Treatment outcomes of using inhalation sedation for comprehensive dental care within the hospital dental service by utilising the Indicator of Sedation Need (IOSN) assessment tool

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The candidate confirms that the work submitted is her own and that appropriate credit has been given where reference has been made to the work of others.

Dedicated to my family

My mum, dad, sister and brothers

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ABSTRACT

Background: Dental fear and anxiety are common encounters in paediatric dentistry. Therefore, it is important to understand the causes and types of dental anxiety in order to implement the appropriate behaviour management strategies so that high quality dental care could be delivered and disruptive behaviour is minimised. Some dentally anxious individuals have reported that the provision of a form for sedation would facilitate their dental treatment. Therefore assessing the need for sedation would be beneficial. **Aim:** To assess the treatment outcomes of using inhalation sedation for comprehensive dental care within the hospital dental service by utilising a modified version of the Indicator of Sedation Need (IOSN) assessment tool. **Materials and Methods:** The present study was carried out in two phases: *Retrospective Phase* – A study of the treatment outcomes when using inhalation sedation for comprehensive dental care within the hospital dental service. *Prospective Phase* - A study investigating the outcomes of dental treatment of patients referred to the sedation unit at the LDI when the paediatric version of the indicator of sedation need (p-IOSN) was utilised. **Results:** *Retrospective Phase*: the records of 453 patients (213 males and 240 females) were evaluated. Mean age was 10.30 (SD = 2.95) years. Treatment was completed successfully in 63.6% of the cases. Results revealed that age below 10 years was significantly associated with the outcome that "treatment abandoned in sedation unit and child referred to receive treatment under general anaesthesia (GA)". No significant association was found between gender and treatment outcome. *Prospective Phase*: Forty patients (16 males and 24 females) of mean age 9.99 (SD = 3.14) years were followed up to ascertain treatment outcomes when the p-IOSN was used. Of the total of 40 children included in the prospective study, 20 (50%) scored 6 on p-IOSN. Treatment completion rate was 72.5%. Although major differences existed between age and treatment outcomes, they failed to achieve statistical significance. No significant association was found between gender and p-IOSN of any score with any treatment outcome. **Conclusions:** p-IOSN is a useful tool that can be utilised to predict child patients who would benefit from sedation for their dental treatment. However, the p-IOSN is still in the investigational stages and further research is required prior to its use on the clinical grounds.

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ABBREVIATIONS

ANOVA	Analysis of Variance
ASA	American Society of Anaesthesiologists
BSPD	British Society of Paediatric Dentistry
cc	Cubic centimetre
CDAS	Corah's Dental Anxiety Survey
CFSS	Children's Fear Survey Schedule
CFSS-DS	Dental Subscale of the Children's Fear Survey Schedule
CI	Chief Investigator
CNS	Central Nervous System
DREC	Dental Research Ethics Committee
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, Fourth edition
EAPD	European Academy of Paediatric Dentistry
FIS	Facial Image Scale
GA	General Anaesthesia
GABA	Gamma Aminobutyric Acid
GIT	Gastro-intestinal Tract
HOM	Hand-Over-Mouth
HOMAR	Hand-Over-Mouth with Airway Restriction
HSD	Honestly Significant Difference
ICU	Intensive Care Unit
IHS	Inhalation Sedation
IOSN	Indicator of Sedation Need
IV	Intra-venous
kg	Kilogram
LA	Local Anaesthesia
LDI	Leeds Dental Institute
LTHT	Leeds Teaching Hospital Trust
MAC	Minimum Alveolar Concentration
MCDAS	Modified Child Dental Anxiety Scale
$MCDAS_f$	Faces version of the Modified Child Dental Anxiety Scale

mcg	Microgram
MDAS	Modified Dental Anxiety Survey
mg	Milligram
min	Minute
MM	Maryam Madouh
N	Number
N_2O	Nitrous Oxide
NRES	National Research Ethics Service
O_2	Oxygen
p-IOSN	Paediatric version of the Indicator of Sedation Need
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SD	Standard Deviation
SEP	Selective Exclusion of Parents
SFP	Smiley Faces Program
SFP-R	Revised Smiley Faces Program
SPSS	Statistical Package for the Social Sciences
TCI	Target Controlled Infusion
TSD	Tell-Show-Do
UK	United Kingdom
VPS	Venham Picture Scale

1.0 LITERATURE REVIEW

Reviewing the literature is an essential process to understand any subject. With the help and availability of various search engines and databases, the relevant published literature has been identified and evaluated in order to establish a reasonable knowledge about the use of conscious sedation for the dental treatment of anxious paediatric patients.

Dental fear and anxiety are common problems in dentistry and particularly in paediatric dentistry (Welbury et al., 2012). Therefore, it is important to understand the aetiology and pattern of the dental anxiety in order to employ the appropriate behaviour management technique(s) so that high quality dental care could be delivered and disruptive behaviour is eliminated (Chadwick, 2002). Some dentally anxious individuals have reported that the provision of sedation would facilitate their dental treatment (Girdler and Hill, 1998). Therefore assessing the need for sedation would be very beneficial.

In the following sections of this chapter dental anxiety, behaviour management techniques, methods to assess the need for sedation and the aim of the present study were further discussed.

1.1 DENTAL ANXIETY

Fear of dental treatment and dental anxiety are prevalent in children. They have negative impact on their quality of life and on the quality of the dental treatment they could receive both in terms of the nature of the dental treatment that is likely to be performed and the limiting of attendance for treatment (Newton et al., 2012). In the literature, the prevalence

of dental fear ranged from 5-20% with a mean prevalence of 11% (Themessl-Huber et al., 2010). According to Klingberg and Broberg (2007) anxiety is a multi-dimensional concept that consists of somatic, cognitive, and emotional elements, whereas dental fear is a normal emotional reaction to one or more specific frightening stimuli in the dental setting. Therefore, dental anxiety represents a state of apprehension that something related to the dental treatment will be dreadful, and it is coupled with a feeling of losing control. Whereas, dental phobia represents a severe type of dental anxiety and is characterised by marked and persistent anxiety in relation either to clearly discernible situations or objects. Based on the Diagnostic and Statistical Manual of Mental Disorders (DSM–IV) published by the American Psychiatric Association, the criteria for a diagnosis of a specific phobia are (American Psychiatric Association, 1994):

- Unreasonable and excessive marked fear that is persistent.
- Exposure to the fearful stimuli almost invariably provokes an immediate anxiety response.
- The person recognises that the fear is excessive or unreasonable (this is probably absent in children).
- The phobic situation is avoided or else endured with extreme nervousness or distress.

Therefore, for a diagnosis of dental phobia it must result either in avoidance of required dental treatment altogether or tolerating treatment only with dread and in an adjusted treatment situation (e.g. specialised paediatric dentistry). It is important here to note that the terms dental fear, dental anxiety and dental phobia are used interchangeably within the dental literature (Klingberg and Broberg, 2007).

1.1.1 Aetiological Factors of Dental Fear and Anxiety

Children's phobia is believed to be multi-factorial and multi-dimensional. It has a complex aetiology involving genetic, constitutional and environmental factors (King et al., 1997). In this scope, Rachman has proposed an influential three pathways theory of phobia onset (Rachman, 1977). According to this theory, phobias are acquired through direct conditioning, vicarious conditioning or transmission of information and instructions. The three pathways are:

- Direct conditioning (Direct Pathway): refers to the association between an unconditioned stimulus and a neutral stimulus. In the dental situation this means that a bad experience in one of the dental visits could cause a child to associate the dental situation in general with bad experience leading to aversive feelings and fear, and potentially avoidance of the situation. Children who have had negative experiences associated with medical treatment may be more anxious about dental treatment (Wright et al., 1973a). Similarly, fear sustained from previous unhappy dental visits has also been related to poor behaviour and fear at subsequent visits (Johnson and Baldwin Jr, 1968, McTigue, 1984). Milsom and colleagues believed that direct conditioning is the strongest predictor of child dental anxiety status. They have found that dental anxiety in children was closely related to traumatic treatment interventions (extraction), symptomatic, irregular attendance pattern, and having a dentally anxious parent. Therefore, they have recommended that dentists adopt a wait and watch approach rather than extraction in the very young children or children who are already dentally anxious (Milsom et al., 2003).

- Vicarious conditioning (Indirect Pathway): it implies that children's fear could be acquired by observing significant others (e.g. parents, peers and siblings) reacting fearfully to a stimulus (emotional contagion hypothesis). A direct relationship between maternal anxiety and difficulties in child patient management at all ages has been reported by many studies (Corkey and Freeman, 1994, Freeman, 1999). A negative behaviour exhibited by a child patient during their first dental visit was positively associated with increased anxiety of their mother (Johnson and Baldwin Jr, 1968, Koenigsberg and Johnson, 1975). This relationship was more evident in children less than four years of age (Wright and Alpern, 1971, Wright et al., 1973b).
- Transmission of information (Indirect Pathway): this indirect pathway refers to negative information about stimuli provided by significant others, books or media (Rachman, 1977). Several studies on common childhood fear provided support for the role of negative information, by asking children retrospectively about their experiences in the development of anxiety (King et al., 1998, Muris et al., 1997).

Several other determinant factors have been associated with dental fear and phobia. Results on gender differences in relation to dental fear are controversial. Some studies have found no gender differences in children's and adolescent's dental fear (Locker et al., 2001, Majstorovic et al., 2003, Muris et al., 2005). However, several studies reported that girls are more dentally anxious than boys (Klingberg and Broberg, 2007, Majstorovic and Veerkamp, 2004). These results seem to differ according to the age of the children. In younger age groups, no significant gender effect has been found. On the other hand, more dental fear has been found in adolescent girls than in boys of the same age (Holst et al., 1988, Neverlien, 1994). In a longitudinal study conducted by Murray and co-workers in

1989, it was found that self-efficacy, fear of death, and the number of dentists visited were the predictors of dental anxiety for boys. For girls, dental anxiety three years before, peer ratings and medical fear were found to be predictors of dental anxiety (Murray et al., 1989). It has been suggested that boys with dental anxiety may be more responsive to stress to their environment, while girl's dental anxiety could be more internally mediated (Liddell, 1990). These results suggest that dental fear and the factors associated with it differ with gender.

Both dental fear and phobia are more common in young children, reflecting the influence of child's psychological development on his or her ability to cope with dental treatment. A younger child may experience and understand the dental situation differently than an older child. One major reason for this is that the process of understanding and having the motivation to comply with dental treatment differs depending on the psychological development. The latter also depends on the communication skills of the dental team (Klingberg and Broberg, 2007). In a study constructed on 2,865 Dutch children aged 4-11 years old, they confirmed that the highest level of dental anxiety was at age 4 years and overall decrease in dental anxiety occurred as children became older. In different age groups dental anxiety seems to be related to different aspects of dentistry, indicating the causes shift from simple initial stimuli to more complex events (Majstorovic and Veerkamp, 2005).

A study by Fayle and Tahmassebi (2003) has suggested that there are more factors that could contribute to the development of dental anxiety. One of which is the dentist's manner. A dentist with calm, caring and empathetic approach is more likely to manage an anxious child with success. Moreover, physical and eye contact can reinforce positive

behaviour and enable communication while criticism and tease are ineffective and result in diminished confidence and increased anxiety. Another factor is the intellectual capacity of the child. Children with communication or learning difficulties (e.g. mental retardation or impaired hearing or vision) may be more likely to show anxiety-related behaviour in the dental setting (Fayle and Tahmassebi, 2003).

1.1.2 Evaluation of Dental Phobia and Behaviour Classification

Different types of measures have been developed aiming to assess dental fear and anxiety in children and classify their behaviour in the dental operatory. The most widely used measures are the following:

- Behaviour rating scores where the dentist or another member of the dental team observes the child's behaviour during the treatment and then record a "score" for it.
- Anxiety self-reports completed by the child or the parent.

1.1.2.1 Behaviour rating scores

The knowledge of these rating scores is beneficial in different ways. It can assist in directing the management technique as well as provide a means for systematically recording behaviours. These rating scores can also be used in different research projects (Welbury et al., 2012).

1.1.2.1.1 Frankl behaviour rating scale

This rating system divides observed behaviour into four categories, ranging from definitely positive to definitely negative. It is summarised in Table 1.1 (Frankl et al., 1962).

Table 1.1 Frankl Behaviour Rating Scale

Rank	Symbol	Description
Definitely negative	- -	• Refusal of treatment • crying forcefully • fearful • any other overt evidence of extreme negativism
Negative	-	• Reluctant to accept treatment • Uncooperativeness • Some evidence of negative attitude but not pronounced
Positive	+	• Acceptance of treatment • Cautious behaviour at times with reservation • Willingness to comply and cooperatively follows dentist's directions
Definitely positive	++	• Good rapport with the dentist • Interest in the dental procedures • Laughter and enjoyment

Frankl behaviour rating score is the most frequently used scale both in research and clinical grounds because of its ease of use and brevity. However, a limitation of this scale is that it does not provide sufficient clinical information regarding the uncooperative behaviour of the child. For example, if the child is judged as "negative" this could be interpreted as that the child was uncooperative throughout the procedure while this was recorded because the child was tearful when local anaesthesia was being delivered. Therefore, recording "-, tearful with LA" would be a better description of the clinical situation (Dean et al., 2010).

1.1.2.1.2 Houpt rating score

Houpt rating score is another tool to evaluate children's behaviour during a dental visit (Lourenço-Matharu et al., 2012). Nevertheless, it is less often used than Frankl's score. Description of Houpt rating score is presented in Table 1.2.

Table 1.2 Houpt Rating Score

Score	Description	Treatment Result
1	No treatment rendered	Aborted
2	Treatment interrupted; only partial treatment was completed	Poor
3	Treatment interrupted but eventually completed	Fair
4	Difficult but all treatment was performed	Good
5	Some limited crying or movement	Very Good
6	No Crying or movement	Excellent

1.1.2.2 Anxiety self-reports

1.1.2.2.1 Corah`s Dental Anxiety Survey (CDAS)

This is a four-item measure developed in 1969. It assesses patients' reaction to four different dental treatment situations: before attending the dental surgery, waiting in the dental operatory, sitting in the dental chair and undergoing treatment. Each question has five pre-structured answers evaluated on a scale from one to five; one indicates no anxiety whereas five indicates the maximum level of anxiety. Therefore, CDAS score ranges from 4 (no anxiety) to 20 (extreme high anxiety). Anxiety using CDAS is rated as follows (Corah, 1969):

- 9-12: moderate anxiety but have specific stressors that should be discussed and managed

- 13-14: high anxiety
- 15-20: severe anxiety

CDAS is widely used in research for assessing dental anxiety in adults across the world. It has a high level of reliability and predictive value. However, it has been criticised for exhibiting a range of scores too narrow to be used effectively in clinical studies. Yet, it is efficient in the clinical setting as it can be completed in less than five minutes (Guinot et al., 2011).

1.1.2.2.2 Modified Dental Anxiety Survey (MDAS)

Based on the fact that injection is a major cause of anxiety for many individuals, CDAS has been modified by adding a fifth question concerning local anaesthetic. The answer options were rephrased and modified as well to reflect anxiety in a more clear order. MDAS has become the most frequently used dental anxiety questionnaire in the United Kingdom. The total score is the sum of the all 5 items which ranges from 5 to 25. Nineteen and above is the cut-off value that indicates a high level of anxiety (Humphris et al., 1995).

1.1.2.2.3 Venham Picture Scale (VPS)

VPS has been developed in 1977 and consists of eight pairs of pictures (Sonnenberg and Venham, 1977). Each pair consists of a child in a non-fearful pose and in a fearful pose and for each pair, the child is asked to choose the picture which more accurately reflects their feeling at the time. The final score is the sum of the number of times the child selects the high-fear stimulus (the minimum score is zero whereas the maximum is eight). VPS has

shown a strong test-retest reliability and internal consistence (0.70-0.84) (Venham and Gaulin-Kremer, 1979). VPS has shown many advantages when used in research, it is simple, quick to use and suitable for use with children 2-8 years old (Foster and Park, 2012). Even children with limited verbal and intellectual ability have used it successfully. However, VPS does have some limitations (Buchanan and Niven, 2002). It has failed to differentiate between anxious and non-anxious children because no parameters were set to indicate high levels of anxiety. In addition, the figures on the card are all male which might present a problem when the young patient is a girl. Moreover, for teenagers some figures are ambiguous in what they are portraying (Aartman et al., 1997).

1.1.2.2.4 Facial Image Scale (FIS)

FIS has a row of five faces ranging from very happy to very unhappy thus making the choice easier for very young children. Children are asked to point at which face they felt most like at the moment. The scale is scored by giving a value of one to the most positive affect face and five to the most negative affect face. The scale has shown good validity in research. FIS has advantages over questionnaires in that it is quicker and easier to be used in clinical situations, takes a very short time, more suitable for very young children (3 years old) who lack the cognitive ability to understand and complete questionnaire and gives an immediate indication about child anxiety as well as provide interesting results regarding prevalence of child dental anxiety (Buchanan and Niven, 2002).

1.1.2.2.5 Smiley Faces Program (SFP)

SFP is a four item computerised scale using faces as a response set to assess dental anxiety in children. The child will select from a range of seven facial expressions indicating how they feel. It is based on the MDAS and involves four questions relevant to a child`s experience in the dental practice environment (having dental treatment the following day, sitting in the waiting room, having injection and a tooth drilled). The SFP has a number of benefits. First, it is short in length and in turn takes a short time to complete. Second, all the items included are relevant to most children`s dental experiences. Third, the computer graphics help the child to engage with the dental anxiety scale. Children have found these graphics enjoyable and preferred them over the pen and paper questionnaire. Fourth, it identifies children who are anxious of a particular procedure. Finally, it has the advantage of facilitating data collection and standardising assessment. However, this scale could be too complicated for children younger than 6 years and children with learning difficulties to complete. Moreover, access for computer equipment is needed. The scale demonstrated good reliability (Buchanan, 2005). The SFP was revised (SPF-R) by Buchanan to include a fifth item concerning dental extraction. In addition, the graphics and instructions were updated in the revised SFP (Buchanan, 2010).

1.1.2.2.6 Modified Child Dental Anxiety Scale (MCDAS)

MCDAS has been developed by Wong and Humphris based on the concept of CDAS (Wong and Humphris, 1998). It consists of eight questions to measure dental anxiety about specific dental procedures. Four questions are similar to those of the CDAS in addition to questions likely to distress children such as how the child feels about injections, extraction

and general anaesthesia. A five-point Likert scale with answer options arranged in ascending order of the dental anxiety level is used to assess anxiety: relaxed/not worried, very slightly worried, fairly worried, worried a lot and very worried. The total score ranges from 8 to 40. The scale has a good test-retest reliability and internal consistency (0.84) (Howard and Freeman, 2007). It has been used in 8 to 15-year-olds and has shown a good internal consistency and validity. The MCDAS has an advantage over the CFSS (discussed below) in being shorter, thus faster to complete. It is beneficial in planning interventions that aim to reduce dental anxiety (Guinot et al., 2011).

A faces version of the MCDAS ($MCDAS_f$) has been introduced for assessing dental anxiety in young children by adding a faces rating scale above the original numeric form (Howard and Freeman, 2007).

1.1.2.2.7 Children`s Fear Survey Schedule (CFSS)

CFSS consists of 80 items on a five-point Likert-scale. The significant length of this scale has resulted in the development of a shorter version called the Dental Subscale of the Children`s Fear Survey Schedule (CFSS-DS). It involves 15 items, and each item can be given five different scores ranging from "not afraid at all" (1) to "very much afraid" (5). It has a total score range from 15 to 75, with a score of 38 or more indicating clinical dental fear. The scale has a good internal consistency (0.85-0.92) (Howard and Freeman, 2007). It is precise and provides detailed data for a dental clinic (Guinot et al., 2011). Aartman and co-workers argued that CFSS-DS is to be preferred to both CDAS and VPS for the following reasons (Aartman et al., 1997):

- It covers more aspects of the dental situation

- It measures dental fear more precisely than the other scales
- Normative data are available on this scale
- It has slightly superior psychometric properties

1.2 BEHAVIOUR MANAGEMENT TECHNIQUES IN PAEDIATRIC DENTISTRY

1.2.1 Nonpharmacological Techniques

These are the techniques that a paediatric dentist could utilise to create a positive attitude towards the dental environment and procedures on the patients' part so that future dental visits become more comfortable and pleasant (Wright, 1975, Wright et al., 1987, Chadwick, 2002).

1.2.1.1 Preparatory information

Parental anxiety is one of the known factors that have been implicated in the aetiology of dental anxiety of children. Therefore, strategies that have been used to decrease parental anxiety, such as pre-appointment letters, may help the child patient in his/her dental visit. These are usually in the form of a letter welcoming the new patient and family to the practice. Such letters give an overall idea about what will happen at the visit, give advice on preparing the child, and help to reduce parental anxiety and in turn, the child's anxiety (Rosengarten, 1961, Bailey et al., 1973, Wright et al., 1973a, Chadwick, 2002). Wright and colleagues have demonstrated the beneficial effect of a pre-appointment letter sent to parents of new paediatric patients. The five paragraphs letter compliments the parents for being concerned about their child's dental health, states what will be done at the first appointment, and encourages the parents to be calm and natural when telling their child

about their appointment with the dentist. Children of parents, who received the letter, were more cooperative in the dental clinic when compared to children whose parents did not receive the letter. In addition, maternal anxiety was less in the pre-appointment letter group (Wright et al., 1973b).

1.2.1.2 Non-verbal communication

This form of communication occurs constantly during a dental visit and may emphasise or oppose verbal signals. Having a child-friendly environment and a happy, smiling dental team could be included in the context of such communication (Wright et al., 1987). Moreover, gentle pats and squeezes on the shoulder have been found to minimise distress (Weinstein et al., 1982, Chadwick, 2002).

1.2.1.3 Voice control

Young children often show better response to the tone of voice rather than the actual words (Wright et al., 1987). Voice control techniques involve using a controlled alteration of voice, volume, tone or pace to influence and direct a patient's behaviour. Such techniques aim to improve attention and compliance as well as to establish authority. For example, a sudden change from soft to firm voice would gain the attention of a child who is not complying. In this case, what the dentist says is not as important as the way it is said because the aim is to create a direct influence on behaviour rather than through understanding (Feigal, 2001). Voice control has been shown to decrease disruptive behaviours without producing long-term negative effects (Greenbaum et al., 1990). Nevertheless, while reported as widely used by dentists it may not be acceptable to all

parents or clinicians. The technique is useful for inattentive but communicative children (Murphy et al., 1984, McKnight-Hanes et al., 1993, Roberts, 1995). However, it is not suitable for very young children or for those with intellectual or emotional problems (Chadwick, 2002).

1.2.1.4 Tell-show-do (TSD)

This technique is largely used to familiarise child patients with a procedure that is unknown to them (McKnight-Hanes et al., 1993). This simple approach aims to introduce a new experience, whilst minimising fear of the unknown. The first stage (tell) is a description of the procedure that is about to be performed, secondly, the procedure is demonstrated to the child and finally it carried out (Fayle and Tahmassebi, 2003). The "tell" phase involves an age appropriate explanation of the procedure. The "show" phase is used to physically demonstrate the procedure, for example demonstrating the practice of polishing with a slow handpiece on a finger. The "do" phase is initiated with a minimum delay, in this case a polish. It is important that the language used is appropriate to the child's age, which is frequently termed in the literature as 'childrenese'. Many dentists use a personal version of this 'childrenese' and the whole dental team must adopt the same approach. An example of this childrenese language is to use the word "hoover" to describe the suction (Fayle and Crawford, 1997). An example of 'childrenes' is presented in Table 1.3. Specifically emotive or negative words like "pain" or "blood" should be avoided. It has been shown to be an effective way of reducing anticipatory anxiety in new child patients (Carson and Freeman, 1998). This technique is contraindicated only in patients who are unable to communicate (Chadwick, 2002).

Table 1.3 Example of Childrenese Terms for Dental Equipment

(from Fayle and Crawford, 1997)

Actual Terms	Childrenese Terms
Low speed handpiece	Buzzy bee
High speed handpiece	Whizzy brush or Mr. whistle
Triplespray/ inhalation sedation	Magic wind
Local anaesthesia	Jungle juice
Administering local anaesthesia	Spray your teeth off to sleep
Rubber dam	Rubber raincoat
Rubber dam clamp	Clip or button
Fissure sealant	Tooth paint

1.2.1.5 Enhancing control

In this technique, the patient is given a degree of control over their dentists' behaviour through the use of a stop signal. Such signals have been shown to reduce pain during dental treatment (Wardle, 1982). The stop signal, usually raising a hand, should be practiced and the dentist should quickly respond to it when used (Thrash et al., 1982, Feigal, 2001, Fayle and Tahmassebi, 2003). Again, this technique is useful for all patients who can communicate (Chadwick, 2002). Allen and co-workers reported that enhancing control as a behaviour management technique has decreased the disruptive behaviour in children aged 3-7 years. They also found that this strategy did not require extra time to bring the disruptive behaviour under control compared to other behaviour management techniques (Allen et al., 1992).

1.2.1.6 Behaviour shaping and positive reinforcement

Many dental procedures require fairly complex behaviours and actions from the patients which need to be explained and learned. For children, this requires small clear steps. This process is termed behaviour shaping. It consists of a defined series of steps towards ideal behaviour (Wright, 1975). In other words, it is a technique that involves developing an appropriate behaviour by reinforcing sequential approximations to the desired behaviour until it is accomplished (Fayle and Tahmassebi, 2003). This is most easily achieved by selective reinforcement. Reinforcement is the strengthening of a pattern of behaviour, increasing the probability of that behaviour being displayed again in the future (Sawtell et al., 1974). Anything that the child finds pleasant or rewarding can act as a positive re-inforcer; stickers – for example – can be used at the end of a successful appointment. However, the most powerful re-inforcers are social stimuli, such as, facial expression, positive voice modulation, or verbal praise. A child-centred, empathic response giving specific praise, for example, "I like the way you keep your mouth open" has been shown to be more effective than a general comment such as "Good boy" (Weinstein and Nathan, 1988). As with TSD the use of age specific language is crucial (Wright et al., 1987). The Inability to communicate is the only contraindication to the use of this technique (Chadwick, 2002).

1.2.1.7 Modelling

This technique is based on the psychological principle that people normally know about their environment by observing the behaviour of others. Therefore, by using a model, either live or by video to exhibit appropriate behaviour in the dental environment might be very

effective in behaviour management (Ghose et al., 1969, Johnson and Machen, 1973, Machen and Johnson, 1974, Stokes and Kennedy, 1980). This may demonstrate appropriate behaviour via a third party, decrease anxiety by showing a positive outcome to a procedure a child requires themselves, and illustrate the rewards for performing appropriately. To achieve the best effects, models should be the same age as the target child, should exhibit appropriate behaviour and be praised (Fayle and Tahmassebi, 2003). They should also be shown entering and leaving the surgery (Melamed et al., 1975). Where an appropriate model is available, this technique would be very useful (Chadwick, 2002).

1.2.1.8 Distraction

This approach aims to shift the patient's attention from the dental setting (i.e. potentially unpleasant experience) to a totally different situation (Fayle and Tahmassebi, 2003). Some studies have advocated the use of audio tapes as effective means of distraction (Ingersoll et al., 1984). Short-term distractors such as diverting the attention by pulling the lip as a local anaesthetic is given or asking the patients to raise their legs to stop them from gagging during radiography may also be useful. Talking during the application of the topical paste or administering local anaesthetic is also considered a form of distraction with words (Wright et al., 1987). The technique is useful for all patients who can communicate verbally (Chadwick, 2002).

1.2.1.9 Systematic desensitisation

This technique helps individuals with specific fears to overcome them by repeated contacts. A hierarchy of fear-producing stimuli is constructed, and the patient is exposed to them gradually, starting with the stimulus posing the lowest threat. The fundamental psychological principle underlying systemic desensitisation is that it is not possible to experience two mutually incompatible psychological responses at the same time, e.g. it is not possible to be concurrently relaxed and anxious about a certain thing or situation (Fayle and Tahmassebi, 2003). In the dental treatment situation, fears are usually related to a specific procedure like the use of local anaesthetic; in which case, the patient is taught to relax first, and then exposed to each of the anxiety-provoking stimuli in the hierarchy, only progressing to the next when they feel able. For true phobias several relaxation sessions with a psychologist or dentist who has received training in relaxation or hypnosis techniques may be required (Wright et al., 1987). Actually one reported case required nine separate one hour-long sessions with a therapist (Gale and Ayer, 1969). The technique is useful for children who can clearly identify their fears and who can verbally communicate (Chadwick, 2002).

1.2.1.10 Negative reinforcement

Negative reinforcement is where an unpleasant or undesirable stimulus is applied to all behaviours being exhibited and is only removed immediately after the desired behaviour is displayed, thus reinforcing the preferred behaviour (Fayle and Tahmassebi, 2003). It should not be confused with punishment, which is the application of an unpleasant stimulus to

inappropriate behaviour. Well known examples in dental practice are selective exclusion of the parent (SEP) and hand over mouth (HOM) techniques (Chadwick, 2002).

To use the technique of selective exclusion of the parent (SEP), parental consent is required. When inappropriate behaviour is exhibited the parent is asked to leave. Ideally, the parent should be able to hear, but be out of sight of the child. When appropriate behaviour is exhibited the parent is asked to return, thus reinforcing that behaviour (Chadwick, 2002).

Hand-over-mouth (HOM) involves placing a hand over the child's mouth (to allow the child to hear). The nose must not be covered. The dentist then talks softly to the child explaining that the hand will be removed as soon as crying stops. As soon as this happens the hand is removed and the child is praised. If protests start again the hand is replaced. This technique aims to gain the child's attention and allow communication, re-inforce good behaviour and establish that avoidance is futile. Those who advocate the technique recommend it for children aged 4-9 years when communication is lost or during temper tantrums (AAPD, 1994, Fayle and Crawford, 1997). Parental consent is important and the technique should never be used on children too young to understand or with those who suffer intellectual or emotional impairment (Levitas, 1974).

Although still utilised in North America, HOM technique remains controversial. Its use was supported in some studies (Wright et al., 1987, Barton et al., 1993); while other studies revealed that it was not acceptable to parents (Fields et al., 1984) and that dentists think it should never be used (Newton et al., 2004). There have been no studies on the effectiveness of HOM (Chadwick, 2002). Its legality (regarding restraint and individual rights) has also been questioned (Roberts, 1995). Nowadays, the use of HOM is not acceptable and it has

been eliminated from the American Academy of Paediatric Dentistry clinical guidelines on behaviour management in 2006 (Oueis et al., 2010) for the following reasons:

- The available literature showed that HOM effectiveness is not evidence-based.
- The utilisation of the technique as well as its teaching has declined dramatically over the years.
- The acceptance of this technique by parents has significantly declined too.

Hand-over-Mouth with Airway Restriction (HOMAR) is another controversial behaviour management technique similar to HOM but more aversive. In a study done to investigate behavior management techniques use among paediatric dentists practicing in the southeastern United States it was found that the majority of participants (90.5%) have never used HOMAR. The results revealed that there was significant association between age and use of HOMAR. The younger dentists (under 30 years) were more likely to respond that they have "never used" HOMAR than did older dentists, especially the over 50 years age group. The older dentists were the most likely to report that they "sometimes use" HOMAR (Carr et al., 1999). A study by Acs and colleagues has found that there is a change in the perspective of using HOMAR over the years in postdoctoral paediatric dental education. This study showed that there was a significant reduction in the use of HOMAR (only one program director reported its use) (Acs et al., 2001).

1.2.2 Pharmacological Techniques

These techniques involve the administration of a drug or a combination of drugs that are centrally-acting to help in the management of patients' anxiety or disruptive behaviour

(Heasman, 2008). Pharmacological behaviour management techniques could be broadly divided into two categories: conscious sedation and general anaesthesia (Wilson, 2004).

1.2.2.1 Conscious sedation

Conscious Sedation is defined by the Standing Dental Advisory Committee (2003) as:

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

The level of sedation must be within a limit that ensures that the patient remains conscious, maintains the protective reflexes and understands and responds to verbal commands. In any case where these criteria are not fulfilled and a state of 'deep sedation' occurs, this must be considered as a case of general anaesthesia (General Dental Council, 1997). The three most common techniques of sedation used in dentistry are: inhalation, oral and intra-venous sedation. These techniques are effective and adequate for most of the patients (Standing Dental Advisory Committee, 2003). In the literature, intra-muscular, intra-nasal and rectal sedation were also suggested as other methods of sedation for dental treatment (Roberts et al., 1996, Hosey, 2002). The required technique should be selected so that it provides the most appropriate and yet the least interventional method of anxiety relief for the individual patient. As a general rule the simplest technique to match the requirements should be

employed (Standing Dental Advisory Committee, 2003). The use of conscious sedation for dental treatment aims to reduce anxiety and improve cooperation so that treatment can be completed successfully without resorting to general anaesthesia (Roberts and Rosenbaum, 1991, Standing Dental Advisory Committee, 2003). The objectives of conscious sedation are (Lindsay and Roberts, 1980):

- To enable the delivery of quality dental care
- To manage disruptive behaviour
- To bring the patient back relatively quickly to a physiological state in which it is safe to go home
- To produce a positive psychological response to dental treatment

A child of any age who appears unwilling or incapable to cooperate in the dental chair may well be unsuitable for conscious sedation. Obviously there are circumstances where conscious sedation is inappropriate and where referral to general anaesthesia should be considered (Standing Dental Advisory Committee, 2003). A Study by Ashley and co-workers revealed that there was a slight difference between referring dentists' views of sedation or general anaesthetic for the provision of dental treatment for uncooperative children (Ashley et al., 2010).

Conscious sedation must only be carried out by teams that have adequate training and experience in case selection, behaviour management and administration of sedation for children and only in an appropriate setting. It should be an adjunct to rather than a

substitute for the non-pharmacological behaviour management techniques (General Dental Council, 1997, Standing Dental Advisory Committee 2003).

1.2.2.1.1 Inhalation Sedation

Techniques of inhalation sedation tend to vary in popularity. Alternative terminology of inhalation sedation included relative analgesia and inhalation psychosedation (Hosey, 2002). Inhalation sedation with nitrous oxide/oxygen mixture is the first choice for child patients who are unable to tolerate dental treatment with local anaesthesia alone and who have a sufficient ability to communicate. It is usually offered to children with mild to moderate anxiety to facilitate a treatment that is anticipated to be complex like comprehensive dental treatment that requires several visits or multiple extractions (Crawford, 1990, Shaw et al., 1996, Hosey, 2002). Nevertheless, there are other sedative agents (e.g. sevoflurane) that have been used for the employment of inhalation sedation (Hosey, 2002, Soldani et al., 2010).

1.2.2.1.1.1 Inhalation sedation agents

Nitrous oxide/oxygen (N_2O/O_2) mixture

It is well established nowadays that inhalation sedation with nitrous oxide/ oxygen (N_2O/O_2) mix is the first choice of conscious sedation employed in paediatric dentistry (Hosey, 2002). The basic pharmacology of nitrous oxide gas is briefly discussed below.

Nitrous oxide (N_2O) is a colourless and almost odourless gas with a slightly sweet smell (Girdler and Hill, 1998, Paterson and Tahmassebi, 2003). It has a specific gravity of 1.53 which means that it is 1.5 times heavier than air and tends to collect at floor level (Girdler and Hill, 1998). When N_2O is inhaled into the lungs, it has a rapid uptake as it is quickly absorbed from the alveoli and is held in a simple solution in the serum. The alveolar concentration of N_2O rapidly reaches the inspired concentration. As N_2O is relatively insoluble, it passes down a gradient into other tissues and cells in the body like the central nervous system (CNS). Consequently, equilibration between the level of N_2O in the alveoli and that in the blood will be rapid and in turn, induction and recovery will be extremely quick (Girdler and Hill, 1998). The concentration of N_2O that is needed to produce sedation shows a discrepancy among individuals. Nitrous oxide is rapidly excreted from the lungs. Once N_2O is no longer being inhaled, N_2O within the CNS will rapidly pass down the gradient into the bloodstream and out of the body via the lungs. A very small amount is excreted in body fluids. Nitrous oxide is 34 times more soluble in blood than nitrogen and, hence, diffusion hypoxia may occur. This is the reason for the importance of administering 100% oxygen for 3–5 minutes to the patient once the N_2O has been turned off (Paterson and Tahmassebi, 2003).

Nitrous oxide is a good but mild sedative agent. It produces both euphoria and a depressant effect on the CNS and therefore, memory, attention and intelligence are reduced (Girdler and Hill, 1998, Paterson and Tahmassebi, 2003). It has little effect on the respiratory system and it is non-irritant to the mucosa. It causes negligible depression in cardiac output whilst peripheral resistance is slightly increased, thus maintaining the blood pressure (Paterson and Tahmassebi, 2003).

N_2O is a slightly potent analgesic. It was found to significantly minimise the intensity of pain experienced during cavity preparation in primary dentition (Hammond and Full, 1982). A concentration of 50% inhaled N_2O has been equated to that of a standard dose of parenteral morphine injection; thus, it would help in decreasing the pain of injections in those who require local anaesthesia (Girdler and Hill, 1998).

Sevoflurane

In the field of sedation research, sevoflurane is receiving a lot of attention as a possible sedative agent for use in dentistry. It is sweet-smelling, non-flammable and volatile gas. It is used for the induction and maintenance of general anaesthesia. It is a potent agent with a minimum alveolar concentration (MAC) value of below 2, leaving it with a narrow margin of safety. If sevoflurane is to be used in sedation, it is necessary to use a specialised vapouriser to ensure that its level is kept to a sub-anaesthetic value of 0.3% (Girdler and Hill, 1998). Its use in children's dentistry should be limited until further research emerges (Hosey, 2002). There were two studies comparing the use of sevoflurane in addition to N_2O/O_2 to the use of N_2O/O_2 alone for inhalation sedation in paediatric dentistry. The first was a randomised clinical trial (based in Newcastle, UK) which reported that there was a significant difference between standard nitrous oxide inhalation sedation and sevoflurane inhalation sedation. This difference was in favour of the latter technique. The study concluded that using sevoflurane in combination with nitrous oxide was a safe and efficient method of inhalation sedation when administered by an anaesthetist (Lahoud and Averley, 2002). Nevertheless, it should be taken into account that they used a fixed concentration of

N_2O (40%) for all the patients throughout all the appointments in both sedation techniques, which is not in compliance with the current guidelines concerning the need to titrate the concentration of the sedation agent to the individual child's needs (Soldani et al., 2010). The second study was a randomised controlled, double blinded, cross-over pilot trial. It was carried out to compare the relative effectiveness of inhalation sedation using (A) nitrous oxide and oxygen with (B) nitrous oxide, oxygen and sevoflurane in the management of children receiving dental extractions and secondly, to determine patient and guardian preference between the two sedation techniques. The results showed that there was no statistically significant difference between the two methods of sedation. There was, however, a small but significant patient preference in favour of method B (Soldani et al., 2010).

Methoxyflurane

There is evidence that methoxyflurane has been used earlier in dental sedation research. In a study by Edmunds and Rosen comparing nitrous oxide and methoxyflurane for inhalation sedation the authors felt that the patients were significantly less cooperative during treatment when methoxyflurane was used (Edmunds and Rosen, 1975). Nephrotoxicity has been linked to the use of methoxyflurane; yet this is unlikely in low concentration (Girdler and Hill, 1998).

Other inhalation sedation agents

Although other inhalation sedation agents such as isoflurane and halothane have been reported, their use should be limited until more research emerges (Girdler and Hill, 1998).

1.2.2.1.1.2 Advantages of inhalation sedation

One of the advantages of inhalation sedation is its rapid onset of action compared to that of oral, rectal, intra-nasal or intra-muscular sedation. In addition, peak clinical effect does not develop in most techniques for a considerable time. Although variations do exist, peak clinical actions do not develop for most orally, rectally, intra-nasally and intra-muscularly administered drugs for a period of time, which makes titration impossible. Only inhalation and IV drug administration provide peak clinical actions in a time span permitting titration. For the IV route, time-to-peak effect varies with the drug administration ranging from 1 minute to approximately 20 minutes. On the other hand, the inhalation route has a 3 to 5 minute peak action. Another advantage is that the depth of sedation achieved with inhalation sedation may be altered from moment to moment, permitting the drug administrator to increase or decrease the depth of sedation easily. With no other techniques of sedation does the administrator have such control over the clinical actions of the drugs. The degree of control represents a significant safety feature of inhalation sedation (Paterson and Tahmassebi, 2003, Malamed, 2009). The duration of action is an important consideration in the selection of a pharmaco-sedative technique in an outpatient. In situations in which a sedation technique has a relatively fixed duration of clinical activity, dental treatment must be tailored to this, whereas in those techniques with a flexible duration of action, the planned procedure may be of any length. With inhalation sedation the duration of action is variable just at the preference of administrator (Malamed, 2009). Moreover, recovery time from inhalation sedation is rapid and is the most complete of any pharmaco-sedation technique. As discussed, titration is the ability to administer small,

incremental doses of a drug until a desired clinical action is obtained. It is thought that the ability to titrate a drug represents the greatest safety feature a technique can possess because it permits the drug administrator virtually absolute control over the actions of the drug (Stewart, 1985). Significant drug overdose will not develop in techniques in which titration is possible as long as the administrator does indeed titrate the drug. In an outpatient setting, it is advantageous for the patient to be discharged from the office following a procedure with no prohibitions on activities (Paterson and Tahmassebi, 2003, Malamed, 2009).

Unfortunately, because all of the drugs administered for the reduction of fear and anxiety are central nervous system (CNS) depressants, the patient may not be permitted to leave the office unescorted to operate a motor vehicle or to perform tasks requiring mental alertness for a number of hours following the administration of these drugs. To do so is to increase the potential risk to both the patient (physical risk) and the dentist (legal risk). Recovery must be complete, with absolutely no doubt in the mind of the dentist that the patient is able to function normally; if not, the patient should not be permitted to leave the office unescorted. With inhalation sedation, recovery is almost always complete; patient usually may be discharged from office alone, with no cautions about activities. One of the most important advantages of inhalation sedation is that no injections are required for the administration (although local anaesthesia is still necessary) (Paterson and Tahmassebi, 2003, Malamed, 2009).

As N_2O is the preferred drug for the employment of inhalation sedation, the advantages of N_2O use in particular for IHS are further discussed below (Hosey, 2002, Foley, 2005, Woolley et al., 2009) . N_2O/O_2 is safe; very few side-effects are associated with its use. The

drugs used in this technique have no adverse effects on the liver, kidneys, brain, or cardiovascular and respiratory systems (Hosey, 2002). Because N_2O is not metabolised by the body, the gas is rapidly and virtually completely eliminated from the body within 3 to 5 minutes. In all other techniques, the recovery from sedation is considerably slower (Faddy and Garlick, 2005). Lastly, inhalation sedation with N_2O/O_2 can be used instead of local anaesthesia in certain procedures. N_2O does possess analgesic properties when given in the usual sedative concentrations (Hammond and Full, 1982, Malamed, 2009). Certain procedures, such as those involving soft tissues (e.g. scaling), may be performed in many instances without using local anaesthesia (Paterson and Tahmassebi, 2003, Malamed, 2009).

It is worth mentioning here that the analgesia produced by a 20% concentration of N_2O is equivalent to that of 10 to 15 mg of morphine (Girdler and Hill, 1998). However, the degree of analgesia is quite variable from patient to patient and therefore cannot be relied on to provide all of the pain control required for a procedure (Paterson and Tahmassebi, 2003, Malamed, 2009).

1.2.2.1.1.3 Disadvantages of inhalation sedation

In spite of the fact that inhalation sedation for dental treatment has many advantages, there are a number of issues that make inhalation sedation disadvantageous in certain situations. The following are disadvantages associated inhalation sedation (Malamed, 2009):

- It is quite expensive to install and use the inhalation sedation armamentarium as the initial cost of the equipment is high as well as the continuing cost of consuming the gases.

- The equipment required for inhalation sedation occupies considerable space within the dental surgery room.
- A degree of cooperation is required from the patient. For inhalation sedation to be effective, the patient must be able to inhale the gases through the nose. Should the patient be unable (due to certain medical conditions for example) or unwilling to do so, clinical failure will result.
- All members of the sedation team must receive training in its safe and effective use (Hosey, 2002).
- The nasal hood that is required to administer the sedative gas could be problematic (Paterson and Tahmassebi, 2003):
    - Its position close to the operation site might interfere with some procedures like in injections in the upper anterior region.
    - It can be displaced during patient movement which will break the nasal seal rendering the sedation less effective and exposing the staff to the sedative gas.
    - It might be rejected by some children especially those with a previous history of GA.
- There is a possibility that unscavenged traces of nitrous oxide can be deleterious in the long term (Paterson and Tahmassebi, 2003).
    - Chronic exposure to N_2O was found to cause haematological abnormalities and reproductive problems for members of the dental team (Spence, 1987, Rowland et al., 1995, Hoerauf et al., 1999).

- N_2O is not a potent agent. When it is used in combination with at least 20% O_2, there will be a small percentage of patients in whom the technique will fail to produce the desired clinical actions. In no circumstance should N_2O ever be administered with less than 20% O_2. Failures will occur primarily because of the lack of potency of the agent or due to the administration and/or titration technique. This effect can be influenced by the semi-hypnotic approach and psychological preparation of the patient (Hosey, 2002). Therefore, the great dependence on psychological reassurance to achieve the best effect could be considered a disadvantage (Paterson and Tahmassebi, 2003).

1.2.2.1.1.4 Indications and contra-indication of inhalation sedation

The management of dental fear and anxiety is the primary indication for the use inhalation sedation (Girdler and Hill, 1998, Hosey, 2002, Paterson and Tahmassebi, 2003, Malamed, 2009). The indications for the use of inhalation sedation are outlined in Table 1.4.

The contra-indications to relative analgesia sedation are only relative rather than absolute (Roberts, 1990a, Roberts, 1990b, Girdler and Hill, 1998, Paterson and Tahmassebi, 2003). It is essential to balance the risk of giving the patient sedation against the risk of administering general anaesthesia, which is in many cases the only option for severely anxious patients (Paterson and Tahmassebi, 2003). The contra-indications to inhalation sedation are summarised in Table 1.4 below.

Table 1.4 Indications and Contra-Indications of Inhalation Sedation

[Adapted from Hosey (2002), Paterson & Tahmassebi (2003) and Malamed (2009)]

Indications	Contra-indications
• Fear or anxiety • Needle phobia • Where more profound local anaesthesia cannot be obtained, e.g. acute pulpitis; hypoplastic teeth • Gag reflex • Prolonged or unpleasant treatment, e.g. surgical extractions • Persistent fainting • An alternative to GA for some special needs/medically compromised patients like sickle cell disease or trait, some cardiac conditions and cerebral palsy • Cardiovascular disorders (because N_2O reduces anxiety, elevates the pain threshold and provides increased levels of oxygen) • Liver/kidney disease (as N_2O does not undergo biotransformation in the body) • Severe asthma (as a high oxygen tension is maintained)	• Inability to communicate • Fear of the mask • Mouth breathing • Unwilling/unable to nose breathe • Cold/rhinitis • Chronic obstructive airways disease, e.g. emphysema, chronic bronchitis (because the lowered blood oxygen level is the stimulus for breathing) • Severe muscular depression activity, e.g. multiple sclerosis • Severe psychiatric disorders • Behavioural/personality problems • Learning difficulties • Psychological (i.e. patient disliking the felling of loss of control) • First trimester of pregnancy • Bleomycin chemotherapy • Otitis media (because N_2O causes pressure volume effects on the ear)

Key:
GA: General Anaesthesia
N_2O: Nitrous Oxide

1.2.2.1.2 Intra-venous sedation

Intra-venous sedation for children is only appropriate in a limited number of cases and should only be provided by those who are trained and experienced in sedation for children as well as the administration of intra-venous drugs (Hosey, 2002, Scottish Intercollegiate Guideline Network, 2004, Girdler et al., 2009). Its use may be indicated in older children for whom inhalational sedation has been unsuccessful (Standing Dental Advisory Committee, 2003).

1.2.2.1.2.1 Pharmacology of intra-venous sedation

Induction of sedation

(Girdler et al., 2009, Giovannitti Jr, 2013)

Upon IV injection, the plasma level of a sedative drug will rise rapidly. The agent will pass through the venous system to the right side of the heart. Once in the arterial system it will reach the brain, but it will only start to have its effect once diffusion across the lipid membranes has occurred. The final plasma concentration of the sedative agent depends on a) total dose of drug, b) rate of injection, c) cardiac output, and d) circulating blood volume.

Recovery from sedation

(Girdler et al., 2009, Giovannitti Jr, 2013)

Recovery from sedation occurs in two manners:

1. Redistribution of the sedative agent from the CNS into the body fat
2. Uptake and metabolism of the sedative agent in the liver and elimination via the kidneys

The initial peak plasma concentration forces the sedative agent into tissues that are well perfused such as the brain. As time passes, more of the sedative agent is taken up into the adipose tissues. The high mass of body fat and the lipid solubility of sedative agents do promote redistribution to the fat stores. Ultimately the plasma concentration of drugs decreases and the blood-brain concentration gradient is reversed. This forces the sedative agent out of the brain and back into the blood stream.

The uptake, metabolism and elimination result in a final reduction in plasma concentration leading to complete recovery for the patient.

In general, redistribution is responsible for the initial recovery from sedation, followed by elimination of the remaining drug. In comparing different drugs, it is the elimination half-life that can be used to compare the pharmacokinetic effects of different sedative agents.

1.2.2.1.2.2 Intra-venous sedation agents

Benzodiazepines: Diazepam

Diazepam is the first benzodiazepine agent to be utilised for IV sedation. Nevertheless, due to its relative insolubility in water, it has to be dissolved in an organic solvent. This solvent formulation caused a high incidence of vein damage; that is why it is no longer used. Diazelmus is a non-irritant preparation that overcomes the problem of venous damage. Diazepam is metabolised in the liver and eliminated via the kidneys. It has a long elimination half-life of about 43 hours, while the distribution half-life is 40 minutes. The active metabolite (n-desmethyldiazepam) can cause rebound sedation for up to 72 hours following initial administration. For that reason, in addition to the long recovery period, diazepam has been considered unsuitable as a sedative agent for short dental procedures and its use has largely been superseded by midazolam (Girdler et al., 2009). According to the UK national clinical guidelines in paediatric dentistry, there is no role for intra-venous diazepam sedation in paediatric dentistry (Hosey, 2002).

Benzodiazepines: Midazolam

Midazolam was first employed in clinical practice in the early 1980's (Meechan et al., 1998, Girdler et al., 2009). Nowadays, midazolam is the sedative agent of choice for IV sedation in dentistry (Girdler et al., 2009). IV midazolam is recommended for adolescents who are psychologically and emotionally suitable (Hosey, 2002). Midazolam is an imadazobenzodiazeine that is water soluble, has a pH value of less than 4 and is non-irritant

to veins. Once injected into the blood stream at physiological pH, it becomes lipid soluble and is readily able to penetrate the blood-brain barrier. It is rapid acting and has an elimination half-life of 1.9 hours. It is mainly metabolised in the liver with some metabolism occurring in the bowel. The active metabolite is alpha-hydroxymidazolam and it has a short half-life of 1.25 hours so there is no true rebound sedation. The administered dose should be titrated according to the patients' response, most require a dose in the range of 0.07-0.1 mg/kg (Kupietzky and Houpt, 1993, Girdler et al., 2009). The UK national clinical guidelines in paediatric dentistry suggest that IV midazolam should be administered only by an experienced dental sedationist with a trained dental nurse in an appropriate facility; for patients who are under 14 years of age, it should be carried out in a hospital setting (Hosey, 2002). In a randomised clinical pilot trial conducted to test the effect of IV midazolam as a conscious sedation technique for anxious children requiring dental treatment (Averley et al., 2004), the participant children were distributed to 3 groups: a) group 1 received IV midazolam with 'medical air', b) group 2 received IV midazolam in addition to 40% N_2O/O_2, and c) group 3 received IV midazolam together with 40% N_2O/O_2 and 0.3% sevoflurane. The dentist was blinded to the group number. Fifty percent, 73% and 83% completed treatment successfully in groups 1, 2 and 3 respectively. This pilot study revealed that IV midazolam especially in combination with N_2O/O_2 or N_2O/O_2 and sevoflurane was promising, safe and an effective technique, sufficient to justify proceeding with a definitive RCT with appropriate methods. Another randomised controlled, cross-over clinical trial (Wilson et al., 2003) was performed to compare IV midazolam sedation with nitrous oxide sedation in children undergoing dental extractions. There were 40

patients with a mean age of 13.2 years requiring two appointments for equivalent but contralateral extractions for orthodontic purposes. They received conscious sedation with IV midazolam titrated from 0.5mg/min to a maximum of 5 mg in one visit and IHS with N_2O/O_2 titrated to 30%/70% in the other visit. Median time to maximum sedation level was 8 minutes for midazolam and 6 minutes for N_2O/O_2. Vital signs for both techniques were similar and within acceptable clinical limits. The difference in mean recovery time (52 min for midazolam and 23 min for N_2O/O_2) was statistically significant. Of the patients included in the study, 51% preferred IV midazolam, 38% preferred N_2O/O_2 and 11% had no preference. The study concluded that IV midazolam sedation appeared to be as effective as IHS with N_2O/O_2 for 12-16 years old healthy paediatric patients.

Benzodiazepine antagonist (Flumazenil)

The discovery of flumazenil in 1978 was a major advance in the practice of intra-venous sedation. It was the first drug to effectively and completely reverse the effect of almost all of the benzodiazepines. It is a true benzodiazepine with almost no intrinsic therapeutic action. It has a greater affinity for the benzodiazepines receptors than all the other active drugs which rendered it an effective antagonist. It reverses temporarily the sedative, cardiovascular and respiratory effects of diazepam and midazolam. It has an elimination half-life of about 53 minutes. It is administered by giving 200mcg then waiting for a minute. A further 100mcg is then administered every minute until the patient is completely recovered (Girdler et al., 2009). Flumazenil is currently only for use in emergency

situations; it should not be used as a routine part of the conscious sedation procedure or as a way of accelerating recovery. If it were to be used for routine reversal, there is a theoretical risk of reoccurrence of benzodiazepine sedation once the flumazenil has worn off because it has a shorter elimination half-life than active benzodiazepines (Hosey, 2002, Girdler et al., 2009). Flumazenil may also induce convulsions (Royal Pharmaceutical Society of Great Britain, 2012).

Propofol

Propofol is a potent IV hypnotic agent that is widely used for the induction and maintenance of anaesthesia and for sedation in the ICU. It has an oil form at room temperature and is insoluble in aqueous solution. It appears to act by enhancing the GABA neurotransmitter system. Propofol has a rapid recovery because its elimination half-life is 30-40 minutes. Its distribution half-life is 2-4 minutes (therefore rapid distribution into peripheral tissues). Its effects wear off substantially within 30 minutes of administration. For the maintenance of general anaesthesia, propofol is administered as a continuous infusion. Upon completion of the procedure, the infusion is stopped and the patient regains consciousness within a few minutes. It can be administered in sub-anaesthetic doses in one of the following techniques (Girdler et al., 2009):

- Target controlled infusion (TCI – consists of an infusion pump containing software simulating the best pharmacokinetic model for propofol)
- Patient-controlled target infusion

- Intermittent bolus administration

The use of propofol for dental sedation is still in the experimental stages and requires the help of a qualified anaesthetist in a hospital setting (Hosey, 2002, Girdler et al., 2009). The studies performed to assess the suitability of propofol as an IV sedative for dental treatment show promising results (Rodrigo and Jonsson, 1989, Oei-Lim et al., 1991, Stephens et al., 1993). In a study by Hosey and co-workers (2004) that was conducted to assess the use of propofol for anxious children in a specialist paediatric dentistry unit, 32 out of 34 patients had successfully completed treatment at their first visit. The mean propofol dose injected was 2.5mg/kg. All procedures were performed with anaesthetist assistance. Sedation and recovery were uneventful for all the patients. The study concluded that sub-anaesthetic doses of propofol used for IV conscious sedation infusion facilitated dental treatment for anxious children (Hosey et al., 2004). Another study was conducted to compare the effects of IHS with N_2O/O_2 to the influence of IV propofol on dental anxiety of children undergoing dental treatment. The two techniques showed comparable efficacy in reducing the anxiety level of the referred anxious children. It was found that participants who underwent IV propofol sedation were older and that IV sedation with propofol permitted more treatment to be carried out at each visit. It was suggested that further propofol conscious sedation studies were required (Alexopoulos et al., 2007). However, there were some limitations: the study was not randomised, there were many operators who were not calibrated, some patients were first enrolled in the study on their 2nd sedation visit and that treatment offered was various.

1.2.2.1.2.3 Advantages and disadvantages of intra-venous sedation

The advantages and disadvantages of the use of intra-venous sedation technique for dental procedures are presented in Table 1.5 Below (Meechan et al., 1998, Girdler et al., 2009).

Table 1.5 Advantages and Disadvantages of Intra-Venous (IV) Sedation

Advantages	Disadvantages
• Fast onset of sedation • Ability to titrate the sedative agent according to the patient's response • Reasonably wide margin of safety between end point of sedation and loss of consciousness or anaesthesia • Relative comfort of administration • IV access is preserved • A satisfactory level of sedation is achieved pharmacologically rather than psychologically • Recovery happens within a reasonable period	• The need to establish a venous access • For a short period after injection the laryngeal reflex might be weakened • Excessively rapid IV injection can cause significant respiratory depression • Adverse reactions are severe • Once administered, the drug cannot be recovered *[Thus, the operator has to wait for the natural metabolism and elimination to take place. The management of an overdose includes basic life support or the use of an antagonist. The antagonist will not speed up the elimination of the active drug but will block its effects]* • Does not produce useful clinical analgesia (although it may alter patients perception about pain) • May cause disinhibition rather than sedation occasionally; so instead of becoming more relaxed the patient becomes more anxious and difficult to manage

1.2.2.1.2.4 Indications of intra-venous sedation

Intra-venous sedation is suitable for most adult dental patients. According to the BSPD guidelines, IV sedation could be used as a means to manage anxious adolescents who are psychologically and emotionally suitable. Furthermore, IV sedation for children under the age of 14 years should be carried out in a hospital environment. IV sedation is helpful to counteract moderate to severe dental anxiety. It is a good option for claustrophobics and patients suffering from phobias related to anaesthetic equipment. It is indicated for traumatic surgical procedures and for patients with mild medical conditions which might be aggravated by the stress of dental treatment – e.g. mild hypertension or asthma- or those with mild intellectual or physical disability (Meechan et al., 1998, Girdler et al., 2009).

1.2.2.1.2.5 Contra-indications of intra-venous sedation

IV sedation is contraindicated in the following situations (Meechan et al., 1998, Girdler et al., 2009):

- History of allergy to the sedative agent (e.g. benzodiazepines)
- Impaired renal or hepatic function
- Pregnancy or breast feeding
- Severe psychiatric disease
- Drug dependency
- Needle phobia

- Children: IV sedation should be approached with caution as it can have unpredictable effects. Children can lose their controlling inhibitions and become uncooperative. Even slight over-sedation could result in respiratory depression and airway obstruction.

1.2.2.1.3 Oral Sedation

This technique is not in general use for dentistry at present; if it is to be used, then it should be provided by a health care provider who is experienced in its use (Standing Dental Advisory Committee, 2003). The oral sedative agent should only be prescribed and given by the operating dentist within the facility where the dental treatment is to be performed. Moreover, children who had the sedative drug should be placed in a quiet room together with their guardian and a competent member of staff. The sedated children should be monitored clinically and electronically (Hosey, 2002).

1.2.2.1.3.1 Oral sedation agents

Midazolam:

The oral formulation of midazolam was previously associated with a bad taste but now available in hospitals in a blackcurrant flavoured solution. It reaches the systemic circulation via the portal circulation. This decreases the drug's bioavailability which necessitates a higher dose compared to intra-venous administration. Only 15-30% of the

administered oral dose reaches the systemic circulation. The onset of oral midazolam is variable (ranges from 15-30 minutes) and is largely dependent on the patient's rate of absorption from the GIT, which can be affected by the rate of gastric clearance, amount of food in the stomach and time of the day. The peak plasma level is reached in 30-60 minutes. It is recommended that a dose of 0.5-0.75 mg/kg administered 30 minutes before treatment. The patient then should be monitored after administration. Its duration of action is 30 minutes while the half-life is approximately 1.2 hours (Meechan et al., 1998, Hallonsten et al., 2003). The provision of oral midazolam for dental treatment of anxious children was found to be as effective as IHS using N_2O/O_2 in many papers (Wilson et al., 2002a, Wilson et al., 2002b, Wilson et al., 2006). In a study performed to investigate the use of oral midazolam conscious sedation as an alternative to general anaesthesia, the behaviour of 74% of the participants was excellent or very good. Vital signs were monitored and were within clinical limits for all patients. The study concluded that oral midazolam was a safe and effective means of conscious sedation although some children were agitated and distressed either during or after treatment; for which, parents need to be warned (Lourenço-Matharu and Roberts, 2010). Another study has retrospectively assessed the effectiveness of oral midazolam in two centres, Leeds (UK) and Westmead (Australia). The results showed that oral midazolam doses used in Leeds were 0.5 – 0.7mg/kg while they were 0.2-0.3mg/kg in Westmead. Success rates were 65% and 91% in Leeds and Westmead respectively; the difference in success rate was statistically significant. The study concluded that oral midazolam was found to be a useful drug for the management of young children with disruptive behaviour. It suggests though that the use of oral midazolam

in children is limited to simple dental procedures over a maximum of two visits (Day et al., 2006).

Choral hydrate:

Chloral hydrate was the first of the hypnotic group of drugs. In the past, it had been utilised for the management of dentally anxious patients. It is formed by adding one molecule of water to the carbonyl group of chloral and is largely used as a hypnotic agent for dental procedures. It has been considered the drug of choice for conscious sedation for many paediatric dentists because of its safety, efficacy and relatively easy oral administration (Avalos-Arenas et al., 1998). However, repeated administration of chloral hydrate carries a theoretical risk of carcinogenesis. Moreover, the use of chloral hydrate should be within a hospital setting (Hosey, 2002).

1.2.2.1.3.2 Advantages, disadvantages, indications and contra-indications of oral sedation

The advantages, disadvantages, indications and contra-indications of the use of oral sedation techniques are summarised in Table 1.6 (Meechan et al., 1998).

Table 1.6 Summary of Advantages, Disadvantages, Indications and Contra-Indications of Oral Sedation

Advantages	Disadvantages
• Low cost • Non-invasive • Ease of administration • Decreased incidence and severity of adverse reactions • Specialised training not vital (although strongly advised)	• Compliance is crucial • Variable onset • Variable absorption • Inability to titrate • Inability to alter sedation level • Short duration of action
Indications	**Contra-indications**
• Failure of alternatives • Adjunct to behaviour techniques • Pre-cooperative/special needs • Short procedures • Mild-moderate anxiety • Premedication	• Morbid obesity • Sleep apnoea • Airway obstruction • Concomitant viral/tonsillar infection • Allergy/hypersensitivity to the sedative agent • Current medication with benzodiazepines, other central nervous system depressants or muscle relaxants

1.2.2.1.4 Intra-nasal sedation

Midazolam has been used as an intra-nasal sedative agent that is administered with a 1 or 2 cc syringes and a mucosal atomisation device usually into alternate nares. Dose is limited by the volume of the solution. The recommended dose is 0.2-0.3mg/kg and additional doses can be repeated after 10 minutes if required. The peak plasma level is reached after 15

minutes. The use of intra-nasal midazolam was reported in the literature to induce allergic reaction which emphasise the need of close post-administration monitoring (McIlwain et al., 2004).

A study by Gilchrist and colleagues assessed the use of intra-nasal midazolam in the treatment of paediatric dental patients. There were 20 patients aged 2-9 years who required simple surgical procedures. The midazolam was administered intra-nasally using a mucosal atomisation device (0.25mg/kg). Compliance of the full dose was achieved in 14/20 cases, 13 of whom completed treatment. Three patients did not allow any midazolam to be administered. Eleven patients did not suffer any side-effects – like coughing or sneezing – on delivery while one patient vomited at home post-operatively. The study concluded that 0.25mg/kg intra-nasal midazolam provided adequate anxiolysis for the majority of children to complete their treatment whilst maintaining stable oxygen saturation and verbal contact (Gilchrist et al., 2007). Another study by Fuks and co-workers was carried out to assess the use of two different doses of intra-nasal midazolam for sedation of young paediatric dental patients. There were 30 children needing at least 2 restorative appointments. They were randomly assigned to receive either 0.2 or 0.3mg/kg of midazolam intra-nasally in the 1st visit and the alternative regimen in the 2nd. Administration of 50% N_2O/O_2 was then initiated using rapid induction technique. A papoose board was also used. The results showed that there is no difference in behaviour, no adverse effects observed and all treatment was successfully completed. The study concluded that 0.2mg/kg of midazolam (as no difference was observed with 0.3mg/kg) was an adequate sedation modality and

could be recommended for dental treatment in preschool children (Fuks et al., 1994). However, the results of this study could not be generalised as the effect of the midazolam was confounded by the co-administration of N_2O/O_2 as well as the use of physical restraint. The advantages, disadvantages, indications and contra-indications of intra-nasal midazolam are summarised in Table 1.7 (Meechan et al., 1998).

Table 1.7 Advantages, Disadvantages, Indications and Contra-Indications of Intra-Nasal Midazolam

Advantages	**Disadvantages**
• Rapid absorption • Rapid onset (produces sedative effect within 5 minutes) • Amnesia can be induced • Less cooperation is needed compared to oral or intra-venous routes	• Short duration • Could cause a nasal burning sensation • Could cause respiratory depression occasionally • No analgesic effect
Indications	**Contra-indications** (Hosey, 2002)
• Mild to moderate anxiety • Pre-cooperative	• Copious nasal secretions or upper respiratory tract infection • Treatment to be carried out in a non-hospital setting

1.2.2.2 General anaesthesia

Some patients lack the ability to cooperate during dental treatment like those suffering from severe mental and/or physical impairment; hence, for such patients, treatment under general anaesthesia may be the only solution. Moreover, some surgical procedures are so extended in time and tiring that no other methods of pain and anxiety control can be considered (Koch and Poulsen, 2009, Welbury et al., 2012). The clinician should ensure that the benefits of treatment outweigh the risks when making a decision to treat a child under general anaesthesia. Economic factors and access to anaesthetic facilities should also be considered (Cameron and Widmer, 2008).

When performed in a hospital setting, the prevalence of serious complications associated with dental treatment under general anaesthesia is very low. Almost certainly, general anaesthesia is safer than giving deep sedation to a patient in a regular dental setting. The indication for dental treatment under general anaesthesia, however, must be restricted because anaesthesia itself can exert physical and mental stress compared with the other treatment options (Blain and Hill, 1998, Cameron and Widmer, 2008, Welbury et al., 2012). It should be the last resort when all efforts to treat a child in the conventional manner have failed (Cameron and Widmer, 2008, Koch and Poulsen, 2009). Proper consent should be obtained prior to the procedure as well as a thorough pre-anaesthetic assessment (Cameron and Widmer, 2008). The shared airway may pose a challenge to the anaesthetist as the operating dentist often encroaches upon the airway especially when performing lower arch extractions (Cameron and Widmer, 2008, Welbury et al., 2012).

1.3 ASSESSING THE NEED FOR DENTAL SEDAION

It is well-known now that dental fear and anxiety could represent a barrier for seeking dental care. It was reported that 23 million people with dental fear would be more willing to visit a dentist if a form of sedation was offered (Girdler and Hill, 1998). Many studies have been conducted to assess the need for sedation utilising either a paper questionnaire posted to dental health care providers as well as the general population or via telephone contact. The results of these studies revealed that clinicians felt that sedation for dental treatment should be available to all children. In addition, respondents from the general population showed preference to receive sedation as a way of anxiety relief and they were more willing to go to the dentist more often when such services were available (Dionne et al., 1998, Chanpong et al., 2005, Boynes et al., 2006, Chadwick et al., 2006, Woolley et al., 2009, Abdulwahab et al., 2010).

1.3.1 The Indicator of Sedation Need (IOSN)

As discussed above, it can be argued that there are some dentally anxious patients who are not being offered conscious sedation to facilitate their treatment and at the same time sedation services may be demand rather than needs-led. For that reason Coulthard and co-workers developed the Indicator of Sedation Need (IOSN). The IOSN is a tool – as its name indicates – to be used to assess the need for sedation. The IOSN can be used as a) a referral tool to help clinicians to make a decision about referring adult patients to have sedation for their dental treatment, and b) as a health needs assessment tool for

commissioners. It basically investigates the need for sedation by ranking a combination of information on patient anxiety, medical history and the complexity of the clinical treatment. This tool was introduced recently (September 2011) to be utilised for adult patients and not for children. This is because it is composed of three components; one of which – namely the anxiety component – is completed by the patient. This component is simply an anxiety scale and the scale used in the IOSN is an adult one: the Modified Dental Anxiety Scale (MDAS). The second component is medical status which is largely based on the patient's ASA class (American Society of Anesthesiologists, 2006). The last component is the treatment complexity and again, the indicative list of treatment provided is based on treatment offered to adults. The latter two components are completed by the clinician. Each of these components is given a score and the sum of all of them will be the IOSN score, based on which a need for sedation can then be assessed. Table 1.8 describes the IOSN scoring tool in brief (Coulthard et al., 2011).

Table 1.8 IOSN Scoring Tool

IOSN Domain	Score	Source
Anxiety	1-3	Based on MDAS score: MDAS between 5-11 is minimal anxiety, scores 1 MDAS between 12-18 is moderate anxiety, scores 2 MDAS between 19-25 is high anxiety, scores 3
Medical history	1-4	A range of medical and behavioural indicators is provided; as a general rule, ASA class is utilised: ASA I, scores 1 ASA II and/or strong gag reflex, scores 2 or 3 (depends on clinical judgment) ASA III, scores 4
Treatment Complexity	1-4	An indicative list of treatments is provided. If the user of this tool is in doubt about the complexity of any given treatment they are asked to score high

IOSN metric	IOSN description	Sedation need?
3-4	Minimal need for sedation	No
5-6	Moderate need for sedation	No
7-9	High need for sedation	Yes
10-11	Very high need for sedation	Yes

Key:

IOSN: Indicator of Sedation Need

MDAS: Modified Dental Anxiety Scale

ASA classification: American Society of Anaesthesiologists classification of physical health

ASA I: Healthy

ASA II: Mild Systemic Disease

ASA III: Severe Systemic Disease (that does not pose a constant threat to life)

1.4 AIM OF THE STUDY

The aim of the present study was to assess the treatment outcomes of using inhalation sedation for comprehensive dental care within the hospital dental service by utilising a modified version of the Indicator of Sedation Need (IOSN) assessment tool.

The objectives of the present study were:

- To retrospectively assess the outcomes of treatment under nitrous oxide/oxygen inhalation sedation at the Leeds Dental Institute (LDI) sedation unit.
- To assess the outcomes of treatment under nitrous oxide/oxygen inhalation sedation of patients referred to the sedation unit in the LDI utilising a modified version of the Index of Sedation Needs (IOSN) as a health needs assessment tool on a prospective basis. [Note: the modified version here is abbreviated as p-IOSN]
- To compare the results of the retrospective part of the study to the prospective part and identify any significant differences in the treatment completion rates.

The null hypothesis for this study:

- There is no significant difference between the completion rate of dental treatment under inhalation sedation with or without the use of p-IOSN of any score.

2.0 MATERIALS AND METHODS

The present study was carried out in two phases: retrospective phase and prospective phase. The methodology of gaining ethical approval, obtaining the data for both phases and statistical analysis is described in this chapter.

2.1 ETHICAL APPROVAL

Ethical approval was first sought from the Dental Research Ethics Committee (DREC) at the Leeds Dental Institute (LDI) (Appendix 1). Subsequently, it was sought from the National Research Ethics Service (NRES) committee of North West – Preston (REC reference number: 12/NW/0770, Appendices 2 and 3). Following this the study received approval from the Leeds Research and Development Directorate (R&D) in order for it to be performed at the Leeds Teaching Hospital Trust (LTHT R&D number: DT12/10541, Appendix 4).

The Chief Investigator (CI: MM) made certain that the present study was carried out in full conformance with the laws and regulations of the country in which the research was conducted and the World Medical Association Declaration of Helsinki (World Medical Association, 2008).

2.2 RETROSPECTIVE PHASE

The clinical records of all the child patients who received dental treatment in the sedation unit at the LDI during the period of 2006-2011 were requested from the administrative

office. The CI reviewed all the notes and transferred the following information to a data-collection sheet (Appendix 5):

a. Age
b. Gender
c. Treatment outcome

2.2.1 Recording the Outcome of Treatment

There were five possible treatment outcomes:

1. Treatment completed as planned
2. Modified treatment completed
3. Treatment abandoned and child referred on to be treated under general anaesthesia
4. Treatment abandoned in sedation unit and child referred to be treated under local anaesthesia
5. Child failed to return to complete treatment

The treatment outcome was recorded as "completed as planned" if the record showed that the treatment which the child patient had received was in accordance with the proposed treatment plan that was documented in the patient's file. In cases where the patient received a modified treatment than that originally planned, then the outcome was recorded as "modified treatment received". For example, if the patient had the restorations carried out under IHS then referred to have the extractions under GA, while the initial treatment plan was to perform the whole treatment under IHS, then that would be considered a modified treatment. There were patients who had been assessed in the sedation unit to have comprehensive treatment performed under IHS, but then they did not cope well with the

treatment, hence they were referred to have their treatment under GA. In this case the outcome was recorded as “treatment abandoned and child referred on to be treated under general anaesthesia”. On the other hand, there were patients for whom the treatment did not require IHS and were referred to complete their treatment under LA; in which case, the outcome was recorded as “treatment abandoned in sedation unit and child referred to be treated under local anaesthesia”. The outcome was recorded as “child failed to return to complete treatment” if the patient’s record showed that there was a plan to carry out their treatment under IHS but they never showed up to have it performed.

Inclusion Criteria

- All the patients who had undergone dental treatment under inhalation sedation at the LDI during the period of 2006-2011.
- Less than 17 years of age.

Exclusion Criteria

- Patients for whom a decision was made to treat them utilising means other than IHS on their initial assessment visit at the sedation unit.

2.2.2 Sample Size Determination

Statistical advice was sought and revealed that it was not required to specify a sample size for this part of the study because it was considered as an audit. Therefore, all the patients

who received dental treatment in the sedation unit at the LDI during the period of 2006-2011 who were eligible for the study were included.

2.3 PROSPECTIVE PHASE

In this phase of the study, the outcomes of treatment under IHS were obtained on a prospective basis as well as the p-IOSN score. Therefore, a parent's information sheet (Appendix 6) explaining the current study was posted to all paediatric patients attending the sedation unit at the LDI for assessment along with their appointment letter. On the day of their appointment, potential participants and their parents were introduced to the study by the CI in the sedation unit (Figure 2.1).

Figure 2.1 Sedation Unit at the Leeds Dental Institute

Upon their willingness to participate, the parent or legal guardian was asked to sign a consent form (Appendix 7). Similarly, the child patient was assented to participate; it was a verbal assent for children under 10 years of age (Appendix 8) and written assent for older children (Appendix 9). After that, each child participant was asked to complete an anxiety questionnaire. There were two anxiety questionnaires; the FIS (Appendix 10) was used for children under 10 years of age and the $MCDAS_f$ (Appendix 11) for older children. According to the score the patients achieved on the anxiety scale, the CI calculated an "anxiety score" for each child and transferred this to the data collection sheet (Appendix 12). The following data were also transferred to the data collection sheet:

a. Age
b. Gender
c. p-IOSN : which is the sum of:
    - Anxiety score
    - Treatment complexity score
    - Medical status score

The means by which p-IOSN was calculated will be discussed in the following section (2.3.1).

Upon completion of the course of the treatment in the sedation unit, the CI reviewed the participants' clinical records to note the treatment outcome which was then entered into the data collection sheet. The treatment outcome was recorded as discussed above in section 2.2.1.

Inclusion Criteria

- All the patients who were assessed for dental treatment under inhalation sedation at the LDI during the period of January to June 2013 and agreed to participate.

- Aged between 5 and 16 years inclusive.

Exclusion Criteria

- Patients for whom a decision was made to treat them utilising means other than IHS on their initial assessment visit at the sedation unit.

2.3.1 Calculation of p-IOSN Score

p-IOSN is the paediatric version of the IOSN which the investigators of the current study have modified from the IOSN. The IOSN was recently introduced by Coulthard and co-workers in 2011 (Coulthard et al., 2011). The modification of the IOSN was carried out in order for it be suitable for use in paediatric dentistry. The IOSN was designed to be used for adult patients as the anxiety scale it utilises is an adult scale and the treatment complexity ranking was based on treatment that was not usually performed in the paediatric dentistry field (Appendix 13). Therefore the components of IOSN (and then symbolised as p-IOSN to emphasise the modifications to fit paediatric dentistry) were modified by the investigators as follows:

Anxiety

Due to the wide age range of the study group, the investigators decided to use two anxiety scales; the FIS was used for children less than 10 years of age because of its ease of use and briefness; with the minimum FIS score being 1 and maximum 5. The patients who had minimal anxiety (FIS 1) were scored 1 on the anxiety domain of the p-IOSN. Those who had moderate anxiety (FIS 2-3) were scored 2 on the anxiety domain; highly anxious patients (FIS 4-5), were scored 3. For older patients the $MCDAS_f$ was used to evaluate their anxiety levels. $MCDAS_f$ can yield a minimum score of 8 and a maximum of 40. Consequently, patients who scored 8-17 on $MCDAS_f$ were considered as having minimal anxiety and scored 1 on the anxiety domain of the p-IOSN. Those who had moderate anxiety ($MCDAS_f$ 18-28) were scored 2 on the anxiety domain of the p-IOSN. Patients were given a score of 3 on p-IOSN for the anxiety domain if they scored 29 to 40 on $MCDAS_f$. It is worth mentioning here that the cut-off points for categorising the level of anxiety were determined arbitrarily by the investigators.

Treatment Complexity

The treatment complexity ranking score proposed by the IOSN authors could not be used in paediatric dentistry. Hence, the investigators modified the treatment complexity rank score to the one used in the p-IOSN as described in Table 2.1. The score of treatment complexity of p-IOSN ranges from 1-4.

Table 2.1 Treatment Complexity Rank Score for the Paediatric Version of the Indicator of Sedation Need (p-IOSN)

Rank	Description	Score
Routine	Polishing, fluoride application, fissure sealants, one-surface restorations	1
Intermediate	2-surface restorations, extraction of 1 primary tooth, one-quadrant restorative dentistry	2
Complex	Crown preparation, pulp treatment, extraction of multiple primary teeth, multiple-quadrant restorative dentistry, extraction of 1 permanent tooth	3
High complexity	Multiple extractions of permanent teeth, surgical extractions, biopsy Any treatment considered more complex than above or are multiples of the above	4

Medical Status

The medical status scoring was adopted from the same ranking score of the IOSN and ranged from 1-4. It was based on the ASA class. Patients who were ASA I had a score of 1 on p-IOSN. Those who were ASA II and/or have a strong gag reflex were given a score of 2 or 3 depending on the severity of the case. Finally those who were ASA III had a score of 4. A summary of calculating p-IOSN is presented in Table 2.2.

Table 2.2 Summary of p-IOSN Scoring System

p-IOSN domain	Source	Score
Anxiety	**For 5 to 9 years old patients [Facial Image Scale (FIS)]:**	
	FIS score of 1 is minimal anxiety	1
	FIS score of 2 or 3 is moderate anxiety	2
	FIS score of 4 or 5 is high anxiety	3
	For 10 to 16 years old patients [Faces version of the Modified Child Dental Anxiety Scale ($MCDAS_f$)]:	
	$MCDAS_f$ between 8-17 is minimal anxiety	1
	$MCDAS_f$ between 18-28 is moderate anxiety	2
	$MCDAS_f$ between 29-40 is high anxiety	3
Treatment complexity	Routine	1
	Intermediate	2
	Complex	3
	High Complexity	4
Medical status	ASA I	1
	ASA II and/or strong gag reflex (depends on clinical judgment)	2-3
	ASA III	4
Total p-IOSN score	Anxiety score + treatment complexity score + Medical status score	3-11

Key:

p-IOSN: Paediatric version of the Indicator of Sedation Need

ASA classification: American Society of Anaesthesiologists classification of physical health

ASA I: Healthy

ASA II: Mild Systemic Disease

ASA III: Severe Systemic Disease (that does not pose a constant threat to life)

2.3.2 Sample Size Determination

Statistical advice was sought and revealed that because there were no previous studies to investigate the IOSN for children then a sample size could not be calculated. It was recommended though to have as many participants as possible because the larger the sample size, the more chance that their responses would reflect the population.

2.4 ANALYSIS OF DATA

The collected data were compiled into Excel sheets (Microsoft Excel 2010) and then statistical analysis was carried out using the SPSS statistical package for windows version 19 (SPSS Inc. Illinois). A significance level of $\alpha < 0.05$ was adopted.

The Following statistical methods were performed (Harris and Taylor, 2004):

- One-way Analysis of Variance (ANOVA): a statistical technique used for numerical data. It is used to compare the means of two or more samples to see whether they come from the same population.
- Chi-Squared test: used for normally distributed data to measure the difference between actual and expected frequencies.
- Descriptive statistics: Descriptive statistics like means and standard deviations were computed using SPSS and Microsoft Excel 2010.
- Levene's test: used to test the homogeneity (equality) of variances. *P* value of more than 0.05 indicates that equal variances are assumed whilst *p* value of less than 0.05 indicates that equal variances are not assumed.

- *Post hoc* analysis: consists of looking at the data – after the experiment has concluded – for patterns that were not specified earlier
- Tukey's HSD (honestly significant difference) test: is a single-step multiple comparison procedure and statistical test. It is used in conjunction with an ANOVA to find means that are significantly different from each other. It is a type of *post hoc* tests.
- Fisher's exact test: is an accurate test for association between categorical variables. It is used also to analyse contingency tables.
- Kruskal–Wallis one-way analysis of variance by ranks (named after William Kruskal and W. Allen Wallis) is a non-parametric method for testing whether samples originate from the same distribution. It is used for comparing more than two samples that are independent, or not related.
- Difference in proportion tests: Compare two sample proportions using the 2-sample z-test. P-values can be calculated for one- or two-tailed comparisons and are compared results to a specified significance level.
- Independent sample t-test: is used to compare only samples. It tests the probability that the samples come from a population with the same mean value. It used for normally distributed data sets.

3.0 RESULTS

3.1 RETROSPECTIVE PHASE RESULTS

A total of 465 patient notes were received from the administrative office. The CI reviewed all the notes; out of the 465 notes received, 455 of the notes were for patients who were treated in the sedation unit at the LDI. Of the 455 patients' records, 453 met the inclusion criteria. One patient was excluded because they were 19 years of age; the other was excluded due the fact that the treatment they required at the time of referral was no longer indicated when they attended the sedation unit. There were slightly more female patients (n= 240) than males (n= 213) with a mean age of about 10.30 (SD = 2.95) years. The majority of patients were treated by senior postgraduate paediatric dentistry students; the rest were treated by specialist registrars in paediatric dentistry. Initially, two analyses were conducted on the retrospective data, which consisted of a one-way ANOVA focusing upon the relationship between patient age and treatment outcome, and a Chi-square analysis conducted between patient gender and treatment outcome.

3.1.1 Relationship between Patient Age and Treatment Outcome

The following table (Table 3.1) summarises the descriptive statistics conducted focusing upon patient age on the basis of treatment outcome.

Table 3.1 Descriptive Statistics: Age (Years) by Treatment Outcome (Retrospective Phase)

Treatment Outcome	N	%	Mean	SD
Outcome 1	288	63.6	10.428	2.894
Outcome 2	32	7.1	10.762	2.523
Outcome 3	72	15.9	9.087	2.835
Outcome 4	10	2.2	11.857	3.060
Outcome 5	51	11.2	10.657	3.281
Total	453	100	10.295	2.953

Key:

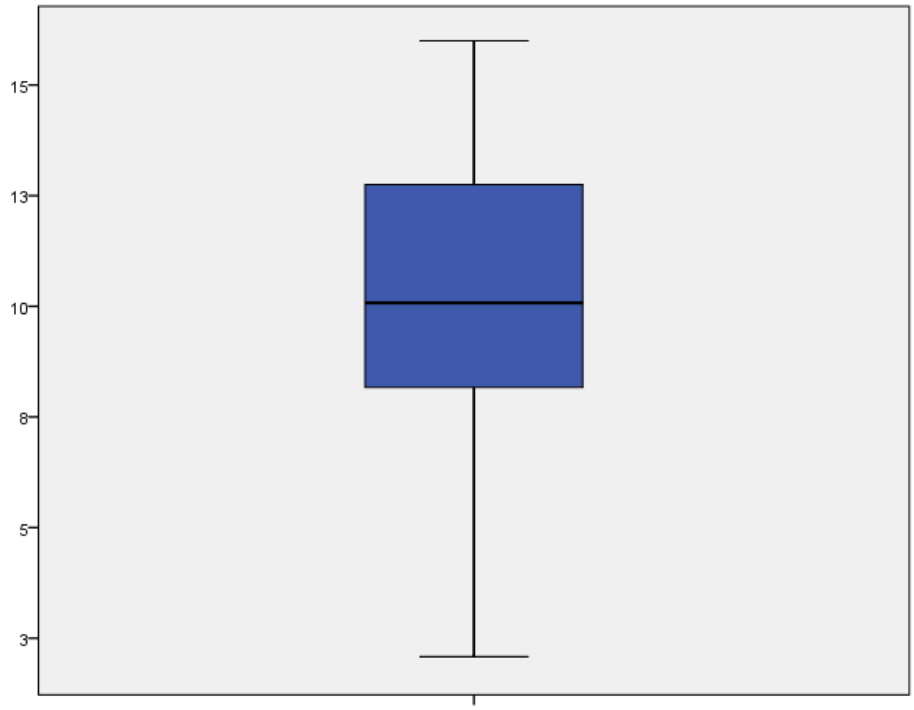
N: Number

SD: Standard Deviation

Outcome 1: treatment completed as planned, Outcome 2: modified treatment completed, Outcome 3: treatment abandoned in sedation unit and child referred to be treated under general anaesthesia, Outcome 4: treatment abandoned in sedation unit and child referred to be treated under local anaesthesia, Outcome 5: child failed to return to complete treatment

These results indicated the lowest mean age in cases where the treatment was abandoned and the child was referred to be treated under GA, with the highest mean age found in cases where treatment was abandoned in the sedation unit and the child was referred to be treated under LA. The following box plot (Figure 3.1) was conducted on patient age and indicated a mean age of approximately 10 years, with an interquartile ranging from slightly above 8 to slightly above 13 years.

Figure 3.1 Box Plot: Patient Age in Years (Retrospective Data)



Following this, Levene's test was conducted for the homogeneity of variances. This analysis failed to achieve statistical significance, Levene statistic (4, 448) = 1.543, p = 0.189. This result indicated that the assumption of the homogeneity of variances was not violated in this analysis. Next, the one-way ANOVA itself did achieve statistical significance, F(4, 448) = 4.375, p = 0.002. This significant result indicated that significant mean differences in patient age were present on the basis of treatment outcome.

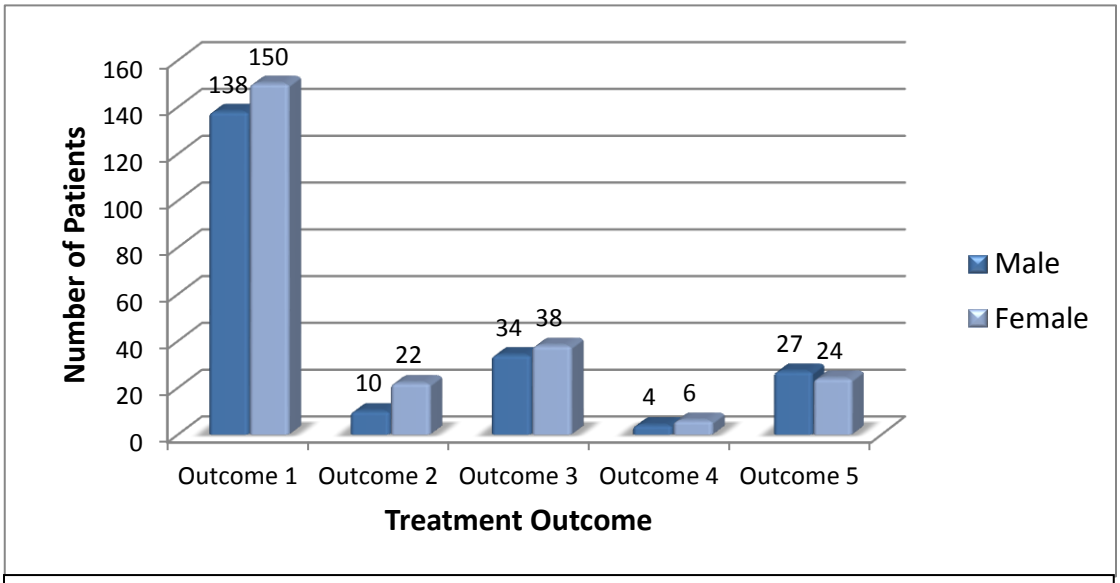
A series of post-hoc analyses were conducted using Tukey's HSD in order to determine between which specific treatment outcomes there existed significant differences in patient age. In total, three significant pairwise comparisons were indicated. Specifically, the following three treatment outcomes: Completed as planned, treatment abandoned in sedation unit and child referred to be treated under LA, and child failed to return to

complete treatment. All had significantly higher mean patient ages as compared with treatment abandoned and child referred to be treated under GA.

3.1.2 Relationship between Patient Gender and Treatment Outcome

Following this, Chi-square analyses along with Fisher's exact test were conducted in order to determine whether a significant association existed between patient gender and treatment outcome. No significant association was indicated between these two measures, χ^2 (4) = 4.204, p = 0.383, Fisher's exact test = 4.210, p = 0.378. Figure 3.2 illustrates the distribution of treatment outcome based on patient gender.

Figure 3.2 Distribution of Treatment Outcome Based on Patient Gender (Retrospective Phase)



Key:
Outcome 1: treatment completed as planned, Outcome 2: modified treatment completed, Outcome 3: treatment abandoned in sedation unit and child referred to be treated under general anaesthesia, Outcome 4: treatment abandoned in sedation unit and child referred to be treated under local anaesthesia, Outcome 5: child failed to return to complete treatment

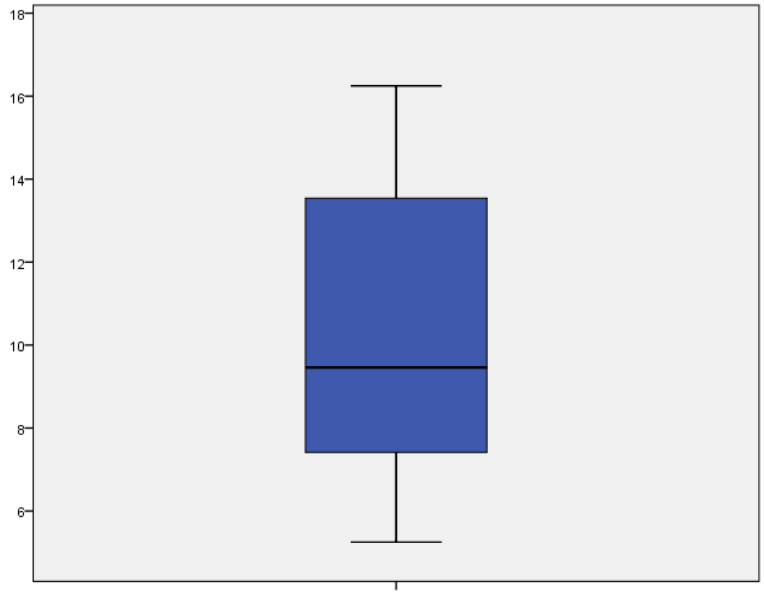
3.2 PROSPECTIVE PHASE RESULTS

During the period of January to June 2013, 42 patients agreed to participate in the study. However, two patients were excluded from the study because they were referred to have their dental treatment under GA on the day of their assessment at the sedation unit. The sample consisted of 40 patients; 16 males and 24 females. The mean age was 9.99 years (SD = 3.14). All the patients included in this phase of the study were treated by postgraduate students in paediatric dentistry. In the next sections, a series of analyses were conducted in order to determine whether significant associations were found between treatment outcome and patient age, gender, p-IOSN, anxiety score, treatment complexity, and medical status using the prospective data.

3.2.1 Relationship between Patient Age and Treatment Outcome

The following figure (Figure 3.3) presents a box plot constructed on patient age with respect to the prospective data. As shown, this presents a mean age slightly above 9 years, with an interquartile ranging from slightly above 7 to slightly above 13 years.

Figure 3.3 Box Plot: Patient Age in Years (Prospective Phase)



In order to determine whether a significant association existed between patient age and treatment outcome, a one-way analysis of variance was conducted on these data. While substantial differences in patient age were found on the basis of treatment outcome in this data set, the ANOVA failed to achieve statistical significance, $F(4, 35) = 1.815$, $p = 0.148$. This result indicated no significant mean differences in patient age on the basis of treatment outcome. Table 3.2 summarises the descriptive statistics conducted focusing upon patient age on the basis of treatment outcome.

Table 3.2 Descriptive Statistics: Age (Years) by Treatment Outcome (Prospective Phase)

Treatment Outcome	N	%	Mean	SD
Outcome 1	29	72.5	10.25	3.085
Outcome 2	1	2.5	5.25	0.000
Outcome 3	5	12.5	8.40	2.670
Outcome 4	3	7.5	12.86	2.290
Outcome 5	2	5	8.25	0.330
Total	40	100	9.99	3.140

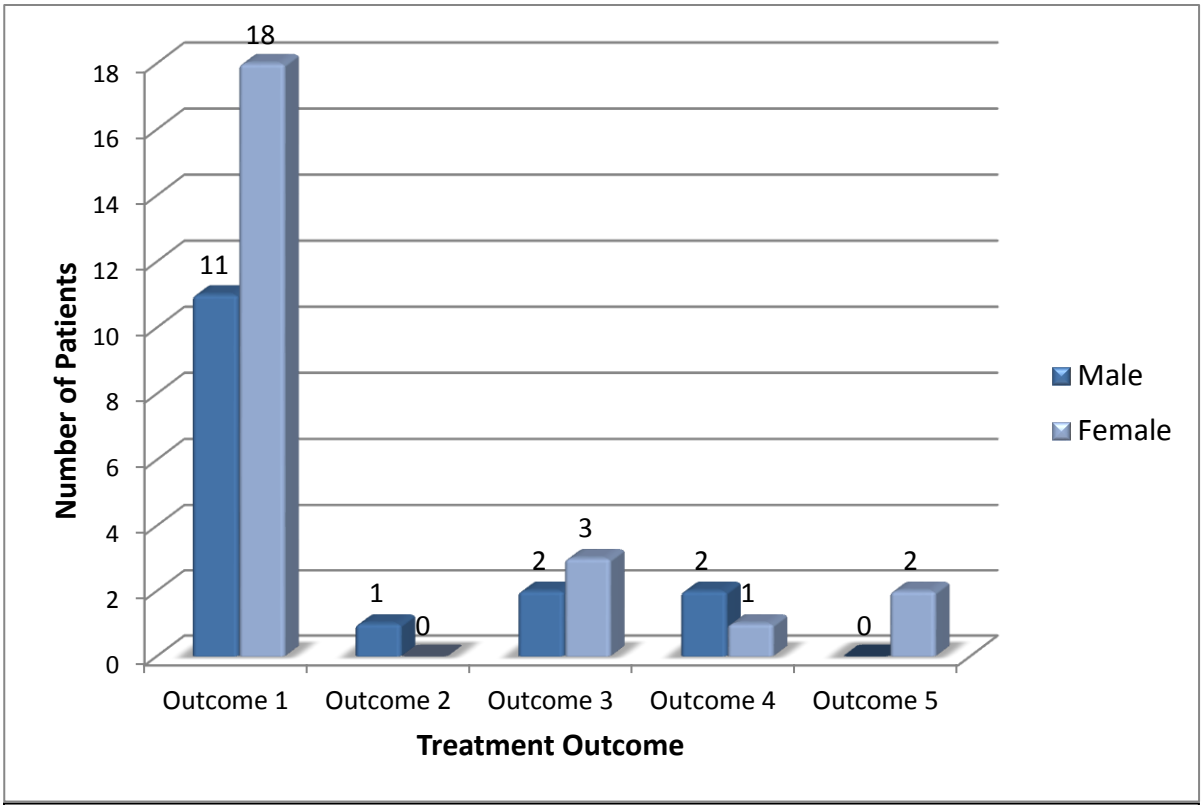
Key:
N: Number
SD: Standard Deviation
Outcome 1: treatment completed as planned, Outcome 2: modified treatment completed, Outcome 3: treatment abandoned in sedation unit and child referred to be treated under general anaesthesia, Outcome 4: treatment abandoned in sedation unit and child referred to be treated under local anaesthesia, Outcome 5: child failed to return to complete treatment

3.2.2 Relationship between Patient Gender and Treatment Outcome

A Chi-square analysis along with a Fisher's exact test was conducted in order to determine whether a significant association existed between patient gender and treatment outcome. These analyses did not indicate any significant association between these two measures, χ^2

(4) = 3.774, $p = 0.516$, Fisher's exact test = 3.484, $p = 0.565$. Figure 3.4 demonstrates the distribution of treatment outcome based on patient gender.

Figure 3.4 Distribution of Treatment Outcome Based on Patient Gender (Prospective Phase)

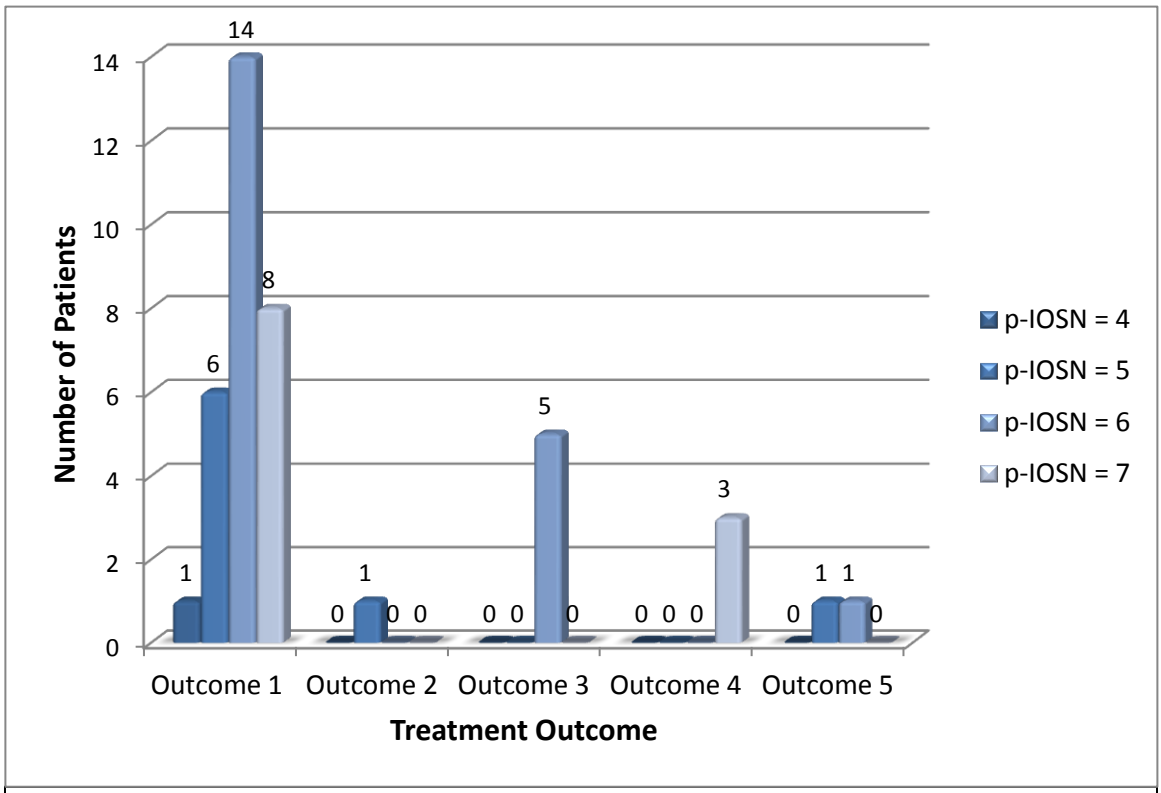


Key:
Outcome 1: treatment completed as planned, Outcome 2: modified treatment completed, Outcome 3: treatment abandoned in sedation unit and child referred to be treated under general anaesthesia, Outcome 4: treatment abandoned in sedation unit and child referred to be treated under local anaesthesia, Outcome 5: child failed to return to complete treatment

3.2.3 Relationship between p-IOSN Score and Treatment Outcome

In order to determine whether a significant association was present between p-IOSN scores and treatment outcome, a Kruskal-Wallis ANOVA was conducted on these data. This non-parametric ANOVA was selected for this analysis as p-IOSN scores were not continuous. This test failed to indicate a significant difference in median p-IOSN scores on the basis of treatment outcome, K (4) = 7.050, p = 0.133. Figure 3.5 below shows the distribution of p-IOSN scores according to treatment outcomes.

Figure 3.5 Distribution of P-IOSN Score Based on Treatment Outcome (Prospective Phase)



Key:
Outcome 1: treatment completed as planned, Outcome 2: modified treatment completed, Outcome 3: treatment abandoned in sedation unit and child referred to be treated under general anaesthesia, Outcome 4: treatment abandoned in sedation unit and child referred to be treated under local anaesthesia, Outcome 5: child failed to return to complete treatment; p-IOSN: Paediatric version of the Indicator of Sedation Need

3.2.4 Relationship between Anxiety Level and Treatment Outcome

An additional Kruskal-Wallis ANOVA was conducted in order to determine whether significant median differences in patient anxiety level existed on the basis of treatment outcome. This analysis did not indicate any significant differences, K (4) = 4.406, p = 0.354.

3.2.5 Relationship between Treatment Complexity and Treatment Outcome

Additionally, the Kruskal-Wallis ANOVA conducted between treatment complexity and treatment outcome also failed to indicate any significant differences in treatment complexity on the basis of treatment outcome, K (4) = 1.747, p = 0.782.

3.2.6 Relationship between Medical Status and Treatment Outcome

A Chi-square analysis and Fisher's exact test were conducted in order to determine whether a significant association was present between medical status and treatment outcome. The results of these analyses did not indicate any significant association between these two measures, χ^2 (4) = 8.785, p = 0.146, Fisher's exact test = 7.299, p = 0.134.

3.3 DIFFERENCE IN PROPORTIONS TESTS

Additionally, a series of difference in proportions tests were conducted in order to determine whether the percentage of patients who had completed their treatment as planned (determined to be 63.6% in the retrospective phase) significantly differed from the same proportions of patients in the data collected in the prospective phase. With regard to the retrospective phase data, 288 patients completed the treatment as planned out of a total of

453. The data obtained in the prospective phase are summarised in the following table (Table 3.3).

Table 3.3 Prospective Phase: Patients Completing Treatment as Planned

p-IOSN Score	N Completed Treatment	N Total	%
4	1	1	100
5	6	7	85.7
6	14	21	66.6
7	8	11	72.7

Key:
N: Number
p-IOSN: Paediatric version of the indicator of sedation need

In order to determine whether any significant differences in these proportions are present, a series of four difference in proportions tests were conducted between the data obtained in the retrospective phase and these four percentages of patients found to have completed treatment on the basis of p-IOSN score in the prospective phase. None of these four individual difference in proportions tests or an additional test conducted combining all data with respect to the prospective phase was found to achieve statistical significance at the 0.05 alpha level. These results indicated that none of these individual percentages with respect to the prospective phase data significantly differed from the value of 63.6% observed in the retrospective phase data.

3.4 DIVIDING THE SAMPLE INTO TWO AGE GROUPS

A decision was made to divide the sample into two groups based on age for the following reasons:

- The analyses in section 3.1.1 (retrospective part) showed that there was a statistically significant association between patients' age and treatment outcome. Therefore comparing these two age groups would further explore this association.
- In the prospective phase of the study, age-specific anxiety scales were used. Hence, dividing the sample into two groups would point out whether or not the use of any of them was superior to the other.

Initially, a series of differences in proportions tests were conducted focusing upon differences in treatment outcome on the basis of patient age. For the purposes of these analyses, age was dichotomised into the following two categories: less than 10 years of age, and 10 years of age or more. First, the following table (Table 3.4) summarises the results of the analyses conducted focusing on each of the two data sets individually and comparing patient treatment outcome on the basis of age category.

Table 3.4 Analyses of Treatment Outcome Based on Age Group

Treatment Outcome	< 10 years	≥ 10 years	z
Retrospective[a]			
Outcome 1	64.1%	63.1%	0.221
Outcome 2	5.5%	8.6%	1.285
Outcome 3	19.5%	12.4%	2.068**
Outcome 4	1.4%	3.0%	1.1.55
Outcome 5	9.5%	12.9%	1.145
Prospective[b]			
Outcome 1	63.6%	83.3%	1.388
Outcome 2	4.5%	0.0%	0.911
Outcome 3	18.2%	5.6%	1.198
Outcome 4	4.5%	11.1%	0.790
Outcome 5	9.1%	0.0%	1.313

Key:
Outcome 1: treatment completed as planned, Outcome 2: modified treatment completed, Outcome 3: treatment abandoned in sedation unit and child referred to be treated under general anaesthesia, Outcome 4: treatment abandoned in sedation unit and child referred to be treated under local anaesthesia, Outcome 5: child failed to return to complete treatment
**$p<.05$
N: Number
[a]Less than 10 years: N = 220; 10 years or more: N = 233
[b]Less than 10 years: N = 22; 10 years or more: N = 18

In order to determine whether significant differences were present in the proportion of patients referred to each type of treatment on the basis of age, a series of difference in proportions tests were conducted.

First, with regard to the retrospective data set, for both age groups, approximately 63%-64% of patients had treatment completed as planned. Next, among younger patients, 5.5% had a modified treatment completed, while among older patients, this figure was slightly above 8.5%. Nearly 20% of individuals less than 10 years of age had their treatment abandoned and were referred to GA, while this figure was approximately 12.5% among older patients. This difference in proportions test was also found to achieve statistical significance at the 0.05 level, indicating that younger patients were significantly more

likely to have treatment abandoned and be referred to GA as compared with older patients. Next, approximately 1.5% of younger patients had treatment abandoned and were referred to LA, while 3% of older patients fell into this category. Finally, 9.5% of younger patients failed to return to complete treatment, while close to 13% of older patients failed to return. Next, with regard to the prospective data set, approximately 63.5% of younger patients had treatment completed as planned, while this figure was slightly above 83% with regard to older patients. Next, 4.5% of younger patients had a modified treatment completed, while no older patients fell within this category. Following this, slightly above 18% of younger patients had treatment abandoned and were referred to GA, while this figure was only slightly above 5.6% with regard to older patients. Additionally, while 4.5% of younger patients had treatment abandoned and were referred to LA, this figure was slightly above 11% among older patients. Finally, among younger patients, slightly above 9% failed to return to complete treatment, while this figure was 0% among older patients. None of the difference in proportions tests conducted on the prospective data set was found to achieve statistical significance.

Subsequently, an independent-samples *t*-test was conducted in order to determine whether a significant difference in p-IOSN scores existed on the basis of age category. This test was not found to achieve statistical significance, indicating no significant mean difference in scores on the basis of age group, $t(38) = 1.787$, $p = 0.082$.

The following table (Table 3.5) summarises the results of the difference in proportions tests comparing retrospective and prospective data sets on the basis of age group as well as treatment outcome.

Table 3.5 Difference in Proportions Tests: Comparing both Data Sets

Treatment Outcome	Retrospective[a]	Prospective[b]	z
< 10 years			
Outcome 1	64.1%	63.6%	0.047
Outcome 2	5.5%	4.5%	0.198
Outcome 3	19.5%	18.2%	0.147
Outcome 4	1.4%	4.5%	1.078
Outcome 5	9.5%	9.1%	0.061
≥ 10 years			
Outcome 1	63.1%	83.3%	1.726
Outcome 2	8.6%	0.0%	1.297
Outcome 3	12.4%	5.6%	0.858
Outcome 4	3.0%	11.1%	1.782
Outcome 5	12.9%	0.0%	1.624

Key:
Outcome 1: treatment completed as planned, Outcome 2: modified treatment completed, Outcome 3: treatment abandoned in sedation unit and child referred to be treated under general anaesthesia, Outcome 4: treatment abandoned in sedation unit and child referred to be treated under local anaesthesia, Outcome 5: child failed to return to complete treatment
N: Number
[a]Less than 10 years: N = 220; 10 years or more: N = 233
[b]Less than 10 years: N = 22; 10 years or more: N = 18

The first set of analyses conducted focused specifically on patients who were under 10 years of age. With regard to both data sets, approximately 64% of these patients had treatment completed as planned, while approximately 5% had a modified treatment completed. Next, 18%-20% of patients had treatment abandoned and were referred to GA. Following this, approximately 1.5% of patients in the retrospective data set had treatment abandoned and were referred to LA, while 4.5% of patients in the prospective data set fell

within this category. Finally, slightly above 9% of patients failed to return to complete treatment across both data sets.

The final set of analyses conducted again compared both of these two data sets, but focused specifically on patients who were aged 10 years old or greater. First, slightly above 63% of individuals in the retrospective data set had treatment completed as planned, while this figure was found to be slightly above 83% in the prospective data set. Next, in the retrospective data set, slightly above 8.5% of patients had a modified treatment completed, while no patients in the prospective data set fell within this treatment category. While approximately 12.5% of patients in the retrospective data set had treatment abandoned and were referred to GA, this figure was slightly above 5.5% in the prospective data set. Following this, 3% of patients in the retrospective data set had treatment abandoned and were referred to LA, while this figure was found to be slightly above 11% in the prospective data set. Finally, close to 13% of patients in the retrospective data set failed to return to complete treatment, while no patients in the prospective data set fell within this treatment category. Among all 10 of these differences in proportions tests, statistical significance was not found in any case, indicating no significant differences in these proportions.

4.0 DISCUSSION

In this chapter, further discussion of the most important components of the current study was carried out.

4.1 STUDY DESIGN AND METHODOLOGY

The Indicator of Sedation Need (IOSN) assessment tool was first introduced to the dental literature in September 2011 by Coulthard and colleagues (Coulthard et al., 2011). It is a novel tool that could be used as:

- Referral tool; to help clinicians to identify those patients who would benefit from sedation for their dental treatment and refer them accordingly, or
- Health need assessment tool; to help commissioners to recognise the need of a certain population for sedation services.

Subsequently, two other papers were published by the same group of authors to assess the use of the IOSN to serve both of the above mentioned purposes (Pretty et al., 2011, Goodwin et al., 2012). The introduction of the IOSN has inspired the investigators of the present study to bring it to light.

The IOSN was modified by the investigators of the current study so that it could be used in paediatric dentistry as explained previously in section 2.3.1. In the current study, using the IOSN as a referral tool was assessed. The modified version is abbreviated as p-IOSN in order to differentiate it from the IOSN and to refer to the paediatric-dentistry-based modification.

The p-IOSN tool is a novel tool which has been developed by the investigators of this study and therefore, at this stage it cannot be used to refer patients to the sedation services as it

has to be investigated and evaluated first. Therefore, the present study was carried out in two phases. The retrospective phase was carried out to assess the treatment outcomes under IHS without the use of p-IOSN. The prospective phase aimed to explore the treatment outcomes of patients who had already been referred to the sedation unit using p-IOSN score. The results of the two phases were compared and contrasted and any effects of p-IOSN use were identified.

4.1.1 Sample Size

Following statistical advice by a qualified biostatistician at the Centre of Epidemiology and Biostatistics, University of Leeds, the sample size of the current study was determined as follows:

- Retrospective phase: because this part of the study was considered an audit; a formal power calculation of the sample size was not indicated. Therefore, all the patients who had received dental treatment in the sedation unit at the LDI during the period of 2006-2011 who were eligible for the study were included. The sample size determination method carried out for the retrospective phase in the present study was similar to methods performed in previous sedation studies that are reported in the literature (Bryan, 2002, Ashley et al., 2010).
- Prospective phase: Since there was no previous published data in the literature, a formal power calculation could not be conducted. The biostatistician advised that a sample size of at least 20 patients was required to allow useful statistical analysis. However, the inclusion of more patients in this phase would improve the quality of

the statistical comparisons made between the data of the retrospective and prospective phases. This is because the sample size of the retrospective phase was relatively large and hence, the larger the sample of the prospective phase, the more realistic the results of the statistical analysis would be.

Although the sample size of the retrospective phase was larger than the sample size studied in the prospective phase, statistical analysis was still possible by utilising the difference in proportion test.

4.2 ASSESSMENT OF TREATMENT OUTCOMES

In the present study, 63.3% and 72.5% of the participants in the retrospective phase and prospective phase respectively completed their dental treatment as planned under inhalation sedation. These figures were noticeably lower than what have been reported previously in the literature (Crawford, 1990, Shaw et al., 1996, Bryan, 2002, Foley 2005).

The proportion of patients for whom the treatment was abandoned in the sedation unit and were referred to have it performed under general anaesthesia was 15.9% and 12.5% in the retrospective and prospective phases respectively. This was in accordance with the studies by Carwford (1990) and Shaw et al (1996). However, these figures were substantially larger than the work performed by Bryan (2002) where only 2.4% of the child patients were referred to have their treatment carried out under general anaesthesia.

It is important to note here that these studies were conducted using different methodologies than the one carried out in the present study and the nature of treatment provided also varied widely. The study by Bryan (2002) was conducted in a similar way as the present

study in that all the records of children who were referred to have various dental procedures under IHS were evaluated and possible treatment outcomes were considered. However, all the analyses were performed retrospectively which might be disadvantageous as the enrollment of participants is based on treatment records of which, some might be insufficient or lost. In the present study, the information yielded by the prospective phase would have compensated for that potential unwanted effect caused by data analysis of the retrospective phase alone. In both Carwford (1990) and Shaw et al (1996) studies, only the patients who were referred to have extractions or minor surgical procedures were included which might cause a form of selection bias. Moreover, in both studies the use of IHS was assessed as an alternative to GA; other possible outcomes of the treatment (e.g. modified treatment completed) could not be assessed.

4.3 EVALUATION OF CHILDREN AGE

4.3.1 The Mean Age of Children

The mean age of the patients included in the retrospective phase of this study was 10.3 (SD = 2.95) years; prospective phase, 9.99 (SD = 3.14) years. These figures were comparable to the mean age of participants in the study by Soldani and co-workers which compared different inhalation sedation agents for dental treatment of children where the mean age was 10.6 years (Soldani et al., 2010).

On the other hand, the mean age of patients included in the present study was considerably more than the mean age found by Bryan (2002) which was 7.2 years and also contrasted

with the study by Ashley et al. who reported on the sedation of children in the primary care sector in the UK; the mean age was 8.5 years (Bryan, 2002, Ashley et al., 2010).

In contrast, the child patients in the present study were younger than some of the other previous studies. In a number of studies conducted to compare midazolam (delivered by various routes) to nitrous oxide sedation for paediatric dental care the mean age of patients ranged from 12.5 years to 13.2 years (Wilson et al., 2002a, Wilson et al., 2003, Wilson et al., 2007). Another study comparing nitrous oxide to propofol IV sedation for the dental treatment of anxious children revealed that the mean age of patients treated under nitrous oxide sedation was 11 years (Alexopoulos et al., 2007).

4.3.2 Association between Child Age and Treatment Outcome

In the present study there was a statistically significant association between patient age and that "treatment is abandoned in the sedation unit and child referred to have treatment under GA" as a treatment outcome when the retrospective data were analysed. This association failed to achieve statistical significance when the prospective data were analysed. This could be attributed to the relatively small sample size assessed in the prospective phase. When that significant association was further explored, it was found that the patients who were younger than 10 years were more likely to require general anaesthesia for their dental treatment. This is in agreement with previous studies which reported that children with mean age ranging from about 3 years to slightly above 7 years were referred to have their dental treatment under general anaesthesia (Eidelman et al., 2000, Harrison and Nutting, 2000, Camilleri et al., 2004). Although the mean age of patients who completed the

treatment successfully under IHS in the study conducted by Bryan (2002) was substantially lower than the mean age of the patients that participated in the current study, it also suggested that children younger than 5 years of age were more likely to require general anaesthesia for their dental treatment.

In the present study, no significant association was found between patient's age and any treatment outcome other than outcome 3 (i.e. treatment abandoned in sedation unit and child was referred to have their treatment under GA). This is expected as inhalation sedation is the recommended route for conscious sedation for paediatric dentistry in addition to its numerous advantages (Hosey, 2002).

4.4 EVALUATION OF PATIENT GENDER

4.4.1 The Male to Female Ratio of Patients Referred to Sedation

Girls represented the majority of the sample included in both phases of the current study. This compares favourably with the findings of Soldani and co-workers (Soldani et al., 2010) whilst there were more males in the cohorts studied by other researchers (Bryan, 2002, Foley, 2005, Ashley et al., 2010, Lourenço-Matharu and Roberts, 2010).

The literature is equivocal regarding the association between gender and dental anxiety. Some studies have found no gender differences in children's and adolescent's dental fear (Locker et al., 2001, Majstorovic et al., 2003, Muris et al., 2005). However, several studies reported that girls were more dentally anxious than boys (Majstorovic and Veerkamp, 2004, Klingberg and Broberg, 2007).

4.4.2 The Association of Patient Gender and Treatment Outcome

It is interesting to note that in the present study, there was no significant association between gender and any particular treatment outcome. This contrasts with the results of Foley's study on the perception of IHS where male participants less than 10 years of age were found to cope better with IHS than female patients of the same age (Foley, 2005). Many studies in the literature however lacked the investigation of gender differences on the basis of treatment outcome. For example, the study by Bryan has commented on the percentage of males and females included in the study population which was 51.2% and 48.8% respectively, but failed to relate any gender differences to treatment outcomes (Bryan, 2002). Similarily, the female to male ratio was 3:2 in Soldani and co-workers study, but there was no mention about gender differences based on treatment outcomes (Soldani et al., 2011).

4.5 ASSESSMENT OF THE p-IOSN TOOL

As discussed previously, the p-IOSN is an assessment tool that has been developed by the investigators of the current study from the IOSN which was introduced as a novel assessment tool that could be utilised to predict the sedation need of adult dental patients (Coulthard et al., 2011, Pretty et al., 2011, Goodwin et al., 2012). For that reason, careful assessment of the suitability of this newly devolved tool (p-IOSN) to serve its meant purpose was crucial.

Similar to the IOSN, the p-IOSN tool is composed of three components: anxiety score, medical status and treatment complexity. Statistical analysis was performed to investigate whether or not there was an association between the score of any component and any

particular treatment outcome. The analysis resulted in that neither anxiety score, medical status nor treatment complexity score was associated with any specific outcome; which indicates that all of these components are equally important in assessing the need for sedation. This is expected as these three components embrace the indications for dental sedation in general. According to the EAPD guidelines on sedation in paediatric dentistry, sedation is indicated for the dental treatment of the children who have low coping ability, dental anxiety, or disruptive behaviour as well as those who require extensive dental treatment (Hallonsten et al., 2003). Moreover, it is reported in the literature that inhalation sedation with nitrous oxide/oxygen is indicated for dentally anxious patients, some medical conditions (especially for which GA is contra-indicated) and for extensive or unpleasant dental procedures (Hosey, 2002, Paterson and Tahmassebi, 2003).

4.6 EVALUATION OF THE ANXIETY SCALES

In the current study, the FIS and $MCDAS_f$ were used to assess the level of dental anxiety of participating children and then determine the score of the anxiety component of the p-IOSN. The purpose of choosing two and not only one anxiety scale was due to the relatively wide age range of the patients included in the study; hence, age-specific anxiety scales were used. The FIS is a valid anxiety scale that can be employed to evaluate the anxiety of children of any age from 3 to 18 years (Buchanan and Niven, 2002). However, this scale cannot indicate the details of the potential sources of the anxiety. Therefore, the $MCDAS_f$ was also used as it consists of eight questions that tackle different aspects of dentistry which could be potential causes of dental anxiety. The $MCDAS_f$ is a valid and reliable measure of dental anxiety in children aged 8-12 years (Howard and Freeman,

2007). Therefore, both FIS and $MCDAS_f$ were used so that the anxiety of the 5-16 years old children included in the present study could be evaluated.

The FIS was used to assess the anxiety level in 5-9 year old children enrolled in the present study, while the $MCDAS_f$ was used for children who were 10-16 years. Statistical analysis revealed that differences between treatment outcomes yielded by the two age groups failed to achieve statistical significance. This would imply that both FIS and $MCDAS_f$ were equally effective in measuring the anxiety of children in the respective age groups. This is expected as both scales have been previously validated.

Although both FIS and $MCDAS_f$ have been validated by previous research (Buchanan and Niven, 2002, Howard and Freeman, 2007), a recent paper by Guinot and colleagues have argued that because children's anxiety is of a multi-dimensional nature, more studies are needed to determine the reliability and validity of the measures used to assess dental anxiety in children. The authors further explained that the low level of correlation among the different methods of assessing anxiety in children seems logical given the physiological, cognitive and motor responses that manifest in different ways in each individual (Guinot et al., 2011). In another study assessing pain-related behaviour in children over two dental appointments, the dental subscale of the children's fear survey schedule (CFSS-DS) was used to assess the level of dental anxiety of the patients. One of the girls who participated in the study mentioned "Look," pointing at face #2 "I choose this one; and you know why?" The dentist shook his head. "Because last time I picked this one (pointing at #4) and next time I will choose this one (pointing #6)" (Hembrecht et al., 2013). This shows that children may not have the appropriate cognitive level to use the anxiety scales correctly.

There was some debate that completing a dental anxiety questionnaire prior to a dental procedure would increase anxiety. However, a paper by Carlsen and co-workers had disproved this belief. In their study, they included 195 children aged from 7-16 years attending four community dental clinics to determine whether pre-treatment enquiries about anxiety and pain influenced their subsequent reports of pain and anxiety immediately after treatment. Contrary to some expectations, answering questions about dental anxiety did not cause deleterious effects on patients. In fact, completing these questions appeared to be beneficial in reducing self-reported pain experience. The authors attributed this effect to the fact that encouraging children to consider how anxious they were about certain dental procedure and the prospect of discomfort enabled them to be prepared psychologically for their dental treatment (Carlsen et al., 1993). A randomised controlled trial had been conducted on adults to assess the same issue, and had comparably concluded that the completion of a brief dental anxiety survey before seeing the dentist had no significant effect on their anxiety levels post-operatively (Humphris et al., 2006).

4.7 ASSESSING THE NULL HYPOTHESIS

The treatment was completed as planned in the retrospective phase in 63.3% of the cases compared with 72.5% in the prospective phase. The difference did not achieve statistical significance. Further analysis of treatment completion rate in the prospective phase revealed that treatment completed as planned in 100% of the patients who scored 4 on the p-IOSN, 85.7% of the patients who scored 5 on the p-IOSN, 66.6% of the patients who scored 6 on the p-IOSN and 72.7% of the patients who scored 7 on the p-IOSN. The difference between all of these percentages and the completion rate with regard to the retrospective phase (63.3%) was not statistically significant. Therefore, the null hypothesis which stated that "There is no significant difference between the completion rate of dental treatment under inhalation sedation with or without the use of p-IOSN of any score" was accepted.

It is important to note that at the LDI, the decision to refer patients to the sedation unit for dental treatment is made by consultants in paediatric dentistry; or at least, that decision is supported and confirmed by the consultants. All the patients included in the present study were referred to the sedation unit in the same manner. By accepting the null hypothesis, it could be suggested that the use of p-IOSN as a referral tool – which was found to be comparable to experienced consultant opinion – might be beneficial in primary care centres to help less-experienced clinicians in decision making.

Fifty percent of the patients in the prospective phase (n=20) scored p-IOSN of 6, 27.5% scored p-IOSN of 7, 20% scored p-IOSN of 5, and only 2.5% scored p-IOSN of 4. There was no significant association between any of the treatment outcomes and any particular p-IOSN score. Based on that, it could be proposed that a p-IOSN score of less than 5 would

mean minimal need for sedation, a p-IOSN score of 5 would mean moderate need for sedation and a p-IOSN of greater than 5 would mean high need for sedation. This is slightly different than what the authors of the IOSN suggested, where an IOSN score of 3-4 was minimal need for sedation, an IOSN score of 5-6 was moderate need for sedation, 7-9 was high need for sedation and an IOSN of 10-11 was very high need for sedation (Coulthard et al., 2011). Obviously, the p-IOSN descriptors mentioned here should be considered as suggestions only rather than guidelines until further research on the p-IOSN tool emerges.

4.8 SUGGESTIONS FOR FUTURE RESEARCH

The p-IOSN is a new tool that is still in the investigational stages. Hence, further research is needed prior to adopting its use in the clinical field. The results yielded by the current study could form the basis of future research. Below, suggestions for further investigations on p-IOSN are discussed.

4.8.1 Sample Size

Although the sample size studied in the prospective phase using the p-IOSN was relatively small, statistical analysis was still possible and revealed beneficial results. However, a larger sample size would allow more reasonable comparisons and would be more representative of the studied population.

4.8.2 Assessing the Behaviour Score

Many studies in the literature have scored behaviour of children undergoing sedation for dental treatment. These studies reported that the behaviour of the majority of the patients who completed treatment successfully was excellent or very good (Foley, 2005, Lourenço-Matharu and Roberts, 2010). This means that there was a small proportion of patients who had completed the proposed treatment successfully but with lower behaviour scores.

In the present study, the treatment completion rate ranged from 63.6% to 72.5%. Nevertheless, the behaviour score was not assessed although Frankl and Houpt behaviour rating scores were available in treatment records. The reason for not evaluating this piece of information in the present study was that scoring the behaviour of a child could vary widely among clinicians and could differ across different treatment visits and different procedures (e.g. restoration vs extraction). In Soldani et al (2009) study, there was no agreement between observers' Frankl scores given to child participants. Therefore, assessing the behaviour score by a number of calibrated assessors along with the outcome of dental treatment under sedation should be considered in future research and investigations using the p-IOSN.

4.8.3 Experience Level of the Dentist

One of the objectives of Bryan's study (2002) about the success of inhalation sedation for dental care was to relate the outcomes of treatment to the experience of the operating dentist. The results showed that there was no difference in the number of failures in relation to the experience of the operator (Bryan, 2002). In the present study, such association was not explored. The majority of patients were treated by postgraduate paediatric dentistry

students while very few patients included in the retrospective phase were treated by a specialist registrar in paediatric dentistry who had a significantly longer training period than the postgraduate students. There was no significant difference in treatment outcomes found when retrospective and prospective phases of the study were compared. This might imply that the experience level of the treating dentist did not affect treatment outcome; yet, this should be considered in future research especially when use of inhalation sedation is being investigated, where the psychological reassurance ability of the dentist is important (Paterson and Tahmassebi, 2003). Another interesting point to consider is the experience level of the referring dentist. In the LDI where the current study was conducted, the decision to refer patients to the sedation unit was confirmed and supported by consultants in paediatric dentistry. This is not the case in every dental clinic. Therefore, investigating the relation between experience of the referring dentist and treatment outcome in future research would add valuable information.

4.8.4 Anxiety Scales

In the present study the FIS and $MCDAS_f$ were chosen among other anxiety scales for several reasons as discussed previously (section 4.6). There are other valid anxiety scales, however, that have been used previously in dental research (Venham et al., 1977, de Menezes Abreu et al., 2011, Hembrecht et al., 2013). So, assessing the incorporation of other anxiety scales in the p-IOSN tool would be an area of future research. For example, Venham picture scale could potentially be used as it is easy to apply, understandable for a wide age range of children and provides more information about the dental situation than

the FIS. Moreover the use of CFSS-DS which is consisted of 15 items is precise, allows measurement of trait anxiety and provides very useful data (Guinot et al., 2011).

4.8.5 Other Types of Sedation

The present study only evaluated the use of p-IOSN for children undergoing inhalation sedation with nitrous oxide and oxygen mixture. In the literature though, other inhalation sedative agents (Soldani et al., 2010) as well as other routes of conscious sedation have shown promising results (Wilson et al., 2002a, Wilson et al., 2003, Wilson et al., 2006, Alexopoulos et al., 2007, Gilchrist et al., 2007, Wilson et al., 2007). Although inhalation has been advocated as the recommended route for conscious sedation for paediatric dentistry (Hosey, 2002), the authors of a review paper were not able to reach any definitive conclusion on which was the most effective sedative agent or route of sedation used for the dental care of anxious children due to issues with the quality and validity of published studies (Matharu and Ashley, 2007). Therefore, the use of p-IOSN to assess the need for other sedation methods than the one utilised in the current study would shed light on other useful information.

5.0 CONCLUSIONS

Based on the results of the current study on the treatment outcomes of dental treatment under inhalation sedation utilising p-IOSN tool, it can be concluded that:

- Children under 10 years of age are more likely to require general anaesthesia to facilitate their dental treatment.
- Utilising p-IOSN may be beneficial in predicting child patients who would benefit from sedation for their dental treatment.
- Caution is to be considered when using the p-IOSN assessment tool as further research and investigation should be carried out prior to its formal use in the clinical field.

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7.0 APPENDICES

APPENDIX 1: Dental Research Ethics Committee (DREC) Recommendations and Approval

Date: Fri, 17 Aug 2012 14:10:15 +0100 [17/08/2012 14:10:15 BST]

From: Julie McDermott <J.K.McDermott@leeds.ac.uk>

To: 'Maryam Madouh' <dnmm@leeds.ac.uk>

Cc: Gail Douglas <G.V.A.Douglas@leeds.ac.uk>, Jinous Tahmassebi <J.Tahmassebi@leeds.ac.uk>, Medicine and Health Research Governance <governance-ethics@leeds.ac.uk>

Subject: Ethics application 'Outcomes of dental treatment under inhalation sedation: using IOSN'

Part(s): 2 Standard Sponsor Review Guidance August 2011version 0 4.pdf [application/pdf] 29 KB

1 unnamed [text/html] 6.38 KB

Dear Maryam,

Thank you for submitting the above Ethics application to DREC. Your application has been re-reviewed and it is recommended that the following points are addressed prior to submitting your application for Faculty sponsorship sign-off and NHS Research Ethics Committee approval:

-Under sections A6-1 and A10 please provide further information on the IOSN tool, who introduced it and how it has been validated

-Under section A6-2 it is recommended using bullet points or numbering for each phase as the ** are confusing with the text relating to 'criminal bureau clearance' at the bottom of the section

-It is recommended that each section of the form is answered correctly rather than referring back to previous sections of the form, as it currently states in sections A11, A12, A13 and A14

-Under section A13 please explain the purpose for carrying out Phase 1 and how it is linked to Phase 2 and approximately how many patients you anticipate to include for Phase 1

-Although there are no risks to participants it may be that some patients who have undergone sedation may find it difficult to complete the questionnaire immediately after their treatment. It is recommended to state here that the information sheet and questionnaire will be handed out to patients before their treatment to help minimise the burden on them after their sedation

-Under section A24 please amend to state that although there will be no direct benefit to patients taking part in the study, the results from the study may benefit future patients

-Under section A57 please confirm which treatment outcomes are being compared

-Please provide an answer to section A58, if there are none, please state this

-Under section A59 please provide details of the sample size to be used for the pilot study

-Under section A74 amend to state that the Academic Supervisor will be responsible for monitoring the research and the sponsor will be responsible for auditing the research

-Under Part B section 3.2 mention that age appropriate Information sheets for children aged 5-9 years and 10-16 years will be used and under section 4 amend to state that a child's assent form for children aged 10-16 years will be used and for children aged 5-9 years parental consent will be obtained

-It is recommended amending the titles on the Information sheets and Consent form as they are not written in lay language

You are not required to re-submit the application back to DREC, however, it is strongly recommended that the above points are addressed and discussed with the Academic supervisor prior to submitting to the NHS for review.

If you need any further information, please do not hesitate to contact me.

Attached is a copy of the Faculty Standard Sponsorship Review Guidance. Please read this as it contains important information with regards to submitting your REC form for Faculty sponsorship sign-off.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, signed consent forms, participant information sheets and all other documents relating to the study. This should be kept in your study file, and may be subject to an audit inspection. If your project is to be audited, you will be given at least 2 weeks' notice.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

With best wishes for the success of your project.

For and on behalf of

Professor Gail Douglas

DREC Chairman

APPENDIX 2: National Research Ethics Service (NRES) Approval

NHS
Health Research Authority
National Research Ethics Service

NRES Committee North West - Preston
HRA NRES Centre - Manchester
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7818
Facsimile: 0161 625 7299

11 October 2012

Dr Maryam Madouh
Leeds Dental Institute
University of Leeds
Clarendon Way
LS2 9LU

Dear Dr Madouh

Study title:	**Treatment outcomes of using inhalation sedation for comprehensive dental care within the hospital dental service by utilizing the Indicator of Sedation Need (IOSN) assessment tool**
REC reference:	**12/NW/0770**
IRAS reference:	**103361**

The Proportionate Review Sub-committee of the NRES Committee North West - Preston reviewed the above application on 15 October 2012.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, **subject to the conditions specified below.**

Ethical review of research 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.

Further conditions specified by the REC:

a. The Committee would like to see the Participant Information Sheet revised to
   i) Include under "Do I have to take part?" after the first sentence "There will be no changes to your child's proposed treatment whether you take part or not"
   ii) Include under "What do I have to do?" "The researchers will look at your child's notes to compare the questionnaire with the treatment given"
   iii) Include a section on "What if I need to complain", stating that the normal complaints process will apply and giving the local and independent (e.g. PALS) contact details
   iv) Put onto letter headed paper
b. The Committee would like to see the Consent Form revised to
   i) Include a further point "I agree my child's notes can be looked at by the researchers
   ii) Put onto letter headed paper

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).

You must notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of insurance or indemnity		
Investigator CV	Madouh	
Investigator CV	Tahmassebi	
Other: Data Collection Sheet retrospective	1	26 September 2012
Other: Data Collection Sheet prospective	1	26 September 2012
Other: FIS age 5-9	1	26 September 2012
Participant Consent Form: Assent age 5-9	1	26 September 2012
Participant Consent Form: Assent age 10-16	1	26 September 2012

Protocol	1	26 September 2012
Questionnaire: p-ISON	1	26 September 2012
Questionnaire: MCDAS age 10-16	1	26 September 2012
REC application	3.4	08 October 2012

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

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

12/NW/0770	**Please quote this number on all correspondence**

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

Yours sincerely

Dr Patricia Wilkinson
Chair

Email: nrescommittee.northwest-preston@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers"

Copy to: *Faculty Research Ethics and Governance Administrator*
Ms Ann Gowing, Leeds R&D LTHT

A Research Ethics Committee established by the Health Research Authority

NRES Committee North West - Preston

Attendance at PRS Sub-Committee of the REC meeting w/c 8 October 2012

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr David Abbotts	Lay member	Yes	
Mr Mike Hammond	Lay Member	Yes	
Mrs Vasanthi Vasudevan	Diabetes Research Nurse	Yes	
Dr Patricia Wilkinson	General Practitioner	Yes	

APPENDIX 3: National Research Ethics Service (NRES) Approval: Conditions Met

NHS
Health Research Authority
National Research Ethics Service

NRES Committee North West - Preston
HRA NRES Centre - Manchester
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7818
Facsimile: 0161 625 7299

12 October 2012

Dr Maryam Madouh
Leeds Dental Institute
University of Leeds
Clarendon Way
LS2 9LU

Dear Dr Madouh

Full title of study: **Treatment outcomes of using inhalation sedation for comprehensive dental care within the hospital dental service by utilizing the Indicator of Sedation Need (IOSN) assessment tool**
REC reference number: **12/NW/0770**
IRAS reference: **103361**

Thank you for your email of 11 October 2012. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 15 October 2012. Please note these documents are for information only and have not been reviewed by the committee.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant Information Sheet	2	11 Oct 2012
Participant Consent Form	2	11 Oct 2012

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

12/NW/0770	Please quote this number on all correspondence

Yours sincerely

Mrs Carol Ebenezer
Committee Co-ordinator

E-mail: nrescommittee.northwest-preston@nhs.net

Copy to: *Faculty Research Ethics and Governance Administrator*
Ms Ann Gowing, Leeds R&D LTHT

APPENDIX 4: Research and Development Approval (Leeds Teaching Hospital NHS Trust)

The Leeds Teaching Hospitals NHS
NHS Trust

Ref: Amanda Bird

28/11/2012

Research & Development

Leeds Teaching Hospitals NHS Trust
34 Hyde Terrace
Leeds
LS2 9LN

Tel: 0113 392 2878
Fax: 0113 392 6397

r&d@leedsth.nhs.uk
www.leedsth.nhs.uk

Dr Maryam Madouh
Leeds Dental Institute
University of Leeds
Clarendon Way
LS2 9LU

Dear Dr Maryam Madouh

Re: NHS Permission at LTHT for: Treatment outcomes of using inhalation sedation for comprehensive dental care within the hospital dental service by utilizing the Indicator of Sedation Need (IOSN) assessment tool
LTHT R&D Number: DT12/10541
REC: 12/NW/0770

I confirm that *NHS Permission for research* has been granted for this project at The Leeds Teaching Hospitals NHS Trust (LTHT). NHS Permission is granted based on the information provided in the documents listed below. All amendments (including changes to the research team) must be submitted in accordance with guidance in IRAS. Any change to the status of the project must be notified to the R&D Department.

Permission is granted on the understanding that the study is conducted in accordance with the *Research Governance Framework for Health and Social Care*, ICH GCP (if applicable) and NHS Trust policies and procedures available at http://www.leedsth.nhs.uk/sites/research_and_development/.

This permission is granted only on the understanding that you comply with the requirements of the *Framework* as listed in the attached sheet "Conditions of Approval".

If you have any queries about this approval please do not hesitate to contact the R&D Department on telephone 0113 392 2878.

Indemnity Arrangements

The Leeds Teaching Hospitals NHS Trust participates in the NHS risk pooling scheme administered by the NHS Litigation Authority 'Clinical Negligence Scheme for NHS Trusts' for: (i) medical professional and/or medical malpractice liability; and (ii) general liability. NHS Indemnity for negligent harm is extended to researchers with an employment contract (substantive or honorary) with the Trust. The Trust only accepts liability for research activity that has been managerially approved by the R&D Department.

The Trust therefore accepts liability for the above research project and extends indemnity for negligent harm to cover you as investigator and the researchers listed on the Site Specific Information form. Should there be any changes to the research team please ensure that you inform the R&D Department and that s/he obtains an appropriate contract, or letter of access, with the Trust if required.

Yours sincerely

Dr D R Norfolk
Associate Director of R&D

Approved documents
The documents reviewed and approved are listed as follows

Document	*Version*	*Date of document*
NHS R&D Form	3.4	15/10/2012
SSI Form	3.4	16/11/2012
Directorate Approval		20/11/2012
REC Letter confirming favourable opinion		11/10/2012
Insurance/ Indemnity	Zurich	29/09/2012
Questionnaire: P-ISON	V1	26/09/2012
Questionnaire: MCDAS 10 - 16	V1	26/09/2012
Protocol	V1	26/09/2012
Patient information sheet (REC approved)	V2	11/10/2012
Consent form (REC approved)	V2	11/10/2012
Other: FIS 5 - 9	V1	26/09/2012
PCF – Assent 5 - 9	V1	26/09/2012
PCF – Assent 10 - 16	V1	26/09/2012
Data Collection Retro Part	V1	26/09/2012
Data Collection Prospective	V1	26/09/2012

Conditions of NHS Permission for Research:

- Permission from your Directorate must be obtained before starting the study.
- Favourable Opinion of the appropriate Research Ethics Committee, where necessary, must be obtained before starting the study.
- Arrangements must be made to ensure that all members of the research team, where applicable, have appropriate employment contracts or letter of agreement to carry out their work in the Trust.
- Agreements must be in place with appropriate support departments regarding the services required to undertake the project and arrangements must be in place to recompense them for the costs of their services.
- Arrangements must be in place for the management of financial and other resources provided for the study, including intellectual property arising from the work.
- Priority should be given at all times to the dignity, rights, safety and well being of participants in the study
- Healthcare staff should be suitably informed about the research their patients are taking part in and information specifically relevant to their care arising from the study should be communicated promptly.
- Each member of the research team must be qualified by education, training and experience to discharge his/her role in the study. Students and new researchers must have adequate supervision, support and training.
- The research must follow the protocol approved by the relevant research ethics committee. Any proposed amendments to or deviations from the protocol must be submitted for review by the Research Ethics Committee, the Research Sponsor, regulatory authority and any other appropriate body. The R&D Department should be informed where the amendment has resource implications within the Directorate and the Directorate research lead/clinical director notified.
- Adverse Events in clinical trials of investigational medicinal products must be reported in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.
- Complete and return Study Status Reports, when requested, to the R&D Department within 28 days of receipt as requested. (NB Failure to comply to such request with the requirement will lead to suspension of NHS Permission.)
- Procedures should be in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage.

- Arrangements must be made for the appropriate archiving of data when the research has finished. Records must normally be kept for 15 years.

- All data and documentation associated with the study must be available for audit at the request of the appropriate auditing authority. Projects are randomly selected for audit by the R&D Department. You will be informed by letter if your study is selected.

- Findings from the study should be disseminated promptly and fed back as agreed to research participants.

- Findings from the study should be exposed to critical review through accepted scientific and professional channels.

- All members of the research team must ensure that the process of informed consent adheres to the standards GCP outlined in the UK Clinical Trials Regulations. Investigators are directed to the R&D website for further information and training availability.

- Where applicable, this NHS Permission includes aspects of the study previously covered by the NRES Site Specific Assessment (SSA) process.

- Appropriate permissions must be in place for studies which are covered by the Human Tissue Act.

- Patient Information Sheet and Consent form must be on The Leeds Teaching Hospitals headed paper and include local contact details.

Commercially Sponsored Trials
If the study is commercially sponsored, NHS Permission is given subject to provision of the following documents.

- Clinical Trials Agreement - agreed and signed off by the R&D Department (on behalf of the Leeds Teaching Hospitals NHS Trust) and the Sponsor. Investigators do not have the authority to sign contract on behalf of the Trust.

- Indemnity agreement, if not included in the Clinical Trials Agreement- (standard ABPI no fault arrangements apply) signed by the R&D Department and the Sponsor

It is essential that all the responsibilities set out in the Research Governance Framework, including those outlined above are fulfilled. The Trust reserves the right to withdraw NHS Permission where the above criteria are not being met. The Trust will not accept liability for any activity where NHS Permission has not been granted.

APPENDIX 5: Data Collection Sheet (Retrospective Part)

	1	2	3	4	5	6	7	8	9	10
Personal details										
Age										
Gender (m:0, f:1)										
Treatment outcomes										
Completed as planned (0)										
Modified treatment completed (1)										
Treatment abandoned and child referred to be treated under GA (3)										
Treatment abandoned in sedation unit and child referred to be treated under local anaesthesia (4)										
Child failed to return to complete treatment (5)										

APPENDIX 6: Parents Information Sheet

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T + 44 (0) 113 343 6199
F + 44 (0) 113 343 6165
E dentistry @leeds.ac.uk

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E j.tahmassebi@leeds.ac.uk

UNIVERSITY OF LEEDS

Parent's information sheet [V.2]

Research Title

A research project to construct an objective means that will help dentists and health care providers to identify people who are very likely to require sedation for their dental treatment

Introduction

You and your child are invited to take part in the above research study at Leeds Dental Institute.

Before you decide whether or not to take part, please take time to read the following information carefully in order to understand what this research is about and what your participation involves. Please feel free to discuss with other people and ask us if you wish to clarify any matters regarding this research. Taking part in the study will approximately add 5-10 minutes to your appointment.

Study Purpose

The purpose of this study is to help dentists and dental care providers to identify people who are very likely to require sedation for their dental treatment; so that sedation services would be used appropriately.

Some Questions You May Have

Why have I been chosen?

You and your child have been chosen because your child is attending their first visit in the sedation unit at Leeds Dental Institute.

Do I have to take part?

You are not obliged to participate. There will be no changes to your child's proposed treatment whether you take part or not. We will go through this information sheet and explain this study to you. If you decide to take part, you will be required to sign a consent form, although you are free to withdraw from the study at any time without giving a reason. This will not affect yours or your child's treatment in any way.

What do I have to do?

Leeds Dental Institute
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E j.tahmassebi@leeds.ac.uk

UNIVERSITY OF LEEDS

We would like your child to fill a questionnaire about how they feel at the moment (i.e. being at the dentist). The answer(s) to the question(s) will be entered in our assessment tool that we are developing in this study. The researchers then will look at your child's notes to compare the questionnaire with the treatment given.

What are the possible benefits of taking part?

Although there are no immediate benefits for those people participating in the project, it is hoped that this work will improve the way that child patients are being referred by the dentists to have their treatment under sedation.

What will happen if I decided not to continue with the study?

You can withdraw from the study at any time; this will not affect your child's treatment in any way. Unless expressed otherwise, we will use the information already collected.

What will happen to the result of the research?

The information will be stored safely and securely in the usual manner that all other clinical data/records are stored. Moreover, the results of this study will be used for professional doctorate research project by Maryam Madouh, and possibly published in Dental Journals and presented at conferences. There will be no mention of specific individuals.

What if I need to complain?

The normal complaints process will apply. You can have more information on the NHS Patient Advice and Liaison Service (PALS) website [http://www.pals.nhs.uk/]. You can also contact the local PALS office in Leeds; their contact details are as follows:

Telephone: 0800 0525270

Email: pals@leedspct.nhs.uk

Office Address:

Patient Advice & Liaison Service
NHS Leeds
1st floor rear
North West House
West Park Ring Road
Leeds
West Yorkshire
ENGLAND
LS16 6QG

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UNIVERSITY OF LEEDS

Who is organising and funding this research?

This research is funded by the Faculty of Medicine and Health, University of Leeds.

Who reviewed this study?

The University of Leeds has reviewed the study. This study has been approved by **National Research Ethics Service (NRES) Committee North West – Preston**.

Who can I contact for further information?

If you have further questions, you can contact Miss M. Madouh or the lead supervisor, Dr Jinous Tahmassebi, through the following methods:

Miss M. Madouh:
Email: dnmm@leeds.ac.uk
Telephone: 07879753818

Dr Jinous Tahmassebi:
Email: J.Tahmassebi@leeds.ac.uk
Telephone: 01133433955

Thank you

APPENDIX 7: Consent Form

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UNIVERSITY OF LEEDS

Consent form [V.2]

Patient Identification Number/Name:

Project Title:

A research project to construct an objective means that will help dentists and health care providers to identify people who are very likely to require sedation for their dental treatment

Please initial the box if you agree with the statement to the left.

1 I confirm that I have read and understand the information sheet/letter explaining the above research project and I have had the opportunity to ask questions about the project. ☐

2 I understand that my participation and my child's are voluntary and that we are free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should we not wish to answer any particular question or questions, we are free to decline. ☐

3 I understand that my child's name will not be linked with the research materials, and we will not be identified or identifiable in the report or reports that result from the research. ☐

4 I agree my child's notes can be looked at by the researchers ☐

5 I agree for the data collected from our participation can be used in future research and for educating dentist and the dental team. ☐

6 I and my child agree to take part in the above research project. ☐

_____	_____	_____
Name of participant	Date	Signature

(*or legal representative and relationship*)

_____	_____	_____
Lead researcher	Date	Signature

To be signed and dated in presence of the participant

Copies:

Once this has been signed by all parties the participant should receive a copy of the signed and dated participant consent form, the letter/pre-written script/information sheet and any other written information provided to the participants. A copy of the signed and dated consent form should be kept with the project's main documents which must be kept in a secure location.

11/10/2012 Ref No 12/NW/0770 V.2

APPENDIX 8: Assent Form (For 5-9 Year Old Patients)

APPENDIX 9: Assent Form (For 10-16 Year Old Patients)

Assent form (for 10-16 years old patients) [V.1]

Patient Identification Number/Name:

Project Title:

A research project to construct an objective means that will help dentists and health care providers to identify people who are very likely to require sedation for their dental treatment

Please ***circle*** all that you agree with (if you are unable to do so, your parents may help you).

Have you read (or had read to you) about this project?	Yes/No
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
Do you understand all the answers to your questions?	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 <u>any</u> answers are 'No' or you do not want to take part, don't sign your name!

If you <u>do</u> want to take part, you can write your name below

Name (Block Capitals): _____

Child's Signature: _____

Date: _____

Name (Block Capitals): _____

Parent/Guardian Signature: _____

Date: _____

The dentist who explained this project to you needs to sign too:

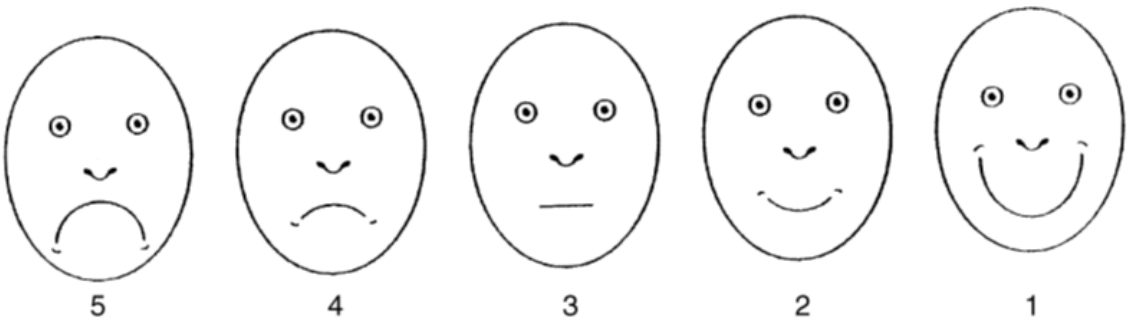
Name (Block Capitals): _____

Signature: _____

Date: _____

APPENDIX 10: Facial Image Scale (For 5-9 Year Old Patients)

Please circle the "face" that is most applicable to you now:



Thank you

Appendix 11: Faces Version of the Modified Child Dental Anxiety Scale (For 10-16 Year Old Patients)

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. To show me how relaxed or worried you feel, please use the simple scale below. The scale is like a ruler going from 1which would show that you are relaxed, to 5 which would show that you are very worried.

1 would mean: relaxed/not worried

2 would mean: very slightly worried

3 would mean: fairly worried

4 would mean: worried a lot

5 would mean: very worried

Please circle the most applicable number to each of the following questions:

How do you feel about ...					
... going to the dentist generally?	1	2	3	4	5
... having your teeth looked at?	1	2	3	4	5
... having your teeth scraped and polished?	1	2	3	4	5
... having an injection in the gum?	1	2	3	4	5
... having a filling?	1	2	3	4	5
... having a tooth taken out?	1	2	3	4	5
... being put to sleep to have treatment?	1	2	3	4	5
... having a mixture of 'gas and air' which will help you feel comfortable for treatment but cannot put you to sleep?	1	2	3	4	5

Thank you

APPENDIX 12: Data Collection Sheet (Prospective Part)

		1	2	3	4	5	6	7	8	9	10
Personal details											
Age											
Gender (m:0, f:1)											
Patient's p-IOSN score	Anxiety score										
	Tx Complexity										
	Medical status										
	Total										
Treatment outcomes											
Completed as planned (0)											
Modified treatment completed (1)											
Tx abandoned and child referred to be treated under GA (3)											
Treatment abandoned in sedation unit and child referred to be treated under LA (4)											
Child failed to return to complete treatment (5)											

APPENDIX 13: Indicator of Sedation Need (IOSN)

Indicator of Sedation Need (IOSN)

ANXIETY QUESTIONNAIRE TO BE COMPLETED BY THE PATIENT

Can you tell us how anxious you get, if at all, with your dental visit?

Please indicate by putting a 'X' in the appropriate box

1. If you went to your Dentist for TREATMENT TOMORROW, how would you feel?

Not Anxious ☐	*Slightly Anxious* ☐	*Fairly Anxious* ☐	*Very Anxious* ☐	*Extremely Anxious* ☐

2. If you were sitting in the WAITING ROOM (waiting for treatment), how would you feel?

Not Anxious ☐	*Slightly Anxious* ☐	*Fairly Anxious* ☐	*Very Anxious* ☐	*Extremely Anxious* ☐

3. If you were about to have a TOOTH DRILLED, how would you feel?

Not Anxious ☐	*Slightly Anxious* ☐	*Fairly Anxious* ☐	*Very Anxious* ☐	*Extremely Anxious* ☐

4. If you were about to have your TEETH SCALED AND POLISHED, how would you feel?

Not Anxious ☐	*Slightly Anxious* ☐	*Fairly Anxious* ☐	*Very Anxious* ☐	*Extremely Anxious* ☐

5. If you were about to have a LOCAL ANAESTHETIC INJECTION in your gum, above an upper back tooth, how would you feel?

Not Anxious ☐	*Slightly Anxious* ☐	*Fairly Anxious* ☐	*Very Anxious* ☐	*Extremely Anxious* ☐

Humphris GM, Morrison T and Lindsay SJE. The Modified Dental Anxiety Scale: Validation and United Kingdom Norms. *Community Dental Health* 1995; 12:143-150.

Dentist to score Anxiety Questionnaire

Each of the five answers is scored as follows:

Not anxious	= 1
Slightly anxious	= 2
Fairly anxious	= 3
Very anxious	= 4
Extremely anxious	= 5

So the total Questionnaire Score is a sum of all five items (range 5 to 25)

_____

Indicator of Sedation Need (IOSN)

MATRIX TO BE COMPLETED BY THE DENTIST

1. Anxiety Questionnaire (MDAS) Rank Score

Questionannaire Score is converted to Rank Score			Please circle one
MDAS	5-9	(minimal anxiety)	1
MDAS	10-12	(moderate anxiety)	2
MDAS	13-17	(high anxiety)	3
MDAS	18-25	(very high anxiety)	4

2. Medical & Behavioural Indicator Rank Score

Please circle one

No medical or behavioural indicators	1
Systemic disorders (not of severity to exclude sedation) that may be exacerbated by treatment Fainting attacks/ hypertension/ angina/ asthma/ epilepsy/ other *(please state)* *Systemic disorders that compromise ability to cooperate* Arthritis/parkinsonism/ multiple sclerosis/ other (please state) *As a rule of thumb ASA II would generally be 2 or 3 and an ASA III would result in a grade of 4* Gag reflex	2, 3, or 4

These indicators are not designed to replace your usual full medical history

3 Treatment Complexity Rank Score

Please circle one

This guidance is not exhaustive – if in doubt about score then please score higher value	
ROUTINE – Scale, single rooted extraction of 1 or 2 teeth, small soft tissue biopsy, single quadrant restorations, crown preparations or anterior endodontic treatment	1
INTERMEDIATE – Scale and root planning, multi-rooted tooth extraction, surgical extraction without bone removal, apicectomy anterior tooth, 2 quadrant restorative, posterior endodontic treatment	2
COMPLEX – Periodontal surgery, surgical extraction with bone removal, apicectomy posterior tooth, multiple quadrant restorative, multiple posterior endodontics	3
HIGH COMPLEXITY - Any treatment considered more complex than above or are multiples of the above	4

SEDATION NEED 1 + 2 + 3 scores

Total Rank Score	Source Descriptor	Sedation Need
3-4	Minimal need	No
5-6	Moderate	No
7-9	High need	Yes
10-12	Very high need	Yes

Coulthard P, Bridgman CM, Gough L, Longman L, Pretty IA, Jenner T. Estimating the need for dental sedation. 1. The Indicator of Sedation Need (IOSN) - a novel assessment tool. *British Dental Journal* 2011;9:211(5):E10.

APPENDIX 14: Abstract of Part of the Present Study Presented as an Oral Presentation at the Leeds Dental Institute Research Day (10 July 2013)

Maryam Madouh

Utilising the indicator of sedation need (IOSN) tool for children's dental care

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Inhalation sedation is one of the pharmacological behaviour management strategies. The IOSN tool was recently introduced to aid clinicians in decision making with regards to referring patients to have dental treatment using conscious sedation.

Objectives: To assess the outcomes of treatment under nitrous oxide/oxygen inhalation sedation of patients referred to the sedation unit in the Leeds Dental Institute (LDI) utilising a modified version of the Index of Sedation Needs (IOSN) as a health needs assessment tool

Methods: An IOSN score was calculated and given to the patients referred to the sedation unit at the LDI for dental treatment under inhalation sedation on their initial assessment appointment. The patients' treatment records were then reviewed – when their course of treatment was completed at the sedation unit – to determine the treatment outcome.

Results: The convenient sample was comprised of 23 patients with a mean age of 10.36 years. Sixteen patients had completed their treatment as planned in the sedation unit, one had a modified treatment completed, three were referred to have treatment under general anaesthesia and three were referred to have treatment under local analgesia. An independent-samples Kruskal-Wallis test showed that significant differences in IOSN scores existed on the basis of treatment outcome ($p = 0.021$). There were no significant associations between age or gender and the treatment outcome.

Conclusions: IOSN is a useful tool that can be utilised to guide dentists to predict those patients who would benefit from conscious sedation for their dental treatment. However, it is a novel tool and requires further research and investigation.