

## Sedation for paediatric auditory electrophysiology in South Africa

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**Background:** The sedation of children in the medical and allied professional fields has been a topic of controversy and debate internationally. Limited information is available on the use of sedation for auditory electrophysiology testing in South Africa.

**Objectives:** The aim of this study was to determine how sedation information is recorded in electrophysiology audiology reports where diagnostic electrophysiology testing was used, and to obtain baseline information on sedation procedures and medications used during diagnostic electrophysiology testing.

**Methods:** Audiology reports of 169 children undergoing auditory electrophysiology testing were reviewed for sedation information.

**Conclusion:** Sedation data is not clearly documented and the use of medical or anaesthetist monitoring during sedation is not routinely included in reports. Sedation medication is varied and does not always include medications listed as safe for use with the paediatric population. This places doubt on procedures and protocols as well as the safety mechanisms in place for auditory diagnostic testing of children in South Africa.

**Keywords:** auditory electrophysiology, diagnostic audiology, sedation

The sedation of children for diagnostic and therapeutic procedures has been a topic of controversy and debate within the medical world for the last decade<sup>1</sup> with the acknowledgement that paediatric sedation is a challenge encountered across all continents.<sup>2</sup>

Included in the controversial discussions is the increase in demand for paediatric sedation outside the operating room.<sup>3</sup> The variety of medical locations requiring sedation services includes radiology, dentistry, paediatric inpatient services, emergency departments and nuclear medicine.<sup>1</sup> Added to this is the periodic need for sedation with diagnosis in allied medical professions such as optometry, audiology and physiotherapy. In paediatric audiology, sedation is used during diagnostic electrophysiology testing.

Diagnostic electrophysiology testing includes measures such as the Auditory Brainstem Response (ABR) and Auditory Steady State Response (ASSR). ABR is an electrophysiological far-field recording used for assessment of the integrity of the auditory system and for threshold estimation in young children and difficult-to-test populations, while ASSR systems are programmed to use statistical measures to determine hearing thresholds.<sup>4</sup> Both ABR and ASSR recordings require the child to be very still during recording to reduce movement stimulus artefact. Electrophysiology testing may be conducted under one of three different conditions<sup>5</sup>: (1) during the natural deep sleep for infants (0–6 months); (2) using conscious sedation medication such as chloral hydrate (which requires monitoring of heart rate, respiration, oxygen saturation and blood pressure by a nurse or physician), or the synthetic form of a naturally occurring substance called melatonin, which does not require medical monitoring — the child may be tested in the therapy room or theatre; and (3) using general anaesthesia where there is a drug-induced loss of consciousness, patients are not rousable and cardiorespiratory function may be impaired.<sup>6</sup>

Whether for surgery, diagnostic testing or therapeutic procedures, sedation is also associated with certain possible risks and therefore there are specific guidelines for medical monitoring throughout the sedation process.<sup>5</sup> The risks associated with sedation include the possibility of adverse events such as neurologic injury, airway obstruction and even death.<sup>6</sup> Risks are related to the sedation medication used, dosage administered and the availability of medical personnel for monitoring of the child during and after sedation administration. Yet, there is currently a lack of legislated standards (that are able to be monitored and enforced) for what is effective and safe practice.<sup>1</sup>

South African guidelines for the safe administration of paediatric sedation have been developed, including: drugs recommended, essential equipment, recommendations for monitoring based on the sedation methods used, discharge criteria, and recommended documentation before and after sedation.<sup>10</sup> However, this is a guideline document and is based on recommended practice. The importance of regulated sedation practice is further highlighted as the demand for sedation outside the operating room has increased, together with the need for nurses and paediatric specialists to deliver sedation.<sup>1</sup> The need for monitoring of patients through the sedation procedure and ability to assist with resuscitation (if necessary) is important, as is practitioners' understanding of the pharmacology of the sedative agents and possible adverse effects.<sup>3</sup>

The use of sedation and general anaesthesia for auditory electrophysiology specifically has not been extensively studied. In developed countries ABR testing is conducted as part of diagnostic testing soon after a referral from a newborn hearing screening programme, and thus may be conducted in the 0–6-month age period when the child is able to enter a deep natural sleep. With older children (beyond the age of six to nine months for whom deep sleep is not easily achieved) the need for sedation or general anaesthesia may be increased to reduce the natural movement artefact and thereby get a more accurate ABR

or ASSR recording. In South Africa, it has been found that auditory electrophysiology testing is conducted on older children<sup>9</sup> and there is thus an increased need for the use of sedation. Studies on the use of sedation and anaesthesia for auditory electrophysiology in the paediatric population in South Africa were not found.

### Objectives

The aim of this study was twofold: (1) to determine the recording of sedation information in audiology reports where diagnostic electrophysiology testing was used, and (2) to obtain baseline information on sedation medications used and medical monitoring during the sedation process.

### Methods

This study forms part of a larger retrospective review of the diagnostic audiology records of 711 children referred to the HI HOPES Early Intervention programme from September 2006 to December 2011.<sup>18</sup> The sampling method was convenience sampling of audiology records that were available from the programme.

### Study population

Of the 711 children referred to the programme 532 children (75%) were identified as having sufficiently complete data for research purposes and are included in the larger research study relating to paediatric hearing loss and early intervention.<sup>18</sup> Of these 532 children, 230 children (43%) in the sample had comprehensive diagnostic audiology reports included as part of their data. These diagnostic audiology reports were reviewed and 171 of the 230 children (74%) were identified as having an electrophysiology test completed as part of their diagnostic audiology evaluation. Sedation data information on 171 children undergoing auditory electrophysiology testing thus forms the sample for this study. Geographically, 101 children (59%) were from Gauteng, 50 children (29%) were from KZN and 20 children (12%) were from the Western Cape. Testing occurs in various settings, and in our sample 22 children (13%) had electrophysiology testing in public sector audiology departments, 134 children (78%) were tested in private audiology consulting rooms and 15 children (9%) at university audiology departments. The sample is representative of our national sample ( $n = 532$ ) records, with Gauteng having the largest number as it is the province in which the early intervention programme was first implemented.

### Procedures

The audiology records of the 171 children identified as having electrophysiology testing conducted were accessed. The sedation data of these children was extracted from the general audiological data included in the audiology reports and was logged according to four variables: (1) number of times the child was sedated, (2) sedation medication used, (3) dosage information and (4) medical monitoring of the children during the sedation procedure.

### Data analysis

The data were transferred to a Microsoft Excel® (Microsoft Corp, Redmond, WA, USA) spreadsheet for analysis. Data analysis techniques included basic descriptive statistics including average values, standard deviation, frequencies and percentages.

### Ethics

All families gave written consent for all data, including paediatric audiology records, to be used for research purposes. Permission

Table 1: Sedation method and age of sedation

Sedation method	No sedation		Sedation			
	Natural sleep		General anaesthetic		Conscious sedation	
	(n = 7)		(n = 6)		(n = 48)	
	Public Sector	Private Sector	Public Sector	Private Sector	Public Sector	Private Sector
n	5	2	2	4	41	7
Average age (months)	40.8	9.0	48	25.8	40.0	27.7
Standard deviation	33.7	2.8	25.5	16.9	18.6	5.8
Range	9–90	7–11	30–66	15–51	7–87	18–32

for the study of all data and records relating to the early intervention programme was provided by the University of the Witwatersrand Ethical Clearance Board. All identifying information from the paediatric audiology records was removed by the early intervention programme and a coding system for tracking and storage of information for data analysis was used so as to ensure privacy and confidentiality of data.

### Results

The audiology records of the 171 children undergoing diagnostic electrophysiology testing were reviewed for information on the use of sedation for auditory electrophysiology testing. Information related to the use and method of sedation was recorded for 61 (36%) of the sample. For the remaining 110 children (64%) it is not known whether the child was sedated as this information is not included in the audiology reports. Of the 61 children for whom sedation information was provided, seven (11%) children were not sedated and electrophysiology testing was conducted under natural sleep. Six (10%) children had diagnostic electrophysiology testing under general anaesthesia and the remaining 48 (79%) children were sedated using medication for conscious sedation.

The number of children for which each type of sedation method is used as well as the average age of sedation using each method in the public and private sector<sup>1</sup> is given in Table 1.

The data show clearly that conscious sedation is the preferred method of sedation in this sample, with public health making up 85% (41) and private health making up 15% (7) of the 48 children that were sedated using conscious sedation. The private sector showed a greater tendency for general anaesthesia, comprising four of the six children (67%) for whom general anaesthesia was used as a sedation method. Of the 48 children on whom conscious sedation was used, 44 (92%) were sedated once and 4 children (8%) were sedated on two separate occasions for auditory electrophysiology testing. The second sedation was due to the initial sedation not being effective enough to allow for the electrophysiology testing to be completed. For the four children having sedation for a second time, two children had the sedation method changed to general anaesthesia, one child had the sedation dosage increased and for the last child the sedation medication was changed.

The medication and dosage information for each of the 48 children where conscious sedation was used is detailed in Table 2.

Table 2: Medication used for sedation

Conscious sedation			
Sedation medication	Dosage specified (n = 19)	Dosage not specified (n = 29)	Total (n = 48)
Unknown sedative agent			
Medication not stated	–	19 (40%)	19 (40%)
Single sedative agent			
Trimeprazine	12 (25%)	1 (2%)	13 (27%)
Chloral hydrate	3 (6%)	1 (2%)	4 (8%)
Promethazine	3 (6%)	–	3 (6%)
Multiple sedative agents			
Trimeprazine and droperidol	1 (2%)	6 (13%)	7 (15%)
Midazolam and propofol	–	2 (4%)	2 (4%)
Total	19 (40%)	29 (60%)	48 (100%)

There are two different sedation techniques: simple (requires appropriate nil per os status and covers the administration of a single sedative agent) and advanced (encompasses techniques in which multiple sedatives are administered).<sup>2</sup> The South African guidelines for sedation<sup>10</sup> provide a list of recommended sedation medications, which are listed below (before we address the sedation medication used for our sample):

- sedatives in the benzodiazepines category: midazolam (the benzodiazepine receptor agonist);
- anaesthetic agents: ketamine, propofol and 'ketofol' — a combination of propofol and ketamine;
- alpha-agonists: clonidine and dexmedetomidine;
- other (non-categorised) sedative agents: chloral hydrate, trichlorphos, trimeprazine, and droperidol).

The sedative agents used for 45 children (92%) are included in the list of drugs for sedation in South Africa. Promethazine, which was used for sedation of three children (6%), is not included in the list of sedative drugs recommended in the South African Guidelines.<sup>10</sup> Nine (19%) of the children had multiple sedatives administered, of which 8/9 (89%) did not have a dosage specified.

The reports of 4 of the 48 (8%) children indicate medical monitoring by an anaesthetist during the sedation procedure. For the other 44 children (92%) information on anaesthetist or medical monitoring was not provided.

## Discussion

Paediatric sedation is a controversial field in which there is considerable debate regarding who should be administering sedation, when sedation should be used, and appropriate sedation medication as well as medical monitoring through the sedation process.<sup>1</sup> The diagnostic audiology records for children who had electrophysiology audiology testing conducted allowed for initial information on sedation within the allied medical profession of audiology to be collected in a South African context. In this discussion we will address three key issues: (1) recording of sedation information in audiology records, (2) sedation medication used and (3) medical supervision during sedation.

Sedation information was available for 61 of 171 children (36%) who had electrophysiology testing conducted. This is evidence of the gaps in recording of sedation information in audiology reports in this data set. Data recording of sedation has been identified as important for gathering baseline information on the safety of anaesthesia, identification of high-risk patients for making informed decisions on patient care, obtaining informed consent from families aware of the anaesthetic-related risks and for the facilitation of research on anaesthetic safety.<sup>11</sup> Access to data records on sedation will allow for planning of future sedation and assess the risk based on previous sedation medication, dosage and any possible adverse effects. This is especially important when it is considered that children may have a number of auditory electrophysiology tests, either to gain complete information or when parents consult a different audiologist for a second opinion.

Paper-based patient records have variations in quality and may result in insufficient information being provided in the referral letter/report as well as the possibility that information may not be provided in time for the primary healthcare providers to be informed of all factors for follow-up care.<sup>12</sup> This is evident in the number of children having conscious sedation medication administered for whom dosage of the medication was not provided (60%) and also for whom the type of medication used was not specified (40%). Insufficient or incomplete information on medication, sedation and dosage used could lead to possible adverse events during the sedation process due to drug combinations and interaction as well as leading to a possibility of a repeat of adverse sedation events in the future. Insufficient or incomplete records also means that there may be inadequate or no information to hand if the patient returns after discharge with a complication potentially related to the sedation.

As per South African paediatric sedation guidelines,<sup>10</sup> trimeprazine and droperidol are not recommended for use in 'outpatient'<sup>2</sup> procedures due to the long duration of action for these drugs.<sup>12</sup> For 27% ( $n = 13$ ) of this sample trimeprazine was used as a single sedative agent and for a further 15% ( $n = 7$ ) a combination of trimeprazine and droperidol was used, all of which were done in an 'outpatient' context. These 20 children (42%) in this sample were sedated using medication that is considered to be unsafe for use in an outpatient setting (i.e. trimeprazine and droperidol). In addition, a further 4% (2) were sedated with propofol, which is recommended to be used only by highly experienced sedation practitioners.

The range of sedation medications used in this sample is extensive, especially since the monitoring of the children by medical personnel during the sedation procedure is not clearly documented. Where the sedative agent was specified in the sample, trimeprazine was the most commonly used sedative agent ( $n = 20$ ; 42%) with chloral hydrate the second most commonly used ( $n = 4$ ; 8%).

In our search of the national and international literature on sedation, studies on the use of trimeprazine as a sedative agent in the paediatric population were not found. A study on the methods of sedation for ABR testing in the USA found that chloral hydrate in carefully measured doses based on the child's weight is safe and effective for the majority of patients.<sup>13</sup> A study on the effectiveness of chloral hydrate as a sedative agent has shown that it has a low incidence of acute toxicity when administered orally in the short term in recommended doses.<sup>14</sup>

However, it has been noted that when using sedative agents that have longer durations of action (including chloral hydrate, trimeprazine and droperidol), the child should be observed and monitored for longer periods even after recovery and discharge criteria (as indicated in SA paediatric sedation<sup>10</sup> guidelines) used by the audiologist doing the testing have been reached.<sup>7,8,15,16</sup> This is especially important in a South African context where the child might be carried on the parent's back, as there is an increased possibility of airway obstruction due to the possibility of prolonged drug effects.<sup>9</sup> Chloral hydrate, used for four children (8%) in our sample, has recently been reclassified as a Section 21 drug in South Africa. This means that the use of chloral hydrate is regulated and has to be authorised by the Medicines Control Council of South Africa.

The American Academy of Pediatrics<sup>14</sup> recommends that sedation not be administered without the safety net of medical supervision. Medical supervision data are only available for 8% ( $n = 4$ ) of the sample, who were monitored by an anaesthetist. The adherence to basic guidelines for safety of all children in this sample receiving anaesthetic medication cannot be commented on. SASA Guidelines state that a person separate from the operator should monitor the patient.

In advanced sedation, someone other than the operator must be responsible for administration of sedation, monitoring of vital signs and, should complications of sedation arise, rescue of the patient. It is recommended that, in such cases, a medical practitioner performs this role.<sup>10</sup> From the diagnostic audiology records, it is not clear if these guidelines are adhered to.

Globally there is the challenge of neither standardisation of sedation practice, nor guidelines and credentials necessary for sedation of the paediatric population.<sup>2</sup> While South Africa has published a document related to guidelines for procedural sedation and analgesia in the paediatric population specifically,<sup>10</sup> adherence to guidelines is difficult to determine.

## Conclusion

This research investigated the use of sedation for auditory electrophysiology testing in a sample of 171 children enrolled in an early intervention programme in South Africa.

The study has shown that, when logged, sedation medication and dosage is not clearly documented and that the use of medical or anaesthetist monitoring during sedation is not routinely included in reports. The lack of data sets on sedation has been identified as a challenge in low-income countries due to inadequate information technology infrastructure as well as limited data due to difficulties with patient follow-up.<sup>11</sup> The drugs used for conscious sedation in this sample are extensive, and include medication not recommended in the South African Guidelines, as well as the use of multiple sedative agents. These factors, together with the lack of information on medical monitoring during the sedation process, raise the question of what quality assurance checks are in place for sedation during diagnostic electrophysiology testing of children in South Africa.

South Africa has developed a document called 'Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children: 2010',<sup>10</sup> an update of which is imminent. This was developed after consultation with paediatricians, paediatric radiologists, paediatric surgeons, emergency medicine specialists, paediatric intensive care specialists, paediatric oncologists and sedation practitioners,

after the Western Cape Provincial Coordinating Clinician for Anaesthesia highlighted the importance of providing children with safe sedation and analgesia.

The documented guidelines for sedation<sup>10</sup> have provided South African-specific information on sedation medication as well as procedures to be followed for sedation with the paediatric population. A recent study<sup>11</sup> has identified the challenges of sedation in South Africa, including staff with limited or a lack of anaesthesia training, equipment challenges, difficulties with referral and transport as well as difficulties with medication supply. Internationally, there has been a focus on the core issues of the qualifications and training necessary to administer sedation, with the field of paediatric sedation acknowledged to be one shared between paediatric specialists and not limited to the domain of anaesthesiologists alone.

Current research on sedation for auditory electrophysiology in a South African context is limited to a study on the use of melatonin as a sedative agent in adults undergoing auditory brainstem response testing.<sup>17</sup> The present study has contributed to the understanding of sedative agents used for a small sample of paediatric clients undergoing auditory electrophysiology testing in both the public and private sector in South Africa. However, the research was limited in that the retrospective data were restricted to 532 children enrolled in an early intervention programme in South Africa and include a sample of 171 children for whom electrophysiology audiology reports were made available. This limits the generalisability of results and more extensive research is needed. More research is also needed to better understand the possible adverse effects of sedation, the use of medical personnel involved in sedation and the costs involved with the use of different sedation techniques and sedative agents.

This article has highlighted the inconsistencies in recording of sedation information in electrophysiology audiology reports as well as the variation in the use of sedation medication and practice in a paediatric population undergoing auditory electrophysiology testing. The development of guidelines by the HPCSA Board for Speech and Hearing Professions (relating to actual practice as well as data recording and management of sedation information and monitoring) will be an initial step in ensuring adherence to best practice as well as safety of paediatric clients.

## Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

## Authors' contributions

This article is a write-up of part of Selvarani Moodley's (University of the Witwatersrand) PhD, of which Professor Claudine Storbeck is the academic supervisor. The data analysis was completed by the first author, with the writing of the article being a collaborative process.

## Notes

1. In the private sector sedation medication is generally provided by an anaesthesiologist. In the public sector, sedation medication is prescribed and administered by a doctor in the medical department and the child returns to the audiology department for testing. The availability of staff and resuscitation equipment is not stated in reports.
2. 'Outpatient' refers to a setting in which children attend audiology appointments at a public hospital/clinic or private sector audiology rooms. The use of discharge criteria, period of time before discharge or assessment after the sedation is not indicated in reports.

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Received: 03-03-2016 Accepted: 13-09-2016