Statement in relation to the Public Consultation Paper from the Medical Board of Australia concerning registered medical practitioners who provide cosmetic and surgical procedures

[redacted]

May 2015

Confidentiality

Given the sensitive nature of this topic, this submission is made in confidence. The authors agree to the publishing or making public of any or all of the information contained so long as it is done in a fully de-identified fashion. This would include deletion of the face page and Section 2 of this document. This submission is not to be used in legal proceedings without the authors' prior approval. The authors acknowledge that the submission represents their opinions on these issues at this current point of time, but acknowledge that these opinions may change in the future. The authors look forward to guidance from the Board as to what should constitute the proper legal and professional standards of care in the future.

1.0 Introduction

We make this submission in regards to section 7 of the 'Option 3 draft guidelines' of the Public Consultation Paper from the Medical Board of Australia concerning registered medical practitioners who provide cosmetic and surgical procedures ('paper'), which concerns the '*prescribing and administering of Schedule 4 (prescription only) cosmetic injectables'*[1].

We strongly submit that 'option 3' is the correct approach for AHPRA to take in order to better the standard of care offered to patients in this completely elective field of medicine.

We submit answers to questions 8, 9, 10, 13, 17.6 and 17.7, 18 of the paper.

The submission comprises four parts.

First, to provide context for our submission, we provide brief details about our backgrounds.

Second, we discuss some details about the area of cosmetic injectable medicine to provide insight and principles that we consider of relevance to the formulation of guidelines for medical practitioners in this area.

Third, we answer the questions (8 - 17.7) drawing on the existing regulations in place in the state of Victoria to illustrate why we believe they have failed to translate into safe clinical practice for the public.

Finally, we discuss question 18 and make suggestions about additional areas the guidelines could cover in the interest of clear guidance for practitioners and safer care for patients.

[1] Attachment B – Option three – Draft guidelines, section 7

[redacted]

[redacted]

[redacted]

3.0 Our observations of the working culture of practitioners within the cosmetic industry

At the outset we would like to state that cosmetic injectable medicine is an area where explicit guidelines can have a significant impact on the safety afforded to patients. There are strong conflicting commercial interests in this area, and many practitioners, in our observation, will tend toward cutting corners to increase their profits. This is completely elective medicine, done for purely cosmetic reasons, and with considerable financial incentives for the practitioners and clinic owners. This is an area of medicine where patient protection from governing bodies is most relevant and most important.

During our years working in this industry, we have found that – despite some very clear legal and professional obligations that apply to this area - there

remains immense variability in the level of compliance with these obligations by practitioners who undertake cosmetic injectable work.

We believe these variations exist due to complex factors. The culture in this industry and amongst its practitioners is often one of lax standards. The drug companies seem to care very little about the regulations regarding supply of the drug to registered practitioners. They also train practitioners (such as nurses) to perform injections but provide them with little to no training in respect to the extent of the risks and the constraints of their legal and professional scopes of practice. Little mention is made in the training about the need to be properly supervised by a qualified doctor.

Many practitioners order nurses to administer Schedule 4 poisons and surgical implants without proper assessments, whilst being fully aware that these procedures are going to be carried out in unsupported and ill-equipped locations, most often in parlors owned and run by beauty therapists or hair salons. Increasing numbers of non-medical commercial entities and chains are now also entering this field of practice as it is seen as lucrative and unregulated. These beauty therapists, entities and chains employ like-minded nurses and doctors.

Keeping up with the legal and professional regulations in this field with proper staffing, training, facilities, equipment and medical care, comes with significant commercial costs.

In our observation, many practitioners exhibit an intentional disregard of the legal rules and regulations that apply in this field, choosing instead to favor commercial interests, whilst openly labeling AHPRA as a ‘toothless tiger’ which is unlikely to ‘do anything to enforce breaches in the industry’. These practitioners are the first to say that the regulations, including the guidelines being currently proposed, are pointless and unnecessary and do not reflect ‘modern medical practice’. We submit that these assertions about ‘unrequired’ or ‘outdated’ regulations could not be further from the truth. Cosmetic injectable treatments carry significant risks (many of which require

time dependent emergency treatment) and are completely elective in nature. Strict regulation is incredibly important in this field especially given the significant and growing commercial conflicts of interest that exist.

Many practitioners exhibit a non-intentional but nevertheless reckless or negligent disregard of the rules. On the other end of the spectrum, there are certainly many that are genuinely confused by what the law and professional standards require of them. A minority of practitioners, in our experience, actually apply stringent standards of care and do their best to protect patients, albeit at the expense of profits, and fierce competition from other practitioners who offer cheaper prices to patients, which are made possible through lax standards. We believe from our experience that the public, usually seeing Australia as a properly regulated medical workforce, do not tend to - in general - question whether cheaper prices in certain facilities are due to lax standards. In other words, in our opinion, patients rely on the belief that the industry is properly regulated when they make decisions about which service they choose on the basis of price. Furthermore, advertising regulations for the medical workforce, make it difficult to advertise on the basis of suggesting to the client that one medical practice has better professional standards than another.

This is an area in medicine where we absolutely agree that specific guidelines are required to define a clear and enforceable standard of practice.Clear guidelines are required, for this is an area where the standards, aided by the culture of laxity, tend to quickly slip to the lowest common denominator on the grey part of the spectrum of what practitioners feel is the minimum required care for the patients. Also contributing to this problem is the fact that patients and the public in general are largely ignorant about the applicable regulations and the standards they should expect. Most patients, for example, do not know that a medical consultation is required before prescription of a new course of treatment with cosmetic injectables for any particular indication.

It is an area where the predominant culture in the industry is to ‘gloss over’ even the most minimal legal and professional requirements, when really

practice in the field of cosmetic medicine (owing to its unique elective circumstances) should instead demand the best available standard of care possible.

Guidelines are a way to help put the industry back on the right track in terms of amending its culture.

We will give specific observations and suggestions in relation to these findings throughout this submission.

4.0 'Fillers are different' - Not all 'Cosmetic Injectables' work in the same way or carry the same risks

Though not clearly defined in the paper, we consider the term 'cosmetic injectables', as utilised in section 7 of the draft guidelines, to encompass all cosmetic medical treatments that are delivered to the body by the mode of injection into or under the skin. In common routine practice, this term would apply to such treatments as Botulinum Toxin, dermal filler injections (both permanent and temporary) and much less commonly, poly-L-lactic acid injectable treatments.

The biggest difficulty of using the term 'cosmetic injectables' to group these treatment modalities together, is that it implies that each individual treatment should have the same regulatory considerations. It is important to remember that these treatments are used to treat different indications, carry very different risks and the technique of administration is very different (as should be the training requirements).

Botulinum Toxin treatments are injected intramuscularly to temporarily weaken the contraction of muscles. The indications are varied and include treating fine wrinkles (i.e. crows feet, frown lines, bunny lines), dynamic muscle contractions (such as masseter treatments for increased masseter bulk or teeth grinding), migraine headaches or hyperhidrosis. The risks of Botulinum Toxin injection include allergic reaction, unpredictable effect

(particularly in patients with pre-existing neuromuscular conditions), and the effects of local or distant spread of the toxin. Most importantly, the applicable risks differ depending on the indication and site treated together with the dosage used.

Dermal fillers on the other hand are *injectable implants*. They come in temporary or permanent forms, and can and do have significant risks – especially when administered by inadequately or untrained individuals. The more serious risks of fillers include intravascular injection (which can result in permanent blindness, skin necrosis, and rarely stroke, severe scarring and deformity), and the risk of infection (which can result in acute abscess, tissue loss, and chronic bio-film formation). In the case of intravascular injections, it is important to note that treatment to reduce the impact of the vascular blockage's complications **is a time critical emergency treatment,** as the clinician must take all possible steps to dissolve the filler and re-establish the effected circulation of skin, deeper tissues, or organs such as the eye. In the case of allergic reactions, anaesthetic reactions, and severe neurogenic shock (vasovagal collapse) - these can be life threatening complications and adequate training, protocols, equipment, medications and facilities are vital for resuscitation when required. Perhaps one of our greatest concerns with the consultation paper is the suggestion that injectable dermal fillers should be regulated only owing to the fact that they are Schedule 4 poisons (a classification they carry because they contain local anaesthetics). Dermal fillers are far more than just Schedule 4 poisons, they are in fact subcutaneous or intradermal **surgical implants,** and should be regulated in this regard also.

We have attached to our submission a recent paper reviewing just the reported occurrence of blindness as a complication after dermal filling injections, and note that 44 cases of blindness have been reported in Korea

alone. The incidence of this and other complications continues to rapidly increase in recent times[2].

On page 17 of the paper, it is stated that:
'Adverse events and harm following minor (non-surgical) cosmetic procedures are less common and less severe as these procedures do not require a general anaesthetic and do not include cutting beneath the skin (greatly reducing the likelihood of infection).'

We submit that this differentiation of risk based on whether the procedure does or does not cut the skin does not hold true in the case of dermal filler treatments. Whilst dermal filler injections do not require cutting of the skin, *they do* require piercing of overlying skin or mucous membrane to deliver a surgical implant to the sub dermal/subcutaneous or deeper tissues adjacent to vital structures such as nerves, arteries, veins, the parotid duct, bones and muscles. This carries significant risks due to the potential physical effect of fillers on the function, structure and viability of human tissues. We submit that the very serious complication of intravascular injection is poorly reported in the industry. It is widespread knowledge within the industry that the majority of clinics in Australia have - at some time or another - experienced one or more vascular occlusion complications, though the rate of reporting of these complications remains relatively low.

It is also relevant to note that not all fillers on the market are temporary and dissolvable Hyaluronic Acid implants. Some are instead permanent implantable materials that carry much more significant risks. It is our submission that permanent filler insertions should never be carried out by nurses, and their use should be limited only to doctors appropriately trained in their use.

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[2] This paper - *Iatrogenic occlusion of the ophthalmic artery after cosmetic facial filler injections: a national survey by the Korean Retina Society* - is attached as Appendix 1.

Cosmetic 'nurse injectors' often inject Botulinum Toxin, dermal fillers, or both. But it is our submission that the regulations for these two procedures should be different to reflect the different modes of treatment.

5.0 Questions

Question 8

Is there evidence that the current regulation of medical practitioners who provide medical and surgical procedures in not adequately protecting the public and not providing clear guidance on the Board's expectations of practitioners?

Yes, we believe there is strong evidence of this in the industry. These treatments can have very significant side effects.

In our experience, it is commonplace in this industry for patients to be treated with injectable cosmetic treatments **without**:

- Proper assessment by a medical practitioner of the patient's mental state, past medical history, and indications for treatment (including a proper physical examination). Often – maybe even usually – there is no proper doctor-patient relationship in place prior to the injection.

- Proper informed consent obtained by a medical practitioner, which takes into account the indication for treatment, the available options, and a clear two way face to face discussion about the material significant risks applicable to the specific patient.

- Proper education of the patient as to what they are having injected (patients are sometimes surprised to be notified by us that they have had a **permanent** filler injected and not a temporary one).

- The proper medical environment for these injections – in terms of universal precautions and without the availability and proper training required to treat the life threatening complications which can rarely result.

- In the case of dermal fillers - the proper medical equipment and expertise required to urgently recognize, treat and monitor the response to treatment of a vascular occlusion (which can result in skin necrosis, blindness and stroke).

Furthermore, without clear guidelines from the Board, we believe many clinicians actively turn a blind eye to safety considerations and regulations for the sake of commercial benefit. The conflict of interest in this field necessitates very clear guidelines in this regard.

We have heard of instances in this industry where:

- Doctors have on-sold, at profit, Schedule 4 poisons to nurses to administer to patients without any interaction with the doctor. These allegations if investigated, could result in serious criminal charges.

- Nurses have shared syringes of filler (which come in pre-packaged quantities) between different patients, comprising a significant risk of blood-borne infection to patients.

- Nurses' routine work practice involves transiting between multiple beauty salons transporting large amounts of Schedule 4 medicines and fillers for administration to prospective clients who will not see a doctor and therefore have not had any prior prescriptions made out for them.

- Patients with significant body dysmorphic disorders have been given repeated and excessive injections of filler for considerable financial benefit disregarding the potential detriment to the patient's well being.

- Patients have sustained serious complications such as skin necrosis, but have been given false explanations as to the cause of these complications by the treating nurse (who has told the patient that the resulting scarring was instead a simple unavoidable skin infection).

- Patients who have been told by nurses and their reception staff at beauty salons (non-medical facilities) that a medical consultation with a

doctor is not required before cosmetic injection treatments as nurses perform these routinely without a doctor's involvement.

Question 9

Does the Board's current code of conduct and the existing codes and guidelines of the professional bodies provide adequate guidance to medical practitioners providing cosmetic medical and surgical procedures?

No

Question 10

How effective are existing professional codes and guidelines in addressing the problems identified by the Board?

In the area of cosmetic injectables, we believe the existing professional codes and guidelines have been terribly ineffective at addressing the problems identified.

This area of medicine is strongly influenced by commercial factors, and we find many practitioners are willing to declare black and white legal responsibilities as 'gray areas', believing that the Medical Board is not interested in policing them.

Consider, for example, the following observations we have made:

- It is very common for nurses to operate out of beauty salons; injecting patients with Schedule 4 products without any treatment orders from medical practitioners.

- It is common for injections to take place **without any discussion** or documentation of the involved risks prior to the injection.

- It is common for practices to advertise with time-limited price discounts for Botulinum Toxin and dermal filler treatments.

- The drug companies that supply Botulinum Toxin and Hyaluronic Acid filler products train nurses on administration independent of any doctor

involvement, and provide little to no education on the regulatory requirements of needing a doctor's involvement in their future practice

- Telemedicine consults occur in this area of medicine and not in others (except for situations of remoteness and emergencies), simply because of the commercial benefit of being able to inject at multiple sites at once, without a doctor located in the vicinity. Such telemedicine consults are often a formality only and last only as much time as is required for the doctor to say hello and give the nurse permission to proceed immediately with an unspecified course of injections. These consultations do not adequately create the level of doctor-patient relationship required for good medical care.

We would say that the existing professional codes and guidelines are failing dramatically in controlling this industry. We think explicit guidelines are essential as the industry is becoming less and less professional by the day.

Question 13
Would consumer education material be effective in addressing the problem?

We think it would be very helpful but not completely effective to restore patient safety without accompanying clear guidelines from the Board for the conduct of medical practitioners.

Many patients have become used to going to beauty salons and skin or laser centres and having injections without seeing doctors. Many have come to believe that this is normal practice, and in our experience, patients coming to our clinic having had treatments elsewhere are often surprised when they see a doctor and are told of the potential risks associated with their proposed treatments. Consumer education in this regard would be very useful to raise the public awareness about the standards they should expect when they undertake cosmetic injectable treatments.

Question 17.6
Should there be further restrictions for patients under the age of 18 who seek cosmetic and surgical procedures?

We have both personally turned away a number of young patients who have come in asking for facial filler or Botulinum Toxin treatments because they are under 18 years of age. We have done this because we enforce a blanket rule at our clinic that unless two doctors have seen the patient and deemed the treatment in the patient's best interests, the treatment will not be administered at our clinic. We have found that adolescent patients who seek these treatments often have insecurities and concern about their appearance, which is very often actually a manifestation of more complex psychological concerns.

Question 17.7
Should a medical practitioner be expected to have a face-to-face consultation with a patient before prescribing Schedule 4 prescription only cosmetic injectables?

Absolutely, yes. It is remarkable to us that this is even a question for discussion, and it shows us just how troubled and affected by commercial motivations this industry has become. Why, other than for commercial reasons, would a doctor be suggesting that a telemedicine consult is appropriate as a standard rule in this area of cosmetic medicine? This is not a matter of convenience because a doctor is operating and the patient needs an emergency treatment for nausea or pain – this is a new elective cosmetic procedure, where often the doctor is doing a recreational activity.

We have heard of incidences in the industry when the doctor called to 'FaceTime' the patient by a nurse has been driving, lying at the beach, or in one case - walking to a train station, at the same time as being required to assess, consent and give an order of approval for a nurse to administer a cosmetic procedure. Is this the standard we want for this field of medicine?

Telemedicine is not the norm of current medical practice outside of this area
In both of our independent non-cosmetic medical practices, both in hospitals and in our clinics, we have only very rarely used telemedicine to consult with patients. The one or two times we have done so, have been in desperate settings where the patient has been rural and there is an urgency to the treatment that necessitates us to forego talking face-to-face at first instance. This is because face-to-face conversations and examinations are irreplaceable in medicine. It is very difficult to establish the appropriate level of doctor-patient relationship required for good medical practice through a telemedicine consult, especially when it is brief and treated as a 'technicality'.

Telemedicine does not allow for a proper examination of cosmetic concerns
Furthermore 'Skype' or 'FaceTime' consultations do not allow a proper assessment of the 3D nature, and contours of the human face – the colour of the skin, its texture, its temperature, the extent of shadows, the palpable feeling of deeper tissues, the assessment of underlying structural support, and assessment for local abnormalities such as infections, inflammatory conditions, deep scarring, lymphatic oedema and impaired circulation, or whether other fillers (including permanent fillers or solid implants) underlay the skin – these are simply impossible to assess over a computer interface.

Furthermore, the medium of telemedicine only shows limited and often poor quality view of both the doctor and the patient which impairs the communication process and inevitably leads to information and cues being missed by either party - information such as body language that would be easily detected by a real face-to-face consultation.

We do not see patients via 'Skype' in our clinics. We do not have nurses see our patients and present to us their findings on the patient via 'Skype'. The only time we do phone orders, are when the treatment is an emergency and we are unable to see the patient (such as – for example – nausea and pain on a hospital PRN medication chart).

Whilst we agree that telemedicine may be appropriate in fields of medicine where urgency of the medical treatment or remoteness of the patient's location in a rural setting are prioritized over a proper assessment, why should cosmetic injectable treatments – which are completely elective, and put the patient at risks of complications for a purely aesthetic aim, be an exception to the rule that we only use telemedicine in severe circumstances?

Allowing widespread 'Skype' or 'FaceTime' consultations promotes an inappropriate doctor-patient relationship in the cosmetic field of medicine.

The doctor-patient relationship is fundamental to the provision of acceptable medical care. These relationships are complex and are reliant on proper rapport, and a mutual understanding between doctor and patient of the shared responsibility for the patient's health care. The doctor-patient- relationship in telemedicine and Internet medicine is inherently different. It is likely, that the doctor and patient will never meet in-person. Can we be certain that patients will be aware of the complexity of this sort of relationship? Will they feel they know where to go when a complication takes place after a procedure? Is this compromise justified in a non-elective and totally cosmetic field of medicine? The obligations and professional standards required of a medical practitioner who is assessing, consenting, and treating a patient for cosmetic purposes should be considered more stringent than those that apply to other areas of medicine. This is certainly the situation at common law, where many cases have held that the standard required of the doctor when consenting patients for cosmetic procedures is far more onerous than when consenting for patients for non-cosmetic procedures.[3]

'Skype' or 'FaceTime' are restricted communication media which impair the doctor's ability to fully assess the psychological state of the patient

Cosmetic consultations are always complex – a doctor needs to consider the patient's medical history, the exact nature of the concern of the patient, the patient's psychological situation, the alternative treatment options available

[3] See for example *D v S* (1981) 93LSJS 405 (SC(SA)), *Shaw v Langley* (unreported, Pratt DCJ, DC (Qld), no 485/91, 24 November 1993, *Dunning v Scheibner* (unreported, Wood J SC(NSW), No 1377607 of 1988

and the expectations of the patient. A vital part of this communication is the development of proper rapport so that the patient can properly express his or her expectations, concerns, fears and psychological insecurities to the medical practitioner. Far from something that can be done on 'FaceTime', this is an incredibly important consultation that can protect the patient who has significant psychological concerns from serious harm, and that should be done in the best environment possible.

The medium of telemedicine only displays a limited view of both doctor and patient on a screen, plus both audio and visual transmission can be interrupted or of poor quality. This impairs or corrupts aspects of the assessment and communication process causing risk of important information (such as sound bites or body language cues) not being transmitted or received by one or other party - information that would be accurately transferred at a real face to face consultation.

Privacy is not guaranteed via consumer Internet tools

'Skype' and 'FaceTime' are not highly encrypted 'industrial' methods of Internet communication (unlike more robust forms of telemedicine systems) and are susceptible to hacking/illegal hijacking of the video and audio stream. This poses a significant risk to a patient's privacy and confidentiality.

We submit that any doctor or nurse who is engaging 'Face time' or 'skype' to issue scripts to patients is not only failing to meet their professional obligations, they are also treating the regulatory framework as a technicality in the interest of commercial gain. This culture puts patients at significant risk and is the wrong message to give to other practitioners working in the industry who want to do the right thing by their patients.

Telemedicine consultations are still meant to be proper consultations

Notwithstanding our arguments against telemedicine in this area of medicine, the fact remains that when telemedicine is applied in other areas of medical practice, it is still supposed to proceed as a usual consultation between doctor and patient. In other words, the consultation proceeds just like a usual

consultation between patient and doctor, and it is only the method of communication that is different in that is occurs via virtual means.

This is not the case with most of the consultations currently occurring in this area of medicine via 'Skype' and 'FaceTime'. Instead of the patient engaging a doctor through telemedicine and having a complete consultation, what is usually occurring is that a nurse is seeing the patient, undertaking the consultation, and then ringing the doctor for an order for administration. The consultation between doctor and patient is truncated at best, and non-existent at worst. What the patient is usually experiencing is instead a 'Skype' phone order.

We submit that this form of consultation is not undesirable just because it utilises telemedicine technology in an elective setting, but also because it encourages an improper and completely truncated consultation between the doctor and the patient, even when it does occur.

We strongly encourage AHPRA to make a ruling in this regard, because given the culture in this industry, the lack of a ruling, once the question has been explicitly raised, will be seen by many as a declaration from AHPRA that the standard of 'Skype' or 'FaceTime' communication is valid.

Question 18
Are there any other elements not included in the draft guidelines at Attachment B that could be included?

Yes, there are many considerations that we would like to discuss. As mentioned multiple times, the Board should consider that this is an industry where, without explicit guidelines, the rules are more often than not likely to be skewed in the favor of commercial interests, at the expense of patient safety.

Here are some suggestions to consider when formulating the guidelines:

i. Guidelines on cosmetic injectable treatments could be further broken down into 'Botulinum Toxin' and 'dermal filler' treatments.

The risks are very different. The indications are completely different. Fillers are not just a Schedule 4 poison (owing to the fact they contain local anaesthetics), they are also an **implant**, and thought should be given to what circumstances nurses should be allowed to administer them, bearing in mind the significant risk of causing vascular occlusion, allergic or inflammatory reaction, or other tissue damage due to the physical effect of the filler. We can't think of other situations in medicine where nurses are administering implants or performing surgical procedures on patients with so much discretion. The risks for filler treatments vary significantly depending on where in the body they are being injected, and the level of expertise of the injector.

ii. Doctors need to make sure they are assessing and ordering treatments for specific indications

S.8 of The Drugs, Poisons and Controlled Substances Regulations 2006 (Vic) ('the **regulations**') requires that

> (2) A …. medical practitioner must not …..prescribe…. a Schedule 4 poison unless -
>
> (a) that poison is for the medical treatment of a person under his or her care; and
>
> (b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

Determining a therapeutic need for a medication in the cosmetic medicine setting, in our opinion requires a medical practitioner to take a history to determine the patient's health and specific concerns, perform an appropriate examination of the patient and the concerns, consider and discuss the options of treatments and the risks involved of different treatment options, and finally to determine that, on balance, a need for the specific medication exists. The doctor should then undergo a two-way face-to-face discussion to determine the significant risks that should be discussed in the patient's particular case.

The indications should be specific because the discussion is always specific to the patient's concern. If a patient would like lip filler to add volume to the lips, this is a very different conversation – in terms of risks, alternative options etc - to adding volume deep in the cheek, or filling the tear troughs beneath the eyes.

If a patient would like to treat their frown lines with Botulinum Toxin, this is a very different consultation to treating the underarms for hyperhidrosis or the masseters for teeth grinding/muscle bulk.

It is not enough for a medical practitioner to just sign of for 'Botulinum Toxin' as a blanket drug prescription – the indications should be specific to ensure that the patient gets the right information for each type of proposed treatment, and so that the nurse is clear on the scope of his or her authorised practice.

The doctor needs to discuss the indication, the alternative options, the treatment, its risks – which are specific not just to the modality of the treatment, but the specific indication being considered. When the situation changes, or new areas require treatment, this should result in further face to face assessment and consultation by the doctor before any such treatment is performed. This is an elective area of medicine with no urgency, that dictates proper patient assessment and care.

iii. Consent requirements for medical practitioners

It is important to note that when a medical practitioner orders the administration of a schedule 4 poison, it is the doctor's – and not the nurse who administers the drugs – duty to adequately consent the patient. This is no different to a doctor writing up a medication – such as an intravenous antibiotic for example – on a drug chart in a hospital, and the nurse administering that treatment based on the chart. It is the doctor and not the nurse's duty to have discussed and consented the patient for this treatment beforehand.

Similarly, a doctor cannot delegate his or her duty to consent to a nurse. Cosmetic medicine is very complex, and a nurse simply has not been trained sufficiently in clinical medicine, medications, or psychological assessment to take on this duty and be able to appropriately meet the required standard of care. It is also important to note that indemnity providers do not insure nurses in this respect and accordingly this should also define limitations on their acceptable scope of practice.

As already discussed above, when undertaking a consent for a cosmetic procedure, the medical practitioner should be aware that the standard of information giving required of them is higher than that what is required from them for non-cosmetic procedures.

iv. Consents for 'off label' treatments

Many of the cosmetic injectable treatments performed commonly are 'off label' and the medical practitioner needs to be aware of this when consenting patients.

v. Protocols to ensure proper safety

Treating different areas

Different treatments to different areas of the face carry considerably different risks. This is especially true for dermal filler treatments. A medical practitioner who orders a nurse to administer a treatment on a patient needs to personally make sure that the nurse is adequately trained and skilled in delivering the type of treatment ordered for the patient.

Nurse's Scope of Practice

The scope of practice for nurse injectors should be clearly defined by their supervising doctor, including their obligations and responsibilities under the relevant poisons regulations.

In parts of the industry nurses have been informed by doctors that nurse consultations can substitute for consultations with a doctor. The doctor should inform the nurse that in this field of completely elective and cosmetic

medicine, a nurse's consultation should not substitute in any way for a full doctor's consultation before any prescription or administration.

The scope of practice for nurse injectors should be clearly defined by their supervising doctor. When a doctor provides an order for treatment, the nurse should be provided with clear guidelines as to in which situations he or she should refer the patient back to the doctor for further review. These situations should at least include when the medical history of the patient changes, when the indication changes, when new indications arise (which require further orders), when the patient has further questions or when there are any new circumstances, which might affect the ongoing care of the patient.

The level of complexity and risk varies between different injectable products and also the depths and areas of treatment. Doctors should therefore be required to assess the knowledge and competence of each nurse and provide appropriate documented guidelines to each nurse on what exactly is within and outside their personal scope of practice for administration of injectables.

Injection Facility / Location

Proper protocols need to be in place to ensure that the location is suitable for injections from the point of view of hygiene/infection control, equipment available in case of emergency and access to medical staff. It is not uncommon for patients to faint during these procedures, and staff need to be adequately equipped to deal with this eventuality also.

Documentation

Whenever a doctor prescribes a treatment course for a nurse to follow, this prescription must be in writing and must clearly document all instructions required of the administering nurse. This information must include the indication, area for treatment, and dose of treatment. This information plus any special precautions required must be documented for consideration by the nurse before the administration is performed. Practices will need to ensure that proper ongoing documentation is being kept about the

circumstances of the patient's treatment, as it may be relevant for continuity of patient care.

Emergency protocol

Complications such as allergic reactions or vascular occlusions are medical emergencies, and the doctor authorising the treatment needs to make sure that proper training and protocols are in place to protect the patient should these complications occur. The doctor needs to be available within a reasonable time to tend to such complications.

vi. Drug Company Training

Companies (such as Allergan and Galderma) that sell Hyaluronic Acid and Botulinum Toxin treatments should, when directly training nurses in often complex injection techniques, include training about the legal and professional obligations of nurses and doctors who administer the treatments. Nurses need careful training and supervision under a fully qualified medical practitioner, and should not be given the impression at these training sessions that they can function as autonomous practitioners. Nurses should also be trained about their scope of practice and when they should seek assistance from a doctor before continuing an administration order.

vii. Possession of Schedule 4 Poisons and the need for Poisons Permits

These restrictions need to be looked at carefully and reiterated, not just because nurses are dealing with Schedule 4 poisons, but also because those poisons have considerable commercial value which can (and we believe do) result in illegal trade.

Under the regulations, and where no specific 'poisons permit' covering the situation is in place, a nurse is only authorised to possess a Schedule 4 poison if properly authorised by s(5)(2) of the 'regulations' which states :

> '... A nurse is authorised to possess those Schedule 4 poisons …..that are necessary for administration to a patient under the care of that nurse in accordance with –
>
> (a) the instructions of and upon the authorisation for that patient by-

(i) in the case of a Schedule 4 poison ... a registered medical practitioner…..

The Schedule 4 medications must remain under the control of a medical practitioner at all times, and only the amount required for the necessary purpose of carrying out a **particular valid instruction for administration for a particular patient** must be personally dispensed. A nurse should not, therefore, have access to significant amounts of Botulinum Toxin or dermal fillers without valid orders to account for the possession.

A Poisons Permit allows people other than medical practitioners to be in charge of medications under the guidance of strict protocols. For example, Poisons Permits allow 'drug rooms' in hospitals where nurses can access medications under strict guidelines, without the presence of a doctor.

It is important to note that during our liaisons with the Drugs and Poisons authority, it is evident that they have not granted Poisons Permits to many cosmetic clinics, and they have also expressed to us clearly that they have not (for reasons of protecting the public), issued a Permit to any clinic which has declared an intention to allow injections by nurses of Botulinum Toxin or dermal fillers in places remote to the primary clinic. When a Poisons Permit is granted it is thus usually granted under the condition that nurses will not take medications away from the approved clinic for injection off site in any premises without authorization under a Poisons Permit. Clinics should be reminded that if the doctor is not personally dispensing all Schedule 4 medications to a nurse for a specific patient and for a specific order, then the clinic owner may, depending on their local state or territory laws, be legally required to meet further requirements such as, in the case of the State of Victoria, the requirement of obtaining requisite Poisons Permit.

AHPRA should consider **amending item 7.1** of their proposed guidelines to include a reference to Posons Permits – by asking all practitioners and clinic owners take steps to ensure that they have met their local drugs and poisons legislation, **including whether they are required by law to obtain a**

Poisons Permit. This guideline could be effective in limiting the number of unsafe off-site injections that are taking place in Australia at the moment, simply by changing the wording of the guideline.

viii. Offsite injection is prohibited

Medical practices are properly equipped to deal with allergic reactions and/or vascular occlusions, offsite injections outside of these supported situations should not be encouraged or allowed. The cosmetic and completely elective nature of these procedures simply does not justify the risks to the public involved with offsite injections. It should be noted that, in our experience, the drugs and poisons authority is unlikely to grant a poisons permit to a practices who allow for off-site injections, and so requiring cosmetic practices where the doctor is not administering the medication to obtain a poisons permit could be an efficient way of implementing this standard. It is strongly recommended that the Drugs and Poisons authority, as the responsible body, should be involved in the formulation of future guidelines that relate to the area of their jurisdiction.

ix. On-selling of drugs

The 'on-selling' of drugs (i.e. by doctors to nurses) is not permitted and may be grounds for criminal prosecution.

x. Consumer education

Information should be made available for patients by AHPRA for what to look out for with practitioners in terms of the standards they need to put in place, and who to report to if they observe that requirements are not being met.

xi. Perioperative nurse practitioners must not prescribe Botulinum Toxin or hyaluronic acid fillers in the cosmetic setting, which is out of their scope of practice

This is an important area for the Board to consider, and is an example of how people in this industry seem to always be looking for 'ways around the regulations' at the expense of patient safety.

A number of nurses are now undertaking the 'perioperative stream' of the nurse practitioners program in the mistaken belief that this will legally allow them to prescribe Botulinum Toxin and Hyaluronic Acid fillers in cosmetic clinic situations out of the operative setting. They have reached this view because quite remarkably, Botulinum Toxin and Hyaluronic Acid have been included in the schedule of drugs approved by the Minister for Health, that nurses practitioners in the perioperative stream are or may be allowed to prescribe[4].

We do not believe it is appropriate for nurses to be prescribing cosmetic injectable treatments on patients in the peri-operative setting. Cosmetic injection treatments should only be performed in an area planned for surgery under the specific direction and supervision of the responsible operating surgeon and only for the reason of enhancing the results from a surgery.

There are a number of extra issues and risks that result from having fillers or Botulinum Toxin treatments performed in the peri-operative period. With facial surgery, the administration of injectables can impair the surgeon's assessment of the surgical site due to interference with the structure or function of the area - for example due to swelling and bruising around fillers, and loss of a muscle's function and supportive effect after Botulinum Toxin. The peri-operative use of injectables is highly likely to increase the risks from the surgery, and also the injectables themselves, due to factors such as cross-contamination, cross-infection, oedema, and interference with sensation and circulation. The occurrence of such adverse effects will impair the performance of the surgery as well as the recovery from surgery. Additionally, identifying and treating any complications soon after surgery requires assessment which can be impossible or at least compromised by the presence of adverse effects or complications due to injectables.

It is difficult to see how Botulinum Toxin or Hyaluronic Acid **would ever be relevant in the peri-operative setting** (and hence this raises the question of

[4] http://www.health.vic.gov.au/dpu/downloads/perioperative_care.pdf

who thought to include it in the list and for what purpose – something that perhaps the Board should investigate to rule out corruption as a factor in this). It is obvious that the scope of practice of a peri-operative nurse practitioner does not include operating a cosmetic clinic in the community that performs no operative care.[5] Furthermore, it is now common belief among many nurses in the industry that such peri-operative nurse practitioners can now legally prescribe Botulinum Toxin and fillers for administration by multiple other "regular nurses" who are then able to perform these injections on patients from beauty salons or other non-medical premises independent of any surgery - all without the involvement of a doctor. This is yet another example of inappropriate behavior and acting outside the law if not acting outside the intention of the regulations.

There are a number of nurses we know of who are now doing this course purely for the purposes of working in cosmetics, and we feel AHPRA should issue some guidance in this regard, as it is a waste of government funded training for areas of need nursing, and it is clearly not legally valid practice for these nurses to operate in this way.

[5] As per the Deakin University Nurse Practitioner's page, in regards to the scope of perioperative nursing: 'Perioperative nurses work in operating rooms and post anaesthesia care units. Perioperative nursing requires skills and abilities in managing patients in the preoperative, intraoperative and postoperative environment. In the post anaesthesia care units, nurses recover patients following general or regional anaesthesia. Perioperative nurses are skilled communicators, problem-solvers and patient advocates. In their daily work, perioperative nurses assist in preparing an individual for surgery, offering comfort and support, using sound nursing skills and problem-solving techniques together with specialised skills to ensure a safe experience.' - See http://www.deakin.edu.au/nursing-midwifery/study-options/master-of-nursing-practice-and-specialist-streams-h771

Original Investigation | CLINICAL SCIENCES

Iatrogenic Occlusion of the Ophthalmic Artery After Cosmetic Facial Filler Injections
A National Survey by the Korean Retina Society

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IMPORTANCE Iatrogenic occlusion of the ophthalmic artery and its branches is a rare but devastating complication of cosmetic facial filler injections.

OBJECTIVE To investigate clinical and angiographic features of iatrogenic occlusion of the ophthalmic artery and its branches caused by cosmetic facial filler injections.

DESIGN, SETTING, AND PARTICIPANTS Data from 44 patients with occlusion of the ophthalmic artery and its branches after cosmetic facial filler injections were obtained retrospectively from a national survey completed by members of the Korean Retina Society from 27 retinal centers. Clinical features were compared between patients grouped by angiographic findings and injected filler material.

MAIN OUTCOMES AND MEASURES Visual prognosis and its relationship to angiographic findings and injected filler material.

RESULTS Ophthalmic artery occlusion was classified into 6 types according to angiographic findings. Twenty-eight patients had diffuse retinal and choroidal artery occlusions (ophthalmic artery occlusion, generalized posterior ciliary artery occlusion, and central retinal artery occlusion). Sixteen patients had localized occlusions (localized posterior ciliary artery occlusion, branch retinal artery occlusion, and posterior ischemic optic neuropathy). Patients with diffuse occlusions showed worse initial and final visual acuity and less visual gain compared with those having localized occlusions. Patients receiving autologous fat injections (n = 22) had diffuse ophthalmic artery occlusions, worse visual prognosis, and a higher incidence of combined brain infarction compared with patients having hyaluronic acid injections (n = 13).

CONCLUSIONS AND RELEVANCE Clinical features of iatrogenic occlusion of the ophthalmic artery and its branches following cosmetic facial filler injections were diverse according to the location and extent of obstruction and the injected filler material. Autologous fat injections were associated with a worse visual prognosis and a higher incidence of combined cerebral infarction. Extreme caution and care should be taken during these injections, and physicians should be aware of a diverse spectrum of complications following cosmetic facial filler injections.

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