Division	**Operations**	**Ref. No.**	**EXA-RGH-007**
Department	**Global Health**		
Title	**Dangerous Drugs**		

1 PURPOSE

This policy governs the acquisition, storage, handling and handover of dangerous drugs used by the Royal Australasian College of Surgeons (RACS) on the RACS Global Health Program. When handling dangerous drugs RACS acts in accordance with the *Drugs, Poisons and Controlled Substances Act 1981 NO 9719 of 1981 Authorised version incorporating amendments as at 1 July 2020* (Vic) ('the Act') and the relevant regulations, the *Drugs, Poisons and Controlled Substances Regulations 1995 2017 S.R NO. 29/2017 Authorised Version incorporating Amendments as at 23 July 2020* (Vic) ('the Regulations'). A failure to comply with the legislation and regulations will render RACS liable to prosecution.

2. SCOPE

Global Health Programs are conducted with the assistance of medical specialists, surgeons anaesthetists and nurses who volunteer on the program, who often travel in Visiting Medical Teams to program locations across the Asia-Pacific region. These teams often carry with them a range of dangerous drugs for use when providing medical and surgical services. RACS is responsible for ensuring that the acquisition, storage and handling of dangerous drugs by the Global Health Medical Equipment Coordinator or another designated registered nurse, and their hand over to nominated volunteer team member, is compliant with The Act and Regulations.

This policy therefore guides the work of the Global Health Medical Equipment Coordinator or another designated registered nurse in Australia when procuring, storing, and handling dangerous drugs and includes the handover of dangerous drugs to volunteer specialists and nominated team members participating in RACS Global Health programs.

3. DEFINITIONS

3.1. Schedule 8 (S8) Poisons

S8 poisons are drugs with strict legislative controls including but not limited to morphine (MS Contin, Kapanol), pethidine, oxycodone (Oxycontin, Endone, Proladone), methadone (Physeptone), hydromorphone (Dilaudid), flunitrazepam (Hypnodorm), fentanyl (Durogesic, Sublimaze*).*

Schedule 8 Drugs: describes those medications which are listed in Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) which is incorporated within the Drugs, Poisons, and Controlled Substances Act 1981. Schedule 8 drugs are also known as drugs of addiction[1].

3.2 Schedule 4 (S4) Poisons

S4 poisons include other drugs for which prescriptions are required, including but not limited to cardiovascular drugs, antibiotics and nitrous oxide.

Schedule 4 Drugs of Dependence: those medications which are listed in schedule 4 of the SUSDP which is incorporated within the Drugs, Poisons, and Controlled Substances Act 1981. Schedule 4 Drugs of Dependence describes the Schedule 4 drugs that are also listed in Schedule 11 to the Drugs, Poisons, and Controlled Substances Act 1981 and are subject to misuse and trafficking e.g. benzodiazepines, dextropropoxyphene, midazolam. To avoid confusion these Schedule 4 drugs of dependence are **not** to be referred to as S11[2]

[1] Epworth Medication Guidelines: Medication Supply Protocol Doc ID 5411; Version 0.0

[2] Epworth Medication Guidelines: Medication Supply Protocol Doc ID 5411; Version 0.0

3.3 Schedule 2 and 3 (S2 & S3) Poisons

S2 & 3 poisons are those that may only be supplied (in an open shop) by pharmacists.

3.4 Drugs of Dependence

The Act describes 'drugs of dependence' as all S8 poisons as well as S4 poisons that are subject to misuse and trafficking, e.g. benzodiazepines, dextropropoxyphene and anabolic steroids.

This means a substance that is:

(a) a drug – (i) specified in column 1 of Part 1 of Schedule Eleven; or (ii) included in a class of drug specified in column 1 of Part 1 of Schedule Eleven; or

(b) any fresh or dried parts of any plant specified in column 1 of Part 2 of Schedule Eleven; or

(ba) prescribed as a drug of dependence in accordance with section 132AA whether specified as included in Part 1, Part 2 or Part 3 of schedule 11; or

(c) a drug –

(i) specified in column 1 of Part 3 of schedule Eleven; or

(ii) included in a class of drug specified in column 1 of Part 3 of Schedule 11

and includes-

(d) any form of a drug specified in column 1 of Part 1 or column 1 of Part 3 of Schedule 11, whether natural or synthetic, and the salts, analogues, derivatives and isomers of that drug and any salt of those analogues, derivatives and isomers; and

(e) any-

(i) drug specified in, or drug included in column 1 Part 1 or column 1 of Part 3 of Schedule Eleven, whether natural or synthetic; or

(ii) salts, analogues, derivatives, or isomers of a drug specified in column 1 of Part 1 or column 1 of Part 3 of Schedule Eleven; or

(iii) salt of any analogue, derivative or isomer mentioned in sub paragraph (ii) – contained in or mixed with another substance;[3]

3.5 Cold Chain

The medication is to be maintained in the range of 2-8 degrees celsius at all times

3.6 Medication

Including medicine, scheduled poison, drug, over-the-counter medicine, complementary and alternative medicine.

3.7 Nurse

Registered Nurse, Registered Midwife or Enrolled Nurse (as defined in the regulations) means a registered nurse or an enrolled nurse – not including an enrolled nurse with a notation on registration indicating that he/she is not qualified to administer medication

[3] Drugs Poisons and Controlled Substances Act 1981 No. 9719 of 1981 (Vic) p13-14

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4. POLICY STATEMENT

RACS Global Health's vision is that safe surgical and anaesthetic care is available and accessible to everyone.

In supporting this vision, the RACS Global Health Medical Coordinator and associated staff, ensure that dangerous drugs are handled in strict accordance with the Act and the Regulations at all times, as follows:

4.1 Acquisition of Dangerous Drugs/Drugs of Dependence/Medications

The Medical Equipment Coordinator or another designated registered nurse, is responsible for ordering and taking possession of dangerous drugs/drugs of dependence. Any dangerous drugs/drugs of dependence received from a pharmacist or other relevant supplier for use on a Global Health program should be signed in by the Medical Equipment Coordinator and/or by and with another designated registered nurse.

4.2 Receiving Dangerous Drugs/Drugs of Dependence/Medications

When dangerous drugs/drugs of dependence/medications are delivered to the Medical Equipment Room, it is the Medical Equipment Coordinator's responsibility (or that of the designated registered nurse) to verify the quantities ordered and received and to demonstrate accountability by signing and dating the delivery docket and invoice. When receiving Schedule 8 and Schedule 4(controlled drugs), a registered nurse must receive and sign for the medications, the S8/S4 drugs must be stored in the drug safe, counted in by two designated registered nurses and signed for in the Controlled Drug (S8/S4) Administration Register. The transaction is entered and balances checked.

4.3 Medications Requiring Refrigeration

Medications requiring refrigeration are delivered to the Medical Equipment Room securely packaged in a fridge bag or Styrofoam container to maintain the cold chain. The package contains only refrigerated medication. When delivered the refrigerated medication is placed in the medication refrigerator.

4.4 Disposal of Dangerous Drugs/Drugs of Dependence/Medications

Medication is date checked once per month, out of date medication is discarded by emptying ampoules of contents and disposing ampoules and contents into appropriate sharps containers. S8 drugs must **NOT** be destroyed unless:

- The destruction is witnessed by another person, being a medical practitioner, surgeon, or nurse: however the authorised health practitioners cannot include a combination of 2 nurses where any one of them is **not** a nurse practitioner[4].
- The person(s) destroying the drug ensures that the following information is recorded in Controlled Drug Administration Register, in respect of the drug immediately after its destruction, fullnames and signatures of the person and the witness to the destruction, the trade name or approved name of the drug, the amount, strength of the drug,the date and time of the destruction, the amount of the drug (if any) now remaining in stock on the premises at which the drug was destroyed.

[4] Drugs, Poisons and Controlled Substances Regulations 2017 Part 14 – Destruction of Schedule 8 poisons and Schedule 9 poisons pg 122

4.5 Storage of Dangerous Drugs/Drugs of Dependence

Prior to handing over the dangerous drugs/*drugs of dependence* to the nominated team member, RACS is responsible for the safe and appropriate storage of the drugs. All keys and combinations must not be accessible to or known by unauthorised persons. Keypads should be fitted with view shields if there is a possibility that the combination could be overseen.

4.5.1 S8 Poisons

The Regulations require S8 poisons (labelled 'Controlled Drug') to be stored in a lockable storage facility that provides not less security than:

- being constructed of mild steel plate of 10 mm thickness;
- being constructed with continuous welding of all edges;
- having a door of mild steel plate of 10 mm thickness, swung on hinges welded to the door and body of the cabinet, with the door being flush fitting with a clearance around the door of not more than 1.5 mm;
- being fitted with a fixed locking bar, welded to the inside face of the door near the hinge edge, which engages in a rebate when the door is closed;
- being fitted with a 6-lever lock securely affixed to the rear face of the door and securely attached to a wall or floor in such a manner that it will resist attack by hand tools for 30 minutes or power tools for 5 minutes;
- S8 poisons must not be stored with any other items (e.g. money) other than Schedule 4 drugs of dependence. It is an offence to store S8 poisons with anything (including money) other than drugs of dependence.

The medication safe is only used for the storage of S8/S4 medication. All S8/S4 medication are stored in the medication safe. Due to the nature and abuse potential of these medications there are additional legislative requirements regarding the storage, access, documentation and recording of transactions for medication stored in the medication safe[5]., as follows:

- the Medication safe can be accessed by authorised persons, a nurse in the presence of another authorised person (nurse or doctor);
- all transactions and balance checks are recorded in the Drug Administration Book;

The Drug Administration Book entries must be completed in full and include: medication strength and form, discarded/disposal of drugs, transfer or stock in/out, balance of the medication, signature, printed name, and designation;

The two people involved, sign the entry in the Drug Administration Book and print their full name legibly. When totals are transferred from page to page in the Drug Administration Book. or from an old to a new book the entry is signed by the authorised person making the transfer. The balance of the medication is checked and recorded after each transaction. The balance recorded in the Drug Administration Book must always coincide with the actual stock on hand. Entries in the Drug Administration Book are not to be altered or obliterated. An entry made in error is ruled out with a single line and date, time, initialled, and a new correct entry written on the next available line

[5] Epworth Medication Storage Protocol Doc ID 5710

Completed Drug Administration Books are filed in the Medical Equipment Room

On **NO** occasion are S8/S4 drug stock left unsecured and out of the safe.

4.5.2 S4 Poisons

Due to the nature and abuse potential of these medications there are additional requirements regarding the storage, access, documentation and recording of transactions for S4 medications, as described above for S8 medications

The Regulations require S4 poisons (Prescription Only Medicine) to be stored in a lockable storage facility (e.g. cupboard, drawer, fridge or filing cabinet). The Act strongly recommends that script pads (and pages for computer-generated scripts) be similarly secured.

Currently the specified S4 drugs of dependence are: Oral benzodiazepines (Temazepam, Midazolam, Clonazepam, Nitrazepam Diazepam, Oxazepam etc), Codeine 30mg or less and with another ingredient (e.g. Panadeine Forte), Tramadol

4.5.3 S2 & S3 Poisons

The Regulations recommend that S2 and S3 poisons (labelled Pharmacy Medicine or Pharmacist Only Medicine respectively) should be stored and handled in a similar manner to S4 poisons.

4.5.4 Drugs of Dependence

The *Act* states that drugs of dependence may be stored in the same manner as other S4 poisons or in the drug cabinet with S8 poisons.

4.6 Health Services Permit

In order to purchase or obtain certain scheduled poisons, RACS is required to hold a Permit to Purchase or Obtain Scheduled Poisons for the Provision of Health Services – Health Services Permit (HSP). A permit holder must develop and maintain a Change or Review Form with an allocated tracking code (Formally Poisons Control Plan), in order to hold a permit. The HSP allows drugs to be purchased by or supplied directly to RACS. Any drugs received become the responsibility of RACS and are subject to the controls specified in the conditions of the permit.

The HSP will identify one or more Responsible Person(s) who must ensure compliance with the conditions of the permit and the contents of the Poisons Control Plan. In RACS' case, the designated Responsible Person is the Medical Equipment Coordinator. The *Regulations* state that the Responsible Person will act in the role of agent of the body that holds the permit and, as such, will be authorised to possess those S4 and S8 poisons as named on the licence to the extent and for the purpose specified in the permit.

The responsibilities of the Responsible Person include:

- ensuring that the permit holder complies with the conditions of the permit;
- notifying the Department of Human Services (DHS) of any amendments which may be required to the permit or the conditions of the permit (e.g. change of name of permit holder, change of address, change of Responsible Person);
- maintain the Poisons Control Plan; provide annual confirmation (at the time of permit renewal) that the permit holder is operating in a manner consistent and compliant with the Poisons Control Plan; and
- notify the Department of Human Services of any amendments to the Poisons Control Plan.

4.7 Handover of Dangerous Drugs

Dangerous drugs/drugs of dependence should be secured and handed/sent over .to the nominated responsible team member, as per requirements of The “Act”. This is usually, but may not always be the team anaesthetist. The drug case is securely padlocked. All dangerous drugs are transferred in locked containers and secured with tamper evident cable ties and combination locks. The code to the combination lock/locks can be sent electronically to the Volunteer Team Member who will be directly responsible for the safety of the dangerous drugs/drugs of dependence.

4.8 Reporting

Following the requirements of The Act, where an S8/S4 drug of dependence count discrepancy has been identified, it is necessary to:

1. Alert the Head of Global Health
2. Ensure discrepancies are immediately and thoroughly investigated, including conducting a recount of all the S8 and S4 drugs of dependence medications; and corelating that with the last transactions.
3. Determine, where possible the cause of the discrepancy, and detailing that in the Drug Administration Book
4. Identify where the cause of the discrepancy cannot be identified and ensure further investigation is undertaken
5. Generate an Incident Report
6. Report all unresolved discrepancies involving loss or theft of scheduled poisons to the Department of Health and Human Services and/or the police. This is a mandatory reporting requirement.

5. ASSOCIATED DOCUMENTS

Global Health Program Manual

Global Health Volunteer Manual

Approver International Engagement Committee
Authoriser Council