Critical Care Clinical Guideline

Portsmouth Intensive Care Emergency Anaesthetic Drug Pack (EADP)

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1. INTRODUCTION

The Emergency Anaesthetic Drug Pack (EADP), or 'grab bags', are for emergency use for patients requiring intubation and stabilisation on ICU and the wards. In order to mitigate risk of drug errors, the grab bags contain a selection of induction and paralysing agents, some of which are provided in pre-filled syringes.

2. PURPOSE

The purpose of this guideline is to provide information on the safe storage and use of controlled drugs and unlicensed drugs within the EADP for use at Queen Alexandra Hospital, Portsmouth.

3. SCOPE

This guideline applies to the use of EADP's on the Department of Critical Care, Queen Alexandra Hospital, Portsmouth (DCCQ).

4. DEFINITIONS

EADP: Emergency Anaesthetic Drug Pack
DCCQ: Department of Critical Care Queen Alexandra Hospital

5. EADP LOCATION

EADP's to be stored in drugs fridge within the locked Pharmacy cupboard on Critical Care. The door must be closed at all times when not occupied, and non-DCCQ staff are to be supervised at all times in the pharmacy room.

6. EADP CHECKING AND RESTOCKING PROCEDURE

a) When taking EADP's from Fridge

The Grab Bag log book must be signed by the doctor removing the grab bag (NOT Retrospectively on return) and must include:

- Date,
- Time,
- Location of incident (e.g. G4 or MAU orange)
- Signature

Example

Date	Time	Patient's Name	Amount Given	Given By (Signature)	Witnessed By (Signature)	Stock Balance
19/07/17	*12:40*	*Bag taken to G4*			*ASmith*	

NB a standard controlled drug book will be used and the grey column headings have therefore been adapted for our use

b) Returning EADP's to the Fridge

Immediately after use the Grab bag must be returned to the fridge and Grab Bag log signed:

If the seal <u>is not</u> broken it can be signed by into the book by 1 person

Date	Time	Patient's Name	Amount Given	Given By (Signature)	Witnessed By (Signature)	Stock Balance
19/07/17	*12:40*	*Returned from G4. Tag code:*			*ASmith*	

If the seal <u>is</u> broken it must be checked/restocked as below (see restocking procedure)

c) Restocking procedure

If the tamper proof seal is broken, all items must be checked and restocked according to the contents list (See attached laminates), by 2 trained members of staff.

If no controlled or prefilled drugs were used: (Ketamine/Midazolam/metaraminol), the contents should be checked by 2 trained members of staff and the bag resealed with a tamperproof tag and the new tag number documented in the log, and log signed by 2 trained members of staff.

Date	Time	Patient's Name	Amount Given	Given By (Signature)	Witnessed By (Signature)	Stock Balance
18/07/17	*08:00*	*Grab bag contents checked and resealed, contents as above*			*ASmith*	

If any controlled or prefilled drugs were used: (Ketamine/Midazolam/metaraminol), the following must be documented:

<u>Name of patient</u> and <u>date of birth</u>, <u>to whom the drugs were administered</u> and the <u>amount of each given</u>.

Date	Time	Patient's Name	Amount Given	Given By (Signature)	Witnessed By (Signature)	Stock Balance
19/07/17	*13:30*	*Bag returned from G4, 200mg Ketamine, 5mg midazolam & 2.5mg metaraminol administered to T Carter (DOB 2/2/64)*			*ASmith*	

Controlled or prefilled drugs must then be restocked and signed into the EADP's, in the following way:

The controlled drugs must be signed out of the ward Controlled Drugs book, into the bag documenting which grab bag they are placed in e.g. Bag 1 or Bag 2, and signed by 2 trained members of staff as per standard CD policy.

Name, Form of Preparation and Strength: *Midazolam Injection 1mg/ml (5mg/5ml) ampoule*						
Date	Time	Patient's Name	Amount Given	Given By (Signature)	Witnessed By (Signature)	Stock Balance
16/07/13	*14:00*	*Received from pharmacy*		*JSmith*	*LBrown*	*10*
17/07/13	*09:00*	*1 x 5mg/5ml ampoule transferred to Emergency Anaesthetic Drug Pack 1*		*MJones*	*JSmith*	*9*

The following should then be documented in the corresponding EADP log Book (Book 1 or 2),

- The total amount of Midazolam in the bag
- The total amount of Ketamine in the bag and the batch numbers
- The total amount of Metaraminol in the bag and the batch numbers

The rest of the bag contents must then be checked, bag sealed with a tamperproof tag, tag number entered into the log and signed by 2 members of staff.

Name, Form of Preparation and Strength: *Emergency Anaesthetic Drug Pack (EADP)*						
Date	Time	Patient's Name	Amount Given	Given By (Signature)	Witnessed By (Signature)	Stock Balance
17/07/17	*09:00*	*2x Ketamine10mg/ml (100mg/10ml) syringe BN: XYZ, EXP: 09/2018x2*		*M Jones*	*JSmith*	*2*
		2x Midazolam 1mg/ml (5mg/5ml) ampoule BN: LMN, EXP: 09/2018x2		*M Jones*	*JSmith*	*2*
		2x Metaraminol 2.5mg/5ml syringe BN: OPQ, EXP: 09/2018x2		*M Jones*	*JSmith*	*2*
		Tag code: ABCDE1		*MJones*	*JSmith*	

7. DAILY CHECKS

EADP's must to be checked immediately after morning and evening handover, by the registrar carrying bleep 2003 (or consultant if registrar is not available). If the tag is in place, the logbook should be signed by this doctor to indicate the bag has been checked.

'Grabs bags checked' to be included in the daily morning and evening safety briefs.

Date	Time	Patient's Name	Amount Given	Given By (Signature)	Witnessed By (Signature)	Stock Balance
18/07/17	08:00	Seal checked and correct			*THarvey*	

Appendix A: EADP content

The 2 x EADP's will include the following:

1. Prefilled Ketamine 10mg/ml (x 2 10ml syringes)
2. Prefilled Metaraminol (1mg/ml)
3. Pre-filled saline flushes x 2
4. Pre-filled Adrenaline (100micrograms/ml)
5. Pre-filled Glucose 50% (50mls)
6. Pre-filled Sodium bicarbonate 8.4% (50mls)
7. Other drugs, presented in ampoules
    a. Rocuronium (10mg/ml)
    b. Suxamethonium (50mg/ml)
    c. Propofol (10mg/ml)
    d. Midazolam (1mg/ml)

Appendix B: EADP Risk Assessment for controlled drug use

Midazolam in Airway Trolley on Critical Care

Midazolam is a Schedule 3 Controlled Drug and although according to the Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001 does not require entry in a CD register or custody in a locked controlled drugs cupboard Portsmouth Hospital Trusts controlled Drugs Policy does require increased security for midazolam due to local issues with CD incidents and theft/abuse of CDs in the past.

Midazolam and anaesthetic drugs are stored within the pharmacy drawer of airway trolleys on critical care. Trolleys are not always under direct supervision of staff members and could be accessed by non-clinical staff and visitors.

There is also no written record of the quantities of Midazolam stored the within airway trolleys and no accountability or audit trail of its use. The trust and individual doctors could be legally vulnerable if evidence of harm to persons inside and outside the organisation from illicit trade or use was discovered.

Risk Classification pre assurance mechanism: Likelihood 1, Consequence 3.

Assurance mechanism: Midazolam to be removed from airway trolleys with introduction of Grab Bags containing prefilled anaesthetic drugs.

Risk Classification post assurance mechanism: Risk removed completely

Midazolam and anaesthetic drugs within current grab bags, and drugs being transferred to ward area by transfer teams:

Midazolam and anaesthetics drugs, stored within unsealed grab bags, are taken off the intensive care unit by doctors attending crash calls and transfer teams attending ward incidents e.g. ketamine and are consequently do not have safe custody arrangements and written records of quantities within bags, taken off unit by other staff or amounts administered can be incomplete. Quantities of unused drugs when concentrated forms are used e.g. Ketamine are often unaccounted for. There is a risk of Grab Bags or individual drugs being left on wards or lost, with one incident occurring in recent months. The trust and individual doctors could be legally vulnerable if evidence of harm to persons inside and outside the organisation from illicit trade or use was discovered. None of the above risks are listed on the trusts risk register and is not currently covered by Trust cd policy meaning the trust does not have to support the event in the events of a legal/criminal dispute.

Risk Classification pre assurance mechanism: Likelihood 3 – Consequence 3

Assurance mechanism: EADP's will now contain all controlled and anaesthetic drugs normally required for emergency use, and where possible in the correct concentrated and volumes for clinical use, largely removing the need for drugs to be transferred outside of the sealed grab bags from critical care.

All drugs will be kept within a grab bag which is sealed with a tamperproof tag and stored inside the locked pharmacy cupboard on critical care when not in use, reducing the risk of interference, loss or theft of drugs being transported for use outside of critical care.

A robust procedure of logging the location of bags when removed from the locked pharmacy store has been developed. This policy provides:

- A restocking procedure where all drugs including controlled drugs are checked by 2 trained members of staff,
- A robust audit trail of the movement and location of drugs/grab bags at all times and the quantities of controlled drugs used.
- A twice daily checking procedure to assure the location of contents of each EADP is known.

This procedure should mitigate the risk of loss of individual drugs, loss of entire grab bags and their contents, provides an appropriate audit trail for controlled drugs and reduces the risk to individuals and the department in the event of legal/criminal dispute.

Risk Classification post assurance mechanism: Likelihood 2 – Consequence 3

Unlicensed Metaraminol and Ketamine prefilled syringes

The metaraminol and ketamine pre filled syringes, contained within EADP's are manufactured locally and therefore are unlicensed drugs. Consequently a record of their use is required in case of batch recall.

Assurance mechanism: batch numbers and patients are to be recorded in Grab Bag logbook when unlicensed drugs are administered.

Risk Classification post assurance mechanism: Likelihood 1 – Consequence 2

Controlled Drugs contained within EADP's

The EADP contains controlled and anaesthetic drugs, including Ketamine (Schedule 2 Controlled, which requires custody arrangements to conform with Misuse of drugs legislation and trust policy) and Midazolam (A schedule 3 Controlled drug, which trust policy demands must have increased security and safe custody arrangements made). However the EADP's need to be available for use in emergency situation within and outside of critical care and so must be easily accessible to individual members of the medical and nursing staff in this scenario. This requires them to the stored outside of the key locked controlled drugs cupboard for speed and ease of access as is normal practice for controlled drugs at Queen Alexandra hospital. This creates the risk of loss, theft or interference with controlled and anaesthetic drugs, opening individual medical and nursing staff as well as the department open legal liability, without the guarantee of trust support as it is outside of Trust CD policy and is not listed on the departmental risk register.

Assurance Mechanism: All drugs will be stored with a grab bag which is sealed with a tamperproof tag inside a locked pharmacy cupboard on critical care when not in use.

A robust procedure of logging when bags are taken from and returned to the unit has been developed, see appendix 1. This policy also includes a daily checking and restocking procedure, where all drugs including controlled drugs are checked by 2 trained members of staff, mitigating the risk of loss of individual drugs, loss of grab bags and there contents and provide a robust audit trail of the movement and location of drugs/grab bags at all times and the quantities of controlled drugs used, in line with trust CD policy, removing the risk of loss of trust backing in the event of legal/criminal dispute.

Risk Classification post assurance mechanism: Likelihood 2 – Consequence 3

Wrong drug and dose/dilution errors.

There is a risk of wrong drug administration or dose errors when drugs are incorrectly drawn up, diluted and labelled, with the potential for serious patient harm. This risk is increased when drugs are prepared in emergency situations by members of staff unfamiliar with the drugs being requested or distracted by clinical and resuscitation tasks.

Drug errors are an infrequent but well known risk to patients, frequently highlighted in Datix, National Patient Safety Association and Safe Anaesthesia Liaison Groups reports.

Risk Classification pre assurance mechanism: Likelihood 3 – Consequence 3

Risk Assurance mechanism:

Combined with risk assurance mechanism below.

Risk Classification post assurance mechanism: Likelihood 2 – Consequence 3

Delay in availability of emergency intubation and resuscitation on intensive care.

Unforeseen emergency situations are not infrequently occurring events in a large district general hospital such as Portsmouth, often requiring timely resuscitation and emergency airway support. Currently anaesthetic drugs are stored in a number of different locations within critical care because of the practicalities of storage of drugs, legal and manufacturers requirements. Many of these drugs are currently only available on concentrated forms, which require dilution, and all must be drawn up individually before they can be used. When combined these issues can lead to a significant delay in the availability of anaesthetic drugs for emergency use, especially outside of critical care when distances are larger, creating the potential for serious patient harm.

Risk Classification pre assurance mechanism: Likelihood 3 – Consequence 3

Risk assurance mechanism:

A commonly used drug list has been developed and where possible drugs on this have been sourced either in:

- Pre-diluted and prefilled syringes where possible if appropriate stability data is available, and costs associated with their production is not prohibitive.
- The appropriate concentration for clinical use, which can then be drawn up for use without dilution

Where prefilled syringes cannot be sourced or appropriate concentrations cannot be produced, a clear and concise standard operating procedure and laminate has been procedure and included within the grab bag to mitigate the risk of wrong drug and dilution errors.

Risk Classification post assurance mechanism: Likelihood 1 – Consequence 3

	CONSEQUENCE				
LIKELIHOOD	**1 Insignificant**	**2 Minor**	**3 Moderate**	**4 Major**	**5 Catastrophic**
1 – Rare Not expected to occur		**Use of Unlicensed drugs (Ketamine/Metaraminol prefilled syringes)**	**Delay in Emergency Drug Availability** ***(Midazolam in Airway trolley – risk removed)****		
2 – Unlikely Occurs infrequently			**Wrong drug or dose/dilution errors** **Loss theft or interference with Controlled/anaesthetic drugs**		
3 – Possible Once or twice a year					
4 – Likely Hazard will occur but is not persistent. There are no issues of custom and practice.					
5 –Certain Constant threat is custom and practice					

*Risk removed