

Toolkit for Conscious Sedation Research

Background

There is a paucity of high-quality research in the field of conscious sedation, especially for paediatric dental patients in the UK. In a recent Cochrane systematic review of paediatric dental sedation (2005), the authors found that the overall quality of studies was disappointing, with poor reporting frequently the main problem. In addition, the variety of drug regimes compared and the outcome measures used within the included studies made it impossible to aggregate the data reported or to conduct a meta-analysis. Consequently, the authors were unable to reach a definitive conclusion about the most effective sedation method for anxious children. However, they did make detailed recommendations for future studies assessing sedative agents. These apply equally to conscious sedation research for children and adults.

It was also reported that the vast majority of publications concerned with conscious sedation in dentistry were not reported well enough to allow reliable judgements to be made about how the trials had been conducted and the validity of the results.

Those who have an interest in conscious sedation research have an opportunity to develop and improve the quality of work being carried out in this area. Appropriate, robust studies are required in order to develop a sound evidence base to support best practice, with regard to drug regimes and sedation techniques.

Cochrane recommendations

When designing and carrying out clinical trials the first principles researchers should adhere to are the CONSORT guidelines (Consolidated Standards of Reporting Trials) [2].

The CONSORT statement is an important research tool that takes an evidence-based approach to improve the quality of reports of randomised trials. Its critical value to researchers, healthcare providers, peer reviewers, journal editors and health policy makers is the guarantee of integrity in the reported results of research. CONSORT comprises a checklist and flow diagram to help improve the quality of reports of randomised controlled trials. It offers a standard way for researchers to report trials. The checklist includes items, based on evidence, that need to be addressed in the report; the flow diagram provides readers with a clear picture of the progress of all participants in the trial, from the time they are randomised until the end of their involvement. The intent is to make the experimental process clearer, flawed or not, so that users of the data can more appropriately evaluate its validity for their purposes.

The Cochrane Review authors give more specific recommendations regarding sedation-related clinical trials, intended as the basis for further debate in this area.

These included:

Blinding: ideally the operator, assessor and patient should be blind to the sedation agent and techniques being used. However, realistically it is accepted that this may not always be possible, for example where an inhalational sedation technique is being used.

Sample: it is essential that an appropriate sample size is calculated prior to commencing any trial to ensure statistical significance can be appropriately calculated. It was clear from many of the studies reviewed that different age groups were being studied and a recommendation was made to divide age into three bands in accordance with the prescribing of drugs as laid out in the British National Formulary (BNF). The bands are 1 to 6 years, 6 to 12 years and over 12 years. One issue with

this is that many dental trials are designed around the dental age of the patient, which may differ.

Design: it is essential to prior design the trial appropriately taking into consideration carry over effects that may be witnessed when studying the effects of sedation.

Outcome measures: issues regarding the most appropriate outcome measures must be clarified. In general, behaviour and anxiety are used to measure outcome of the management regime. It is important to ensure standard, validated and reliable tools are being used to allow direct comparison of work.

The statistical tools that are used to analyse data must also be ratified and consistent.

Helpful tips

First steps and essential starting points

Like many areas of dentistry, sedation is in dire need of a strong evidence base.

Unlike many areas of dentistry, sedation is not a desperately difficult area to research and there are real prospects for conducting meaningful research in primary care.

However, research is a discipline in itself and it does not always come easily to a clinician, partly because in order to conduct a project you have to stop being a clinician for a while, and that is not easy.

The most important piece of advice is simply this: never try to do a project on your own. If you have something that you want to do and feel you can do, then that is excellent, but you will need support from a number of sources, and should get this at the earliest opportunity. What may seem like a perfectly sensible study design to you may be simply unworkable or statistically unsound. Modern clinical research is highly professional now and tightly regulated. The regulation of research is such that someone with recent experience of the regulatory system, including ethics and trust approval mechanisms and honorary trust contracts, is an essential part of the process. Research also costs money. You will have to decide whether you are going to try and obtain additional resources for a project. You can go some distance on goodwill of course but cannot always rely on this. There are plenty of people who could advise you.

The points where help and advice are essential are included below. Finding the right person is sometimes difficult and we would advise contact either with your closest academic unit, or linking through this sedation network.

Steps

The following are the key steps you need to take if you are interested in pursuing a piece of research:

- Identifying a research question
- Designing a project
- Reviewing the literature
- Compiling a protocol.

Identifying a research question

You need to start by asking a precise question, and that means *precise*! Once you have formulated a question, check that it fulfils the following criteria:

- Keep it limited (i.e. specific and focused)
- Keep it small
- It must be precise.

The best research questions are based on your own experience or problems you have faced.

Precision is key. For example, asking ‘How is blood pressure affected by drug A?’ is too vague. However, ‘Does mean diastolic blood pressure increase during routine dental treatment when drug A is used as an oral sedative agent when compared with drug B?’ asks a question that is specific enough for you to be able to design a study to answer it. You know what is being compared (drug A with drug B), in precisely what circumstances (routine dental treatment) and you also know the outcome measure you will use (mean diastolic blood pressure). This last part is critical – your outcome measure determines much of how you collect your data.

It can take a long time to get to the right question. Sometimes you need to have reviewed the literature before you can get to this stage, but get to it you must.

Designing a project – preliminary

It helps to be aware of the design options when considering your research questions. Here is a conventional view:

X people – randomly assigned to drug A (intervention) or drug B (control – normal medication) – measure and compare outcomes.

This is basically an RCT (randomised controlled trial) and provides a high level of evidence, *but* you really need to know what you are doing. However, this is only one of many valid and useful approaches. Take a step back. Do you need numeric data at all?

Qualitative research – interviews, focus groups, etc.

This can be invaluable for exploring complex opinions and attitudes. It is also essential in designing questionnaires and other new outcome measures. It involves focus groups or interviews and really gets beneath the surface. It is fantastically useful but uses narrative text as data, not numbers or statistics. It is increasingly widely used and is excellent for understanding attitudes, barriers and beliefs. It is also invaluable before compiling a questionnaire as a way of making sure your questionnaire asks the right questions.

Quantitative research

Pure clinical trials (as above) are time-consuming, frustrating and difficult to do well. However, they are very useful.

Laboratory or experimental studies have no need for patients, though you may need volunteers.

Questionnaire-based studies and surveys are much more difficult than they seem but can be done in a short time. You need to design your questionnaire scientifically and are strongly advised to seek help. A bad questionnaire is a waste of everyone's time. Choose an approach that will answer your research question with maximum efficiency. However, rather than just choosing it, find someone who knows about research methodology and involve them in key decisions at an early stage.

Reviewing the literature

It is essential you do this before you go too far. The last thing you want is to start your trial without realising that it has already been done, or that someone has got a perfect way of measuring outcome that you did not know about. Often you will need to review the literature before even tightening up the question. The more systematically you review the literature the better. Try to record your strategy for searching for literature. Publicly accessible databases such as PubMed have revolutionised this process. We would suggest the following pointers:

- Read widely initially.
- It is highly unlikely that anyone will have done precisely what you are planning, so don't get paranoid.
- Be critical: don't just report what you read; think. Quite a lot of published research is very flawed.
- When you start to review, *never lose sight of your research question/aim/hypothesis.*
- When you are reviewing, stay narrow and deep around your aim, not wide and shallow, and avoid running down blind alleys.
- Be careful not to revert to being a clinical dentist; use the evidence, not clinical judgements.

Designing a protocol

This is your working manual, your point of reference, your rule book. It is important to stick to it. You will need this for applying to an ethics committee and for getting trust approval. A protocol is demanded by these organisations for good reason. If you have prepared one it means you have thought through the process. Bear in mind the following:

- You cannot begin to do this unless your research question is crystal clear.
- When drafting this it is worth taking your time and making sure that you get appropriate help. The areas you will need help with will almost certainly be for methodology and statistics (the two often go together). If you are intending to undertake any sort of quantitative analysis it is very important that you secure that stats advice early on.
- Sort out ethical approval early on, read the guidance instructions carefully and stick to them.

Finally:

- Clarify the question/aim/hypothesis and set some specific objectives
- Keep the project manageable
- Keep focused
- Don't try to change the world
- Get help.

Research tools

For clinical trials it is important to ensure that standard, validated and reliable tools are being used to allow direct comparison of work. These should include tools to measure the following: (suggested tools are detailed below).

Pre-operative assessment of:

- Patient anxiety
- Cooperation
- Invasiveness of the intended procedure
- Recording of baseline physiological data.

During treatment, assessment of:

- Level of consciousness
- Level of cooperation
- Oxygen saturation (all vital signs are important)
- Pulse and, if appropriate, blood pressure.

Post-operative assessment:

- Oxygen saturation (all vital signs)
- Pulse and, if appropriate, blood pressure
- Level of consciousness
- Level of cooperation
- Success of treatment.

Other assessments:

- Patient/parent satisfaction
- Reporting of untoward or unexpected incidents

- Worst oxygen saturation (or falls below % of baseline)
- Any loss of responsiveness to verbal commands
- Assessment of amnesia
- Assessment of recovery over following 24 hours.

Cooperation scales

A description of behaviour appropriate for adults and children.

Venham L, Quatrocetti S. The young child's response to repeated dental procedures. *J Dent Res* 1977;56:734–8.

The six-point Venham scale

1. **Relaxed:** Smiling, able to converse, best possible working conditions. Displays the behaviour desired by the dentist spontaneously, or immediately when asked.

2. **Uneasy:** Concerned. During stressful procedure, may protest briefly and quietly to indicate discomfort. Child willing and able to interpret experience as requested. Tense facial expression. Breath is sometimes held in. Capable of cooperating well with treatment.

3. **Tense:** Tense tone of voice, questions and answers reflect anxiety. During stressful procedure, verbal protest, quiet crying, hands tense and raised, but not interfering much. Child interprets situation with reasonable accuracy and continues to cope with his or her anxiety. Protest more, distracting and troublesome. Child still complies with request to cooperate. Continuity is undisturbed.

4. **Reluctant:** Tends to reject the treatment, difficulty in assessing threat. Pronounced verbal protest, crying. Using hands to try to stop the procedure. Protest out of proportion to threat, or is expressed well before the threat. Copes with situation with great reluctance. Treatment proceeds with difficulty.

5. **Anxious:** Anxiety interferes with ability to assess situation. General crying not related to the treatment. Prominent body movements, needing restraint on occasion. Child can be reached through oral communication, and eventually with reluctance and great effort begins to cope. Protest disrupts procedure.

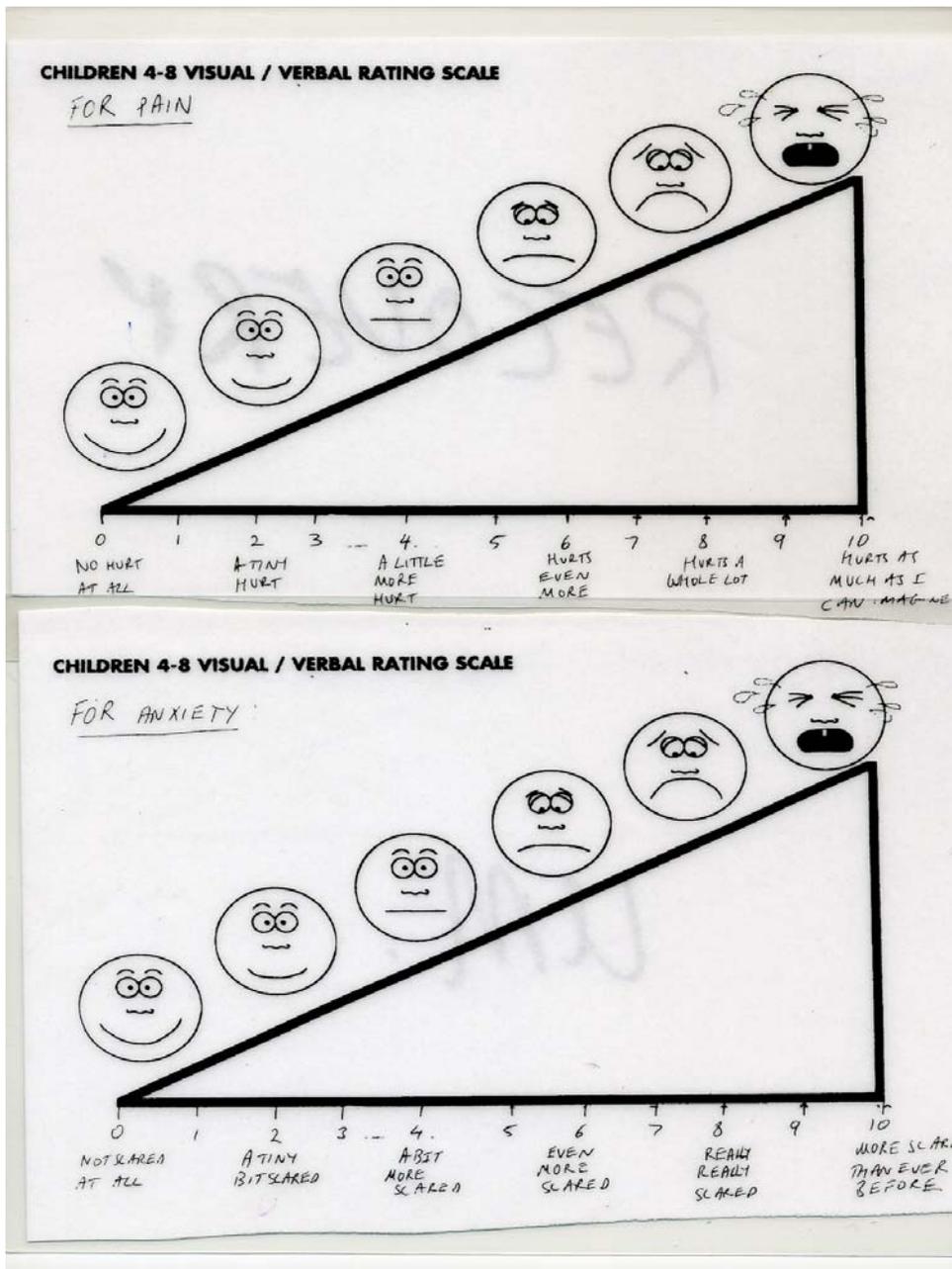
6. **Out of control:** Fails to grasp the reality of the threat, hard loud crying. Screaming, swearing. Unable to listen to oral communication. Regardless of age reverts to primitive flight responses. Actively involved in escape behaviour. Treatment impossible to complete.

Consciousness scale

Mária Némethy BA, Paroli L et al. Assessing sedation with regional anesthesia: Inter-rater agreement on a modified Wilson sedation scale [local Anaesthesia]. *Anesthesia and Analgesia* 2002;94:723–8.

- Fully awake and orientated
- Drowsy
- Eyes open and responds to speech (partial ptosis and/or slurred speech)
- Eyes closed and responds to speech
- Eyes closed, responds to mild physical stimulation
- Unresponsive to mild stimulation.

Visual/verbal rating scale for children



Wong DL, Baker CM. Smiling faces as anchor for pain intensity scales. *Pain* 2001;89:295-300.

Wong DL, Baker CM. Children's visual and verbal rating scale. *Paediatric Nursing* 1988;14:1.

Anxiety scale for adults

Modified Dental Anxiety Scale (Humphris et al.'s modification of the Corah DAS)

Invasiveness score

The invasiveness of the planned dental procedure using a numerical scale where one point is scored per quadrant of the mouth being treated, one point is scored per primary tooth treated, and two points are scored per permanent tooth.

Assessment of underlying state and trait anxiety and depression

The Hospital Anxiety and Depression Scale is a well validated method of measuring state anxiety and depression in adult patients. Alternatively, the EPQR Short Scale, available from Hodder and Stoughton Educational, London, UK, can be used. The Spielberger Self-Evaluation Questionnaire, available from Consulting Psychologists Press, Palo Alto, California, is a validated method of assessing trait anxiety in adult patients.

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