Service evaluation

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A retrospective analysis of ketamine administration by critical care paramedics in a pre-hospital care setting

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Abstract

Objective: This project aims to describe pre-hospital use of ketamine in trauma by South East Coast Ambulance Service critical care paramedics and evaluate the occurrence of any side effects or adverse events.

Methods: A retrospective analysis of patients receiving pre-hospital ketamine for trauma between 16 March 2013 and 30 April 2017. Administrations were identified from Advanced Life Saving Interventions and Procedures reports submitted by the clinician and, later, from an electronic database. Each was scrutinised for patient demographics, doses and reports of side effects or adverse events.

Results: A total of 510 unique administrations were identified. Following the exclusion of 61 records, 449 (88.0%) administrations remained. The most common indication for administration of ketamine was lower limb injury, with 228 (50.8%) administrations. Ketamine was only administered intravenously, and the median dose of ketamine for all administrations was 30 mg (interquartile range 20–40 mg). The gender split was dominated by males who accounted for 302 (67.3%) administrations compared to 147 (32.7%) females. The median age of patients was 44 years (interquartile range 28–58 years), with women on average being older than men. Telephone calls to a consultant were made for 243/449 (54.1%) of the administrations, reflecting a need for sanctioning of the drug, advice on dosages or indications, for example.

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Conclusions: Critical care paramedics within a well governed system are able to safely administer ketamine within an approved dosing regimen under a Patient Group Direction. Median doses are in keeping with nationally approved guidelines. Reported side effects were within the described frequencies in the British National Formulary. Prospective studies are now needed in order to confirm the safety and efficacy of ketamine administration among the advanced paramedic population.

Keywords
analgesia; emergency medical technicians; ketamine

Introduction

In the national and international pre-hospital setting, ketamine has been used for many years, both in military and civilian medicine. While ketamine has been successfully administered by paramedics in the UK out-of-hospital setting, there is very little information available regarding paramedic use, and it is far less widely reported when compared to physicians (McQueen, Crombie, Cormack, & Wheaton, 2014). Ketamine is not listed in Schedule 17 of the Human Medications Regulations 2012, and as such it is only used by paramedics under a Patient Group Direction (PGD). Some specialist paramedics have locally written PGDs and Clinical Management Plans (CMPs) which allow the administration of ketamine (McQueen et al., 2014; Von Vopelius-Feldt & Benger, 2014). However, nationally, many of these normally operate within, or are aligned to, an air ambulance service.

South East Coast Ambulance Service NHS Foundation Trust (SECAmb) has developed a critical care programme, comprised of experienced paramedics (minimum three years post registration) who undertake a further year of Level 7 postgraduate study, obtaining a Postgraduate Certificate in Patient Assessment and Management (Critical Care). In addition, an enhanced governance system and 24-hour consultant physician support have permitted the administration of ketamine under a PGD (Table 1).

There are currently nine critical care paramedic (CCP) teams distributed across the Trust's geographical area. Each geographical team comprises seven CCPs, including

Table 1. Basic summary of PGD.

Indications (analgesia)	Management of moderate to severe pain
Indications (sedation)	Life or limb threatening conditions that require sedation for emergency care. Management of the undifferentiated cerebrally agitated trauma patient.
Inclusion criteria (analgesia)	Adults and children aged 12 years and above who are in traumatic pain *and* other analgesia contra-indicated or have failed to control the pain *or* the patient has life/limb threatening injuries and the pain is preventing emergency treatment.
Inclusion criteria (sedation)	Adults and children over 12 years of age who require analgesia and sedation to facilitate a life or limb saving intervention such as fracture reduction. *Or* Adults and children over 12 years of age who are combative and unmanageable due to cerebral agitation after suffering undifferentiated trauma. Another trained pre-hospital care provider competent in airway management must be present at scene.
Exclusion criteria	Known allergy to ketamine or excipients, where essential monitoring (including $EtCO_2$) is not possible, known concurrent theophylline administration, significant hypertension, severe coronary/myocardial disease, severe CVS disease, raised ICP, raised IOP, known history of psychosis, pre-eclampsia, eclampsia, acute porphyria, intracranial mass lesions, hydrocephalus.
Dosing (analgesia)	Initial bolus dose of 0.1 mg/kg; repeat doses of 0.1 mg/kg by titration to achieve intended analgesic effect. For practical purposes: • Small adult (40–70 kg): 5 mg aliquots • Large adult (≥ 70 kg): 10 mg aliquots Pain must be reassessed between doses to a maximum dose of 0.5 mg/kg in 30 minutes.
Dosing (sedation)	Initial bolus dose of 0.1–0.2 mg/kg repeated by 0.1–0.2 mg/kg per minute by titration to achieve intended sedative effect. For practical purposes: • Small adult (40–70 kg): 5 mg aliquots • Large adult (≥ 70 kg): 10 mg aliquots Pain must be reassessed between doses to a maximum dose of 0.5 mg/kg in 30 minutes.

Note: In order to exceed the maximum dose, a consultant telephone call must be made.

two practice leads. Each of the seven CCPs are allocated to one of seven 'horizontal' teams that meets every seven weeks for a period of shared governance and skills assurance training. This governance time is paramount to ensure patient safety as it allows for a high level of oversight, combined with revalidation training, uplift of new skills and a platform for continued professional development. Each of these sessions is overseen by a CCP practice lead.

Within SECAmb, ketamine is administered as an analgesic, forming part of a multi-modal analgesia approach, and as a procedural sedative in the case of traumatic injury and the management of agitated head injuries. It is also indicated as a sedative where there is a need for transcutaneous pacing or cardioversion, though these latter two indications have not been included in this evaluation (Table 1). Since this evaluation, the SECAmb PGD has been revised and updated (Supplementary 1 and 2). Note that, unlike many international paramedic programmes, ketamine is not currently administered within SECAmb for any kind of acute behavioural disturbance outside the context of traumatic head injury.

Ketamine is only administered by CCPs in SECAmb. In the first year of a CCP's practice, ketamine can only be administered following a consultant phone call. If, after this year, competence can be proven both theoretically and in practice, then autonomous administration can commence.

Methods

Setting

SECAmb is an urban, suburban and rural NHS funded ambulance service that broadly encompasses the counties of Sussex, Surrey and Kent and receives nearly 862,000 calls each year (South East Coast Ambulance Service NHS Foundation Trust, n.d.). It employs 2700 clinical staff of which 60 (2.2%) were operating as CCPs as of 30 April 2017.

Patient selection

All patients receiving ketamine for a traumatic aetiology, who had ketamine administered by a CCP, and who had a completed record on the CCP registry of Advanced Life Saving Interventions and Procedures (ALSIP), or on CCPBase (Medic One Systems Ltd), between 16 March 2013 and 30 April 2017, were included. A complete record includes: date of incident, patient age, indication for administration and dose administered. Records were excluded if administration was for a medical aetiology, the ALSIP was incomplete or ketamine was administered by a non-CCP (e.g. a doctor employed by the Trust). All included entries were reviewed for side effects and adverse events that occurred during/after administration, while the patient was still in the care of the CCP.

Statistical analysis

The data were collated in Microsoft Excel (2010) and analysed using R 3.3.3 (R Core Team, 2017). Following anonymisation of the data (both patient and CCP), descriptive statistics were generated. It was not possible to capture the precise dosing regimen (weight, intervals, etc.) as this was not part of the original dataset.

Results

A total of 510 unique administrations were identified. Following the exclusion of 61 records (Table 2), 449 (88.0%) administrations remained for inclusion. The most common indication for administration of ketamine was lower limb injury, with 228 (50.8%) administrations (Figure 1 and Table 3). All ketamine was administered intravenously, and the median dose of ketamine for all administrations was 30 mg (interquartile range (IQR) 20–40 mg). The gender split was dominated by males who accounted for 302 (67.3%) of the administrations compared to 147 (32.7%) females (Figure 2). This is in keeping with the most recent trauma epidemiology statistics for the UK (Kehoe, Smith, Edwards, Yates, & Lecky, 2015). The median age of patients was 44 (interquartile range (IQR) 28–58), with women on average being older (median 53, IQR 31–75) than men (median 40, IQR 26–54). Telephone calls to a consultant were made for 243/449 (54.1%) of the administrations, reflecting a need for sanctioning of the drug, advice on dosages or indications, for example.

Side effects and adverse events

Side effects or adverse events were noted in 16/449 (3.6%) of the administrations (Table 4). All of the side effects are in line with the expectancy of known side effects for ketamine analgesia and sedation (Joint Formulary Committee, 2017). No harm was reported in any of the events, and each record documented how the incident was managed by the CCP. This typically involved simple airway manoeuvres, including a period of bag-valve-mask ventilation. Vomiting was not reported in any patient that could not clear their own airway.

Discussion

As far as we are aware, this is the largest published evaluation of out-of-hospital ketamine administration by

Table 2. Excluded records with rationale.

Exclusion rationale	Number
Non-traumatic aetiology	27
No complete ALSIP	23
Ketamine drawn up but not administered	8
Ketamine not administered by CCP	1
Duplicate entry	2
Total	**61**

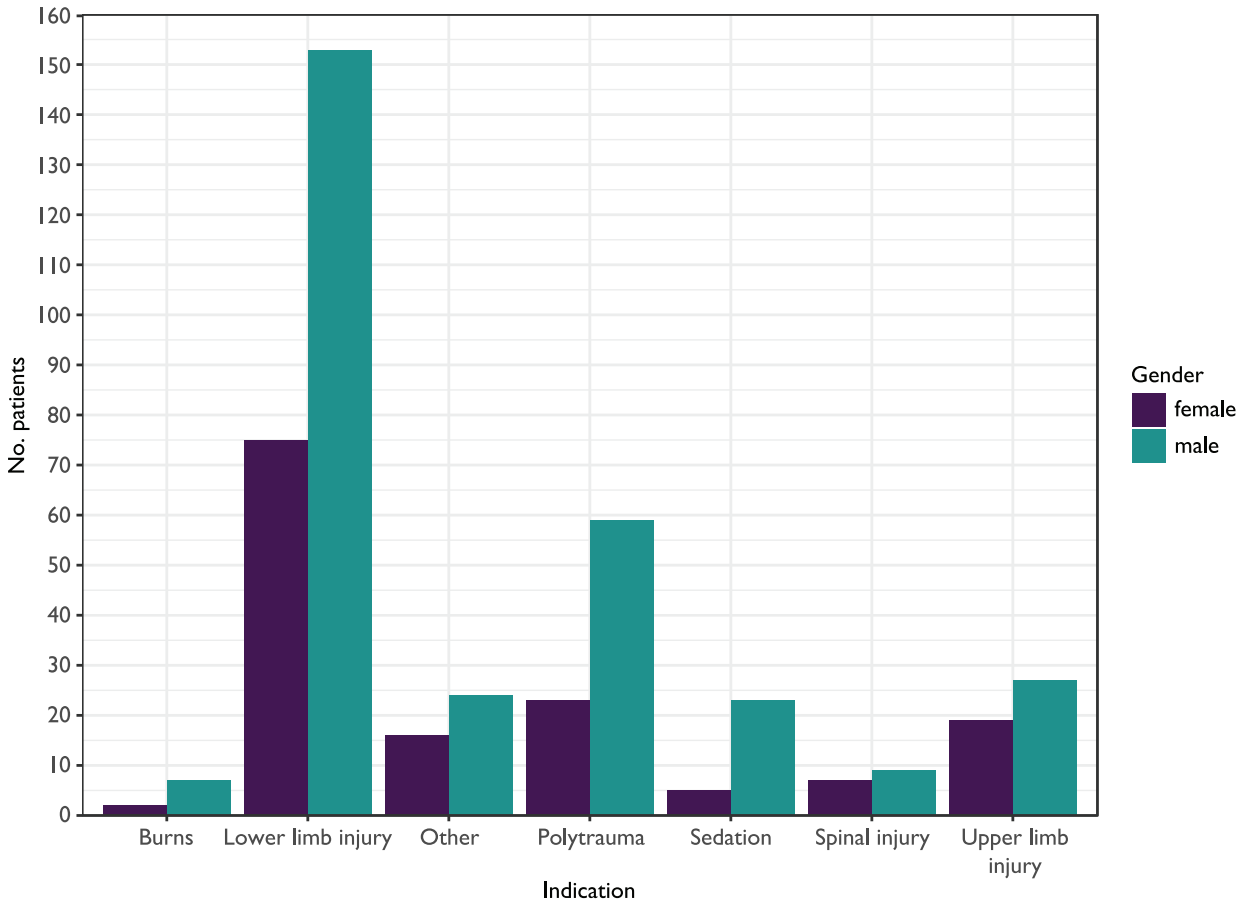

Figure 1. Simple bar chart showing patient counts for each indication, stratified by gender.

Table 3. Basic summary table.

Indication	n	Median total dose (mg)	IQR total dose (mg)	Min total dose (mg)	Max total dose (mg)	Male	Female	Median age (years)	IQR age (years)	Min age (years)	Max age (years)
Lower limb injury	228	30	20–40	5	90	153	75	44	25–61.5	7	96
Polytrauma	82	30	20–40	10	80	59	23	40	28–53	18	86
Upper limb injury	46	30	20–40	5	80	27	19	46	33–60	17	91
Other	40	20	10–30	5	180	24	16	44	38.5–57.5	20	88
Sedation	28	22.5	20–35	10	90	23	5	52	25.5–64.5	16	85
Spinal injury	16	22.5	17.5–37.5	10	60	9	7	46	33.5–51	20	78
Burns	9	50	40–70	10	80	7	2	32	30–40	26	47
Total	**449**	**30**	**20–40**	**5**	**180**	**302**	**147**	**44**	**28–58**	**7**	**96**

Table 4. Side effects and adverse incidents as a result of ketamine administration by CCP.

Side effects	n	Median total dose (mg)	IQR (mg)	Minimum total dose (mg)	Maximum total dose (mg)
Transient blood pressure increase	6	30	20–40	15	50
Respiratory depression	3	30	25–35	20	40
Vomiting	3	25	22.5–32.5	20	40
Mild emergence phenomena	2	25	20–30	20	30
Distressed	1	30	30–30	30	30
Adverse events					
Accidental OD	1	180	180–180	180	180
Total	16	30	20–40	15	180

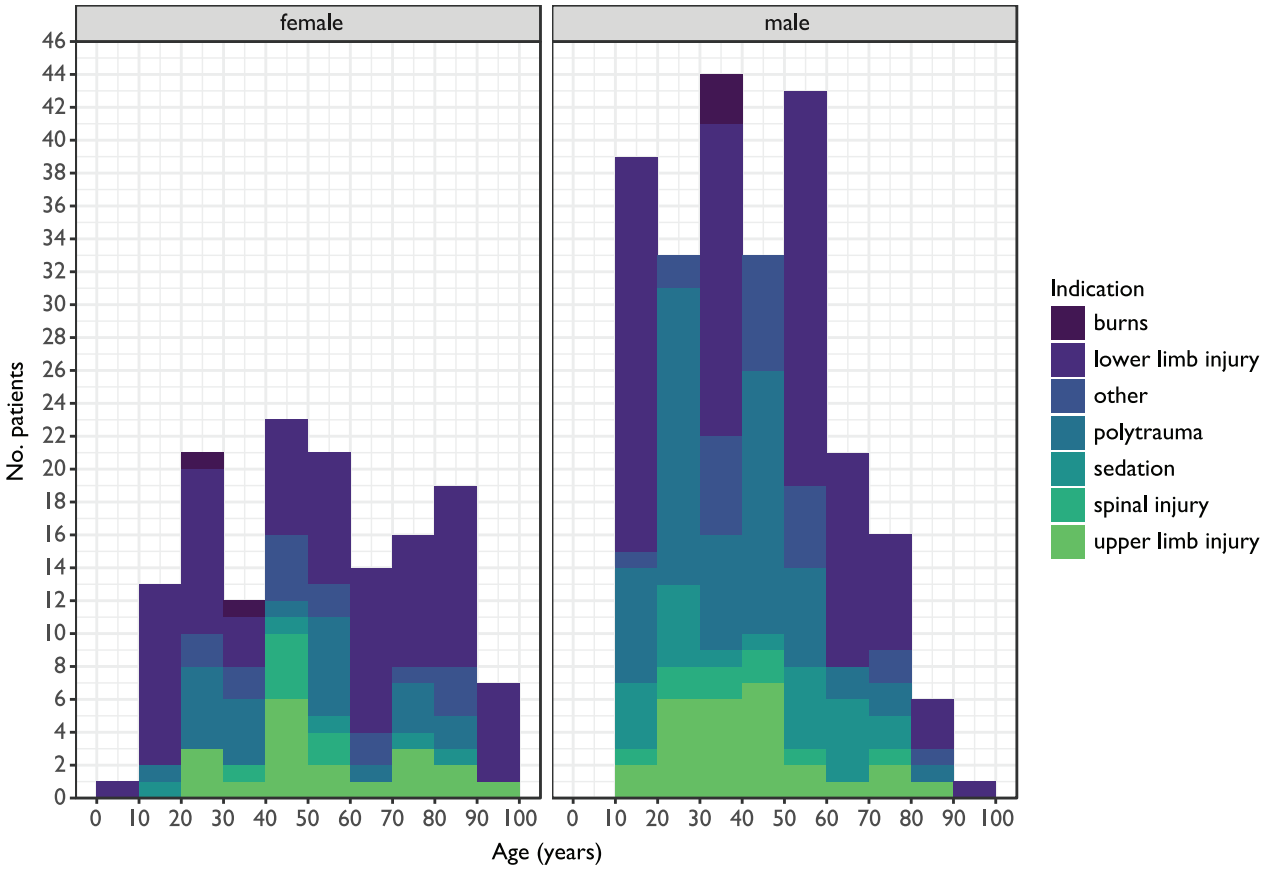

Figure 2. Histogram, comparing age with patient counts. Fill colour shows indication.

paramedics. The demographic in this case shows a higher median age and larger proportion of men than most other comparable studies (Bredmose, Lockey, Grier, Watts, & Davies, 2009; Johansson, Kongstad, & Johansson, 2009: Figures 1 and 2; Porter, 2004). Hollis, Keene, Ardlie, Caldicott, and Stapleton (2017) reported a similar age range profile, though again, a higher proportion of women. The reasons for the different demographics here are not known but are likely to reflect the different pre-hospital environments, and the demographics of the local population. The median therapeutic dose is similar to one study (Johansson et al., 2009), though the qualification of administering clinician in that case is unclear. Other studies report a larger mean dose (Bredmose et al., 2009; Porter, 2004), though they are entirely physician delivered. Hollis et al. (2017) describe paramedic administration but do include a mix of IV/IM administration and a number of patients sedated for acute behavioural disturbance. The only other UK based paramedic articles do not mention mean dose (Edwards, Shaw, Gray, Thomson, & Faulkner, 2016; McQueen et al., 2014).

One point of note is that the total doses used in sedation are no different to those used in analgesia. While the PGD recommends a broadly similar dosing regimen for both, intuitively a sedation indication would involve a higher total dose than in analgesia. The most likely explanation for this is that patients who needed sedating are far likelier to have had their care passed to a Helicopter Emergency Medicine Service (HEMS), and so the total dose given by the CCP would appear relatively low in comparison to those patients who remained with the CCP for their entire pre-hospital phase.

Regarding the site of injury, the results also show that isolated limb injuries were by far the most common indication for ketamine analgesia, and considering Lee and Porter's (2005) discussion around how common this type of injury is in pre-hospital care, and the need for early fracture reduction, this is unsurprising.

Side effects

Side effects are reported in most other studies (Bredmose et al., 2009; Edwards et al., 2016; Galinski et al., 2007; Johansson et al., 2009; Porter, 2004; Svenson & Abernathy, 2007) but sample numbers are too low to draw conclusions. Svenson and Abernathy (2007), Porter (2004) and Edwards et al. (2016) report no adverse effects, while Bredmose et al. (2009) reported a similar proportion to this project. None of these categorised adverse events in the same way, but the proportions observed here are within the range reported in the BNF (Joint Formulary Committee, 2017). No other study reported a medication error but, again, no other study has such a large population size. It should be noted that, even at the size of this population, the frequency of reported side effects was low.

When examining the side effects seen in this evaluation within the context of those stated in the BNF (Joint Formulary Committee, 2017), all except respiratory depression fall in to the *common or very common* category (defined as occurring in 1:100 (1%) to 1:10 (10%) of patients), with respiratory depression occurring *rarely* (1:1000 (0.1%) to 1:100 (1%)). If we take the halfway points of these groups (i.e. 5% and 0.5%), then the number needed to harm can be calculated as 35.7 patients for the *common to very common* side effects and 1000 patients for the *rare* side effects.

The side effects that occurred in this evaluation, while causing no harm to the patient, have the potential to cause complications if not managed correctly. It seems prudent that ketamine continues to be administered only by specialist paramedics, who have received additional, specific training in identifying and managing side effects from the drug, in keeping with the Academy of Medical Royal Colleges (2013) recommendations.

Ketamine use within SECAmb has increased year-on-year, though this is likely to be due both to an increasing scope of practice and numbers of CCPs. The increase may also be due, in part, to improved familiarity with the drug and confidence to administer.

Looking to the future, there may be a role for ketamine use in acute behavioural disturbance, an indication that is commonplace in other parts of the world, and was an indication in the Hollis et al. (2017) study.

Strengths and limitations

This was a retrospective analysis, strengthened most by its large patient population in comparison to other studies of paramedic administered ketamine. However, care must be taken in generalising these results to other clinical areas, trusts or patient populations, but it should serve as a base for further prospective studies and service development.

Side effects and adverse events did not have a formal method of being recorded, other than in the free text of the report or patient record. Consequently, there is a possibility that side effects or adverse events occurred but were not documented. CCPs are mandated to document any side effects or adverse events, so it is probable that the number of undeclared side effects is low. All CCPs were made aware of the intended study, prior to data collection, so they could retrospectively enter any adverse effects that had not been previously noted, though the authors accept the limitations here that people may not sufficiently recall incidents that are in the past or could have edited them to appear more favourable. Other interventions and therapies were not gathered as part of this analysis. Patients are likely to have received other analgesics, such as morphine, which may bias the dose and side effect profile. The use of anti-emetics is also not recorded within this analysis.

Since methods and detail of data collection changed over the years, interrogation of all entries took place but it was not always clear whether the administration was for analgesia or sedation. Clearly this is another limitation of the study, and future analysis should be clear to separate the two as the dosing regimen is likely to be different.

Conclusion

Ketamine has been administered over 500 times by CCPs operating within the South East Coast Ambulance Service NHS Trust area. In the largest retrospective analysis of its kind, and one of very few focusing on paramedic only administration, levels of side effects and adverse events are in line with nationally documented expectations. Patient demographics show an increased age when compared with other studies, and a larger proportion of males. These statistics are in line with epidemiological studies in traumatology, and are likely to reflect the traumatic nature of the indications for use, and the older demographic of the geographical region in which the CCPs operate.

This evaluation provides a useful platform for increasing the evidence base for paramedic administered ketamine. However, prospective studies are now needed in order to confirm the safety and efficacy of ketamine administration among the advanced paramedic population.

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Author contributions

All named authors met the *British Paramedic Journal* guidelines for authorship. In addition:

AC/NG/AW were principally involved with data acquisition, initial design and drafting.
AC/PW/NG/JW/FM were involved with data interpretation, drafting and critical revision.

Conflict of interest

While there are no formal competing interests to declare, AC/PW/FM are all employed by the Trust at the time of publication.

Ethics

This study met UK Health Research Agency criteria for a service evaluation. All the data utilised for this study were routinely collected as part of standard pre-hospital patient data collection, sanctioned by the CCP lead, chief pharmacist and Trust medical director. Formal ethical approval was therefore not required.

Funding

None.

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This Patient Group Direction (PGD) must only be used by Critical Care Paramedics (CCPs) who have been named and authorised by their organisation to practice under it. The most recent and in-date final signed version of the PGD must be used.

Patient Group Direction

for the administration of

Ketamine

by Critical Care Paramedics for

Management of pain

in South East Coast Ambulance Service NHS Foundation Trust

Date Issued:	**18/10/2017**
Issued By:	**Carol-Anne Davis-Jones**
PGD Reference:	**PGD-CCP001**
Review Date:	**21/01/2019**
Expiry Date:	**21/07/2019**

Upon issue of this version of the PGD, all previous versions must be removed from use. No supply or administration may be made under the terms of this PGD after the expiry date above.

Change history

Version number	Change details	Date
0.1	Routine update	23/05/2017
0.2	Review and transfer to new template	23/05/2017
0.3	Addition of Paediatric dosing	06/06/2017
0.4	Review	07/07/2017
0.5	Review by Medical Directorate	12/10/2017
1.0	Published version	18/10/2017

KETAMINE 10mg per mL injection	KET	POM CD2

PGD development

Name	Job title and organisation	Date
Lead HCP	Mark Lilley	12/10/2017
Lead Doctor	Fionna Moore	12/10/2017
Lead Pharmacist	Carol-Anne Davies-Jones	12/10/2017
Other Paramedics/ Nurses involved in development/ review	David Griffiths Samantha Rea Fiona Wray	12/10/2017

PGD Authorisation

Senior Doctor	**Name:** Fionna Moore **Position:** Executive Medical Director **Signature:** **Date:** 18/10/2017.
Senior Pharmacist	**Name:** Carol-Anne Davies-Jones **Position:** Trust Pharmacist **Signature:** **Date:** 18/10/2017
Senior Representative of Profession Using this PGD	**Name:** Mark Whitbread **Position:** Consultant Paramedic **Signature:** **Date:** 18/10/17.
Organisational Authorisation	**Name:** Steve Lennox **Position:** Director of Nursing and Quality **Signature:** **Date:** 19/10/17

KETAMINE 10mg per mL injection	KET	POM CD2

Training and competency of Critical Care Paramedics

	Requirements of registered Paramedics working under the PGD
Qualifications and professional registration	Professional registration with HCPC as a Paramedic. Current contract of employment with SECAmb as a Critical Care Paramedic (CCP) and holder of a Post Graduate Certificate in Paramedic Practice (Critical Care) or Consultant Paramedic (Critical Care).
Initial training	CCPs must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed. CCPs must be competent to recognise and treat unintended but expected side effects including loss of airway reflexes, respiratory depression and anaphylaxis.
Competency assessment	Current endorsement from the Medical Director to specifically use this PGD which is recorded on the Advanced Lifesaving Intervention Register, held on *Share point* and maintained by CCP Lead (Quality Improvement) CCPs should self-declare that they are competent to use this PGD, assuring themselves that they have the necessary clinical skills and knowledge for treatment of the conditions included and use of the drugs involved. Support for self-assessment will be provided by Trust Standard Operating Procedures (SOPs) and training for the use of PGDs Regular contact with the CCP Practice Leads during CCP shared governance time (Clin8 training days). CCPs should also understand the legislation surrounding use of PGDs and their responsibilities as a PGD user as described in relevant Trust SOPs for PGDs.
Ongoing training and competency	The CCP must meet the requirements of the current prevailing level of education required for PGD use at this level of practice. This must include completion of

KETAMINE 10mg per mL injection	KET	POM CD2

	the Trusts SOPs for medicine management and regular peer review. Attend CCP Skills Assurance Time ("Clin8 Training"). Ongoing competency with CCP governance and skills assurance time. All ongoing regular training requirements (e.g. statutory and mandatory training) as required by the Trust for this role must be completed. The clinician is responsible for keeping him/herself aware of any changes to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of their own individual scope of practice. Ensure compliance to Trust policies and process relating to medicines.

KETAMINE 10mg per mL injection	KET	POM CD2

Clinical condition

Clinical condition or situation	Management of moderate to severe pain.
Inclusion criteria	Adults and children 12 years and above who are in traumatic pain and • Other analgesia contraindicated as per JRCALC or other agents have failed to adequately control the pain. • Or; the patient has life or limb threatening injuries and pain is preventing emergency treatment including transport to an appropriate hospital for life and limb saving care. Or Children under 12 years of age that are in traumatic pain and other analgesic agents are not clinically appropriate or are ineffective. **These cases must always be discussed with, and permission granted by the senior on call clinician.** Or Patients who are in severe pain from any cause where other analgesic agents are contra-indicated or have failed to control pain, and other analgesic agents are not clinically appropriate. **These cases must always be discussed with, and permission granted by the senior on call clinician.** If a CCP is unsure about any of the following exclusions or cautions listed below they should contact the senior on call clinician to discuss the case.
Exclusion criteria	• Known allergy to ketamine or any of the excipients (sodium chloride, benzethonium chloride, water for injections) • Where essential standards of vital sign monitoring including end tidal capnography is not possible. • Known concurrent administration of theophylline. • Significant hypertension. • Severe coronary or myocardial disease • Severe cerebrovascular disease • Raised intracranial pressure • Raised intraocular pressure

KETAMINE 10mg per mL injection	KET	POM CD2

	• Known history of psychosis or hallucinations • Pre-eclampsia • Eclampsia • Acute porphyria • Intracranial mass lesions • Hydrocephalus

KETAMINE 10mg per mL injection	KET	POM CD2

Cautions (including any relevant action to be taken)	Increased risk of hypertension and tachycardia in patients with hyperthyroidism or receiving thyroid replacement. Consider less frequent doses and slower administration therefore accepting slower titration to effect. Risk of laryngospasm in patients with pulmonary or upper respiratory tract infections. Consider less frequent doses and slower administration therefore accepting slower titration to effect. In patients with liver disease, a prolonged duration of action may be seen. Consider less frequent doses and slower administration therefore accepting slower titration to effect. Increased myocardial oxygen consumption may exacerbate hypovolaemia and dehydration, and known cardiac disease, including mild to moderate hypertension and tachyarrhythmias. Consider less frequent doses and slower administration therefore accepting slower titration to effect. Known barbiturate or narcotic consumption. Consider half doses (0.05mg/kg), slower administration and increased time between doses therefore accepting slower titration to effect. Chronic alcoholics/ acute alcohol intoxication. Consider less frequent doses and slower administration therefore accepting slower titration to effect. . Patients with 'neurotic traits' or psychiatric illness. Consider less frequent doses and slower administration therefore accepting slower titration to effect. Epilepsy – use with caution if history of seizers or uncontrolled epilepsy. Consider less frequent doses and slower administration therefore accepting slower titration to effect. Patients entrapped or in confined spaces. Ketamine should be used with caution in these patients as management of any adverse effects is likely to be difficult. Ketamine's use in these circumstances should be considered primarily to aid the extrication process. FRAIL Adults or Children aged 12 and above (e.g. Elderly, debilitated or comorbid patients). Consider less frequent doses and slower administration therefore accepting slower titration to effect.

KETAMINE 10mg per mL injection	KET	POM CD2

Pregnancy and breast feeding	Ketamine has not been subject to controlled clinical studies in pregnancy. Ketamine crosses the placenta but it is unknown what the effect on the baby is. Ketamine's safe use during lactation has not been established. There is no data on the effects in the infant. The benefits of administration must outweigh any potential risk.
Arrangements for referral for medical advice	Patient who receive ketamine should be fully monitored (ECG, NIBP, SpO2 and EtCO2) and conveyed to the nearest appropriate hospital or handed over to an enhanced care team who are able to manage a patient who has had ketamine administered. The receiving clinical team must be verbally informed and the patient record should clearly show: • At what time the patient had ketamine administered. • How much ketamine the patient has had administered. • Whether the patient had capacity to provide informed consent.
Action to be taken if patient excluded	Consider other analgesic agents. Ensure exclusion is recorded in patient records.
Action to be taken if patient declines treatment	Ensure the patient understands the information and rationale for the proposed administration and is therefore able to make an informed choice. It is possible in the context of traumatic pain the patient may not be able to make an informed choice. Therefore, the CCP should act in the best interests of the patient at all times. Offer other analgesic agents if appropriate.

KETAMINE 10mg per mL injection	KET	POM CD2

Details of the medicine

Name, form and strength of medicine	Ketamine 10mg/mL solution for injection
Legal category	POM CD Schedule 2
Route/method of administration	Intravenous injection (IV) Intraosseous injection (IO) The IV or IO dose should be administered over 30-60 seconds.
Dose and frequency	Estimate the patient's weight. (In children under 12 years of age, refer to JRCALC 'age page') **Adults and children aged 12 years and over:** Initial bolus dose of 0.1mg/kg; repeat doses of 0.1mg/kg by titration to achieve intended analgesic effect. For practical purposes: • Small adult: (40kg – 70kg): 5mg aliquots • Large adult (≥70kgs) 10mg aliquots **Children under 12 years of age:** ***KETAMINE MUST BE DILUTED TO A CONCENTRATION OF 1MG / ML BEFORE USE. SEE 'Quantity to be administered' SECTION.*** Children under 12 years of age that are in traumatic pain and other analgesic agents are not clinically appropriate or are ineffective. **These cases must always be discussed with, and permission granted by the senior on call clinician.** Time between doses should be no shorter than 2 minutes which reflects the following: Ketamine has an onset time of approx. 30 seconds Ketamine has a peak effect time of approx. 1 minute. Ketamine has a half-life of 10-15 minutes.

KETAMINE 10mg per mL injection	KET	POM CD2

Pain must be reassessed between doses.

To a maximum dose of 0.5mg/kg in 30 minutes.
Consider multimodal analgesia as appropriate.

Dosing for **children under 12 years** of age:

WEIGHT		INITIAL BOLUS DOSE 0.1MG/KG	VOLUME (after dilution in 20ml)	DOSE INTERVAL	Max Dose in 30 minutes (0.5mg/kg)	Max Volume in 30 minutes
Birth	3.5kg	0.35mg	0.35mls	2min	1.75mg	1.75mls
3mths	6kg	0.6mg	0.6mls	2min	3mg	3.0mls
6mths	8kg	0.8mg	0.8mls	2min	4mg	4.0mls
12mths	10kg	1mg	1.0mls	2min	5mg	5.0mls
18mths	11kg	1.1mg	1.1mls	2min	5.5mg	5.5mls
2yrs	12kg	1.2mg	1.2mls	2min	6mg	6.0mls
3yrs	14kg	1.4mg	1.4mls	2min	7mg	7.0mls
4yrs	16kg	1.6mg	1.6mls	2min	8mg	8.0mls
5yrs	19kg	1.9mg	1.9mls	2min	9.5mg	9.5mls
6yrs	21kg	2.1mg	2.1mls	2min	10.5mg	10.5mls
7yrs	23kg	2.3mg	2.3mls	2min	11.5mg	11.5mls
8yrs	26kg	2.6mg	2.6mls	2min	13mg	13mls
9yrs	29kg	2.9mg	2.9mls	2min	14.5mg	14.5mls
10yrs	32kg	3.2mg	3.2mls	2min	16mg	16mls
11yrs	35kg	3.5mg	3.5mls	2min	17.5mg	17.5mls

Dosing for adults and children aged 12 years and over:

WEIGHT	INITIAL BOLUS DOSE 0.1MG/KG	VOLUME (not diluted)	DOSE INTERVAL	Max Dose in 30 minutes (0.5mg/kg)	Max Volume in 30 minutes
40kg	5mg	0.5mls	2min	20mg	2mls
45kg	5mg	0.5mls	2min	22.5mg	2.25mls
50kg	5mg	0.5mls	2min	25mg	2.5mls
60kg	5mg	0.5mls	2min	30mg	3mls
70kg	10mg	1mls	2min	35mg	3.5mls
80kg	10mg	1mls	2min	40mg	4mls
90kg	10mg	1mls	2min	45mg	4.5mls
100kg	10mg	1mls	2min	50mg	5mls
110kg	10mg	1mls	2min	55mg	5.5mls
120kg	10mg	1mls	2min	60mg	6mls

KETAMINE 10mg per mL injection	KET	POM CD2

Quantity to be administered and/or supplied	**Adults and children aged 12 years and over:** 0.5mg/kg ketamine 10mg / ml to be drawn up from an ampoule into a labelled **10ml syringe.** A syringe cap should then be fitted. **Children under 12 years of age - dilute ketamine:** 18ml of sodium chloride 0.9% to be drawn up into a labelled **20ml syringe.** 2ml (20mg) ketamine 10mg / ml to be drawn up from an ampoule into the labelled **20ml syringe.** **There will now be a full 20ml syringe with a concentration of ketamine 1mg / ml.** **This must be performed under discussion with the senior on call clinician and using the CMP for reference.**
Maximum or minimum treatment period	Administer over 30-60 seconds, titrate to a maximum dose of 0.5mg/kg in 30 minutes.
Administration details	Ketamine should be counter checked to ensure the medication being drawn up is ketamine, 10mg / ml and is in date. Administer over 30-60 seconds to reduce risk of side effects. After administration flush with 2.5-5mls.of 0.9% sodium chloride. All patients must be fully monitored including EtCO2, SpO2, ECG and BP. Resuscitation equipment must always be available and accompany the patient. In very young children ketamine should be initially drawn up in the same way (diluted in a 20ml syringe) then use of a 1ml / 2ml syringe may allow for more accurate administration.

KETAMINE 10mg per mL injection	KET	POM CD2

Adverse effects Adverse effects should be reported via the Yellow Card scheme, and via Datix (IRW1)	**Common side effects** (more than 1 in 100 but less than 1 in 10) • Emergence reaction: (e.g. hallucinations, abnormal dreams, nightmares, confusion, agitation, abnormal behaviour) • Nystagmus • Hypertonia • Tonic-clonic movements • Diplopia • Increased blood pressure • Increased heart rate • Increased respiratory rate • Nausea and vomiting (up to 10% incidence) • Erythema • Morbilliform rash (up to 10% incidence) **Uncommon** (more than 1 in 1000 but less than 1 in 100) • Anorexia • Anxiety • Bradycardia • Arrhythmia • Hypotension • Respiratory depression • Laryngospasm • Injection site pain or rash **Rare** (more than 1 in 10,000 but less than 1 in 1000) • Anaphylaxis • Delirium, flashback, dysphoria, insomnia, disorientation • Obstructive airway disorder • Apnoea • Salivary hypersecretion • Cystitis/ haemorrhagic cystitis **Unknown frequency** • Raised intraocular pressure
Record to be kept (*in cases where the patient lacks the ability to communicate or does not have capacity this may be	• Record that valid, informed consent was given by the patient. • In cases where the patient lacks mental capacity, a record of how mental capacity was assessed and how the administration of this medicine was in the best interest of the patient. • CAD incident number. • * Patient's name, address, date of birth

KETAMINE 10mg per mL injection	KET	POM CD2

omitted if reasonable efforts have failed to obtain this information)	• *Contact details of GP (if registered) • Diagnosis or working diagnosis • Dose given and route given by • Batch number and expiry date of drugs given • Time of administration • Advice given to patient • Signature and name of staff who administered medication • Details of any adverse reactions and action taken • Details must be stored on CCP base including any Advanced Life Saving Interventions Procedure calls to the senior on call clinician.
Indicate any off-label use (if relevant)	Ketamine is not licensed as an analgesic agent. Its off-label use for the management of pain is supported by nationally recognised guidelines from NICE guidelines (13), the Royal College of Emergency Medicine (5), Intensive Care Society (6) JRCALC (3) and other well established prehospital critical care systems (2).

KETAMINE 10mg per mL injection	KET	POM CD2

Patient information

Written information to accompany the patient	The patient record must show: • Which medications have been administered. • The strength of medications administered. • The batch number of medications administered. • What time medications where administered. • The effect (intended or unintended) of medications administered The patient record must demonstrate that informed patient consent has been gained. If the patient lacks mental capacity a record of how the administration of the medicine is in the best interest of the patient. In cases where the patient has mental capacity: • Consent had been gained for IV access and to administer medication. • The patient must be informed why treatment is required and what the intended effects of the medication are • Potential side-effects of the medication must be explained
Follow-up advice to be given to patient or carer	Patients who received ketamine should be conveyed to the nearest appropriate hospital or handed over to an enhanced care team able to manage a patient with ketamine. The receiving clinical team must be verbally informed and the patient record should clearly show: • At what time the patient had ketamine administered. • How much ketamine the patient has had administered. • Whether patient had capacity to provide informed consent.

KETAMINE 10mg per mL injection	KET	POM CD2

Appendices

Appendix A Key references

1. http://www.medicines.org.uk/emc/medicine/12939. The electronic Medicines Compendium website.
2. Bredmose, P. P., et al. "Pre-hospital use of ketamine for analgesia and procedural sedation." Emergency Medicine Journal 26.1 (2009): 62-64.
3. Brown, S. N., Kumar, D., Millins, M., & Mark, J. (Eds.). (2016). UK ambulance services Clinical practice guidelines JRCALC 2016. Bridgwater: Class Professional
4. Royal College of Emergency Medicine (2017) Pharmacological Agents for Procedural Sedation and Analgesia in the Emergency Department http://www.rcem.ac.uk/docs/College%20Guidelines/Pharmacological%20Agents%20for%20Procedural%20Sedation%20and%20Analgesia%20(Jan%202017%20Revised).pdf
5. Intensive Care Society (2014) Intensive Care Society review of best practice for analgesia and sedation in the critical care
6. St John New Zealand (2016) Clinical Procedures and Guidelines – Comprehensive edition 2016-2018 http://www.rgpn.org.nz/Network/media/documents/St%20John%20CPGs%202016-18/St-John-CPGs,-comprehensive-edition,-2016-2018.pdf
7. Soar, Jasmeet, et al. "European Resuscitation Council Guidelines for Resuscitation 2015 Section 3. Adult advanced life support." *Resuscitation* 95 (2015): 100-147.
8. Maconochie, Ian K., et al. "European Resuscitation Council guidelines for resuscitation 2015: section 6. Paediatric life support." (2015): 223-248.
9. Online BNF, NICE Evidence Services, May 2017. https://www.evidence.nhs.uk/formulary/bnf/current/15-anaesthesia/151-general-anaesthesia/1511-intravenous-anaesthetics/drugs-used-for-intravenous-anaesthesia/ketamine
10. Bredmose, P. P., Grier, G., Davies, G. E., & Lockey, D. J. (2009). Pre-hospital use of ketamine in paediatric trauma. *Acta Anaesthesiologica Scandinavica*, *53*(4), 543-545.
11. Barker, C. L., & Weatherall, A. D. (2014). Prehospital paediatric emergencies treated by an Australian helicopter emergency medical service. European Journal of Emergency Medicine, 21(2), 130-135.
12. Patient Group Directions. Medicines Practice Guide NICE August 2013.
13. National Institute for Health and Care Excellence (2016) Major trauma: assessment and initial management, NICE guideline [NG39]

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Appendix B Health professionals' agreement to practise

PGDS DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice within the limits of their own competence and in accordance with their own professional code of conduct.

Note to authorising managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to administer this medicine only in accordance with this PGD.

Name of paramedic	Signature	Senior representative authorising paramedic	Date

This Patient Group Direction (PGD) must only be used by Critical Care Paramedics (CCPs) who have been named and authorised by their organisation to practice under it. The most recent and in-date final signed version of the PGD must be used.

Patient Group Direction

for the administration of

KETAMINE

by Critical Care Paramedics for

Procedural sedation and sedation of the undifferentiated cerebrally agitated trauma patient

in South East Coast Ambulance Service NHS Foundation Trust

Date Issued:	**18/10/2017**
Issued By:	**Carol-Anne Davis-Jones**
PGD Reference:	**PGD-CCP002**
Review Date:	**21/01/2019**
Expiry Date:	**21/07/2019**

Upon issue of this version of the PGD, all previous versions must be removed from use. No supply or administration may be made under the terms of this PGD after the expiry date above.

Change history

Version number	Change details	Date
0.1	Routine update	23/05/2017
0.2	Review and transfer to new template	23/05/2017
0.3	Addition of Paediatric dosing	06/06/2017
0.4	Review	07/07/2017
0.5	Review by Medical Directorate	17/10/2017
1.0	Published version	18/10/2017

Patient Group Direction for Critical Care Paramedics

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PGD development

Name	Job title and organisation	Date
Lead HCP	Mark Lilley	23/05/2017
Lead Doctor	Peter Westhead	07/07/2017
Lead Pharmacist	Carol-Anne Davies-Jones	07/07/2017
Other Paramedics/ Nurses involved in development/ review	David Griffiths Samantha Rea Fiona Wray	07/07/2017

PGD Authorisation

Senior Doctor	**Name:** Fionna Moore **Position:** Executive Medical Director **Signature:** **Date:** 18/10/2017
Senior Pharmacist	**Name:** Carol-Anne Davies-Jones **Position:** Trust Pharmacist **Signature:** **Date:** 18/10/2017
Senior Representative of Profession Using this PGD	**Name:** Mark Whitbread **Position:** Consultant Paramedic **Signature:** **Date:** 18.10.17
Organisational Authorisation	**Name:** Steve Lennox **Position:** Director of Nursing and Quality **Signature:** **Date:** 19/10/17

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Training and competency of Critical Care Paramedics

	Requirements of registered Paramedics working under the PGD
Qualifications and professional registration	Professional registration with HCPC as a Paramedic. Current contract of employment with SECAmb as a Critical Care Paramedic (CCP) and holder of a Post Graduate Certificate in Paramedic Practice (Critical Care) or Consultant Paramedic (Critical Care).
Initial training	CCPs must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed. CCPs must be competent to recognise and treat unintended but expected sided effects including loss of airway reflexes, respiratory depression and anaphylaxis.
Competency assessment	Current endorsement from the Medical Director to specifically use this PGD which is recorded on the Advanced Lifesaving Intervention Register, held on *Share point* and maintained by CCP Lead (Quality Improvement) CCPs should self-declare that they are competent to use this PGD, assuring themselves that they have the necessary clinical skills and knowledge for treatment of the conditions included and use of the drugs involved. Support for self-assessment will be provided by Trust Standard Operating Procedures (SOPs) and training for the use of PGDs Regular contact with the CCP Practice Leads during CCP shared governance time (Clin8 training days). CCPs should also understand the legislation surrounding use of PGDs and their responsibilities as a PGD user as described in relevant Trust SOPs for PGDs.
Ongoing training and competency	The CCP must meet the requirements of the current prevailing level of education required for PGD use at this level of practice. This must include completion of

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	the Trusts SOPs for medicine management and regular peer review. Attend CCP Skills Assurance Time ("Clin8 Training"). Ongoing competency with CCP governance and skills assurance time. All ongoing regular training requirements (e.g. statutory and mandatory training) as required by the Trust for this role must be completed. The clinician is responsible for keeping him/herself aware of any changes to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of their own individual scope of practice. Ensure compliance to Trust policies and process relating to medicines.

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Clinical condition

Clinical condition or situation	Life or limb threating conditions that require sedation for emergency care. Management of the undifferentiated cerebrally agitated trauma patient.
Inclusion criteria	Adults and children over 12 years of age who require analgesia and sedation to facilitate a life or limb saving intervention such as: • Cardioversion • Cardiac pacing • Fracture reduction Or Adults and children over 12 years of age who are combative and unmanageable due to cerebral agitation after suffering undifferentiated trauma. Or Children under 12 years of age who require analgesia and sedation to facilitate a life or limb saving intervention such as fracture reduction. **These cases must always be discussed with, and permission granted by the senior on call clinician.** . Another trained pre-hospital care provider competent in airway management must be present at scene.
Exclusion criteria	• Known allergy to ketamine or any of the excipients (sodium chloride, benzethonium chloride, water for injections) • Where essential standards of vital sign monitoring including end tidal capnography is not possible. • Where there is no other trained pre-hospital care provider at scene. • Significant hypertension • Severe coronary or myocardial disease • Severe cerebrovascular disease • Raised intracranial pressure • Raised intraocular pressure • Known history of psychosis or hallucinations • Pre-eclampsia

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	• Eclampsia • Acute porphyria • Intracranial mass lesions • Hydrocephalus

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Cautions (including any relevant action to be taken)	Increased risk of hypertension and tachycardia in patients with hyperthyroidism or receiving thyroid replacement Consider less frequent doses and slower administration therefore accepting slower titration to effect. Risk of laryngospasm in patients with pulmonary or upper respiratory tract infections. Consider less frequent doses and slower administration therefore accepting slower titration to effect. In patients with liver disease, a prolonged duration of action may be seen. Consider less frequent doses and slower administration therefore accepting slower titration to effect. Increased myocardial oxygen consumption may exacerbate hypovolaemia and dehydration, and known cardiac disease, including mild to moderate hypertension and tachyarrhythmias. Consider less frequent doses and slower administration therefore accepting slower titration to effect. Known barbiturate or narcotic consumption. Consider less frequent doses and slower administration therefore accepting slower titration to effect. Chronic alcoholics/ acute alcohol intoxication. Consider less frequent doses and slower administration therefore accepting slower titration to effect. Patients with 'neurotic traits' or psychiatric illness. Consider less frequent doses and slower administration therefore accepting slower titration to effect. Epilepsy – use with caution if history of seizers or uncontrolled epilepsy. Consider less frequent doses and slower administration therefore accepting slower titration to effect FRAIL Adult or Children aged 12 and above (e.g. Elderly, debilitated or comorbid patients). Consider less frequent doses and slower administration therefore accepting slower titration to effect Patients entrapped or in confined spaces. Ketamine should be used with caution in these patients as management of any adverse effects is likely to be difficult. Ketamine's use in these circumstances should be considered primarily to aid the extrication process.

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Pregnancy and breast feeding	Ketamine has not been subject to controlled clinical studies in pregnancy. Ketamine crosses the placenta but it is unknown what the effect on the baby is. Ketamine's safe use during lactation has not been established. There is no data on the effects in the infant. The benefits of administration must outweigh any potential risk.
Arrangements for referral for medical advice	Patient who received ketamine should be conveyed to the nearest appropriate hospital or handed over to an enhanced care team who are able to manage a patient who has had ketamine administered. • The receiving clinical team must be verbally informed and the patient record should clearly show: • At what time the patient had ketamine administered. • How much ketamine the patient has had administered. • Whether the patient had capacity to provide informed consent.
Action to be taken if patient excluded	Consider other analgesic agents.
Action to be taken if patient declines treatment	Ensure the patient understands the information and rationale for the proposed administration and is therefore able to make an informed choice. Offer other analgesic agents if appropriate. It is likely in the context of life or limb-threating conditions that require sedation for emergency care the patient may not be able to make an informed choice. Therefore, the CCP should act in the best interests of the patient at all times.

KETAMINE 10mg per mL injection	KET	POM CD2

Details of the medicine

Name, form and strength of medicine	Ketamine 10mg/mL solution for injection
Legal category	POM CD Schedule 2
Route/method of administration	Intravenous injection Intraosseous injection
Dose and frequency	Estimate the patient's weight. (In children under 12 years of age, refer to JRCALC 'age page') Titration to effect When administering intravenous conscious sedation, the initial drug dose should be determined by careful pre-assessment of the patient and any relevant history, and this dose must have taken full effect before any additional dose is given. "The use of fixed doses or boluses is unacceptable. Subsequent doses, if necessary, should be carefully titrated to achieve the desired effect. Safe sedation demands knowledge of each drug's time of onset, peak effect and duration of action. In principle, titrating a drug/ drugs to optimal effect is critical to safely achieving a recognised sedation endpoint, thereby avoiding inadvertent over-sedation or general anaesthesia." **Adults and children aged 12 years and over:** Initial bolus dose of 0.1 – 0.2mg/ kg repeated by 0.1 – 0.2mg/kg per minute by titration to achieve intended sedative effect. For practical purposes: small adult: (40kg – 70kg): 5mg aliquots; Large adult (≥70kgs) 10mg aliquots. **Children under 12 years of age:** ***KETAMINE MUST BE DILUTED TO A CONCENTRATION OF 1MG / ML BEFORE USE. SEE 'Quantity to be administered' SECTION.*** **These cases must always be discussed with, and permission granted by the senior on call clinician.**

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Time between doses reflect:

Ketamine has an onset time of approx. 30 seconds
Ketamine has a peak effect time of approx. 1 minute.
Ketamine has a half-life of 10-15min

To a maximum dose of 0.5mg/kg.

After successful completion the intervention consider multimodal analgesia as appropriate.

Children **under 12 years of age**:

WEIGHT		INITIAL BOLUS DOSE 0.1MG/KG	VOLUME (after dilution in 20ml)	DOSE INTERVAL	Max Dose in 30 minutes (0.5mg/kg)	Max Volume in 30 minutes
Birth	3.5kg	0.35mg	0.35mls	2min	1.75mg	1.75mls
3mths	6kg	0.6mg	0.6mls	2min	3mg	3.0mls
6mths	8kg	0.8mg	0.8mls	2min	4mg	4.0mls
12mths	10kg	1mg	1.0mls	2min	5mg	5.0mls
18mths	11kg	1.1mg	1.1mls	2min	5.5mg	5.5mls
2yrs	12kg	1.2mg	1.2mls	2min	6mg	6.0mls
3yrs	14kg	1.4mg	1.4mls	2min	7mg	7.0mls
4yrs	16kg	1.6mg	1.6mls	2min	8mg	8.0mls
5yrs	19kg	1.9mg	1.9mls	2min	9.5mg	9.5mls
6yrs	21kg	2.1mg	2.1mls	2min	10.5mg	10.5mls
7yrs	23kg	2.3mg	2.3mls	2min	11.5mg	11.5mls
8yrs	26kg	2.6mg	2.6mls	2min	13mg	13mls
9yrs	29kg	2.9mg	2.9mls	2min	14.5mg	14.5mls
10yrs	32kg	3.2mg	3.2mls	2min	16mg	16mls
11yrs	35kg	3.5mg	3.5mls	2min	17.5mg	17.5mls

Adults and children aged 12 years and over:

WEIGHT	INITIAL BOLUS DOSE 0.1MG/KG	VOLUME (not diluted)	DOSE INTERVAL	Max Dose in 30 minutes (0.5mg/kg)	Max Volume in 30 minutes
40kg	5mg	0.5mls	2min	20mg	2mls
45kg	5mg	0.5mls	2min	22.5mg	2.25mls
50kg	5mg	0.5mls	2min	25mg	2.5mls
60kg	5mg	0.5mls	2min	30mg	3mls
70kg	10mg	1mls	2min	35mg	3.5mls
80kg	10mg	1mls	2min	40mg	4mls

KETAMINE 10mg per mL injection	KET	POM CD2

	90kg	10mg	1mls	2min	45mg	4.5mls
	100kg	10mg	1mls	2min	50mg	5mls
	110kg	10mg	1mls	2min	55mg	5.5mls
	120kg	10mg	1mls	2min	60mg	6mls

KETAMINE 10mg per mL injection	KET	POM CD2

Quantity to be administered and/or supplied	**Adults and children aged 12 years and over:** 0.5mg/kg ketamine 10mg / ml to be drawn up from an ampoule into a labelled **10ml syringe.** A syringe cap should then be fitted. **Children under 12 years of age - <u>dilute</u> ketamine:** 18ml of sodium chloride 0.9% to be drawn up into a labelled **20ml syringe.** 2ml (20mg) ketamine 10mg / ml to be drawn up from an ampoule into the labelled **20ml syringe.** **There will now be a full 20ml syringe with a concentration of ketamine 1mg / ml.** **This must be performed under discussion with the senior on call clinician and using the CMP for reference.**
Maximum or minimum treatment period	Administer over 30-60 seconds, titrate to a maximum dose of 0.5mg/kg in 30 minutes.
Administration details	Ketamine should be counter checked to ensure the medication being drawn up is ketamine, 10mg/ml and is in date. Administer over 30-60 seconds to reduce risk of side effects. After administration flush with 2.5-5mls.of 0.9% sodium chloride. All patients must be fully monitored including EtCO2, SpO2, ECG and BP. Resuscitation equipment must always be available and accompany the patient. In very young children ketamine should be initially drawn up in the same way (diluted in a 20ml syringe) then use of a 1ml / 2ml syringe may allow for more accurate administration.

KETAMINE 10mg per mL injection	KET	POM CD2

Adverse effects Adverse effects should be reported via the Yellow Card scheme, and via Datix (IRW1)	**Common side effects** (more than 1 in 100 but less than 1 in 10) • Emergence reaction: (e.g. hallucinations, abnormal dreams, nightmares, confusion, agitation, abnormal behaviour) • Nystagmus • Hypertonia • Tonic-clonic movements • Diplopia • Increased blood pressure • Increased heart rate • Increased respiratory rate • Nausea and vomiting (up to 10% incidence) • Erythema • Morbilliform rash (up to 10% incidence) **Uncommon** (more than 1 in 1000 but less than 1 in 100) • Anorexia • Anxiety • Bradycardia • Arrhythmia • Hypotension • Respiratory depression • Laryngospasm • Injection site pain or rash **Rare** (more than 1 in 10,000 but less than 1 in 1000) • Anaphyalxis • Delirium, flashback, dysphoria, insomnia, disorientation • Obstructive airway disorder • Apnoea • Salivary hypersecretion • Cystitis/ haemorrhagic cystitis **Unknown frequency** • Raised intraocular pressure
Record to be kept (*in cases where the patient lacks the ability to communicate or does not have capacity this may be	• Record that valid, informed consent was given by the patient. • In cases where the patient lacks mental capacity, a record of how mental capacity was assessed and how the administration of this medicine was in the best interest of the patient. • CAD incident number. • * Patient's name, address, date of birth

KETAMINE 10mg per mL injection	KET	POM CD2

omitted if reasonable efforts have failed to obtain this information)	• *Contact details of GP (if registered) • Diagnosis or working diagnosis • Dose given and route given by • Batch number and expiry date of drugs given • Time of administration • Advice given to patient • Signature and name of staff who administered medication • Details of any adverse reactions and action taken • Details must be stored on CCP base including any Advanced Life Saving Interventions Procedure calls to the senior on call clinician
Indicate any off-label use (if relevant)	Ketamine is not licensed as an analgesic agent. It is licensed for procedural sedation and is supported by nationally recognised guidelines from the Royal College of Emergency Medicine (5), Intensive Care Society (6) JRCALC (3) and other well established prehospital critical care systems (2).

KETAMINE 10mg per mL injection	KET	POM CD2

Patient information

Written information to accompany the patient	The patient record must show: • Which medications have been administered. • The strength of medications administered. • The batch number of medications administered. • What time medications where administered. • The effect (intended or unintended) of medications administered The patient record must demonstrate that informed patient consent has been gained. If the patient lacks mental capacity a record of how the administration of the medicine is in the best interest of the patient. In cases where the patient has mental capacity: • Consent had been gained for IV access and to administer medication. • The patient must be informed why treatment is required and what the intended effects of the medication are • Potential side-effects of the medication must be explained
Follow-up advice to be given to patient or carer	Patients who received ketamine should be conveyed to the nearest appropriate hospital or handed over to an enhanced care team able to manage a patient with ketamine as an analgesia. The receiving clinical team must be verbally informed and the patient record should clearly show: • At what time the patient had ketamine administered. • How much ketamine the patient has had administered. • Whether patient had capacity to provide informed consent.

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Appendices

Appendix A Key references

1. http://www.medicines.org.uk/emc/medicine/12939. The electronic Medicines Compendium website.
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3. Brown, S. N., Kumar, D., Millins, M., & Mark, J. (Eds.). (2016). UK ambulance services clinical practice guidelines 2016. Bridgwater: Class Professional
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5. Intensive Care Society (2014) Intensive Care Society review of best practice for analgesia and sedation in the critical care
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KETAMINE 10mg per mL injection	KET	POM CD2

Appendix B Health professionals' agreement to practise

PGDS DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice within the limits of their own competence and in accordance with their own professional code of conduct.

Note to authorising managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to administer this medicine only in accordance with this PGD.

Name of paramedic	Signature	Senior representative authorising paramedic	Date

KETAMINE 10mg per mL injection	KET	POM CD2