Submission No 22

COSMETIC HEALTH SERVICE COMPLAINTS IN NEW SOUTH WALES

Organisation: The Australasian College of Cosmetic Surgery

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The Australasian College of Cosmetic Surgery Submission to

Inquiry into cosmetic health service complaints in New South Wales

13th April 2018

Introduction

The Australasian College of Cosmetic Surgery (The College) appreciates the invitation to submit to this enquiry. It is important to state at the outset that the College supports an accessible and effective complaints process to assist in the protection of patients engaging in this rapidly expanding area of medical practice.

The College has been monitoring the complaints process for some time and has developed a store of knowledge and experience on many related matters.

Complaints relating to cosmetic health services arise primarily from patients, other medical practitioners and sometimes Regulatory Bodies.

Patient Generated Complaints

Overwhelmingly, it appears that patient generated complaints to regulatory bodies or the broader civil litigation arena relate more to unmet expectations rather than from negligent practice. Poor practice or negligent practice can be identified and addressed fairly easily and there are adequate measures to manage this. Indeed, The College has a long and positive working relationship with the HCCC in the enforcement space. We applaud the HCCC on its work to date and we look forward to continuing to work together long into the future.

Unmet expectations however are a difficult source of complaint whereby the performance of a procedure may be competent and appropriate, but the patient was expecting a different outcome and hence is disappointed with the result. Alternatively, a complication



may have occurred which has mitigated against the best outcome or has not been managed well enough. Even though it is broadly acknowledged that complications occur in any medical procedure and in the best of hands; some patients have little tolerance for a less than 'perfect' result. Known and recognised complications may be well presented to patients beforehand and their risks of occurrence acknowledged but sometimes poorly tolerated.

In addressing this issue of expectation, it revolves around the process of obtaining informed consent and the documentation of that process. This in turn, is an area in which the College expends a significant amount of energy to educate and guide its Fellows. One such example is the College produced "Patient Information Brochure" (Appendix 1) which details for a patient the potential for complications to occur and to provide some guidance to patients as to how to handle such an event. This brochure also guides the patient into how to make a complaint to the appropriate authorities. It is a requirement of College Fellows to provide this brochure to all patients considering a cosmetic surgical procedure. More recently the NSW HCCC has produced an excellent document titled "PUBLIC WARNING UNDER S94A OF THE HEALTH CARE COMPLAINTS ACT 1993: UNSAFE AND ILLEGAL PRACTICES AT BEAUTY AND COSMETIC CLINICS" (Appendix 2). A compilation of both those documents could be offered as a general information notice

 The College would recommend that a form of Patient Information brochure be developed and required to be provided to ALL patients intending to undergo a cosmetic procedure.

Complaints from Other Medical Practitioners

These tend to fall into two categories: patients who have poor outcomes from cosmetic procedures; and issues around advertising and promotions by competitors.

As previously noted, poor or negligent medical practice is usually fairly easy to identify and address at a disciplinary level.

Advertising breaches include a misrepresentation of potential outcomes, glossing over possible complications, or offers of financial incentives.



It is this second category of complaints which can often prove more difficult to assess and manage. This is because there is no recognised specialist standard for cosmetic surgery, meaning patients have no easy way of assessing the claims of their intended practitioner with respect to their qualifications and experience in cosmetic surgery. Certainly, it is difficult for patients to assess the appropriateness of any proposed surgery and its attendant risks.

As recently as its 2017 report the Australian Medical Council notes in its Specialist Medical College Accreditation report - Royal Australasian College of surgeons 2017, regarding plastic surgery training that:

"There is currently a deficit in the experience available to trainees with regards to aesthetic surgery which is a significant part of plastic and reconstructed surgery practice, but not often available in public hospitals. Currently the training sites have difficulty providing aesthetic surgery training experience for their trainees and so those graduating from the training program will have a gap in this area of practice".

Unfortunately, this means there are a number of medical practitioners practicing cosmetic surgery who have little or no training in the field. Fellows of The College, on the other hand, have undertaken extensive cosmetic surgery training and are subject to rigorous examinations, a CME programme, and observe a strict Code of Conduct.

• The College would recommend tighter restrictions on the use of the title Cosmetic Surgeon, limited to those who can demonstrate appropriate training in that field.

A further sub group of advertising issues relating to practitioners with few or absent qualifications also occurs in Australia in foreign language publications and online fora. This can be extremely difficult to detect and monitor due to issues of translation. A notable example of a tragedy arising from this issue is the death of the Beauty Therapy Clinic owner in Sydney who 'imported' an unregistered medical practitioner from Asia to conduct procedures in Australia on her and her clients.

• The College would recommend that any advertisement in a foreign language be accompanied by translated English text. This would allow a more transparent assessment of the appropriateness of that advertisement.



The rise of 'discount chain' practices offering significant discounts has been dramatic. Unfortunately, such practices may sacrifice patient safety and practice quality. There have been proven instances whereby some clinics and individuals have imported 'counterfeit' products to assist their low pricing.

Even though the Cosmetic Surgery Guidelines in the National Law prohibit the offering of financial inducements to 'snare' a patient, this predatory discounting programme appears to be immune from regulatory activity.

Cosmetic surgery operates in a marketplace and downward pressure on prices will always exist, however attention should be given to this issue.

Co-ordination of Regulatory Activity

The fragmented nature of Australian medical practice regulation means complaints often reach a range of regulatory agencies, such as the Medical Board, AHPRA, TGA, poisons and prescription monitoring agencies, and HCCC. Hence it is important to consider the sources of complaint generation.

It follows that an ability needs to exist whereby the various agencies may share information and act in a co-ordinated manner. An offence in one jurisdiction will often be associated with a breach in another jurisdiction.

• The College would recommend the formulation of regulation or legislation to allow information sharing between agencies tasked with the monitoring of medical practice if such avenues do not currently exist.

Recent media have shown clinics in Sydney and Melbourne selling fillers and neurotoxin products which had not been approved by TGA are widespread. HCCC officers have executed a number of search warrants to confirm such illegal practice. While the College appreciates all persons are entitled to due process and the justice system can be slow, there is very little information in the public domain about the prosecutorial processes underway in these and other cases. Regulatory agencies in other sectors often release enforcement actions underway, especially where a strong prima facie case exists. A case for such a change in the way the HCCC operates is justified, given that its work, tragically, touches matters of life and death.



Further, there is a perception that there is no ongoing penalty if caught operating illegally. Related to this is the appearance that there is a degree of immunity against illegal practice for those who are not medically qualified.

• The College would recommend that the framing of regulations in the cosmetic surgery/medicine field of practice be altered to include not only medically qualified persons but also any person or entity operating in this field whether medically qualified or not.

We are seeing an increase in illegal overseas-based operators offering both surgery and medical procedures in Australia, with no signs of abatement. This has already occurred and shown graphically on television; unqualified persons performing eyelid surgery on patients in hotel rooms and in private apartments on the couch. The rise of 'fly in, fly out' overseas personnel with dubious qualifications, if any at all, is disturbing. If authorities are not seen to be acting quickly and decisively to stamp out such practices the public will continue to be put at risk. This unfortunately has the result that those most skilled and knowledgeable in this field are alienated and disenchanted with the regulatory system. Further, it denies the agencies the full co-operation of its most skilled advisors.

The College understands that agencies are hindered by the sheer workload of monitoring and prosecuting illegal practices within the cosmetic surgery and medicine area, and the Government may have to invest more heavily into the staffing of these bodies. Professional organisations such as The College are a ready resource to HCCC to provide assistance in reporting breaches as they come to our attention, and further, can provide a valuable advisory resource in the investigation of such cases.

 The College recommends consideration be given to the establishment of a cross jurisdictional framework for information sharing and include professional organisations such as The College as advisory bodies.



Triage of Complaints

To restate the College position: The College supports an accessible and effective complaints process.

It has been the case in the past that the act of lodging a complaint is used as a method to unfairly target a practitioner by building a profile of complaints. However, a more appropriate measure would be an effective triage or assessment process of complaints to try to differentiate between genuine grievances, real or perceived, and vexatious complaints. Should this not occur a more acute culture of complaint by some patients and competitors will arise. This culture can be used to coerce practitioners into acquiescing to inappropriate procedures out of fear of accumulating further complaints. At this time, there is zero protection for practitioners subject to a spurious complaint.

- The College would recommend that only validated and adjudicated complaints against practitioners be logged on their record. Such record should not be publicly available, with the exception of serious patient safety issues.
- The College would recommend that a "grading system" be used to categorised minor or inadvertent breaches from more egregious patient safety issues.

It would be difficult to put in place a system whereby patients are held accountable for vexatious or spurious complaints as this would act as a deterrent to patients making genuine complaints. Although this system would be considered manifestly unfair to practitioners, perhaps it will have to be tolerated. However, the existence of such activity needs to be acknowledged.

Yet other practitioners or clinics who engage in spurious or vexatious complaints against a competitor should be held accountable for their actions if a complaint is adjudged to be vexatious.

 The College would recommend a system be developed to address spurious or vexatious complaints from other Health Practitioners or Clinics to provide some redress for such anticompetitive and unfair behaviour.

Such a system would be essential for transparency. A lop sided and biased complaints handling process is not conducive to transparency and creates unfair distortions.



I trust this information is of assistance to the Inquiry. The College remains available for further comment or clarification if required.

Yours faithfully



Dr. John Flynn For and on behalf of The Australasian College of Cosmetic Surgery

Questions you should ask your doctor

Are you a Member of the Australasian College of Cosmetic Surgery?

How many times have you performed this procedure before and in the last year?

What are the risks associated with the procedure and what is your own complication rate?

What are the alternatives to the procedure being considered?

Can I see photographs of the results of your own patients who looked similar to me before their surgery?

Can I see photographs of the kind of result it will be impossible for me to achieve?

The biggest factor determining what you will look like after a cosmetic procedure is what you look like now.

Seeing both types of photos will help you to understand the kind of result you should realistically be able to achieve.

Do not be afraid to ask these questions. No competent doctor will mind answering them.

Questions you should ask yourself

Do I feel confident with this doctor?

Do I feel confident about having this procedure?

Have all my questions been answered satisfactorily?

Am I happy with all the arrangements which have been made for me?

Do I understand that there are risks and potential complications with this procedure?

Remember that cosmetic procedures are elective.
You can and should delay procedures
until a time that is appropriate, bearing in mind
other commitments such as family or other
social activities, work commitments and finance.

Most importantly, you should not proceed until you are satisfied that you have selected the right doctor and have received and considered all the necessary information to make an informed decision.

What to do when things go wrong

If you feel the outcome of your procedure is not appropriate or if there has been a complication, first draw your concerns to the attention of your doctor. They are usually in the best position to respond and ensure the best outcome.

If you are uncomfortable voicing your concerns with your doctor personally, talk to the nurse or other clinic staff and ask them to convey your concerns to the doctor. Hopefully, with everyone working as a team, the problems can be rectified.

If you feel you cannot approach the clinic with your concerns or if you wish to make a complaint about your treatment, there are a number of options available to you. All ACCS Fellows and Members must adhere to a strict and enforceable Code of Practice. Accordingly, you may:

 lodge a complaint with the College, which will be acknowledged and placed before an investigating panel with disciplinary authority. A copy of the College's Patient Satisfaction Assurance procedure is enclosed for your information.

Alternatively, you may:

- lodge a complaint with your state or territory health care complaints commission - a government body specially tasked to investigate and advise on patients' health complaints.
- lodge a complaint with the Medical Registration Board in your State.
- seek legal redress against the practitioner by engaging a solicitor.

Please call the ACCS on 1800 804 781 if you would like further information.

ABN 89 086 383 431

Registered office:

Level 2, 96 Phillip Street Parramatta NSW 2150

All correspondences to :

PO Box 36 Parramatta NSW 2124

Phone 1800 804 781 . Facsimile 02 9687 1799 admin@accs.org.au . www.accs.org.au



AUSTRALASIAN COLLEGE OF COSMETIC SURGERY

PATIENT INFORMATION BROCHURE

"Things you should know"

Raising Standards, Protecting Patients

Choosing your doctor

You should choose a doctor based on the doctor's relevant education, training, experience and proven competence with respect to the specific procedure you are considering.

Cosmetic Surgery and Plastic and Reconstructive Surgery – what is the difference?

Although Cosmetic Surgery and Plastic Surgery are frequently talked of interchangeably, they are different. Cosmetic surgery is performed on normal healthy structures of the body in order to change or improve the patient's appearance and elevate their self-esteem. Plastic and Reconstructive Surgery is different to Cosmetic Surgery because it is performed to improve function or repair appearance



Cosmetic medicine and cosmetic surgery – what is the difference?

Doctors who are fellows of the ACCS are accredited as either surgical or medical fellows.

It is important to note that membership of a particular professional group does not guarantee the cosmetic surgery provider's experience in a particular procedure.

So make sure you ask your doctor whether they are accredited by the College for the procedure you are contemplating.

ACCS Accreditations

"FACCS" means Fellow of the Australasian College of Cosmetic Surgery. These doctors are trained in cosmetic surgery and accredited by the College to perform invasive cosmetic surgery such as liposuction and breast augmentation. To qualify as an FACCS a doctor must have three years basic surgery training post medical school and a further two years specific cosmetic surgery training.

"FFMACCS" means Fellow of the Faculty of Medicine of the Australasian College of Cosmetic Surgery. The Faculty of Medicine represents trained cosmetic physicians who have been accredited by the College in the field of cosmetic medicine.

Fellows of the Faculty of Medicine (FFMACCS) are not accredited by the College to perform invasive cosmetic surgery. Some FFMACCS, because of special training and experience obtained outside of the College's accredited programs, may have the expertise to perform these procedures competently, but you should establish with the doctor their training and experience in the procedure you are considering.

Procedure specific registers

In addition to the Fellowship qualifications, the College maintains "Procedure Specific Registers".

These registers, which are available on the College's website, provide reassurance that you are in the hands of a trained, accredited and experienced practitioner.

To be included on a Procedure Specific Register a doctor has to have done a minimum of 50 such procedures.

In some cases the minimum is 100 cases.



When considering a cosmetic procedure you want to be sure that you get all of the information you need to make an informed choice.

Be sure of what it is that you are trying to correct. This is more important than concentrating on asking about a specific procedure because there will usually be a number of different options to achieve the result you seek.

Don't be afraid to ask questions. If you do not understand something, then say so. Any competent doctor will want you to understand everything to your satisfaction, and it will help your doctor understand what you are trying to achieve. It doesn't matter if you think the questions are minor - if they worry you then they are important.

Risks and complications

You should consider seeking a second opinion before having any invasive elective procedure.

Every procedure, whether it is an operation or a non-surgical procedure, carries an element of risk. This is important to understand and discuss during your consultation.

Some risks are minor, such as redness or bruising after an injection. Some risks are more serious, such as a severe infection, scarring or unevenness. Sometimes a procedure may not turn out the way a patient would like, despite the best appropriate efforts.

Sometimes patients hope for a result that is difficult or sometimes impossible to achieve. It is important for both you and your doctor to make sure that expectations are realistic and reasonably achievable.

You need to make sure your doctor discusses risks and complications with you to your satisfaction. If you are not sure then you should not proceed.



The Australasian College of Cosmetic Surgery

Raising Standards, Protecting Patients

APPENDIX 2

Public Warning under s94A of the Health Care Complaints Act - Unsafe and Illegal Practices at Beauty and Cosmetic Clinics

28 Sep 2017

PUBLIC WARNING UNDER S94A OF THE HEALTH CARE COMPLAINTS ACT 1993: UNSAFE AND ILLEGAL PRACTICES AT BEAUTY AND COSMETIC CLINICS

The NSW Health Care Complaints Commission is concerned about complaints regarding cosmetic procedures undertaken in cosmetic clinics and the risks to the health and safety of people attending those clinics.

What should consumers do to protect themselves?

The Commission strongly urges those individuals seeking cosmetic procedures or cosmetic surgery to be vigilant in their research prior to proceeding. In all cases the following factors should be considered before committing to the procedure or surgery:

1. Is the procedure supported by a practitioner who is appropriately qualified, experienced and accredited?

Cosmetic procedures typically involve the use of Schedule 4 drugs

which include, but are not limited to, Botulinum toxin type A (Botox) and hyaluronic acid injection preparations (Dermal fillers)and medications designed to numb tissue such as Lidocaine in injectable and cream form. For these medications, the consumer is required to have a consultation with a registered medical practitioner (in person or by video), for a management plan to be created and for that medical practitioner to prescribe the restricted substance. The consumer is required to be under the direct care or supervision of the medical practitioner.

2. Is the facility appropriately registered, infection controlled and equipped?

Cosmetic procedures are wide ranging and there are a number of relevant requirements in legislation regarding the licensing and registration requirements of these facilities.

Consumers considering skin penetration procedures should be mindful that if there is no registered practitioner working at premises where skin penetration procedures are performed, the facility must be notified to the relevant local council. This enables random inspections to be conducted to monitor compliance with the Regulations.

Consumers should also satisfy themselves of the following:

The premises needs to be clean and hygienic, have a waste disposal bin, have a hand basin that has a clean supply of water and have liquid soap and single use towels or a hand dryer for drying hands;

Protective equipment needs to be worn by the person carrying out the procedure, including the use of gloves that have never been worn and a clean gown or apron;

Needles used must not have been previously used and need to be disposed of using an appropriate sharps container.

Medication ampoules must only be used once and the consumer is

entitled to ask that the single use ampules are shown to them before and / or during the procedure.

3. Are you having cosmetic surgery?

There are extra protections in place for consumers who are undergoing cosmetic surgery (which includes procedures such as significant liposuction, fat transfer, facial implants that are on the bone or involve deep tissue surgery, breast augmentation or reduction, and "tummy tuck").

These procedures are the subject of new legislative requirements that came into operation in March 2017. The full list of cosmetic surgical procedures which need to be conducted at licensed premises is at http://www.legislation.nsw.gov.au/regulations/2016-288.pdf.Consumers should assure themselves that any facility that involves the administration of anesthetic (including a general, epidural or major regional anesthetic to achieve more than conscious sedation) or that involves cosmetic surgery of the kind listed in the regulation is in fact licensed.

Cosmetic surgical procedures are also required to be performed by a medical practitioner and the consumer should be assessed by that medical practitioner before scheduling the procedure. Consumers are encouraged to ask a medical practitioner about their qualifications, training and experience. They can also check to see if a practitioner is registered in Australia through the Australian Health Practitioner Regulation Agency (AHPRA) website on www.ahpra.gov.au. If the practitioner is not registered in Australia, you should not proceed.

4. Are you appropriately informed?

The practitioner performing the procedure should provide the consumer with enough information to make an informed decision about whether to have the procedure. Consumers should be provided with at least the following information:

What does the procedure involve?

Is the procedure new or experimental?

What products are being used in the procedure and are these products

registered?

What are the range of possible outcomes of the procedure?

What are the risks and possible complications associated with the

procedure?

Why is this warning being issued?

In NSW consumers are increasingly spending money on a range of cosmetic services. These services include a range of skin penetration

procedures including micro-needling and Platelet Rich Plasma

treatment, non-surgical breast and hip enhancements, nose bridge

lifts, double eyelid suturing and anti-ageing facial treatments. The

procedures often include the administration of Schedule 4 prescription-

only medication including Botulinum toxin type A (Botox) and

hyaluronic acid injection preparations (Dermal fillers), in addition to

medications designed to numb tissue such as Lidocaine in injectable

and cream form.

The issues raised in the complaints received include:

- Whether the products being used in these treatments are registered

or unregistered products. Use of unregistered products which may be

of inferior quality and untested pose a health risk. The import and supply of medication that is not on the Australian Register of

Therapeutic Goods (ARTG) is unlawful and dangerous since there is no

way of determining the efficacy and safety of the medicines.

- Whether the person prescribing the medication is registered under

the Health Practitioner Regulation National Law. The Schedule 4

medications typically used in cosmetic treatments must be prescribed to the individual by a registered medical practitioner. The administration of medications by non-registered and unqualified persons without a prescription is dangerous because there is no informed assessment of the clinical risks associated with the treatment and no validation of their qualifications and experience. Consumers who receive treatment in these circumstances are taking unnecessary risks that could ultimately lead to life changing injuries or indeed death.

In response to these complaints the Commission has completed and is conducting a range of investigations. One key element of this work is the active investigation of complaints concerning the care and treatment of a woman who died following a cosmetic procedure at the Medi Beauty Laser and Contour Clinic in Chippendale, NSW.

The Commission is also involved in joint operations with the NSW Department of Health's Pharmaceutical Regulatory Unit to inspect beauty/cosmetic clinics in a number of areas across Sydney to examine their operations and identify and address any areas of non-compliance.

The Commission has serious concerns that persons are carrying out medical-related procedures to 'improve' aesthetic appearance whilst not appropriately registered as a medical practitioner. No registered medical practitioners were present during the inspections of any of these clinics. The inspections also provided evidence that medicines that are not on the ARTG continue to be unlawfully imported into Australia and used in beauty/cosmetic clinics.

A number of non ARTG medications were seized during the joint operation. These included Lidocaine cream with significant strength (ranging from 10.5 to 19.8 %), Erythromycin Ointment, (an antibiotic) and Schedule 4 medication unlawfully imported in bulk from China, and non ARTG Botulinum toxin type A imported from South Korea. In

addition, Hyaluronidase, A (an injectable enzyme solution that speeds the natural breakdown of hyaluronic acid) was seized. This medication is used to counteract the effects of hyaluronic acid based fillers for patients whose original dermal filler treatments did not turn out as they expected. Non ARTG approved Iodine and Vitamin B and C injections were also seized together with anesthetic lip and eyebrow paste.

A significant amount of non- ARTG medical devices imported from China were also found. These included Cannulas, needles, sutures, gauze, masks and gloves. These devices must be sterile and such imported devices cannot be guaranteed to have been sterilized to Australian standards therefore potentially increasing the risk of infection to consumers.