decision-making and paediatric dental sedation and GA.

3.5.2 Method of administration

The varying methods of administration across treatment options was one of the key themes emerging from the data collected in the first stage of the study. In this instance the data could be broadly categorised into two separate sub-themes. The first sub-theme related to issues surrounding the use of a needle and cannula when administering IV sedation or GA. In this instance, a general fear of needles was cited as a common reason for opting against IV sedation or GA. However, interestingly, patients often made a distinction between the delivery of LA in the gum and the delivery of sedatives or GA in the hand or arm. For this reason, patients who feared dental injections were still willing to accept IV sedation or GA with treatment.

When viewing needle phobia in dentistry, the literature has centered mainly on the fear of dental injections, with the previous findings suggesting that this fear is cited as one of the most common reasons for the experience of dental anxiety (Bedi et al., 1992). When considering these findings, further evidence to support the distinction made between dental injections and the administration of IV sedation and GA in the current study can be found in a cross-sectional study including 2,865 patients, aged 4 to 11 years old, which reported that needle phobia and dental anxiety are unrelated and should be treated as separate concepts (Majstorovic and Veerkamp, 2004).

This distinction reported in the current research appeared to relate to the size and site of needle, with patients suggesting that the use of a cannula appeared less threatening. Previous research has also reported that appearance of instruments used plays an important role, particularly when young people are anxious (Kuscu and Akyuz, 2006). When considering the negative aspects associated with the use of cannulas to

administer GA, one study also suggested that patients who received gas induction are often distressed to discover a cannula on their hand or arm when they awake (Rodd et al., 2014). This issue was not raised in the current data, most likely because gas induction is not frequently used for older GA patients at both sites of recruitment. However, these findings and other reports of children feeling unprepared in this study do lend further justification for the need for decisional support tools for children undergoing dental treatment with sedation or GA and also for the inclusion of specific information regarding the use of cannulas in the current decision aid.

The second sub-theme identified centered on the use of the mask when administering inhalation sedation. The appearance, smell and taste of the mask all contributed to the patients' treatment preference. Similar issues have not been explored thoroughly in the previous literature, however qualitative accounts of undergoing dental treatment with GA suggests that smell does play a role when a gas induction is implemented (Rodd et al., 2014). Researchers have also found that taste is not an issue for patients receiving inhalation sedation when compared to the unfavourable taste associated with the transmucosal administration of midazolam as an alternate sedation method (Wilson et al., 2007).

3.5.3 Time

The data suggested that time taken to recover following treatment also played a role in the decision-making process and should therefore be included in the decision aid. The decision aid addressed this issue by including information relating to when patients can leave the hospital. In this instance it was stated that patients can expect to leave immediately following inhalation sedation, from 30-60 mins following IV sedation and within 2 hours following GA. These approximations were dictated by the procedures already in place at the dental hospital. However, when considering the previous literature, variations in recovery time were evident. For example, recovery time following intravenous propofol has been shown to range from 10 to 150 minutes (Takarada et al., 2002). Furthermore, it should be noted that, as suggested by current guidelines (Royal College of Anaesthetists, 2015), the responsibility to discharge patients does usually rest with the healthcare professional, with individual differences in recovery rates being taken into account.

It was nonetheless felt that the inclusion of data regarding recovery times was relevant, particularly given data from the qualitative interviews which suggested that the main concern over recovery time were related to the more pronounced long term effects associated with GA. These differences in recovery times have been more clearly established in the existing literature (Lyratzopoulos and Blain, 2003), with the enduring cognitive effects of undergoing a dental GA being well documented (Millar et al., 2014). These effects often last 24 hours following treatment which support the information given in the decision aid that an immediate return to school is not possible.

A further sub-theme emerging from the data, which has also been reported in the previous literature, was the impact of pre-operative fasting. For example, qualitative accounts from children who had undergone dental treatment with GA suggested that the hunger, experienced as a result of fasting, had a strong negative impact on patients (Rodd et al., 2014). Furthermore, research has also shown that these fasting times are often excessive and cause patients a considerable amount of distress. Research focusing on patient's attitudes towards fasting prior to IV sedation, also suggests that pre-operative fasting may also lead to heightened anxiety for some patients (McKenna et al., 2010). As there is currently some debate over the need for pre-operative fasting, particularly in relation to conscious sedation, it is suggested that further research is required in this area, particularly when considering the potential impact that relaxing these guidelines could have on patient wellbeing.

3.5.4 Side effects and perceived risks

When discussing the inclusion of perceived side effects and risks of the treatment options in the decision aid, the greatest challenge related to presenting data on mortality rates following GA. Here, it was apparent that parents/guardians were often unwilling to discuss this issue in front of their child and clinicians were also unsure about the inclusion of specific probabilities being presented in the decision aid. For these reasons the decision aid stated that 'very occasionally there may be a serious complication' while also mentioning that this is 'unlikely if you are fit and well'.

3.5.4.1 Consent

This failure to include specific probabilities raises broader questions in relation to the concept of informed consent, which states that patients should be given all the information available in regards to what the treatment entails, including all relevant benefits and risks. However, it should be recognised that decision aids are seen as supplementary to the decision-making process and should not be designed as a replacement to the routine clinical counselling and consent processes already in place. Therefore, it could be argued that introducing the topic encourages further discussion of the issue and therefore helps the clinician fulfil their obligation of ensuring patients are fully informed. It could be suggested that further steps should be taken throughout healthcare to encourage patients to be more fully informed, particularly when considering research suggesting that informed consent is not always obtained. For example, a recent study showed that 30% of paediatric pre-anaesthesia consultations failed to discuss the associated risks (Lagana et al., 2012). Furthermore it was noted that the majority of these consultations which failed to discuss the associated risks were actually conducted by senior clinicians, with trainees more likely to discuss specific risks with patients and their family members.

3.5.4.2 Framing effects

A further challenge posed when communicating risks in the decision aid, related to the framing or presentation of the information. For example, two separate reviews have shown that the presentation of risk information numerically can increase comprehension when compared to the use of words (Trevena et al., 2006; Stacey et al., 2014). However, the lack of conclusive evidence, particularly in relation to morbidity associated with inhalation and IV sedation, meant that the use of non-numerical data was often the only feasible option available. Taking this into account, the decision aid attempted to incorporate both numerical and non-numerical data when comparing the relative risks associated with each option, with numerical data more prominent when discussing risks relating to GA, due to the fact that more conclusive evidence was available.

When numerical data relating to risks were presented in the decision aid, further recommendations from the literature also suggest that data should be presented using absolute as opposed to relative risks (Trevena et al., 2013). Relative risk refers to the

comparison of risk between separate groups, and whether membership in one group increases probability of being affected by the issue under discussion. For example, whether smokers are more likely to develop cancer than non-smokers. In contrast, absolute risk refers to the total or overall risk of adverse events in relation to the population at risk. The reason for these recommendations relate to research that has suggested that when making decisions, relative risks are often perceived to be greater and more persuasive, suggesting that presenting risks in this manner may lead patients to misinterpret the evidence available (Akl et al., 2012). For these reasons the decision aid stated that 1 in 3 people feel sick and 1 in 4 people shiver, following GA.

Research has also been undertaken on the relative benefits of presenting probabilities using frequencies or percentages. In this instance, contrasting findings have been reported. A review of the alternative formats used for the presentation of risks in healthcare suggested that individuals understood the use of frequencies better than percentages (Akl et al., 2012). This included studies involving both consumers and healthcare professionals. In contrast, a more recent review of the literature published in association with the IPDAS collaboration proposed that the use of single figures when presenting risk information, for example percentages, should be preferred over the use of multiple figures used when presenting frequencies (e.g. 5 in 100) (Trevena et al., 2013). However, it appears these proposals are based solely on findings from one study which employed a national survey looking at the use of hypothetical drug treatments (Woloshin and Schwartz, 2011). In contrast, the review published by Akl and colleagues (2012) provided evidence based on 35 different studies focusing on the presentation of risk information. Due to these findings it was considered that frequencies would be used to present information regarding the risks associated with GA.

When considering the use of frequencies it is also suggested that the same denominator should be used when forming comparisons between the different treatment options (Trevena et al., 2013), as proposed on Item 14 on the IPDAS 30-item checklist (see Table 4). This proposal is based on findings from two separate studies looking at the hypothetical treatment of headaches and associated side effects (Peters et al., 2011) and hypothetical scenarios associated with cancer treatment (Cuite et al., 2008). However, as previously mentioned, the lack of conclusive data

relating to morbidity and mortality associated with inhalation sedation or IV sedation made it impossible to include numerical data for each treatment option. This once again raises the question over the appropriate course of action to take in such circumstances and whether the omission of all numerical data is preferred to presenting information in varying formats. There have been some suggestions, that the inclusion of inconclusive data could still be warranted if patients are informed of the level of uncertainty relating to the provided estimates (Trevena et al., 2013). However, evidence on the methods of portraying such uncertainty and its impact on the decision-making process and patient outcomes are relatively unknown (Arora and McHorney, 2011; Han et al., 2011; Han, 2013).

Research has also suggested that the additional inclusion of graphical data may also be beneficial when presenting risk information, as it can lead to better understanding (Tait et al., 2010). In particular, the use of pictographs are specifically recommended as they may prevent potential bias and are more comprehensible than alternate graphical formats (Fagerlin et al., 2005; Garcia-Retamero and Galesic, 2010; Garcia-Retamero et al., 2010; Garcia-Retamero and Cokely, 2011). However, contrasting research has also suggested that the inclusion of graphical data can actually lead to overestimations of low probabilities and underestimations of high probabilities (Gurmankin et al., 2005). Furthermore, there appear to be considerable variations in individuals' ability to understand graphical data, with suggestions that the implementation of the graphical literacy scale on the target population should be considered prior to developing healthcare information (Galesic and Garcia-Retamero, 2011). Although this recommendation was considered when developing the decision aid, it was felt that as probabilistic information was only available for the risks associated with treatment under GA, the inclusion of graphs may lead to an imbalance of the information provided across the three options. Furthermore, concerns over the potential misinterpretation of graphical data as demonstrated by Gurmankin and colleagues (2005), was also taken into account when choosing to exclude graphical data.

It is also proposed that the order of information should be considered carefully during the development of decisional support tools, due to potential 'order effects' (Fagerlin et al., 2011b). This refers to the fact that patients' perceptions and knowledge may be

impacted upon by the order in which the information is presented. For example, research has demonstrated that women at a high risk of cancer were more likely to be concerned of the risks associated with use of the drug Tamoxifen, if a decision aid presented the benefits followed by the risks (Ubel et al., 2010). Alternatively, the participants viewed the drug more favourably if the benefits were presented last. For these reasons, it has been suggested that it may be more beneficial to include information regarding risks towards the end of decisional support tools, in order to highlight the potential importance of these associated risks. However, this suggestion is only valid if there is evidence available to suggest that the risks associated with treatment options are in fact most important to patients. Furthermore, patients' and parents/guardians' interpretation of whether certain factors are seen as positive or negative features may vary considerably. For example, although some patients may view being conscious during treatment as a positive feature of sedation, very anxious patients may in fact deem this as an undesirable factor. As there was no conclusive evidence available regarding which factors patients and parents/guardians valued as more important, such order effects could not be controlled for in the current decision aid. More attention was therefore focused on previously discussed issues such as the balance and content of the decision aid. It is clear, however, that further research is required in this field to determine the importance of such effects on the decision-making process, especially when considering that the order effects demonstrated in previous decision aid research were relatively small.

A further issue when discussing the inclusion of risk information relates to the use of loss- or gain-framed messages. Gain-framed messages place emphasis on the benefits associated with the treatment option, whereas loss-framed messages emphasise the potential costs or risks. In the current study, the decision aid employed loss-framed messaging to convey probabilities on the risk of sickness and experience of shivering following treatment with GA. The inclusion of loss-framed messages was partially dictated by the information provided by the dental hospital at Liverpool, to ensure that participants did not receive what could be perceived as conflicting information. Furthermore this allowed the study to control for any potential framing effects on patient outcomes.

However, when considering the wider evidence base, findings regarding the impact of framing on health behaviours remains inconclusive, with perceptions that framing effects may often be context dependent (Akl et al. 2011). For example, a systematic review of the literature, focusing mainly on dental hygiene, suggested that gain-framed messages are significantly more persuasive than loss-framed messages (O'Keefe and Jensen, 2007), with the opposite conclusions reached in a review of health information relating to cancer screening (O'Keefe and Jensen, 2009). Furthermore, a more recent review has suggested that there is no significant difference between either of these approaches on health behaviour with an overall quality of evidence being described as low to moderate (Akl et al., 2011). These findings suggest that further research is required to determine the impact of framing on health messages, and in particular how the framing of messages in decisional support tools may impact on the decision-making process.

3.5.5 Treatment type

Any variation in treatment procedures performed under the three available options related mainly to number of proposed extractions, with patients more likely to have teeth extracted, rather than restored, if undergoing treatment under a GA. This patient perception may have in fact had a clinical basis. Treatment planning for a dental GA attempts to avoid the need for a repeat GA, thus any teeth of poor prognosis are more likely to be extracted than restored. Furthermore, waiting lists for restorative care under GA are frequently longer than extraction-only lists and children with underlying medical needs may take priority where capacity is exceeded. Patients may therefore be faced with the option of multiple extractions under GA or an attempt to restore or root treat some of these teeth with or without sedation. Not surprisingly, the prospect of extractions may present aesthetic concerns to patients and parents/guardians. This focus on dental aesthetics in young people and children has been demonstrated frequently throughout the literature, with findings suggesting that dental conditions can impact upon perceptions of intelligence, social abilities, popularity, athletic performance and leadership ability in relation to both children and adults (Shaw, 1981; Shaw et al., 1985; Kerosuo et al., 1995; Eli et al., 2001; Hunt et al., 2001; Newton, et al., 2003; Henson et al., 2011). The challenge of including information regarding treatment type once again related to how treatment plans vary across individual patients. This meant that specific information could not be included

in the side-by-side display table in step one and as an alternative, was listed as a bullet point below the table as a further point to consider.

3.5.6 Control and communication

Patients often desired a certain level of control over their dental treatment and frequently related this control to being conscious during treatment. They felt this would enable them to have an understanding of the treatment they were receiving and communicate any issues to the dentist. This can be seen as an extension to the aforementioned findings which imply children prefer an active role in the decision-making process.

The desire of parents/guardians to be present during treatment has been demonstrated in the previous literature, with a recent cross-sectional study suggesting that 78% of parents from the USA preferred to be present when their child was scheduled to undergo dental treatment (Shroff et al., 2015). This study also reported that the main reason cited for wanting to be present during treatment was the belief that the child would be more comfortable if their parent was also in attendance (62%). These findings were consistent with previous research which also stated that 78% of parents wished to be present when their child was receiving dental care (Arathi and Ashwini, 1999), primarily to offer support to their child. Other frequent reasons given for parental presence have included a general concern for their child's well-being (45%) and a desire to gain more knowledge of the dental procedure itself and the treatment their child was receiving (36%) (Shroff et al., 2015). This latter finding, once again highlights the consistent theme portrayed throughout this thesis, which is the desire of parents/guardians to be more informed. Parents/guardians also stated that poor relationships with the dentist (25%) played a role in their desire to be present during their child's treatment. This lends further support for the more frequent use of decisional support tools in paediatric dentistry, in terms of to the potential benefit such tools could have in encouraging the communication of values between patients, family members and healthcare practitioners. Furthermore, research has also suggested that when a parent's desire to be present during their child's dental treatment is fulfilled, greater satisfaction with the appointment and a more positive attitude towards the dentists are reported (Kim et al., 2012).

Although it is clear that the majority of parents do wish to be present during their child's treatment, findings reporting the impact this may have on the child remain inconclusive, with various studies and reviews suggesting that parental presence has no significant impact on children's behavior or anxiety (Piira et al., 2005; Chundamala et al., 2009;). Nonetheless, it can still be argued that parental presence could be a useful tool in aiding communication in the decision-making process, something which has been advocated in guidelines provide by the American Academy of Pediatric Dentistry (AAPD, 2015). Further research on how parental presence could affect behaviour of patients undergoing dental treatment with sedation or GA induction may be warranted. It should, however, be clarified that parents are not permitted in a GA operating theatre whilst their child is undergoing a procedure, but may occupy the child in the anaesthetic room during the GA induction.

3.5.7 Experience of sedation

A further challenge faced when developing the decision aid was to communicate the actual experience of undergoing treatment with sedation and GA with patients and parents/guardians. In this instance the decision aid attempted to use similar terminology as reported in the qualitative data. Previous qualitative accounts of dental treatment under GA were also consulted, with terms such 'dizzy', 'wobbly' and 'weird' reportedly used by young patients when describing their experience (Rodd et al., 2014). The inclusion of relatively subjective information is often addressed in previous decisional support tools through the use of personal stories from former patients. However, although commonly implemented in decision aids a recent review of the literature has concluded that the impact of personal stories remains inconclusive (Bekker et al. 2013). In this review, 11 journal articles reporting the effect of the inclusion of personal stories in decision aids were identified. These studies related to a range of healthcare decisions including cancer, bypass surgery, mastectomy, dialysis and end-of-life care for cancer and dementia patients. In this review the authors analysed the findings in relation to the concepts of system 1 and system 2 processing (Evans and Curtis-Holmes, 2005). System 1 processing relates to quick, emotional-based responses to the decision-making process, whereas system 2 processing describes more deliberative, informed decision-making associated with shared decision-making and the use of decision aids. Findings from the included studies suggested that personal stories can have an impact upon both of these

proposed systems. For example, evidence of increased system 1 processing was suggested in one study that demonstrated that when providing information relating to dialysis modality, patients were more likely to choose an option if it was presented by a former patient in comparison to a clinician (Winterbottom et al., 2011). In contrast, increases in knowledge and reductions in decisional conflict associated with the inclusion of personal stories in a decision aid aimed at cancer patients suggests evidence of increased system 2 processing (Jibaja-Weiss et al. 2010). These contrasting findings heavily influenced the decision to exclude personal stories from the current decision aid, with it being apparent that further research is required to determine the potential benefit of including such information in decisional support tools.

3.5.8 Long term impact

Previous research has suggested that past negative experiences of undergoing dental treatment can heighten levels of dental anxiety (Townend et al., 2000). Taking this into account it could be hypothesised that if previous positive experiences of dental treatment with sedation or GA have been encountered, these may have an impact on the patient's ability to undergo dental treatment in the future. As previously mentioned, there is existing support that inhalation sedation can have a long-term influence on reduced patient anxiety (Veerkamp et al., 1995). However, further longitudinal research looking at the direct impact of treatment with sedation or GA on patient outcomes and their future treatment choices is still required, particularly as there are findings to suggest that although undergoing dental treatment with GA does increase patients' and parents' quality of life, greater dental fear has also been reported following treatment (Cantekin et al., 2014). This raises questions over the potential dual role of dental treatment with sedation or GA and whether such interventions should be solely considered as a method of completing treatment or whether long-term effects are and should also be considered by clinicians.

3.5.9 Information received

Perceptions from the present data that some patients received insufficient information have been partially supported in the previous literature from the aforementioned findings that 30% of consultations prior to paediatric anaesthesia failed to communicate the associated risks to patients and family members (Lagana et al.,

2012). Both these findings lend further support for the rationale behind the development of decision aid for patients undergoing dental treatment with sedation or GA. The finding that some patients desire more information and greater involvement also concurs with findings from previous studies which suggest that patients do want to be part of the decision-making process (Rothenbacher et al., 1997; Guadagnoli and Ward, 1998; Stewart et al., 2000; Davison et al., 2002; Floer et al., 2004a; Janz et al., 2004; Kremer et al., 2007).

3.5.10 Format

As mentioned previously, the format of the decision aid in the current study was largely determined by feasibility issues relating to concerns over whether a web-based decision aid would be accessible to all patients. These concerns have also been addressed in a recent review of the literature conducted in association with the IPDAS collaboration (Hoffman et al., 2013), in which it was also stated that feasibility issues may prevent the delivery of certain interventions for communities that lack internet access or adequate mobile phone service. Taking this into account however, it could also be argued that young patients may be the most suitable population for targeting web based decision aids at, as figures show that 96% of households with children have an internet connection, in contrast to 41% of single households with one adult who is aged 65 or over (Office for National Statistics, 2014). However, it is still clear that not all patients would necessarily have access to the decision aid if based on the internet. Furthermore, previous research on the potential impact of web-based decision aids and the use of interactive tools when presenting risks has shown lower levels of knowledge and poor decision-making being demonstrated in relation to animated graphics (Zikmund-Fisher et al., 2011; Zikmund-Fisher et al., 2012). These findings suggest that the use of web-based decision aids should be approached with caution, as the relative impact of varying decision aid formats on patient outcomes in relation to the decision-making process requires further attention. Furthermore, the impact of the decision aid format on the cost-effectiveness of such tools also warrants further investigation.

3.5.11 Adherence to IPDAS criteria

When discussing the initial development of the decision aid in relation to the IPDAS criteria (see Table 4), it is clear that not every criterion was met. For example, a lack

of conclusive data meant it was impossible to adhere to Item 14. This item suggests that the decision aid compares probabilities across options using the same denominator. In addition, Item 15, which suggests that probabilities of options are compared over the same time period. Furthermore, there are several other criteria such as items relating to screening decisions (Items 11 and 12), which are clearly not applicable to the current decision aid. These findings highlight previously stated concerns regarding strict adherence to the IPDAS checklist, which suggest that failing to critically assess the relevance of certain criteria to different healthcare decisions may impede the decision aid in enabling better decision-making (Bekker, 2010). Furthermore, the difficulties of applying the IPDAS criteria to new patient populations have also been highlighted. As the current study is one of the first to develop a decision aid aimed directly at young patients, failure to adhere to each criterion may not necessarily impact upon the quality of the decision aid.

3.5.12 Power imbalance

When considering the current study, the potential power imbalance between the child participant and the adult researcher must be addressed (Punch, 2002). One of the main challenges of conducting research with children is trying to resolve this imbalance, to ensure children have a voice in research. Attempts to reduce any potential power imbalance in the present study included making it explicit to the child that it was their choice to take part in the study and allowing them to provide input to when the interview would take place. Furthermore, assurances of confidentiality were reiterated both before and after each interview. In order to create an informal tone and build rapport, the interview also began by asking questions that the participant would already know the answer to (e.g. favourite subject at school, hobbies, daily events), a technique well established in the literature relating to the inclusion of children in research (Mauthner, 1997). Informality was also maintained throughout the interview through the use of humour. Other methods to reduce power included de-briefing the child participant following the interview and thanking them for their contribution. In addition, although the chief investigator was associated with the dental hospital, not being recognised as a member of the child's treatment team or actually being a dentist may have reduced the participant's perception of the interviewer as being an authority figure.

To further reduce the power imbalance and encourage participation in the interview process the use of participatory techniques could also have been included in the study (O'Kane, 2000). These often involve the use of visual methods, such as photographs, video diaries and drawings (Hanna and Jacobs, 1993; Hanna et al., 1995; Radley and Taylor, 2003; Guillemin, 2004; Smith et al., 2006a) or activities such as timelines and life grids (Marshman and Hall, 2008). However, there were concerns over how this would impact upon the parents/guardians' contributions to the interviews, as their views also played a key role in informing the content of the decision aid. Furthermore, many of these techniques are often aimed at younger participants and would potentially not be suitable for the older participants included in the study.

3.5.13 Parental presence

When considering power relationships relating to research with children and young people, the impact of parental presence must also be addressed. In this instance, research has suggested that the presence of the parents/guardians during the interview process may actually inhibit child responses, with younger participants more likely to provide richer data when they can voice their personal views away from their parents/guardians (Gardner and Randall, 2012). In contrast, however, others have purported that the inclusion of parents/guardians in qualitative research, may actually result in richer data being produced, with the parents/guardians' understanding of their child allowing them to act as a proxy in the interview process. Interestingly, the data from the current study suggested that the presence of the child during the interview actually appeared to inhibit parents/guardians responses, as they were often unwilling to discuss sensitive and potentially distressing subjects, such as the risk of death often associated with GA, in front of their child.

3.5.14 Setting

A home environment is often desired when conducting qualitative interviews, as it can provide a more natural setting, which is conducive to the provision of rich data (Kvale, 1996). In contrast, a clinical environment, as associated with the current study setting, may actually inhibit participation during the interviews and add further to the aforementioned power imbalance often related to research with children. In an attempt to address this issue and provide a less threatening environment, the location of the interviews at each site was situated away from the paediatric dental department,

in a room which included furniture and décor more closely associated with a home environment, including the provision of a comfortable sofa for participants. Furthermore, conducting interviews away from their actual home enabled the assurance of privacy, with concerns over whether participants' responses may be affected by the presence of other family members and whether unwanted distractions, such as the presence of a television, would disrupt the interview process. In addition, conducting interviews at the dental hospitals also facilitated greater recruitment of participants, as they were more willing to take part if the interview was scheduled on the same day as their existing appointments. It should be noted that no interviews were scheduled immediately following treatment under sedation or GA, to ensure the interview did not impact upon the patients' recovery or vice versa.

3.5.15 Language

Differences in the use of language are also an issue in research involving children, with there being the potential for misinterpretations between the adult researcher and the child participant (Punch, 2002). For example, use of technical terms within the interviews such as 'IV sedation' or 'general anaesthetic' could inhibit a child's understanding of the questions being asked. It was therefore vital to establish how the child described these terms as in their own words. Establishing what language the child used was also paramount in informing the language used in the actual decision aid, to ensure it was understandable and related to patients aged 10-16 years.

3.5.16 Sample composition

Although, purposive sampling was employed, due to time constraints, ethnic minority groups were unrepresented in the sample, with only one patient and one parent/guardian from an ethnic minority group included in this stage of the study. It was therefore impossible to fully explore how ethnicity may have impacted upon perceptions of the decision-making process in stage one of the study. The reasons for this underrepresentation are unclear, however it has been suggested that ethnic minorities may be less willing to participate in health research due to the language issues (Hussain-Gambles et al., 2004). For example, the current research was unable to implement the use of interpreters, meaning that many participants from ethnic minority groups who could not speak English were automatically excluded. Helping meet the language needs of ethnic minority groups in future research could therefore

increase participation. Furthermore, it has also been suggested that research participation is a relatively Westernised concept, meaning that an unfamiliarity with the process may exclude certain ethic minority groups in the UK (Hussain-Gambles et al., 2004).

An over-representation of female participants also diminishes the generalisability of the study findings to larger groups. This gender bias has been well documented in qualitative research, with reports showing that on average, 74% of samples involved in qualitative health research were females (Polit and Beck, 2013). These findings were derived from a review of 300 studies which included participants from all age groups. It is suggested that this lack of male representation in qualitative research may relate to the fact that females are more emotionally expressive than males (White and Johnson, 1998; Addis and Mahalik, 2003; Smith et al., 2006b). Various strategies have been proposed to address such issues, including the use of humour and self-deprecation (Adler and Adler, 2001), how this would impact upon the number of participants recruited however, remains unclear. The sample is also limited in regards to the age of the young patients included. For example, although ages ranged from 10-16 years, only two of the participants were under the age of 13. For these reasons it could be suggested that the informational and decisional needs of younger patients within the age bracket may not have been fully considered. However, as stated in section 2.4.3, the competence of the child and their ability to engage in decision-making is not necessarily age dependent, therefore it could be suggested that this failure to include a balanced sample in terms of age may not have impacted upon the applicability of the findings. Such issues relating to the stages of cognitive development and the use of paediatric decision aids are explored in greater detail in section 5.9.9.

The self-selecting nature of the sample also has implications for research findings, as the study only included patients and parents/guardians who were willing to discuss their previous treatment experiences with sedation or GA and the associated decision-making process. The study therefore failed to take into account the views of those who were less willing to discuss the subject matter, which in some instances may relate to high levels of distress experienced in prior appointments. The perceptions of

these individuals could have added additional valuable insights to inform the content of the decision aid.

3.5.17 Ethical considerations

Due to the subject area, the potential for the occurrence of upsetting issues during the interview process was relatively low. However various procedures were put in place should such issues arise during the interview. Firstly, participants were continually informed of the voluntary nature of the research, with it being stated that they could opt out of the study, without giving reason, in the initial information sheets, during further telephone correspondence and immediately prior to the interview. Secondly, if a participant did become distressed, it was planned that the interview could be terminated immediately, based on the participants wishes. Finally, appropriate contact information was provided to all participants if they held any particular concerns regarding the study or their treatment. In relation to issues of confidentiality, it was made clear to patients that all data would be anonymised and that all patient-related information would be kept in locked filing cabinets and all computerised data would be password protected on a designated PC in the School of Clinical Dentistry.

To ensure valid consent was obtained, all participants were also given at least 24 hours from receiving the information sheet to decide if they were willing to take part. Furthermore, the importance of providing information sheets tailored to the participants' age was also recognised, with particular attention paid to the inclusion of information regarding how their participation in the study impacts upon them, something which has been identified as being particularly difficult to convey (Mauthner, 1997; Kortesluoma, et al., 2003).

3.6 Summary

In summary, this chapter has detailed the methods used to address the following research objective:

> 1. To explore what factors are involved, from the young persons' and parents/guardians' viewpoint, when making the decision whether or not to undergo sedation or GA for dental treatment, and subsequently to determine the needs of those involved

This objective relates to the first stage of development process suggested by the original IPDAS framework which involves assessing the decisional needs of the patient. This stage of the study was crucial in reinforcing the need for decisional support for young patients undergoing dental treatment with sedation and GA and also in informing the content of the draft decision aid, whose development has also been detailed in this chapter. As well as providing insight into the decisional needs of patients and family members this first stage of the research has also enabled identification of various challenges associated with the development of a decision aid, which have previously been ignored in the literature. These challenges relate primarily to the paucity of conclusive evidence regarding the potential side effects associated with conscious sedation and the potential impact of including related risk information in decision aids. Furthermore, due to a lack of research on the development of decision aids aimed directly at young people, further issues relating to the presentation of potentially distressing risk factors, such as mortality rates associated with GA, have also had implications on the content of the current decision aid and wider clinical implications relating to issues of informed consent and assent. These implications will be discussed further in Chapter Six. Following assessment of the patient's decisional needs and the initial development of the decision aid, the second stage of the research, which will also incorporate clinicians' views in the further development and review of the decision aid, will be described.

Chapter Four: Further Decision Aid Development and Review

4.1 Introduction

This chapter will describe the second stage of the development process in which the initial decision aid was presented to two separate groups for further review and development. These two groups included:

- Experts in the clinical care involved including general dental practitioners who refer patients for sedation, paediatric dentists, dental sedationists and anaesthetists.
- Expert patients and their family members, who have already experienced the decision to undergo dental treatment with sedation or GA.

This chapter details the methods which contributed further to addressing the following objective:

2. To explore clinicians', patients' and parents/guardians' initial perceptions towards the decision aid (see Table 1)

This specific objective addresses the second and third stages presented in the original IPDAS development framework (see Table 1), which describe the formation of groups used to further review and develop the decision aid and the related iterative process, in which the decision aid is re-drafted, reviewed, and revised until it is ready for pilot evaluation.

4.2 Ethical approval and research governance

Ethical approval for the study was obtained from the NRES Committee for Yorkshire and The Humber – Sheffield (13/YH/0142) on 6th August 2013 (Appendix A). Local permission to undertake the study, in terms of research governance, was also obtained from the Sheffield Teaching Hospitals NHS Foundation Trust (STH17248 – 6th

August 2013) (Appendix B) and the Royal Liverpool & Broadgreen University Hospitals Trust (4626 – 29th August 2013) (Appendix C).

4.3 Expert clinical group method

4.3.1 Sample

The inclusion of expert clinicians was deemed as a necessary stage in the development process by the IPDAS collaboration (IPDAS, 2005a). Furthermore, it is proposed that shared decision-making is a two-way process between healthcare professionals and patients (Charles et al., 1997). Therefore, clinicians' opinions on the feasibility of implementing the decision aid and on what information should be included were also considered important. Recruitment for this stage of the study took place from 23rd December, 2013 to 6th January, 2014. Nine experts involved in the clinical care relating to dental treatment provision under sedation or GA were selected (see Table 9). Of the nine experts originally selected, six agreed to take part in the focus group. The three participants who declined to take part (DM, HS and WS) provided feedback on the decision aid via email. It is often suggested that focus groups should not have a sample size larger than 10 in order to allow each participant the opportunity to express their views. Smaller focus groups are also preferred in situations when the participants have a high level of knowledge and experience of the subject matter. Purposive sampling was employed to recruit a sample from a variety of professional backgrounds involved in the clinical care relating to dental treatment provision under sedation or GA.

Table 9: *Profession of participants included in the study*

Name	Profession
AE	General dentist
ES	General dentist
GF	Paediatric dentist with special interest in dental sedation
WS	Dental sedationist
HS	Dental sedationist
PS	General dentist
DM	Anaesthetist
HJ	General dentist
EA	General dentist

4.3.2 Procedure

Expert clinicians were invited to take part in a focus group either through direct contact at the Charles Clifford Dental Hospital or via email. Each potential participant also received an information sheet explaining the details of the study. After 24 hours for reflection, the participants were contacted again to see if they were willing to take part in the study. The date and time of the focus group was then arranged at a time convenient for all those who agreed to take part. Written consent was obtained prior to the focus group (Appendix E). Further feedback from three expert clinicians who declined to take part in the focus group was also provided via email.

4.3.3 Focus group

The focus group was facilitated by JH. Conducting focus group discussions with professionals who were involved in the provision of dental sedation and GA services allowed JH to focus on some of the underlying causes of the themes which emerged from the previous interviews with patients and family members. Furthermore, focus group discussions can also be effective in highlighting some of the practical issues involved in the implementation of services or interventions. The use of a focus group also allowed more direct comparisons to be made between the data as it emerged and enabled participants to hear other individuals' views, leading to greater reflection and the provision of richer data. As in the previous interviews, the focus group began by JH reiterating the purpose of the research and reassuring participants of any confidentiality issues. As previously, a voice recorder was used to record the discussion and this was made clear to all participants before the focus group commenced. As with the semi-structured interviews, the focus group also employed the use of a topic guide (Appendix F) to direct the discussion. A semi-structured approach once again allowed the emergence of previously recognised themes, while also enabling the discussion of certain topics of interest deriving from the previous interviews, reviews of the literature and the IPDAS framework (IPDAS, 2005a). Topics included in this guide were focused towards the acceptability of the draft decision aid and any potential barriers towards its implementation. The focus group took place in a seminar room at the Charles Clifford Dental Hospital and all participants were debriefed following the discussion. The discussion lasted 53 mins.

4.3.4 Analysis

The discussion was once again analysed and transcribed using framework analysis (see Section 3.2.5).

4.4 Focus group results and further revisions

The following section will detail the main themes derived from the expert clinician focus group and the impact these findings had on the subsequent refinement of the decision aid. These results are reported narratively, with a table also detailing the subsequent revisions made to each step of the draft decision aid (see Table 10). In total, five separate themes emerged from the data, these included: availability of the various treatment regimens; method of administration; language; alternative options and time.

4.4.1 Availability

The first major theme emerging from the data related to the availability of the sedation and GA options to every patient. For example, the clinicians had concerns over how the differing levels of intellectual development among children aged 10-16 years may make the dentist more reluctant to provide treatment under IV sedation for younger patients:

> *Yeah because if you've got some adolescents that are kind of more intellectually immature you wouldn't want to give them IV sedation, so there might be an 11 year old who you think yeah they're gonna cope with that. But actually another 11 year old may not be able to cope with the concept of having IV sedation so we wouldn't offer it to them.*
>
> *(GF, Paediatric dentist with special interest in dental sedation)*

Due to these concerns the original wording of 'what are my options?' and 'The 3 options available are' were changed to 'So here are the options you may have'. This minor change allowed clinicians more flexibility when discussing the treatment plan with the patient and their parents/guardians.

4.4.2 Method of administration

The second issue highlighted in the data related to the use of the word 'injection' on the opening page. Clinicians felt that the use of this word may lead to an immediate rejection of treatment under IV sedation or GA for needle phobic patients.

> *Well I just thought, thinking of the patients we see, we make this decision, many of them are needle phobic, so I wonder whether they would home immediately on that and whether there was a way of leaving that until later to where you discuss it in, because it looked like a difference between the 3, where in fact all 3 of them involve some kind of injection.*
>
> *(HJ, General dentist)*

For these reasons the use of the words 'needle' or 'injection' was avoided on the opening page of the decision aid, with a greater emphasis placed upon the method of administration in the later stages of the booklet. The above quote also reiterates the previous findings from the original interviews with patients and parents/guardians where it was noted that a clear distinction between a needle in the hand and gum is often made by patients. This added further support for the need to make this distinction being highlighted throughout the decision aid.

When considering the method of administration, the phrase 'It will not have been used by anyone else before' was also questioned, with clinicians highlighting the fact that non-disposable masks are often used in the delivery of inhalation sedation.

> *On the bit about how it will be given. Erm and you said it will not have been used by anyone else before. Like ours aren't disposable so they have been used on someone before so it's more about the sterility and cleanliness*
>
> *(GF, Paediatric dentist with special interest in dental sedation)*

Following confirmation that non-disposable masks were in fact used at the Liverpool Dental Hospital, where the decision aid was to be piloted, the decision aid was adapted to state that the mask 'will have been cleaned before you use it' so as not to mislead the patient.

The potential use of a mask for administering GA and in the recovery phase was also highlighted in the discussion, something which the original decision aid failed to discuss.

> *With the GAs, I'm not sure here, but in Derbyshire, the anaesthetist will give them a choice of injection in the back of the hand gas an induction and I think that tends to sway a lot of our patients as they don't need an injection at all and they can be put to sleep with just with a mask.*
>
> *(PS, General dentist)*

For these reasons, the following sentence was added to section discussing how GA is usually delivered: 'Sometimes you may need to wear a mask over your nose and mouth as well; this is something you can discuss with your dentist.'

4.4.3 Language

A lack of consistency in the decision aid was also raised by the focus group, with particular attention being paid to the use of the word 'worried'.

> *You've put that for the IV sedation, 'more relaxed' but on this one you've said 'less worried' so I thought consistency might help.*
>
> *(GF, Paediatric dentist with special interest in dental sedation)*

In this instance it was also suggested that the word 'worried' may hold negative connotations which could bias the information being delivered. Consistent use of the word relax as an alternative was also supported from the previous interviews with patients and parents/guardians, in which this exact term was frequently used by the patients to describe their experience of treatment under inhalation sedation or IV sedation. Below is an abstract from a transcript that also demonstrates the reasoning behind the inclusion of the phrase 'and then you will wake up' when providing information regarding whether the patient will be asleep during treatment under GA.

> *Just on the GA bit again, the 'will I still be awake?' and you talk about it 'making you go to sleep', quite a few children that we talk to are a bit worried about how they wake up again so it might be worth saying that they will wake*

up again. I know that sounds daft, but if you say that they are going to go off to sleep and the connotations with that are mentioned around medicine sometimes the children do get a bit worried about what happens after they go to sleep. So you could say that you will be asleep until the treatment has finished and then you will wake up.

(GF, Paediatric dentist with special interest in dental sedation)

In relation to the above statement there was also detailed discussion around how to present information regarding the, albeit low, mortality rates associated with GA.

When we do the consent forms for the GA it's the same sort of discussions that we have and we had a long conversation about what to write for the complications and I think in the end we came up with a small risk to life. Which then we could expand on further because we were face to face with them. Whereas here it's even difficult to put even that down without conjuring up quite negative black and white things so it's probably enough I think.

(PS, General dentist)

Following further discussion, it was determined, that although not ideal, the phrasing used in the original decision aid was the most suitable option, with clinicians reluctant to include specific probabilities regarding the possibility of death following GA.

4.4.4 Alternative options

Clinicians also raised the question regarding the lack of information describing the treatment plan for patients wanting treatment without the use of sedation of GA.

What if I don't want any of these options?

(EA, General dentist)

This point also relates to the fourth criterion listed on the IPDAS checklist which states that 'The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken.' For these reasons extra information was provided on the opening page of the decision aid which reiterated the fact that the

patient may still choose to have dental treatment without sedation or GA and also the potential consequences of opting to avoid treatment entirely. This impact of including a 'do nothing' option in decision aids is currently undetermined. Although it has been recently suggested that simply providing some information about the negative impact of failing to have treatment, could be an appropriate solution (Abhyankar et al., 2013).

4.4.5 Time

When discussing the amount of time off school, the expert clinician group also pointed out that impacts on school attendance may stem from the number of separate appointments patients might require for a course of treatment.

> *The one thing I was just going to mention about the time off school, erm was that sometime, you're saying that generally you might need more time off school if you choose a GA but sometimes you have a series of appointments for inhalation sedation that could take a lot longer and that could be quite a big factor if they want it over and done with.*
>
> *(GF, Paediatric dentist with special interest in dental sedation)*

For these reasons, an extra row was added to steps 1 and 2 of the decision aid in order to highlight the fact that more appointments are usually required when undergoing treatment under IV sedation or inhalation sedation when compared to GA, where all treatment is usually completed in one visit.

Table 10: *Revisions made to the draft decision aid following expert clinical group discussion*

Stage of the decision aid	Influential theme(s)	Revisions made to decision aid
Introduction	Availability	Original wording of *'what are my options?*' changed to *'So here are the options you may have'.*
	Method of administration	Terms *'needle'* and *'injection'* removed.
	Language	The term *'less worried'* changed to *'relax'*
	Alternative options	Inclusion of following information: *You may also decide.....* ● *To have your dental treatment without any type of sedation or a general anaesthetic.* ● *Or not to have any treatment at all. If you decide this you will be more likely to have further dental problems, such as infection around the tooth which could spread around the face and body if left untreated.*
Stage One	Method of administration	The phrase *'It will not have been used by anyone else before'* changed to state that the mask *'will have been cleaned before you use it'.* The following sentence was added to section discussing how GA is delivered: *'Sometimes you may need to wear a mask over your nose and mouth as well; this is something you can discuss with your dentist.'*
	Language	Inclusion of the phrase *'and then you will wake up'* when providing information regarding whether the patient will be asleep during treatment under GA.
	Time	Additional row added to step one table of the decision aid entitled *'How many appointments will I need to have'*. This feedback also lead to removal of the phrase *'The number of appointments you need to have'* from the bottom of page 3.

4.5 Expert patient group method

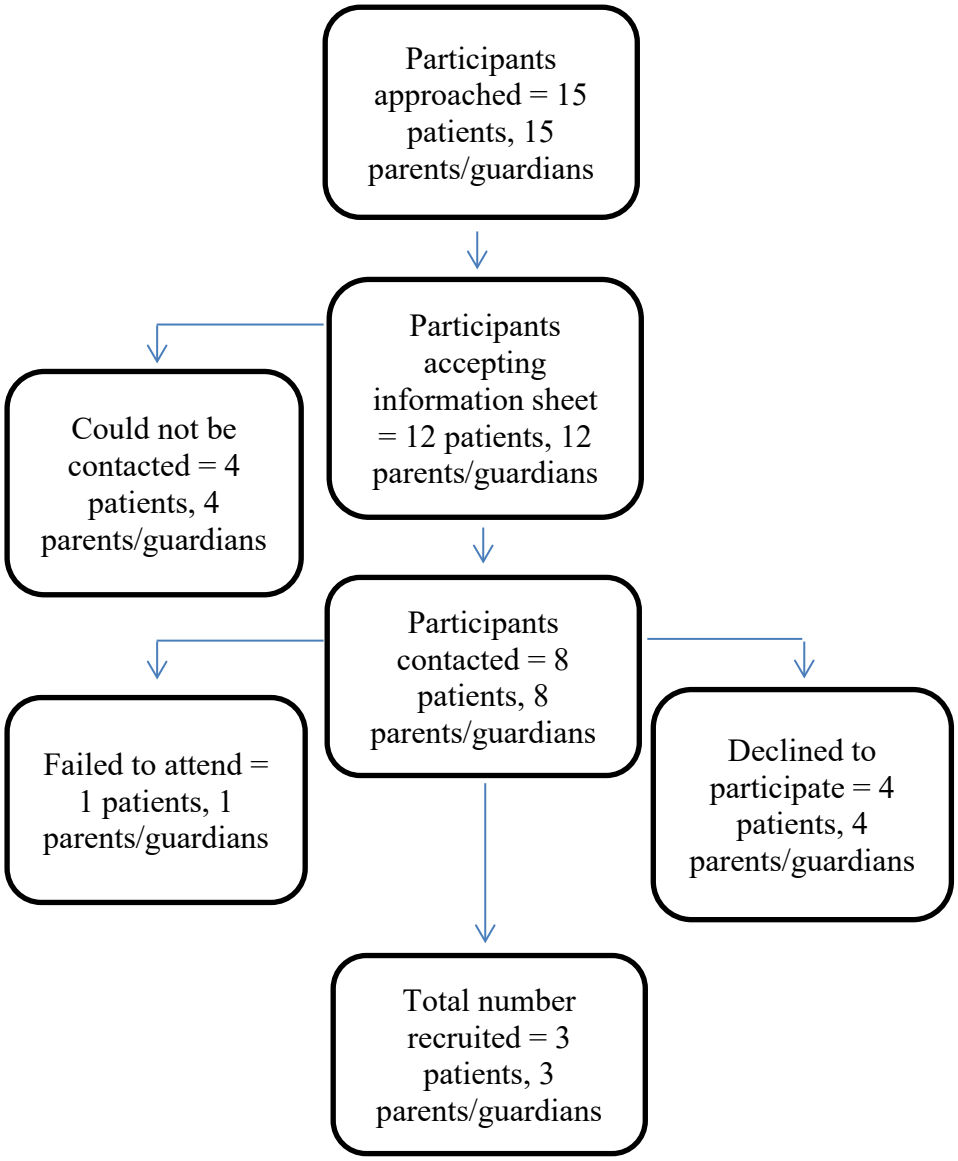
4.5.1 Sample

The following inclusion and exclusion criteria were once again adopted:

- Inclusion criteria
    - children and young people aged 10-16 years of age at recruitment
    - children who have already undergone dental sedation/GA
- Exclusion criteria
    - any child who needs urgent treatment because of acute symptoms
    - children with severe learning disabilities who lack verbal articulacy
    - non-English speaking children and parents

Recruitment commenced on 10th January, 2013 and ended on the 27th February, 2014. Purposive sampling was once again employed in an attempt to recruit participants with a range of ages, both male and female, of different ethnic groups and with different dental experiences. However, poor response rates once again made it difficult to recruit a representative sample (see Table 11). A total of 15 patients and 15 parents/guardians were initially invited to take part in the study. Of these, 10 patients and 10 parents/guardians accepted the patient information sheet and agreed to be contacted at a later date. However, a high proportion of these participants were lost at different stages of the recruitment process as detailed in Figure 2.

Figure 2: *Recruitment process (expert patient group)*



As found previously in the study, work and school commitments were cited as the only given reason for declining to take part. The participants who could not be contacted failed to respond to phone calls or voicemail messages. The patient and parent/guardian who failed to attend the interview also failed to respond to any subsequent phone calls made.

Table 11: *Characteristics of patients included in the expert patient group*

Name	Age	Gender	Ethnicity	Previous treatment
CR	14	Male	White British	GA
EJ	12	Male	White British	Inhalation sedation
GI	13	Female	White British	GA

4.5.2 Procedure

Patients were recruited from the Charles Clifford dental hospital and the University of Liverpool Dental Hospital. Potentially suitable participants were identified by their direct care team at their routine clinic visit. The care team staff were briefed by the chief investigator regarding inclusion criteria for the study and they introduced interested patients to the chief investigator for a more detailed discussion. During this discussion patients and parents/guardians were also each given age-appropriate information sheets providing more details of the study. After a 24-hour period of reflection, patients and parents/guardians who were willing to take part in the research were contacted by JH to arrange a convenient date for the interview to take place. Written informed consent was obtained from both children and parents prior to the interview (Appendix E).

4.5.3 Interviews

Due to the infeasibility of conducting a focus group, joint semi-structured face-to-face interviews were once again employed for this stage of the study with patients and parent/guardians together. All interviews were undertaken by JH and these began by JH reiterating the purpose of the research, gaining consent and reassuring participants of confidentiality issues. The fact that the interviews would be recorded using a voice recorder was once again highlighted. Subject areas to be covered in the interview were established through the use of a topic guide, the focus of this guide concentrating more on the participants' attitudes towards the draft decision aid. Prior to the interview, participants also received a copy of the draft decision aid on which annotations could be made. Extracts from these annotated copies can be seen in Figures 3 and 4. Following each interview, the participants were de-briefed about the study and given two five pound gift vouchers and relevant travel expenses to acknowledge their participation. All qualitative interviews took place at the Charles

Clifford Dental Hospital or the Liverpool Dental Hospital and at no point in the study were any of the child participants interviewed without a parent or guardian present. The mean duration of the interviews was 36 minutes.

4.5.4 Analysis

Interviews were once again transcribed verbatim with data being analysed using framework analysis. Changes were made to the decision aid as new themes emerged.

4.6 Expert patient group results and final revisions

The following section will detail the main themes derived from the joint interviews with expert patient and family members and the impact these findings had on the final development of the decision aid. These results are once again reported narratively, with a table also detailing the revisions made to each step of the draft decision aid (see Table 12). In total, five separate themes emerged from the data, these including: use of images; values clarification; language; length and format.

4.6.1 Use of images

When discussing the content of the draft decision aid, one of the main controversies emerging from the data was the use of clinical pictures. During the interview process patients were presented with various images which could have potentially been included in the decision aid. These images related to some of pieces of equipment used in the delivery of IV sedation and GA, including pictures of monitoring equipment and IV lines. In this instance, patients and parents/guardians displayed concerns over the associations that could be made between certain apparatus displayed in the pictures and the risk of serious complications.

> *I reckon some people might think it would be cool but I think others, again with the bag of the drip, normally you see that when someone's in intensive care on a programme and like if that's gonna happen what could be happening.*
>
> *(CR, 14 year old male)*

I just don't see the point of them seeing that. I don't want to say too much in front of EJ but the only time they are going to see them is if there's been a problem and you might have to stay in for a bit and then you'll wake up and see a monitor on you……. I don't think it's good, no.

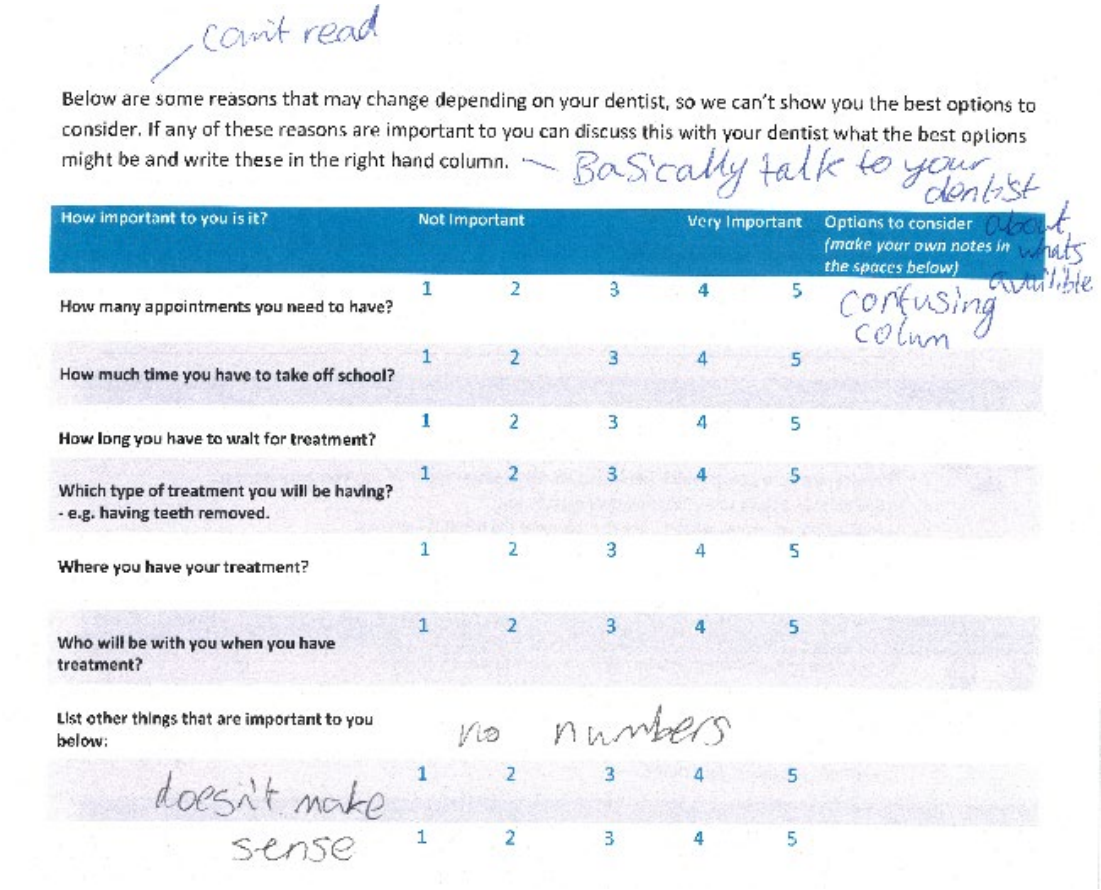
(Father of EJ, 13 year old male)

Due to concerns that these images could bias the information presented in the decision aid it was agreed that they should be not be included. This also prompted the removal of an image depicting the mask used to administer inhalation sedation which was initially included in the decision aid. The purpose of removing this picture was to ensure the decision aid adhered to the following IPDAS criterion which states that 'The decision aid shows the negative and positive features of the options with equal detail.' In line with this criterion the column widths of each table were also made identical so as not to introduce any further visual bias.

4.6.2 Values clarification

Feedback relating to the explicit values clarification exercise, included in the second step of the decision aid, also led to further changes being made. In this instance it was noted that some former patients regarded the final column which displayed 'Options to consider' as a *'confusing column'* that *'doesn't make any sense'*. This apparent confusion can be seen in the annotated version of the decision aid shown in Figure 3, which was completed by a 13 year old girl prior to the interview. For these reasons more detail was added by including the following heading: 'Your 'best' option(s) to consider if this reason is important to you are shown below'. Further confusion was also noted in relation to the section including the 'values clarification exercise', which allowed patients and parents/guardians to enter their own reasons for choosing each option, with one respondent stating that they *'don't see the point in this bit'*. Once again, further clarity was added to this section through instructing respondents to 'Write their own reasons below' in the first column and to 'Write what the dentist says below' in the final column which related to what the best option may be for the patient.

Figure 3: *Extract from the decision aid annotated by GI (13, year old female)*



4.6.3 Language

Further revisions were also made to the terminology used throughout the decision aid in accordance with findings that children were confused by words such as 'inhalation' and 'intravenous'. Furthermore the word intravenous was repeatedly described as a *'scary word'* by the patients. For these reasons inhalation sedation was primarily described as 'gas and air' with the terms 'happy air', 'laughing gas' or 'inhalation sedation' placed in brackets and IV sedation was primarily described as 'IV sedation' as opposed to 'intravenous sedation'.

Further difficulties with comprehensibility also prompted the revision of the phrase 'review step 2' to 'go back to step 2' under the values section in step 3 of the decision aid. These difficulties are highlighted in the annotated version of the decision aid shown in Figure 4, which was completed by the mother of a participant who had previous experience of dental treatment with GA. Changes to the heading of this section were also made due to concerns that patients would not comprehend the terms

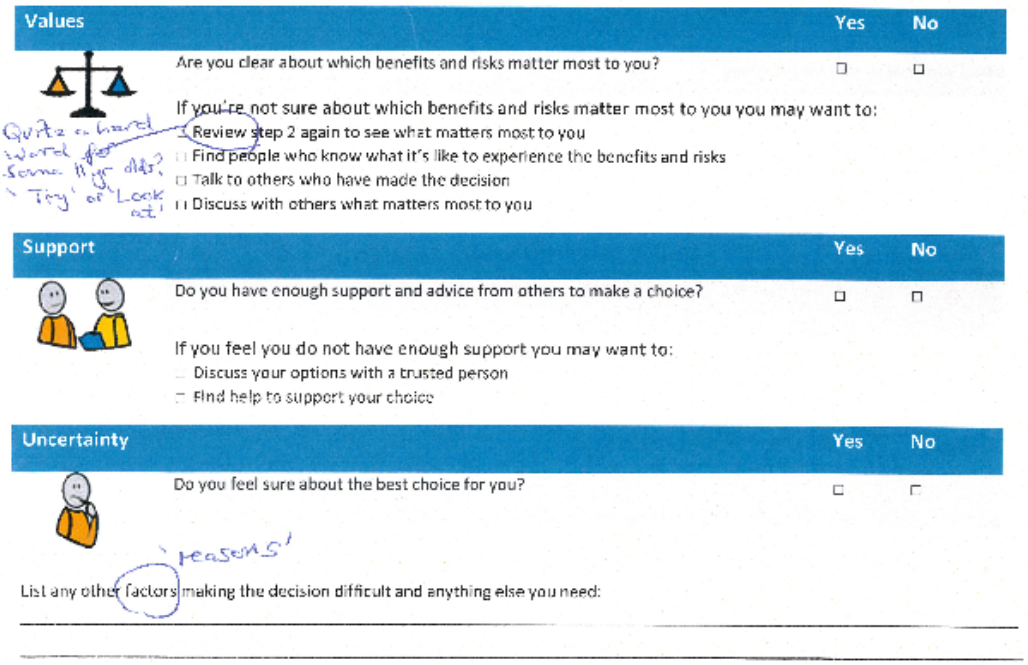
'benefits and risks'. Participants also raised issues the negative connotations attached to the term 'risk', as demonstrated below:

> *If you do see benefits and risks, you're like there's risks? And it starts to scare you.*
>
> *(CR, 14 year old male)*

The following phrase was therefore used in its place 'Are you clear about which reasons to choose each option matter most to you?' a term frequently used in the available Ottawa decision aids included in the DALI system (Ottawa Hospital Research Institute, 2015).

To further ensure the decision aid was understandable to patients aged 10-16 years a readability test was also undertaken, with results suggesting the text in the decision aid held a SMOG (Simple Measure of Gobbledygook) grade of 5.7. This grade is based on the USA education system, with children in grade 5 usually aged 10-11 years and children in grade 6 usually aged 11-12 years. The use of these scores was also crucial to adhere to Item 28 on the IPDAS criteria, relating to the development process, which states that 'the decision aid (or available technical document) reports readability levels.'

Figure 4: *Extract from the decision aid annotated by the mother of GI*



4.6.4 Format

The format of a decision aid was a further theme which emerged from the data. As in the initial interviews with patients and parents/guardians the potential benefits of the decision aid being available as an online resource were discussed:

> *I suppose if it is on the internet as well you could also like depending on what age you have, you could have it like so it says, so it's more detailed for one age than it is for another age. And also like, and also it would be able to have a bit for the parents so they could read over it in maybe a bit more detail and you wouldn't have to worry about words that might scare children.*
>
> *(CR, 14 year old male)*

However, the data also suggested that the provision of the decision aid online may not enable young people to look through the decision aid with family members:

> *It's a bit annoying if it's like a family thing and you're trying to look at it with your parents. If you're like both trying to see the screen at the same time could be quite hard.*
>
> *(CR, 14 year old male)*

Furthermore, concerns over the accessibility of the decision aid to all patients if only available online were once again reiterated:

> *Yeah but it depends, some people do and some don't* (have access to the internet)*, so you could generate a booklet for everybody.*
>
> *(Father of EJ, 13 year old male)*

Following final consideration, it was determined that to ensure all patients and parents/guardians had access to the resource, the final decision aid would be developed and provided as an A4 paper booklet.

4.6.5 Length

Finally, with regards to the length and format of the decision aid, the majority of reactions were positive, with patients and parents/guardians suggesting that the resource would be suitable for use at home prior to their pre-sedation or prevention appointment.

> *Absolutely fine... You can look through it yourself as the adult, then get them to look through it together. I think it's brilliant.*
>
> *(Father of EJ, 13 year old male)*

Table 12: *Revisions made to the draft decision aid following expert patient group discussion*

Stage of the decision aid	**Influential theme(s)**	**Revisions made**
Stage one	Use of images	Removal of image depicting mask.
Stage two	Values clarification	Inclusion of following heading *'Your 'best' option(s) to consider if this reason is important to you are shown below'*.
		Inclusion of instruction to *'Write their own reasons below'* in the first column of the values clarification exercise.
		Inclusion of instruction *to 'Write what the dentist says below'* in the final column of the values clarification exercise.
Step four	Language	The phrase *'review step 2'* changed to *'go back to step 2'* under the values section in step 3 of the decision aid.
		The term *'benefits and risks'* was excluded from the heading of step 3. The following phrase was used in its place: *'Are you clear about which reasons to choose each option matter most to you?*'
Throughout the decision aid	Language	Inhalation sedation primarily described as *'gas and air'* with the terms *'happy air'*, *'laughing gas'* or *'inhalation sedation'* placed in brackets. IV sedation primarily described as *'IV sedation'* as opposed to *'intravenous sedation'*.

4.7 Summary

The presentation of the initial draft of the decision aid to expert clinicians and patients and parents/guardians who had already experienced dental sedation/GA decision-making formed a crucial step in the development process. Firstly, this step enabled the identification of any potential issues with comprehensibility, with recommendations leading to changes being made to some of the language originally used in the decision aid and further detail being added to Step 2 of the resource.

Furthermore, the focus group with expert clinicians also created the opportunity to explore any potential issues regarding the feasibility of implementing the decision aid in secondary care and how to ensure that the information provided in the decision aid does not conflict with the information provided by the dentist, particularly when considering the varying availability of the sedation and GA options provided to patients. The final version of the decision can be seen in Appendix H.

4.8 Discussion

4.8.1 Introduction

The following section will discuss the findings from the review stage of the decision aid development process. In this section the main themes deriving from the qualitative interviews and focus groups and their influence on the content of the draft decision aid will be discussed in relation to the wider literature on decision-making and paediatric dental sedation and GA.

4.8.2 Availability

Clinicians' concerns over the availability of all the options presented in the decision aid may have broader implications regarding the wider applicability of certain decision aids and the appropriateness of having these interventions widely available on the internet. The issue raised in the current study related to suggestions that a minority of patients may not be able to undergo certain treatment options. Therefore the term 'So here are the options you may have' was introduced into the decision aid to avoid any potential conflict with the options provided by the clinician. However, there are a variety of decision aids available online which present options which may not be available to all patients. For example, when considering dental sedation the options vary greatly in terms of the sedatives used, methods of administration and pre- and post-operative procedures (Lourenco-Matharu et al., 2012). As research shows that patients are increasingly relying on the internet for the provision of healthcare information (Akerkar and Bichile, 2004) it could be suggested that the inclusion of specific decision aids on the internet and the subsequent introduction of healthcare options not available to some patients, may hinder the decision-making process. There have been review suggestions that the delivery of decision aids via the internet may actually allow the patient to tailor the information provided to their own

needs (Hoffman et al., 2013), however the feasibility of implementing tailor-made information in relation to the patients' place of treatment or medical history is undetermined and there is little evidence to suggest that many of the decision aids currently displayed online provide this opportunity. Therefore it could be suggested that the availability of some decision aids should be limited specifically to their intended audience.

4.8.3 Alternative options

This inclusion of a 'do nothing' option in decision support tools is currently still under debate. However, it has been suggested that providing the patient with information about the negative impact of failing to have treatment, without justifying this choice, may be the best solution (Abhyankar et al., 2013). It could also be argued that further information regarding treatment under LA only should also be incorporated into the booklet in the side-by-side display of information and the values clarification exercise. However, it was deemed that this was not applicable to the current decision aid, mainly due to the fact that it was designed specifically to be presented to patients who had already been assessed as unsuitable for LA only treatment and referred for treatment with sedation or GA.

4.8.4 Images

The use of images to depict the medical equipment associated with each of the options was excluded from the final version of the decision aid, due to concerns that the negative connotations attached to some of the images could bias the decision-making process. When addressing the previous literature, reviews have suggested that the use of images in healthcare information can have a positive impact upon comprehension, attention, and recall of information (Houts et al., 2006; Katz et al., 2006). In relation to comprehension, findings have shown that the inclusion of pictures can significantly increase patients' understanding of discharge instructions following treatment for lacerations (Austin et al., 1995), information pamphlets on cervical cancer prevention (Michielutte et al., 1992) and instructions on medication use (Morrow et al., 1998; Mansoor and Dowse, 2003). These studies measured comprehension through the percentage of correct answers given by participants in response to questions relating to the content of the healthcare information received. A study demonstrating higher patient knowledge following viewing of video animations

in comparison to written information can also be taken in support for the use of images in healthcare information (Leiner et al., 2004) However, it could be argued that the inclusion of such audio-visual information contrasts significantly with the standard use of images in healthcare information.

When discussing attention to information, findings are more limited however, with one study suggesting that patients were significantly more likely to read information leaflets which included images than leaflets which just contained text (Delp and Jones, 1996). Once again these findings related to the care of lacerations following discharge. This same study also demonstrated significant increases in the amount of information recalled when images were used in healthcare information. Significant increases in the amount of information recalled by patients have also been demonstrated across studies which involved the use of medication (Sojourner and Wogalter, 1998) the treatment of dehydration (Patel et al., 1990), and the management of symptoms associated with cancer and HIV/AIDS (Houts et al., 1998; Houts et al., 2001). In contrast, one study suggested the use of cartoons in booklets relating to the treatment of gout had no influence on recall (Moll et al., 1977). These findings were related attributed to the fact that patients in both groups already had gout and therefore held high levels of interest in the subject matter.

It could be argued that this previous evidence offers strong support for the inclusion of images in the current decision aid. However, it must be considered that the available evidence does not explicitly relate to the provision of information for patients facing healthcare decisions. In this instance it suggested that the inclusion of images should be approached with caution, with previous findings suggesting that the use of images can have both negative and positive impacts on patients' intentions and behaviour, depending upon their emotional response to the image (Houts et al., 2006). For example the negative connotations detailed by patients in relation to images portraying methods of administration for IV sedation and GA could lead to the rejection of certain options without full consideration of all the information available. For these reasons the current decision aid only included neutral cartoon images that did not relate directly to the information being presented, in an attempt to increase attention without eliciting negative emotional responses. It is suggested that further research into the use of images throughout decision aids is required, with a focus on

how the inclusion of information may affect the balance of the content included. Further attention to the nature of images used must also be addressed, with previous research also suggesting that simple images often lead to greater comprehension.

4.8.5 Values clarification

A recent review of the literature suggests that the inclusion of values clarification exercises are likely to improve the decision-making process (Fagerlin et al., 2013). However, it is difficult to draw firm conclusions due to the small number of studies that have evaluated this area and the heterogeneity of outcomes measured across studies. For example, only 13 studies were included in this recent review of the literature by Fagerlin and colleagues (2013), with measures such as decisional conflict, which is often used as a primary outcome measure in decision aid evaluation, only reported in five of the included studies. One study has previously suggested that the use of explicit values clarification exercises significantly reduce ambivalence and decisional conflict in comparison to implicit values clarification techniques (Abhyankar et al., 2011). However, there has been little further research on the relative impact of these related methods or on the specific characteristics of values clarification methods which determine their impact. For these reasons it could be suggested there is little guidance available on how to develop values clarification exercises, with the current study relying upon using similar designs to the methods used in previous effective decision aids. It is clear further research is required to inform the development and use of values clarification techniques in decision aids.

4.8.6 Language

The use of language was particularly prominent in the current study due to the involvement of children, with particular challenges relating to the inclusion of unfamiliar terms such as ‘intravenous’ and ‘general anaesthetic’. To help ensure comprehension the use of the SMOG test was applied to the decision aid to ensure the text could be comprehended by patients aged 10-16 years. Previous papers have stressed the use ‘plain language’ when communicating healthcare information (Fagerlin et al, 2011b), with these recommendations being based primarily on research which describe the benefits of using ‘plain language’ in terms of improved comprehension of healthcare literature in low literacy populations (Clement et al., 2009). However, when considering low literacy populations specifically in regards to

the use of decision aids, a recent review suggests that the needs of low literacy patients are often ignored, with only three relevant decision aids being identified (McCaffery et al., 2013). This suggests that further research is required to enable the development of decision aids which can be more broadly applied. The discussion of the language used in the decision aid by the expert clinician group can also be related to the presentation of risks and side effects discussed in Chapter Three. In this instance, particular attention was once again given to the discussion of risks associated with a GA, with clinicians reinforcing suggestions that the exclusion of risk information in this instance is warranted, providing patients and parents/guardians are given the opportunity to discuss these factors in more detail during consultations.

4.8.7 Length

It has been suggested in previous research that the inclusion of too much information in healthcare resources can be distracting for patients and divert focus away from important information (Zikmund-Fisher et al., 2010; Fagerlin et al., 2011b). For example, a report of three studies focusing on the provision of healthcare information, reached an overall conclusion that less information leads to increased comprehension and better choices regarding hospital costs and service quality (Peters et al., 2007). In addition, findings deriving from several studies on the use of an online decision-making resource for breast cancer patients also suggested that greater understanding was achieved when information was presented sequentially and when simpler graphical formats, with fewer options displayed together, were implemented (Zikmund-Fisher et al., 2008; Zikmund-Fisher et al., 2011).

In this instance the authors argued that removing options that are no longer under consideration from the decision-making process could be beneficial for patients, however although this may be feasible through the use of online tools relating to cancer therapy, whether such findings are applicable to this current study and the wider range of decision aids being developed is debated. The main reason for this, when discussing the current study, is that as the decision aid is not provided online, it would be impractical to make constant changes to the information included. Furthermore, there are also questions over who decides which options are no longer

suitable, and obligations to ensure the patient remains fully informed of all options available.

In contrast to previous findings, more recent and comprehensive reviews of the literature suggests that more detailed decision aids can improve knowledge and reduce decisional conflict when compared to the more simple presentation of information (Feldman-Stewart et al., 2013; Stacey et al., 2014). However, it could be argued that there are still questions over what constitutes a 'detailed' or 'simple' decision aid and what the minimum amount of information required is. Furthermore, research appears to be lacking on how the length and amount of information included in decision aids may impact upon the appeal of the tool and the level of patient engagement, especially when children are involved in the decision-making process.

4.8.8 Repeated themes

Several themes that emerged from the data in the initial qualitative interviews with patients and parents/guardians were repeated in the data from the focus group with expert clinicians and in the further interviews with patients and parents/guardians. These themes included 'method of administration', 'time' and 'format'.

4.8.8.1 Method of administration

Once again, when discussing the method of administration, the distinction between the use of needles in the arm to deliver IV sedation or GA and the use of dental injections in the gum to deliver the LA was reinforced by clinicians. These findings corroborate distinctions made in the previous literature which separate the concepts of dental anxiety and needle phobia (Majstorovic and Veerkamp, 2004). In addition, clinicians also raised issues relating to the use of a gas induction prior to treatment under GA. As noted previously, although it was not raised as an issue amongst patients and parents/guardians in the current study, the use of gas induction has been cited as an important issue in the previous literature (Rodd et al., 2014). Although not a regular technique at the current study site, the fact that it could still be used on occasions meant the issue was taken into consideration in the final draft of decision aid. Finally, the discussion highlighting the use of the varying use of disposable masks, once again highlighted the potential difficulties in producing decision aids which are applicable across different sites.

4.8.8.2 Format

The repeated theme of format, once again centred around the delivery of decision aids on the internet. In this instance, patients once again discussed the potential tailoring of information as highlighted in a recent review of the literature (Hoffman et al., 2013). These findings also lend further support for the need for further research on the feasibility of tailored web-based interventions in order to determine the extent to which such interventions can be tailored in relation to how the options available and associated procedures may differ for individual patients. In addition, concerns over the accessibility to the decision aids for all patients, were also raised in relation to internet-based decision aids. With these concerns supported by the fact that although internet access is rapidly rising, 16% of UK households still do not have access (Office for National Statistics, 2014).

4.8.8.3 Time

Once again time was raised as an issue in relation to how multiple appointments may impact upon the overall amount of time the patient will be absent from school. When discussing absence from school in the initial qualitative interviews with patients and parents/guardians detailed in Chapter Three, data suggested that participants' main concerns were related to the impact absence from school would have on patients' academic achievements. However, it is also feasible to suggest that some patients may view time off school as a potential benefit of the treatment options. This hypothetical situation could raise questions over whether the inclusion of certain information which may lead patients to choose certain options for what could be considered the 'wrong' reason is always justified. However, arguments from a shared decision-making perspective could also suggest that all information relevant to the patient should be discussed (Charles et al., 1997; Charles et al., 1999). Who ultimately decides what information is relevant to make the healthcare decision can still however, be debated.

4.8.9 Methodological issues – expert clinician group

It is suggested that a focus group provides a more natural environment in comparison to individual interviews, with the interviewer playing less of a role in the actual direction of discussion, with participants themselves often taking over the role of the

'interviewer' (Kreuger and Casey, 2000; Ritchie and Lewis, 2003). Nevertheless, this does not diminish the effort required to facilitate the focus group, with careful management of the situation often crucial in the collection of meaningful data (Bloor et al., 2001). For example, one challenge facing the researcher is to find a balance between encouraging open discussion, while also ensuring that individual participants do not dominate the focus group. When considering the fact that the chief investigator was younger than the interviewees and not a dentist or healthcare professional, difficulties in controlling the process could have arisen. However, despite the fact that the interviewees could have viewed themselves as holding more authority, they were not dismissive of the investigator's role as facilitator and no issues, such as disagreements between participants, arose. The facilitator also faced potential challenges in comprehending the clinical terminologies and nuances of the expert group's dialogue. This did not prove a problem however, as the investigator had already familiarized himself with the clinical context and was able to readily clarify any issues within the group.

4.8.9.1 Sample composition

Although study group diversity is usually desired in research, it must be noted that too much diversity can often have a negative impact on the collection of data using focus groups (Ritchie and Lewis, 2003). The reasoning behind this is that participants may be less willing to disclose information in a group setting if surrounded by participants who differ distinctly from themselves. In contrast, it is also proposed that a homogeneous sample may have a detrimental effect on data collection. In this instance it is suggested that if participants are too similar it may be hard to differentiate separate views across participants. Furthermore, it is also proposed that participants may not fully express their own viewpoint due to assumptions that other members of the group already understand their perspective. Taking these factors into account, it is acknowledged that there was a degree of familiarity among participants in the current sample, which encouraged discussion. This familiarity related to the fact that all participants were involved in the profession of dentistry and the majority were employed in the same dental hospital. However, diversity among the sample with regards to ethnicity, gender, area of expertise and department of employment ensured diverse views were obtained. One limitation of the sample however, was the failure to include anaesthetists and dental sedationists directly in the focus group,

with feedback from these three participants being provided by email. This meant that the development of spontaneous issues during the focus group could not be addressed directly from the viewpoint of the anaesthetist or sedationist and therefore the content of the decision aid could be biased towards the need of the general dentist. However, this bias was controlled for to some extent through eliciting the views of sedationists and anaesthetists via email in relation to the themes derived from the focus group discussion.

4.8.9.2 Setting

Once again, factors that are conducive to the provision of rich data must be also considered when conducting focus group research. In this instance disclosure of information was encouraged through the fact that the research took place in a familiar, comfortable and private setting and at a time that was mutually convenient for busy clinicians.

4.8.10 Methodological issues – expert patient group

The potential issues relating to power imbalance, parental presence, setting and language were duly considered when reflecting on the qualitative interviews with patients and parents/guardians, which formed part of the further review and development process (see Sections 3.5.12 – 3.5.15).

4.8.10.1 Power imbalance

Attempts to reduce the potential power imbalance between the child participant and the adult researcher involved stressing the voluntary nature of the study, assuring participants of confidentiality, informal questioning and thorough de-briefing. Furthermore, the fact that the investigator was not a member of the child's treatment team once again reduced perceptions of him as an authority figure.

4.8.10.2 Parental presence

The potential impact of parental presence on the interview was once again considered, with parents/guardians in this instance appearing to positively influence patients' involvement in the interview process by actively engaging them in the interview when viewing the draft decision aid.

4.8.10.3 Setting

The interviews were situated in a non-threatening environment which was not directly associated with the dental hospital, in order to provide a more natural setting in which participants would be more willing to disclose information. Furthermore, interviewing participants away from a home environment once again ensured privacy and avoided potential distractions which could disrupt the interview process.

4.8.10.4 Language

Potential misinterpretations, due to the differences in language used between adults and children, were once again taken into consideration (Punch, 2002). Continued reference to the comprehensibility of the language used in the draft decision aid in the interview in this stage of the study also enabled the participants to directly address any misinterpretations.

4.8.10.5 Sample composition

Time constraints placed on recruitment may have impacted upon the generalisability of the sample used in this stage of the study, as no patients or parent/guardians from an ethnic minority group were included. For these reasons it was impossible to fully explore how ethnicity may have impacted upon initial perceptions of the decision aid. The relatively small sample size (n=6) used in this stage of the study may also have an impact on the generisability of the findings, as it was not feasible to arrange a suitable date and time for all participants to take part in a focus group, as was originally intended. The self-selecting nature of the sample also had implications for research findings, as the study once again only included patients and parents/guardians who were willing to discuss treatment with sedation or GA. The study therefore failed to take into account the views of those who were less willing to discuss the subject matter. Nonetheless, it was felt that some valuable insights and feedback was obtained from the patient group, which helped to inform the decision aid from a patient and parent/guardian perspective.

4.8.11 Ethical considerations

As before, the potential for upsetting issues to arise in both the focus group with clinicians and during the further interviews with patients and parents/guardians was relatively low. However identical steps as detailed in Section 3.5.17, were put in place

to try and control for the risk of such occurrences. Participants in all groups were once again assured of their confidentiality and that all data would be anonymised and that all information would be kept in locked filing cabinets or password protected on a designated PC in the School of Clinical Dentistry at Sheffield. All participants were given at least 24 hours from receiving the information sheet to decide if they were still willing to take part in the study to ensure informed consent. In addition, all information sheets provided to children were once again tailored to the age of the participant. No ethical or governance issues arose during the conduct of the study, which confirmed the robust procedures set in place by NRES committee and the host Trusts.

4.9 Summary

The further development and review of the decision aid in this second stage of the study was designed satisfy the following objective:

2. To explore clinicians', patients' and parents/guardians' initial perceptions towards the decision aid

This second stage of the research was crucial in further developing the content of the decision aid while also introducing clinicians' perspectives to the development process and to gaining understanding of their decisional needs. Presentation of the draft decision aid to clinicians and expert patients and parents/guardians at this stage of the research also enabled identification of potential feasibility and comprehension issues, while providing some initial evidence regarding the acceptability of the decision aid in terms of the balance and amount of information provided. The findings from this stage of the study also raised broader questions relating to the essential elements required for the development of an effective decision aid, with questions over the relative merit of including images, value clarification exercises and a 'do nothing' option all still under debate. Following final development of the decision aid, the next chapter will evaluate the impact of the decision aid in a secondary care setting.

Chapter Five: Evaluation of the Decision Aid

5.1 Introduction

The final stage of the project was to conduct a pilot evaluation on the effect of the decision aid in terms of changing patient outcomes and experiences within their dental sedation/GA care pathway.

The specific objectives of this stage of the study were:

3. To determine the impact of a decision aid on measures of patients' and parents/guardians' decisional conflict, anxiety, knowledge, attendance and compliance with treatment
4. To determine the acceptability of the decision aid
5. To determine the feasibility of implementing and evaluating a decision aid in a secondary care setting (see Table 1)

These objectives relate specifically to the third stage of the IPDAS development framework which highlights the need to test the decision aid with its target audience in the appropriate clinical setting.

A distinction between pilot studies and feasibility studies can be made when consulting NIHR guidelines (National Institute for Health Research, 2015), For example, it is stated that feasibility studies are pieces of research that are used to determine important aspescts of future research such as the willingness of clinicians to recruit participants and the number of eligible patients and does not include an evaluation of the outcomes of interest. In contrast, pilot studies are described as a smaller version of the main study to ensure all aspects of the research, such as recruitment and the collection of follow up data run according to plan. In these instances data is often analysed and can even contribute to the final analysis undertaken. In these respects, the current study has been described as a pilot study, however, this terminology is based more heavily on the guidelines provided by the

Medical Research Council (Craig et al., 2008), which suggest that pilot and feasibility studies are interchangeable concepts, relating to all preparatory studies.

5.2 Ethical approval and research governance

Ethical approval for the study was obtained from the NRES Committee for Yorkshire and The Humber – Sheffield (13/YH/0142) on 6th August 2013 (Appendix A). Local permission to undertake the study, in terms of research governance, was also obtained from Sheffield Teaching Hospitals NHS Foundation Trust (STH17248 – 6th August 2013) (Appendix B) and the Royal Liverpool & Broadgreen University Hospitals Trust (4626 – 29th August 2013) (Appendix C).

5.3 Care pathway

At the University of Liverpool dental hospital, Dr Sondos Albadri, a senior lecturer/honorary consultant in paediatric dentistry, has established a comprehensive paediatric sedation service with a clear care pathway. Following initial assessment, patients who are thought to potentially need sedation are referred to Dr Albadri's pre-sedation assessment clinic and patients who are thought to need GA for treatment are referred to a specific clinic to receive preventive interventions such as topical fluoride varnish, fissure sealants and diet and tooth brushing advice.

The pre-sedation clinics are held once weekly and prevention clinics are held three times a week. Both these clinics offer a forum for decision-making about treatment with sedation or GA and also incorporate a preventive treatment procedure. The treatment pathway is then dictated according to patient needs and preferences and includes the following options:

- Decline the need for sedation or GA and continue with normal behaviour management techniques and local anaesthetic
- Undergo treatment with nitrous oxide inhalation sedation
- Undergo treatment with IV sedation (Propofol)
- Undergo treatment with a GA

5.4 Recruitment

Participants were recruited to this part of the study at the Liverpool Dental School and formed two groups.

i) 17 patients and 17 parents/guardians who were given conventional clinical counselling prior to pursuing their sedation/GA treatment choice (control group).
ii) 15 patients and 13 parents/guardians who were given the decision aid as well as clinical counselling prior to pursuing their sedation/GA treatment choice (intervention group).

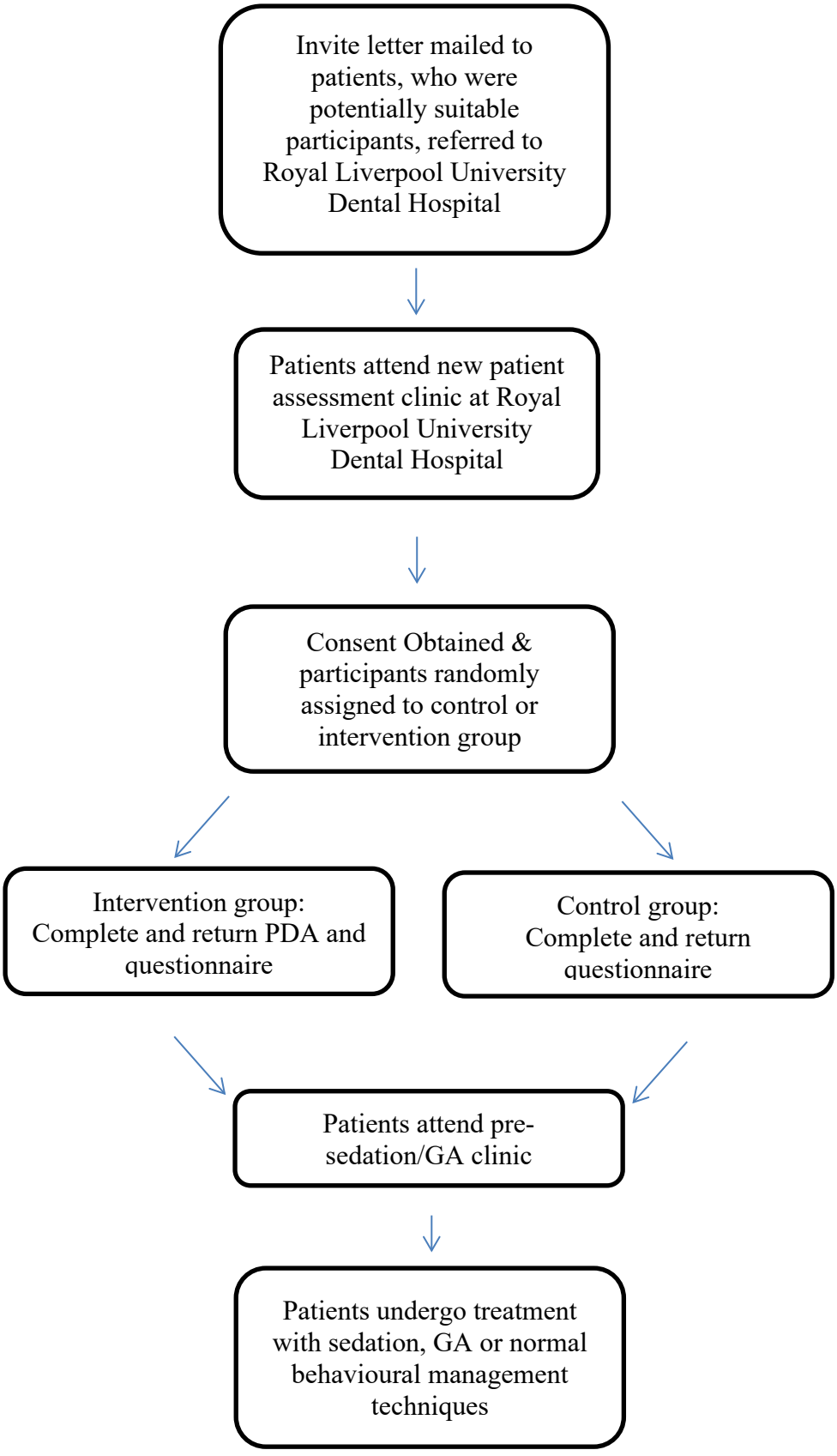
Due to a lack of data in the existing literature regarding the use of decision aids in paediatric dentistry, power calculations were impossible to obtain. For these reasons the sample size was based on the general guidance, that a total of 30 participants is considered acceptable when conducting pilot studies which may then be used for sample size determination for a future trial (Browne, 1995). Due to issues with recruitment the total sample size differed between groups. These issues relating to differences in sample sizes between groups are addressed in Chapter Six.

5.5 Procedure

Both groups were recruited at their initial new patient assessment at the Liverpool University Dental Hospital from the 14th may, 2014 to the 30th January, 2015. Prior to their appointment, all potentially suitable participants were identified by their direct care team and were mailed a study invite letter (Appendix I) and the relative information sheets (see Appendix D). Suitable participants were then approached immediately following their appointment at the dental school and asked if they were willing to take part in the study by the chief investigator. If the patients and parents/guardians were interested in taking part, written consent was obtained and a computer software package (Microsoft Excel) was used to randomly assign participants to one of the two groups (control or intervention). Patients in both groups then received a questionnaire including validated measures of decisional conflict, anxiety and knowledge (see Section 5.6). Parents/guardians in both groups also received a questionnaire including measures of decisional conflict and knowledge. Patients and parents/guardians in the intervention group were given the decision aid to work through and their questionnaire also included specific questions relating to

the acceptability of the decision aid. Participants in both groups were asked to complete the relevant questionnaires prior to their pre-sedation or pre-GA (prevention) appointment and to return them in a pre-paid envelope. It was clearly explained to participants in the intervention group that they needed to work through the decision aid before completing the questionnaires. A phone call prompt was made by JH to participants who failed to return the questionnaires. All participants were given two five pound gift vouchers and relevant travel expenses as a thank you for their participation. At the pre-sedation or pre-GA (prevention) clinic, all patients attended as normal to make a choice about what treatment option to pursue. A record was made of the patient's age, gender, ethnicity and treatment choice (no sedation, inhalation sedation, IV sedation or GA).

Figure 5: *Care pathway*



5.6 Questionnaires

The subsections below provide details of the measures that were used in the pilot evaluation stage.

5.6.1 Decisional conflict

Decisional conflict is defined as the perceived level of uncertainty regarding a planned course of action (O'Connor, 1993). This uncertainty is deemed to be more prominent when an individual is faced with a decision which involves high levels of risk or uncertainty. Decisional conflict is often characterised by verbal expressions of uncertainty or an inability to decide between the options available. An individual may also display physical symptoms of distress when experiencing high levels of decisional conflict and may begin to doubt their own values and beliefs during the decision-making process. Decisional conflict scales have been used to evaluate outcomes relating to a wide variety of healthcare decisions, with a recent systematic review of the impact of decision aids for health treatment or screening decisions finding that 50.4% of 115 studies had included decisional conflict as an outcome measure. In this instance, a meta-analysis of the existing literature suggested that decision aids significantly reduced decisional conflict in relation to the informed and values clarification subscales (Mean Difference=-6.22). Decisional conflict scales have also been used to measure the level of decisional conflict for parents/guardians making difficult healthcare decisions with or on behalf of their child (Guerriere et al., 2003; Mckenna et al., 2010; Jackson et al., 2011). There are currently four versions of the decisional conflict scale available for use and these include:

- Traditional Decisional Conflict Scale: statement format, 16 item, 5 response categories
- Question Format Decisional Conflict Scale: 16 item, 5 response categories
- Low Literacy Decisional Conflict Scale: question format, 10 item, 3 response categories
- SURE test version for clinical practice: 4 items, 2 response categories

The current study implemented the Traditional Decisional Conflict Scale (see Section 5.6.1.1) for parents/guardians and the Low Literacy Decisional Conflict Scale (see Section 5.6.1.2) for patients. Justification of these choices are described below.

5.6.1.1 Traditional Decisional Conflict Scale (O'Connor, 1993)

This scale, which was developed by Connor and colleagues (1995), displays each item in the form of a statement and consists of the following five sub-scales:

Informed Subscale
e.g. I know which options are available.
Values Clarity Subscale
e.g. I am clear about which risks and side effects matter most.
Support Subscale
e.g. I have enough support from others to make a choice.
Uncertainty Subscale
e.g. I feel sure about what to choose.
Effective Decision Subscale
e.g. I am satisfied with my decision.

The total scale consists of 16 items with 5 tick-box response categories for each item (0=strongly agree, 1=agree, 2=neither agree nor disagree, 3=disagree, 4=strongly disagree)

Scoring

To obtain a total score, the 16 items are summed, divided by 16 and multiplied by 25. Scores consequently range from 0-100. A score of 0 representing no decisional conflict and a score of 100 representing extremely high decisional conflict. Scores below 25 are related to the implementation of decisions, whereas scores above 37.5 are associated with decisional delay.

A similar formula is used to obtain individual scores for each subscale, as described below:

- Uncertainty Subscale

Scores from items 10, 11 and 12 are summed, divided by 3 and multiplied by 25. Scores range from 0-100. A score of 0 indicates the participant feels extremely certain about their best choice, a score of 100 indicates the participant feels extremely uncertain about their best choice.

- Informed Subscale

Scores from items 1, 2 and 3 are summed, divided by 3 and multiplied by 25. Scores range from 0-100. A score of 0 indicates the participant feels extremely informed, a score of 100 indicates the participant feels extremely uninformed.

- Values Clarity Subscale

Scores from items 4, 5 and 6 are summed, divided by 3 and multiplied by 25. Scores range from 0-100. A score of 0 indicates the participant feels extremely clear about personal values for benefits and risks/side effects, a score of 100 indicates the participant feels extremely unclear about personal values.

- Support Subscale

Scores from items 7, 8 and 9 are summed, divided by 3 and multiplied by 25. Scores range from 0-100. A score of 0 indicates participants feels extremely supported in decision-making, a score of 100 indicates the participant feels extremely unsupported in decision-making.

- Effective Decision Subscale

Scores from items 13, 14, 15 and 16 are summed, divided by 4; and multiplied by 25. Scores range from 0-100. A score of 0 indicates a bad decision, a score of 100 indicates a good decision.

Reliability and validity

The scale has demonstrated good internal consistency and reliability with Pearson r and Cronbach's alpha coefficients of 0.78 or higher for the overall scale (O' Connor,

1995). The scale has been shown to discriminate between groups facing decisions on accepting influenza vaccination and breast cancer screening (O'Connor, 1993). In this instance the scale significantly discriminated ($p < 0.01$) between those with strong intentions and those who were uncertain and between those who made decisions and those who delayed decisions. Significant inverse correlations have also been noted between knowledge scores and the Decisional Conflict Scale. For the full scale see Appendix J.

Effect sizes of the overall scale have been reported to range from 0.4 to 1.2 in studies looking at the impact of decision aids using a before/after design. In terms of discriminating between decision aids, usual care and alternate interventions findings have been less consistent, with effect sizes ranging from 0 to 0.4 for total scores and sub scores (O'Connor, 1993). With regards to predictive validity it has been reported that a one unit increase in decisional conflict scores meant individuals were more likely change their mind, delay a decision, display regret and fail a related knowledge test (Sun, 2005). It is suggested that a scores below 25 are related to the implementation of decisions, whereas scores over 37.5 are related to a decision being delayed (O'Connor, 1993).

5.6.1.2 Low Literacy Decisional Conflict Scale (O'Connor, 1993)

Patients participating in the current study received a lower literacy version of the decisional conflict scale (O'Connor, 1993). Although there is some evidence suggesting that the traditional Decisional Conflict Scale is suitable for studies involving young children, this evidence is based on decisions regarding life-limiting illnesses and the broad age range (1-18 years) is not directly applicable to the current study (Knapp et al., 2009). Furthermore, this previous study used telephone survey data when determining the reliability and validity of the scale, whereas questionnaires for young people in the present study were self-administered. Therefore, to ensure full understanding, a lower literacy version was implemented.

This scale includes ten questions with three tick-box response categories for each item (0=Yes, 2=Unsure, No=4). The scale includes the following four subscales:

Uncertainty subscale:
e.g. Are you clear about the best choice for you?
Informed subscale
e.g. Do you know which options are available to you?
Values clarity subscale
e.g. Are you clear about which benefits matter most to you?
Support subscale
e.g. Do you have enough support from others to make a choice?

Scoring
To obtain a total score, the 10 items are summed, divided by 10 and multiplied by 25. Scores consequently range from 0-100. A score of 0 representing no decisional conflict and a score of 100 representing extremely high decisional conflict. A similar formula is used to obtain individual scores for each subscale, as described below:

- Uncertainty subscale:

Items 9 and 10 are summed, divided by 2 and multiplied by 25. Scores range from 0 to 100. A score of 0 indicates that the participants feels extremely certain about their best choice, a score of 100 indicates that the participant feels extremely uncertain about their best choice.

- Informed subscale:

Scores from items 1, 2 and 3 are summed, divided by 3 and multiplied by 25. Scores range from 0-100. A score of 0 indicates the participant feels extremely informed, a score of 100 indicates the participant feels extremely uninformed.

- Values clarity subscale:

Scores from items 4 and 5 are summed, divided by 2 and multiplied by 25. Scores range from 0-100. A score of 0 indicates the participant feels extremely clear about

personal values for benefits and risks/side effects, a score of 100 indicates the participant feels extremely unclear about personal values.

- Support subscale:

Scores from items 6, 7 and 8 are summed, divided by 3 and multiplied by 25. Scores range from 0-100. A score of 0 indicates participants feels extremely supported in decision-making, a score of 100 indicates the participant feels extremely unsupported in decision-making.

Psychometric properties

The scale has demonstrated good internal consistency with an alpha coefficients above 0.80 reported (Allen et al., 2008; Linder et al., 2011). The scale has also demonstrated some evidence of good construct validity with Pearson correlation coefficients exceeding 0.40 and has been shown to discriminate between individuals who had made a decision and those who had not (Linder et al., 2011). Responsiveness to change has also been reported following the implementation of a decision aid (O'Connor, 1993). The scale has been used for individuals facing a variety of healthcare decisions. For the full scale see Appendix K.

5.6.1.3 Alternate Decisional Conflict Scales

As mentioned previously, two alternate decisional conflict scales were available which were not employed in the current study. These include a Question Format Decisional Conflict Scale: (16 item, 5 response categories) and the SURE test version for clinical practice (4 items, 2 response categories) (O'Connor, 1993). The Traditional DCS was preferred to the Question Format DCS due to the fact that the latter scale remains relatively untested and psychometric properties were not available. Findings relating to the psychometric properties of the SURE test have also been limited, with moderate internal consistency being demonstrated for both French (α=0.54) and English speaking female patients (α=0.65) in a study looking at the use of decision aids for a variety of health conditions (Legare et al. 2010). Furthermore, the use of this scale was not considered appropriate, as it was mainly developed as a shortened decisional conflict scale, more suited to everyday clinical practice.

5.6.2 Modified Child Dental Anxiety Scale (MCDAS) (Wong et al., 1998)

A number of self-completed measures of child anxiety have been described in the existing literature, with the Modified Child Dental Anxiety Scale (MCDAS) (Wong et al., 1998) generally accepted as one of the most favoured scales for use. Indeed, a recent systematic review of the literature identified a total of nine child dental anxiety measures and reported that the MCDAS was used in 10 of the 60 studies included in the review (Porritt et al., 2013). The scale has been used with young people aged 4-17 years. The MCDAS includes eight questions used to assess dental anxiety in children and young people (see Appendix L). Participants are asked how they would feel about specific dental procedures such as extraction (e.g. *having a tooth taken out*), general anaesthesia (e.g. *being put to sleep to have treatment*) and injections (e.g. *having an injection in the gum*). The measure has been derived from Corah's Dental Anxiety Scale (Corah, 1969) and responses are measured using a five-point likert scale, where respondents use a tick box response to indicate their response (1=relaxed/not worried, 2=very slightly worried, 3=fairly worried, 4=worried a lot, 5=very worried).

Scoring

Total scores on the MCDAS range from 8 (little or no dental anxiety) to 40 (extreme dental anxiety). A cut-off point of >26 has been reported as defining a child as dentally anxious (Porritt et al., 2013). However, this cut-off point remains somewhat empirical and lacking in clinically meaningful correlations.

Reliability and validity

This measure has been demonstrated to have good internal consistency (Cronbach's alpha=0.78-0.84), and varying test-retest reliability (r=0.5-0.1). Concurrent validity has also been demonstrated through correlations with the Children's Fear Survey Schedule Dental Subscale (r=0.8) (Cuthbert and Melamed, 1982), the revised Smiley faces programme (r=0.6) (Buchanan, 2005) and the Dental Anxiety Scale (r=0.7) (Corah, 1969; Porritt et al., 2013).

5.6.3 Knowledge Scale (O'Connor, 2000)

This scale was adapted from the Knowledge questionnaire provided through the Ottawa Decision Support Framework (O'Connor, 2000). The original scale consists

of 32 statements relating to potential risks, benefits and side effects associated with the available treatment options (see Appendix M).

Scoring

Respondents are asked to indicate whether they believe each statement to be 'true', 'false', or whether they are 'unsure'. A score of 1 is given to each correct response. Items which are answered incorrectly are scored as 0. Similarly, a score of 0 is also given to items in which the respondent answers 'unsure'. Total scores can either be presented as a mean knowledge score or converted to a percentage of correct responses.

Reliability and validity

This scale has been shown to demonstrate good internal consistency with a Cronbach's alpha of 0.82 (Man-Son-Hing et al., 1999) and 0.83 (O'Connor et al., 1998a; O'Connor et al, 1998b) and content validity (O'Connor et al., 1998a; Fiset et al., 2000; Grant et al., 2001; Mitchell et al., 2001; Cranney et al., 2002; Stacey et al., 2003).

5.6.4 Acceptability Scale (O'Connor and Cranney, 2000)

This scale was adapted from the acceptability questionnaire developed through the Ottawa Decision Support Framework (for the full scale see Appendix N). The tool includes a series of 10 statements and questions relating to participants' perceptions of the following:

1. The way the information was presented
2. The length of the aid
3. The amount of information included
4. The balance of the information
5. The usefulness of the information
6. Ease of use
7. Impact on the decision-making process (i.e. did it make it more easy or more difficult)
8. Whether enough information was included to help make a choice
9. What they liked about the aid
10. What could be improved

The original scale was developed for a decision aid looking at therapy options for osteoporosis. For the purpose of the present study, minor changes were made to all items. The main revisions made to the original scale related to item 1, as the original scale asked participants to judge the way the information was presented on:

- Impact of osteoporosis
- Risk factors
- Types of research studies
- Self-care options
- Evidence about self-care
- Medication options
- Evidence about medications
- Stories about others

As many of these statements were not relevant to the current study, these items were replaced, and the participant was simply asked to rate how they felt the information was presented in relation to inhalation sedation, IV sedation and GA. Further minor changes included changing the term 'worksheet' or 'presentation' to 'decision aid' where applicable and replacing all references to osteoporosis to refer to treatment under sedation or GA, this making the tool relevant for the current study.

The response format for the scale varies between questions. For example item 1 asks participants to circle one of four possible responses (poor, average, good, excellent), whereas items 2-8 use tick boxes to record patients responses. These response categories vary according to each item. Items 9 and 10 ask patients to write down the response to their items in their own words. Participants are also encouraged to provide extra written comments in response to items 5-8. It is suggested that responses to the acceptability scale should be reported descriptively in terms of the frequency of responses given to each item, with additional comments also reported to explore the acceptability of the decision aid. For these reasons, psychometric properties cannot be reported. However, it should be noted that the test has been previously used in a number of studies looking at the use of decision aids in relation to decisions about atrial fibrillation (Man-Son-Hing et al. 1996), hormone

replacement therapy (O'Connor et al. 1998), lung cancer (Fiset et al. 2000), prenatal testing (Drake et al. 1999), blood donation (Grant et al. 2001) and osteoporosis (Cranney et al. 2002). For the full acceptability scale used in the current study and the entire questionnaire booklet given to patients and parents/guardians, see Appendices O, P, Q and R.

5.6.5 Attendance

In addition to the measures described, it was felt that patient attendance may be a potential indicator of the positive outcomes associated with the use of a decision aid. It was also important to assess patient attendance when considering the feasibility of implementing and evaluating the decision aid in a secondary care setting. Thus patient progress was monitored and the following clinical outcomes were noted at dental appointments:

- Attended and completed treatment
- Attended and unable to complete treatment as planned (required further support, e.g. a GA)
- Failed to attend (if the appointment was cancelled and rescheduled the outcomes at this appointment were subsequently recorded)

5.7 Statistical analysis

Separate independent samples t-tests were used to determine the impact of the decision aid on measures of knowledge and anxiety. Due to the non-normal distribution of data, separate Mann-Whitney U tests were used to analyse the impact of the decision aid on measures of overall decisional conflict and associated sub scores. Acceptability of the decision aid and attendance were reported descriptively. All data were analysed using the statistical software package IBM SPSS Statistics for Macintosh, Version 22.0.

5.8 Results

5.8.1 Sample characteristics

Characteristics of the participants are displayed in Tables 13 and 14. Overall, the mean age of patients was 13 years (SD=1.71, range=10-16) and the mean age of

parents/guardians was 43 years (SD=8.01, range=30-62). Of the 29 parents/guardians taking part in the study, 3 of the participants failed to give any information regarding their age. Therefore pairwise deletion was used to exclude these 3 participants from the descriptive data regarding age. With regards to gender, the patient group was split equally between males and female, but the majority of parents/guardians were female (76.7%). The majority of each group identified themselves as White British, with one patient and parent describing themselves as White Irish. No other ethnic minority groups were represented in either sample.

Table 13: *Characteristics of patients included in the evaluation stage*

	Patients (n = 32)		
Age (years)	Mean	Standard Deviation	Range
	13	1.71	10-16
Gender	Males	Females	
	16 (50%)	16 (50%)	
Ethnicity	White British	White Irish	Other
	31 (97%)	1 (3%)	0 (0%)

Table 14: *Characteristics parents/guardians included in the evaluation stage*

	Parents/guardians (n = 30)		
Age (years)	Mean	Standard Deviation	Range
	44	8.01	30-62
Gender	Male	Females	
	7 (23.3%)	23 (76.7%)	
Ethnicity	White British	White Irish	Other
	29 (97%)	1 (3%)	0 (0%)

5.8.2 Knowledge

5.8.2.1 Reliability Analysis

Reliability refers to the consistency of scale and is commonly assessed through measures of internal consistency using Cronbach's alpha. The knowledge scale demonstrated good internal consistency for both patient, α=0.77 and parent guardian groups, α=0.80 (see Tables 15 and 16).

Table 15: *Internal consistency of the patient knowledge scale*

	Cronbach's Alpha
	0.77
Item	**Cronbach's Alpha if item deleted**
You won't have to wear a mask	0.78
You will need to have a needle in the gum	0.77
You will be asleep during treatment	0.75
You may have a light meal 2 hours before the appointment	0.77
You may not remember everything that happened	0.75
You will have to wear a mask	0.76
You should have a big meal just before the appointment	0.74
You will need to have a needle in the hand or arm	0.77
You won't need to have a needle in the gum	0.75
You will be awake during treatment	0.76
You will be asleep during treatment	0.75
You should not eat anything for six hours before the appointment	0.75
You will be able to go straight home afterwards	0.75
You won't need to have a needle in the hand or arm	0.77
There is a 1 in 10 chance of feeling sick afterwards	0.76

Table 16: *Internal consistency of the parent/guardian knowledge scale*

	Cronbach's Alpha
	0.80
Item	**Cronbach's Alpha if Item deleted**
He/she will have to wear a mask	0.76
He/she will need to have a needle in the gum	0.79
He/she will be asleep during treatment	0.78
He/she may have a light meal 2 hours before the appointment	0.81
He/she may not remember everything that happens	0.78
He/she will have to wear a mask	0.78
He/she should have a big meal just before the appointment	0.77
He/she will need to have a needle in the hand or arm	0.78
He/she won't need to have a needle in the gum	0.77
He/she will be awake during treatment	0.78
He/she will be asleep during treatment	0.79
He/she should not eat anything for six hours before the appointment	0.79
He/she will be able to go straight home afterwards	0.79
He/she won't need to have a needle in the hand or arm	0.78
There is a 1 in 10 chance of him/her feeling sick afterwards	0.79

5.8.2.2 Assumptions

An independent samples t-test was used to analyse differences in knowledge scores between the control and intervention groups. The basic assumptions of the t-test are described below.

Normal distributed data

One requirement of all parametric tests is that the samples are from normally distributed populations. Viewing a histogram of the sample data in the present study suggested that the data in this case were normally distributed for both patient and parent/guardian groups. To test this assumption the Kolmogorov-Smirnov test was

also applied to the data, with results verifying that the data were significantly normal for the patient sample, $D(31)=0.13$, $p > 0.05$ and parent/guardian sample, $D(30)=0.14$, $p > 0.05$. Significantly normal distribution was also indicated when consulting the Shapiro-Wilk test statistics for patient, $W(31)=0.96$, $p >0.05$ and parent data, $W(30)=0.96$, $p >0.05$.

Homogeneity of variance

This assumption states that variances throughout the data are equal and this is tested using the Levene's test. Once again a non-significant value suggested that this assumption had not been violated for patient, $F(1, 29)=0.02$, $p>0.05$ or parent/guardian groups, $F(1, 28) = .08$, $p>0.05$.

Independence

A further assumption is that scores are independent and there was no indication that any observation was influenced by another.

Interval data

It was also assumed that intervals on the scale used to measure knowledge were equal.

Missing data

All questionnaire data were complete with the exception of data from one participant who failed to complete 10 of the 15 knowledge items included in the scale. For these reasons, pairwise deletion was implemented, meaning that these data were excluded from this particular analysis.

5.8.2.3 Main findings

On average, significantly higher knowledge scores were demonstrated by patients who received the decision aid (Mean=9.93, SE=0.79) when compared to patients in the control group (Mean=6.59, SE=0.77, $t(19)=-2.99$, $p<0.05$, $r=0.48$). A medium effect size was noted. Parents/guardians in the intervention group (Mean=10.62, SE=0.92) also displayed significantly higher levels of knowledge than parents/guardians in the control group (Mean=7.89, SE=0.75, $t(28) =-2.33$, $p<0.05$, $r=0.39$). Once again a medium effect size was recorded (see Table 17).

Table 17: *Differences in levels of knowledge between the control and intervention groups*

	N	Mean	Standard Deviation	Standard Error Mean	95% Confidence Interval of the means		P value	Effect size
					Lower	Upper		
Patients								
Control	17	6.59	3.18	0.77	4.95	8.22	0.01	0.48
Intervention	14	9.93	2.97	0.79	8.21	11.65		
Parents/ guardians								
Control	17	7.89	3.08	0.75	6.54	9.11	0.03	0.39
Intervention	13	10.62	3.31	0.92	8.37	13.01		

P value refers to independent samples t-test

5.8.2.4 Individual items

Table 18 demonstrates the mean score for each individual item recorded in the scale. Data here shows that, overall, patients scored highest on item 11 (Mean=0.84) with the majority of participants correctly identifying that 'you will be asleep during treatment' with GA. The lowest scoring item overall for patients was item 15 (Mean=0.19), which asks participants to correctly identify whether there is 'a 1 in 10 chance of feeling sick' following treatment with GA.

The highest and lowest scoring items for the patient control group were also items 11 (Mean=0.82) and 15 (Mean=0.06) respectively. The highest scoring items in the intervention group were items 6, 7 and 10, each with a mean score of 0.93. All three of these items related to knowledge of dental treatment with inhalation sedation. The lowest scoring item for the intervention group on average was once again item 15 (Mean=0.19). The biggest difference in mean scores between the patient intervention (Mean=0.93) and the patient control group (Mean=0.39) was recorded for item 7, this suggesting that the decision aid had the biggest impact on knowledge regarding pre-operative fasting in relation to inhalation sedation.

Table 18: *Mean patient scores for the individual items on the knowledge scale*

Item	Control	Intervention	Overall
IV sedation:			
1.You won't have to wear a mask	0.47	0.5	0.48
2.You will need to have a needle in the gum	0.41	0.5	0.45
3. You will be asleep during treatment	0.35	0.57	0.45
4. You may have a light meal 2 hours before the appointment	0.24	0.43	0.32
5. You may not remember everything that happened	0.53	0.86	0.68
Inhalation sedation:			
6. You will have to wear a mask	0.53	0.93	0.71
7. You should have a big meal just before the appointment	0.39	0.93	0.77
8. You will need to have a needle in the hand or arm	0.35	0.57	0.45
9. You won't need to have a needle in the gum	0.29	0.64	0.45
10.You will be awake during treatment	0.47	0.93	0.68
GA:			
11. You will be asleep during treatment	0.82	0.86	0.84
12. You should not eat anything for six hours before the appointment	0.53	0.86	0.68
13. You will be able to go straight home afterwards	0.41	0.43	0.42
14. You won't need to have a needle in the hand or arm	0.47	0.57	0.52
15. There is a 1 in 10 chance of feeling sick afterwards	0.06	0.36	0.19

Table 19 shows that on average, the highest scoring item for parents/guardians overall was once again item 11 (Mean=0.93) and the lowest scoring was item 15 (Mean=0.07). When taking into account individual groups, the control group also scored highest on item 11 (Mean=0.94) and lowest on item 15 (Mean=0). However, items 7, 11 and 12 scored highest on average in the intervention group (Mean=0.92). Item 15 was once again the most frequently incorrectly answered question on average for the intervention group (Mean=0.15). The biggest difference in mean scores

between the parent/guardian intervention group (Mean=0.77) and the parent/guardian control group (Mean=0.35) was recorded for item 1. This item asked parents/guardians to correctly identify whether their child would have to wear a mask when undergoing treatment with IV sedation.

Table 19: *Mean parent/guardian scores for the individual items on the knowledge scale*

Item	Control	Intervention	Overall
IV sedation			
1. He/she will have to wear a mask	0.35	0.77	0.53
2. He/she will need to have a needle in the gum	0.41	0.69	0.53
3. He/she will be asleep during treatment	0.59	0.54	0.57
4. He/she may have a light meal 2 hours before the appointment	0.18	0.38	0.27
5. He/she may not remember everything that happens	0.53	0.77	0.63
Inhalation sedation:			
6. He/she will have to wear a mask	0.71	1.00	0.83
7. He/she should have a big meal just before the appointment	0.65	0.92	0.77
8. He/she will need to have a needle in the hand or arm	0.76	0.69	0.73
9. He/she won't need to have a needle in the gum	0.53	0.62	0.57
10. He/she will be awake during treatment	0.53	0.85	0.67
GA:			
11. He/she will be asleep during treatment	0.94	0.92	0.93
12. He/she should not eat anything for six hours before the appointment	0.76	0.92	0.83
13. He/she will be able to go straight home afterwards	0.53	0.62	0.57
14. He/she won't need to have a needle in the hand or arm	0.41	0.77	0.57
15. There is a 1 in 10 chance of him/her feeling sick afterwards	0.00	0.15	0.07

5.8.3 Anxiety

5.8.3.1 Reliability analysis

The anxiety scale (MCDAS) demonstrated good internal consistency, α=0.89, with the alpha only increasing marginally if items 7 or 8 were removed (see Table 20).

Table 20: *Internal consistency of the anxiety scale (MCDAS)*

	Cronbach's Alpha
	0.89
Item	**Cronbach's Alpha if item deleted**
1. Going to the dentist generally?	0.87
2. Having your teeth looked at?	0.87
3. Having teeth scraped and polished?	0.87
4. Having an injection in the gum?	0.87
5. Having a filling?	0.86
6. Having a tooth taken out?	0.87
7. Being put to sleep to have treatment?	0.90
8. Having a mixture of 'gas and air' which will help you feel comfortable for treatment but cannot put you to sleep?	0.90

5.8.3.2 Assumptions

An independent samples t-test was used to analyse differences in anxiety between the control and intervention groups. Non-significant values given by the Kolmogorov-Smirnov test, $D(32)=0.12$, $p>0.05$. The Shapiro-Wilk test, $W(32)=0.96$, $p>0.05$ once again confirmed that the data were normally distributed. Homogeneity of variance was also indicated, $F(1, 30)=0.97$, $p>0.05$. Furthermore all scores collected were independent and interval scale data were collected. No missing data was recorded.

5.8.3.3 Main findings

On average, patients who did not receive the decision aid (Mean=22.88, SE=2.32) experienced greater anxiety than patients who did (Mean=20.20, SE=1.98). However, this difference was not significant and the effect size was small, $t(30)=0.89$, $p>0.05$, $r=0.16$.

Table 21: *Differences in levels of anxiety between the control and intervention groups*

	N	Mean	Standard Deviation	Standard Error Mean	95% Confidence Interval of the means		P value	Effect size
					Lower	Upper		
Control	17	22.88	9.21	2.32	18.15	27.62	0.38	0.16
Intervention	15	20.20	7.66	1.98	15.96	25.04		

P value refers to independent samples t-test

5.8.3.4 Individual items

Table 22 shows that when consulting individual items, on average, patients were most worried about having teeth extracted, with item 6 demonstrating the highest scores on average for both the control group (Mean=3.71) and intervention group (Mean=3.53). Each item was scored from 1-5. On average, item 2 scored lowest overall (Mean=1.39) and for the control group (Mean=1.54). This suggested patients were least anxious about having their teeth 'looked at'. On average, participants in the intervention group scored lowest on item 3 (Mean=1.80), which relates to how worried patients were about having their teeth 'scraped and polished'. The biggest difference between mean scores for the intervention group and the control group was recorded for item 8 which asks children to state how worried they are about receiving inhalation sedation.

Table 22: *Mean patient scores for the individual items on the anxiety scale*

Item	Control	Intervention	Overall
1. Going to the dentist generally?	2.41	2.27	2.34
2. Having your teeth looked at?	2.12	1.87	2.00
3. Having teeth scraped and polished?	2.47	1.80	2.16
4. Having an injection in the gum?	3.59	3.13	3.38
5. Having a filling?	3.18	3.00	3.09
6. Having a tooth taken out?	3.71	3.53	3.63
7. Being put to sleep to have treatment?	2.29	2.47	2.38
8. Having a mixture of 'gas and air' which will help you feel comfortable for treatment but cannot put you to sleep?	3.12	2.13	2.66

5.8.4 Decisional conflict

5.8.4.1 Reliability analysis

The low literacy decisional conflict scale as a whole demonstrated good internal consistency in relation to the patient groups, α=0.80 (see Table 23).

Table 23: *Internal consistency of the low literacy decisional conflict scale*

	Cronbach's Alpha
	0.80
Item	**Cronbach's Alpha if item deleted**
Do you know which options are available to you?	0.75
Do you know the benefits of each option?	0.75
Do you know the risks and side effects of each option?	0.74
Are you clear about which benefits matter most to you?	0.80
Are you clear about which risks and side effects matter most to you?	0.77
Do you have enough support from others to make a choice?	0.80
Are you choosing without pressure from others?	0.85
Do you have enough advice to make a choice?	0.77
Are you clear about the best choice for you?	0.79
Do you feel sure about what to choose?	0.81

The scale used to measure levels of decisional conflict for parents/guardians demonstrated excellent overall internal consistency, α=0.95 (see Table 24).

Table 24: *Internal consistency of the traditional decisional conflict scale*

	Cronbach's Alpha
	0.95
Item	**Cronbach's Alpha if Item deleted**
I know which options are available to me.	0.95
I know the benefits of each option	0.95
I know the risks and side effects of each option	0.95
I am clear about which benefits matter most to me	0.95
I am clear about which risks and side effects matter most to me	0.95
I am clear about which is more important to me (the benefits or the risk and side effects)	0.95
I have enough support from others to make a choice	0.95
I am choosing without pressure from others	0.95
I have enough advice to make a choice	0.95
I am clear about the best choice	0.95
I feel sure about what to choose	0.95
This decision is easy for me to make	0.95
I feel I have made an informed choice	0.95
My decision shows what is important to me	0.95
I expect to stick with my decision	0.95
I am satisfied with my decision	0.95

5.8.4.2 Assumptions

When analysing the distribution of sample data for decisional conflict, the Kolmogorov-Smirnov test suggested that the data were normally distributed for parent/guardian data, $D(30)=0.15$, $p>0.05$. However, contrasting results from the Shapiro-Wilk test statistics suggested the distribution of data was significantly non-normal $W(30)=0.89$, $p<0.01$. A histogram of the sample data supported the Shapiro-Wilk test statistic and it was determined that the data on decisional conflict were positively skewed for the parent/guardian group. A histogram of the sample data relating to patients' decisional conflict also suggested the data was positively skewed.

The test statistics for the Kolmogorov-Smirnov test, $D(32)=0.18$, $p<0.01$ and Shapiro-Wilk test, $W(32)=0.84$, $p<0.05$, confirmed scores deviated significantly from normal distribution.

In an attempt to reduce the positive skew, a log transformation was applied to the data. As it is impossible to create a log value for zero or negative scores a constant was added to all the data prior to applying the transformation. Following the log transformation, the data were still judged to be significantly skewed, so an alternate square root transformation was applied, with a constant once again added to the data before being transformed. Once again the data remained positively skewed so a Mann-Whitney U test was used to analyse differences between the two groups. The Mann-Whitney U Test is a non-parametric equivalent of the independent t-test, which makes no assumptions regarding the distribution of the data.

5.8.4.3 Main findings

There were no significant differences in measures of decisional conflict between patients who received the decision aid (Median=5) and patients who solely received routine clinical counselling (Median=20) and the effect size was small, $U=90$, $p>0.05$, $r=0.26$. Differences between parents/guardians who received the decision aid (Median=17.19) and those who did not (Median=21.88) were also non-significant and the effect size was small, $U=97$, $p>0.05$, $r=0.10$.

5.8.4.4 Individual items

Table 25 shows that on average item 3 scored highest in both the patient intervention (Mean=1.07) and patient control group (Mean=1.53). This item formed part of the 'informed' subscale and asked patients if they felt they knew 'the risks and side effects of each option'. The lowest scoring item for the patient control group was item 7 (Mean=0.24), which asks patients if they are choosing 'without pressure from others'. Items 6 (Mean=0.13) and 9 (Mean=0.13) scored lowest for the intervention group. Item 6 relates to whether patients felt they had 'enough support from others to make a choice' and item 9 asks patients if they were 'clear about the best choice' for them. Overall, the lowest scoring items were items 7 (Mean=0.31) and 8 (Mean=0.31). Item 8 asked patients whether they felt they had 'enough advice' and forms part of the 'support' subscale with items 6 and 7. The greatest difference in mean scores between

the patient control group (Mean=0.82) and the patient intervention group (Mean=0.13) was recorded for item 9.

Table 25: *Mean patient scores for the individual items on the low literacy decisional conflict scale*

Item	Control	Intervention	Overall
1. Do you know which options are available to you?	0.71	0.40	0.56
2. Do you know the benefits of each option?	1.29	0.93	1.13
3. Do you know the risks and side effects of each option?	1.53	1.07	1.31
4. Are you clear about which benefits matter most to you?	0.82	0.80	0.81
5. Are you clear about which risks and side effects matter most to you?	1.29	0.80	1.06
6. Do you have enough support from others to make a choice?	0.35	0.13	0.25
7. Are you choosing without pressure from others?	0.24	0.40	0.31
8. Do you have enough advice to make a choice?	0.35	0.27	0.31
9. Are you clear about the best choice for you?	0.82	0.13	0.50
10. Do you feel sure about what to choose?	0.59	0.27	0.44

As seen in Table 26, on average parents/guardians scored item 1 lowest (Mean=0.5), which asked participants if they felt they knew 'which options were available'. Item 11, which asks if patients were 'sure about what to choose' (Mean=0.93) was scored highest overall. This score was still relatively low however, suggesting overall parents/guardians were quite certain about which option they preferred. Parents/guardians in the control group scored lowest on item 8 (Mean=0.47) and highest on items 6 (Mean=0.94) on average. Item 6 asked if the parent/guardian were clear about which values mattered most to them and item 8 relates to whether parents/guardians felt they were choosing without pressure. On average, parents/guardians in the intervention group scored lowest on item 2 (Mean=0.24) and highest on items 6 (Mean=0.77) and 10 (Mean=0.77). Item 2 asked if parents/guardians knew what the benefits of each option were and item 10 asked if participants were 'clear about the best choice'. The greatest difference in mean scores between the parent/guardian control group (Mean=0.82) and the parent/guardian intervention group (Mean=0.13) was also recorded for item 2, suggesting the decision

aid had the biggest impact on informing parents/guardians of the relative benefits of each option.

Table 26: *Mean parent/guardian scores for the individual items on the traditional decisional conflict scale*

Item	Control	Intervention	Overall
1. I know which options are available to me.	0.53	0.46	0.50
2. I know the benefits of each option	0.82	0.24	0.77
3. I know the risks and side effects of each option	0.82	0.69	0.77
4. I am clear about which benefits matter most to me	0.76	0.62	0.70
5. I am clear about which risks and side effects matter most to me	0.88	0.69	0.80
6. I am clear about which is more important to me (the benefits or the risk and side effects)	0.94	0.77	0.87
7. I have enough support from others to make a choice	0.58	0.69	0.63
8. I am choosing without pressure from others	0.47	0.62	0.53
9. I have enough advice to make a choice	0.82	0.69	0.77
10. I am clear about the best choice	0.82	0.77	0.80
11. I feel sure about what to choose	0.88	1.00	0.93
12. This decision is easy for me to make	0.82	0.69	0.77
13. I feel I have made an informed choice	0.65	0.46	0.57
14. My decision shows what is important to me	0.76	0.46	0.63
15. I expect to stick with my decision	0.76	0.46	0.63
16. I am satisfied with my decision	0.65	0.62	0.63

5.8.4.5 Treatment preferences

Both scales used to measure decisional conflict were preceded with a question about treatment preferences (see Appendices O, P, Q and R). Pairwise deletion was applied to the six patients and four parents/guardians who failed to respond to this item. As shown in table 27, 38.5% of patients stated that they would prefer treatment with

inhalation sedation, 11.5% stated they would prefer IV sedation, 30.8% suggested they would prefer GA and 19.2% of patients were unsure. Table 28 shows that 34.6% of parents/guardians preferred their child to have treatment under inhalation sedation, 23.1% preferred treatment under IV sedation, a further 23.1% stated they would prefer their child to have treatment with GA and 19.2% were unsure.

Table 27: *Treatment preferences for patients*

Treatment preference	Frequency	Percentage
Inhalation sedation	10	38.5
IV sedation	3	11.5
GA	8	30.8
Unsure	5	19.2

Table 28: *Treatment preferences for parents/guardians*

Treatment preference	Frequency	Percentage
Inhalation sedation	9	34.6
IV sedation	6	23.1
GA	6	23.1
Unsure	5	19.2

5.8.5 Decisional conflict subscales

5.8.5.1 Reliability analysis

When analysing the low literacy decisional conflict scale, the uncertainty, α=0.75, and informed subscales, α=0.88, demonstrated good internal consistency (see Table 29). In contrast, the internal consistency of the values subscale was poor α=0.58, and the support subscale was deemed to display extremely low internal consistency, α=0.16 (see Table 30). The alpha level of the support subscale would increase to α=0.44 if item 7 was removed, however this level of internal consistency could still be deemed unacceptable. The effect of removing an item would have on the internal consistency of the subscale could not be determined for both the informed support subscales. This is due to the fact that each subscale only contained two items.

Table 29: *Internal consistency of the low literacy informed subscale*

	Cronbach's Alpha
	0.88
Item	**Cronbach's Alpha if item deleted**
Do you know which options are available to you?	0.92
Do you know the benefits of each option?	0.75
Do you know the risks and side effects of each option?	0.79

Table 30: *Internal consistency of the low literacy support subscale*

	Cronbach's Alpha
	0.16
Item	**Cronbach's Alpha if Item Deleted**
Do you have enough support from others to make a choice	-0.29
Are you choosing without pressure from others	0.44
Do you have enough advice to make a choice	0.14

When analysing the traditional decisional conflict scale, good internal consistency was demonstrated for the subscales measuring feelings of being informed, α=0.86 (see Table 31) and uncertainty, α=0.87 (see Table 32). The values clarity, α=0.95 (see Table 33), support, α=0.90 (see Table 34) and effective decision, α=0.92 subscales (see Table 35) also displayed excellent levels of internal consistency.

Table 31: *Internal consistency of the traditional DCS informed subscale*

	Cronbach's Alpha
	0.86
Item	**Cronbach's Alpha if item deleted**
I know which options are available to me	0.91
I know the benefits of each option	0.65
I know the risks and side effects of each option	0.78

Table 32: *Internal consistency of the traditional DCS uncertainty subscale*

	Cronbach's Alpha
	0.87
Item	**Cronbach's Alpha if item deleted**
I am clear about the best choice	0.74
I feel sure about what to choose	0.87
This decision is easy for me to make	0.83

Table 33: *Internal consistency of the traditional DCS values clarity subscale*

	Cronbach's Alpha
	0.95
Item	**Cronbach's Alpha if item deleted**
I am clear about which benefits matter most to me	0.93
I am clear about which risks and side effects matter most to me	0.89
I am clear about which is most important to me	0.96

Table 34: *Internal consistency of the traditional DCS support subscale*

	Cronbach's Alpha
	0.90
Item	**Cronbach's Alpha if item deleted**
I have enough support from others to make a choice	0.79
I am choosing without pressure from others	0.89
I have enough advice to make a choice	0.87

Table 35: *Internal consistency of the traditional DCS effective decision subscale*

	Cronbach's Alpha
	0.92
Item	**Cronbach's Alpha if item deleted**
I feel I have made an informed choice	0.86
My decision shows what is important to me	0.90
I expect to stick with my decision	0.95
I am satisfied with my decision	0.87

5.8.5.2 Assumptions

When analysing several closely related dependent variables a Multivariate Analysis of Variance (MANOVA) is often implemented to ensure the familywise error rate is not inflated. When conducting analysis using a MANOVA, additional parametric assumptions of multivariate normality and homogeneity of covariances are required to be met. Multivariate normality refers to the normal distribution of the dependent variables collectively and because univariate normality is a requirement of multivariate normality, initial indications can be gained by once again looking at the Kolmogorov-Smirnov and Shapiro-Wilk test results. Homogeneity of covariances is an extension to the assumption of homogeneity of variance which has been previously discussed in this chapter. In addition to assuming that variances are equal throughout the data, it is also assumed that the covariance between the dependent variables is similar in each group. This assumption is tested by consulting the Box's M test, with a significant value suggesting the assumption has been violated.

With regards to multivariate normality, significant values for each of the subscales from the Kolmogorov-Smirnov and Shapiro-Wilk tests suggested that the data were not normally distributed (see Table 36), with histograms suggesting that in each case the data were positively skewed. Log and square root transformations of the data once again failed to significantly reduce the skew of the data for each dependent variable. With no viable non-parametric alternative to MANOVA being established in the literature, it was determined that the most appropriate solution would be to use several Mann Whitney U tests to analyse the data, with a Bonferonni correction applied post hoc. The Bonferroni correction method involves dividing the level of significance by the number of comparisons being made and is used to protect against the increased risk of type I error associated with conducted multiple comparisons on related data sets. A type I error refers to detecting a significant effect that is not actually present. A Bonferroni correction therefore attempts to eliminate this risk by setting a more conservative level of significance. The level of significance for this analysis was therefore set at 0.01 for both patient and parent/guardian groups.

Table 36: *Tests of normality for decisional conflict subscales*

	Kolmogorov-Smirnov			Shapiro-Wilk		
Patients						
	Statistic	df	P value	Statistic	df	P value
Uncertainty	0.41	32	<0.05	0.57	32	<0.05
Informed	0.30	32	<0.05	0.74	32	<0.05
Values clarity	0.32	32	<0.05	0.78	32	<0.05
Support	0.44	32	<0.05	0.60	32	<0.05
Parents/guardians						
Uncertainty	0.20	30	<0.05	0.86	30	<0.05
Informed	0.23	30	<0.05	0.86	30	<0.05
Values clarity	0.24	30	<0.05	0.84	30	<0.05
Support	0.26	30	<0.05	0.83	30	<0.05
Effective decision	0.26	30	<0.05	0.81	30	<0.05

5.9.5.3 Main findings

5.8.5.3.1 Uncertainty

Levels of uncertainty were not significantly different between patients who received the decision aid (Median=0) and patients who did not (Median=0), U=103.5, p>0.01, r=0.20. No significant differences in levels of uncertainty could be identified between parents/guardians who received the decision aid (Median=25) and those who didn't (Median =25), U=110.5, p>0.01, r=0.00. Effect sizes were small for both tests.

5.8.5.3.2 Informed

Patients who received the decision aid (Median=0) did not feel significantly more informed than patients assigned to the control group (Median=16.67), U=108.5, p>0.01, r=0.14. Differences in scores on the informed subscale between parents/guardians in the intervention (Median=8.33) and control groups (Median=25) were also non-significant, U=97.5, p>0.01, r=0.10. Effect sizes were small for both tests.

5.8.5.3.3 Values Clarity

Scores on the values clarity subscale were not significantly different between patients in the intervention group (Median=0) and control group (Median=25), U=103, p>0.01, r=0.18. Differences in measures of values clarity were also non-significant

between parents/guardians who received the decision aid (Median=25) and parents/guardians in the control group (Median=25), U=99, p>0.01, r=0.09. Effect sizes were small for both tests.

5.8.5.3.4 Support

Measures of support were not significantly different between patients who received the decision aid (Median=0) and patients who did not (Median=0) U=104.5, p>0.01, r=0.04. Once again, differences in how parents/guardians perceived their level of support were also non-significant between the intervention group (Median=0) and control group (Median=16.67) U=96, p>0.01, r=0.05. Effect sizes were small for both tests.

5.8.5.3.5 Effective decision

Scores on the effective decision subscale were not significantly different between parents/guardians in the intervention group (Median=0) and parents/guardians assigned to the control group (Median=25) and the effect size was small, U=90, p>0.01, r=0.17.

Table 37: *Differences in levels of decisional conflict between the control and intervention groups (patients)*

	N	Mean Rank	Median	Mean	Standard deviation	95% Confidence Interval for the mean		P value	Effect size
						Lower	Upper		
Informed									
Control	17	17.62	16.67	29.41	36.58	10.61	48.22	0. 44	0.14
Intervention	14	15.23	0.00	20.00	31.62	2.49	37.51		
Values Clarity									
Control	17	17.94	25.00	26.47	25.72	13.24	39.69	0.33	0.18
Intervention	14	14.87	0.00	20.00	33.00	1.72	38.27		
Support									
Control	17	16.76	0.00	7.84	13.33	.99	14.70	0.90	0.04
Intervention	14	16.20	0.00	6.67	12.28	-0.13	13.47		
Uncertainty									
Control	17	17.91	0.00	17.65	30.32	2.06	33.23	0.28	0.20
Intervention	14	14.90	0.00	5.00	10.35	-0.73	10.73		
Total Decisional Conflict									
Control	17	18.71	20.00	20.00	18.71	10.38	29.62	0.15	0.26
Intervention	14	14.00	5.00	13.00	18.01	3.03	22.97		

P value refers to Mann-Whitney U test

Table 38: *Differences in levels of decisional conflict between the control and intervention groups (parents/guardians)*

	N	Mean Rank	Median	Mean	Standard deviation	95% Confidence Interval for the mean		P value	Effect size
						Lower	Upper		
Uncertainty									
Control	17	15.50	25.00	21.08	22.65	9.43	32.73	1.00	0.00
Intervention	13	15.50	25.00	20.51	20.30	8.24	32.78		
Informed									
Control	17	16.26	25.00	18.14	15.66	10.09	26.19	0.60	0.10
Intervention	13	14.50	8.33	12.18	13.86	3.80	20.56		
Values Clarity									
Control	17	16.18	25.00	21.57	21.05	10.74	32.39	0.63	0.09
Intervention	13	14.62	25.00	17.31	18.77	5.96	28.65		
Support									
Control	17	15.85	16.67	15.69	14.40	8.28	23.09	0.81	0.05
Intervention	13	15.04	0.00	16.67	20.97	3.99	29.34		
Effective Decision									
Control	17	16.71	25.00	17.65	15.82	9.51	25.78	0.38	0.17
Intervention	13	13.92	0.00	12.50	17.49	1.93	23.07		
Total Decisional Conflict									
Control	17	16.29	21.88	18.75	15.00	11.04	26.46	0.58	0.10
Intervention	13	14.46	17.19	16.23	16.42	6.30	26.15		

P value refers to Mann-Whitney U test

5.8.6 Acceptability

5.8.6.1 Patient perspectives

Three patients failed to complete the acceptability questionnaire, with one participant failing to respond to question 4, one patient failing to respond to questions 5, 6, and 7 and one patient failing to respond to question 5. Once again, pairwise deletion was applied. As seen in Tables 39, 40 and 41, in response to item 1, over half of the respondents declared that the information given regarding the three options was 'good', with over 20% describing it as 'excellent'.

Table 39: *Patient responses to item 1a: Please circle either 'poor', 'average', 'good', or 'excellent' to show us what you think about the way the information was presented on gas and air*

	Frequency	Percent	Cumulative Percent
Poor	0	0	0
Average	1	6.7	6.7
Good	10	66.7	73.3
Excellent	4	26.7	100

Table 40: *Patient responses to item 1b: Please circle either 'poor', 'average', 'good', or 'excellent' to show us what you think about the way the information was presented on IV sedation*

	Frequency	Percent	Cumulative Percent
Poor	0	0	0
Average	3	20	20
Good	9	60	80
Excellent	3	20	100

Table 41: *Patient responses to item 1c: Please circle either 'poor', 'average', 'good', or 'excellent' to show us what you think about the way the information was presented on general anaesthetic*

	Frequency	Percent	Cumulative Percent
Poor	0	0	0
Average	2	13.3	13.3
Good	8	53.3	66.7
Excellent	5	33.33	100

In response to items 2 and 3, the majority of the patients felt the length (93.3%) and amount of information included in decision aid (86.7%) was 'just right' (see Tables 42 and 43). As seen in Table 42, 6.7% of respondents felt that the length of the decision aid was 'too short' and no participants deemed the decision aid as 'too long'. Table 43 shows that 6.7% of patients described the amount of information as 'too little' and a further 6.7% described the amount of information as 'too much'.

Table 42: *Patient responses to item 2: Did you think the length of the decision aid was…*

	Frequency	Percent	Cumulative Percent
Too long	0	0	0
Too short	1	6.7	6.7
Just right	14	93.3	100

Table 43: *Patient responses to item 3: Did you think the amount of information in the decision aid was…*

	Frequency	Percent	Cumulative Percent
Too much	1	6.7	6.7
Too little	1	6.7.	13.3
Just right	13	86.7	100

As seen in Table 44, 78.6% described the decision aid as 'balanced', with 14.3 % of respondents suggesting the decision aid was slanted towards choosing inhalation sedation and 7.1 % of respondents stating that they felt the decision aid was slanted towards choosing treatment with IV sedation. No patients believed the decision aid was slanted towards choosing dental treatment under GA.

Table 44: *Patient responses to item 4: Did you find the decision aid was…*

	Frequency	Percent	Cumulative Percent
Slanted towards having dental treatment with gas and air?	2	14.3	14.3
Slanted towards having dental treatment with IV sedation?	1	7.1	21.4
Slanted towards having dental treatment with general anaesthesia?	0	0	21.4
Balanced?	11	78.6	100

Responses to item 5 and show that 84.6% of respondents felt the decision aid was useful, with the remaining 15.4% suggesting it wasn't (see Table 45).

Table 45: *Patient responses to item 5: Did you find the decision aid useful when making the decision about having dental treatment with sedation or general anaesthesia?*

	Frequency	Percent	Cumulative Percent
Yes	11	84.6	84.6
No	2	15.4	100

Table 46 shows that 100% of patients believed the decision aid was easy to use when responding to item 6.

Table 46: *Patient responses to item 6: Did you find the decision aid was….*

	Frequency	Percent	Cumulative Percent
Easy to use	14	100	100
Difficult to use	0	0	100

When discussing the impact of the decision aid in item 7, 78.6% of respondents felt it made the decision easier, with the remaining 21.4% stating that they felt the decision aid made the decision more difficult (see Table 47).

Table 47: *Patient Responses to item 7: Did the decision aid make the decision….*

	Frequency	Percent	Cumulative Percent
Easier	11	78.6	78.6
More difficult	3	21.4	100

Finally, Table 48 shows that all participants (100%) believed the decision aid included enough information to help a young person decide whether to have dental treatment with inhalation sedation, IV sedation or GA.

Table 48: *Patient responses to item 8: Do you think we included enough information to help a young person decide whether to have dental treatment with sedation or general anaesthesia?*

	Frequency	Percent	Cumulative Percent
Yes	15	100	100
No	0	0	100

5.8.6.2 Parental perspectives

One parent/guardian failed to complete the entire acceptability questionnaire, with no response given for question 7. Once again pairwise deletion was used when reporting the descriptive statistics. Tables 49, 50 and 51 shows that in response to item 1, The majority of parents/guardians believed the information given on inhalation sedation (53.8%), IV sedation (61.5%) and GA (53.8%) was 'good'. Data also shows that 15.4% of participants rated the information regarding IV sedation and GA as 'average' and that 23.1 % of respondents rated the information regarding inhalation sedation as 'average'. Only information given regarding treatment under GA was described as poor (7.7%).

Table 49: *Parent/guardian responses to item 1a: Please circle either 'poor', 'average', 'good', or 'excellent' to show us what you think about the way the information was presented on gas and air*

	Frequency	Percent	Cumulative Percent
Poor	0	0	0
Average	3	23.1	23.1
Good	7	53.8	76.9
Excellent	3	23.1	100

Table 50: *Parent/guardian responses to item 1b: Please circle either 'poor', 'average', 'good', or 'excellent' to show us what you think about the way the information was presented on IV sedation*

	Frequency	Percent	Cumulative Percent
Poor	0	0	0
Average	2	15.4	15.4
Good	8	61.5	76.9
Excellent	3	23.1	100

Table 51: *Parent/guardian responses to item 1c: Please circle either 'poor', 'average', 'good', or 'excellent' to show us what you think about the way the information was presented on general anaesthetic*

	Frequency	Percent	Cumulative Percent
Poor	1	7.7	7.7
Average	2	15.4	23.1
Good	7	53.8	76.9
Excellent	3	23.1	100

In response to items 2 and 3, Tables 52 and 53 shows that 92.3% of the respondents deemed the length and amount of information given as 'just right'. 7.7% of participants described the length of the decision aid as 'too short' and the amount of information as 'too little'. No participants deemed the length of the decision aid as 'too long' or the amount of information included as 'too much'.

Table 52: *Parent/guardian responses to item 2: Did you think the length of the decision aid was…*

	Frequency	Percent	Cumulative Percent
Too long	0	0	0
Too short	1	7.7	7.7
Just right	12	92.3	100

Table 53: *Parent/guardian responses to item 3: Did you think the amount of information in the decision aid was…*

	Frequency	Percent	Cumulative Percent
Too much	0	0	0
Too little	1	7.7	7.7
Just right	12	92.3	100

Table 54 shows that 92.3% of participants deemed the presentation of information was 'balanced', with 7.7% of participants describing the information included as slanted towards choosing IV sedation and 0% of participants suggesting that information was slanted towards choosing inhalation sedation.

Table 54: *Parent/guardian responses to item 4: Did you find the decision aid was…*

	Frequency	Percent	Cumulative Percent
Slanted towards having dental treatment with gas and air?	0	0	0
Slanted towards having dental treatment with IV sedation?	1	7.7	7.7
Slanted towards having dental treatment with general anaesthesia?	12	92.3	100
Balanced?	0	0	100

Table 55: *Parent/guardian responses to item 5: Did you find the decision aid useful when making the decision about your child having dental treatment with sedation or general anaesthesia?*

	Frequency	Percent	Cumulative Percent
Yes	10	76.9	76.9
No	3	23.1	100

In response to items 5 -7, 76.9 % of parents/guardians described the decision aid as useful and 100% of respondents thought the decision aid was 'easy to use' and made the decision 'easier' (see Tables 55, 56 and 57).

Table 56: *Parent/guardian responses to item 6: Did you find the decision aid was…*

	Frequency	Percent	Cumulative Percent
Easy to use	13	100	100
Difficult to use	0	0	100

Table 57: *Parent/guardian responses to item 7: Did the decision aid make the decision…*

	Frequency	Percent	Cumulative Percent
Easier	12	100	100
More difficult	0	0	100

As seen in Table 58, 92.3% of participants also believed the decision aid included sufficient information to help a young person faced with the decision to undergo dental treatment with either sedation or GA.

Table 58: *Parent/guardian responses to item 8: Do you think we included enough information to help a young person decide whether to have dental treatment with sedation or general anaesthesia?*

	Frequency	Percent	Cumulative Percent
Yes	12	92.3	92.3
No	1	7.7	100

5.8.6.3 Additional comments

The acceptability questionnaire also provided space for respondents to leave comments under items 5, 6 and 7. Respondents were also encouraged to provide further written information regarding what they liked about the decision aid and suggestions on how to improve the decision aid on items 9 and 10. Patient and parent responses to these items are detailed below.

Table 59: *Additional comments given in relation to item 5*

5. Did you find the decision aid useful when making your decision about having dental treatment with sedation or general anaesthesia?	
Patient comments	**Parent/guardian comments**
I would now prefer to go to sleep	Have not been given an option!
Not useful	Answered extra questions
Unsure	Clear precise, covered all aspects
I had already decided	We had already decided what we wanted to do based on a bad experience in the past

Table 60: *Additional comments given in relation to item 6*

6. Did you find the decision aid was: **- Easy to use?** **- Difficult to use?**	
Patient comments	**Parent/guardian comments**
It was fine to use	
The options were discussed in a pre-sedation appointment, no aids	

Table 61: *Additional comments given in relation to item 7*

7. Did the decision aid make the decision: **- More easy?** **- More difficult?**	
Patient comments	**Parent/guardian comments**
Yes	Again, no option given to us.
Already decided.	Daughter had already made decision
	Helped reassure me that I/we had made the best choice

Table 62: *Additional comments given in relation to item 8*

8. Do you think we included enough information to help a young person decide whether to have dental treatment with sedation or general anaesthesia?	
Patient comments	**Parent/guardian comments**
A child friendly leaflet or letter explaining the 3 methods in detail would help	Understood the booklet very well

Table 63: *Additional comments given in relation to item 9*

9. What do you like about the decision aid?	
Patient comments	**Parent/guardian comments**
It helped me decide if I want a sedation, laughing gas or go to sleep	An informative leaflet
Yeah it was alright	Good, clear info for older children (and parents) unsure if suitable for younger children (under 7)
Had an appointment at Dentistry hospital not an aid?	Explained in simple terms, no jargon and in clear format so that easy comparisons could be made for all 3 options
It was very easy to read and understand the information	I liked the way it explained everything in a way children can understand and also the parent.
Easy to read	I understood what it meant it wasn't saying anything was right or wrong, just gave the facts about the types of treatment
There is plenty of information about each of methods and explains fully about the positives and negatives	Informative and easy language aimed towards child.
	Informative
	A lot of useful information

Table 64: Additional comments given in relation to item 10

10. What suggestions do you have to improve the decision aid?	
Patient comments	**Parent/guardian comments**
None, it was fine	More basic version for younger children
Gave more info about it	More pictures to help younger or disabled children understand. Maybe larger print too.
Appointments should be shorter times	
For young people it is a nervous time and both parents and adult need to know what is best for a child	

In general, the additional comments provided by the patients and parents/guardians reinforced the qualitative findings that the decision aid was comprehensible and beneficial to the decision-making process. For example, as demonstrated in Table 63, when asked what they liked about the decision aid, participants repeatedly declared the decision aid as 'informative' and 'easy to read'. In terms of negative feedback, suggestions relating to the actual decision aid were limited, with one child stating that they required more information still and further comments from parents/guardians suggesting the inclusion of pictures, larger print and more basic information may be beneficial if the decision aid was to be aimed at younger patients (see Table 64). Interestingly, several participants also questioned the appropriateness of the decision aid through their comments that a treatment decision had already been made. These assertions are demonstrated in separate responses to items by both patients and parents/guardians detailed in Tables 59 and 61. These findings once again question the appropriateness of delivering the decision aid in secondary care. In addition to this, further evidence relating to the potential importance of time in the decision-making process was also highlighted in Table 64 through one patient's suggestion that 'Appointments should be shorter times'. These additional comments and how they relate to the relevance of the current research and the wider literature will be discussed in Chapter Six.

5.8.7 Feasibility

5.8.7.1 Attendance

To determine the feasibility of implementing and evaluating the decision aid in a secondary care setting, patients who originally consented to take part in the study were followed throughout their care pathway, with data collected in relation to the number of appointments and attendance patterns. Of the 44 patients originally consenting to take part in the study, 32 of these patients completed and returned the questionnaire. Figure 6 displays the pathway of all 44 patients who were initially recruited to take part in the study. As shown here, following their new patient assessment, five patients were not referred for a pre-sedation/prevention appointment. Of these patients, one was discharged from the hospital, one received treatment under local anaesthetic, without sedation or GA, and three patients received emergency treatment under inhalation sedation. Of the remaining 39 patients referred for pre-

sedation/GA, 15 failed to attend the initial appointment and four patients who did attend were referred for additional pre-sedation appointments. As shown in Figure 6, a further two patients was discharged mid-way through the care pathway, two more patients received emergency treatment under inhalation sedation and complete data was missing for nine patients. Only ten of the original 44 patients passed through the first two stages of the care pathway (new patient appointment and pre-sedation/prevention appointment) and completed treatment with either sedation or GA. Furthermore, 15 patients remained on the waiting list for final treatment at the time of this study's completion. The study had originally intended to assess impact of decision aid on attendance and compliance with treatment, however due to the lack of complete data, this analysis was not feasible.

As shown in Table 65, there was a higher percentage of patients who completed treatment under inhalation sedation (13.6%) in comparison to patients who completed treatment with IV sedation (4.5%) or GA (4.5%). Furthermore, there were a higher number of patients remaining on the waiting list for treatment with inhalation sedation (22.7%) when the study finished, than for IV sedation (9.1%) or GA (2.3%). Of the original 44 patients who consented to take part in the study, 38.6% failed to attend an appointment on at least one occasion. Similar figures were also reported for the total number of patients who cancelled or failed to attend pre-sedation clinics throughout 2013/2014 (see Table 67). The annual attendance rates for new paediatric patient clinics at the Liverpool Dental Hospital also report that 24% of patients either cancelled or failed to attend appointments during 2013 and 2014 (see Table 66). It was not possible to obtain attendance rates for pre-GA/prevention clinics.

Table 65: *Patients' attendance throughout care pathway*

	Number of patients	Percentage
Completed treatment (IHS)	6	13.6
Completed treatment (IV)	2	4.5
Completed treatment (GA)	2	4.5
Completed treatment (LA)	2	4.5
Waiting list (IHS)	10	22.7
Waiting list (IV)	4	9.1
Waiting list (GA)	1	2.3
Discharged	3	6.8
Incomplete data	9	20.5
Emergency IHS	5	11.4

Did not attend (on at least one occasion)	17	38.6
Received additional pre-sedation appointments	4	9.1

Table 66: *Annual attendance at new patient clinics*

New Patient clinic 2013/14

Attend Status	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Total
ATT	18	32	15	38	5	34	65	42	31	62	56	56	454
DNA	7	8	12	14	3	7	21	12	11	18	18	12	143
DNA %	28.0	20.0	44.4	26.9	37.5	17.1	24.4	22.2	26.2	22.5	24.3	17.6	24.0

Table 67: *Annual attendance at pre-sedation clinics*

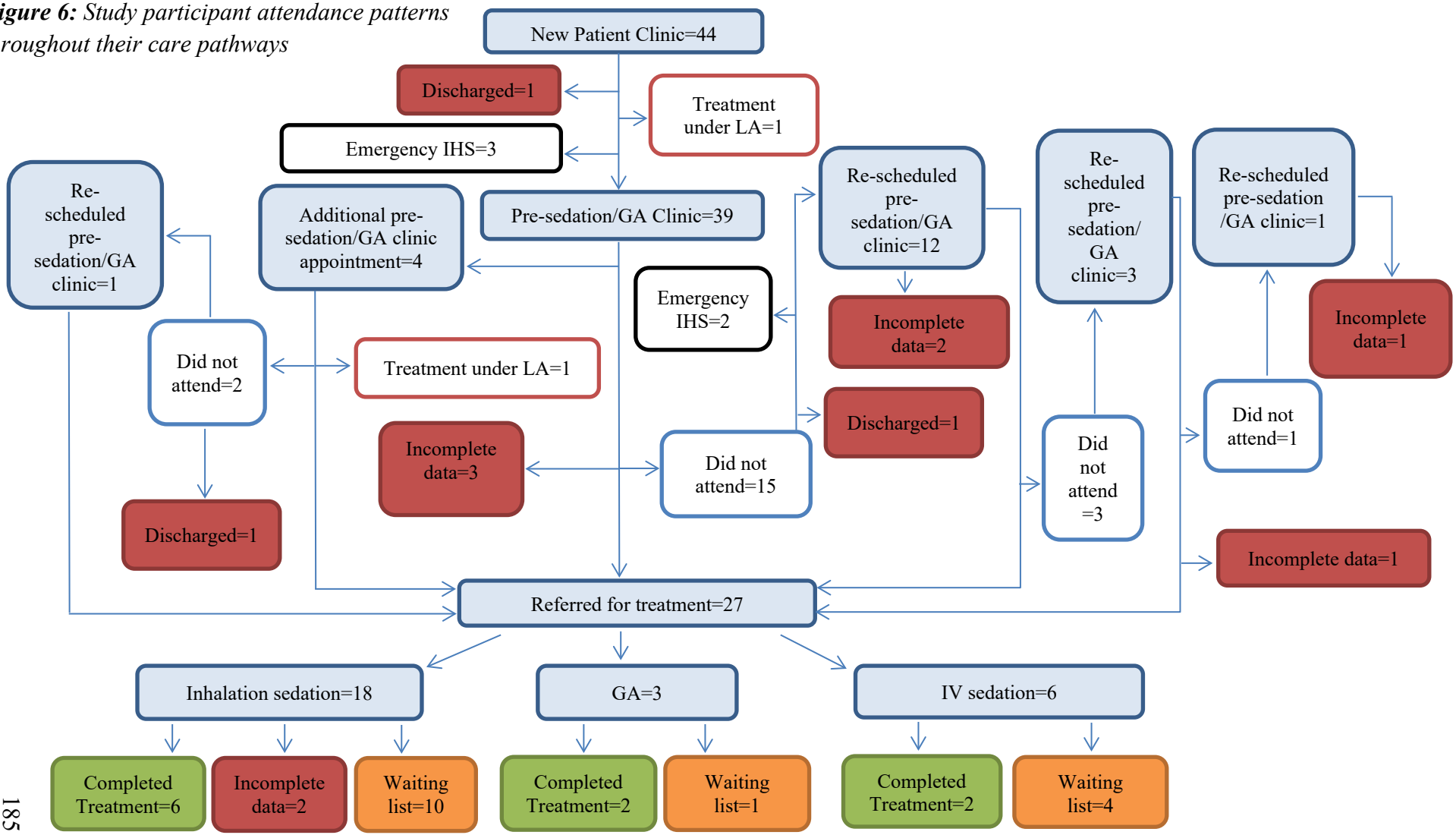
Pre-sedation clinic 2013/2014

Attend Status	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Total
ATT	12	16	21	14	N/A	17	31	15	11	20	11	19	187
DNA	3	12	10	9	N/A	11	11	7	1	1	3	2	70
DNA %	25.0	75.0	47.6	64.3	N/A	64.7	35.5	46.7	9.1	5.0	27.3	10.5	37.4

ATT = number of patients scheduled to attend

DNA = number of patients who failed to attend or cancelled the appointment

Figure 6: *Study participant attendance patterns throughout their care pathways*



5.8.7.2 Previous treatment experience

Self-reports of previous treatment experience of the patients were also collected, with the data showing that just under half of the patients included in the study had received treatment under GA or inhalation sedation previously (see Table 68). However, only 3.3 % of patients had prior experience of treatment under IV sedation and some patients were unsure of their previous experiences of the different regimens (GA = 3.2%, inhalation sedation = 13.3%, IV sedation = 6.7%).

Table 68: *Patients' reported experience of previous treatment*

	GA (%)	Inhalation sedation (%)	IV sedation (%)
Yes	45.2	46.7	3.3
No	51.6	40	90
Don't know	3.2	13.3	6.7

5.8.7.3 Sample size calculations

Sample size calculations for future research were made using mean scores and standard deviations from the current data and the statistical power analysis tool, G*power 3.1.9.2 (Faul et al., 2007). Separate calculations were made in relation to knowledge and decisional conflict scores from both the patient and parent/guardian groups. All calculations were made for research using a between subjects design, with a power of 0.80 and an alpha level of 0.05. As shown in table 69, it is estimated that a sample of 30 patients is sufficient to detect a significant effect on knowledge and a sample of 218 patients is sufficient to detect a significant effect on decisional conflict. For calculations relating to parents/guardians, it is estimated that a sample of 60 participants would be required to detect a significant effect on knowledge and a sample of 1226 would be required to detect a significant effect on decisional conflict. Further pilot research would be required to determine accurate sample size calculations for studies used mixed factorial designs in primary care settings.

Table 69: *Sample sizes required for future research*

	Sample size required (Patients)	Sample size required (Parents/guardians)
Knowledge	30	60
Decisional conflict	218	1226

5.8.8 Summary

Results from this initial pilot evaluation, suggested that the current decision aid may be beneficial for patients faced with the decision have treatment with sedation (inhalation or IV) or GA and their parents/guardians, in terms of significantly increasing knowledge. In contrast, although lower scores relating to measures of dental anxiety and decisional conflict were noted for patients who received the decision aid in comparison to standard care, neither of these differences were statistically significant. Furthermore, the study also raised some issues relating to missed/cancelled appointments and long waiting lists which could challenge the implementation and evaluation of the decision aid in a secondary care setting, with some of these concerns were echoed in the additional comments provided by participants in relation to the acceptability of the decision aid. However, when considering the key findings from the acceptability questionnaire, the majority of responses suggested that the decision aid was easy to understand, included an appropriate amount of information and was perceived to enhance the decision-making process by both young patients and their parents/guardians.

5.9 Discussion

5.9.1 Introduction

The following section will reflect on the processes and outcomes arising from the pilot evaluation of the decision aid. Key findings deriving from this final stage of the study will be discussed in relation to the wider literature on decision-making and the clinical context of paediatric dental sedation and GA.

5.9.2 Decisional conflict

The results suggested that the decision aid did not significantly reduce overall decisional conflict for both patient and parent/guardian groups. Furthermore the impact of the decision aid on subscales relating to feelings regarding uncertainty, being informed, clarity of values, support and whether the 'right' decision was made were not significant. These results contrast greatly with the wider literature on the impact of decision aids on decisional conflict. For example, the aforementioned systematic review of the literature suggests that there when compared to standard care, decision aids do reduce decisional conflict in relation to feeling informed and clarity of values (Stacey et al. 2014, see Section 2.3.2). In this instance, Stacey and colleagues reported that when comparing decision aids to standard care, a meta-analysis of the previous literature showed an overall mean difference of -6.22 with a 95% CI of -8.00 to -4.44, with lower decisional conflict associated with the implementation of the decision aid. Furthermore, three studies that could not be included in the meta-analysis also reported significant decreases in decisional conflict in relation to the use of a decision aid (Weymiller et al., 2007; Schwartz et al., 2009; Arterburn et al., 2011). These studies related to decisions taken by adult patients, regarding bariatric surgery, genetic testing and diabetes treatment. A further three studies also reported that there was no significant impact of decision aids on decisional conflict, interestingly all three of these studies related to decisions regarding cancer treatment (Krist et al., 2007; Ozanne et al., 2007; Leighl et al., 2011). It should also be noted that one of these studies reported findings from a pilot study, comprising only 30 patients (Ozanne et al., 2007). As in the current study, the primary aims of such pilot studies are to gain an indication of the acceptability of the decision aid amongst the specific patient group and clinicians, explore potential feasibility issues and gather data which can be used for sample size calculations in future research. Interestingly, a further study that could not be included in the meta-analysis, once again relating to cancer prevention, actually found an increase in

decisional conflict following the use of a decision aid when compared to standard care (Fagerlin et al., 2011a). The potential reasons for these increases are not discussed in the literature, but it could be suggested that the introduction of further treatment options in relation to difficult healthcare decisions may actually lead to increased feelings of uncertainty in some contexts. This suggestion is partially supported by findings which suggest that cancer patients and clinicians are concerned with the additional stress caused by the introduction of further treatment options and the provision of genetic testing (Ardern-Jones et al., 2005). However, it should be noted that these findings have not been widely replicated in the existing literature on decision aid research (Stacey et al., 2014), and may relate specifically to long-term healthcare decisions which involve high levels of emotional distress such as those relating to cancer treatment.

When comparing decision aids to standard care in relation to subscales measuring feelings of being informed, the overall mean difference was -7.26 (95% CI=-9.73 to -4.78) and in relation to clarity of personal values the overall mean difference was -6.09 (95% CI=-8.50 to -3.67) (Stacey et al., 2014). Further meta-analyses comparing decision aids to standard care reported overall mean differences of -2.47 (95% CI=-4.28 to -0.66) for subscale measures of uncertainty, -4.77 (95% CI=-6.86 to -2.69) for subscale measures of support and of -4.86 (95% CI=-7.04 to -2.68) for subscale measures of effective decisions. These analyses included studies looking at a range of healthcare decisions, however none of the included studies included looked at decisions relating to paediatric healthcare, dental sedation or dental GA. In addition, no studies included in the systematic review measured parental decisional conflict. Therefore it should be noted that due to the relatively novel concept of creating a paediatric dental sedation and GA decision aid, designed for both patients and parents/guardians, it is difficult to draw direct comparisons with previous research. Furthermore, when considering the use of the low literacy decisional conflict scales, only one study was included when comparing decision aids to standard care. This study did find significant reductions in decisional conflict when compared to standard care in relation to bowel cancer screening (Smith et al., 2010). However, on this occasion the use of the low literacy scale was used to assess adults with low levels of education.

One potential explanation for the non-significant differences in decisional conflict between groups in the present study is that the scores were relatively low for each group. For example, overall decisional conflict mean and median scores were less than

25 for all groups, with scores less than 25 associated with the implementation of decisions. Similarly, only two mean subscale scores exceeded 25 (mean control group scores on the 'Informed' and 'Values Clarity' subscales) for all patient and parent groups, and neither of these scores exceeded a score of 37.5, which is associated with decisional delay or being unsure about the implementation of the options available. These low levels of decisional conflict could be related to the stage at which the decision aid was implemented and when measures of decisional conflict were taken. For example, the decision aid was delivered in a secondary care setting, following initial referral from the patients' general dental practitioner. Patients and families therefore may have already had chance to discuss and consider the treatment options available to them, leading to reduced decisional conflict at the time the decision aid was implemented and outcome measures were recorded. This proposal is supported by findings from the present study which show that the majority of patients and parents/guardians already held a treatment preference, with under 20% of participants stating that they were still unsure of which option they would prefer. It could also be suggested that patients and parents/guardians who were excluded from the study, because they cancelled or failed to attend appointments, may be the more conflicted than those who do attend. As seen in section 4.8.7, this group of patients and parents/guardians who do not attend new patient and pre-sedation appointments is of considerable size.

It was also noted that a high proportion of the patients had already undergone treatment with some form of sedation or GA, with previous experience of treatment potentially impacting upon patients' experience of the decision-making process. Although not recorded in this study it is speculated that participating families may also have gained previous understanding of sedation or GA through the experience of other young people. In the main, children in this study were undergoing dental treatment for dental caries, and it is speculated that there is a higher likelihood of previous family members also requiring dental treatment under GA or sedation. For example, if patients or siblings had good previous experiences of treatment under one of the available options, decisional conflict could be expected to be relatively low for both patients and parents/guardians. Similarly, negative experiences of previous treatment with sedation or GA could also lead to reduced decisional conflict, with patients being more certain about which of the options available are most suitable for them on this occasion. These issues could be explored more thoroughly in future studies through collecting data on

parents, siblings and other family members previous experience of care to try and determine how such factors may influence the decision-making process and also the eventual decision being made.

5.9.3 Anxiety

The non-significant impact on anxiety reported in the current study mirrors overall findings in the previous decision aid literature (Stacey et al., 2014). It has been reported that only 2 of 23 studies measuring anxiety within one month of the decision aid allocation, found a significant decrease in relation to the use of a decision aid. These two studies were related to decisions regarding birthing options **(**Montgomery et al., 2007) and treatment of menorrhagia **(**Protheroe et al., 2007). The only study in the systematic review relating to dentistry, related to a decision aid for patients undergoing endodontic treatment (Johnson et al., 2006). Although results suggested that the decision board had no impact on anxiety in this instance, these findings should be approached with caution as the reliability and validity of the anxiety measures used had not been established, with patient anxiety simply measured from responses to the following item: *"Did the explanation of treatment options make you more or less anxious about the treatment?"*

One explanation for this noted lack of impact of decision aids on patient anxiety levels may relate to previous debates on whether anxiety is in fact an appropriate measure of decision aid effectiveness (Bekker et al., 2003). For example, a systematic review of the literature concluded that anxiety is not a suitable measure of decision aid effectiveness, due to reports that increased anxiety is often linked to effective decision-making strategies and certain stressful health interventions. More precisely, it was reported that patients demonstrate increased anxiety when making screening or treatment decisions relating to invasive procedures. However, it may still be argued that the use of anxiety as an outcome measure was appropriate in the current study as one of the reasons patients are referred for treatment under sedation or GA is due to feelings of anxiety.

Interestingly, this proposal is not supported by current findings as patients in the intervention group and control group reported mean scores of anxiety lower than 26 out of a possible 40, which suggests neither group were dentally anxious. It could be suggested that these relatively low levels of anxiety may be related to the time of assessment. For example, it could be expected that patients would experience

heightened anxiety nearer their treatment, with substantial delays being recorded between pre-sedation and treatment appointments. It would therefore be suggested that future research would need to measure patient/parent anxiety at multiple time points in order to assess changes throughout the care pathway. This would also include the inclusion of post-operative measures of anxiety, something which has been reported as lacking in the wider literature focusing on the impact of sedation and GA (Lourenco-Matharu et al., 2012). It could also be suggested that the low levels of anxiety experienced by all patients may again be related to a high prevalence of previous treatment experience, with research showing that previous experience of sedation may significantly reduce future experience of anxiety (Veerkamp et al., 1995). Previous research, which associated high levels of dental anxiety with irregular dental attendance (Taani, 2002), could also explain the low levels of anxiety in the present sample, as patients who cancelled or failed to attend new patient appointments could not be recruited. It is proposed that it is this group of patients who may benefit most from the decision aid in terms of reduced dental anxiety.

Finally, one factor that the current research failed to take into account was the role of the family and how parents may influence their child's dental anxiety. For example, previous research has demonstrated that parental dental anxiety is closely associated with and predictive of child dental anxiety (Peretz et al., 2004). For these reasons it has been suggested that efforts to reduce parental anxiety may also be beneficial to the child. The implementation of parental anxiety measures in future research is therefore required, to help determine if the decision aid has any impact on parental anxiety, and if so whether this impact has a resulting effect on their child's level of anxiety.

5.9.4 Knowledge

Initial findings suggested that the decision aid significantly increased knowledge for both patients and parent/guardians. These results are consistent with those in the wider literature, which suggest decision aids do have a positive impact on knowledge when compared to standard care (Stacey et al., 2014). In Stacey and colleagues (2014) recent review an overall mean knowledge score difference of 13.34 was reported following a meta-analysis data, (95% CI=11.17 to 15.51). Once again, none of the studies included in this analysis included decisions relating to paediatric healthcare, however one study did report the impact of a decision aid designed for adult dental patients. In this instance it was found that the use of a chairside decision board for patients attending a

postgraduate endodontic clinic led to significantly increased knowledge when compared to usual care. When considered in conjunction with the findings from the current study, this lends some support for the introduction of decision aids in dental settings and in particular dental teaching hospitals. Furthermore, increased recall of information has also been demonstrated in study looking the provision of decisional support in the form of a video intervention in paediatric dental healthcare (Lewis et al., 1991). In this instance increased recall of medical recommendations was recorded for patients aged 5-15 years.

One potential confounding issue when considering the current findings of increased knowledge relates to the fact that the decision aids and questionnaires were given to the participants to complete in their own time, away from the clinic. Therefore it was impossible to assess whether participants directly consulted the decision aid when completing the scale relating to knowledge of the treatment options available. However, the potential effects of this should have been minimised by the fact that standard patient information leaflets, which included similar information, were provided to both the intervention and control groups. To further control for this it could be suggested that participants completed the questionnaires when attending the dental hospital. However, due to the lack of time available before and after consultations, the potential impact on clinic running times and a general desire from participants to complete the questionnaires in their own time, this option was not deemed feasible. The increased level of knowledge reported in the current study does support the use of a decision aid for patients undergoing dental treatment with sedation or GA and their parents/guardians, through the evidence that increased knowledge leads to a more informed choice being made. Comparing these findings with the lack of significant differences reported in relation to the decisional conflict scales, raises further questions over the most appropriate measures to determine the impact of a decision aid on the decision-making process. More specifically it raises the question as to whether an increase in knowledge can lead to better decisions being made even if patients do not perceive themselves to be more informed.

5.9.5 Acceptability

Overall, the findings from the acceptability scale suggested that the content, balance and amount of information included in the decision aid were acceptable. Additionally, the decision aid itself was easy to use for patients and parents/guardians. However, it should

be noted that the level of response to this scale was relatively low. It is acknowledged that some bias may have been introduced, as patients who found the decision aid easy to use, may have been more willing to complete and return the related questionnaires. Whereas, the participants who found the decision aid to be too long and difficult to understand, may have been less likely to continue their participation in the study.

When considering the additional comments given, the findings were once again mainly positive. However, there were also reports that the decision aid was of no benefit because a treatment decision had already been made. These opinions may indicate that the decision aid would be more beneficial if implemented in primary care. Furthermore, these assertions also support the proposal that the low levels of anxiety and decisional conflict across patients and parents/guardians in the current study is related to the stage of assessment. It could be argued that patients and parents/guardians may have experienced low anxiety and decisional conflict, in both the intervention and control groups, due to the fact that a decision had already been made. Thus, patients and parents/guardians would have attended the secondary care service with a general acceptance of their treatment options. Indeed, it is a requirement stipulated by the General Dental Council that dentists referring patients for further treatment should discuss the options with the patient and fully explain the referral process (General Dental Council, 2013).

Further comments given regarding the acceptability of the decision aid by parents/guardians, suggested that a choice of treatment options was not available to all patients. It was unclear whether these lack of options were related to medical reasons, or whether patients were not given an equal role in the decision-making process. When discussing the former situation, the wider application of the decision aid is once again questioned, with more general issues over the appropriateness of internet decision aids once again being raised. However, if the lack of options given were due to a lack of patient engagement in the decision-making process it could suggest that previously cited barriers to shared decision making relating to time constraints and clinician attitudes may still be an issue (Legare et al., 2008b).

When considering previous research, significantly high levels of acceptability have generally been reported across several studies looking at the use of decision aids for

decisions relating to cancer (Tiller et al., 2006), blood donation (Grant et al., 2001), prenatal testing (Drake et al., 1999) and diabetes (Weymiller et al., 2007). The majority of these studies only present descriptive findings relating to acceptability (Drake et al., 1999; Grant et al., 2001; Weymiller et al., 2007). However, statistically significant increased levels of acceptability have been noted in a study comparing a decision aid to standard pamphlets, for women who were at increased risk of developing ovarian cancer (Tiller et al., 2006). Statistically significant differences have also been noted in a study looking at the relative acceptable of two decisional support tools amongst high literacy and low literacy participants (Volk et al., 2008). In this instance, significant differences were identified in relation to such factors as the amount, length and clarity of the decision aid. A review of the existing literature also demonstrates that, although measures of decision aid acceptability are frequently implemented, findings are often underreported, with studies often failing to describe either quantitative or qualitative data (O'Connor et al., 1998b; Man-son-hing et al., 1999; Diefenbach et al., 2012). It appears the Ottawa Acceptability Scale (O'Connor and Cranney, 2000) is the most frequently employed scale for measuring acceptability in the existing literature. However, it should be noted that the only scale available relates specifically to a decision aid developed for treatment options associated with osteoporosis. It could therefore be suggested that a more widely applicable scale should be developed, with appropriate scoring guidelines developed and psychometric properties reported.

5.9.6 Feasibility

The main difficulties which arose in regards to the implementation and evaluation of the decision aid in the current study, related to the relatively high levels of missed and re-scheduled appointments. The complexity of the patient care pathways was a challenge to both patient recruitment and retention. For example, the associated delays between patient appointments made it difficult to assess the impact of the decision aid on compliance with treatment and attendance, as some patients continued to remain on the waiting list when the study finished. Furthermore, when considering the varying nature of the care pathway, it would also have been difficult to compare changes between patients over time, with various time-points being associated with different stages of the care pathway for each patient. These findings question the feasibility of implementing and evaluating the current decision aid in a secondary care setting. In addition to this, the relatively low attendance rates recorded for the new patient clinic also had an impact

on the overall number of patients recruited to the study. These low rates of recruitment support the need for a multi-site study in future research. However, as previously noted, consideration would have to be given to minor modifications of the decision aid across various sites, due to the heterogeneity of treatment options offered and the associated methods used. The potential impacts of poor attendance rates on recruitment should also be considered more thoroughly, and strategies put in place, before embarking on a future study.

The current study also failed to assess whether the decision aid would be more beneficial to patients and parents/guardians if the resource was utilised with the clinician during the patient's consultation, with the majority of patients opting to use the decision aid at home with their parents/guardians. In this instance the main issue was a lack of time during consultations to directly refer to the decision aid. A lack of time has been previously identified as one of the main barriers to implementing shared-decision making, and observations from this recent study support this (Caress et al., 2005). However, as mentioned previously, whether decision aids have a significant impact on consultation time has yet to be determined (Stacey et al., 2014). Further factors also have to be considered when implementing decision aids during the consultation, such as how a noisy clinic environment may actually hinder the decision-making process (Park and Song, 2005; Ruan and Lambert, 2008). Evaluation of 17 studies examining the feasibility of decision aids in clinical practice, suggested that a lack of confidence held by clinicians regarding the information included in the decision aids, and concerns over how decision aids may disrupt their workflow, also pose challenges (Elwyn et al., 2013).

Difficulties in obtaining relevant patient information was experienced in the current study, and would need to be addressed in future studies. Poor quality of record keeping within the NHS has been highlighted previously in the wider literature (Beach and Oates, 2014), with widespread evidence of incomplete data and inconsistent record keeping. As well as impacting upon the completeness of the data in the current study, these issues also have wider implications in terms of potential negative impacts on the quality of patient care. The increasing drive towards paperless patient records throughout the NHS will undoubtedly facilitate the accurate retrieval of patient-related data within clinical research.

5.9.7 Shared decision-making

It had been recently proposed that the process of shared decision-making mainly occurs within the clinical encounter (Hargraves and Montori, 2014). As the majority of decision aids have been developed for use outside of the consultation, it is therefore suggested that there is no guarantee that they will encourage shared decision-making between patients, family members and healthcare professionals (Agoritsas et al., 2015). In line with these proposals, more innovative approaches to decision aid development have been recommended. For example, one study has presented an alternate approach to decision aid development, which included observing conversations between clinicians and patients in order to develop a decision aid specifically focused on creating two-way conversations (Montori et al., 2007). However, although the findings from this study suggested that this decision aid did helped create conversations between patients and clinicians, these findings have also been replicated in studies using more traditional development techniques (Stacey et al., 2014). Although findings from the current study suggest that the decision aid may help patients and family members make more informed decisions, it is difficult to assess whether the decision aid had a direct impact on the shared decision-making process. Therefore, the use of scales measuring patient involvement, such as the OPTION scale, would be beneficial in future research. Finally, in relation to paediatric healthcare, a recent review of the use of interventions for encouraging shared decision-making for children with cancer failed to identify any high quality research (Coyne et al., 2013). These findings further highlight the lack of decision aids developed for children and young people.

When considering how decision aids will be delivered in paediatric healthcare and the impact such interventions may have on shared decision-making, the role of the parent and other family members once again have to be considered. This complex process could be explored in future research through taking into account how the decision aid impacts on the consultation process itself and also how it impacts upon shared decision-making between the patient and family members outside the clinical encounter. The development of separate decision aids for both patients and parents could also be explored to determine how independent interventions may facilitate or limit discussion between patients, family members and clinicians.

In addition it could also be suggested that psychological theories and models regarding information seeking styles could be addressed more thoroughly in future research

focusing on the impact of decision aids on shared decision-making. For example, some models suggest that some patients may actively avoid information, if paying attention will cause mental distress or discomfort (Case et al., 2005). In relation to this, the terms monitoring and blunting have often been used to distinguish between information-seeking styles (Folkman and Lazarus, 1980). The term blunting refers to individuals who avoid information or find methods of distracting themselves from information, whereas 'monitors' often search the environment for potential information or threats. It could be suggested that such differences in information-seeking behaviour could have a significant influence on patients preferred role in the decision-making process and the implementation of decision aids throughout healthcare.

5.9.8 Health inequalities

A recent systematic review has also suggested that shared decision-making interventions, such as decision aids could help reduce health inequalities (Durand et al., 2014). This proposal is supported by findings that such interventions most benefited disadvantaged, low literacy patient groups in comparison to patients with higher literacy, education and socio-economic status in terms of increased knowledge, informed choice and greater involvement in the decision-making process. As shown in recent findings, areas of lower deprivation are associated with higher rates of dental caries, which in turn could lead to the need for more demanding treatment, such as multiple extractions, under the provision of sedation or GA (Holmes et al., 2015). This is supported from findings in the current research that show that 53% of the patients and their family members recruited in the pilot study were from the most deprived areas of the UK, as classified by the Multiple Deprivation Index, with only 7% of patients being from the least deprived areas. It could therefore be suggested that future research may also want to take into account such measures of deprivation and other factors, such as health literacy, to determine the differential impact of decision aids on different socio-economic groups and the potential to reduce such health inequalities. Measures relating to attendance and compliance with treatment would also be beneficial in assessing such impact, with the potential to explore how decision aids may be used in conjunction with other methods of reducing non-attendance in healthcare, such as SMS text messaging and postal reminders.

5.9.9 Stages of development

A further issue which must be considered when developing decision aids for young people is the relative stages of cognitive development. For example, as mentioned in section 2.4.3, previous findings have proposed that individuals under the age of 14 years do not possess the necessary ability to be involved in the decision-making process (Weithorn and Campbell, 1982). Furthermore, when considering the stages of cognitive development as described by Piaget (1971), it is thought that although logical reasoning can begin to develop at the age of 7 years, this reasoning is restricted to objects that are present and tangible. This theory states that complex reasoning does not begin to develop until the age of 12 years. However, as noted previously, it is now recognised that these levels of development are not consistently related to age and instead are more dependent upon the situation which the young patient faces (Alderson, 1993; Christensen, 1998; Halpern-Felsher, and Cauffman, 2001; Nova et al., 2005; Alderson et al., 2006; Alderson, 2007). This is partially supported by findings from the current study which show that 78.6% of the patients felt the decision aid made the decision-making process easier, suggesting patients were able to assess the relative benefits of the options available. Nonetheless, it is clear that this issue should be addressed more thoroughly in future research on the use of decision aids for young patients, with measures of child development being incorporated in studies to aid the exploration of such issues and to gain further knowledge on how concepts such as decisional conflict are managed by younger patients

5.9.10 Ethical considerations

In relation to issues of confidentiality, it was made clear to patients that all data would be anonymised and that all patient-related information would be kept in locked filing cabinets and all computerised data would be password protected on a designated PC in the School of Clinical Dentistry. To ensure valid consent was obtained, all participants were also given at least 24 hours from receiving the information sheet to decide if they were still willing to take part. Furthermore, the importance of providing information sheets tailored to the participants' age was also recognised, with particular attention paid to the inclusion of information regarding how their participation in the study would impact upon them, something which has been identified as being particularly difficult to convey (Mauthner, 1997; Kortesluoma et al., 2003). No ethical concerns or participant complaints arose during the period of this study.

5.9.11 Strengths and limitations

5.9.11.1 Study design

With regards to study design, one of the major limitations of the current research was the lack of a within-group comparison. By failing to analyse differences in patient outcomes at different stages in the clinical care pathway, the impact of time could not be considered in the final analysis. When designing the study protocol, the project originally aimed to address this issue by collecting data on decisional conflict, anxiety and knowledge both before and after the patients attended the pre-sedation assessment or prevention clinic. However, it was soon recognised that long waiting lists and high number of cancelled appointments meant that this was out of the scope of the current study. On the other hand, despite some of the limitations of the study, it is the first to explore the use of a decision aid within paediatric dentistry and will provide a new body of work to the existing decision aid literature.

5.9.11.2 Sample composition

Ethnic minority groups were unrepresented in the sample, with only one patient and one parent/guardian from an ethnic minority group being included in stage one of the study. For these reasons it was impossible to fully explore how ethnicity may have impacted upon patient's experience of the decision-making process and on measures of decisional conflict, knowledge and anxiety. Furthermore, a lack of ethnic diversity within the sample groups also diminishes the generalisability of the study findings to larger groups. This lack of ethnically diverse populations being used in decision aid research is something that has been noted previously in literature, indeed the problem was addressed directly in a study viewing the impact of a decision aid relating to cancer screening (Frosch et al., 2008b). As well as highlighting the lack of ethnically diverse samples used in previous research, this study also determined that ethnic minority groups benefit from increased knowledge as result of viewing decision support tools, a finding which is common in the previous literature focused on primarily caucasian populations. A study focusing on prostate cancer screening suggested that ethnicity may influence screening preferences, with one study including an entirely African-American sample showing that men who received additional decisional support were more likely to choose to undergo screening (Myers et al., 2005). This finding was, however, not mirrored in a wider review of the use of decision aids for prostate cancer screening (Evans et al., 2005). Once again, the reasons for the underrepresentation of ethnic

minority groups could be due to a number of factors, including the fact that interpreters were not employed when recruiting participants (Hussain-Gambles et al., 2004).

The fact that the sample was relatively small, unpowered and differed in size between groups could also be considered limitations of the current study. For these reasons it was difficult to accurately detect significant differences between groups. However, it should be noted that due to the novel nature of the study, an accurate sample size could not be calculated, due to the lack of previous data relating to the implementation of decision aids in paediatric dental healthcare (Stacey et al., 2014). Furthermore it should also be noted that for this stage of research, the current sample size should be considered sufficient to determine feasibility issues and to conduct power analysis so that accurate sample size calculations can be made for future research. One method to aid recruitment would be from the greater use of Patient and Public Involvement (PPI) throughout the study. For example, the inclusion of patients and public members from ethnic minority backgrounds in project steering groups could have been beneficial in helping identify some of the issues which meant that an ethnic minority groups were not fully represented in the study sample. Research has also shown that PPI can be beneficial when developing project materials such as information sheets and study invite letters, which again could have helped increase recruitment (Crawford et al., 2002).

All measurement scales used in the study demonstrated acceptable to excellent reliability, with the exception of the values clarity and support subscales included on the low literacy Decisional Conflict Scale (O'Connor, 1993). Furthermore, there was no indication that the removal of certain items from the subscales would have a sufficient impact on internal consistency. This could imply that these subscale measures may not be suitable for use in the current sample of young patients. However, it should be noted that the overall scale did still demonstrate good internal consistency. Once again, increased PPI could have helped to further ensure the validity of adapted knowledge and acceptability measures used.

5.10 Summary

The pilot evaluation of the decision aid in secondary care was implemented to assess the following objectives:

3. To determine the impact of a decision aid on measures of patients' and parent/guardians' decisional conflict, anxiety, knowledge, attendance and compliance with treatment
4. To determine the acceptability of the decision aid
5. To determine the feasibility of implementing and evaluating a decision aid in a secondary care setting

Findings from this pilot evaluation of the decision aid suggest that the decision aid could increase knowledge of the treatment options for patients and their parents/guardians when compared to standard care. Furthermore, findings also suggest that the decision aid was acceptable in terms of the balance and amount of information included, and it was easy to use for both patients and parents/guardians. However, within this small sample group, the decision aid had no significant impact on anxiety or decisional conflict for both patients and parents/guardians. It should be noted however, that as a pilot study, these findings should be interpreted with caution, as the main focus of the research was to assess feasibility issues relating to the implementation and evaluation of the decision aid in a secondary care setting, the implications of which are discussed in the final chapter.

Chapter Six: Conclusions and Implications

6.1 Introduction

The following chapter will briefly summarise findings in relation to the original study aims and objectives, present the main conclusions from the current research and describe the overall implications for clinical care and future research.

6.2 Summary of findings

The overall aim of the current research was to develop a decision aid for patients undergoing dental treatment with sedation or GA and their parents/guardians. To meet this aim, five objectives were established in accordance with the original IPDAS development framework (see Table 1). The following section will summarise he main study findings in relation to the specific objectives.

1. **To explore what factors are involved, from the young persons' and parents/guardians' viewpoint, when making the decision whether or not to undergo sedation or GA for dental treatment, and subsequently to determine the needs of those involved**

The above objective was satisfied through an initial series of qualitative interviews with patients and parents/guardians who had previously undergone treatment with inhalation sedation, IV sedation or GA. The data from these interviews allowed the identification of various issues that played a key role in the decision-making process, with these factors subsequently informing the content of the decision aid. Findings triangulated well with features that had been recognised in the previous literature, such as the impact of pre-operative fasting, and also more novel findings, such as the importance placed on control and communication during the treatment process. This stage of the study also played a role in identifying patients' and parents/guardians' preferences in regards to the amount of information needed and the format in which it was presented.

2. **To explore clinicians', patients' and parents/guardians' initial perceptions towards the decision aid**

To explore initial perceptions, the draft decision aid was presented to expert clinicians and patients who had already undergone treatment with sedation or GA and their parents/guardians. Presentation of the decision aid to these two separate groups allowed further revisions to be made to the decision aid, satisfying the stage presented in the original IPDAS development framework which describes the importance of re-drafting, reviewing, and revising the decision aid until it is ready for pilot testing. This stage of the study played a key role in highlighting some potential issues relating to the feasibility of implementing the decision aid and problems with the appropriateness and comprehensibility of information included in the decision aid.

3. **To determine the impact of a decision aid for paediatric dental sedation on measures of patients' and parents/guardians' decisional conflict, anxiety, knowledge, attendance and compliance with treatment**

The above objective was addressed in the final stage of the study, which involved the pilot evaluation of the decision aid in a secondary care setting. Although, at this stage of the research it was not possible to conclusively determine the impact of the decision aid on measures of decisional conflict, anxiety and knowledge, the current study was beneficial in determining effect sizes, which can be used to calculate appropriate sample sizes required for future research. A lack of complete data made it impossible to assess the impact of the decision aid on attendance and compliance with treatment.

4. **To determine the acceptability of the decision aid**

Acceptability of the decision aid was also assessed during the pilot evaluation stage of the research. Although, it was only possible to report descriptive findings in relation to the acceptability of the decision aid, there were suggestions that the patients and parents/guardians who received the decision aid found the content, balance and amount of information acceptable. Furthermore, they reported that the decision aid was helpful and easy to use.

5. **To determine the feasibility of implementing and evaluating a decision aid in a secondary care setting**

The final pilot evaluation stage of the research was also employed to assess the feasibility of implementing the decision aid in a secondary care setting. This stage of the research was crucial in highlighting the potential barriers to implementing and evaluating the decision aid in a secondary care setting. These issues related primarily to high cancellation rates, long waiting lists and low levels of recruitment.

6.3 Conclusions

The conclusions from the research are as follows:

- This was the first study to develop a decision aid aimed at young people faced with the decision to undergo dental treatment with either inhalation sedation, IV sedation or GA and their parents/guardians.

- This was also the first study of note to produce a decision aid that actively involves young people in any healthcare decision-making process.

- Initial findings suggest that the decision aid could benefit patients faced with the decision to undergo dental treatment with sedation or GA and their parents/guardians in terms of increased knowledge of the healthcare options available.

- Preliminary data indicate that patients and parents/guardians found the content, balance and amount of information acceptable and found that the decision aid was helpful and easy to use.

- Initial findings suggest that the decision aid has no impact upon patient and parent/guardian decisional conflict or patient dental anxiety in a secondary care setting, although it is acknowledged that the study was insufficiently powered to detect such differences if they existed.

- There are difficulties in the implementation and evaluation of paediatric dental decision aids in a secondary care setting. These difficulties relate mainly to high

rates of missed or cancelled appointments and the related issues of long waiting list times and relatively low levels of recruitment.

6.4 Implications and recommendations

The following section will highlight the overall implications and make recommendations for future research and clinical care.

6.4.1 Implications and recommendations for future research

6.4.1.1 Decision aids in paediatric healthcare

Initial findings from the current study suggest that further research focusing on the development and evaluation of decision aids aimed at younger patients facing healthcare decisions and their parents/guardians should be encouraged. The present study has demonstrated that such decision aids may be beneficial in increasing patient and parent/guardian knowledge and that both younger patients and their parents/guardians hold positive attitudes towards the use of such tools. When combining these findings with previous suggestions that children often desire a greater role in the decision-making process, and the current lack of decision aids aimed at children, it is apparent that the development of more decision aids which focus explicitly on involving children in the decision-making process is indicated within the wider healthcare arena.

6.4.1.2 Stage of implementation

Findings from this study suggest that further research should investigate the implementation of the current decision aid within primary care. It is speculated that the implementation of the decision aid at an earlier stage of the decision-making process, and the use of a controlled before/after design, may help gain a better understanding of its impact on such outcomes as decisional conflict and anxiety, and how these measures may vary over time. The feasibility of the decision aid being allocated by the general dental practitioner or member of the dental team, at the point of referral, warrants enquiry. However, there are several barriers in place, relating to increase costs, which may pose challenges when implementing and evaluating the decision aid in primary care settings. For example, it could be expected that a lesser volume of patients requiring dental treatment with sedation or GA would visit primary care sites; therefore a multi-site study would be essential. Furthermore, it would be impossible to screen

potentially eligible patients prior to their initial consultation with their general dental practitioner, meaning that a member of the research team would have to be on site at all times or extra costs would be incurred through training dentists to recruit their own patients to the study. In order to address these issues, it is suggested that dental practices situated in areas of low deprivation could be targeted as potential sites to be included in the research. This is due to the fact that these areas are associated with higher levels of dental caries, which could lead to the greater need for more demanding treatment under sedation or GA. The tracking of referral letters from secondary care settings could also be used to identify the primary care services which on average refer higher volumes of patients eligible to take part in the research.

It is also suggested that further research is required to better understand whether involvement in the decision-making may differ in relation to whether the decision aid is implemented during consultations with the healthcare professional, or whether patients and family members use the decision aid away from the clinical setting. The impact this will have in relation to consultation length and expenditure should also be examined.

6.4.1.3 Presenting risk information

Further attention to the inclusion of risk information in decision aids is required. In particular, the current study highlighted the need for additional guidance on the appropriate steps to be taken when conclusive information regarding the risks and benefits of certain treatment options are not available and whether the provision of narrative information can be deemed as a suitable replacement in such instances. The current research also raised concerns related to the inclusion of information in decision aids aimed at children that may potentially be distressing for them. This raises further questions over whether the exclusion of such information can be justified if parents/guardians and clinicians would prefer this to be discussed separately.

6.4.1.4 Appropriate outcome measures

There appears to be a lack of agreement on the most appropriate measures to assess the effectiveness of decision aids and at what stage these measures should be implemented. The current study employed the use of the decisional conflict and knowledge scales in order to satisfy IPDAS criteria relating to effectiveness. However, there are still questions over whether outcome measures such as anxiety are appropriate for assessing decision aid effectiveness, even if related to the healthcare decision being considered.

Another research priority would be to determine the most appropriate scales used to assess the effectiveness of decision aids aimed at younger patients and whether separate scales also need to be developed to assess the impact of decision aids on other individuals, such as parents/guardians, who are also involved in the decision-making process. It is also suggested that future research needs to focus more heavily on how decision aids may impact upon wider practical issues such as treatment costs, attendance rates and compliance with treatment, with the use of health economic analysis encouraged in future study designs.

6.4.1.5 Decision aid format

It is apparent that further research is required to explore the different modes of delivery associated with decision aids and the relative benefits of these varying methods. The main question relates to the potential impact of web-based decision aids, with concerns over whether a web-based decision aid hinders accessibility to patients. Further research on such feasibility issues and the cost-effectiveness associated in the delivery and maintenance of decision aids via the internet is warranted. In addition, further research on the development of 'self-tailored' decision aids available via the internet should also be addressed, with developments potentially offering solutions relating to the wider applicability and availability of decision aids. For example, it was noted in the current study that the heterogeneity of treatment options and related procedures associated with certain healthcare decisions has implications for the appropriateness of the wide-spread provision of such tools to all patients.

6.4.1.6 Values clarification exercises

The use of values clarification exercises in decision aids and the exact features and mechanisms of these exercises that make them beneficial to patients is an area that remains inconclusive. A greater understanding of the key features of values clarification methods could also aid the establishment of guidelines for the development of values clarification exercises, something which is currently lacking in the literature, particularly when considering healthcare decisions which have numerous treatment options.

6.4.1.7 Use of images in decision aids

The role of images in decision aids also requires further attention. Although it has been suggested that the use of images may help improve comprehension, the potential

emotional impact of certain images on patients and how this influences the decision-making process lacks an evidence-base. For example, findings in the current research suggested that although some patients desired the inclusion of pictorial information in the decision aid, there was also evidence suggesting that the negative connotations attached to some images could potentially bias the decision-making process.

6.4.2 Clinical implications and recommendations

6.4.2.1 Need for decisional support

Findings from the present study have demonstrated the need for some form of additional decisional support for patients and parents/guardians of patients faced with a decision to have dental treatment with sedation or GA. This need was highlighted by findings from the qualitative enquiry, which suggested that patients and parents/guardians often lacked knowledge regarding certain aspects of the treatment options available. Furthermore, it appeared that some patients and parents/guardians either did not receive or fully engage with the standard pre-treatment written information provided.

6.4.2.2 Informed consent

Current guidelines propose that children under the age of 16 may give consent to treatment if considered mentally competent (Children Act, 2004). However, findings from the current research suggest that parents/guardians and even clinicians may be reluctant to present risk information to young people due to concerns that it may be distressing to the child. This has wider implications when considering how the withdrawal of some information may prevent valid consent being obtained. It could be suggested that decision aids may play a role in encouraging the discussion of topics that could be considered potentially distressing. On the other hand, the exclusion of some risk information in the current decision aid could reinforce the inclination of parents/guardians and clinicians to exclude such information. Further research on the potential role of decision aids in this instance and the wider implications relating to valid consent or assent for young patients is encouraged.

6.4.2.3 Missed appointments

The high rates of missed and cancelled appointments and long waiting times for treatment not only impacted on recruitment for the current study, but also has wider clinical implications in terms of costs incurred by the healthcare provider and delays in

treatment for patients. Numerous previous studies have attempted to account for and address missed appointments within paediatric dentistry (Badri et al., 2014). It is conceivable, that in some cases, reluctance to undergo a treatment procedure may be the cause of failed or cancelled appointments. The use of a decision aid by the referrer may help to avoid at least some of these failed appointments, by involving the patient and family more actively at the outset of the GA/sedation referral pathway. It is suggested that further research focusing on methods to reduce high cancellation rates associated with paediatric dental sedation/GA are required, and the evaluation of the potential impact decision aids on improving compliance and attendance, warrants further attention.

6.4.2.4 Fasting guidelines

Qualitative findings from the present study reinforced previous research that found patients are often uncomfortable with the pre-operative fasting times currently in place for treatment with IV sedation and GA. Due to the fact that current guidelines regarding pre-operative fasting prior to IV sedation are under debate, further research may be helpful in determining how pre-operative fasting may impact upon patients' treatment experiences.

6.4.2.5 Parental presence

An interesting observation from this present study was that parents/guardians are often unaware of their role during their child's treatment session with sedation or GA. Further understanding of the impact of parental presence on both the patient and clinician could be beneficial, with further efforts being made to communicate to what extent parents can be present during treatment. Once again, the implementation of decision aids could be considered a useful resource in the communication of these fundamental issues.

6.4.2.6 Patient choice

As highlighted in the introduction, there may be underlying clinical reasons relating to patient safety that limit the ‘real’ choice that a young patient may have between the different sedation options and GA. This factor does not diminish the need for a decision aid, and may provide the patient and their parent the prompt to discuss these issues with their clinician and thereby gain greater understanding of the particular risks and benefits for them as an individual.

Furthermore, there may be local differences in the range of dental services offered to patients. In some UK hospital or community paediatric dentistry units, only inhalation sedation, and not IV services are available to patients. In other centres, there may be more limited opportunities for restorations to be performed under GA, with services restricted to extractions only under GA. This inequality in the accessibility to different paediatric dentistry services according to geographical region is a current concern within the NHS. The British Society of Paediatric Dentistry continues to highlight the need for more equable access for children to all services (The British Society of Paediatric Dentistry, 2015). Future commissioning of paediatric dentistry services in England, including GA and sedation, must address these current deficiencies, so that children and their families do have options and are not disadvantaged by the lack of local services.

6.4.3 Summary of implications for research and clinical practice

In summary, the use of paediatric decision aids in healthcare offer the potential to improve the patient experience. Furthermore, any role in improving patient attendance would be of great benefit to the NHS and deserves further investigation within the sedation/GA care pathway. Ultimately, the design and conduct of a randomised control trial in primary care settings would offer definitive evidence for the benefits of a decision aid in this context.

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Appendices

Appendix A: NRES ethical approval

NHS
Health Research Authority

National Research Ethics Service

NRES Committee Yorkshire & The Humber - Sheffield
HRA NRES Centre Manchester
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7832
Facsimile: 0161 625 7299

19 July 2013

Mr Joe Hulin
University of Sheffield
School of Clinical Dentistry
31 Claremont Crescent
Sheffield
S10 2TA

Dear Mr Hulin

Study title:	**Decision aids in paediatric dental sedation: helping children choose what is right for them**
REC reference:	**13/YH/0142**
IRAS project ID:	**126826**

Thank you for your letter of 07 June 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Miss Helen Penistone, nrescommittee.yorkandhumber-sheffield@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter from Joe Hulin		22 April 2013
REC application		25 April 2013
Investigator CV	Joe Hulin	22 April 2013
Investigator CV	Professor Helen Rodd	22 April 2013
Investigator CV	Dr Sarah Baker	22 April 2013
Participant Consent Form: Stage 2 - clinician	1	25 January 2013
Questionnaire: Decisional Conflict Scale		
Questionnaire: Modified Child Dental Anxiety Scale		
Questionnaire: Acceptability Sample Tool		
Questionnaire: Knowledge Sample Tool		
Interview Schedules/Topic Guides	Stage 1 v1	26 January 2013
Interview Schedules/Topic Guides	Stage 2 Development v1	26 January 2013
Interview Schedules/Topic Guides	Stage 2 Review	26 January 2013
Evidence of insurance or indemnity		17 April 2013
Other: Letter from funder		28 September 2011
Response to Request for Further Information		07 June 2013
Protocol	2	27 May 2013

Advertisement	2	26 May 2013
Letter of invitation to participant	2	09 July 2013
Participant Information Sheet: Young Person Stage 1	3	09 July 2013
Participant Information Sheet: Young Person Stage 2	3	09 July 2013
Participant Information Sheet: Young Person Stage 3	3	09 July 2013
Participant Information Sheet: parent/guardian Stage 1	3	09 July 2013
Participant Information Sheet: parent/guardian Stage 2	3	09 July 2013
Participant Information Sheet: Parent/guardian Stage 3	3	09 July 2013
Participant Information Sheet: Clinician Stage 2	3	09 July 2013
Participant Consent Form: Stage 1 & 2 - young person	2	24 May 2013
Participant Consent Form: Stage 3 - young person	2	24 May 2013
Participant Consent Form: Stage 1 & 2 - parent/guardian	2	24 May 2013
Participant Consent Form: Stage 3 - parent/guardian	2	24 May 2013
Participant Consent Form: Stage 1 & 2 - participant (parent/guardian)	2	24 May 2013
Participant Consent Form: Stage 3 - participant (parent/guardian)	2	24 May 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/YH/0142	**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

On behalf of
Professor Basil Sharrack
Chair

Email: nrescommittee.yorkandhumber-sheffield@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Dr Nana Theodorou
Clinical Research Office
Sheffield Teaching Hospitals
1st Floor
11 Broomfield Road
Sheffield
S10 2SE

Appendix B: Sheffield Teaching Hospitals NHS Foundation Trust approval

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

6 August 2013

Prof Helen Rodd
School of Clinical Dentistry
31 Claremont Crescent
Sheffield, S10 2TA

Dear Prof Rodd

Project Authorisation
NHS Permission for Research to Commence

STH ref:	**STH17248**
NIHR CSP ref:	**126826**
REC ref:	**13/YH/0142**
Study title:	**Decision aids in paediatric dental sedation**
Chief Investigator:	**Mr Joe Hulin, University of Sheffield**
Principal Investigator:	**Professor Helen Rodd, University of Sheffield**
Sponsor:	**Sheffield NHS Teaching Hospitals Foundation Trust**
Funder:	**The Society for the Advancement of Anaesthesia in Dentistry (SAAD)**
NIHR TARGET FPFV RECRUITMENT DATE	**11 October 2013**

The Research Department has received the required documentation as listed below:

1.	**Sponsorship Agreement**	Not applicable
	Clinical Trial Agreement	Not applicable
	Material Transfer Agreement	Not applicable
	Funding Award Letter	SAAD C Boyle, 28 Sept 2011
2.	**Monitoring Arrangements**	Sheffield NHS Teaching Hospitals FT
3.	**STH registration document**	R & D Form J Hulin, 18 Jul 2013 A Pinder, 11 Jul 2013
4.	**Evidence of favourable scientific review**	SAAD C Boyle, 28 Sept 2011
5.	**Protocol – final version**	Version 2, 27 May 2013
6.	**Participant Information sheet**	
	Participant Information sheet: Young Person Stage 1	Version 3, 9 Jul 2013
	Participant Information sheet: Young Person Stage 2	Version 3, 9 Jul 2013
	Participant Information sheet: Young Person Stage 3	Version 3, 9 Jul 2013
	Participant Information sheet: parent/guardian Stage 1	Version 3, 9 Jul 2013
	Participant Information sheet: parent/guardian Stage 2	Version 3, 9 Jul 2013
	Participant Information sheet: parent/guardian Stage 3	Version 3, 9 Jul 2013
	Participant Information sheet: Clinician Stage 2	Version 3, 9 Jul 2013

Ref: STH17248/NT 1

7.	**Consent form**	
	Participant consent form: Young Person Stage 1 & 2	Version 2, 24 May 2013
	Participant consent form: Young Person Stage 3	Version 2, 24 May 2013
	Participant consent form: parent/guardian Stage 1 & 2	Version 3, 6 Aug 2013
	Participant consent form: parent/guardian Stage 3	Version 3, 6 Aug 2013
	Participant consent form: participant (parent/guardian) Stage 1 & 2	Version 3, 6 Aug 2013
	Participant consent form: participant (parent/guardian) Stage 3	Version 3, 6 Aug 2013
8.	**Insurance Certificate (non-clinical trial)**	University of Sheffield 17 Apr 2013
9.	**ARSAC certificate / IRMER assessment**	Not applicable
10.	**Ethical review- Letter of approval from NHS REC**	NRES committee Yorkshire & Humber- Sheffield, 13/YH/0142, 19 Jul 2013
11.	**Site Specific Assessment**	SSI Form H Rodd, 30 Jul 2013
12.	**Clinical Trial Authorisation from MHRA**	Not applicable
13.	**Evidence of hosting approvals**	
	- **STH Principal Investigator**	H Rodd, 20 Jun 2013
	- **Clinical Director**	I Brook, 23 Jun 2013
	- **Research Finance**	L Fraser, 30 Apr 2013
	- **Data Protection Officer**	P Wilson, 28 Jun 2013
14.	**Honorary Contract/Letter of Access**	J Hulin, NHS Honorary contract with CCDH
15.	**Associated documents**	
	Letter of invitation	Version 2, 9 July 2013
	Advertisement	Version 2, 26 May 2013
	Interview schedules/Topic guides Stage 1	Version 1, 26 Jan 2013
	Interview schedules/Topic guides Stage 2 Development	Version 1, 26 Jan 2013
	Interview schedules/Topic guides Stage 2 Review	Version 1, 26 Jan 2013
	Questionnaire: Decisional conflict scale	
	Questionnaire: Modified child dental anxiety scale	
	Questionnaire: Acceptability sample tool	
	Questionnaire: Knowledge sample tool	

This project has been reviewed by the Research Department. NHS permission for the above research to commence has been granted on the basis described in the application form, protocol and supporting documentation on the understanding that the study is conducted in accordance with the Research Governance Framework, GCP and Sheffield Teaching Hospitals policies and procedures (see attached appendix).

Yours sincerely

[redacted]

Professor S Heller
Director of R&D, Sheffield Teaching Hospitals NHS Foundation Trust
Telephone +44 (0) 114 2265934
Fax +44 (0) 114 2265937

Appendix C: Royal Liverpool & Broadgreen University Hospitals Trust approval

The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Royal Liverpool University Hospital
Prescot Street
Liverpool
L7 8XP

Tel: 0151 706 2000
Fax: 0151 706 5806

TRUST APPROVAL LETTER FOR NON-CTIMP STUDIES

Dr Sondos Albadri
Liverpool University Dental Hospital
School of Dentistry
Pembroke Place
Liverpool
L3 5PS

REC: **13/YH/0142**
RDMIS: **126826**
Date: **29/08/2013**

Dear Dr Albadri

RD&I No: 4624
Decision aids in paediatric sedation

The above study is a Non-Commercial, Questionnaire / Quantitative study, sponsored by Sheffield Teaching Hospital and funded by Society for the Advancement of Anaesthesia in Dentistry (SAAD). The Trust is now happy for you to commence work on this study, using the following ethically approved documents.

Document	Version	Dated
Participant Consent Form: Stage 2 clinician	1	25 January 2013
Questionnaire: Decisional Conflict Scale		
Questionnaire: Modified Child Dental Anxiety Scale		
Questionnaire: Acceptability Sample Tool		
Questionnaire: Knowledge Sample Tool		
Topic Guides	Stage 1 v1	26 January 2013
Topic Guides	Stage 2 Development v1	26 January 2013
Topic Guides	Stage 2 Review	26 January 2013
Protocol	2	27 May
Advertisement	2	26 May 2013
Letter of Invitation to Participant	2	09 July 2013
Participant Information Sheet: Young Person Stage 1	3	09 July 2013
Participant Information Sheet: Young Person Stage 2	3	09 July 2013
Participant Information Sheet: Young Person Stage 3	3	09 July 2013
Participant Information Sheet: Parent/Guardian Stage 1	3	09 July 2013
Participant Information Sheet: Parent/Guardian Stage 2	3	09 July 2013
Participant Information Sheet: Parent/Guardian Stage 3	3	09 July 2013
Clinician Information Sheet: Clinician Stage 2	3	09 July 2013
Participant Consent Form: Stage 1 & 2 – Young Person	2	24 May 2013
Participant Consent Form: Stage 3 – Young Person	2	24 May 2013
Participant Consent Form: Stage 1 & 2 – Parent/Guardian	2	24 May 2013

Participant Consent Form: Stage 3 – Parent/Guardian	2	24 May 2013
Participant Consent Form: Stage 1 & 2 – Participant (parent/guardian)	2	24 May 2013
Participant Consent Form: Stage 3 – Participant (parent/guardian)	2	24 May 2013

May I to take this opportunity to remind you of your responsibilities as PI for this study to:-

- Report SAE's as per protocol and Trust policy and record total number on OSIRIS
- Ensure that all screening and recruitment activity is updated on OSIRIS every Friday (training can be obtained if required by phoning Ext 3782)
    - Department of Health target for this study is first patient recruited by **14th October 2013**
    - Please provide a timely response to requests for information regarding achievement of this target
- For Trust sponsored studies, provide RD&I with copies of regulatory annual progress and safety reports to Ethics
- Complete and return the RD&I annual report form in a timely manner
- Comply with the Research Governance Framework 2nd Ed 2005 including but not limited to the Medicines for Human use (Clinical Trials) 2004 act plus it's appendices and the Data Protection Act 1998
- Read, disseminate to research team and acknowledge to RD&I, Trust research SOP announcements (details of relevant SOP's can be found at http://staffintranet/departments_and_services/corporate_services/research_and_development/documents/documents.aspx)
- Inform RD&I of any amendments to, or changes of status in, the study.
- Ensure any conditions to approval stipulated by the MHRA/ REC have been addressed prior to implementation of approved changes
- Maintain the study site file (if not provided by the sponsor a template is available on the Trust intranet)
- Provide copies of publications

Investigators who do not comply with the above will be dealt with in accordance with the Trust Disciplinary policy and/or will have their research stopped.

I wish you every success with your research. Please contact the RD&I Department if you require any advice on the above points.

Yours sincerely

[redacted]

Julia West
Operational Director RD&I

cc Head of Directorate
Sheffield Teaching Hospital

.....

I agree to the terms and conditions of the Trust research approval for RD&I **4624, Decision aids in paediatric sedation** and am aware of my responsibilities under the Research Governance framework and Trust Research SOP's.

Signed: ..... Dated: .....

Please return a copy of this letter to the RD&I Department, 4th Floor Linda McCartney Centre, Royal Liverpool Hospital, Prescot Street, Liverpool, L7 8XP

Thank you

Appendix D: Information sheets

Helping young people choose at the dentist

Young person information sheet

Hello, my name is Joe Hulin and I am a PhD student at the University of Sheffield Dental School. Thank you for reading my information sheet. This sheet will tell you why the research is being done and what it will involve. It is important you read this before deciding whether you want to take part in the study.

Why am I doing this research?

I am doing this research to find out how young people feel about having sedation (gas and air) or general anaesthesia (going to sleep) at the dentist. This information can then be used to help make a patient decision aid. This is something that can help young people and their parents or guardians make better decisions about having sedation or general anaesthesia in the future.

Why have I asked you to take part?

I have invited you to take part in this study because you have already had sedation or general anaesthesia at the dentist. You will not be the only person taking part. I plan to speak to about 20 young people in total. If you do choose to take part you and your parent/guardian will each receive a £5 pound gift voucher plus help paying for any extra costs needed to travel here.

Do you have to take part?

No. It is up to you. We will ask you for your assent and then ask if you would sign a form. We will give you a copy of this information sheet and your signed form to keep. You are free to stop taking part **at any time during the research** without giving a reason. If you decide to stop, this will not affect the care you receive.

What will happen to you if you do take part?

If you do decide to take part you and your parent/guardian will need to come to see me so you can tell me about your experiences of having dental treatment with sedation (gas and air) or general anaesthetic (being asleep). This will take place here at the hospital. You and your parent can talk to me for as long you wish but on average it should last about 30 minutes. Sound recordings will be made of these conversations. I am doing this so that I can remember what you say.

Is there anything to be worried about if you take part?

There are no known risks to you from taking part in the study. You don't have to talk about anything you don't want to. You can choose a different name so that no one will be able to tell what you said.

What are the possible benefits of taking part?

The study will not benefit you directly, but we hope that the study will help young people in the future.

What happens when the research stops?

When the study is finished I will look at all the information that I have gained from you and other people taking part. I will then write a report on my findings and send you and your parents a copy. You will continue your treatment at the dentist as normal.

What if there is a problem or something goes wrong?

If you or your parents are unhappy about anything, I will be happy to talk to you at any time. You can stop taking part at anytime. You can tell me or ask your parents or guardians to tell me if you prefer. If you'd prefer not to talk to me and you're a patient at Sheffield either you or your parent/guardian can also contact:

Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email PST@sth.nhs.uk

Or if you're a patient at Liverpool either you or your parent/guardian can contact:

The Royal Liverpool and Broadgreen University Hospitals NHS Trust Customer Relations Team. You can call them on 0151 706 4903.

Will anyone else know you're doing this?

We will keep your information in confidence. This means we will only tell those who have a need or right to know. Wherever possible, we will only send out information that has your name and address removed. All the tapes and other information from the study will be kept securely at the University of Sheffield and destroyed five years after the study has been completed.

Who is organising and paying for the research?

The study is being organised by Joe Hulin, who is a PhD student at the University of Sheffield and is funded by the Society for the Advancement of Anaesthesia in Dentistry (SAAD).

Who has decided if it's OK to do the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the Yorkshire and the Humber Research Ethics Committee.

Contact details

If you have any questions or want to find out more, please contact me by telephone: 07732828405 or email: jhulin1@sheffield.ac.uk

Thank you for reading this. Please ask any questions if you need to.

Helping young people choose at the dentist

Parent/guardian information sheet

Hello, my name is Joe Hulin and I am a PhD student at the University of Sheffield Dental School. Thank you for reading my information sheet. This sheet will tell you why the research is being done and what it will involve. It is important you read this before deciding whether you are happy for you and your child to take part in the study

Why am I doing this research?

I am carrying out research to find out young people's experience of dental sedation and/or general anaesthesia and young person's and parent's experience of the decision making process. The overall aim of the study is to develop a patient decision aid to help children and their parents or guardians make informed choices about having sedation for dental treatment.

Why have I asked you and your child to take part?

I have approached you and your child as your child has already received some dental treatment under sedation or general anaesthesia. I am hoping to talk to 20 children and 20 parents/guardians in total. If you and your child do choose to take part you will each receive a £5 pound gift voucher plus any reasonable travel expenses. Please note that these travel expenses will only be paid on the production of a receipt.

Do you have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign two consent forms, one for your own participation and one for your child's participation. We will give you a copy of these consent forms along with a copy of the information sheet. Your child will also be asked to sign an assent form. Both you and your child are **free to withdraw at any time**, without giving a reason. This would not affect the standard of care your child receives.

What will happen to you if you do take part?

If you do choose to take part you and your child will need to come to see me so you can tell me about your experiences of having dental treatment with sedation or general anaesthetic and the decision-making process. The interview will take place here at the hospital and will take the form of an informal chat. The sessions can last as long as you wish but on average should last 30 minutes. We will need to discuss a convenient time for me to meet you and your child. Please note that sound recordings will be made of the interview so that all information gathered is accurate.

Is there anything to be worried about if you take part?

There are no known risks to you or your child from taking part in the study. You do not have to talk about anything you don't want to. Your names will not appear in any report written about the study, so you need not worry that other people will know what you've said.

What are the possible benefits of taking part?

The study will not change the care or treatment you receive at the Dental Hospital. The study will not benefit you or your child directly, but we hope that the study will help improve dental care for children and young people in the future.

STH reference no. 17248

What happens when the research stops?

When the study is finished I will look at all the information that I have gained from you and other participants. I will then write a report on my findings and send you a copy. Your child will continue their regular dental care as normal.

What if there is a problem or something goes wrong?

I can't see anything going wrong during the study but if you or your child are unhappy about anything, I will be happy to talk to you at any time. You can also stop taking part at anytime.

What if you are not happy about the way the study has been conducted?

If you or your child are harmed by taking part there are no special compensation arrangements. If you or your child are harmed due to someone's negligence, then you may have grounds for legal action. You may have to pay for this. Regardless of this, if you wish to complain, or have any concerns about any aspects of the way you have been approached or treated during the course of this study, the normal National Health Service complaints service is available to you. If you have any complaints or concerns, please contact Joe Hulin on the number overleaf. If that is not satisfactory, if your child is a patient at the Charles Clifford Dental Hospital please contact: Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email PST@sth.nhs.uk

Or alternatively, if your child is a patient at the Liverpool Dental Hospital please contact: The Royal Liverpool and Broadgreen University Hospitals NHS Trust Customer Relations Team. You can contact them directly on 0151 706 4903.

Will anyone else know you are taking part?

All information collected about you and your child is confidential. Any information will have your names and address removed so that you cannot be identified. The only people who will see the information will be the researchers. Nothing that identifies you o your child will be kept on a computer. All the information from the study will be kept securely at the University of Sheffield. The reports will not name any participants. Interview tapes and transcripts will be kept for five years before being destroyed.

Who is organising and funding the research?

The study is being organised by Joe Hulin, who is currently a PhD student at the School of Clinical Dentistry at the University of Sheffield. Joe is supported by an experienced supervisory team including Professor Helen Rodd and Dr Sarah R Baker. Funding to help support the study was awarded by the Society for the Advancement of Anaesthesia in Dentistry (SAAD).

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire and the Humber Research Ethics Committee.

Contact details

If you have any questions or want to find out more, please contact me by telephone: 07732828405 or email: jhulin1@sheffield.ac.uk

Thank you for taking the time to read this. Please feel free to ask any questions if you need to.

Helping young people choose at the dentist

Young person information sheet

Hello, my name is Joe Hulin and I am a PhD student at the University of Sheffield Dental School. Thank you for reading my information sheet. This sheet will tell you why the research is being done and what it will involve. It is important you read this before deciding whether you want to take part in the study.

Why am I doing this research?

I am doing this research to find out how young people feel about having sedation (gas and air) or general anaesthesia (going to sleep) at the dentist. This information can then be used to help make a patient decision aid. This is something that can help young people and their parents or guardians make better decisions about having sedation or general anaesthesia in the future.

Why have I asked you to take part?

I have invited you to take part in this study because you have already had sedation or general anaesthesia at the dentist. You will not be the only person taking part. I plan to speak to about 20 young people in total. If you do choose to take part you and your parent/guardian will each receive a £5 pound gift voucher plus help paying for any extra costs needed to travel here.

Do you have to take part?

No. It is up to you. We will ask you for your assent and then ask if you would sign a form. We will give you a copy of this information sheet and your signed form to keep. You are free to stop taking part **at any time during the research** without giving a reason. If you decide to stop, this will not affect the care you receive.

What will happen to you if you do take part?

If you do decide to take part you and your parent/guardian will need to come to take part in a discussion with other young people and their parents/guardians to see what you think about our decision aid which we have made. This will take place here at the hospital and should last about one hour. Sound recordings will be made of these discussions. I am doing this so that I can remember what you say.

Is there anything to be worried about if you take part?

There are no known risks to you from taking part in the study. You don't have to talk about anything you don't want to. You can choose a different name so that no one will be able to tell what you said.

What are the possible benefits of taking part?

The study will not benefit you directly, but we hope that the study will help young people in the future.

What happens when the research stops?

When the study is finished I will look at all the information that I have gained from you and other people taking part. I will then write a report on my findings and send you and your parents a copy. You will continue your treatment at the dentist as normal.

What if there is a problem or something goes wrong?

If you or your parents are unhappy about anything, I will be happy to talk to you at any time. You can stop taking part at anytime. You can tell me or ask your parents or guardians to tell me if you prefer. If you'd prefer not to talk to me and you're a patient at Sheffield either you or your parent/guardian can also contact:

Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email PST@sth.nhs.uk

Will anyone else know you're doing this?

We will keep your information in confidence. This means we will only tell those who have a need or right to know. Wherever possible, we will only send out information that has your name and address removed. All the tapes and other information from the study will be kept securely at the University of Sheffield and destroyed five years after the study has been completed.

Who is organising and paying for the research?

The study is being organised by Joe Hulin, who is a PhD student at the University of Sheffield and is funded by the Society for the Advancement of Anaesthesia in Dentistry (SAAD).

Who has decided if it's OK to do the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the Yorkshire and the Humber Research Ethics Committee.

Contact details

If you have any questions or want to find out more, please contact me by telephone: 07732828405 or email: jhulin1@sheffield.ac.uk

Thank you for reading this. Please ask any questions if you need to.

Helping young people choose at the dentist

Parent/guardian information sheet

Hello, my name is Joe Hulin and I am a PhD student at the University of Sheffield Dental School. Thank you for reading my information sheet. This sheet will tell you why the research is being done and what it will involve. It is important you read this before deciding whether you are happy for you and your child to take part in the study

Why am I doing this research?

I am carrying out research to find out young people's experience of dental sedation and/or general anaesthesia and young person's and parent's experience of the decision making process. The overall aim of the study is to develop a patient decision aid to help children and their parents or guardians make informed choices about having sedation for dental treatment.

Why have I asked you and your child to take part?

I have approached you and your child as your child has already received some dental treatment under sedation or general anaesthesia. I am hoping to talk to 6-8 children and their parents/guardians in total. If you and your child do choose to take part you will each receive a £5 pound gift voucher plus any reasonable travel expenses. Please note that these travel expenses will only be paid on the production of a receipt.

Do you have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign two consent forms, one for your own participation and one for your child's participation. We will give you a copy of these consent forms along with a copy of the information sheet. Your child will also be asked to sign an assent form. Both you and your child are **free to withdraw at any time**, without giving a reason. This would not affect the standard of care your child receives.

What will happen to you if you do take part?

If you do choose to take part you and your child will need to come to the Dental School to form part to form part of an organised discussion, known as a focus group, which will help review the decision aid. The session should last approximately 1 hour. We will need to discuss a convenient time for me to meet you and your child. Please note that sound recordings will be made of the focus group so that all information gathered is accurate.

Is there anything to be worried about if you take part?

There are no known risks to you or your child from taking part in the study. You do not have to talk about anything you don't want to. Your names will not appear in any report written about the study, so you need not worry that other people will know what you've said.

What are the possible benefits of taking part?

The study will not change the care or treatment you receive at the Dental Hospital. The study will not benefit you or your child directly, but we hope that the study will help improve dental care for children and young people in the future.

What happens when the research stops?

When the study is finished I will look at all the information that I have gained from you and other participants. I will then write a report on my findings and send you a copy. Your child will continue their regular dental care as normal.

What if there is a problem or something goes wrong?

I can't see anything going wrong during the study but if you or your child are unhappy about anything, I will be happy to talk to you at any time. You can also stop taking part at anytime.

What if you are not happy about the way the study has been conducted?

If you or your child are harmed by taking part there are no special compensation arrangements. If you or your child are harmed due to someone's negligence, then you may have grounds for legal action. You may have to pay for this. Regardless of this, if you wish to complain, or have any concerns about any aspects of the way you have been approached or treated during the course of this study, the normal National Health Service complaints service is available to you. If you have any complaints or concerns, please contact Joe Hulin on the number overleaf. If that is not satisfactory, please contact: Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email PST@sth.nhs.uk

Will anyone else know you are taking part?

All information collected about you and your child is confidential. Any information will have your names and address removed so that you cannot be identified. The only people who will see the information will be the researchers. Nothing that identifies you o your child will be kept on a computer. All the information from the study will be kept securely at the University of Sheffield. The reports will not name any participants. Interview tapes and transcripts will be kept for five years before being destroyed.

Who is organising and funding the research?

The study is being organised by Joe Hulin, who is currently a PhD student at the School of Clinical Dentistry at the University of Sheffield. Joe is supported by an experienced supervisory team including Professor Helen Rodd and Dr Sarah R Baker. Funding to help support the study was awarded by the Society for the Advancement of Anaesthesia in Dentistry (SAAD).

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire and the Humber Research Ethics Committee.

Contact details

If you have any questions or want to find out more, please contact me by telephone: 07732828405 or email: jhulin1@sheffield.ac.uk

Thank you for taking the time to read this. Please feel free to ask any questions if you need to.

Decision aids in paediatric dental sedation

(Helping young people choose at the dentist)

Clinician information Sheet

Hello, my name is Joe Hulin and I am a PhD student at the University of Sheffield Dental School. Thank you for reading my information sheet. This sheet will tell you why the research is being done and what it will involve. It is important you read this before deciding whether you are happy for you and your child to take part in the study

Why am I doing this research?

I am carrying out research to find out young people's experience of dental sedation and/or general anaesthesia and young person's and parent's experience of the decision making process. The overall aim of the study is to develop a patient decision aid to help children and their parents or guardians make informed choices about having sedation for dental treatment.

Why do I want to talk to you?

I have approached you as you are an expert in the clinical care involved in sedation and/or general anaesthesia in dentistry.

Do you have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason.

What will happen to you if you agree to take part?

If you do choose to take part you will need to come to the Dental School to form part of an organised discussion which will help develop and review the decision aid. The session should last approximately 1 hour. The focus group will be digitally recorded so all information gathered is accurate.

There is a sheet to fill in if you do want to take part. Please complete the sheet and post it to me. If you don't want to join in, that's fine. I will contact you either by email or telephone to arrange a convenient time, date and place to meet.

Is there anything to be worried about if you do take part?

There are no known risks to you from taking part in the study. You do not have to talk about anything you don't want to. Your names will not appear in any report written about the study.

What are the possible benefits of taking part?

The study will not benefit you directly, but we hope that the study will help young people in the future.

What happens when the research stops?

When the study is finished I will look at all the information that I have gained from you and other participants. I will then write a report on my findings and send you a copy.

What if there is a problem or something goes wrong?

If you are unhappy about anything, I will be happy to talk to you at any time. You can stop taking part at anytime. You can tell me or if you prefer you can also contact Mrs Tracey Plant, Clinical Hospital Manager, Charles Clifford Dental Hospital, Sheffield S10 2SZ or the Patient Services Team on 0114 271 2400 or email PST@sth.nhs.uk

Will anyone else know you are taking part?

All information collected about you is confidential. Any information will have your names and address removed so that you cannot be identified. The only people who will see the information will be the researchers. Nothing that identifies you will be kept on a computer. All the information from the study will be kept securely at the University of Sheffield. The reports will not name any participants. Interview tapes and transcripts will be kept for five years before being destroyed.

Who is organising and funding the research?

The study is being organised by Joe Hulin, who is currently a PhD student at the School of Clinical Dentistry at the University of Sheffield. Joe is supported by an experienced supervisory team including Professor Helen Rodd and Dr Sarah R Baker. Funding to help support the study was awarded by the Society for the Advancement of Anaesthesia in Dentistry (SAAD).

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire and the Humber Research Ethics Committee.

Contact details

If you have any questions or want to find out more, please contact me by telephone: 07732828405 or email: jhulin1@sheffield.ac.uk

Thank you for taking the time to read this. Please feel free to ask any questions if you need to.

Helping young people choose at the dentist

Young person information sheet

Hello, my name is Joe Hulin and I am a PhD student at the University of Sheffield Dental School. Thank you for reading my information sheet. This sheet will tell you why the research is being done and what it will involve. It is important you read this before deciding whether you want to take part in the study.

Why am I doing this research?

I am doing this research to find out how young people feel about having sedation (gas and air) or general anaesthesia (going to sleep) at the dentist. This information can then be used to help make a patient decision aid. This is something that can help young people and their parents or guardians make better decisions about having sedation or general anaesthesia in the future.

Why have I asked you to take part?

I have invited you to take part in this study because you have an appointment to come to the Liverpool Dental Hospital. Sometimes at these appointments it is decided that you may need to have sedation (gas and air) or general anaesthesia (going to sleep) when you finally have your dental treatment. These are medicines that can help to make you less worried and can also help you cope with your dental treatment. You may not need sedation or general anaesthesia but I am letting you know about the study now so you have lots of time to decide if you might want to take part or not. If you do decide to take part you will not be the only person. I hope about 60 young people will take part in total. If you do choose to take part you and your parent/guardian will each receive a £5 pound gift voucher plus help paying for any extra costs needed to travel here.

Do you have to take part?

No. It is up to you. We will ask you for your assent and then ask if you would sign a form. We will give you a copy of this information sheet and your signed form to keep. You are free to stop taking part **at any time during the research** without giving a reason. If you decide to stop, this will not affect the care you receive.

What will happen to you if you do take part?

We will ask you and your parent to fill in a short booklet which includes some questions about yourself and your treatment. This will take about 15 minutes to do. It is not a test and there are no right or wrong answers. You may also be asked to work through a patient decision aid before your treatment. If you are given the decision aid, this will take about 20 minutes to work through and will give you and your family information about making a choice about having dental treatment with sedation or general anaesthetic. If you are not chosen to have the decision aid, you will still get exactly the same written information about sedation or general anaesthesia that would normally be given to you by your dentist.

STH reference no. 17248

Is there anything to be worried about if you take part?

There are no known risks to you from taking part in the study. You don't have to talk about anything you don't want to. You can choose a different name so that no one will be able to tell what you said.

What are the possible benefits of taking part?

The study will not benefit you directly, but we hope that the study will help young people in the future.

What happens when the research stops?

When the study is finished I will look at all the information that I have gained from you and other people taking part. I will then write a report on my findings and send you and your parents a copy. You will continue your treatment at the dentist as normal.

What if there is a problem or something goes wrong?

If you or your parents are unhappy about anything, I will be happy to talk to you at any time. You can stop taking part at anytime. You can tell me or ask your parents or guardian to tell me if you prefer. If you prefer not to contact me, you or your parent/guardian can also contact: The Royal Liverpool and Broadgreen University Hospitals NHS Trust Customer Relations Team. You can call them on 0151 706 4903.

Will anyone else know you're doing this?

We will keep your information in confidence. This means we will only tell those who have a need or right to know. Wherever possible, we will only send out information that has your name and address removed. All information from the study will be kept securely at the University of Sheffield and destroyed five years after the study has been completed.

Who is organising and paying for the research?

The study is being organised by Joe Hulin, who is a PhD student at the University of Sheffield and is funded by the Society for the Advancement of Anaesthesia in Dentistry (SAAD).

Who has decided if it's OK to do the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the Yorkshire and the Humber Research Ethics Committee.

Contact details

If you have any questions or want to find out more, please contact me by telephone: 07732828405 or email: jhulin1@sheffield.ac.uk

Thank you for reading this. Please ask any questions if you need to.

Helping young people choose at the dentist

Parent/guardian information sheet

Hello, my name is Joe Hulin and I am a PhD student at the University of Sheffield Dental School. Thank you for reading my information sheet. This sheet will tell you why the research is being done and what it will involve. It is important you read this before deciding whether you are happy for you and your child to take part in the study

Why am I doing this research?

I am carrying out research to find out young people's experience of dental sedation and/or general anaesthesia and young person's and parent's experience of the decision making process. The overall aim of the study is to develop a patient decision aid to help children and their parents or guardians make informed choices about having sedation for dental treatment.

Why have I asked you and your child to take part?

I have invited you both to take part in this study because your child has been referred for an appointment at the Liverpool Dental Hospital. Sometimes in these appointments it is decided that your child may need to have sedation or general anaesthesia when having dental treatment. Your child may not need sedation or general anaesthesia but I am informing you about the study at this stage so you have sufficient time to decide if you might want to take part or not. You will not have to make this decision until after your child's appointment. I am hoping to recruit 60 young people and 60 parent/guardians in total. If you and your child do choose to take part you will each receive a £5 pound gift voucher plus any reasonable travel expenses. Please note that these travel expenses will only be paid on the production of a receipt.

Do you have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign two consent forms, one for your own participation and one for your child's participation. We will give you a copy of these consent forms along with a copy of the information sheet. Your child will also be asked to sign an assent form. Both you and your child are **free to withdraw at any time**, without giving a reason. This would not affect the standard of care your child receives.

What will happen to you if you do to take part?

If you do choose to take part you and your child will be asked to complete a questionnaire measuring different aspects of the decision making process. This questionnaire should take around 15 minutes to complete. You and your child may also be asked to work through a patient decision aid depending on which of the two groups you are randomly allocated to. If you are selected to look at the decision aid, this will take about 20 minutes of your time and has been designed to give you and your child information about making a choice about having dental treatment under sedation or general anaesthetic. If you are not selected to have the decision aid, you will still get exactly the same written information about sedation or general anaesthesia that is normally provided.

Is there anything to be worried about if you take part?

There are no known risks to you or your child from taking part in the study. You do not have to talk about anything you don't want to. Your names will not appear in any report written about the study, so you need not worry that other people will know what you've said.

What are the possible benefits of taking part?

The study will not change the care or treatment you receive at the Dental Hospital. The study will not benefit you or your child directly, but we hope that the study will help improve dental care for children and young people in the future.

What happens when the research stops?

When the study is finished I will look at all the information that I have gained from you and other participants. I will then write a report on my findings and send you a copy. Your child will continue their regular dental care as normal.

What if there is a problem or something goes wrong?

I can't see anything going wrong during the study but if you or your child are unhappy about anything, I will be happy to talk to you at any time. You can also stop taking part at anytime.

What if you are not happy about the way the study has been conducted?

If you or your child are harmed by taking part there are no special compensation arrangements. If you or your child are harmed due to someone's negligence, then you may have grounds for legal action. You may have to pay for this. Regardless of this, if you wish to complain, or have any concerns about any aspects of the way you have been approached or treated during the course of this study, the normal National Health Service complaints service is available to you. If you have any complaints or concerns, please contact Joe Hulin on the number overleaf. If that is not satisfactory, please contact: The Royal Liverpool and Broadgreen University Hospitals NHS Trust Customer Relations Team. You can contact them on 0151 706 4903.

Will anyone else know you are taking part?

All information collected about you and your child is confidential. Any information will have your names and address removed so that you cannot be identified. The only people who will see the information will be the researchers. Nothing that identifies you or your child will be kept on a computer. All the information from the study will be kept securely at the University of Sheffield and destroyed five years after the study has been completed. The reports will not name any participants.

Who is organising and funding the research?

The study is being organised by Joe Hulin, who is currently a PhD student at the School of Clinical Dentistry at the University of Sheffield. Joe is supported by an experienced supervisory team including Professor Helen Rodd and Dr Sarah R Baker. Funding to help support the study was awarded by the Society for the Advancement of Anaesthesia in Dentistry (SAAD).

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire and the Humber Research Ethics Committee.

Contact details

If you have any questions or want to find out more, please contact me by telephone: 07732828405 or email: jhulin1@sheffield.ac.uk

Thank you for taking the time to read this. Please feel free to ask any questions if you need to.

Appendix E: Consent and assent forms

Decision aids in paediatric dental sedation. Young person assent form. Stages 1 & 2. Version 2. 24th May, 2013.

Participant Identification Number:

YOUNG PERSON ASSENT FORM

Project title: Helping young people choose at the dentist

Name of researcher: Joe Hulin

Young person (or if unable, parent on their behalf) to circle all they agree with:

Has somebody else explained this project to you?	Yes/No
Do you understand what this project is about?	Yes/No
Have you asked all the questions you want?	Yes/No
Have you had your questions answered in a way you understand?	Yes/No
Do you understand that a sound recording will be made of the interview?	Yes/No
Do you understand it's OK to stop taking part at any time?	Yes/No
Are you happy to take part?	Yes/No

If any answers are 'no' or you don't want to take part, don't sign your name!

If you do want to take part, you can write your name below

Your name _____

Date _____

The researcher who explained this project to you needs to sign too:

Print Name _____

Sign _____

Date _____

Thank you for your help.

STH reference no. 17248

Participant Identification Number:

CONSENT FORM

Project title: Helping young people choose at the dentist

Name of researcher: Joe Hulin

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 9th July, 2013 (version 3) 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 my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that sound recordings will be made and that the purpose for which the material will be used has been explained in terms which I have understood. ☐

4. I understand that any information will be used for research purposes only; including research publications and reports. Anonymity and confidentiality will be preserved at all times. ☐

5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent.	Date	Signature

STH reference no. 17248

Participant Identification Number:

PARENT/GUARDIAN CONSENT FORM

Project title: Helping young people choose at the dentist

Name of researcher: Joe Hulin

Name of young person to be involved in the research: _____

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 9th July, 2013 (version 3) 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 we are free to withdraw at any time without giving any reason, without our medical care or legal rights being affected. ☐

3. I understand that sound recordings will be made and that the purpose for which the material will be used has been explained in terms which I have understood. ☐

4. I understand that any information will be used for research purposes only; including research publications and reports. Anonymity and confidentiality will be preserved at all times. ☐

5. I agree that my child can take part in the above study. ☐

Name of Parent/guardian	Date	Signature
Name of Person taking consent.	Date	Signature

STH reference no. 17248

Participant Identification Number:

YOUNG PERSON ASSENT FORM

Project title: Helping young people choose at the dentist

Name of researcher: Joe Hulin

Young person (or if unable, parent on their behalf) to circle all they agree with:

Has somebody else explained this project to you?	Yes/No
Do you understand what this project is about?	Yes/No
Have you asked all the questions you want?	Yes/No
Have you had your questions answered in a way you understand?	Yes/No
Do you understand it's OK to stop taking part at any time?	Yes/No
Are you happy to take part?	Yes/No

If any answers are 'no' or you don't want to take part, don't sign your name!

If you do want to take part, you can write your name below

Your name _____

Date _____

The researcher who explained this project to you needs to sign too:

Print Name _____

Sign _____

Date _____

Thank you for your help.

STH reference no. 17248

Participant Identification Number:

CONSENT FORM

Project title: Helping young people choose at the dentist

Name of researcher: Joe Hulin

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 9th July, 2013 (version 3) 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 my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that any information will be used for research purposes only; including research publications and reports. Anonymity and confidentiality will be preserved at all times. ☐

4. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent.	Date	Signature

STH reference no. 17248

Participant Identification Number:

PARENT/GUARDIAN CONSENT FORM

Project title: Helping young people choose at the dentist

Name of researcher: Joe Hulin

Name of young person to be involved in the research: _____

Please initial all boxes

1. I confirm that I have read and understand the information sheet 9th July, 2013 (version 3) 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 we are free to withdraw at any time without giving any reason, without our medical care or legal rights being affected. ☐

3. I understand that any information will be used for research purposes only; including research publications and reports. Anonymity and confidentiality will be preserved at all times. ☐

4. I agree that my child can take part in the above study. ☐

Name of Parent/guardian	Date	Signature
Name of Person taking consent.	Date	Signature

STH reference no. 17248

Appendix F: Topic guides

Topic Guide
Stage 1 - Interviews

The interviewer will be open to the participants' narratives and flexible in switching between the interview topics.

- Previous experience of dental treatment with sedation/general anaesthesia
    - Background - when/where etc.
    - memory of actual procedure

- Explore the decision made to have treatment with sedation/general anaesthesia
    - How they felt about having to make this decision
    - What factors influenced the decision

- Information they received prior to decision:
    - what they were told
    - how this information was presented
    - when this information was presented
    - the amount of information
    - attitudes towards the above factors
    - information they would've like to have received

- Who was involved in the decision-making process
    - Child
    - Parent/guardian
    - Doctor
    - Others

- Opportunities to be involved in the decision-making process
    - when/where

- Who made the final decision

- Did anyone feel pressured towards choosing a particular option
    - who by
    - at what stage

- Explore how they felt about discussing the decision with the dentist

- Explore how the patient felt about discussing the decision with their parents/guardians

- Explore how the parents/guardians felt about discussing the decision with their child

- Who do they feel should be responsible for the decision
    - reasons for these views

- Attitudes towards the final decision
    - How did they feel about the decision afterwards
    - Was it the right decision

Revised Topic Guide
Stage 1 - Interviews

The interviewer will be open to the participants' narratives and flexible in switching between the interview topics.

- Previous experience of dental treatment with sedation/general anaesthesia
    - Background - when/where etc.
    - memory of actual procedure

- Explore the decision made to have treatment with sedation/general anaesthesia
    - How they felt about having to make this decision
    - What factors influenced the decision

- Information they received prior to decision:
    - what they were told
    - how this information was presented
    - when this information was presented
    - the amount of information
    - attitudes towards the above factors
    - information they would've like to have received

- Who was involved in the decision-making process
    - Child
    - Parent/guardian
    - Doctor
    - Others

- Opportunities to be involved in the decision-making process
    - when/where

- Who made the final decision

- Did anyone feel pressured towards choosing a particular option
    - who by
    - at what stage

- Explore how they felt about discussing the decision with the dentist

- Explore how the patient felt about discussing the decision with their parents/guardians

- Explore how the parents/guardians felt about discussing the decision with their child

- Who do they feel should be responsible for the decision
    - reasons for these views

- Attitudes towards the final decision
    - How did they feel about the decision afterwards
    - Was it the right decision

- Role of dental treatment in the decision-making process

- Current attitudes towards dental treatment and sedation/GA

- Experience of after-care/recovery

- Attitudes towards the pre-treatment procedures – e.g. fasting

- Attitudes towards the method of administration

Topic Guide
Stage 2 - Focus Group
Development Stage
(Clinicians)

- Explore the key information they feel should be provided to young people (aged 11-16) and their carers who are undergoing the decision to receive dental treatment with inhalation sedation, intravenous sedation or general anaesthesia
    - e.g. Key risk factors/benefits

- The format they think this information should be given

- Challenges involved in giving this information

- Aspects of the procedure and pre-procedure that require specific information or instructions

- Particular aspects of undergoing treatment with sedation/general anaesthesia that patients and parents/guardians find difficult to understand

- Aspects of undergoing treatment with sedation/general anaesthesia that patients and parents/guardians find provoke particular anxiety/distress

Questions specific to the initial draft of the decision aid:

- Specific items in the decision aid they feel should be excluded/included

- Attitudes towards the length of the decision aid and the amount of information presented

- Attitudes towards the design of the decision aid

- Attitudes towards the format of the decision aid

Topic Guide
Stage 2 - Focus Group
Review Stage
(Former patients and family members)

- How easy they found the decision aid to use
- Whether they could they understand the information presented
- Aspects of the decision aid they had difficulty working through
- Any unnecessary information
- Any information that requires adding
- Attitudes towards the design of the decision aid
- Attitudes towards pictures
- Attitudes towards format of the decision aid and how they would prefer the decision aid to presented (e. g. electronic, copy, hard copy...)

Revised Topic Guide
Stage 2 - Focus Group
Review Stage
(Former patients and family members)

- How easy they found the decision aid to use
- Whether they could they understand the information presented
- Aspects of the decision aid they had difficulty working through
- Any unnecessary information
- Any information that requires adding
- Attitudes towards the design of the decision aid
- Attitudes towards pictures
- Attitudes towards format of the decision aid and how they would prefer the decision aid to presented (e. g. electronic, copy, hard copy...)
- Attitudes towards the length of the decision aid
- Attitude towards the balance of information

Appendix G: Original draft of the decision aid

Helping young people choose the right treatment at the dentist
A decision aid for young people and their parents

Sometimes young people may need to have medicine to help them relax or go to sleep while they are having treatment at the dentist. This booklet has been written to help young people and their parents or carers to make a choice about the options they have been given.

What are my options?

The 3 options available are:

- Inhalation sedation (also known as 'laughing gas' or 'gas and air'):
  - This involves breathing a gas through your nose. You will still be awake but the gas helps to make you feel less worried and help you cope with the treatment.

- Intravenous sedation (also known as 'IV sedation')
  - This involves having an injection, usually in the back of the hand, which will help you feel more relaxed about having treatment. You will still be awake but you will not remember much about having the treatment.

- General Anaesthetic (also known as 'GA' or 'going to sleep')
  - This will involve going to the hospital to have an injection, usually in the back of the hand, which will send you to sleep while you are having treatment.

1

Step 1: What do these options involve?

Here is some more information about each of the different options.

	Inhalation sedation ('laughing gas' or 'gas and air')	Intravenous sedation ('IV sedation')	General anaesthetic ('GA' or 'going to sleep')
What does it feel like?	The gas will make you feel relaxed and may make you feel a bit sleepy.	The medicine will make you feel relaxed and may make you sleepy. This medicine usually makes you feel sleepier than 'gas and air' and you won't be able to remember much about what happened afterwards.	The medicine, given by a doctor, will make you fall asleep so you won't feel anything.
How will it be given?	You will breathe in the gas through a little mask that fits over your nose. The mask will not cover your mouth. Below is a picture of the mask. It will not have been used by anyone else before. 	You will be given the medicine through a small plastic tube which is usually put in your arm or the back of your hand. A needle is used to put it in, but it is taken out and only the tube stays in. Before you have the tube you will have cream put on your hand or arm, to make sure it's not sore. The medicine can feel a bit stingy as it travels up your arm but this only lasts a short time.	You will be given the medicine, by a doctor, through a small plastic tube which is usually put in your arm or the back of your hand. A needle is used to put it in, but it is taken out and only the tube stays in. Before you have the tube you will have cream put on your hand or arm, to make sure it's not sore. The medicine can feel a bit stingy as it travels up your arm but this only lasts a short time.
Will I still be awake?	Yes you will still be fully awake and know what's happening.	Yes but it may feel as though you have been asleep as you won't be able to remember much about what happened.	No, the medicine will make you go to sleep. You will remain asleep until the treatment has finished.
Will I still need a needle in the gum?	Yes, this will happen after you have had the 'gas and air' so you won't worry so much about the injection. This is to numb your tooth or mouth so you don't feel any pain.	Yes, this will happen after you have had needle in the back of your hand so you won't worry so much about the injection.. This is to numb your tooth or mouth so you don't feel any pain.	Yes, you will still have a little injection in your gum but you won't feel it as you will already be asleep.
Are there any side effects?	Usually there are no side effects at all from the treatment. Occasionally, some people might feel a bit dizzy afterwards.	1 in 10 people might have a headache, feel sick or dizzy, or be sick.	When you wake up will feel a bit wobbly and dizzy and about 1 in 3 people who have general anaesthetic feel sick afterwards. Other side-effects also include having a sore throat, feeling cold and shivering. Very occasionally there may be a serious complication with the anaesthetic but this is unlikely if you are fit and well.

	Inhalation sedation ('laughing gas' or 'gas and air')	Intravenous sedation ('IV sedation')	General anaesthetic ('GA' or 'going to sleep')
Where will I have my treatment?	You will usually have gas and air at the dental clinic.	You will usually have gas and air at the dental clinic.	You will usually have a GA at hospital.
Can I eat or drink anything before?	You should eat and drink normally, but don't have a big meal just before your appointment.	Depending on where you are having your treatment you may be asked to not eat or drink anything before your appointment. This is something which your dentist will tell you before.	You are usually not allowed to eat or drink anything for at least 6 hours before you have the medicine to put you to sleep. This is something which your dentist will tell you before.
When can I go home?	You will usually be able to go home straight after your treatment.	You may need to stay at the dentist or hospital until you are ready to leave. This usually takes about 30 - 60 mins but can be longer.	If you are only asleep for a short time you can usually go home after one hour. If treatment takes longer you may need to stay longer but most young people will be able to go home within two hours.
When can I go back to school?	You will usually be able to go straight to back to school if you feel ok.	You will need to take the rest of the day off school after having the treatment. You may need to take more days off school depending on how you feel. This is something you may also have to talk about with your school.	You will need to take the rest of the day off school after having the treatment. You may need to take more days off school depending on how you feel. This is something you may also have to talk about with your school.

There are other things you also need to think about and talk to your dentist about:

- How long you have to wait for your appointment
- The number of appointments you need to have
- How long you have to wait between appointments
- How long you have to wait on the day of your appointment
- The treatment you have. For example, whether you have teeth taken out or not.

Step 2: Which option suits you best?

Below are some common reasons why you may choose one of the options. For each question, circle how much each reason matters to you on a scale from 1 to 5. '1' means it is not important to you. '5' means it is very important to you. When answering the questions below, if you decide a reason is important to you, your best options are shown on the right. You should discuss these with your dentist.

How important to you is it?	Not Important				Very Important	Options to consider
To be awake when you have treatment?	①	②	③	④	⑤	**Inhalation or IV sedation** *(You will be awake for both inhalation and IV sedation, but you may feel like you've been asleep after IV sedation. If you would rather be asleep you may want to think about choosing GA.)*
To remember what happened?	①	②	③	④	⑤	**Inhalation sedation** *(You will remember everything that happened)*
Not to have a needle in your hand?	①	②	③	④	⑤	**Inhalation sedation** *(You don't need a needle in your hand)*
Not to have a needle in your gum?	①	②	③	④	⑤	**GA**
Not to have a mask on my nose?	①	②	③	④	⑤	**IV sedation or GA**
Not to have to take time off school?	①	②	③	④	⑤	**Inhalation sedation** *(Generally you are more likely to need to take more time off school if you choose GA.)*
To be able to eat or drink before your treatment?	①	②	③	④	⑤	**Inhalation sedation** *(You may also be able to eat or drink before treatment with IV sedation, this is something you can discuss with your dentist.)*
That you're not at the hospital for a long time?	①	②	③	④	⑤	**Inhalation or IV sedation** *(With GA you may have to spend time on the ward before and after treatment.You may also have to stay at the dentist for around 30-60 mins after treatment if you choose IV sedation.)*
To not have any serious side effects?	①	②	③	④	⑤	**Inhalation or IV sedation**
To not feel sick after treatment?	①	②	③	④	⑤	**Inhalation or IV sedation**
To not have to go somewhere different for treatment?	①	②	③	④	⑤	**Inhalation or IV sedation** *(You will usually have general anaesthetic at a different hospital.)*

Below are some reasons that may change depending on your dentist so we can't show you the best options to consider. If any of these reasons are important to you can discuss this with your dentist what the best options might be and fill it in yourself.

How important to you is it?	Not Important				Very Important	Options to consider
How many appointments you have?	①	②	③	④	⑤	
How long you have to wait for treatment?	①	②	③	④	⑤	
Which type of treatment you have? - e.g. having teeth removed.	①	②	③	④	⑤	
List other things that are important:	①	②	③	④	⑤	
	①	②	③	④	⑤	
	①	②	③	④	⑤	

Step 3: What else do you need to make your decision?

Now you can find out how well this decision aid helped you learn important facts.
Put a tick in the box or boxes which you think are the right answers. Some questions might have more than one right answer. You can find the right answers at the end of the booklet.

	Inhalation sedation	Intravenous sedation	General anaesthetic	Don't know
1. I will have to wear a mask if I choose?	☐	☐	☐	☐
2. I will need a needle in the hand if I choose?	☐	☐	☐	☐
3. Which option has the highest chance of making me feel sick?	☐	☐	☐	☐
4. I might be able to go back to school straight away if I choose?	☐	☐	☐	☐

Knowledge		Yes	No
	Do you know enough about each option?	☐	☐
Values		**Yes**	**No**
	Are you clear about which reasons to choose each option matter most to you?	☐	☐
Support		**Yes**	**No**
	Do you have enough support and advice from others to make a choice?	☐	☐
Uncertainty		**Yes**	**No**
	Do you feel sure about the best choice for you?	☐	☐

Step 4: What are the next steps

Check your next steps:

☐ We have decided to have treatment with inhalation sedation ('gas and air')

☐ We have decided to have treatment with intravenous sedation ('IV sedation')

☐ We have decided to have treatment with general anaesthetic ('going to sleep')

☐ I need to discuss the options with _____

☐ I need to read more about my options.

☐Other, please specify_____

Answers to the key fact questions: 1. Inhalation sedation 2. Intravenous sedation and general anaesthetic 3. General Anaesthetic 4. Inhalation sedation

Appendix H: Final version of the decision aid

Helping young people choose at the dentist

A decision aid about sedation and general anaesthesia for young people and their parents

When you have a dental check-up the dentist may say that you need some treatment. For example the dentist may say that you need a filling, or that you need a tooth taken out. Sometimes young people may need to have medicine to help them relax (sedation) or go to sleep (general anaesthesia) while they are having treatment at the dentist. You will be offered some options about the sedation or general anaesthetic. This booklet has been made for you to look at with your parent or carer to help you make the choice that is best for you.

So here are the options you may have.....

- **Having gas and air (also known as 'happy air', 'laughing gas' or 'inhalation sedation')**

  This involves breathing a gas through your nose. You will still be awake but the gas helps you feel more relaxed about having treatment.

- **Having IV sedation (also known as 'intravenous sedation')**

  This involves being given medicine through a small plastic tube, which is usually put in your arm or the back of your hand. This medicine will help you feel more relaxed about having treatment. You will still be awake but you may not remember everything about having the treatment.

- **Having a general anaesthetic (also known as 'GA' or 'going to sleep')**

  This involves being given medicine through a small plastic tube, which is usually put in your arm or the back of your hand. This medicine will send you to sleep while you are having treatment.

You may also decide.....

- To have your dental treatment without any type of sedation or a general anaesthetic.
- Or not to have any treatment at all. If you decide this you will be more likely to have further dental problems, such as infection around the tooth which could spread around the face and body if left untreated.

Step 1: What do the options involve?

Here is some more information about each of the different options.

	Gas and air ('happy air', 'laughing gas' or 'inhalation sedation')	IV sedation ('intravenous sedation')	General anaesthetic ('GA' or 'going to sleep')
Where will I have my treatment?	You will have gas and air at the dental hospital.	You will have IV sedation at the dental hospital.	You will have a GA at the dental hospital or the children's hospital.
Can my parent or carer stay with me?	Yes your parent or carer will be allowed to stay in the room with you while you are having treatment.	Yes your parent or carer will be allowed to stay in the room with you while you are having treatment.	Your parent or carer will be allowed to come into the room with you but they will be asked to leave after you fall asleep. Your parent or carer will then wait near-by while you have treatment. You will then be brought in to see your parent or carer after your treatment has finished and you have woken up.
What does it feel like?	The gas will make you feel relaxed and may make you feel a bit sleepy.	The medicine will make you feel relaxed and may make you sleepy. This medicine usually makes you feel sleepier than gas and air and you may not be able to remember much about what happened afterwards.	The medicine, given by a doctor called an 'anaesthetist', will make you fall asleep so you won't feel anything when you're having treatment.
How will it be given?	You will breathe in the gas through a little mask that fits over your nose. The mask will not cover your mouth and will have been cleaned before you use it.	You will be given the medicine through a small plastic tube which is put in your arm or the back of your hand. A needle is used to put it in, but this is taken out and only the tube stays in. The medicine can feel a bit stingy as it travels up your arm but this only lasts a few seconds.	You will usually be given the medicine through a small plastic tube which is put in your arm or the back of your hand. A needle is used to put it in, but this is taken out and only the tube stays in. The medicine can feel a bit stingy as it travels up your arm but this only lasts a few seconds. Sometimes you may need to wear a mask over your nose and mouth as well; this is something you can discuss with your dentist.
Will I be awake?	Yes you will still be awake and know what's happening.	Yes but it may feel as though you have been asleep as you may not be able to remember everything that happened.	No, the medicine will make you go to sleep. You will remain asleep until the treatment has finished and then you will wake up.
Will I still need a needle in my gum?	Yes, this will happen after you have had the gas and air so you won't worry so much about the needle. This is to numb your tooth or mouth so you don't feel any pain.	Yes, this will happen after you have had the medicine through your arm or hand so you won't worry so much about the needle. This is to numb your tooth or mouth so you don't feel any pain.	You may still have a needle in your gum but you won't notice it as you will already be asleep.

	Gas and air ('happy air', 'laughing gas' or 'inhalation sedation')	IV sedation ('intravenous sedation')	General anaesthetic ('GA' or 'going to sleep')
Are there any side effects?	There are usually no side effects but you might feel a bit dizzy afterwards. Very occasionally some people might have a headache, feel sick, or be sick afterwards.	There are usually no side effects but you might feel a bit dizzy afterwards. Very occasionally some people might have a headache, feel sick, or be sick afterwards.	When you wake up you will feel a bit wobbly and dizzy. About 1 in 3 people who have general anaesthetic feel sick afterwards. About 1 in 4 people begin to shiver afterwards. This shivering usually stops after a few minutes. Other side effects include having a sore throat. Very occasionally there may be a serious complication with the anaesthetic but this is unlikely if you are fit and well.
Should I eat or drink anything before?	You should eat and drink normally, but don't have a big meal just before your appointment. You should have a light meal about two hours before your appointment.	Have a light meal about six hours before your appointment. After this you must not have anything to eat before your treatment. You may have a small non-fizzy drink of water or squash up to two hours before your appointment. After this you must not have anything to drink.	You should not eat anything for six hours before your appointment. You may have a small non-fizzy drink of water or squash up to two hours before your appointment. You should have nothing at all for the last two hours before your appointment, this includes water and chewing gum.
How long will I have to stay after treatment?	You will usually be able to leave straight after your treatment.	You will need to stay at the dental hospital until you are ready to leave. This usually takes about 30 - 60 mins but can be longer.	If you are only asleep for a short time you can usually go home after one hour. If treatment takes longer you may need to stay longer but most young people will be able to go home within two hours.
When can I go back to school?	You will usually be able to go straight back to school after having treatment if you feel ok. However, you should avoid doing any physical activity such as sports, dance or playing outdoors.	You will need to take the rest of the day off school after having treatment and may need to take another day off school depending on how you feel. This is something you may have to talk about with your dentist and your school.	You will need to take the full day off school when having treatment. You may need to take another day off school depending on how you feel. This is something you may have to talk about with your dentist and your school.
How many appointments will I need to have?	You may need to come to the dental hospital more than once to have gas and air before you complete your treatment.	You may need to come to the dental hospital more than once to have IV sedation before you complete your treatment.	You will usually need to come to the dental hospital or children's hospital once to have the GA, as all your treatment will usually be done in one visit.

There are other things you also need to think about and talk to your dentist about:

- **How long will you have to wait for your appointment? For example, there may be a difference in how soon you can get an appointment depending on what you choose.**
- **How long will you have to wait between appointments?**
- **What dental treatment you will have? For example, whether you will be having teeth taken out or not?**

Step 2: Which option suits you best?

Below are some common reasons why you may choose one of the options. For each question, circle how much each reason matters to you on a scale from 0 to 5. '0' means it is not important to you, '5' means it is very important to you. If you decide a reason is important to you, the option(s) that might suit you best are shown on the right hand side. You should discuss these with your dentist.

How important to you is it?	Not Important					Very Important	Your 'best' option(s) to consider if this reason is important to you are shown below ⇩
To be awake when you have treatment?	0	1	2	3	4	5	**Gas and air or IV sedation** *(Because you will be awake for both gas and air and IV sedation, but you may feel like you've been asleep after IV sedation)*
To remember what happened?	0	1	2	3	4	5	**Gas and air** *(Because you will remember everything that happened)*
To avoid having a needle in your hand or arm?	0	1	2	3	4	5	**Gas and air** *(Because you don't need a needle in your arm or hand)*
To avoid feeling the needle in the gum?	0	1	2	3	4	5	**General anaesthetic** *(Because if you do need a needle in your gum you won't notice it as you will already be asleep)*
To avoid having a mask on my nose?	0	1	2	3	4	5	**IV sedation** *(Because you won't have to wear a mask)*
To be able to eat or drink before your treatment?	0	1	2	3	4	5	**Gas and air** *(Because you can eat and drink normally, but don't have a big meal just before your appointment)*
To avoid being at the hospital or dentist for a long time?	0	1	2	3	4	5	**Gas and air or IV sedation** *(Because with GA you may have to spend time on the ward before and after treatment. You may also have to stay at the dentist for around 30-60 mins after treatment if you choose IV sedation.)*
To avoid side effects?	0	1	2	3	4	5	**Gas and air or IV sedation** *(Because you are more likely to avoid side effects if you choose gas and air or IV sedation.)*
To be able to go straight back to school afterwards?	0	1	2	3	4	5	**Gas and air** *(Because you will usually be able to go straight back to school after having treatment with gas and air if you feel ok.)*
To have your treatment at the dental hospital?	0	1	2	3	4	5	**Gas and air or IV sedation** *(Because these are done at the dental hospital but you may have go to the children's hospital for a GA)*
To have your parent/carer with you while you're having treatment?	0	1	2	3	4	5	**Gas and air or IV sedation** *(Because your parent or carer will be able to stay with you while you are having treatment.)*
To have fewer appointments?	0	1	2	3	4	5	**General anaesthetic** *(Because all your treatment will usually be done at the same time under GA.)*

Below is some space for you to list any other reasons that might be important to you. You can write these reasons under 'How important to you is it?' You can then discuss these reasons with your dentist to see what the best options might be. You can then write these options on the right hand side of the table.

How important to you is it? (Write your reasons below….)	Not Important					Very Important	Your 'best' option(s) to consider if this reason is important to you (Write what the dentist says below……)
_____	0	1	2	3	4	5	_____
_____	0	1	2	3	4	5	_____
_____	0	1	2	3	4	5	_____
_____	0	1	2	3	4	5	_____
_____	0	1	2	3	4	5	_____

Step 3: What else do you need to make your decision?

Now you can find out how well this decision aid helped you learn important facts.
Put a tick ☑ in the box or boxes which you think are the right answers. Some questions might have more than one right answer. You can find the right answers at the end of this booklet.

	Gas and air	IV sedation	General anaesthetic	Don't know
1. I will be awake during treatment if I have…	☐	☐	☐	☐
2. I will need a needle in the hand or arm if I have…	☐	☐	☐	☐
3. 1 in 3 people feel sick after having…	☐	☐	☐	☐
4. I might be able to go back to school straight away if I have…	☐	☐	☐	☐

Knowledge	Yes	No
	**Do you know enough about the reasons to choose each option?** **Tick ☑ the box for either yes or no**	☐	☐

If you feel you don't know enough about each option below are some things you may want to try.
Tick ☑ the box if you would like to:

☐ Find out more about the options and the reasons to choose each one
☐ List any questions you still have:

_____
_____

☐ Note down where you are going to try and find the answers:

_____
_____

Values	Yes	No
	**Are you clear about which reasons to choose each option matter most to you?** **Tick ☑ the box for either yes or no**	☐	☐

If you're not sure about which reasons matter most to you below are some things you may want to try.
Tick ☑ the box if you would like to:

☐ Go back to step 2 again to see which reasons to choose each option matter most to you
☐ Talk to other people who know what it's like to experience the different choices
☐ Discuss with others what matters most to you

Support	Yes	No
	**Do you have enough support and advice from others to make a choice?** **Tick ☑ the box for either yes or no**	☐	☐

If you feel you do not have enough support below are some things you may want to try.
Tick ☑ the box if you would like to:

☐ Discuss your options with a trusted person
☐ Find help to support your choice

Uncertainty	Yes	No
	**Do you feel sure about the best choice for you?** **Tick ☑ the box for either yes or no**	☐	☐

List any other things that are making the decision difficult and anything else you need to know:

_____
_____
_____
_____

Step 4: What are the next steps

Check your next steps by ticking ☑ the boxes below:

☐ We have decided to have treatment with gas and air ('happy air', 'laughing gas' or 'inhalation sedation')
☐ We have decided to have treatment with IV sedation ('intravenous sedation')
☐ We have decided to have treatment with general anaesthetic ('GA' or 'going to sleep')
☐ We need to discuss the options with: _____
☐ We need to read more about the options
☐ Other, please write here: _____

This information is not intended to replace the advice of a health care provider.
Answers to the key fact questions: 1. Gas and air and IV sedation 2. IV sedation and general anaesthetic 3. General anaesthetic 4. Gas and air
The decision aid was developed by Joe Hulin, Helen Rodd, Zoe Marshman, Sondos Albadri and Sarah Baker at the School of Clinical Dentistry, University of Sheffield, UK and the Royal Liverpool University Dental Hospital, Liverpool, UK.
Funded by the Society for the Advancement of Anaesthesia in Dentistry (SAAD)

SAAD

Appendix I: Study invite letter

School of Clinical Dentistry
University of Liverpool, Pembroke Place
Liverpool
L3 5PS

Telephone: 01517065301
Email: sondosr@liverpool.ac.uk

(DATE)

Dear (INSERT PARENT/GUARDIAN NAME)

My name is Dr Sondos Albadri and I am a consultant paediatric dentist at Liverpool Dental Hospital. I am writing to inform you about a research project currently taking place here at Liverpool Dental Hospital which you and your child may be eligible to take part in. In order to provide you with more information about the study I have attached two separate information sheets for you to read through before your appointment at the Liverpool Dental Hospital on (INSERT DATE). One information sheet is for you and one is for your child. If you think you might be interested in taking part, a member of the research team will be available to talk to you more about the study at the Dental Hospital following your appointment. Please note that not every person who receives this letter will be eligible for taking part in the study and this will depend on the outcome of your appointment on the (INSERT DATE).

Yours sincerely

Dr Sondos Albadri

STH reference no. 17248

Appendix J: Traditional Decisional Conflict Scale (O'Connor, 1993)

Traditional Decisional Conflict Scale (DCS) – Statement Format: 16 item 5 response categories

This is our most tested version. Many people like the personal response format. However, it is more difficult to respond to than questions in those with limited reading and response skills. Note: We always precede the DCS with an option preference question, which is not included in scoring.
[See item 'A' below].

My difficulty in making this choice

A. Which [insert treatment/screening] option do you prefer? Please check ☑ one.

- ☐ [Option 1]
- ☐ [Option 2]
- ☐ [Option 3]
- ☐ Unsure

B. Considering the option you prefer, please answer the following questions:

	Strongly Agree [0]	Agree [1]	Neither Agree Nor Disagree [2]	Disagree [3]	Strongly Disagree [4]
1. I know which options are available to me.	☐	☐	☐	☐	☐
2. I know the benefits of each option.	☐	☐	☐	☐	☐
3. I know the risks and side effects of each option.	☐	☐	☐	☐	☐
4. I am clear about which benefits matter most to me.	☐	☐	☐	☐	☐
5. I am clear about which risks and side effects matter most to me.	☐	☐	☐	☐	☐
6. I am clear about which is more important to me (the benefits or the risks and side effects).	☐	☐	☐	☐	☐
7. I have enough support from others to make a choice.	☐	☐	☐	☐	☐
8. I am choosing without pressure from others.	☐	☐	☐	☐	☐
9. I have enough advice to make a choice.	☐	☐	☐	☐	☐
10. I am clear about the best choice for me.	☐	☐	☐	☐	☐
11. I feel sure about what to choose.	☐	☐	☐	☐	☐
12. This decision is easy for me to make.	☐	☐	☐	☐	☐
13. I feel I have made an informed choice.	☐	☐	☐	☐	☐
14. My decision shows what is important to me.	☐	☐	☐	☐	☐
15. I expect to stick with my decision.	☐	☐	☐	☐	☐
16. I am satisfied with my decision.	☐	☐	☐	☐	☐

Appendix K: Low Literacy Decisional Conflict Scale (O'Connor, 1993)

4.3 **Question Format DCS - 10 item 3 response categories**

This version is recommended for those with limited reading or response skills.
Note: We always precede the DCS with an option preference question, which is not included in scoring. [See item 'A' below].

4.3.1 Scale

My difficulty in making this choice

A. Which [insert treatment/screening] option do you prefer? Please check ☑ one.

a. ☐ **[Option 1]**
b. ☐ **[Option 2]**
c. ☐ **[Option 3]**
d. ☐ Unsure

B. Considering the option you prefer, please answer the following questions:

	Yes [0]	Unsure [2]	No [4]
1. Do you know which options are available to you?	☐	☐	☐
2. Do you know the benefits of each option?	☐	☐	☐
3. Do you know the risks and side effects of each option?	☐	☐	☐
4. Are you clear about which benefits matter most to you?	☐	☐	☐
5. Are you clear about which risks and side effects matter most to you?	☐	☐	☐
6. Do you have enough support from others to make a choice?	☐	☐	☐
7. Are you choosing without pressure from others?	☐	☐	☐
8. Do you have enough advice to make a choice?	☐	☐	☐
9. Are you clear about the best choice for you?	☐	☐	☐
10. Do you feel sure about what to choose?	☐	☐	☐

Appendix L: Modified Child Dental Anxiety Scale (MCDAS) (Wong et al., 1998)

How do you feel about:

1. **Going to the dentist generally?**

   ☐ Relaxed/not worried
   ☐ Worried a little
   ☐ Fairly Worried
   ☐ Worried a lot
   ☐ Extremely worried

2. **Having your teeth looked at?**

   ☐ Relaxed/not worried
   ☐ Worried a little
   ☐ Fairly Worried
   ☐ Worried a lot
   ☐ Extremely worried

3. **Having teeth scraped and polished?**

   ☐ Relaxed/not worried
   ☐ Worried a little
   ☐ Fairly Worried
   ☐ Worried a lot
   ☐ Extremely worried

4. **Having an injection in the gum?**

   ☐ Relaxed/not worried
   ☐ Worried a little
   ☐ Fairly Worried
   ☐ Worried a lot
   ☐ Extremely worried

5. **Having a filling?**

   ☐ Relaxed/not worried
   ☐ Worried a little
   ☐ Fairly Worried
   ☐ Worried a lot
   ☐ Extremely worried

6. Having a tooth taken out?

- ☐ Relaxed/not worried
- ☐ Worried a little
- ☐ Fairly Worried
- ☐ Worried a lot
- ☐ Extremely worried

7. Being put to sleep to have treatment?

- ☐ Relaxed/not worried
- ☐ Worried a little
- ☐ Fairly Worried
- ☐ Worried a lot
- ☐ Extremely worried

8. Having a mixture of gas and air to help you feel comfortable for treatment but cannot put you to sleep?

- ☐ Relaxed/not worried
- ☐ Worried a little
- ☐ Fairly Worried
- ☐ Worried a lot
- ☐ Extremely worried

Appendix M: Knowledge Scale (O'Connor, 2000)

Sample Tool: Knowledge (Tamoxifen)

A. What I know about options for lowering my risk of breast cancer

We would like to know how much you know about options for lowering your risk of breast cancer after you have used the workbook and audiotape. Don't worry if you can not remember everything … we did not expect you to memorize the information you received. But it would help us learn what things impressed you enough that you can recall them easily. If you wish, you can refer back to the audiotape and workbook.

Below are listed some statements about options for lowering your risk of breast cancer. Please mark if you think they are true, false or you are not sure by circling your answer.

1. **Options for lowing my risk of breast cancer are:**

Exercising regularly	True	False	Unsure
Having a healthy weight	True	False	Unsure
Drinking more alcohol	True	False	Unsure
Eating 5 or more fruit & vegetables a day	True	False	Unsure
Eating foods higher in fibre	True	False	Unsure
Eating foods higher in fat	True	False	Unsure
Taking tamoxifen every day	True	False	Unsure

2. **Tamoxifen can be given:**

To women with breast cancer	True	False	Unsure
To healthy women who have a higher risk of breast cancer	True	False	Unsure
For 5 years	True	False	Unsure

3. **Benefits (pros) of taking tamoxifen for healthy women who are at higher risk of breast cancer are:**

Lowers chance of breast cancer	True	False	Unsure
Lowers chance of cancer of the uterus	True	False	Unsure
Lowers chance of blood clots	True	False	Unsure
Lowers chance of osteoporosis	True	False	Unsure
Lowers blood levels of "bad" cholesterol	True	False	Unsure
Lowers chance of cataracts	True	False	Unsure

4. Risks (cons) of taking tamoxifen for healthy women who are at higher risk of breast cancer are:

Increases chance of breast cancer	True	False	Unsure
Increases chance of cancer of the uterus	True	False	Unsure
Increases chance of blood clots	True	False	Unsure
Increases chance of osteoporosis	True	False	Unsure
Increases blood levels of "bad" cholesterol	True	False	Unsure
Increases chance of cataracts	True	False	Unsure

5. Some side effects of tamoxifen are:

Hot flashes	True	False	Unsure
Insomnia	True	False	Unsure
Breast tenderness	True	False	Unsure
Weight gain	True	False	Unsure
Vaginal dryness	True	False	Unsure

Appendix N: Acceptability Scale (O'Connor and Cranney, 2000)

Sample Tool: Acceptability (Osteoporosis Therapy)

My thoughts on the education package on osteoporosis

We would like to know what you think about the education package you have just received.

1. Please rate each section, by circling 'poor', 'fair', 'good', or 'excellent' to show what you think about the way the information was presented on:

Impact of Osteoporosis	poor	fair	good	excellent
Risk Factors	poor	fair	good	excellent
Types of Research Studies	poor	fair	good	excellent
Self-Care Options	poor	fair	good	excellent
Evidence About Self-Care	poor	fair	good	excellent
Medication Options	poor	fair	good	excellent
Evidence About Medications	poor	fair	good	excellent
Stories About Others	poor	fair	good	excellent

2. The length of presentation was (*check one)*

   |__| too long
   |__| too short
   |__| just right

3. The amount of information was (*check one*)

   |__| too much information
   |__| too little information
   |__| just right

4. I found the presentation (*check one*)

   |__| slanted towards taking self-care or lifestyle options
   |__| slanted towards taking medical therapies
   |__| balanced

5. Would you have found this decision aid useful when you were making your decision about therapy for osteoporosis?

   |__| Yes
   |__| No
   Comments:

6. What did you think of the way to calculate your risk of fractures on the worksheet? (Step 1) Was it

   |__| easy to find your risk level, or
   |__| difficult?
   Comments:

7. What did you think of the rest of the personal worksheet?
   Did it make the decision

   |__| easy, or
   |__| more difficult?
   Comments:

8. Do you think we included enough information to help a woman decide on therapy for osteoporosis?

   |__| Yes
   |__| No
   Comments:

9. What did you like about the decision aid and worksheet?

   _____

   _____

   _____

   _____

   _____

10. What suggestions do you have to improve the decision aid or worksheet?

    _____

    _____

    _____

    _____

    _____

Appendix O: Questionnaire booklet for patients (control group)

ID number:

Questionnaire about 'Helping young people choose at the dentist'

Hello,
Thanks for agreeing to help us with our study. This study is being done so we can understand more about how we can help young people choose the right treatment at the dentist. By answering the questions, you will help us make sure young people have better information in the future. In this booklet, you will find some sets of questions about you, your choice and what you know about your treatment. Please answer all the questions using the instructions. There is no right or wrong answer.

Are you: (please tick ☑ one box)

☐ A boy
☐ A girl

When were you born?

_____/_____/_____
DAY MONTH YEAR

Have you ever had any of these treatments below before? (please tick ☑ one box next to each option)

	Yes	No	I don't know
Gas and air (also known as 'laughing gas', 'happy air' or 'inhalation sedation')	☐	☐	☐
IV sedation (also known as 'intravenous sedation')	☐	☐	☐
General anaesthetic (also known as 'GA' or 'going to sleep')	☐	☐	☐

How would you describe yourself? (please tick ☑ one box)

White
☐ British
☐ Irish
☐ Other white background

Mixed
☐White & Black Caribbean
☐White & Black African
☐White and Asian
☐Other mixed background
☐Other Asian Background

Other
☐Other ethnic group

Black or Black British
☐Caribbean
☐African
☐Other Black background

Asian or British Asian
☐Indian
☐Pakistani
☐Bangladeshi
☐Chinese

Which treatment option do you prefer? (please tick ☑ one box)

☐ Gas and air (also known as 'laughing gas', 'happy air' or 'inhalation sedation')
☐ IV sedation (also known as 'intravenous sedation')
☐ General anaesthetic (also known as 'GA' or 'going to sleep')
☐Unsure

Please answer the following questions. Please tick ☑ one box next to each sentence to tell us whether you agree or disagree with what it says.

	Yes	Unsure	No
1. Do you know which options are available to you?	☐	☐	☐
2. Do you know the benefits of each option?	☐	☐	☐
3. Do you know the risks and side effects of each option?	☐	☐	☐
4. Are you clear about which benefits matter most to you?	☐	☐	☐
5. Are you clear about which risks and side effects matter most to you?	☐	☐	☐
6. Do you have enough support from others to make a choice?	☐	☐	☐
7. Are you choosing without pressure from others?	☐	☐	☐
8. Do you have enough advice to make a choice?	☐	☐	☐
9. Are you clear about the best choice for you?	☐	☐	☐
10. Do you feel sure about what to choose?	☐	☐	☐

For the next eight questions I would like you to show me how relaxed or worried you get about the dentist and what happens at the dentist. Please tick ☑ one box next to each question to show me how you feel.

How do you feel about:

	Relaxed/not worried	Very slightly worried	Fairly worried	Worried a lot	Extremely worried
1. Going to the dentist generally?	☐	☐	☐	☐	☐
2. Having your teeth looked at?	☐	☐	☐	☐	☐
3. Having teeth scraped and polished?	☐	☐	☐	☐	☐
4. Having an injection in the gum?	☐	☐	☐	☐	☐
5. Having a filling?	☐	☐	☐	☐	☐
6. Having a tooth taken out?	☐	☐	☐	☐	☐
7. Being put to sleep to have treatment?	☐	☐	☐	☐	☐
8. Having a mixture of 'gas and air' which will help you feel comfortable for treatment but cannot put you to sleep?	☐	☐	☐	☐	☐

We would also like to find out how much you know about the choices you have been given at the dentist. Below are some sentences about the different choices you were given. Please mark if you think they are true, false or you are unsure by ticking ☑ one box next to each sentence.

If you have IV sedation ('intravenous sedation'):	True	False	Unsure
You won't have to wear a mask	☐	☐	☐
You will need to have a needle in the gum	☐	☐	☐
You will be asleep during treatment	☐	☐	☐
You may have a light meal 2 hours before the appointment	☐	☐	☐
You may not remember everything that happened	☐	☐	☐

If you have gas and air ('laughing gas', 'happy air' or 'inhalation sedation'):	True	False	Unsure
You will have to wear a mask	☐	☐	☐
You should have a big meal just before the appointment	☐	☐	☐
You will need to have a needle in the hand or arm	☐	☐	☐
You won't need to have a needle in the gum	☐	☐	☐
You will be awake during treatment	☐	☐	☐

If you have a general anaesthetic ('GA' or 'going to sleep'):	True	False	Unsure
You will be asleep during treatment	☐	☐	☐
You should not eat anything for six hours before the appointment	☐	☐	☐
You will be able to go straight home afterwards	☐	☐	☐
You won't need to have a needle in the hand or arm	☐	☐	☐
There is a 1 in 10 chance of feeling sick afterwards	☐	☐	☐

Thank you very much for your help!

Appendix P: Questionnaire booklet for patients (intervention group)

ID number:

Questionnaire about 'Helping young people choose at the dentist'

Hello,

Thanks for agreeing to help us with our study. This study is being done so we can understand more about how we can help young people choose the right treatment at the dentist. By answering the questions, you will help us make sure young people have better information in the future. In this booklet, you will find some sets of questions about you, your choice and what you know about your treatment. Please answer all the questions using the instructions. There is no right or wrong answer.

Are you: (please tick ☑ one box)

☐ A boy
☐ A girl

When were you born?

_____/_____/_____
DAY MONTH YEAR

Have you ever had any of these treatments before? (please tick ☑ one box next to each option)

	Yes	No	I don't know
Gas and air (also known as 'laughing gas', 'happy air' or 'inhalation sedation')	☐	☐	☐
IV sedation (also known as 'intravenous sedation')	☐	☐	☐
General anaesthetic (also known as 'GA' or 'going to sleep')	☐	☐	☐

In total, how much time did you spend looking at the decision aid? (Your answer can be 0 minutes!)

Hours: _____ Minutes: _____

How would you describe yourself? (please tick ☑ one box)

White
☐ British
☐ Irish
☐ Other white background

Mixed
☐White & Black Caribbean
☐White & Black African
☐White and Asian
☐Other mixed background
☐Other Asian Background

Other
☐Other ethnic group

Black or Black British
☐Caribbean
☐African
☐Other Black background

Asian or British Asian
☐Indian
☐Pakistani
☐Bangladeshi
☐Chinese

Which treatment option do you prefer? (please tick ☑ one box)

☐ Gas and air (also known as 'laughing gas', 'happy air' or 'inhalation sedation')
☐ IV sedation (also known as 'intravenous sedation')
☐ General anaesthetic (also known as 'GA' or 'going to sleep')
☐Unsure

Please answer the following questions. Please tick ☑ one box next to each sentence to tell us whether you agree or disagree with what it says.

	Yes	Unsure	No
1. Do you know which options are available to you?	☐	☐	☐
2. Do you know the benefits of each option?	☐	☐	☐
3. Do you know the risks and side effects of each option?	☐	☐	☐
4. Are you clear about which benefits matter most to you?	☐	☐	☐
5. Are you clear about which risks and side effects matter most to you?	☐	☐	☐
6. Do you have enough support from others to make a choice?	☐	☐	☐
7. Are you choosing without pressure from others?	☐	☐	☐
8. Do you have enough advice to make a choice?	☐	☐	☐
9. Are you clear about the best choice for you?	☐	☐	☐
10. Do you feel sure about what to choose?	☐	☐	☐

For the next eight questions I would like you to show me how relaxed or worried you get about the dentist and what happens at the dentist. Please tick ☑ one box next to each question to show me how you feel.

How do you feel about:

	Relaxed/not worried	Very slightly worried	Fairly worried	Worried a lot	Extremely worried
1. Going to the dentist generally?	☐	☐	☐	☐	☐
2. Having your teeth looked at?	☐	☐	☐	☐	☐
3. Having teeth scraped and polished?	☐	☐	☐	☐	☐
4. Having an injection in the gum?	☐	☐	☐	☐	☐
5. Having a filling?	☐	☐	☐	☐	☐
6. Having a tooth taken out?	☐	☐	☐	☐	☐
7. Being put to sleep to have treatment?	☐	☐	☐	☐	☐
8. Having a mixture of 'gas and air' which will help you feel comfortable for treatment but cannot put you to sleep?	☐	☐	☐	☐	☐

We would also like to find out how much you know about the choices you have been given at the dentist. Below are some sentences about the different choices you were given. Please mark if you think they are true, false or you are unsure by ticking ☑ one box next to each sentence.

If you have IV sedation ('intravenous sedation'):	True	False	Unsure
You won't have to wear a mask	☐	☐	☐
You will need to have a needle in the gum	☐	☐	☐
You will be asleep during treatment	☐	☐	☐
You may have a light meal 2 hours before the appointment	☐	☐	☐
You may not remember everything that happened	☐	☐	☐

If you have gas and air ('laughing gas', 'happy air' or 'inhalation sedation'):			
	True	**False**	**Unsure**
You will have to wear a mask	☐	☐	☐
You should have a big meal just before the appointment	☐	☐	☐
You will need to have a needle in the hand or arm	☐	☐	☐
You won't need to have a needle in the gum	☐	☐	☐
You will be awake during treatment	☐	☐	☐

If you have a general anaesthetic ('GA' or 'going to sleep'):			
	True	**False**	**Unsure**
You will be asleep during treatment	☐	☐	☐
You should not eat anything for six hours before the appointment	☐	☐	☐
You will be able to go straight home afterwards	☐	☐	☐
You won't need to have a needle in the hand or arm	☐	☐	☐
There is a 1 in 10 chance of feeling sick afterwards	☐	☐	☐

Finally, we would like to know what you think about the decision aid we gave you.

1. Please circle either 'poor', 'average', 'good', or 'excellent' to show us what you think about the way the information was presented on:				
Gas and air ('happy air', 'laughing gas' or 'inhalation sedation')	Poor	Average	Good	Excellent
IV sedation ('Intravenous sedation')	Poor	Average	Good	Excellent
General anaesthetic ('GA' or 'going to sleep')	Poor	Average	Good	Excellent

2.Did you think the length of the decision aid was (please tick ☑ one box):

☐ Too long?

☐ Too short?

☐ Just right?

3. Did you think the amount of information in the decision aid was (please tick ☑ one box):

☐ Too much?

☐ Too little?

☐ Just right?

4. Did you find the decision aid was (please tick ☑ one box):

☐ Slanted towards having dental treatment with gas and air?

☐ Slanted towards having dental treatment with IV sedation?

☐ Slanted towards having dental treatment with general anaesthesia?

☐ Balanced?

5. Did you find the decision aid useful when making your decision about having dental treatment with sedation or general anaesthesia (please tick ☑ one box)?

☐ Yes

☐ No

Comments:

6. Did you find the decision aid was (please tick ☑ one box):

☐ Easy to use?

☐ Difficult to use?

Comments:

7. Did the decision aid make the decision (please tick ☑ one box):

☐ Easier?

☐ More difficult?

Comments:

8. Do you think we included enough information to help a young person decide whether to have dental treatment with sedation or general anaesthesia? (please tick ☑ one box)

☐ Yes

☐ No

Comments:

9. What did you <u>like</u> about the decision aid?

_____
_____
_____
_____

10. What <u>suggestions do you have</u> to improve the decision aid?

_____
_____
_____
_____

Thank you very much for your help!

Appendix Q: Questionnaire booklet for parents/guardians (control group)

ID number:

Questionnaire about 'Helping young people choose at the dentist'

Hello,

Thanks for agreeing to help us with our study. This study is being done so we can understand more about how we can help young people choose the right treatment at the dentist. By answering the questions, you will help us make sure young people have better information in the future. In this booklet, you will find some sets of questions about your child, your choice and what you know about your child's treatment. Please answer all the questions using the instructions. There is no right or wrong answer.

Are you: (please tick ☑ one box)

☐ Male
☐ Female

When were you born?

_____/_____/_____
DAY MONTH YEAR

What is your home postcode?

_____

Has your child ever had any of these treatments before? (please tick ☑ one box next to each option)

	Yes	No	I don't know
Gas and air (also known as 'laughing gas', 'happy air' or 'inhalation sedation')	☐	☐	☐
IV sedation (also known as 'intravenous sedation')	☐	☐	☐
General anaesthetic (also known as 'GA' or 'going to sleep')	☐	☐	☐

How would you describe your ethnic origin? (please tick ☑ one box)

White
☐ British
☐ Irish
☐ Other white background

Mixed
☐White & Black Caribbean
☐White & Black African
☐White and Asian
☐Other mixed background
☐Other Asian Background

Other
☐Other ethnic group

Black or Black British
☐Caribbean
☐African
☐Other Black background

Asian or British Asian
☐Indian
☐Pakistani
☐Bangladeshi
☐Chinese

Which treatment option do you prefer? (please tick ☑ one box)

☐ Gas and air (also known as 'laughing gas', 'happy air' or 'inhalation sedation')
☐ IV sedation (also known as 'intravenous sedation')
☐ General anaesthetic (also known as 'GA' or 'going to sleep')
☐Unsure

Please answer the following questions. Please tick ☑ one box next to each statement.

	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1. I know which options are available to my child	☐	☐	☐	☐	☐
2. I know the benefits of each option	☐	☐	☐	☐	☐
3. I know the risks and side effects of each option	☐	☐	☐	☐	☐
4. I am clear about which benefits matter most to me	☐	☐	☐	☐	☐
5. I am clear about which risks and side effects matter most to me	☐	☐	☐	☐	☐
6. I am clear about which is more important to me (the benefits or the risk and side effects)	☐	☐	☐	☐	☐
7. I have enough support from others to make a choice	☐	☐	☐	☐	☐
8. I am choosing without pressure from others	☐	☐	☐	☐	☐
9. I have enough advice to make a choice	☐	☐	☐	☐	☐
10. I am clear about the best choice for me	☐	☐	☐	☐	☐
11. I feel sure about what to choose	☐	☐	☐	☐	☐
12. This decision is easy for me to make	☐	☐	☐	☐	☐
13. I feel I have made an informed choice	☐	☐	☐	☐	☐
14. My decision shows what is important to me	☐	☐	☐	☐	☐
15. I expect to stick with my decision	☐	☐	☐	☐	☐
16. I am satisfied with my decision	☐	☐	☐	☐	☐

We would also like to find out how much you know about the choices your child has been given at the dentist. Below are some sentences about the different choices that were given. Please mark if you think they are true, false or you are unsure by ticking ☑ one box next to each sentence.

If your child has IV sedation ('intravenous sedation'):	True	False	Unsure
He/she will have to wear a mask	☐	☐	☐
He/she will need to have a needle in the gum	☐	☐	☐
He/she will be asleep during treatment	☐	☐	☐
He/she may have a light meal 2 hours before the appointment	☐	☐	☐
He/she may not remember everything that happens	☐	☐	☐

If your child has gas and air ('laughing gas', 'happy air' or 'inhalation sedation'):	True	False	Unsure
He/she will have to wear a mask	☐	☐	☐
He/she should have a big meal just before the appointment	☐	☐	☐
He/she will need to have a needle in the hand or arm	☐	☐	☐
He/she won't need to have a needle in the gum	☐	☐	☐
He/she will be awake during treatment	☐	☐	☐

If your child has a general anaesthetic ('GA' or 'going to sleep'):	True	False	Unsure
He/she will be asleep during treatment	☐	☐	☐
He/she should not eat anything for six hours before the appointment	☐	☐	☐
He/she will be able to go straight home afterwards	☐	☐	☐
He/she won't need to have a needle in the hand or arm	☐	☐	☐
There is a 1 in 10 chance of him/her feeling sick afterwards	☐	☐	☐

Thank you very much for your help!

Appendix R: Questionnaire booklet for parents/guardians (intervention group)

ID number:

Questionnaire about 'Helping young people choose at the dentist'

Hello,

Thanks for agreeing to help us with our study. This study is being done so we can understand more about how we can help young people choose the right treatment at the dentist. By answering the questions, you will help us make sure young people have better information in the future. In this booklet, you will find some sets of questions about your child, your choice and what you know about your child's treatment. Please answer all the questions using the instructions. There is no right or wrong answer.

Are you: (please tick ☑ one box)

☐ Male
☐ Female

When were you born?

_____/_____/_____
DAY MONTH YEAR

What is your home postcode?

_____

Has your child ever had any of these treatments before? (please tick ☑ one box next to each option)

	Yes	No	I don't know
Gas and air (also known as 'laughing gas', 'happy air' or 'inhalation sedation')	☐	☐	☐
IV sedation (also known as 'intravenous sedation')	☐	☐	☐
General anaesthetic (also known as 'GA' or 'going to sleep')	☐	☐	☐

In total, how much time did you spend looking at the decision aid? (Your answer can be 0 minutes!)

Hours: _____ Minutes: _____

How would you describe your ethnic origin? (please tick ☑ one box)

White
☐ British
☐ Irish
☐ Other white background

Mixed
☐White & Black Caribbean
☐White & Black African
☐White and Asian
☐Other mixed background
☐Other Asian Background

Other
☐Other ethnic group

Black or Black British
☐Caribbean
☐African
☐Other Black background

Asian or British Asian
☐Indian
☐Pakistani
☐Bangladeshi
☐Chinese

Which treatment option do you prefer? (please tick ☑ one box)

☐ Gas and air (also known as 'laughing gas', 'happy air' or 'inhalation sedation')
☐ IV sedation (also known as 'intravenous sedation')
☐ General anaesthetic (also known as 'GA' or 'going to sleep')
☐Unsure

Please answer the following questions. Please tick ☑ one box next to each statement.

	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
1. I know which options are available to my child	☐	☐	☐	☐	☐
2. I know the benefits of each option	☐	☐	☐	☐	☐
3. I know the risks and side effects of each option	☐	☐	☐	☐	☐
4. I am clear about which benefits matter most to me	☐	☐	☐	☐	☐
5. I am clear about which risks and side effects matter most to me	☐	☐	☐	☐	☐
6. I am clear about which is more important to me (the benefits or the risk and side effects)	☐	☐	☐	☐	☐
7. I have enough support from others to make a choice	☐	☐	☐	☐	☐
8. I am choosing without pressure from others	☐	☐	☐	☐	☐
9. I have enough advice to make a choice	☐	☐	☐	☐	☐
10. I am clear about the best choice for me	☐	☐	☐	☐	☐
11. I feel sure about what to choose	☐	☐	☐	☐	☐
12. This decision is easy for me to make	☐	☐	☐	☐	☐
13. I feel I have made an informed choice	☐	☐	☐	☐	☐
14. My decision shows what is important to me	☐	☐	☐	☐	☐
15. I expect to stick with my decision	☐	☐	☐	☐	☐
16. I am satisfied with my decision	☐	☐	☐	☐	☐

We would also like to find out how much you know about the choices your child has been given at the dentist. Below are some sentences about the different choices that were given. Please mark if you think they are true, false or you are unsure by ticking ☑ one box next to each sentence.

If your child has IV sedation ('intravenous sedation'):	True	False	Unsure
He/she will have to wear a mask	☐	☐	☐
He/she will need to have a needle in the gum	☐	☐	☐
He/she will be asleep during treatment	☐	☐	☐
He/she may have a light meal 2 hours before the appointment	☐	☐	☐
He/she may not remember everything that happens	☐	☐	☐

If your child has gas and air ('laughing gas', 'happy air' or 'inhalation sedation'):	True	False	Unsure
He/she will have to wear a mask	☐	☐	☐
He/she should have a big meal just before the appointment	☐	☐	☐
He/she will need to have a needle in the hand or arm	☐	☐	☐
He/she won't need to have a needle in the gum	☐	☐	☐
He/she will be awake during treatment	☐	☐	☐

If your child has a general anaesthetic ('GA' or 'going to sleep'):	True	False	Unsure
He/she will be asleep during treatment	☐	☐	☐
He/she should not eat anything for six hours before the appointment	☐	☐	☐
He/she will be able to go straight home afterwards	☐	☐	☐
He/she won't need to have a needle in the hand or arm	☐	☐	☐
There is a 1 in 10 chance of him/her feeling sick afterwards	☐	☐	☐

Finally, we would like to know what you think about the decision aid we gave you.

1. Please circle either 'poor', 'average', 'good', or 'excellent' to show us what you think about the way the information was presented on:				
Gas and air ('happy air', 'laughing gas' or 'inhalation sedation')	Poor	Average	Good	Excellent
IV sedation ('Intravenous sedation')	Poor	Average	Good	Excellent
General anaesthetic ('GA' or 'going to sleep')	Poor	Average	Good	Excellent

2.Did you think the length of the decision aid was (please tick ☑ one box):

☐ Too long?

☐ Too short?

☐ Just right?

3. Did you think the amount of information in the decision aid was (please tick ☑ one box):

☐ Too much?

☐ Too little?

☐ Just right?

4. Did you find the decision aid was (please tick ☑ one box):

☐ Slanted towards having dental treatment with gas and air?

☐ Slanted towards having dental treatment with IV sedation?

☐ Slanted towards having dental treatment with general anaesthesia?

☐ Balanced?

5. Did you find the decision aid useful when making the decision about your child having dental treatment with sedation or general anaesthesia (please tick ☑ one box)?

☐ Yes

☐ No

Comments:

6. Did you find the decision aid was (please tick ☑ one box):

☐ Easy to use?

☐ Difficult to use?

Comments:

7. Did the decision aid make the decision (please tick ☑ one box):

☐ Easier?

☐ More difficult?

Comments:

8. Do you think we included enough information to help a young person decide whether to have dental treatment with sedation or general anaesthesia? (please tick ☑ one box)

☐ Yes

☐ No

Comments:

9. What did you <u>like</u> about the decision aid?

_____
_____
_____
_____

10. What <u>suggestions do you have</u> to improve the decision aid?

_____
_____
_____
_____

Thank you very much for your help!