Protocol for the use of S4 drugs for cosmetic procedures by

Nurse Practitioners

The Poisons Schedule and the use of S4 drugs

Many medical products used in cosmetic procedures, such as botulinum toxin (Botox), collagen, hyaluronic acid (Hylaform, Restylane), other non-permanent fillers and lignocaine, are classified in the Poisons Schedule as S4 drugs. Their use is controlled in NSW by the Poisons and Therapeutic Goods Act (1966) in order to protect the health and welfare of the community.

The Act requires that S4 drugs be supplied only on the written prescription of a medical practitioner. The Act also restricts control, storage and dispensing of S4 drugs to medical practitioners and pharmacists.

Under the Act, a medical practitioner may supply an S4 drug to a nurse practitioner to subsequently administer to a patient, as long as the patient is under the direct care of the medical practitioner and written patient-specific authorisation to administer the drug has been given to the nurse.

A medical practitioner may not supply an S4 drug to a nurse for administration to a patient who is not under the direct care of that medical practitioner. A nurse may not administer an S4 drug to a patient unless written authorisation has been given by a medical practitioner to administer the substance to that specific patient.

Protocol for the use of S4 drugs in cosmetic procedure

1. Initial consultation with a medical practitioner

The patient is assessed by the medical practitioner as for a normal medical consultation, including a clinical history, and a record of the patient's medications and allergies. A plan of management is decided and must include a discussion of potential side effects and complications of any procedures or drugs to be used. The patient must give informed consent before undergoing any procedures.

2. Administration of S4 drugs

Once the medical practitioner has determined a plan of management, an appropriately trained and qualified nurse (see below) may administer S4 drugs according to the medical practitioner's written instructions. The medical practitioner's prescription should incorporate a maximum limit (eg, the number of units of Botox) and the specific area in which the product is to be used. The medical

practitioner should be immediately contactable to deal with any problems that may occur related to the administration of the drug.

3. Medical practitioner review of the patient

The medical practitioner must review the patient in the following circumstances:

3.1: when a new S4 drug is to be used (eg, Restylane in a patient who has previously had Botox)

3.2: when any adverse event or unexpected outcome of treatment occurs

3.3: when more than 12 months has elapsed since the last medical consultation in which the S4 drug was prescribed.

Minimum standards for nurses who administer S4 cosmetic drugs

A nurse practitioner who administers S4 drugs should have:

1. Full registration with the Nurses and Midwives Board, New South Wales

2. A current certificate in cardiopulmonary resuscitation and competence to manage emergencies such as anaphylactic reactions to drugs

3. Appropriate training in safety and sterility protocols relevant to injections.

4. Training and certification for administration of each individual cosmetic product that is used. This training may be provided by the distributors of the products or other appropriate organisations, such as the Cosmetic Physicians Society, or other medical bodies that offer a training programme for aesthetic nurses.

The nurse may only carry out the written instructions of the medical practitioner.

The nurse should record in the patient's notes how and where the S4 drug was administered, and the dose.

It is recommended that nurses do not inject permanent fillers such as polylactic acid (Newfill), acrylic hydrogel (Dermalive) and polyacrylamide (Aquamid)

Medicolegal issues

Medical practitioners

Medical practitioners who supply S4 drugs to nurses but have no input into the clinical management of the patient, or no physical presence on the premises at which the drugs are injected into the patient, are in contravention of the law and liable to prosecution.

It is recommended that medical practitioners check with their indemnity insurance company to ensure that any nurses employed by them to administer S4 drugs are covered by their policy.

Nurse practitioners

Nurses who function autonomously to store, prescribe and dispense S4 drugs purchased for them by medical practitioners are doing so in contravention of the law. This is outside the nursing scope of competency and practice.

Nurses who treat patients who have not been assessed by a medical practitioner prior to treatment are in contravention of the Poisons and Therapeutic Goods Act.

Nurses who perform injections of S4 drugs without a written prescription from the physician are contravening the law.

Nurses operating outside this advice may find they are not appropriately covered, either professionally or industrially, if a complaint is made by a patient. Most nurses do not have personal indemnity insurance, and instead rely on their employer's professional insurance. In the case of a complaint, the insurance company and the Nurses and Midwives Board would investigate whether the nurse was educationally prepared to perform the procedure and whether it comprised an appropriate scope of practice. If the nurse's actions were found to be inappropriate, the nurse may stand to lose his or her registration. The insurer may also decline to cover the nurse if the nurse's training for the particular procedure is not extensive and well documented, leaving the nurse personally liable for all legal expenses.

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