The Dudley Group NHS
NHS Foundation Trust

Paediatric Procedural Sedation with Ketamine in the Emergency Department

Clinical Guideline

January 2012

Contents

Pathway for Ketamine PPS

Assess patient suitability for procedure using PPS with ketamine

History and examination including fasting and airway assessment

Assess availability of suitable staff, equipment and sedation environment

Discuss procedure with parents / guardians and obtain written consent; give parents information leaflet

Apply EMLA to proposed cannulation / injection site

Transfer patient to Resuscitation room and initiate monitoring

Give ketamine as per dosage chart and begin procedure when dissociation achieved

Assess sedation and begin procedure if adequate; give supplemental dose if needed

Continue pulse / SaO_2 monitoring; minimum stimulation in supervised environment

Home when safe walking / verbalizing / drinking

Doctor in charge of sedation must ensure electronic sedation record is complete

Note that PPS with ketamine should only be undertaken with the knowledge and express permission of the ED Consultant on duty

Introduction

The purpose of this guideline is to describe the use of ketamine for paediatric procedural sedation (PPS) in Emergency Medicine and to demonstrate how it can be used safely and effectively in the Emergency Department (ED) at Russells Hall Hospital. The document must be read by all ED healthcare personnel who may care for children undergoing PPS with ketamine.

One of the primary aims of an Emergency Department should be to minimise any pain or distress experienced by paediatric patients, their relatives or staff. Children may find the ED environment frightening and this is exacerbated by painful conditions and the possibility of undergoing 'minor' procedures such as suturing. Physical restraint of the child was a formerly common practice which is now regarded as unacceptable.

There are several methods (e.g. oral analgesia, distraction, play therapy) which may be used to help reduce pain and anxiety in children attending the ED and these options should always be fully explored. However, assuming that a potentially upsetting procedure is necessary, what is the best technique to ensure safety and comfort of the child with optimal conditions to allow procedural success? Using the example of closure of a facial wound which requires sutures, there are several options which may be considered:

1) **Local infiltration** is painful, can distort the wound and may be technically difficult.
2) **General anaesthesia (GA)** involves the inherent risks of GA, is time-consuming and requires admission to a ward.
3) **Intranasal midazolam** can be used; however the effects may be unpredictable, onset is slow and administration can be poorly tolerated.
4) **Procedural sedation with ketamine** can be used to facilitate short painful procedures, possibly in combination with local anaesthetic techniques. Analgesia is usually substantial or complete. Amnesia for the procedure is typical. The safety profile is excellent in a well organised ED setting.

As well as benefits to the patient and staff, there are also potential gains to be made in terms of reduced costs due to less time spent in hospital and reduced demand for specialist team involvement and operating theatre time.

Whatever methods are used to provide sedation, the principles of patient safety always come first. Safe practice demands that the use of any sedative procedure must include the immediate availability of personnel, drugs and equipment to manage any potential complications.

Procedural sedation

This can be defined as:

"… a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function …… it is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently."

The safe sedation of children requires a systematic approach that includes:

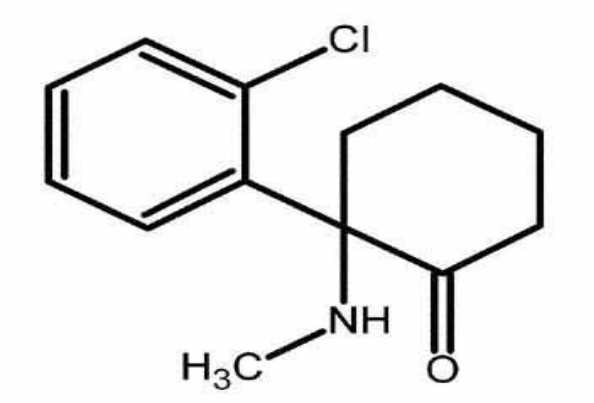
- ✓ **Appropriate patient selection.**
- ✓ **Careful pre-sedation evaluation of the child.**
- ✓ **Assessment of airway and fasting status.**
- ✓ **A clear understanding of any drugs used.**
- ✓ **Supervision by properly skilled and trained staff.**
- ✓ **Appropriate equipment for sedation monitoring and resuscitation.**
- ✓ **A properly equipped and staffed recovery area.**
- ✓ **Recovery to pre-sedation level of consciousness prior to discharge.**
- ✓ **Clear discharge instructions.**

It is generally accepted that there is a continuum of sedation from 'minimal' through 'moderate' to 'deep', and the term 'conscious sedation' is sometimes used to describe the 'moderate' state which is thought to be ideal for procedural sedation. However, in the dosages used for PPS ketamine has an almost unique action, producing a state of 'dissociative anaesthesia' which is not consistent with standard definitions of sedation or general anaesthesia.

The ACEP (2011) definition is: "a trancelike state induced by the dissociative agent ketamine, characterized by profound analgesia and amnesia, with retention of protective airway reflexes, spontaneous respirations and cardiopulmonary stability."

Background and Pharmacology

During the early 1960's, the search for a safe but potent sedative agent led pharmacologists to look for an alternative to phencyclidine (PCP or 'angel dust'), which also had powerful hallucinogenic properties. Ketamine is a derivative of phencyclidine which was first synthesised in 1965 by researchers at the laboratories of Parke-Davis & Company. Ketamine has relatively few adverse effects and was introduced into clinical practice by 1970; it was a common field anaesthetic during the Vietnam War. It has a wide range of clinical effects in humans including analgesia, anaesthesia, hallucinations, amnesia and bronchodilatation. It is also used as a veterinary tranquiliser and illicitly as a recreational drug.



Ketamine has strong amnesic and analgesic properties and may be used to induce a state of 'dissociative anaesthesia' in the paediatric patient. This dissociative state allows painful and / or frightening procedures to be performed (possibly in combination with local anaesthetic techniques) in the Emergency Department without distress or apparent discomfort to the child. It can obviate the need for physical restraint of the child and it has an excellent safety and side-effect profile in comparison to other sedative agents, with the notable property of allowing the patient to maintain their own airway. It is widely used in Emergency Departments in the USA and Australasia where initial resistance to its use from anaesthetists was overcome by demonstration of its safety, efficacy and the competence of Emergency Medicine practitioners. Ketamine is now used in over a quarter of Emergency Departments in the United Kingdom and is recommended for appropriate patients by the College of Emergency Medicine and the American College of Emergency Physicians; both organisations have published guidelines on its use. Recent NICE guidance also suggests ketamine may be used in suitable cases.

Ketamine exerts its actions primarily through non-competitive antagonism of NMDA receptors. The drug exerts its effect by "disconnecting" the thalamo-cortical and limbic system, effectively dissociating the central nervous system from outside stimuli (e.g. pain, sight, sound). It is extremely lipid-soluble and acts rapidly when given intravenously (IV), having an effect within thirty seconds. Intramuscular (IM) administration is also effective, with onset of action after a few minutes.

Patient Selection, Evaluation and Consent

All children should be carefully assessed before sedation; adverse responses during and after sedation may be minimised by a careful review of the child's medical history with particular reference to any contra-indications for ketamine use. The child should be between the ages of 2 and 13 years, requiring a procedure which is anticipated to take no more than 30 minutes. Distraction techniques, local anaesthesia or other methods of achieving a satisfactory result for the child should have been considered or attempted. Examples of suitable procedures include:

- ✓ **Lacerations**
- ✓ **Nail injuries**
- ✓ **Wound toilet**
- ✓ **Small joint or # reduction**
- ✓ **Removal of FB from skin/ear/nose**
- ✓ **Incision and drainage of abscess**

All procedures likely to take over 30 minutes will require referral and Anaesthetic input

A full history and examination must be performed prior to the procedure, with particular regard to any contra-indications or other significant medical problems:

- Precise nature and/or mechanism of the current condition.
- Previous medical history including medications and allergies.
- History of previous sedation episodes.
- Fasting status (see next page).
- Airway anatomy.
- Routine diagnostic testing should not be necessary.

Children with chronic cardiac, respiratory, CNS or neuromuscular disorders or those with active disease in any system should only be considered for PPS with ketamine after discussion with senior Anaesthetic staff.

Family members or guardians should have the procedure explained to them, be given the information leaflet prior to the procedure and be able to provide **written consent**. Clinicians must discuss the characteristics of the dissociative state and potential adverse events associated with ketamine sedation. The known risks are: mild agitation (20%), moderate or severe agitation (1-5%), rash (10%), vomiting (7%), transient clonic movements (5%) and airway problems (1%). It is important to emphasise that nystagmus, purposeless movements and some degree of dissociation are normal during ketamine sedation, so that these are expected.

Fasting Status

The combination of vomiting and loss of airway protective reflexes is an extremely rare occurrence with ketamine sedation, making aspiration an unlikely event. There is little hard evidence regarding suitable pre-procedural fasting times but there have been various attempts made to correlate what evidence there is with expert opinion. The clinician must carefully assess the patient risk and the nature and timing of recent food and fluid ingestion. One should also take into account the relative urgency of the procedure.

Before starting sedation, always confirm and document the timing of last food and fluid intake in the sedation record.

According to NICE, the 2-4-6 fasting rule should be followed for children undergoing sedation for *elective* procedures:

- 2 hours for clear fluids
- 4 hours for breast milk
- 6 hours for solids

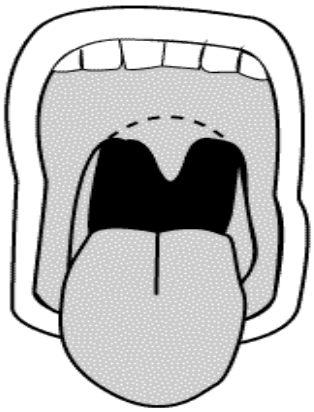
However, there is insufficient evidence to recommend a specific fasting duration before dissociative sedation with ketamine in the Emergency Department. Despite 40 years of continual worldwide use, there are no documented reports of clinically significant ketamine-associated aspiration, except in ill neonates. A systematic review found no apparent association of fasting state with emesis, laryngospasm, or any other complication and large, prospective ED series have also failed to show any association between fasting and adverse effects.

ACEP recommends that a case-by-case risk-benefit assessment is more consistent with the current literature than setting an arbitrary fasting period. Indeed, given its unique protection of airway reflexes, ketamine would appear preferable to alternative sedatives when fasting is incomplete. CEM guidance states that the fasting state of the child should be considered in relation to the urgency of the procedure, but recent food intake should not be considered as an absolute contraindication to ketamine use.

In summary the fasting state of the child should be assessed and documented and a decision made based on the urgency of the procedure. A minimum time of 2 hours since last oral intake of either food or fluids is sensible for most procedures in the ED and caution should be exercised if a large meal has been ingested within the last four hours. If unsure, consult Anaesthetic colleagues.

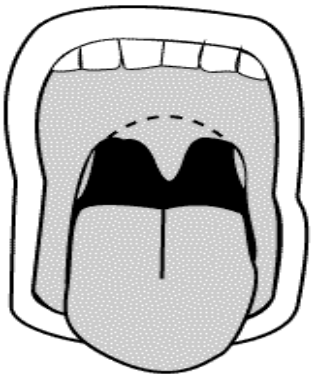
Airway Assessment

An airway assessment should be documented in the electronic sedation record. Pay particular attention to cervical spine movement, mouth opening, condition of teeth (beware loose teeth in children) and the Mallampati score.



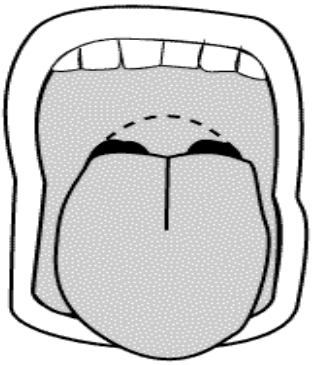
Class I: soft palate, uvula, fauces, pillars visible

No difficulty



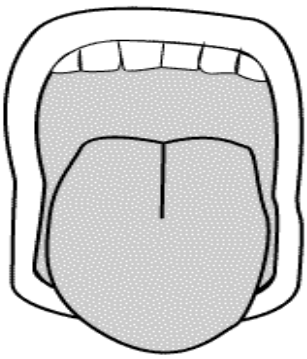
Class II: soft palate, uvula, fauces visible

No difficulty



Class III: soft palate, base of uvula visible

Moderate difficulty



Class IV: hard palate only visible

Severe difficulty

Fig. 4-5. Mallampati signs as indicators of difficulty of intubation. (Adapted from Mallampati and Samsoon and Young.)

Contra-indications to Ketamine Use

Age younger than 24 months

Ketamine use has been recommended for children as young as 3 months and CEM guidance advises that children between the ages of 12 and 24 months may be safely sedated if supervised by a Consultant. However, for safety reasons in our unit ketamine PPS should not be used for children under 2 years of age without Anaesthetist supervision.

Schizophrenia (even if stable or controlled) or other severe behavioural or psychological problems

High risk of laryngospasm due to active respiratory infection or disease

e.g. asthma or current/recent RTI (should be symptom free for 2/52)

History of airway instability or abnormality

e.g. marked tonsillar hypertrophy, tracheal surgery or tracheal stenosis

Procedures within the mouth or pharynx

Known or suspected cardiac disease

Recent significant head injury

Intracranial hypertension with CSF obstruction

Intra-ocular pathology (glaucoma, penetrating injury)

Uncontrolled epilepsy

Hyperthyroidism or thyroid medication

Porphyria

Prior adverse reaction to ketamine

Dosage and Administration

Rather than displaying the dose-response continuum observed with all other procedural sedation and analgesia agents, ketamine dissociation *appears* at a dosing threshold of approximately 1.0 to 1.5 mg/kg IV or 2.5 to 4 mg/kg IM. Within the safe dosage ranges effects are similar and studies have not shown significant differences in treatment effect or incidence of side effects. Accordingly, dissociative sedation can be readily achieved by administration of a single IV or IM loading dose, and the only need for titration (in contrast to other sedatives) is to maintain the dissociative state over time.

Where time permits, topical anaesthesia (EMLA) should be used to reduce the pain of intravenous cannulation or intramuscular injection.

CEM guidance advises doses of 2.5 mg/kg IM or 1.0 mg/kg IV. The CEM recommends that supplemental doses of 0.5mg/kg by slow IV injection or 1mg/kg IM may be given if required.

ACEP recommends a loading dose of 1.5 to 2.0 mg/kg IV (over 30 to 60 seconds) with additional incremental doses of 0.5 to 1.0 mg/kg if necessary. IM dosage recommended by ACEP is 4 to 5 mg/kg.

2011 ACEP guidelines recommend that the intravenous route is preferred because recovery is faster and there is less emesis; also repeated dosing is easier. Intramuscular administration is useful when intravenous access cannot be reliably established with minimal upset, and when the patient is uncooperative or combative. Once dissociation is achieved IV access should be obtained.

Ketamine is not administered until the physician is ready to begin the procedure because onset of dissociation typically occurs rapidly.

In summary there is disagreement in the literature; however given that the effects of ketamine reliably appear at a certain dosing threshold and in order to simplify calculations (and hence improve safety) this guideline recommends an initial loading dosage of 2.0 mg/kg IV, given over 30 seconds. Repeated doses may be given if necessary of 0.5 mg/kg IV.

If IV access is difficult then an initial dose of 4.0 mg/kg IM may be given in the lateral aspect of the thigh. Should this initial IM dose result in insufficient procedural conditions, a repeated half dose is usually always effective.

Side-effects and Potential Complications

One of ketamine's key properties is that it has a wide safety and side-effect profile compared to other agents; in particular, the patients' airway remains patent and cardiovascular stability is preserved.

- **Emergence reactions** are particularly associated with ketamine use but recovery agitation is usually mild (incidence of ≤20%) and is rarely disturbing to children. Clinicians should however be aware of the rare potential for pronounced reactions and titrated benzodiazepines can rapidly and consistently diminish such episodes. The routine pre-treatment of children undergoing PPS with benzodiazepenes is not supported by the evidence or current recommendations.

- **Vomiting** may occur in 5-10% of patients. This usually occurs during the late recovery phase when the patient can clear their own airway. Early adolescence is the peak age for vomiting, with lesser risk in younger and older children. Antiemetics may be necessary if vomiting persists.

- **Transient rash** has a 10% incidence.

- **Transient clonic movements** occur in ≤5% of children undergoing PPS with ketamine.

- **Noisy breathing** is usually due to airway mal-position and occurs at an incidence of approx. 1%. This can normally be corrected by routine airway position management.

- **Laryngospasm** may occur rarely (incidence up to 0.3%). However, clinicians administering ketamine must be prepared to rapidly identify and manage this adverse event. Although some patients may require bag-valve-mask ventilation, tracheal intubation because of ketamine-associated laryngospasm is rare.

- **Respiratory depression and apnoea** are unusual with ketamine and are transient when they do occur.

- **Lacrimation and salivation** may be observed but is rarely of clinical significance. The literature is not supportive of anticholinergic prophylaxis and these drugs should be reserved for the treatment of unusual occurrences of clinically important hypersalivation or for patients with an impaired ability to mobilize secretions.

Personnel Requirements

The concept of SAFE RESCUE is essential for PPS. Procedural sedation with ketamine has been demonstrated to be both safe and effective when properly administered by suitably experienced Emergency Physicians who have the ability to manage any complications.

PPS with ketamine should only be undertaken when an ED Consultant is present in the department and with the full knowledge of that Consultant. Outside of normal Consultant working hours (08:00 – 21:00) staffing levels and other issues may adversely affect the potential safety of such procedures and must not be undertaken under any circumstances.

At least three persons are required: a nominated lead doctor to manage the sedation and airway, a clinician to perform the procedure and a nurse to monitor and support the patient, family and clinical staff. The doctor managing the ketamine sedation and airway should be suitably trained and experienced in paediatric sedation. They should be capable of managing any complications, especially airway obstruction, apnoea and laryngospasm. They must have an understanding of the drugs administered and the ability to monitor the patient's response to PPS.

In addition, the doctor undertaking the lead role in the sedation should be of at least ST4 level and should fulfil the following criteria:

- ✓ **Be qualified to APLS provider level.**
- ✓ **Have experience in managing the paediatric airway, either in the ED or Anaesthetic setting.**
- ✓ **Have undertaken training within the ED regarding ketamine PPS.**
- ✓ **Have suitable experience of the clinical evaluation and monitoring of children who are to undergo sedation.**
- ✓ **Keeps a record of their sedation training and practice.**

A staff nurse with experience of paediatric patients, who has undertaken training in the use of ketamine for PPS and who has experience of sedated children should be able for the procedure and to stay with the patient until recovery has taken place.

Environment and Initiation of PPS

PPS should be undertaken in the paediatric bay in the Resuscitation room. A tilting trolley should be used. The environment should be kept as peaceful as possible and other staff (especially the NIC of the ED) should be informed that sedation is being performed. All personnel who are not immediately required should be excluded from the room. Parents or guardians may witness the procedure if they wish. There is inconclusive evidence that phrasing the dissociative experience in positive terms before sedation can decrease the risk of unpleasant recovery reactions but it is a common practice to encourage patients to "plan" pleasant intra-sedation dreams.

The weight of the child should be recorded and documented in the sedation record. Ketamine (stored in the locked cupboard in Resus.) should be drawn up by the clinician performing the procedure using the calculated dose table below.

	Ketamine Loading dose (mg)	
Weight (kg)	IV	IM
10	20	40
15	30	60
20	40	80
25	50	100
30	60	120
35	70	140
40	80	160
45	90	180
50	100	200

Supplemental doses may be given:

IV = 0.5 mg/kg

IM = 2 mg/kg

Suction equipment, oxygen, a bag-valve-mask, and age-appropriate equipment for advanced airway management should be immediately available and thoroughly checked in advance. Initial readings of pulse, blood pressure, respiratory rate and SaO_2 should be recorded. ECG monitoring is necessary during the procedure but may be delayed until dissociation has begun if the child is distressed or uncooperative.

When the team are ready to undertake the procedure, ketamine should be administered according to the dosing table. Supplemental doses may be used if needed. Visibility of or access to the upper half of the patient should not be impeded by drapes or other equipment during sedation. Supplemental oxygen is not usually necessary but if it is given then capnography must be used.

Adequate sedation is usually indicated after a few minutes (depending on route of administration) by loss of response to verbal stimuli, glazed eyes and nystagmus; heart rate, blood pressure and respiration rate may all increase slightly.

Monitoring, Recovery and Discharge

Continuous monitoring of ECG and SaO_2 should be carried out during the procedure. Pulse and respiratory rate should be recorded at 5 minute intervals.

Lacrimation or hypersalivation may be observed and should be managed by gentle suctioning. Occasional repositioning of the head may be necessary for optimal airway patency. Random movements may occur and should be gently controlled.

If suturing is undertaken then local anaesthetic may be infiltrated into the wound during the procedure to ensure painless awakening.

Once the procedure has been completed, the child should be kept in a semi-sitting position and staff should ensure they are warm and comfortable. The environment should be kept as quiet as possible during this stage and parents or guardians should be present (although premature stimulation of the patient should be avoided).

Recovery should take place in the Resuscitation room until verbal communication is regained. Pulse oximetry should be recorded during this period and a trained staff member should stay with the patient.

The child can be safely discharged once they are able to ambulate and vocalise at pre-sedation levels. An advice sheet should be given to the parent or guardian advising rest and quiet, supervised activity for the next 24 hours. The child should not eat or drink for two hours after discharge because of the risk of nausea and vomiting. Information should include objectives of the sedation and anticipated changes in behaviour after discharge. Instructions must be given to the responsible adult for infants and toddlers who will be transported home in a car safety seat regarding the need to carefully observe the child's head position to avoid airway obstruction. Consideration for a longer period of observation shall be given if the responsible person's ability to observe the child is limited (e.g. only 1 adult who also has to drive). A 24-hour telephone number for assistance should be provided. The medical team should ensure that proper follow-up arrangements have been made.

The doctor in charge of the procedure should ensure that the electronic sedation record has been completed correctly. This will be used to audit sedation practice in the department. Regular audit of sedation practice in the department will be undertaken and any adverse incidents should generate an incident form which will be reviewed by the supervising Consultant.

The Dudley Group NHS
NHS Foundation Trust

Emergency Department
Information Leaflet for Parents or Guardians of Children Sedated Using Ketamine

Part One – What treatment is the doctor suggesting?

Your child needs a medical treatment (e.g. stitches) which may be painful or distressing for them. So that the treatment can be carried out more easily, with less distress and pain for you and your child, the medical team wish to use a drug called ketamine to sedate them.

Sedation is a process of using drugs to make them sleepy, relaxed or in a 'trance-like' state. It is normal that they may not remember the procedure at all, or only remember small amounts.

Ketamine is commonly used in hospitals for sedation of children. There are some special features about sedation with ketamine for you to know:

- Your child will be cared for by a senior doctor and nurse.
- The drug is given by injection into a vein or into the muscle of the thigh.
- Your child may seem to be awake after receiving ketamine.
- Your child may move a little without obvious cause; this is normal.
- Your child's eyes may twitch; this is normal.
- Your child may report odd dreams on waking up, and may become a little agitated (less than 20% of children experience this). This tends to improve if you comfort your child until they are fully awake.
- One in ten children develops a rash.
- One in ten children vomit.
- One in ten children will have some eye watering, or may drool.
- Rarely (0.3%) there can be laryngospasm (vocal cords close) and in 0.02% of cases your child may need to be given a general anaesthetic with a breathing tube placed in their windpipe. The doctors have been trained to recognise and deal with any complications that may develop.

Part Two – How to help your child

Before anything is done, ensure you understand the information in this leaflet and that the doctor or nurse has answered any questions you may have.

Before your child is sedated it is good to reassure them by talking to them calmly and play with them quietly e.g. reading a book. However please note that it is not usually helpful to allow your child to decide the exact moment the procedure is going to happen.

You or another adult (whom your child knows) may stay with them during the procedure. The medical staff may ask you to talk to your child during the procedure to help comfort them.

Following the procedure it is good to stay with your child so that they can recognize a familiar face when they 'wake up'. When they are awake, focus on the good things they did and praise them for their behaviour.

Part Three – After you go home

Most children fully recover (i.e. 'wake up') within 90 minutes, sometimes a little longer. Your child will be safe to go home when they are fully awake, can walk unaided and manage to drink without vomiting.

Sometimes after sedation your child may be a bit confused, sleepy or clumsy and you need to be watchful in caring for them for the next 24 hours. They should avoid any activity such as riding a bike or other sports and active play. Ensure they are supervised when bathing.

Clear fluids (but not fizzy or sugary drinks) should be encouraged but do not allow them to eat until at least two hours have passed uneventfully at home. Provide light meals only until the following day.

Your child may sleep as normal or be more tired than usual.

If you have any concerns that your child may be experiencing problems then please contact the Emergency Department on this number:

RUSSELLS HALL HOSPITAL, EMERGENCY DEPARTMENT 01384 456111 extension 2300 / 2306

Sources and Further Information

This guidance draws material from two primary sources, detailed below. This guidance acknowledges the authors of these sources as the originators of much of the information it contains. All clinicians who deliver ketamine PPS in the ED should be familiar with these documents.

The American College of Emergency Physicians

Clinical Practice Guideline for Emergency Department Ketamine Dissociative Sedation: 2011 Update

Link to Annals of Emergency Medicine article (pay per view):
http://www.annemergmed.com/article/S0196-0644(10)01827-5/abstract#article-footnote-1

The College of Emergency Medicine

Ketamine Sedation of Children in Emergency Departments (September 2009)

In addition, the following sources (amongst others) have been used and give further information:

***NICE clinical guideline 112 (December 2010)*: Sedation in children and young people**

S. Green et al.* Predictors of Airway and Respiratory Adverse Events With Ketamine Sedation in the Emergency Department: An Individual Patient Data Meta-analysis of 8,282 Children. *Annals of Emergency Medicine 2009; 54, 2: 154-168

***S. Green, B. Krauss.* Ketamine is a safe, effective, and appropriate technique for emergency department paediatric procedural sedation.**
Emerg Med J 2004;21:271–272

N. Morton.* Ketamine for procedural sedation and analgesia in pediatric emergency medicine: a UK perspective. *Pediatric Anesthesia 2008 18: 25–29.

AAP, AAPD, Charles J. Coté et al.* Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update. *Pediatrics 2006;118;2587-2602

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